Australian Government

Department of Health and Ageing

# SCHEDULE OF PHARMACEUTICAL BENEFITS

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

## EFFECTIVE

## 1 August 2013 - 31 August 2013

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

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# PHARMACEUTICAL BENEFITS

These changes to the Schedule of Pharmaceutical Benefits are effective from 1 August 2013. The Schedule is updated on the first day of each month and is available on the Internet at www.pbs.gov.au.

## Fees, Patient Contributions and Safety Net Thresholds

The following fees, patient contributions and safety net thresholds apply as at 1 August 2013 and are included, where applicable, in prices published in the Schedule —

| | | |
|---|---|---|
| **Dispensing Fees:** | Ready-prepared | $6.63 |
| | Dangerous drug fee | $2.71 |
| | Extemporaneously-prepared | $8.67 |
| | Allowable additional patient charge* | $4.11 |
| **Additional Fees (for safety net prices):** | Ready-prepared | $1.13 |
| | Extemporaneously-prepared | $1.48 |
| **Patient Co-payments:** | General | $36.10 |
| | Concessional | $5.90 |
| **Safety Net Thresholds:** | General | $1390.60 |
| | Concessional | $354.00 |
| **Safety Net Card Issue Fee:** | | $9.06 |

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

# SUMMARY OF CHANGES

## Additions

### Addition – Item

2698B **Abiraterone**, abiraterone acetate 250 mg tablet, 120 *(Zytiga)*
2640Y **Amino Acid Formula With Vitamins And Minerals Without Methionine**, amino acid formula with vitamins and minerals without methionine oral liquid, 30 x 174 mL pouches *(HCU cooler 20)*
2639X **Amino Acid Formula With Vitamins And Minerals Without Methionine**, amino acid formula with vitamins and minerals without methionine oral liquid, 30 x 87 mL pouches *(HCU cooler 10)*
2701E **Amino Acid Formula With Vitamins And Minerals Without Phenylalanine And Tyrosine**, amino acid formula with vitamins and minerals without phenylalanine and tyrosine oral liquid, 30 x 174 mL pouches *(TYR cooler 20)*
2674R **Amino Acid Formula With Vitamins And Minerals Without Phenylalanine And Tyrosine**, amino acid formula with vitamins and minerals without phenylalanine and tyrosine oral liquid, 30 x 87 mL pouches *(TYR cooler 10)*
2654Q **Amino Acid Formula With Vitamins And Minerals Without Valine, Leucine And Isoleucine**, amino acid formula with vitamins and minerals without valine, leucine and isoleucine oral liquid, 30 x 174 mL pouches *(MSUD cooler 20)*
2651M **Amino Acid Formula With Vitamins And Minerals Without Valine, Leucine And Isoleucine**, amino acid formula with vitamins and minerals without valine, leucine and isoleucine oral liquid, 30 x 87 mL pouches *(MSUD cooler 10)*
2655R **Cephalexin**, cephalexin 250 mg capsule, 20 *(Cefalexin Sandoz, Cephalexin generichealth, Chem mart Cephalexin, Cilex, GenRx Cephalexin, Ialex, Ibilex 250, Keflex, Pharmacor Cephalexin 250, Rancef, Terry White Chemists Cephalexin)*
2669L **Diazepam**, diazepam 1 mg/mL oral liquid, 100 mL *(Diazepam Elixir)*
2697Y **Glucose Indicator Blood**, glucose indicator blood strip: diagnostic, 50 diagnostic strips *(OneTouch Select)*
2673Q **Glucose Indicator Blood**, glucose indicator blood strip: diagnostic, 50 diagnostic strips *(OneTouch Select)*
2712R **Glycomacropeptide And Essential Amino Acids**, glycomacropeptide and essential amino acids oral liquid, 12 x 500 mL bottles *(Camino Pro Restore)*
2696X **Glycomacropeptide And Essential Amino Acids With Vitamins And Minerals**, glycomacropeptide and essential amino acids with vitamins and minerals bar, 7 x 54 g *(Camino Pro Complete)*
2644E **Glycomacropeptide And Essential Amino Acids With Vitamins And Minerals**, glycomacropeptide and essential amino acids with vitamins and minerals bar, 7 x 81 g *(Camino Pro Complete)*
2685H **Glycomacropeptide And Essential Amino Acids With Vitamins And Minerals**, glycomacropeptide and essential amino acids with vitamins and minerals oral liquid: powder for, 28 x 49 g sachets *(Camino Pro Bettermilk)*
2652N **High Fat Formula With Vitamins, Minerals And Trace Elements And Low In Protein And Carbohydrate**, high fat formula with vitamins, minerals and trace elements and low in protein and carbohydrate (3:1 ratio long chain fat to carbohydrate plus protein) oral liquid: powder for, 300 g *(KetoCal 3:1)*
2710P **Mifepristone**, mifepristone 200 mg tablet, 1 *(Mifepristone Linepharma)*
2672P **Misoprostol**, misoprostol 200 microgram tablet, 4 *(GyMiso)*
2691P **Rivaroxaban**, rivaroxaban 15 mg tablet, 28 *(Xarelto)*
2666H **Trimethoprim**, trimethoprim 300 mg tablet, 7 *(Alprim, Triprim)*

### Addition – Brand

9230T *Atorvastatin SZ, HX* – **Atorvastatin**, atorvastatin 10 mg tablet, 30
8213G *Atorvastatin SZ, HX* – **Atorvastatin**, atorvastatin 10 mg tablet, 30
9231W *Atorvastatin SZ, HX* – **Atorvastatin**, atorvastatin 20 mg tablet, 30
8214H *Atorvastatin SZ, HX* – **Atorvastatin**, atorvastatin 20 mg tablet, 30
9232X *Atorvastatin SZ, HX* – **Atorvastatin**, atorvastatin 40 mg tablet, 30
8215J *Atorvastatin SZ, HX* – **Atorvastatin**, atorvastatin 40 mg tablet, 30
9233Y *Atorvastatin SZ, HX* – **Atorvastatin**, atorvastatin 80 mg tablet, 30
8521L *Atorvastatin SZ, HX* – **Atorvastatin**, atorvastatin 80 mg tablet, 30
8295N *Adesan, AF* – **Candesartan**, candesartan cilexetil 4 mg tablet, 30
8295N *APO-Candesartan, TX* – **Candesartan**, candesartan cilexetil 4 mg tablet, 30
8295N *Candesartan Aspen 4, QA* – **Candesartan**, candesartan cilexetil 4 mg tablet, 30
8295N *Candesartan-GA, GM* – **Candesartan**, candesartan cilexetil 4 mg tablet, 30
8295N *Candesartan GH, GQ* – **Candesartan**, candesartan cilexetil 4 mg tablet, 30
8295N *Candesartan Sandoz, SZ* – **Candesartan**, candesartan cilexetil 4 mg tablet, 30
8295N *STADA Candesartan, TD* – **Candesartan**, candesartan cilexetil 4 mg tablet, 30
8296P *Adesan, AF* – **Candesartan**, candesartan cilexetil 8 mg tablet, 30
8296P *APO-Candesartan, TX* – **Candesartan**, candesartan cilexetil 8 mg tablet, 30
8296P *Candesartan Aspen 8, QA* – **Candesartan**, candesartan cilexetil 8 mg tablet, 30
8296P *Candesartan-GA, GM* – **Candesartan**, candesartan cilexetil 8 mg tablet, 30
8296P *Candesartan GH, GQ* – **Candesartan**, candesartan cilexetil 8 mg tablet, 30
8296P *Candesartan Sandoz, SZ* – **Candesartan**, candesartan cilexetil 8 mg tablet, 30
8296P *STADA Candesartan, TD* – **Candesartan**, candesartan cilexetil 8 mg tablet, 30
8297Q *Adesan, AF* – **Candesartan**, candesartan cilexetil 16 mg tablet, 30

8297Q *APO-Candesartan, TX* – **Candesartan**, candesartan cilexetil 16 mg tablet, 30
8297Q *Candesartan Aspen 16, QA* – **Candesartan**, candesartan cilexetil 16 mg tablet, 30
8297Q *Candesartan-GA, GM* – **Candesartan**, candesartan cilexetil 16 mg tablet, 30
8297Q *Candesartan GH, GQ* – **Candesartan**, candesartan cilexetil 16 mg tablet, 30
8297Q *Candesartan Sandoz, SZ* – **Candesartan**, candesartan cilexetil 16 mg tablet, 30
8297Q *STADA Candesartan, TD* – **Candesartan**, candesartan cilexetil 16 mg tablet, 30
8889W *Adesan, AF* – **Candesartan**, candesartan cilexetil 32 mg tablet, 30
8889W *APO-Candesartan, TX* – **Candesartan**, candesartan cilexetil 32 mg tablet, 30
8889W *Candesartan Aspen 32, QA* – **Candesartan**, candesartan cilexetil 32 mg tablet, 30
8889W *Candesartan-GA, GM* – **Candesartan**, candesartan cilexetil 32 mg tablet, 30
8889W *Candesartan GH, GQ* – **Candesartan**, candesartan cilexetil 32 mg tablet, 30
8889W *Candesartan Sandoz, SZ* – **Candesartan**, candesartan cilexetil 32 mg tablet, 30
8889W *STADA Candesartan, TD* – **Candesartan**, candesartan cilexetil 32 mg tablet, 30
8504N *Adesan HCT 16/12.5, AF* – **Candesartan + Hydrochlorothiazide**, candesartan cilexetil 16 mg + hydrochlorothiazide 12.5 mg tablet, 30
8504N *APO-Candesartan HCTZ 16/12.5, TX* – **Candesartan + Hydrochlorothiazide**, candesartan cilexetil 16 mg + hydrochlorothiazide 12.5 mg tablet, 30
8504N *Candesartan Combi Aspen 16/12.5, QA* – **Candesartan + Hydrochlorothiazide**, candesartan cilexetil 16 mg + hydrochlorothiazide 12.5 mg tablet, 30
8504N *Candesartan HCT GH 16/12.5, GQ* – **Candesartan + Hydrochlorothiazide**, candesartan cilexetil 16 mg + hydrochlorothiazide 12.5 mg tablet, 30
8504N *Candesartan HCTZ-GA 16/12.5, GM* – **Candesartan + Hydrochlorothiazide**, candesartan cilexetil 16 mg + hydrochlorothiazide 12.5 mg tablet, 30
8504N *STADA Candesartan HCT 16/12.5, TD* – **Candesartan + Hydrochlorothiazide**, candesartan cilexetil 16 mg + hydrochlorothiazide 12.5 mg tablet, 30
9314F *APO-Candesartan HCTZ 32/12.5, TX* – **Candesartan + Hydrochlorothiazide**, candesartan cilexetil 32 mg + hydrochlorothiazide 12.5 mg tablet, 30
9314F *Candesartan Combi Aspen 32/12.5, QA* – **Candesartan + Hydrochlorothiazide**, candesartan cilexetil 32 mg + hydrochlorothiazide 12.5 mg tablet, 30
9314F *Candesartan HCT GH 32/12.5, GQ* – **Candesartan + Hydrochlorothiazide**, candesartan cilexetil 32 mg + hydrochlorothiazide 12.5 mg tablet, 30
9314F *Candesartan HCTZ-GA 32/12.5, GM* – **Candesartan + Hydrochlorothiazide**, candesartan cilexetil 32 mg + hydrochlorothiazide 12.5 mg tablet, 30
9314F *STADA Candesartan HCT 32/12.5, TD* – **Candesartan + Hydrochlorothiazide**, candesartan cilexetil 32 mg + hydrochlorothiazide 12.5 mg tablet, 30
9315G *APO-Candesartan HCTZ 32/25, TX* – **Candesartan + Hydrochlorothiazide**, candesartan cilexetil 32 mg + hydrochlorothiazide 25 mg tablet, 30
9315G *Candesartan Combi Aspen 32/25, QA* – **Candesartan + Hydrochlorothiazide**, candesartan cilexetil 32 mg + hydrochlorothiazide 25 mg tablet, 30
9315G *Candesartan HCT GH 32/25, GQ* – **Candesartan + Hydrochlorothiazide**, candesartan cilexetil 32 mg + hydrochlorothiazide 25 mg tablet, 30
9315G *Candesartan HCTZ-GA 32/25, GM* – **Candesartan + Hydrochlorothiazide**, candesartan cilexetil 32 mg + hydrochlorothiazide 25 mg tablet, 30
9315G *STADA Candesartan HCT 32/25, TD* – **Candesartan + Hydrochlorothiazide**, candesartan cilexetil 32 mg + hydrochlorothiazide 25 mg tablet, 30
2275R *Clopidogrel-GA, GM* – **Clopidogrel**, clopidogrel 75 mg tablet, 28
9155W *Duloxetine DR GH, GQ* – **Duloxetine**, duloxetine 30 mg capsule: enteric, 28
9156X *Duloxetine DR GH, GQ* – **Duloxetine**, duloxetine 60 mg capsule: enteric, 28
8002E *Famlo, RA* – **Famciclovir**, famciclovir 250 mg tablet, 21
8217L *Famlo, RA* – **Famciclovir**, famciclovir 250 mg tablet, 56
8612G *LaxaCon, GM* – **Macrogol-3350 + Sodium Chloride + Potassium Chloride + Bicarbonate**, 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
5390Q *LaxaCon, GM* – **Macrogol-3350 + Sodium Chloride + Potassium Chloride + Bicarbonate**, 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 **(Palliative Care)**
5389P *LaxaCon, GM* – **Macrogol-3350 + Sodium Chloride + Potassium Chloride + Bicarbonate**, 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 **(Palliative Care)**
1325R *APO-Metoprolol, TX* – **Metoprolol Tartrate**, METOPROLOL TARTRATE Tablet 100 mg, 60
1324Q *APO-Metoprolol, TX* – **Metoprolol Tartrate**, METOPROLOL TARTRATE Tablet 50 mg, 100
8513C *Mirtazapine-GA, GN* – **Mirtazapine**, mirtazapine 30 mg tablet, 30
8883M *Mirtazapine-GA, GM* – **Mirtazapine**, mirtazapine 45 mg tablet, 30
8627C *APO-Montelukast, TX* – **Montelukast**, montelukast 4 mg tablet: chewable, 28
8627C *Chemmart Montelukast, CH* – **Montelukast**, montelukast 4 mg tablet: chewable, 28
8627C *Lukair, FR* – **Montelukast**, montelukast 4 mg tablet: chewable, 28
8627C *Montair 4, GM* – **Montelukast**, montelukast 4 mg tablet: chewable, 28
8627C *Montelukast GH, GQ* – **Montelukast**, montelukast 4 mg tablet: chewable, 28
8627C *Montelukast RBX, RA* – **Montelukast**, montelukast 4 mg tablet: chewable, 28
8627C *Montelukast Sandoz 4, SZ* – **Montelukast**, montelukast 4 mg tablet: chewable, 28
8627C *Respikast 4, QA* – **Montelukast**, montelukast 4 mg tablet: chewable, 28

8627C *Terry White Chemists Montelukast, TW* – **Montelukast**, montelukast 4 mg tablet: chewable, 28
8628D *APO-Montelukast, TX* – **Montelukast**, montelukast 5 mg tablet: chewable, 28
8628D *Chemmart Montelukast, CH* – **Montelukast**, montelukast 5 mg tablet: chewable, 28
8628D *Lukair, FR* – **Montelukast**, montelukast 5 mg tablet: chewable, 28
8628D *Montair 5, GM* – **Montelukast**, montelukast 5 mg tablet: chewable, 28
8628D *Montelukast GH, GQ* – **Montelukast**, montelukast 5 mg tablet: chewable, 28
8628D *Montelukast RBX, RA* – **Montelukast**, montelukast 5 mg tablet: chewable, 28
8628D *Montelukast Sandoz 5, SZ* – **Montelukast**, montelukast 5 mg tablet: chewable, 28
8628D *Respikast 5, QA* – **Montelukast**, montelukast 5 mg tablet: chewable, 28
8628D *Terry White Chemists Montelukast, TW* – **Montelukast**, montelukast 5 mg tablet: chewable, 28
9042X *Cavstat, AF* – **Rosuvastatin**, rosuvastatin 5 mg tablet, 30
9042X *Rostor 5, DO* – **Rosuvastatin**, rosuvastatin 5 mg tablet, 30
9042X *Rosuvastatin GH, GQ* – **Rosuvastatin**, rosuvastatin 5 mg tablet, 30
2606E *Cavstat, AF* – **Rosuvastatin**, rosuvastatin 5 mg tablet, 30
2606E *Rosuvastatin GH, GQ* – **Rosuvastatin**, rosuvastatin 5 mg tablet, 30
3402C *Cavstat, AF* – **Rosuvastatin**, rosuvastatin 5 mg tablet, 30
3402C *Rostor 5, DO* – **Rosuvastatin**, rosuvastatin 5 mg tablet, 30
3402C *Rosuvastatin GH, GQ* – **Rosuvastatin**, rosuvastatin 5 mg tablet, 30
2590H *Cavstat, AF* – **Rosuvastatin**, rosuvastatin 5 mg tablet, 30
2590H *Rosuvastatin GH, GQ* – **Rosuvastatin**, rosuvastatin 5 mg tablet, 30
9043Y *Cavstat, AF* – **Rosuvastatin**, rosuvastatin 10 mg tablet, 30
9043Y *Rostor 10, DO* – **Rosuvastatin**, rosuvastatin 10 mg tablet, 30
9043Y *Rosuvastatin GH, GQ* – **Rosuvastatin**, rosuvastatin 10 mg tablet, 30
2628H *Cavstat, AF* – **Rosuvastatin**, rosuvastatin 10 mg tablet, 30
2628H *Rosuvastatin GH, GQ* – **Rosuvastatin**, rosuvastatin 10 mg tablet, 30
3403D *Cavstat, AF* – **Rosuvastatin**, rosuvastatin 10 mg tablet, 30
3403D *Rostor 10, DO* – **Rosuvastatin**, rosuvastatin 10 mg tablet, 30
3403D *Rosuvastatin GH, GQ* – **Rosuvastatin**, rosuvastatin 10 mg tablet, 30
2584B *Cavstat, AF* – **Rosuvastatin**, rosuvastatin 10 mg tablet, 30
2584B *Rosuvastatin GH, GQ* – **Rosuvastatin**, rosuvastatin 10 mg tablet, 30
9044B *Cavstat, AF* – **Rosuvastatin**, rosuvastatin 20 mg tablet, 30
9044B *Rostor 20, DO* – **Rosuvastatin**, rosuvastatin 20 mg tablet, 30
9044B *Rosuvastatin GH, GQ* – **Rosuvastatin**, rosuvastatin 20 mg tablet, 30
2574L *Cavstat, AF* – **Rosuvastatin**, rosuvastatin 20 mg tablet, 30
2574L *Rosuvastatin GH, GQ* – **Rosuvastatin**, rosuvastatin 20 mg tablet, 30
3404E *Cavstat, AF* – **Rosuvastatin**, rosuvastatin 20 mg tablet, 30
3404E *Rostor 20, DO* – **Rosuvastatin**, rosuvastatin 20 mg tablet, 30
3404E *Rosuvastatin GH, GQ* – **Rosuvastatin**, rosuvastatin 20 mg tablet, 30
2609H *Cavstat, AF* – **Rosuvastatin**, rosuvastatin 20 mg tablet, 30
2609H *Rosuvastatin GH, GQ* – **Rosuvastatin**, rosuvastatin 20 mg tablet, 30
9045C *Cavstat, AF* – **Rosuvastatin**, rosuvastatin 40 mg tablet, 30
9045C *Rostor 40, DO* – **Rosuvastatin**, rosuvastatin 40 mg tablet, 30
9045C *Rosuvastatin GH, GQ* – **Rosuvastatin**, rosuvastatin 40 mg tablet, 30
2594M *Cavstat, AF* – **Rosuvastatin**, rosuvastatin 40 mg tablet, 30
2594M *Rosuvastatin GH, GQ* – **Rosuvastatin**, rosuvastatin 40 mg tablet, 30
3405F *Cavstat, AF* – **Rosuvastatin**, rosuvastatin 40 mg tablet, 30
3405F *Rostor 40, DO* – **Rosuvastatin**, rosuvastatin 40 mg tablet, 30
3405F *Rosuvastatin GH, GQ* – **Rosuvastatin**, rosuvastatin 40 mg tablet, 30
2636R *Cavstat, AF* – **Rosuvastatin**, rosuvastatin 40 mg tablet, 30
2636R *Rosuvastatin GH, GQ* – **Rosuvastatin**, rosuvastatin 40 mg tablet, 30
8622T *Pritor Plus 40/12.5 mg, FI* – **Telmisartan + Hydrochlorothiazide**, telmisartan 40 mg + hydrochlorothiazide 12.5 mg tablet, 28
8623W *Pritor Plus 80/12.5 mg, FI* – **Telmisartan + Hydrochlorothiazide**, telmisartan 80 mg + hydrochlorothiazide 12.5 mg tablet, 28
9381R *Pritor Plus 80/25 mg, FI* – **Telmisartan + Hydrochlorothiazide**, telmisartan 80 mg + hydrochlorothiazide 25 mg tablet, 28

## Addition – Equivalence Indicator

8295N *Atacand, AP* – **Candesartan**, candesartan cilexetil 4 mg tablet, 30
8296P *Atacand, AP* – **Candesartan**, candesartan cilexetil 8 mg tablet, 30
8297Q *Atacand, AP* – **Candesartan**, candesartan cilexetil 16 mg tablet, 30
8889W *Atacand, AP* – **Candesartan**, candesartan cilexetil 32 mg tablet, 30
8504N *Atacand Plus 16/12.5, AP* – **Candesartan + Hydrochlorothiazide**, candesartan cilexetil 16 mg + hydrochlorothiazide 12.5 mg tablet, 30
9314F *Atacand Plus 32/12.5, AP* – **Candesartan + Hydrochlorothiazide**, candesartan cilexetil 32 mg + hydrochlorothiazide 12.5 mg tablet, 30
9315G *Atacand Plus 32/25, AP* – **Candesartan + Hydrochlorothiazide**, candesartan cilexetil 32 mg + hydrochlorothiazide 25 mg tablet, 30
2275R *Clovix 75, QA* – **Clopidogrel**, clopidogrel 75 mg tablet, 28
8612G *Movicol, NE* – **Macrogol-3350 + Sodium Chloride + Potassium Chloride + Bicarbonate**, 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

5389P *Movicol, NE* – **Macrogol-3350 + Sodium Chloride + Potassium Chloride + Bicarbonate**, 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 **(Palliative Care)**

5390Q *Movicol, NE* – **Macrogol-3350 + Sodium Chloride + Potassium Chloride + Bicarbonate**, 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 **(Palliative Care)**

1324Q *Lopresor 50, NV* – **Metoprolol Tartrate**, METOPROLOL TARTRATE Tablet 50 mg, 100

1325R *Lopresor 100, NV* – **Metoprolol Tartrate**, METOPROLOL TARTRATE Tablet 100 mg, 60

8627C *Singulair, MK* – **Montelukast**, montelukast 4 mg tablet: chewable, 28

8628D *Singulair, MK* – **Montelukast**, montelukast 5 mg tablet: chewable, 28

8622T *Micardis Plus 40/12.5 mg, BY* – **Telmisartan + Hydrochlorothiazide**, telmisartan 40 mg + hydrochlorothiazide 12.5 mg tablet, 28

8623W *Micardis Plus 80/12.5 mg, BY* – **Telmisartan + Hydrochlorothiazide**, telmisartan 80 mg + hydrochlorothiazide 12.5 mg tablet, 28

9381R *Micardis Plus 80/25 mg, BY* – **Telmisartan + Hydrochlorothiazide**, telmisartan 80 mg + hydrochlorothiazide 25 mg tablet, 28

### Addition – Restriction

2160Q **Rivaroxaban**, rivaroxaban 15 mg tablet, 42 *(Xarelto)*

2268J **Rivaroxaban**, rivaroxaban 20 mg tablet, 28 *(Xarelto)*

9009E **Vinorelbine**, vinorelbine 20 mg capsule, 1 *(Navelbine)*

9010F **Vinorelbine**, vinorelbine 30 mg capsule, 1 *(Navelbine)*

### Addition – Note

2160Q **Rivaroxaban**, rivaroxaban 15 mg tablet, 42 *(Xarelto)*

2268J **Rivaroxaban**, rivaroxaban 20 mg tablet, 28 *(Xarelto)*

## Deletions

### Deletion – Brand

2751T *Pharmacor Amlodipine 5, CR* – **Amlodipine**, amlodipine 5 mg tablet, 30

2752W *Pharmacor Amlodipine 10, CR* – **Amlodipine**, amlodipine 10 mg tablet, 30

8179L *Anastrozole Synthon, ZT* – **Anastrozole**, anastrozole 1 mg tablet, 30

8258P *GenRx Carvedilol, GX* – **Carvedilol**, carvedilol 25 mg tablet, 60

3058Y *Cephatrust 250, MI* – **Cephalexin**, cephalexin 250 mg capsule, 20

3317N *Cephatrust 250, MI* – **Cephalexin**, cephalexin 250 mg capsule, 20

3119E *Cephatrust 500, MI* – **Cephalexin**, cephalexin 500 mg capsule, 20

3318P *Cephatrust 500, MI* – **Cephalexin**, cephalexin 500 mg capsule, 20

8220P *Citalopram 20, CR* – **Citalopram**, citalopram 20 mg tablet, 28

1453L *Pharmacor Gemfibrozil 600, CR* – **Gemfibrozil**, gemfibrozil 600 mg tablet, 60

9248R *Pharmacor Gemfibrozil 600, CR* – **Gemfibrozil**, gemfibrozil 600 mg tablet, 60

8450R *Pharmacor Glimepiride 1, CR* – **Glimepiride**, glimepiride 1 mg tablet, 30

8451T *Pharmacor Glimepiride 2, CR* – **Glimepiride**, glimepiride 2 mg tablet, 30

8533D *Pharmacor Glimepiride 3, CR* – **Glimepiride**, glimepiride 3 mg tablet, 30

8452W *Pharmacor Glimepiride 4, CR* – **Glimepiride**, glimepiride 4 mg tablet, 30

8245Y *Letrozole-Synthon, ZT* – **Letrozole**, letrozole 2.5 mg tablet, 30

2456G *Lisinopril 5, CR* – **Lisinopril**, lisinopril 5 mg tablet, 30

2457H *Lisinopril 10, CR* – **Lisinopril**, lisinopril 10 mg tablet, 30

2458J *Lisinopril 20, CR* – **Lisinopril**, lisinopril 20 mg tablet, 30

3010K *Chem mart Norfloxacin, CH* – **Norfloxacin**, norfloxacin 400 mg tablet, 14

3010K *Terry White Chemists Norfloxacin, TW* – **Norfloxacin**, norfloxacin 400 mg tablet, 14

1042W *Olanzapine-Synthon, ZT* – **Olanzapine**, olanzapine 10 mg tablet, 28

1024X *Olanzapine-Synthon, ZT* – **Olanzapine**, olanzapine 2.5 mg tablet, 28

1037N *Olanzapine-Synthon, ZT* – **Olanzapine**, olanzapine 5 mg tablet, 28

1041T *Olanzapine-Synthon, ZT* – **Olanzapine**, olanzapine 7.5 mg tablet, 28

2242B *Paroxetine 20, CR* – **Paroxetine**, paroxetine 20 mg tablet, 30

9197C *Pharmacor Paroxo 20, MI* – **Paroxetine**, paroxetine 20 mg tablet, 30

9197C *Paroxetine Synthon, ZT* – **Paroxetine**, paroxetine 20 mg tablet, 30

3050M *Perindopril 2, CR* – **Perindopril**, perindopril erbumine 2 mg tablet, 30

3051N *Perindopril 4, CR* – **Perindopril**, perindopril erbumine 4 mg tablet, 30

8704D *Perindopril 8, CR* – **Perindopril**, perindopril erbumine 8 mg tablet, 30

8457D *Quetiapine-Synthon, ZT* – **Quetiapine**, quetiapine 100 mg tablet, 90

8458E *Quetiapine-Synthon, ZT* – **Quetiapine**, quetiapine 200 mg tablet, 60

8456C *Quetiapine-Synthon, ZT* – **Quetiapine**, quetiapine 25 mg tablet, 60

8580N *Quetiapine-Synthon, ZT* – **Quetiapine**, quetiapine 300 mg tablet, 60

1968N *Pharmacor Quinapril 5, CR* – **Quinapril**, quinapril 5 mg tablet, 30

1969P *Pharmacor Quinapril 10, CR* – **Quinapril**, quinapril 10 mg tablet, 30
1970Q *Pharmacor Quinapril 20, CR* – **Quinapril**, quinapril 20 mg tablet, 30
9120B *Pharmacor Ramipril 1.25, CR* – **Ramipril**, ramipril 1.25 mg capsule, 30
9121C *Pharmacor Ramipril 2.5, CR* – **Ramipril**, ramipril 2.5 mg capsule, 30
2236Q *Sertraline 50, CR* – **Sertraline**, sertraline 50 mg tablet, 30
2237R *Sertraline 100, CR* – **Sertraline**, sertraline 100 mg tablet, 30
2011W *Synthon Simvastatin, ZT* – **Simvastatin**, simvastatin 10 mg tablet, 30
2011W *Pharmacor Simvastatin 10, MI* – **Simvastatin**, simvastatin 10 mg tablet, 30
9242K *Synthon Simvastatin, ZT* – **Simvastatin**, simvastatin 10 mg tablet, 30
9242K *Pharmacor Simvastatin 10, MI* – **Simvastatin**, simvastatin 10 mg tablet, 30
2012X *Synthon Simvastatin, ZT* – **Simvastatin**, simvastatin 20 mg tablet, 30
2012X *Pharmacor Simvastatin 20, MI* – **Simvastatin**, simvastatin 20 mg tablet, 30
9243L *Synthon Simvastatin, ZT* – **Simvastatin**, simvastatin 20 mg tablet, 30
9243L *Pharmacor Simvastatin 20, MI* – **Simvastatin**, simvastatin 20 mg tablet, 30
8173E *Synthon Simvastatin, ZT* – **Simvastatin**, simvastatin 40 mg tablet, 30
8173E *Pharmacor Simvastatin 40, MI* – **Simvastatin**, simvastatin 40 mg tablet, 30
9244M *Synthon Simvastatin, ZT* – **Simvastatin**, simvastatin 40 mg tablet, 30
9244M *Pharmacor Simvastatin 40, MI* – **Simvastatin**, simvastatin 40 mg tablet, 30
8313M *Synthon Simvastatin, ZT* – **Simvastatin**, simvastatin 80 mg tablet, 30
8313M *Pharmacor Simvastatin 80, MI* – **Simvastatin**, simvastatin 80 mg tablet, 30
9245N *Synthon Simvastatin, ZT* – **Simvastatin**, simvastatin 80 mg tablet, 30
9245N *Pharmacor Simvastatin 80, MI* – **Simvastatin**, simvastatin 80 mg tablet, 30
2285G *Terbinafine 250, CR* – **Terbinafine**, terbinafine 250 mg tablet, 42
2804N *Terbinafine 250, CR* – **Terbinafine**, terbinafine 250 mg tablet, 42

### Deletions – Restriction

3036T **Strontium**, strontium ranelate 2 g granules, 28 x 2 g sachets *(Protos 2 g)*

### Deletion – Note

5401G **Fentanyl**, FENTANYL Lozenge 200 micrograms (as citrate), 9 *(Actiq)***(Palliative Care)**
5407N **Fentanyl**, FENTANYL Lozenge 200 micrograms (as citrate), 30 *(Actiq)***(Palliative Care)**
5402H **Fentanyl**, FENTANYL Lozenge 400 micrograms (as citrate), 9 *(Actiq)***(Palliative Care)**
5408P **Fentanyl**, FENTANYL Lozenge 400 micrograms (as citrate), 30 *(Actiq)***(Palliative Care)**
5403J **Fentanyl**, FENTANYL Lozenge 600 micrograms (as citrate), 9 *(Actiq)***(Palliative Care)**
5409Q **Fentanyl**, FENTANYL Lozenge 600 micrograms (as citrate), 30 *(Actiq)***(Palliative Care)**
5404K **Fentanyl**, FENTANYL Lozenge 800 micrograms (as citrate), 9 *(Actiq)***(Palliative Care)**
5410R **Fentanyl**, FENTANYL Lozenge 800 micrograms (as citrate), 30 *(Actiq)***(Palliative Care)**
5405L **Fentanyl**, FENTANYL Lozenge 1200 micrograms (as citrate), 9 *(Actiq)***(Palliative Care)**
5411T **Fentanyl**, FENTANYL Lozenge 1200 micrograms (as citrate), 30 *(Actiq)***(Palliative Care)**
5406M **Fentanyl**, FENTANYL Lozenge 1600 micrograms (as citrate), 9 *(Actiq)***(Palliative Care)**
5412W **Fentanyl**, FENTANYL Lozenge 1600 micrograms (as citrate), 30 *(Actiq)***(Palliative Care)**
9140C **Paliperidone**, paliperidone 3 mg tablet: modified release, 28 tablets *(Invega)*
9141D **Paliperidone**, paliperidone 6 mg tablet: modified release, 28 tablets *(Invega)*

### Deletion – Therapeutic Group Premium Exemption Code

Therapeutic group premium no longer applies to candesartan cilexetil 8 mg tablet, 30, candesartan cilexetil 16 mg tablet, 30 and candesartan cilexetil 32 mg tablet, 30.
The following codes were established to provide for cases where an authority had been obtained that granting exemption from the therapeutic group.

8997M **Candesartan**, candesartan cilexetil 8 mg tablet, 30 *(Atacand)*
8998N **Candesartan**, candesartan cilexetil 16 mg tablet, 30 *(Atacand)*
8999P **Candesartan**, candesartan cilexetil 32 mg tablet, 30 *(Atacand)*

## Alterations

### Alteration – Brand Name

*From:*
9133Q *HCU cooler, VF* – **Amino Acid Formula With Vitamins And Minerals Without Methionine**, amino acid formula with vitamins and minerals without methionine oral liquid, 30 x 130 mL cans
*To:*
9133Q *HCU cooler 15, VF* – **Amino Acid Formula With Vitamins And Minerals Without Methionine**, amino acid formula with vitamins and minerals without methionine oral liquid, 30 x 130 mL cans

*From:*

1923F *MMA/PA cooler, VF* – **Amino Acid Formula With Vitamins And Minerals Without Methionine, Threonine And Valine And Low In Isoleucine**, AMINO ACID FORMULA with VITAMINS and MINERALS without METHIONINE, THREONINE and VALINE and low in ISOLEUCINE Oral liquid 130 mL, 30, 1

*To:*

1923F *MMA/PA cooler 15, VF* – **Amino Acid Formula With Vitamins And Minerals Without Methionine, Threonine And Valine And Low In Isoleucine**, AMINO ACID FORMULA with VITAMINS and MINERALS without METHIONINE, THREONINE and VALINE and low in ISOLEUCINE Oral liquid 130 mL, 30, 1

*From:*

9132P *TYR cooler, VF* – **Amino Acid Formula With Vitamins And Minerals Without Phenylalanine And Tyrosine**, amino acid formula with vitamins and minerals without phenylalanine and tyrosine oral liquid, 30 x 130 mL cans

*To:*

9132P *TYR cooler 15, VF* – **Amino Acid Formula With Vitamins And Minerals Without Phenylalanine And Tyrosine**, amino acid formula with vitamins and minerals without phenylalanine and tyrosine oral liquid, 30 x 130 mL cans

*From:*

2375B *MSUD cooler, VF* – **Amino Acid Formula With Vitamins And Minerals Without Valine, Leucine And Isoleucine**, amino acid formula with vitamins and minerals without valine, leucine and isoleucine oral liquid, 30 x 130 mL cans

*To:*

2375B *MSUD cooler 15, VF* – **Amino Acid Formula With Vitamins And Minerals Without Valine, Leucine And Isoleucine**, amino acid formula with vitamins and minerals without valine, leucine and isoleucine oral liquid, 30 x 130 mL cans

## Alteration – Restriction

9333F **Lacosamide**, lacosamide 50 mg tablet, 14 *(Vimpat)*

9334G **Lacosamide**, lacosamide 100 mg tablet, 14 *(Vimpat)*

9335H **Lacosamide**, lacosamide 100 mg tablet, 56 *(Vimpat)*

9336J **Lacosamide**, lacosamide 150 mg tablet, 14 *(Vimpat)*

9337K **Lacosamide**, lacosamide 150 mg tablet, 56 *(Vimpat)*

9338L **Lacosamide**, lacosamide 200 mg tablet, 56 *(Vimpat)*

8621R **Risedronate**, risedronate sodium 35 mg tablet, 4 *(Acris Once-a-Week, APO-Risedronate, Chem mart Risedronate, Risedronate-GA, Risedronate Sandoz, Risedro once a week, Terry White Chemists Risedronate)*

9391G **Risedronate**, risedronate sodium 150 mg tablet, 1 *(Acris Once-a-Month, Actonel Once-a-Month, APO-Risedronate, Chem mart Risedronate, Terry White Chemists Risedronate)*

8481J **Risedronate**, risedronate sodium 5 mg tablet, 28 *(Actonel)*

8972F **Risedronate**, RISEDRONATE SODIUM Tablet 35 mg (enteric coated), 4 *(Actonel EC)*

8899J **Risedronate (&) Calcium Carbonate**, risedronate sodium 35 mg tablet [4 tablets] (&) calcium (as carbonate) 500 mg tablet [24 tablets], 28 *(Acris Combi, Actonel Combi)*

8973G **Risedronate (&) Calcium Carbonate**, RISEDRONATE SODIUM and CALCIUM CARBONATE Pack containing 4 enteric coated tablets risedronate sodium 35 mg and 24 tablets calcium carbonate 1.25 g (equivalent to 500 mg calcium), 1 *(Actonel EC Combi, Risedronate Winthrop EC Combi)*

8974H **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 *(Actonel EC Combi D, Risedronate Winthrop EC Combi D)*

## Alteration – Manufacturer's Code

| | | *From* | *To* |
|---|---|---|---|
| 8220P | *Pharmacor Citalo 20, CR* – **Citalopram**, citalopram 20 mg tablet, 28 | MI | CR |
| 8358X | *Plavicor 75, CR* – **Clopidogrel**, clopidogrel 75 mg tablet, 28 | MI | CR |
| 2361G | *Felodur ER 2.5 mg, TX* – **Felodipine**, felodipine 2.5 mg tablet: modified release, 30 tablets | ZA | TX |
| 2366M | *Felodur ER 5 mg, TX* – **Felodipine**, felodipine 5 mg tablet: modified release, 30 tablets | ZA | TX |
| 2367N | *Felodur ER 10 mg, TX* – **Felodipine**, felodipine 10 mg tablet: modified release, 30 tablets | ZA | TX |
| 2848X | *Lamotrust 25, CR* – **Lamotrigine**, lamotrigine 25 mg tablet, 56 | MI | CR |
| 2849Y | *Lamotrust 50, CR* – **Lamotrigine**, lamotrigine 50 mg tablet, 56 | MI | CR |
| 2850B | *Lamotrust 100, CR* – **Lamotrigine**, lamotrigine 100 mg tablet, 56 | MI | CR |
| 2851C | *Lamotrust 200, CR* – **Lamotrigine**, lamotrigine 200 mg tablet, 56 | MI | CR |
| 9109K | *Omepral, TX* – **Omeprazole**, omeprazole 20 mg tablet: enteric, 30 tablets | PM | TX |
| 9110L | *Omepral, TX* – **Omeprazole**, omeprazole 20 mg tablet: enteric, 30 tablets | PM | TX |
| 2236Q | *Sertracor 50, CR* – **Sertraline**, sertraline 50 mg tablet, 30 | MI | CR |
| 2237R | *Sertracor 100, CR* – **Sertraline**, sertraline 100 mg tablet, 30 | MI | CR |

# Advance Notices

## Advance Notices – Deletion of Item

The following item will be deleted from the Schedule of Pharmaceutical Benefits on 1 September 2013:

2003K **Salbutamol**, salbutamol 0.5% (5 mg/mL) inhalation: solution, 1 x 30 mL bottle *(Pfizer Australia Pty Ltd)*

The following item will be deleted from the Schedule of Pharmaceutical Benefits on 1 November 2013:

1266P **Cyclophosphamide**, cyclophosphamide 50 mg tablet, 50 *(Cycloblastin)*

2103Q **Tiaprofenic Acid**, tiaprofenic acid 300 mg tablet, 60 *(Surgam)*

# SECTION 100 – HIGHLY SPECIALISED DRUGS PROGRAM

## Additions

### Addition – Brand

6234D *Lamivudine 150 mg + Zidovudine 300 mg Alphapharm, AF* – **Lamivudine + Zidovudine**, lamivudine 150 mg + zidovudine 300 mg tablet, 60 **(Private)**

5775Y *Lamivudine 150 mg + Zidovudine 300 mg Alphapharm, AF* – **Lamivudine + Zidovudine**, lamivudine 150 mg + zidovudine 300 mg tablet, 60 **(Public)**

### Addition – Equivalence Indicator

6234D *Combivir, VI* – **Lamivudine + Zidovudine**, lamivudine 150 mg + zidovudine 300 mg tablet, 60 **(Private)**

5775Y *Combivir, VI* – **Lamivudine + Zidovudine**, lamivudine 150 mg + zidovudine 300 mg tablet, 60 **(Public)**

# SECTION 100 – IVF/GIFT TREATMENT

## Alterations

### Alteration – Brand Name

*From:*

9608Q *Orion Laboratories Pty Ltd, ON* – **Progesterone**, progesterone 100 mg pessary, 15

*To:*

9608Q *Oripro, ON* – **Progesterone**, progesterone 100 mg pessary, 15

*From:*

9609R *Orion Laboratories Pty Ltd, ON* – **Progesterone**, progesterone 200 mg pessary, 15

*To:*

9609R *Oripro, ON* – **Progesterone**, progesterone 200 mg pessary, 15

### Alteration – Restriction

5817E **Corifollitropin Alfa**, corifollitropin alfa 150 microgram/0.5 mL injection, 1 x 0.5 mL syringe *(Elonva)*

# Addresses — Department of Human Services

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

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

## New South Wales and Australian Capital Territory

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

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

## Victoria

Pharmaceutical Branch
Level 10
595 Collins Street
Melbourne Vic 3000
**General and IME enquiries — Tel: 132 290**

## Queensland

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

## Western Australia

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

## South Australia and Northern Territory

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

## Tasmania

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

## National Program Management

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

# Authority Prescription Applications

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

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

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

| | |
|---|---|
| **Mail Applications:** | REPLY PAID No. 9857<br>PBS Authorities Section<br>Department of Human Services<br>GPO Box 9857<br>In your Capital City |
| **Telephone Applications:** | Free call 1800 888 333<br>Australia-wide 24 hour service PBS Authorities Section |

For telephone applications please have the following information available:

| | |
|---|---|
| **Patient:** | Medicare Number<br>Surname<br>First name<br>Full residential address (including post code) |
| **PBS Authority Prescription Number:** | Top right hand side of the handwritten PBS Authority Form |
| **Your Prescriber Number:** | Located below your address block on the personalised forms |
| **Drug Information:** | PBS item<br>Quantity required and number of repeats<br>Daily dose<br>Disease or purpose information |

# Requests for Drugs via the Special Access Scheme (SAS)

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

# Department of Veterans' Affairs

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

# Telephone Interpreter Service

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

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

# Poisons Information Centres

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

## NSW

The New Children's Hospital
Hawkesbury Road
Westmead NSW 2148
Tel: (02) 9845 3111

## VIC

Austin Hospital
Studley Road
Heidelberg VIC 3084
Tel: (03) 9496 4410
www.austin.org.au/poisons

## QLD

Pharmacy Department
Royal Children's Hospital
Herston QLD 4029
Tel: 131 126

## WA

Sir Charles Gairdner Hospital
Hospital Avenue
Nedlands WA 6009
Tel: 131 126

## TAS

Tel: 131 126

## NT

Tel: 131 126

## ACT

Tel: 131 126

# Drug Information Centres

## NSW

Drug Information Pharmacist
New South Wales Medicines Information Centre
PO Box 766
Darlinghurst NSW 2010
Tel: (02) 8382 2136

OR

Drug Information Pharmacist
Hunter Drug Information Service
Newcastle Mater Misericordiae Hospital
Locked Bag 7
Hunter Regional Mail Centre NSW 2310
Tel: (02) 4921 1278
Tel: (02) 4921 1328

## VIC

Drug Information Pharmacist
Austin & Repatriation Medical Centre
Studley Road
Heidelberg Vic 3084
Tel: (03) 9496 5668

OR

Drug Information Pharmacist
Drug Information Centre
Southern Health Care Network
Monash Medical Centre
246 Clayton Road
Clayton Vic 3168
Tel:(03) 9594 2361

## QLD

Assistant Director of Pharmacy
Queensland Drug Information Ctr
Royal Brisbane Hospital
E Floor, Block 7
Herston Road
Herston Qld 4029
Tel: (07) 3636 7098
(07) 3636 7599

## SA

Drug Information Pharmacist
Royal Adelaide Hospital
North Terrace
Adelaide SA 5000
Tel: (08) 8222 5546

OR

Drug Information Pharmacist
Flinders Medical Centre
Bedford Park SA 5042
Tel: (08) 8204 5301

OR

Drug Information Pharmacist
Queen Elizabeth Hospital
Woodville Road
Woodville SA 5011
Tel: (08) 8222 6777

## WA

Drug Information Pharmacist
Sir Charles Gairdner Hospital
Hospital Avenue
Nedlands WA 6009
Tel: (08) 9346 2923

## TAS

Drug Information Pharmacist
Royal Hobart Hospital
GPO Box 1061L
Hobart Tas 7001
Tel: (03) 6222 8737

## NT

Drug Information Pharmacist
Royal Darwin Hospital
PO Box 41326
Casuarina NT 0811
Tel: (08) 8922 8424

## ACT

Drug Information Pharmacist
Canberra Hospital
Yamba Drive
Garran ACT 2605
Tel: (02) 6244 3333

# List of Contact Officers for Recalls of Therapeutic Goods

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

These officers may be contacted —

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

## Australian Recall Coordinator

*Mr Mick O'Connor*

**Bh** 02 6232 8197
**Mobile** 0421 583 361
**Fax** 02 6203 1451
**E-mail** recalls@tga.gov.au

## Australian Capital Territory

Mr Michael Conroy

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

## New South Wales

*Mr B. Battye*

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

*Ms J. Mackson*

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

## Victoria

*Ms M. Smith*

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

*Mr M. McCrone*

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

## Queensland

*Mr C.J. Healey*

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

*Mr A. Hawkins*

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

## South Australia

*Mr S. Morris*

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

*Ms E. Hender*

**Bh** 0418 747 833
**Mobile** 0431 657 090
**Fax** 08 8226 9837
**E-mail** elizabeth.hender@health.sa.gov.au

## Western Australia

*Mr Neil Keen*

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

## Tasmania

*Ms M. Sharpe*

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

*Mr J. Galloway*

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

## Northern Territory

*Ms Helgi Stone*

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

*Mr T. DeZilva*

**Bh** 08 8922 7340
**Mobile** 0400 251 419
**Fax** 08 8922 7200
**E-mail** tyronne.dezilva@nt.gov.au

# Index of Manufacturers' codes

| Code | Manufacturer |
|---|---|
| AB | Abbott Australasia Pty Ltd<br>Sir Joseph Banks Corporate Park<br>32-34 Lord Street<br>BOTANY NSW 2019<br>Tel: 1800 801 478 |
| AE | AFT Pharmaceuticals Pty Ltd<br>Level 1<br>296 Burns Bay Road<br>LANE COVE NSW 2066<br>Tel: 1800 097 639 |
| AF | Alphapharm Pty Ltd<br>Level 1<br>30 The Bond, 30-34 Hickson Rd<br>MILLERS POINT NSW 2000<br>Tel: 1800 028 365 |
| AG | Allergan Australia Pty Limited<br>Level 4<br>810 pacific highway<br>GORDON NSW 2072<br>Tel: 1800 252 224 |
| AL | Alphapharm Pty Ltd<br>Level 1<br>30 The Bond, 30-34 Hickson Rd<br>MILLERS POINT NSW 2000<br>Tel: 1800 028 365 |
| AN | Amgen Australia Pty Limited<br>Avaya House<br>Level 7, 123 Epping Road<br>NORTH RYDE NSW 2113<br>Tel: 1800 803 638 |
| AO | AMO Australia Pty Limited<br>Level 3, Building 2<br>20 Bridge Street<br>PYMBLE NSW 2073<br>Tel: 1800266111 |
| AP | AstraZeneca Pty Ltd<br>Alma Road<br>NORTH RYDE NSW 2113<br>Tel: 1800 805 342 |
| AQ | Alcon Laboratories (Australia) Pty Ltd<br>10/25 Frenchs Forest Road East<br>FRENCHS FOREST NSW 2086<br>Tel: 1800 025 032 |
| AS | Aspen Pharmacare Australia Pty Limited<br>34-36 Chandos Street<br>ST LEONARDS NSW 2065<br>Tel: (02) 8436 8300 |
| AT | Actelion Pharmaceuticals Australia Pty Ltd<br>Suite 6<br>13b Narabang Way<br>BELROSE NSW 2085<br>Tel: (02) 9486 4600 |
| AV | sanofi-aventis Australia Pty Ltd<br>Building D, Talavera Corporate Centre<br>12-24 Talavera Road<br>MACQUARIE PARK NSW 2113<br>Tel: +61 (0)2 8666 2000 |

| Code | Manufacturer |
|---|---|
| BB | Blackmores Limited<br>20 Jubilee Avenue<br>Warriewood NSW 2102<br>Tel: +61 (0)2 9910 5000<br>Fax: +61 (0)2 9910 5555 |
| BD | Biogen Idec Australia Pty Ltd<br>Suite 1<br>Level 5, 123 Epping Road<br>NORTH RYDE NSW 2113<br>Tel: +61 (0)2 8875 3900 |
| BE | Beiersdorf Australia Ltd<br>4 Khartoum Road<br>North Ryde NSW 2113<br>Tel: +61 (0)2 9888 0977<br>Fax: +61 (0)2 9887 3487 |
| BG | Sandoz Pty Ltd<br>Suite 201<br>Level 2, 19 Harris Street<br>PYRMONT NSW 2009<br>Tel: 1800 726 369 |
| BI | Biotech Pharmaceuticals Pty Ltd<br>83 Cherry Lane<br>LAVERTON NORTH VIC 3026<br>Tel: (03) 9278 7555 |
| BN | Bayer Australia Ltd<br>875 Pacific Highway<br>PYMBLE NSW 2041<br>Tel: 1800 673 270 |
| BQ | Bristol-Myers Squibb Australia Pty Ltd<br>Level 2<br>4 Nexus Court<br>Mulgrave VIC 3170<br>Tel: 1800 067 567 |
| BR | B. Braun Australia Pty Ltd<br>Norwest Business Park<br>17 Lexington Drive<br>BELLA VISTA NSW 2153<br>Tel: +61 (0)2 9629 0200 |
| BU | Bausch & Lomb (Australia) Pty Ltd<br>Ground Floor<br>16 Giffnock Avenue<br>MACQUARIE PARK NSW 2113<br>Tel: (02) 9887 1444 |
| BV | B.S.N.<br>315 Ferntree Gully Road<br>Mount Waverley VIC 3149<br>Tel: (03) 8540 6777 |
| BX | Baxter Healthcare Pty Limited<br>1 Baxter Drive<br>OLD TOONGABBIE NSW 2146<br>Tel: 1300 789 646 |
| BY | Boehringer Ingelheim Pty Ltd<br>78 Waterloo Road<br>NORTH RYDE NSW 2113<br>Tel: (02) 8875 8600 |

# Index of Manufacturers' codes

| Code | Manufacturer |
|---|---|
| BZ | Boucher & Muir Pty Ltd<br>Level 1, 134 Willoughby Road<br>Crows Nest NSW 2065<br>Tel: 1800 627 680 |
| CC | ConvaTec A Division of Bristol-Myers Squibb Australia Pty Ltd<br>606 Hawthorn Road<br>East Brighton VIC 3187<br>Tel: 1800 335 276 |
| CH | Apotex Pty Ltd<br>16 Giffnock Avenue<br>MACQUARIE PARK NSW 2113<br>Tel: 1800 276 839 |
| CJ | Celgene Pty Limited<br>Level 7<br>607 St Kilda Road<br>MELBOURNE VIC 3044<br>Tel: (03) 9539 5500 |
| CR | Pharmacor Pty Limited<br>Suite 401<br>7 Oaks Avenue<br>DEEWHY NSW 2099<br>Tel: 1300 138 805 |
| CS | bioCSL (Australia) Pty Ltd<br>63 Poplar Road<br>Parkville VIC 3052<br>Tel: 1800 008 275 |
| CT | Coloplast Pty Ltd<br>33 Gilby Road<br>Mount Waverley VIC 3149<br>Tel: 1800 673 317 |
| CU | Care Pharmaceuticals Pty Limited<br>Suite 303, Level 3, 59-75 Grafton Street<br>Bondi Junction NSW 2022<br>Tel: 1800 788 870 |
| CX | Contact Lens Centre Australia Limited<br>Unit D6, Hallmarc Business Park<br>Cnr Westall and Centre Roads<br>CLAYTON VIC 3168<br>Tel: (03) 9543 1811 |
| DO | Aurobindo Pharma (Australia) Pty Limited<br>Unit 3 North RydeLink Business Park<br>277-283 Lane Cove Road<br>Macquarie Park NSW 2113<br>Tel: 02 9805 6000 |
| DQ | Church & Dwight (Australia) Pty Ltd<br>Unit 1/108 Old Pittwater Road<br>Brookvale NSW 2100<br>Tel: 1800 222 099 |
| DV | Medical Developments International Limited<br>6/56 Smith Road<br>SPRINGVALE VIC 3171<br>Tel: (03) 9547 1888 |
| EH | Entra Health Systems Pty Ltd<br>12/60 Castlereagh Street<br>SYDNEY NSW 2000<br>Tel: (02) 9846 6642 |
| EL | Eli Lilly Australia Pty Ltd<br>112 Wharf Road<br>West Ryde NSW 2114<br>Tel: (02) 9325 4444 |
| EO | Ego Pharmaceuticals Proprietary Limited<br>21-31 Malcolm Road<br>Braeside VIC 3195<br>Tel: (03) 9587 1088 |
| FB | Pierre Fabre Medicament Australia Pty Ltd<br>Unit 3B<br>1 Richardson Place<br>NORTH RYDE NSW 2113<br>Tel: +61 (0)2 8662 9800 |
| FI | Boehringer Ingelheim Pty Ltd<br>78 Waterloo Road<br>NORTH RYDE NSW 2113<br>Tel: (02) 8875 8600 |
| FK | A. Menarini Australia Pty Limited<br>Level 8<br>67 Albert Avenue<br>CHATSWOOD NSW 2067<br>Tel: +61 (0)2 9080 7200 |
| FM | Fawns and McAllan Proprietary Limited<br>34-36 Chandos Street<br>ST LEONARDS NSW 2065<br>Tel: +61 (0)2 8436 8300 |
| FP | Ferring Pharmaceuticals Pty Limited<br>Suite 2B, Level 2<br>Gordon Centre, 802 Pacific Highway<br>GORDON NSW 2172<br>Tel: 1800 337 746 |
| FR | Merck Sharp & Dohme (Australia) Pty Ltd<br>Level 1, Building A<br>26 Talavera Road<br>MACQUARIE PARK NSW 2113<br>Tel: +61 (0)2 8988 8000 |
| FZ | Pfizer Australia Pty Ltd<br>38-42 Wharf Road<br>WEST RYDE NSW 2114<br>Tel: 0298503333 |
| GA | Galderma Australia Pty Ltd<br>Suite 4<br>13B Narabang Way<br>BELROSE NSW 2085<br>Tel: (02) 9479 0600 |
| GC | GlaxoSmithKline Australia Pty Ltd<br>Level 4, 436-438 Johnston Street<br>Abbotsford VIC 3067<br>Tel: +61 (0)3 9721 8600 |
| GH | Mercury Pharma (Australia) Pty Limited<br>Level 1, 134 Willoughby Road<br>Crows Nest NSW 2065<br>Tel: +61 (0)2 9431 6333 |
| GI | Gilead Sciences Pty Limited<br>Level 1, 128 Jolimont Road<br>EAST MELBOURNE VIC 3002<br>Tel: (03) 9272 4400 |

# Index of Manufacturers' codes

| Code | Manufacturer |
|---|---|
| GK | GlaxoSmithKline Australia Pty Ltd<br>Level 4, 436-438 Johnston Street<br>Abbotsford VIC 3067<br>Tel: +61 (0)3 9721 8600 |
| GM | Ascent Pharma Pty Ltd<br>151-153 Clarendon Street<br>SOUTH MELBOURNE VIC 3205<br>Tel: 1800 678 302 |
| GN | Ascent Pharmaceuticals Limited<br>151-153 Clarendon Street<br>SOUTH MELBOURNE VIC 3205<br>Tel: 1800 678 302 |
| GQ | Generic Health Pty Ltd<br>Suite 1<br>Level 1, 1175 Toorak Road<br>CAMBERWELL VIC 3124<br>Tel: +61 (0)3 9809 7900 |
| GX | Apotex Pty Ltd<br>16 Giffnock Avenue<br>MACQUARIE PARK NSW 2113<br>Tel: 1800 276 839 |
| GZ | sanofi-aventis Australia Pty Ltd<br>Building D, Talavera Corporate Centre<br>12-24 Talavera Road<br>MACQUARIE PARK NSW 2113<br>Tel: +61 (0)2 8666 2000 |
| HC | Biotech Pharmaceuticals Pty Ltd<br>83 Cherry Lane<br>LAVERTON NORTH VIC 3026<br>Tel: (03) 9278 7555 |
| HH | Hospira Pty Limited<br>500 Collins Street<br>MELBOURNE VIC 3000<br>Tel: 1300 046 774 |
| HL | Helex-A Pty. Ltd.<br>9/7 Anella Avenue<br>CASTLE HILL NSW 2154<br>Tel: 1800 824 166 |
| HM | Meda Pharmaceuticals Pty Ltd<br>Level 20,<br>Tower A, The Zenith, 821 Pacific Highway,<br>Chatswood NSW 2067<br>Tel: (02) 8448 2080 |
| HR | Paul Hartmann Pty Ltd<br>27-28/11-21 Underwood Road<br>Homebush NSW 2140<br>Tel: 1800 805 839 |
| HX | Sandoz Pty Ltd<br>Suite 201<br>Level 2, 19 Harris Street<br>PYRMONT NSW 2009<br>Tel: 1800 726 369 |
| IA | iNova Pharmaceuticals (Australia) Pty Limited<br>Po Box 5033<br>WEST CHATSWOOD NSW 2067<br>Tel: +61 (0)2 8918 6415 |
| IK | Medtronic Australasia Pty Ltd<br>97 Waterloo Road<br>NORTH RYDE NSW 2113<br>Tel: (02) 9857 9000 |
| IQ | Alcon Laboratories (Australia) Pty Ltd<br>10/25 Frenchs Forest Road East<br>FRENCHS FOREST NSW 2086<br>Tel: 1800 025 032 |
| IS | Ipsen Pty Ltd<br>Suite 6<br>40 Montclair Avenue<br>GLEN WAVERLEY VIC 3150<br>Tel: (03) 8544 8100 |
| IX | Clinect Pty Ltd<br>Level 3<br>484 St Kilda Road<br>MELBOURNE VIC 3004<br>Tel: (03) 9918 5555 |
| JC | Janssen-Cilag Pty Ltd<br>1-5 Khartoum Road<br>North Ryde NSW 2113<br>Tel: +61 (0)2 8875 3333<br>Fax: +61 (0)2 8875 3300 |
| JJ | Johnson & Johnson Medical Pty Ltd<br>1-5 Khartoum Road<br>North Ryde NSW 2113<br>Tel: +61 (0)2 9815 4276 |
| JS | Janssen-Cilag Pty Ltd<br>1-5 Khartoum Road<br>North Ryde NSW 2113<br>Tel: +61 (0)2 8875 3333<br>Fax: +61 (0)2 8875 3300 |
| JT | Johnson & Johnson Pacific Pty Limited<br>45 Jones Street<br>ULTIMO NSW 2007<br>Tel: 1800 029 979 |
| KE | Kendall Australasia Pty Ltd<br>22 Giffnock Avenue<br>North Ryde NSW 2113<br>Tel: 1800 252 467 |
| KN | Abbott Australasia Pty Ltd<br>Sir Joseph Banks Corporate Park<br>32-34 Lord Street<br>BOTANY NSW 2019<br>Tel: 1800 801 478 |
| KP | Eli Lilly Australia Pty Ltd<br>112 Wharf Road<br>West Ryde NSW 2114<br>Tel: (02) 9325 4444 |
| KY | Key Pharmaceuticals Pty Ltd<br>12 Lyon Park Road<br>MACQUARIE PARK NSW 2113<br>Tel: (02) 8113 6200 |
| LB | Life Bioscience Pty Ltd<br>10 Atherton Road<br>OAKLEIGH VIC 3166<br>Tel: 1800 114 610 |

# Index of Manufacturers' codes

| Code | Manufacturer |
|---|---|
| LM | Link Medical Products Pty Ltd<br>Unit 1<br>5 Apollo Street<br>WARRIEWOOD NSW 2102<br>Tel: +61 (0)2 8401 9777 |
| LN | Aspen Pharmacare Australia Pty Limited<br>34-36 Chandos Street<br>ST LEONARDS NSW 2065<br>Tel: (02) 8436 8300 |
| LO | Leo Pharma Pty Ltd<br>Level 3, Tower 1<br>25 Montpelier Road<br>BOWEN HILLS QLD 4006<br>Tel: (07) 32501200 |
| LU | Lundbeck Australia Pty Ltd<br>Ground Floor<br>1 Innovation Road<br>NORTH RYDE NSW 2113<br>Tel: (02) 88691000 |
| LY | Eli Lilly Australia Pty Ltd<br>112 Wharf Road<br>West Ryde NSW 2114<br>Tel: (02) 9325 4444 |
| MD | Roche Products Pty Ltd<br>4-10 Inman Road<br>Dee Why NSW 2099<br>Tel: +61 (0)2 9454 9000<br>Fax: +61 (0)2 9971 7401 |
| MF | Mundipharma Pty Limited<br>50 Bridge Street<br>SYDNEY NSW 2000<br>Tel: 02 9231 7200 |
| MH | Molnlycke Health Care Pty Ltd<br>Building 1, Ground Floor 14 Aquatic Drive<br>Frenchs Forest NSW 2086<br>Tel: +61 (0)2 9453 1144<br>Fax: +61 (0)2 9453 1155 |
| MK | Merck Sharp & Dohme (Australia) Pty Ltd<br>Level 1, Building A<br>26 Talavera Road<br>MACQUARIE PARK NSW 2113<br>Tel: +61 (0)2 8988 8000 |
| MM | 3M Pharmaceuticals Australia Pty Ltd<br>9-15 Chilvers Road<br>Thornleigh NSW 2120<br>Tel: (02) 9875 6333 |
| MQ | Alphapharm Pty Ltd<br>Level 1<br>30 The Bond, 30-34 Hickson Rd<br>MILLERS POINT NSW 2000<br>Tel: 1800 028 365 |
| MS | Abbott Australasia Pty Ltd<br>Sir Joseph Banks Corporate Park<br>32-34 Lord Street<br>BOTANY NSW 2019<br>Tel: 1800 801 478 |
| MT | Mentholatum Australasia Pty Ltd<br>12-16 Janine Street<br>Scoresby VIC 3179<br>Tel: (03) 9763 0322 |
| MW | Biomed Aust Pty Limited<br>C/o Robinson Legal<br>Level 4, 350 Kent Street<br>SYDNEY NSW 2000<br>Tel: +61 (0)2 9815 5405 |
| NA | National Diagnostic Products (Australia) Pty Limited<br>7-9 Merriwa Street<br>GORDON NSW 2072<br>Tel: +61 (0)2 9418 4777<br>Fax: +61 (0)2 9418 4747 |
| NC | Novartis Consumer Health Australasia Pty Ltd<br>327-333 Police Road<br>MULGRAVE VIC 3170<br>Tel: 1800 069 643 |
| NE | Norgine Pty Limited<br>Unit 3, 14 Rodborough Road<br>FRENCHS FOREST NSW 2086<br>Tel: 1800 636 000 |
| NF | Novo Nordisk Pharmaceuticals Pty Limited<br>Level 3, 21 Solent Circuit<br>Baulkham Hills NSW 2153<br>Tel: (02) 8858 3600 |
| NI | Novo Nordisk Pharmaceuticals Pty Limited<br>Level 3, 21 Solent Circuit<br>Baulkham Hills NSW 2153<br>Tel: (02) 8858 3600 |
| NM | Novartis Pharmaceuticals Australia Pty Limited<br>54 Waterloo Road<br>North Ryde NSW 2113<br>Tel: 1800 671 203 |
| NO | Novo Nordisk Pharmaceuticals Pty Limited<br>Level 3, 21 Solent Circuit<br>Baulkham Hills NSW 2153<br>Tel: (02) 8858 3600 |
| NQ | Takeda Pharmaceuticals Australia Pty Ltd<br>Ground Floor, 2-4 Lyonpark Road<br>MACQUARIE PARK NSW 2113<br>Tel: +61 (0)2 9859 6900<br>Fax: +61 (0)2 9859 6950 |
| NT | Nestle Australia Ltd<br>20-24 Howleys Road<br>NOTTING HILL VIC 3168<br>Tel: 1800 025 361 |
| NU | Nutricia Australia Pty Limited<br>Level 4, Building D<br>12-24 Talavera Road<br>MACQUARIE PARK NSW 2113<br>Tel: +61 (0)2 8875 0300 |
| NV | Novartis Pharmaceuticals Australia Pty Limited<br>54 Waterloo Road<br>North Ryde NSW 2113<br>Tel: 1800 671 203 |

# Index of Manufacturers' codes

| Code | Manufacturer |
|---|---|
| NX | Nipro Australia Pty Ltd<br>Suite 3, 500 Pacific Hwy<br>ST LEONARDS NSW 2065<br>Tel: 1800 451 737 |
| OA | Orphan Australia Pty Ltd<br>First Floor<br>34-36 Chandos Street<br>ST LEONARDS NSW 2065<br>Tel: (02) 8436 8300 |
| OB | Oral B Laboratories Pty Ltd<br>Level 3, 90 Mount Street<br>North Sydney NSW 2060<br>Tel: (02) 9957 6499 |
| OE | Omegapharm Pty Ltd<br>21 Queen Street<br>ORMOND VIC 3204<br>Tel: +61 (0)418 351 065 |
| OI | Boian Surgical Pty Ltd<br>486 King georges Road<br>BEVERLY HILLS NSW 2209<br>Tel: (02) 9580 7447 |
| OL | Owen Laboratories Division of Galderma Australia Pty Ltd<br>9 Rodborough Road<br>Frenchs Forest NSW 2086<br>Tel: 1800 800 765 |
| OM | Colgate Oral Care<br>345 George Street<br>Sydney NSW 2000<br>Tel: (02) 9229 5600 |
| ON | Orion Laboratories Pty Ltd<br>25-29 Delawney Street<br>Balcatta WA 6021<br>Tel: 1800 004 110 |
| OZ | Medical Specialties Australia Unit Trust<br>54 Gibbes Street<br>Chatswood NSW 2067<br>Tel: (02) 9417 7955 |
| PE | Allergan Australia Pty Limited<br>Level 4<br>810 pacific highway<br>GORDON NSW 2072<br>Tel: 1800 252 224 |
| PF | Pfizer Australia Pty Ltd<br>38-42 Wharf Road<br>WEST RYDE NSW 2114<br>Tel: 0298503333 |
| PK | Fresenius Kabi Australia Pty Limited<br>964 Pacific Highway<br>PYMBLE NSW 2073<br>Tel: 1300 732 001 |
| PL | The Trustee for Virgo Unit Trust (trading as Phebra)<br>332 Burns Bay Road<br>Lane Cove NSW 2066<br>Tel: 1800 100 013 |
| PM | Pharmaceutical Manufacturing Company Pty Limited<br>5 Alma Road<br>NORTH RYDE NSW 2113<br>Tel: (02) 9978 3500 |
| PP | Petrus Pharmaceuticals Pty Ltd<br>PO Box 1808<br>WEST PERTH WA 6872<br>Tel: +61 (0)8 9368 5954 |
| PQ | PMIP Pty Ltd<br>Unit 1<br>5 Apollo Street<br>WARRIEWOOD NSW 2102<br>Tel: +61 (0)2 8401 9777 |
| PX | Point of Care Diagnostics Australia Pty Ltd<br>Unit 14<br>76 Reserve Road<br>ARTARMON NSW 2064<br>Tel: (02) 9437 1355 |
| PY | Procter & Gamble Pharmaceuticals Australia Pty Ltd<br>99 Phillip Street<br>Parramatta NSW 2150<br>Tel: (02) 9685 4500 |
| QA | Aspen Pharma Pty Ltd<br>34-36 Chandos Street<br>ST LEONARDS NSW 2065<br>Tel: (02) 8436 8300 |
| QB | Bionime Australia Pty Limited<br>75/359 Pitt Street<br>SYDNEY NSW 2000<br>Tel: (02) 9262 6900 |
| QH | Cortex Health Pty Ltd<br>Suite 3<br>309 Hampton Street<br>Hampton VIC 3188<br>Tel: 1800 367 758<br>Fax: +61 (0)3 8677 7663 |
| QL | Amcla Pty Limited<br>Unit 4/490 Frankston Dandenong Road<br>CARRUM DOWNS VIC 3201<br>Tel: +61 (0)3 9782 4777 |
| RA | Ranbaxy Australia Pty Limited<br>Suite 4.02, Building D<br>Level 4, 12-24 Talavera Road<br>NORTH RYDE NSW 2113<br>Tel: +61 (0)2 9887 2600 |
| RB | Bio Revive Pty Ltd<br>182-184 Stawell St<br>Burnley VIC 3121<br>Tel: +61 (0)3 8416 0399 |
| RC | Reckitt Benckiser (Australia) Pty Limited<br>44 Wharf Road<br>West Ryde NSW 2114<br>Tel: 1800226766 |

# Index of Manufacturers' codes

| Code | Manufacturer |
|---|---|
| RD | Roche Diagnostics Australia Pty Limited<br>31 Victoria Avenue<br>CASTLE HILL NSW 2154<br>Tel: 1800 251 816 |
| RI | Dr Reddy's Laboratories (Australia) Pty Ltd<br>Level 1<br>181 Bay Street<br>BRIGHTON VIC 3186<br>Tel: +61 (0)3 9595 3812<br>Fax: +61 (0)3 9595 3800 |
| RO | Roche Products Pty Ltd<br>4-10 Inman Road<br>Dee Why NSW 2099<br>Tel: +61 (0)2 9454 9000<br>Fax: +61 (0)2 9971 7401 |
| RX | Servier Laboratories (Aust.) Pty Ltd<br>8 Cato Street<br>HAWTHORN VIC 3122<br>Tel: (03) 8823 7333 |
| RZ | Dr Reddy's Laboratories (Australia) Pty Ltd<br>Level 1<br>181 Bay Street<br>BRIGHTON VIC 3186<br>Tel: +61 (0)3 9595 3812<br>Fax: +61 (0)3 9595 3800 |
| SA | SciGen (Australia) Pty Limited<br>Suite 1<br>13B Narabang Way<br>BELROSE NSW 2085<br>Tel: 1800 966 303 |
| SB | Nutricia Australia Pty Limited<br>Level 4, Building D<br>12-24 Talavera Road<br>MACQUARIE PARK NSW 2113<br>Tel: +61 (0)2 8875 0300 |
| SE | Servier Laboratories (Aust.) Pty Ltd<br>8 Cato Street<br>HAWTHORN VIC 3122<br>Tel: (03) 8823 7333 |
| SG | Merck Serono Australia Pty Ltd<br>Unit 3-4, 25 Frenchs Forest Road East<br>Frenchs Forest NSW 2086<br>Tel: +61 (0)2 8977 4100 |
| SI | Sigma Company Limited<br>3 Myer Place<br>ROWVILLE VIC 3178<br>Tel: 03 9215 9215 |
| SJ | Sharpe Laboratories Pty Ltd<br>12 Hope Street<br>Melrose Park NSW 2114<br>Tel: +61 (0)2 9858 5622 |
| SN | Smith & Nephew Pty Limited<br>315 Ferntree Gully Road<br>Mount Waverley VIC 3149<br>Tel: 13 13 60 |
| SS | SSL Australia Pty Ltd<br>225 Beach Road<br>Mordialloc VIC 3195<br>Tel: 1800 999 155 |
| SW | sanofi-aventis Australia Pty Ltd<br>Building D, Talavera Corporate Centre<br>12-24 Talavera Road<br>MACQUARIE PARK NSW 2113<br>Tel: +61 (0)2 8666 2000 |
| SY | Bayer Australia Ltd<br>875 Pacific Highway<br>PYMBLE NSW 2041<br>Tel: 1800 673 270 |
| SZ | Sandoz Pty Ltd<br>Suite 201<br>Level 2, 19 Harris Street<br>PYRMONT NSW 2009<br>Tel: 1800 726 369 |
| TA | Actavis Australia Pty Ltd<br>Level 5, 117 Harrington Street<br>The Rocks NSW 2000<br>Tel: 1300 881 893 |
| TD | STADA Pharmaceuticals Australia Pty Ltd<br>Suite 1101<br>46 Market Street<br>SYDNEY NSW 2000<br>Tel: +61 (0)2 9279 4667 |
| TK | Takeda Pharmaceuticals Australia Pty Ltd<br>Ground Floor, 2-4 Lyonpark Road<br>MACQUARIE PARK NSW 2113<br>Tel: +61 (0)2 9859 6900<br>Fax: +61 (0)2 9859 6950 |
| TM | Technipro Marketing Pty Ltd<br>PO Box 38<br>OATLANDS NSW 2117<br>Tel: +61 (0)2 9897 5899 |
| TS | Specialised Therapeutics Australia Pty Ltd<br>PO Box 250<br>EAST KEW VIC 3102<br>Tel: 1300 798 820 |
| TW | Apotex Pty Ltd<br>16 Giffnock Avenue<br>MACQUARIE PARK NSW 2113<br>Tel: 1800 276 839 |
| TX | Apotex Pty Ltd<br>16 Giffnock Avenue<br>MACQUARIE PARK NSW 2113<br>Tel: 1800 276 839 |
| UC | UCB Australia Proprietary Limited<br>Level 1<br>1155 Malvern Road<br>Malvern VIC 3144<br>Tel: +61 (0)3 9828 1800 |
| UM | Unomedical Pty Ltd<br>11-17 Wilmette Place<br>Mona Vale NSW 2103<br>Tel: (02) 9997 8033 |

# Index of Manufacturers' codes

| Code | Manufacturer |
|---|---|
| UN | Unilever Australia Limited<br>20-22 Cambridge Street<br>Epping NSW 2121<br>Tel: 1800 888 449 |
| VE | AbbVie Pty Ltd<br>32-34 Lord Street<br>Botany NSW 2019<br>Tel: 1800 801 478 |
| VF | Vitaflo Australia Pty Limited<br>110 Fyans Street<br>SOUTH GEELONG VIC 3220<br>Tel: (03) 5229 8222 |
| VI | ViiV Healthcare Pty Ltd<br>Level 4, 436 Johnston Street<br>ABBOTSFORD VIC 3067<br>Tel: +61 (0)3 9721 6000 |
| VP | Meda Valeant Pharma Australia Pty Limited<br>Po Box 5033<br>West Chatswood<br>West CHATSWOOD NSW 2067<br>Tel: +61 (0)2 8918 6200<br>Fax: +61 (0)2 8918 6416 |
| VT | Valeant Pharmaceuticals Australasia Pty Limited<br>Level 10<br>12 Help Street<br>CHATSWOOD NSW 2067<br>Tel: +61 (0)2 8918 6322<br>Fax: +61 (0)2 8918 6416 |
| WA | sanofi-aventis Australia Pty Ltd<br>Building D, Talavera Corporate Centre<br>12-24 Talavera Road<br>MACQUARIE PARK NSW 2113<br>Tel: +61 (0)2 8666 2000 |
| WQ | Willow Pharmaceuticals Pty Ltd<br>Level 4, 5 Essex Street<br>THE ROCKS NSW 2000<br>Tel: 1800 708 648 |
| XA | Pharmaxis Ltd<br>20 Rodborough Road<br>FRENCHS FOREST NSW 2086<br>Tel: (02) 9454 7200 |

| Code | Manufacturer |
|---|---|
| XH | MS Health Pty Ltd<br>Suite 129<br>135 Cardigan street<br>Carlton VIC 3053<br>Tel: 1300 515 883<br>Fax: +61 (0)3 9658 7449 |
| XM | The Medicines Company (Australia) Pty Limited<br>Suite 1<br>Level 8, North Tower, 1-5 Railway Street<br>CHATSWOOD NSW 2067<br>Tel: 1800 755 459 |
| XP | Aaxis Pacific Pty Ltd<br>24-32 Forge Street<br>Blacktown NSW 2148<br>Tel: +61 (0)2 9881 3333<br>Fax: +61 (0)2 9881 3322 |
| YA | Agila Australasia Pty Ltd<br>8-12 Ordish Road<br>DANDENONG SOUTH VIC 3175<br>Tel: 1800 149 169 |
| YN | Mayne Pharma International Pty Ltd<br>Level 14<br>474 Flinders street<br>MELBOURNE VIC 3000<br>Tel: 1300 081 849 |
| YT | Mayne Products Pty Ltd<br>Level 14<br>474 Flinders street<br>MELBOURNE VIC 3000<br>Tel: 1300 081 849 |
| ZF | Sun Pharmaceutical Industries (Australia) Pty Ltd<br>1053 Burwood Highway<br>FERNTREE GULLY VIC 3156<br>Tel: (03) 95686102 |
| ZI | Shire Australia Pty Limited<br>Avaya House<br>Level 6, 123 Epping Road<br>NORTH RYDE NSW 2113<br>Tel: 1800 012 612 |
| ZP | Spirit Pharmaceuticals Pty Ltd<br>117 Harrington Street<br>SYDNEY NSW 2000<br>Tel: 1800 065 772 |

# Section 1 — Explanatory Notes

## Introduction

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

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

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

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

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

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

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

## 1. The Schedule — Where to Find What

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

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

### Section 1

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

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

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

### Section 2

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

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

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

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

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

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

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

### Section 3

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

### Section 4

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

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

### Repatriation Schedule of Pharmaceutical Benefits

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

## 2. Prescribing Medicines – Information for PBS Prescribers

### PBS prescribers

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

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

### PBS Prescription forms

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

For doctors:

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

For dentists:

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

For optometrists:

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

For midwives:

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

For nurse practitioners:

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

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

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

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

### *PBS stationery order forms*

Prescribers are asked not to over order. Getting the right amount of forms helps to reduce the cost to taxpayers and helps to reduce paper wastage. Also, the pads may deteriorate if stored over time.
Prescribers can gain access to order forms for standard and authority prescription forms as well as computer prescription forms by downloading the required order form from the Department of Human Services website at www.humanservices.gov.au.

The completed order form should be posted to:

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

## Preparing general PBS prescriptions

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

A PBS prescription is only valid when it is written by a doctor, a dentist, an optometrist, a midwife or a nurse practitioner.

The PBS prescription must be for the treatment of the person named on the PBS prescription. A PBS prescription may only be written for the treatment of one person.

A prescriber cannot write more than one PBS prescription for the same pharmaceutical benefit for the same person on the same day.

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

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

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

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

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

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

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

The following admixtures are not pharmaceutical benefits:

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

### *Writing the PBS prescription*

The following rules apply for writing PBS prescriptions:

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

## Restrictions

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

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

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

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

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

## Authority PBS prescriptions

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

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

Authority PBS prescriptions cannot have retrospective approval.

### *Authority required PBS Prescriptions*

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

- posting an Authority Prescription Form to the Department of Human Services - after approval, the Department of Human Services will forward both copies of the prescription to the patient or the prescriber (if it is to be sent direct to the patient, the prescriber should mark the box next to the patient's details);
- calling the Department of Human Services Telephone Authority Applications Freecall service (1800 888 333); or
- using the Department of Human Services PBS authorities website at www.medicareaustralia.gov.au/provider/pbs/doctor/authorities.jsp.

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

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

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

- the patient/pharmacist copy, which records prescriber, patient, and pharmaceutical benefit item details. Where required a repeat authorisation, which is used for repeat supply, is attached to the pharmacist/patient copy until the last supply is made. The patient/pharmacist copy is then retained by the pharmacist;
- the Department of Human Services/DVA copy which records prescriber, patient, and pharmaceutical benefit item details. After the first dispensing, the Department of Human Services/DVA copy is forwarded to the Department of Human Services for processing and payment;
- the prescriber's copy (for computer generated scripts, this is the tear off portion at the base of the script) or Prescriber/the Department of Human Services/DVA copy (for handwritten scripts this is the long white copy), is kept by the Department of Human Services or the DVA for record purposes when approval is sought in writing. When approval is by telephone or by the authorities website, the prescriber must keep this copy for 12 months. This copy must record the daily dose, details of the disease, clinical

justification for using the item, the patient's age (if the patient is a child) and whether the patient has previously received an authority for this pharmaceutical benefit.

### *Authority required (STREAMLINED) PBS Prescriptions*

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

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

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

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

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

### *Writing authority PBS prescriptions*

The following rules apply:

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

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

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

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

## Maximum quantities and repeats

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

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

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

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

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

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

## Regulation 24

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

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

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

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

## Urgent cases

In urgent cases and where State/Territory law allows, a prescriber may telephone a pharmacist and ask that a PBS prescription be supplied. He/she must then forward the written PBS prescription and duplicate to the pharmacist within **seven days of the date of supply**.

This also applies to 'Authority required' authority PBS prescriptions provided prior approval has been given by the Department of Human Services or DVA. The follow-up written PBS prescription must include the approval number provided over the phone by the Department of Human Services or DVA.

## Drugs of addiction

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

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

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

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

## Prescriber bag supplies

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

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

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

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

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

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

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

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

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

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

### *How to prescribe these items?*

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

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

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

### *Aboriginal and Torres Strait Islander identification*

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

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

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

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

### *Asking about Aboriginal and/or Torres Strait Islander identification*

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

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

### *Aboriginal and Torres Strait Islander health*

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

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

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

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

### *Communication and cultural issues*

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

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

Source: National Aboriginal and Torres Strait Islander Health Council. National Strategic Framework for Aboriginal and Torres Strait Islander Health 2003-2013, Context. Canberra: Commonwealth of Australia; 2004.

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

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

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

You should:

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

For more information, pbs-indigenous@health.gov.au

# 3. Supplying Medicines — What Pharmacists Need to Know

## Eligible suppliers

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

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

Unapproved pharmacists *cannot* supply pharmaceutical benefits.

### *Approval conditions for pharmacists*

A pharmacist approved to supply medicines under the PBS:

- can only supply benefits from the pharmacy that he/she is operating;
- will not supply to anyone any pharmaceutical benefit that attracts a Commonwealth contribution for free, or for a price that is less than the relevant patient contribution;

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

## Before supplying pharmaceutical benefits

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

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

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

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

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

## Supplying pharmaceutical benefits

### *Do's and Don'ts*

Except in urgent cases (see details under '2. Prescribing Medicines ... Urgent cases'), pharmacists are authorised to supply pharmaceutical benefits only after they receive:

- the pharmacist/patient and the Department of Human Services or DVA copies of a valid PBS prescription which is not more than 12 months old; or
- the pharmacist/patient and the Department of Human Services or DVA copies of an approved authority PBS prescription or an authority to prescribe which is not more than 12 months old; or
- a repeat authorisation attached to a patient/pharmacist PBS prescription not more than 12 months after the date of the original PBS prescription.

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

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

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

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

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

Exceptions to this are:

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

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

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

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

### *What to do if the Schedule changes*

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

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

## Suspected forgery

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

## Regulation 24

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

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

## Repeat authorisations

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

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

### *Preparing Repeat Authorisation Forms*

A Repeat Authorisation Form must show:

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

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

### *Repeat authorisations for deferred supply*

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

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

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

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

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

## Authority PBS prescriptions

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

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

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

## Urgent cases

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

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

## Receipts

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

If a pharmaceutical benefit has to be sent through the post, by rail, or by other means, and a receipt is not practical, the pharmacist must certify on the PBS prescription or repeat authorisation that the benefit has been supplied, and write the date of supply and details of how it was sent. For example, if a pharmaceutical benefit is mailed to a patient on 1 April 2008, the pharmacist should write: "Certified supplied – mailed to patient 1 April 2008 (name of pharmacist) (signature of pharmacist) (date of certification)".

If an item is supplied in an urgent case, or to a person who cannot read or write, the pharmacist should sign and date a statement on the PBS prescription or repeat authorisation, stating the item has been supplied and the date on which it was supplied, and explaining why there is no receipt. For example, if a pharmaceutical benefit is supplied to a patient with a broken arm on 1 May 2008, the pharmacist should write: "Certified supplied 1 May 2008 – patient has a broken arm and is unable to sign (name of pharmacist) (signature of pharmacist) (date of certification)".

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

## Prescriber bag supplies

Pharmacists may supply certain pharmaceutical benefit items free of charge to a PBS prescriber if they receive a prescriber bag order form in duplicate, signed by the prescriber. Only items listed under prescriber bag provisions for the relevant prescriber type can be supplied to the prescriber.

Pharmacists must be satisfied the form was completed by a PBS prescribers and includes the prescriber’s name and address. If a pharmacist does not know the prescriber, he/she should confirm the prescriber’s registration or PBS prescriber number and endorse this on the back of the form.

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

# 4. Patient Charges

## Type of patient

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

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

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

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

## Establishing entitlement

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

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

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

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

## What to charge

### *Patient contribution*

Under the PBS, the maximum cost for a pharmaceutical benefit item at a pharmacy is $36.10 for general patients and $5.90 for concessional patients, plus any applicable special patient contribution, brand premium or therapeutic group premium. General patients who have reached the safety net threshold (see details under '5. The Safety Net Scheme') may receive pharmaceutical benefits at the concessional rate, plus any applicable special patient contribution, brand premium or therapeutic group premium.

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

The contribution rate for general patients as outpatients at public hospitals in most of Australia is $28.90. The exceptions are in Queensland and in hospitals participating in the pharmaceutical reforms where they pay the safety net value of an item listed in the Schedule (see details under '5. The Safety Net Scheme'), or up to the general co-payment amount for items not listed in the Schedule. The public hospital pharmaceutical reforms enable participating public hospitals to prescribe and supply pharmaceutical medication from the PBS to outpatients and patients upon discharge. A range of chemotherapy drugs is also available for day-admitted and non-admitted chemotherapy patients.

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

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

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

The patient contribution rates are adjusted on 1 January each year in line with inflation.

### *Patient contributions for early supply of some PBS medicines*

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

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

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

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

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

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

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

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

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

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

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

### *Increased quantities*

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

### *Regulation 24*

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

### *After hours*

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

### *Delivery*

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

## 5. The Safety Net Scheme

- **See also:**
- Safety Net 20 day rule - List of medicines
- Safety Net 20 day rule - FAQ

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

- the partner or de facto partner;

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

The scheme requires pharmacists, on request by patients, to record the supply of PBS and RPBS items on prescription record forms. When a patient reaches the Safety Net threshold within a calendar year, they qualify to receive PBS or RPBS items at a cheaper price or free of charge for the rest of that year. Any applicable special patient contributions, brand premiums or therapeutic group premiums must still be met by the patient.

The safety net threshold is reached by accumulating eligible patient contributions for PBS prescriptions supplied through community pharmacies and private hospitals and for out-patient medication supplied by public hospitals.

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

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

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

## Safety net thresholds

There are two safety net thresholds. The general patient safety net threshold is currently $1390.60. When a person and/or their family's total applicable co-payments reach this amount, they may apply for a safety net concession card and pay the concessional co-payment amount of $5.90 plus any applicable premium for pharmaceutical benefits for the rest of that calendar year.

The concessional safety net threshold is $354.00 (this also applies to gold, white or orange card holders under the RPBS). When a patient and/or their family's total applicable co-payments reach this amount, they may apply for a safety net entitlement card and may receive pharmaceutical benefits free of charge (except for any applicable premium) for the rest of that calendar year.

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

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

### *Safety net cross-over arrangements*

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

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

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

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

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

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

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

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

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

## Recording PBS prescriptions

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

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

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

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

Community pharmacists should record in the 'safety net value' column:

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

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

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

## Hospital prescription record forms

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

## Multi-item prescription forms

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

Excess items should be treated as 'deferred supply' items.

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

## Qualifying PBS prescriptions

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

## Lost prescription record forms

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

## Retrospective entitlement and patient refunds

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

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

If the patient cannot satisfy a pharmacist that they have a current entitlement and is charged the general patient price, the pharmacist should issue the patient with a receipt and a claim form (provided by the Department of Human Services). The patient can then obtain a refund via Medicare Service Centres or PBS processing centres. RPBS prescription refunds are paid at DVA State offices.

The Department of Human Services can only pay refunds for PBS items supplied through approved pharmacies. Refunds for hospital supplied items should be referred to the relevant hospital or health department. Refunds cannot be made where the patient was charged the general or concessional amount instead of the safety net concessional or safety net entitlement amount as a result of the safety net 20 day rule. Receipts for prescriptions where the safety net 20 day rule has applied must include 'SN20DR' to indicate the reason for the amount charged.

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

## Applying for a Safety Net Entitlement/Concession Card

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

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

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

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

## Issuing a Safety Net Entitlement/Concession Card

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

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

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

## Issuing supplementary cards

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

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

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

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

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

Payment will not be made for void cards.

### Lost Safety Net Entitlement/Concession Cards

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

### Pharmacy record of issued cards

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

## 6. Department of Human Services Entitlement Checks

#### *General Patients*

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

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

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

#### *Concessional Patients*

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

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

### Entitlement checking procedures

#### *General Patients*

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

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

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

#### *Concessional Patients*

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

#### *Step by step*

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

- Re-confirm entitlement with the cardholder/customer;
- Contact the Department of Human Services on 132 290, with consent, to confirm the cardholder/customer concession status;
- If the Department of Human Services advises that the cardholder/customer is concessionally entitled to receive the PBS medicines on that day, supply the prescription as a concessional entitlement;

- If the Department of Human Services advises that the cardholder/customer is not concessionally entitled to receive the PBS medicines on that day, supply as a general prescription. Provide the customer with the information sheet "Your entitlement card" which explains entitlement checking to the customer and the steps they can follow if they are concessionally entitled.

# 7. How Pharmacists Claim Reimbursement: Information Required

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

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

## PBS Prescription identification

Pharmacists must include certain information on each PBS prescription sent in for claim, as specified below. It is important that this information is entered correctly and in the right place on the PBS prescription. This information will be included in a sticker produced by pharmacy software.

The sticker should be placed on the extreme left front of a PBS prescription, opposite each item being claimed. It must not obscure any details written by the prescriber. Most prescribers use PBS prescriptions, which have space for the sticker. If a sticker is not used, a PBS prescription identification stamp can be used or the information can be written in the same place, and in the same order.

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

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

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

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

## Serial numbers

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

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

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

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

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

### *Repeat authorisations for authority PBS prescriptions*

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

### *Repeat authorisations for deferred supply*

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

## Dropper containers

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

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

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

### *PBS prescriptions paid on an average price basis*

If the PBS prescription is to be claimed as an exceptional PBS prescription, the pharmacist should write details of the formula supplied on the PBS prescription or repeat authorisation form; price the PBS prescription in accordance with the pricing principles (as detailed in '9. Pricing PBS Prescriptions'); and enter the calculated price on the sticker.

An exceptional PBS prescription is for an extemporaneously-prepared pharmaceutical benefit that is not included in the Standard Formulae List and for which the price of the ingredients (based on basic pricing rules) is twice or more than the recovery price of the ingredients calculated on an average price basis. Further information on pricing PBS prescriptions can be accessed from the book let titled *Explanation of Current Pricing*on the Department of Human Services' website at www.medicareaustralia.gov.au (PBS publications for Health Care Providers).

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

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

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

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

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

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

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

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

# 8. How Pharmacists Claim Reimbursement: Documents to be Submitted

- **See also:**Pharmaceutical Benefits to which the the Safety Net 20 day rule applies

A claim for pharmaceutical benefits consists of:

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

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

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

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

## Completing the claim form

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

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

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

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

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

## Lodging claims

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

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

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

## Reconciliation statements

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

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

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

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

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

# 9. Pricing PBS Prescriptions

## Pricing principles

The same pricing principles apply to all PBS prescriptions.

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

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

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

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

## Pricing dates

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

## Pricing ready-prepared items

### *For maximum quantities*

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

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

### *For lesser quantities*

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

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

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

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

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

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

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

### *Wastage table percentage*

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

Wastage Factor Table

| | |
|---|---|
| Column A - | 5, 10, 15, 20, 25, 30, 35, 40, 45, 50, 55, 60, 65, 70, 75, 80, 85, 90, 95, 100 |
| Column B - | 10, 18, 26, 32, 38, 44, 50, 54, 58, 62, 66, 70, 74, 78, 82, 86, 90, 94, 98, 100 |

The appropriate wastage table percentage is as follows:

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

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

## Pricing extemporaneously-prepared items

### *General*

The price payable for supplying the maximum quantity of standard formula preparations is shown in the Standard Formulae List.

The following principles apply in determining prices of all pre-priced extemporaneous formulae on the list.

They also apply when a pharmacist elects to price extemporaneous PBS prescriptions outside the list, including exceptional PBS prescriptions.

The amount payable is the sum of:

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

### *Pricing of ingredients*

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

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

| **Quantity** | **Basic Pricing Unit** |
|---|---|
| Up to and including 700 mg | 100 mg price rate |
| Over 700 mg and up to and including 1 g | price as if 1 g |
| Over 1 g and up to and including 7 g | 1 g price rate |
| Over 7 g and up to and including 10 g | price as if 10 g |
| Over 10 g and up to and including 80 g | 10 g price rate |
| Over 80 g and up to and including 90 g | price as if 80 g |
| Over 90 g | 100 g price rate |

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

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

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

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

Where liquids are purchased by weight, the recovery price includes the 'Specific Gravity Factor'.

Special pricing provisions apply to drugs marked '(a)' or '(b)' in the Drug Tariff.

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

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

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

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

### *Containers*

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

A double size container is allowed for bulk powders.

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

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

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

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

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

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

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

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

## 10. Miscellaneous

### References

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

### Standards

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

### Legislation

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

# Nurse practitioner PBS prescribing

MEDICINES WHICH MAY BE PRESCRIBED BY AUTHORISED NURSE PRACTITIONERS

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

The medicines listed for prescribing by authorised nurse practitioners fron 1 November 2010 are identified by 'NP' in the PBS Schedule. Nurse practitioners must not write PBS prescriptions for other medicines.

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

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

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

- *Continuing therapy only model*

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

- *Shared care model*

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

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

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

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

PBS medicines, midwives/nurse practitioners can use the authority personalised or non-personalised PBS prescriber forms. Nurse practitioner PBS prescriptions may include repeats.

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

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

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

# Midwife PBS prescribing

MEDICINES WHICH MAY BE PRESCRIBED BY AUTHORISED MIDWIVES

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

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

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

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

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

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

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

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

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

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# Section 2 – READY-PREPARED PHARMACEUTICAL BENEFITS

## SYMBOLS USED IN THE SCHEDULE

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

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

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

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

## RESTRICTED BENEFITS

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

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

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

## BRAND EQUIVALENCE

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

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

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

## BRAND PREMIUM POLICY

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

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

Basically the policy operates by:

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

If a prescription is written generically or for the lowest priced brand, and the lowest priced brand is supplied, there is no brand premium payable.

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

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

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

## THERAPEUTIC GROUP PREMIUM POLICY

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

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

Basically the policy operates by:

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

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

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

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

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

It should be noted that the brand premium or therapeutic group premium is not a Government charge or revenue. The premium arises from the manufacturer's price and the majority goes to the manufacturer with wholesalers and pharmacists receiving a small percentage.

## Prescriber Bag

# PRESCRIBER BAG

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | Dispensed Price for Max. Qty $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|
| 3451P<br>*NP* | **ADRENALINE**<br>adrenaline 1 in 1000 (1 mg/mL) injection, 5 x 1 mL ampoules | 1 | 20.55 | | Link Medical Products Pty Ltd | LM |
| 3453R<br>*NP* | **ATROPINE**<br>ATROPINE Injection 600 micrograms in 1 mL, 10 | 1 | 20.75 | | Pfizer Australia Pty Ltd | PF |
| 3457Y<br>*NP* | **BENZTROPINE**<br>benztropine mesylate 2 mg/2 mL injection, 5 x 2 mL ampoules | 1 | 103.80 | | Cogentin | FK |
| 3486L<br>*NP* | **BENZYLPENICILLIN**<br>benzylpenicillin 600 mg injection, 1 x 600 mg vial | 10 | *49.53 | | BenPen | CS |
| or | or | | | | | |
| 3485K<br>*NP* | **PROCAINE PENICILLIN**<br>procaine penicillin 1.5 g/3.4 mL injection, 5 x 3.4 mL syringes | 1 | 92.43 | | Cilicaine | QA |
| 3487M<br>*NP* | **BENZYLPENICILLIN**<br>benzylpenicillin 3 g injection, 1 x 3 g vial | 1 | 14.22 | | BenPen | CS |
| 3455W<br>*NP* | **CHLORPROMAZINE**<br>chlorpromazine hydrochloride 50 mg/2 mL injection, 10 x 2 mL ampoules | 1 | 20.69 | | Largactil | SW |
| or | or | | | | | |
| 3456X<br>*NP* | **HALOPERIDOL**<br>haloperidol 5 mg/mL injection, 10 x 1 mL ampoules | 1 | 22.49 | | Serenace | QA |
| 3478C<br>*NP* | **CLONAZEPAM**<br>clonazepam 2.5 mg/mL oral liquid, 10 mL | ‡1 | 10.94 | | Rivotril | RO |
| 3472R<br>*NP* | **DEXAMETHASONE SODIUM PHOSPHATE**<br>DEXAMETHASONE SODIUM PHOSPHATE Injection equivalent to 4 mg dexamethasone phosphate in 1 mL, 5 | 1 | 15.00 | [a] | Hospira Pty Limited | HH |
| | | | | [a] | Dexmethsone | AS |
| or | or | | | | | |
| 3470P<br>*NP* | **HYDROCORTISONE SODIUM SUCCINATE**<br>hydrocortisone (as sodium succinate) 100 mg injection [1 x 100 mg vial] (&) inert substance diluent [1 x 2 mL vial], 1 pack | 2 | *16.73 | | Solu-Cortef | PF |
| or | or | | | | | |
| 3471Q<br>*NP* | **HYDROCORTISONE SODIUM SUCCINATE**<br>hydrocortisone (as sodium succinate) 250 mg injection [1 x 250 mg vial] (&) inert substance diluent [1 x 2 mL vial], 1 pack | 1 | 15.75 | | Solu-Cortef | PF |
| 3458B<br>*NP* | **DIAZEPAM**<br>diazepam 10 mg/2 mL injection, 5 x 2 mL ampoules | 1 | 12.50 | | Hospira Pty Limited | HH |
| 3463G<br>*NP* | **DIPHTHERIA TOXOID + TETANUS TOXOID**<br>diphtheria toxoid 2 international units/0.5 mL + tetanus toxoid 20 international units/0.5 mL injection, 5 x 0.5 mL syringes | 4 | *275.23 | | ADT Booster | CS |
| 3466K<br>*NP* | **FRUSEMIDE**<br>frusemide 20 mg/2 mL injection, 5 x 2 mL ampoules | 1 | 9.83 | [a] | Frusemide-Claris | AE |
| | | | | [a] | Frusemide Sandoz | SZ |
| | | | | [a] | Lasix | SW |
| 3467L<br>*NP* | **GLUCAGON HYDROCHLORIDE**<br>glucagon hydrochloride 1 mg injection [1 x 1 mg vial] (&) inert substance diluent [1 x 1 mL syringe], 1 pack | 1 | 49.31 | | GlucaGen Hypokit | NO |
| 3475X<br>*NP* | **GLYCERYL TRINITRATE**<br>glyceryl trinitrate 400 microgram/actuation spray, 200 actuations | ‡1 | 20.34 | | Nitrolingual Pumpspray | SW |
| 3473T<br>*NP* | **HYOSCINE BUTYLBROMIDE**<br>hyoscine butylbromide 20 mg/mL injection, 5 x 1 mL ampoules | 1 | 24.42 | | Buscopan | BY |
| 3474W | **LIGNOCAINE** | 1 | 37.54 | | Pfizer Australia Pty Ltd | PF |

# PRESCRIBER BAG

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | Dispensed Price for Max. Qty $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|
| *NP* | lignocaine hydrochloride anhydrous 2% (100 mg/5 mL) injection, 5 x 5 mL ampoules | | | | | |
| 3489P | **METHOXYFLURANE**<br>methoxyflurane 999.9 mg/g inhalation: solution, 1 x 3 mL bottle | 1 | 44.99 | | Penthrox | DV |
| 3476Y<br>*NP* | **METOCLOPRAMIDE**<br>metoclopramide hydrochloride anhydrous 10 mg/2 mL injection, 10 x 2 mL ampoules | 1 | 13.20 | | Maxolon | VT |
| or | or | | | | | |
| 3477B<br>*NP* | **PROCHLORPERAZINE**<br>prochlorperazine mesylate 12.5 mg/mL injection, 10 x 1 mL ampoules | 1 | 17.03 | | Stemetil | SW |
| 3479D<br>*NP* | **MORPHINE**<br>morphine sulfate 15 mg/mL injection, 5 x 1 mL ampoules | 1 | 17.17 | | Hospira Pty Limited | HH |
| or | or | | | | | |
| 3480E<br>*NP* | **MORPHINE**<br>morphine sulfate 30 mg/mL injection, 5 x 1 mL ampoules | 1 | 19.30 | | Hospira Pty Limited | HH |
| 2200T<br>*NP* | **NALOXONE**<br>naloxone hydrochloride 400 microgram/mL injection, 1 x 1 mL syringe | 10 | *203.43 | | Naloxone minijet | UC |
| 3488N<br>*NP* | **PROMETHAZINE**<br>promethazine hydrochloride 50 mg/2 mL injection, 5 x 2 mL ampoules | 2 | *30.45 | | Hospira Pty Limited | HH |
| 3495Y<br>*NP* | **SALBUTAMOL**<br>salbutamol 100 microgram/actuation inhalation: pressurised, 200 actuations | ‡1 | 10.32 | [a] | Asmol CFC-free | AL |
| | | | | [a] | Airomir | IA |
| | | | | [a] | APO-Salbutamol Inhaler | TX |
| 3495Y<br>*NP* | **SALBUTAMOL**<br>salbutamol 100 microgram/actuation inhalation: pressurised, 200 actuations | ‡1 | 11.49 | [a] | Ventolin CFC-free | GK |
| or | or | | | | | |
| 3496B<br>*NP* | **SALBUTAMOL**<br>salbutamol 2.5 mg/2.5 mL inhalation: solution, 30 x 2.5 mL ampoules | ‡1 | 11.76 | [a] | Salbutamol-GA | GM |
| | | | | [a] | Butamol 2.5 | QA |
| | | | | [a] | Salbutamol Sandoz | SZ |
| | | | | [a] | Asmol 2.5 uni-dose | AF |
| | | | | [a] | Pharmacor Salbutamol 2.5 | CR |
| | | | | [a] | GenRx Salbutamol | GX |
| 3496B<br>*NP* | **SALBUTAMOL**<br>salbutamol 2.5 mg/2.5 mL inhalation: solution, 30 x 2.5 mL ampoules | ‡1 | 12.35 | [a] | Ventolin Nebules | GK |
| 3497C<br>*NP* | **SALBUTAMOL**<br>salbutamol 5 mg/2.5 mL inhalation: solution, 30 x 2.5 mL ampoules | ‡1 | 12.05 | [a] | Pharmacor Salbutamol 5 | CR |
| | | | | [a] | Salbutamol-GA | GM |
| | | | | [a] | Butamol 5 | QA |
| | | | | [a] | Salbutamol Sandoz | SZ |
| | | | | [a] | Asmol 5 uni-dose | AF |
| | | | | [a] | GenRx Salbutamol | GX |
| 3497C<br>*NP* | **SALBUTAMOL**<br>salbutamol 5 mg/2.5 mL inhalation: solution, 30 x 2.5 mL ampoules | ‡1 | 12.62 | [a] | Ventolin Nebules | GK |
| 3491R<br>*NP* | **TERBUTALINE**<br>terbutaline sulfate 500 microgram/mL injection, 5 x 1 mL ampoules | 1 | 30.80 | | Bricanyl | AP |

# PRESCRIBER BAG

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | Dispensed Price for Max. Qty $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|
| 3484J | **TRAMADOL** | 1 | 13.31 | [a] | Tramal 100 | CS |
| *NP* | tramadol hydrochloride 100 mg/2 mL injection, 5 x 2 mL ampoules | | | [a] | Tramadol Sandoz | SZ |

# General Pharmaceutical Benefits

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|---|

# ALIMENTARY TRACT AND METABOLISM

## STOMATOLOGICAL PREPARATIONS

### STOMATOLOGICAL PREPARATIONS

#### *Antiinfectives and antiseptics for local oral treatment*

**AMPHOTERICIN B**

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 2931G *NP* | amphotericin B 10 mg lozenge, 20 | 1 | 1 | .. | 12.24 | 13.37 | | Fungilin | QA |
| 3306B *DP* | amphotericin B 10 mg lozenge, 20 | 1 | .. | .. | 12.24 | 13.37 | | Fungilin | QA |

**NYSTATIN**

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 3033P *NP* | nystatin 100 000 international units/mL oral liquid, 24 mL | ‡1 | 1 | .. | 11.35 | 12.48 | [a] | Mycostatin | FM |
| | | | | [B]2.01 | 13.36 | 12.48 | [a] | Nilstat | QA |
| 3343Y *DP* | nystatin 100 000 international units/mL oral liquid, 24 mL | ‡1 | .. | .. | 11.35 | 12.48 | [a] | Mycostatin | FM |
| | | | | [B]2.01 | 13.36 | 12.48 | [a] | Nilstat | QA |

#### *Other agents for local oral treatment*

**BENZYDAMINE**

**Restricted benefit**

Radiation induced mucositis

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 1121B *NP* | benzydamine hydrochloride 0.15% mouthwash, 500 mL | ‡1 | 1 | .. | 22.47 | 23.60 | | Difflam | IA |
| 5032W *DP* | benzydamine hydrochloride 0.15% mouthwash, 500 mL | ‡1 | .. | .. | 22.47 | 23.60 | | Difflam | IA |

## DRUGS FOR ACID RELATED DISORDERS

### ANTACIDS

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

**ALUMINIUM HYDROXIDE DRIED + MAGNESIUM TRISILICATE + MAGNESIUM HYDROXIDE**

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 2159P *NP* | aluminium hydroxide dried 250 mg/5 mL + magnesium trisilicate 120 mg/5 mL + magnesium hydroxide 120 mg/5 mL oral liquid, 500 mL | 2 | 5 | .. | *17.91 | 19.04 | | Gastrogel | FM |

**ALUMINIUM HYDROXIDE WITH MAGNESIUM HYDROXIDE**

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 2157M *NP* | ALUMINIUM HYDROXIDE with MAGNESIUM HYDROXIDE Oral suspension 200 mg-200 mg per 5 mL, 500 mL, 1 | 2 | 5 | .. | *17.91 | 19.04 | | Mylanta P | JT |

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

#### *H2-receptor antagonists*

**CIMETIDINE**

**Note**

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

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 1158Y *NP* | cimetidine 400 mg tablet, 60 | 1 | 5 | .. | 16.98 | 18.11 | | Magicul 400 | AF |

**FAMOTIDINE**

**Note**

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

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 2487X *NP* | famotidine 20 mg tablet, 60 | 1 | 5 | .. | 12.60 | 13.73 | [a] | Ausfam 20 | QA |
| | | | | | | | [a] | Chem mart Famotidine | CH |
| | | | | | | | [a] | Famotidine Sandoz | SZ |
| | | | | | | | [a] | GenRx Famotidine | GX |
| | | | | | | | [a] | Pamacid 20 | AF |
| | | | | | | | [a] | Pepzan | GM |

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | [a] | Terry White Chemists Famotidine | TW |
| 2488Y *NP* | famotidine 40 mg tablet, 30 | 1 | 5 | .. | 12.60 | 13.73 | [a] | Ausfam 40 | QA |
| | | | | | | | [a] | Chem mart Famotidine | CH |
| | | | | | | | [a] | Famotidine Sandoz | SZ |
| | | | | | | | [a] | GenRx Famotidine | GX |
| | | | | | | | [a] | Pamacid 40 | AF |
| | | | | | | | [a] | Pepzan | GM |
| | | | | | | | [a] | Terry White Chemists Famotidine | TW |
| | **NIZATIDINE** | | | | | | | | |
| | **Note** | | | | | | | | |
| | Helicobacter pylori eradication therapy should be considered prior to commencing initial treatment of peptic ulcer with this drug. | | | | | | | | |
| 1505F *NP* | nizatidine 150 mg capsule, 60 | 1 | 5 | .. | 18.64 | 19.77 | [a] | Nizac | LN |
| | | | | | | | [a] | Tacidine | AF |
| | | | | [B]5.32 | 23.96 | 19.77 | [a] | Tazac | AS |
| 1504E *NP* | nizatidine 300 mg capsule, 30 | 1 | 5 | .. | 18.64 | 19.77 | [a] | Nizac | LN |
| | | | | | | | [a] | Tacidine | AF |
| | | | | [B]5.32 | 23.96 | 19.77 | [a] | Tazac | AS |
| | **RANITIDINE** | | | | | | | | |
| | **Note** | | | | | | | | |
| | Helicobacter pylori eradication therapy should be considered prior to commencing initial treatment of peptic ulcer with this drug. | | | | | | | | |
| 1978D *NP,MW* | ranitidine 150 mg tablet, 60 | 1 | 5 | .. | 14.62 | 15.75 | [a] | Ausran | QA |
| | | | | | | | [a] | Chem mart Ranitidine | CH |
| | | | | | | | [a] | GenRx Ranitidine | GX |
| | | | | | | | [a] | Rani 2 | AF |
| | | | | | | | [a] | Ranitidine Sandoz | SZ |
| | | | | | | | [a] | Ranoxyl | GM |
| | | | | | | | [a] | Terry White Chemists Ranitidine | TW |
| | | | | | | | [a] | Ulcaid | RA |
| | | | | [B]1.72 | 16.34 | 15.75 | [a] | Zantac | AS |
| 1937Y *NP* | ranitidine 150 mg tablet: effervescent, 30 | 2 | 5 | .. | *14.63 | 15.76 | | Zantac | AS |
| 8162N *NP* | ranitidine 150 mg/10 mL oral liquid, 300 mL | 2 | 5 | .. | *24.73 | 25.86 | | Zantac Syrup | AS |
| 1977C *NP* | ranitidine 300 mg tablet, 30 | 1 | 5 | .. | 14.62 | 15.75 | [a] | Ausran | QA |
| | | | | | | | [a] | Chem mart Ranitidine | CH |
| | | | | | | | [a] | GenRx Ranitidine | GX |
| | | | | | | | [a] | Rani 2 | AF |
| | | | | | | | [a] | Ranitidine Sandoz | SZ |
| | | | | | | | [a] | Ranoxyl | GM |
| | | | | | | | [a] | Terry White Chemists Ranitidine | TW |
| | | | | [B]1.72 | 16.34 | 15.75 | [a] | Zantac | AS |

## *Prostaglandins*

**MISOPROSTOL**

**Authority required (STREAMLINED)**

***2630***

Reduction in the incidence of gastrointestinal complications in patients who have a history of peptic ulcer disease and where NSAID therapy is essential

**Authority required (STREAMLINED)**

***2631***

Duodenal ulcer (including pyloric and stomal ulcers), proven by current or prior x-ray, endoscopy or surgery. The date and the method by which the ulcer was proven must be documented in the patient's medical records when treatment is initiated

**Authority required (STREAMLINED)**

***2632***

# ALIMENTARY TRACT AND METABOLISM

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|---|
| | Gastric ulcer, proven by x-ray, endoscopy or surgery within the previous 2 years. The date and the method by which the ulcer was proven must be documented in the patient's medical records when treatment is initiated | | | | | | | | |
| | **Caution** | | | | | | | | |
| | Misoprostol is a prostaglandin analogue. It should not be used in pregnant women. | | | | | | | | |
| 1648R | misoprostol 200 microgram tablet, 120 | 1 | 2 | .. | 45.64 | 36.10 | | Cytotec | PF |

## *Proton pump inhibitors*

**ESOMEPRAZOLE**
**Restricted benefit**
Maintenance of healed gastro-oesophageal reflux disease

**Restricted benefit**
Scleroderma oesophagus

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

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

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 8600P *NP* | esomeprazole 20 mg tablet: enteric, 30 tablets | 1 | 5 | .. | 30.25 | 31.38 | | Nexium | AP |

**ESOMEPRAZOLE**
**Restricted benefit**
Initial treatment of gastric ulcer

**Note**
Helicobacter pylori eradication therapy should be considered.

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

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 8886Q *NP* | esomeprazole 20 mg tablet: enteric, 30 tablets | 1 | 1 | .. | 30.25 | 31.38 | | Nexium | AP |

**ESOMEPRAZOLE**
**Authority required**
Pathological hypersecretory conditions including Zollinger-Ellison syndrome and idiopathic hypersecretion

**Authority required**
Scleroderma oesophagus

**Note**
Continuing Therapy Only:

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

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 3401B *NP* | esomeprazole 40 mg tablet: enteric, 30 tablets | 1 | 5 | .. | 45.90 | 36.10 | | Nexium | AP |

**ESOMEPRAZOLE**
**Restricted benefit**
Healing of gastro-oesophageal reflux disease

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

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 8601Q *NP* | esomeprazole 40 mg tablet: enteric, 30 tablets | 1 | 1 | .. | 45.90 | 36.10 | | Nexium | AP |

**LANSOPRAZOLE**
**Restricted benefit**
Gastro-oesophageal reflux disease

**Restricted benefit**
Scleroderma oesophagus

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 8198L *NP* | lansoprazole 15 mg capsule: enteric, 30 | 1 | 5 | .. | 16.82 | 17.95 | | Zopral | AF |
| 9331D *NP* | lansoprazole 15 mg tablet: orally disintegrating, 28 tablets | 1 | 5 | .. | 16.11 | 17.24 | [a] | Zopral ODT | AF |
| | | | | | | | [a] | Zoton FasTabs | PF |

**LANSOPRAZOLE**

# ALIMENTARY TRACT AND METABOLISM

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|---|
| | **Restricted benefit**<br>Initial treatment of peptic ulcer | | | | | | | | |
| | **Note**<br>Helicobacter pylori eradication therapy should be considered. | | | | | | | | |
| | No applications for increased repeats will be authorised. | | | | | | | | |
| | **Note**<br>Pharmaceutical benefits that have the form lansoprazole capsule 30 mg and pharmaceutical benefits that have the form lansoprazole tablet 30 mg (orally disintegrating) are equivalent for the purposes of substitution. | | | | | | | | |
| 2240X<br>*NP* | lansoprazole 30 mg capsule: enteric, 28 | 1 | 1 | .. | 23.66 | 24.79 | [a] | APO-Lansoprazole | TX |
| | | | | | | | [a] | Lanzopran | RA |
| | | | | | | | [a] | Zopral | AF |
| 9477T<br>*NP* | lansoprazole 30 mg tablet: orally disintegrating, 28 tablets | 1 | 1 | .. | 23.66 | 24.79 | [a] | Zopral ODT | AF |
| | | | | [B]0.96 | 24.62 | 24.79 | [a] | Zoton FasTabs | PF |
| | **LANSOPRAZOLE**<br>**Restricted benefit**<br>Gastro-oesophageal reflux disease | | | | | | | | |
| | **Restricted benefit**<br>Scleroderma oesophagus | | | | | | | | |
| | **Note**<br>Pharmaceutical benefits that have the form lansoprazole capsule 30 mg and pharmaceutical benefits that have the form lansoprazole tablet 30 mg (orally disintegrating) are equivalent for the purposes of substitution. | | | | | | | | |
| 2241Y<br>*NP* | lansoprazole 30 mg capsule: enteric, 28 | 1 | 5 | .. | 23.66 | 24.79 | [a] | APO-Lansoprazole | TX |
| | | | | | | | [a] | Lanzopran | RA |
| | | | | | | | [a] | Zopral | AF |
| 9478W<br>*NP* | lansoprazole 30 mg tablet: orally disintegrating, 28 tablets | 1 | 5 | .. | 23.66 | 24.79 | [a] | Zopral ODT | AF |
| | | | | [B]0.96 | 24.62 | 24.79 | [a] | Zoton FasTabs | PF |
| | **OMEPRAZOLE**<br>**Restricted benefit**<br>Gastro-oesophageal reflux disease | | | | | | | | |
| | **Restricted benefit**<br>Scleroderma oesophagus | | | | | | | | |
| | **Restricted benefit**<br>Zollinger-Ellison syndrome | | | | | | | | |
| 8332M<br>*NP* | omeprazole 10 mg tablet: enteric, 30 tablets | 1 | 5 | .. | 14.08 | 15.21 | | Losec Tablets | AP |
| | **OMEPRAZOLE**<br>**Restricted benefit**<br>Peptic ulcer | | | | | | | | |
| | Treatment Phase: Initial treatment | | | | | | | | |
| | **Note**<br>Helicobacter pylori eradication therapy should be considered. | | | | | | | | |
| | **Note**<br>Pharmaceutical benefits that have the forms omeprazole tablet 20 mg, omeprazole capsule 20 mg and omeprazole tablet 20 mg (as magnesium) are equivalent for the purposes of substitution. | | | | | | | | |
| | **Note**<br>No increase in the maximum number of repeats may be authorised. | | | | | | | | |
| 1326T<br>*NP* | omeprazole 20 mg capsule, 30 | 1 | 1 | .. | 17.20 | 18.33 | [a] | APO-Omeprazole | TX |
| | | | | | | | [a] | Maxor | AF |
| | | | | | | | [a] | Omeprazole Sandoz | HX |
| | | | | | | | [a] | Omepro-GA | GM |
| | | | | | | | [a] | Pemzo | QA |
| | | | | | | | [a] | Pharmacor Omeprazole 20 | CR |

# ALIMENTARY TRACT AND METABOLISM

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | [a] | Probitor | SZ |
| 8331L *NP* | omeprazole 20 mg tablet: enteric, 30 tablets | 1 | 1 | .. | 17.20 | 18.33 | [a] | APO-Omeprazole | TX |
| | | | | | | | [a] | Chem mart Omeprazole | CH |
| | | | | | | | [a] | Meprazol | SZ |
| | | | | | | | [a] | Omeprazole-GA | GM |
| | | | | | | | [a] | Omeprazole generichealth | GQ |
| | | | | | | | [a] | Omeprazole RBX | RA |
| | | | | | | | [a] | Omeprazole Winthrop | WA |
| | | | | | | | [a] | Ozmep | ZP |
| | | | | | | | [a] | Terry White Chemists Omeprazole | TW |
| 9109K *NP* | omeprazole 20 mg tablet: enteric, 30 tablets | 1 | 1 | .. | 17.20 | 18.33 | [a] | Acimax Tablets | AL |
| | | | | | | | [a] | Omepral | TX |
| | | | | | | | [a] | Omeprazole Sandoz | SZ |
| | | | | [B]3.03 | 20.23 | 18.33 | [a] | Losec Tablets | AP |

**OMEPRAZOLE**

**Restricted benefit**

Gastro-oesophageal reflux disease

**Restricted benefit**

Scleroderma oesophagus

**Restricted benefit**

Zollinger-Ellison syndrome

**Note**

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

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 1327W *NP* | omeprazole 20 mg capsule, 30 | 1 | 5 | .. | 17.20 | 18.33 | [a] | APO-Omeprazole | TX |
| | | | | | | | [a] | Maxor | AF |
| | | | | | | | [a] | Omeprazole Sandoz | HX |
| | | | | | | | [a] | Omepro-GA | GM |
| | | | | | | | [a] | Pemzo | QA |
| | | | | | | | [a] | Pharmacor Omeprazole 20 | CR |
| | | | | | | | [a] | Probitor | SZ |
| 8333N *NP* | omeprazole 20 mg tablet: enteric, 30 tablets | 1 | 5 | .. | 17.20 | 18.33 | [a] | APO-Omeprazole | TX |
| | | | | | | | [a] | Chem mart Omeprazole | CH |
| | | | | | | | [a] | Meprazol | SZ |
| | | | | | | | [a] | Omeprazole-GA | GM |
| | | | | | | | [a] | Omeprazole generichealth | GQ |
| | | | | | | | [a] | Omeprazole RBX | RA |
| | | | | | | | [a] | Omeprazole Winthrop | WA |
| | | | | | | | [a] | Ozmep | ZP |
| | | | | | | | [a] | Terry White Chemists Omeprazole | TW |
| 9110L *NP* | omeprazole 20 mg tablet: enteric, 30 tablets | 1 | 5 | .. | 17.20 | 18.33 | [a] | Acimax Tablets | AL |
| | | | | | | | [a] | Omepral | TX |
| | | | | | | | [a] | Omeprazole Sandoz | SZ |
| | | | | [B]3.03 | 20.23 | 18.33 | [a] | Losec Tablets | AP |

**PANTOPRAZOLE**

**Restricted benefit**

Gastro-oesophageal reflux disease

**Restricted benefit**

Scleroderma oesophagus

**Restricted benefit**

Zollinger-Ellison syndrome

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 8399C | pantoprazole 20 mg tablet: enteric, 30 | 1 | 5 | .. | 11.26 | 12.39 | [a] | APO-Pantoprazole | TX |

# ALIMENTARY TRACT AND METABOLISM

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|---|---|---|---|---|---|---|---|---|---|
| *NP* | tablets | | | | | | | | |
| | | | | | | | [a] | Chem mart Pantoprazole | CH |
| | | | | | | | [a] | I-Pantoprazole | CR |
| | | | | | | | [a] | Ozpan | RA |
| | | | | | | | [a] | Panto | TK |
| | | | | | | | [a] | Pantofast 20 | RZ |
| | | | | | | | [a] | Pantoprazole-GA | GM |
| | | | | | | | [a] | Pantoprazole generichealth | GQ |
| | | | | | | | [a] | Pantoprazole Sandoz | SZ |
| | | | | | | | [a] | Salpraz | AF |
| | | | | | | | [a] | Somac | NQ |
| | | | | | | | [a] | Terry White Chemists Pantoprazole | TW |
| | | | | | | | [a] | Torzole 20 | TA |
| 9424B *NP* | pantoprazole 40 mg granules: enteric-coated, 30 sachets | 1 | 5 | .. | 30.92 | 32.05 | | Somac | NQ |
| 8008L *NP* | pantoprazole 40 mg tablet: enteric, 30 | 1 | 5 | .. | 16.15 | 17.28 | [a] | APO-Pantoprazole | TX |
| | | | | | | | [a] | Chem mart Pantoprazole | CH |
| | | | | | | | [a] | I-Pantoprazole | CR |
| | | | | | | | [a] | Ozpan | RA |
| | | | | | | | [a] | Panthron | GN |
| | | | | | | | [a] | Panto | TK |
| | | | | | | | [a] | Pantofast 40 | RZ |
| | | | | | | | [a] | Pantoprazole-GA | GM |
| | | | | | | | [a] | Pantoprazole generichealth | GQ |
| | | | | | | | [a] | Pantoprazole Sandoz | SZ |
| | | | | | | | [a] | Salpraz | AF |
| | | | | | | | [a] | Somac | NQ |
| | | | | | | | [a] | Sozol | QA |
| | | | | | | | [a] | STADA Pantoprazole | TD |
| | | | | | | | [a] | Terry White Chemists Pantoprazole | TW |
| | | | | | | | [a] | Torzole 40 | TA |
| | **PANTOPRAZOLE**<br>**Restricted benefit**<br>Initial treatment of peptic ulcer<br>**Note**<br>Helicobacter pylori eradication therapy should be considered.<br>**Note**<br>No applications for increased repeats will be authorised. | | | | | | | | |
| 9423Y *NP* | pantoprazole 40 mg granules: enteric-coated, 30 sachets | 1 | 2 | .. | 30.92 | 32.05 | | Somac | NQ |
| 8007K *NP* | pantoprazole 40 mg tablet: enteric, 30 | 1 | 2 | .. | 16.15 | 17.28 | [a] | APO-Pantoprazole | TX |
| | | | | | | | [a] | Chem mart Pantoprazole | CH |
| | | | | | | | [a] | I-Pantoprazole | CR |
| | | | | | | | [a] | Ozpan | RA |
| | | | | | | | [a] | Panthron | GN |
| | | | | | | | [a] | Panto | TK |
| | | | | | | | [a] | Pantofast 40 | RZ |
| | | | | | | | [a] | Pantoprazole-GA | GM |
| | | | | | | | [a] | Pantoprazole generichealth | GQ |
| | | | | | | | [a] | Pantoprazole Sandoz | SZ |
| | | | | | | | [a] | Salpraz | AF |
| | | | | | | | [a] | Somac | NQ |
| | | | | | | | [a] | Sozol | QA |
| | | | | | | | [a] | STADA Pantoprazole | TD |

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | [a] | Terry White Chemists Pantoprazole | TW |
| | | | | | | | [a] | Torzole 40 | TA |
| | **RABEPRAZOLE**<br>**Restricted benefit**<br>Gastro-oesophageal reflux disease<br>**Restricted benefit**<br>Scleroderma oesophagus | | | | | | | | |
| 8507R<br>*NP* | rabeprazole sodium 10 mg tablet: enteric, 28 tablets | 1 | 5 | .. | 29.20 | 30.33 | [a] | APO-Rabeprazole | TX |
| | | | | | | | [a] | Chem mart Rabeprazole | CH |
| | | | | | | | [a] | Pariet | JC |
| | | | | | | | [a] | Parzol 10 | ZP |
| | | | | | | | [a] | Prabez | AF |
| | | | | | | | [a] | Rabeprazole-GA | GM |
| | | | | | | | [a] | Rabeprazole generichealth | GQ |
| | | | | | | | [a] | Rabeprazole Sandoz | SZ |
| | | | | | | | [a] | Rabzole | JS |
| | | | | | | | [a] | Razit 10 | DO |
| | | | | | | | [a] | Terry White Chemists Rabeprazole | TW |
| 8508T<br>*NP* | rabeprazole sodium 20 mg tablet: enteric, 30 tablets | 1 | 5 | .. | 29.20 | 30.33 | [a] | APO-Rabeprazole | TX |
| | | | | | | | [a] | Chem mart Rabeprazole | CH |
| | | | | | | | [a] | Pariet | JC |
| | | | | | | | [a] | Parzol 20 | ZP |
| | | | | | | | [a] | Prabez | AF |
| | | | | | | | [a] | Rabeprazole Actavis 20 | TA |
| | | | | | | | [a] | Rabeprazole-GA | GM |
| | | | | | | | [a] | Rabeprazole generichealth | GQ |
| | | | | | | | [a] | Rabeprazole Sandoz | SZ |
| | | | | | | | [a] | Rabzole | JS |
| | | | | | | | [a] | Razit 20 | DO |
| | | | | | | | [a] | STADA Rabeprazole | TD |
| | | | | | | | [a] | Terry White Chemists Rabeprazole | TW |
| | **RABEPRAZOLE**<br>**Restricted benefit**<br>Initial treatment of peptic ulcer<br>**Note**<br>Helicobacter pylori eradication therapy should be considered.<br>**Note**<br>No applications for increased repeats will be authorised. | | | | | | | | |
| 8509W<br>*NP* | rabeprazole sodium 20 mg tablet: enteric, 30 tablets | 1 | 2 | .. | 29.20 | 30.33 | [a] | APO-Rabeprazole | TX |
| | | | | | | | [a] | Chem mart Rabeprazole | CH |
| | | | | | | | [a] | Pariet | JC |
| | | | | | | | [a] | Parzol 20 | ZP |
| | | | | | | | [a] | Prabez | AF |
| | | | | | | | [a] | Rabeprazole Actavis 20 | TA |
| | | | | | | | [a] | Rabeprazole-GA | GM |
| | | | | | | | [a] | Rabeprazole generichealth | GQ |
| | | | | | | | [a] | Rabeprazole Sandoz | SZ |
| | | | | | | | [a] | Rabzole | JS |
| | | | | | | | [a] | Razit 20 | DO |
| | | | | | | | [a] | STADA Rabeprazole | TD |
| | | | | | | | [a] | Terry White Chemists Rabeprazole | TW |

## *Combinations for eradication of Helicobacter pylori*

# ALIMENTARY TRACT AND METABOLISM

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|---|
| | **ESOMEPRAZOLE (&) CLARITHROMYCIN (&) AMOXYCILLIN** | | | | | | | | |
| | **Restricted benefit** | | | | | | | | |
| | Eradication of Helicobacter pylori associated with peptic ulcer disease | | | | | | | | |
| 8738X *NP* | esomeprazole 20 mg tablet: enteric [14 tablets] (&) clarithromycin 500 mg tablet [14 tablets] (&) amoxycillin 500 mg capsule [28 capsules], 1 pack | ‡1 | .. | .. | 60.09 | 36.10 | | Nexium Hp7 | AP |
| | **OMEPRAZOLE (&) CLARITHROMYCIN (&) AMOXYCILLIN** | | | | | | | | |
| | **Restricted benefit** | | | | | | | | |
| | Eradication of Helicobacter pylori associated with peptic ulcer disease | | | | | | | | |
| 8272J *NP* | omeprazole 20 mg capsule [14 capsules] (&) clarithromycin 500 mg tablet [14 tablets] (&) amoxycillin 500 mg capsule [28 capsules], 1 pack | ‡1 | .. | .. | 52.87 | 36.10 | | Probitor Hp7 | SZ |

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

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | **ALGINATE SODIUM + CALCIUM CARBONATE + BICARBONATE** | | | | | | | | |
| 2014B *NP* | alginate sodium 500 mg/10 mL + calcium carbonate 160 mg/10 mL + sodium bicarbonate 267 mg/10 mL oral liquid, 500 mL | 2 | 5 | .. | *14.89 | 16.02 | | Gaviscon P | RC |
| | **SUCRALFATE** | | | | | | | | |
| 2055E *NP* | sucralfate 1 g tablet, 120 | 1 | 2 | .. | 25.61 | 26.74 | a | Ulcyte | AF |
| | | | | B2.07 | 27.68 | 26.74 | a | Carafate | AS |

## DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS

### BELLADONNA AND DERIVATIVES, PLAIN

#### *Belladonna alkaloids, tertiary amines*

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | **ATROPINE** | | | | | | | | |
| | **Note** | | | | | | | | |
| | Shared Care Model: | | | | | | | | |
| | For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners. | | | | | | | | |
| 1089H *NP* | ATROPINE Injection 600 micrograms in 1 mL, 10 | 1 | 1 | .. | 20.75 | 21.88 | | Pfizer Australia Pty Ltd | PF |
| | **ATROPINE** | | | | | | | | |
| 5022H *DP* | ATROPINE Injection 600 micrograms in 1 mL, 10 | 1 | .. | .. | 20.75 | 21.88 | | Pfizer Australia Pty Ltd | PF |

### PROPULSIVES

#### *Propulsives*

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | **DOMPERIDONE** | | | | | | | | |
| 1347X *NP* | domperidone 10 mg tablet, 25 | 1 | .. | .. | 9.10 | 10.23 | | Motilium | JC |
| | **METOCLOPRAMIDE** | | | | | | | | |
| 1207M *NP,MW* | metoclopramide hydrochloride anhydrous 10 mg tablet, 25 | 1 | .. | .. | 8.41 | 9.54 | | Pramin | AF |
| | | | | B3.02 | 11.43 | 9.54 | | Maxolon | VT |
| 5151D *DP* | metoclopramide hydrochloride anhydrous 10 mg tablet, 25 | 1 | .. | .. | 8.41 | 9.54 | | Pramin | AF |
| | | | | B3.02 | 11.43 | 9.54 | | Maxolon | VT |
| 1206L *NP,MW* | metoclopramide hydrochloride anhydrous 10 mg/2 mL injection, 10 x 2 mL ampoules | 1 | .. | .. | 13.20 | 14.33 | | Maxolon | VT |
| 5153F *DP* | metoclopramide hydrochloride anhydrous 10 mg/2 mL injection, 10 x 2 mL ampoules | 1 | .. | .. | 13.20 | 14.33 | | Maxolon | VT |

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|---|

ANTIEMETICS AND ANTINAUSEANTS

## ANTIEMETICS AND ANTINAUSEANTS

### *Serotonin (5HT3) antagonists*

**GRANISETRON**
**Restricted benefit**
Nausea and vomiting

**The Clinical criteria is:**

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

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

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 8728J *NP* | granisetron 2 mg tablet, 1 | 2 | .. | .. | *37.15 | 36.10 | | Kytril | RO |

**GRANISETRON**
**Authority required (STREAMLINED)**
***4102***
Nausea and vomiting

**The Clinical criteria is:**

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

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 8873B *NP* | granisetron 2 mg tablet, 5 | 1 | 1 | .. | 79.60 | 36.10 | | Kytril | RO |

**GRANISETRON**
**Restricted benefit**
Nausea and vomiting

**The Clinical criteria is:**

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

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

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 8729K *NP* | granisetron 3 mg/3 mL injection, 1 x 3 mL ampoule | 1 | .. | .. | 19.11 | 20.24 | [a] | Granisetron Kabi | PK |
| | | | | | | | [a] | Kytril | RO |

**GRANISETRON**
**Authority required (STREAMLINED)**
***4092***
Nausea and vomiting

**The Clinical criteria is:**

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

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 8730L *NP* | granisetron 3 mg/3 mL injection, 1 x 3 mL ampoule | 1 | .. | .. | 19.11 | 20.24 | [a] | Granisetron Kabi | PK |
| | | | | | | | [a] | Kytril | RO |

**ONDANSETRON**
**Authority required (STREAMLINED)**
***3611***
Management of nausea and vomiting associated with radiotherapy being used to treat malignancy

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

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 5472B *NP* | ONDANSETRON Tablet (orally disintegrating) 4 mg, 10 | 1 | 1 | .. | 54.60 | 36.10 | [a] | Ondansetron ODT-DRLA | RZ |
| | | | | | | | [a] | Onsetron ODT 4 | WQ |
| 8412R *NP* | ondansetron 4 mg wafer, 10 | 1 | 1 | .. | 54.60 | 36.10 | [a] | Ondaz Zydis | SZ |
| | | | | | | | [a] | Zofran Zydis | AS |

**ONDANSETRON**
**Restricted benefit**

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|---|
| | Management of nausea and vomiting associated with cytotoxic chemotherapy being used to treat malignancy which occurs within 48 hours of chemotherapy administration. | | | | | | | | |
| | Increased maximum quantities will be limited to a maximum of 7 days per chemotherapy cycle | | | | | | | | |
| | **Note** | | | | | | | | |
| | Pharmaceutical benefits that have the form ondansetron tablet (orally disintegrating) 4 mg and pharmaceutical benefits that have the form ondansetron wafer 4 mg are equivalent for the purposes of substitution. | | | | | | | | |
| 5470X *NP* | ONDANSETRON Tablet (orally disintegrating) 4 mg, 4 | 1 | .. | .. | 26.63 | 27.76 | [a] | Ondansetron ODT-DRLA | RZ |
| | | | | | | | [a] | Onsetron ODT 4 | WQ |
| 8410P *NP* | ondansetron 4 mg wafer, 4 | 1 | .. | .. | 26.63 | 27.76 | [a] | Ondaz Zydis | SZ |
| | | | | | | | [a] | Zofran Zydis | AS |
| | **ONDANSETRON** | | | | | | | | |
| | **Authority required (STREAMLINED)** | | | | | | | | |
| | ***3611*** | | | | | | | | |
| | Management of nausea and vomiting associated with radiotherapy being used to treat malignancy | | | | | | | | |
| | **Note** | | | | | | | | |
| | Pharmaceutical benefits that have the form ondansetron tablet (orally disintegrating) 8 mg and pharmaceutical benefits that have the form ondansetron wafer 8 mg are equivalent for the purposes of substitution. | | | | | | | | |
| 5473C *NP* | ONDANSETRON Tablet (orally disintegrating) 8 mg, 10 | 1 | 1 | .. | 81.53 | 36.10 | [a] | Ondansetron ODT-DRLA | RZ |
| | | | | | | | [a] | Onsetron ODT 8 | WQ |
| 8413T *NP* | ondansetron 8 mg wafer, 10 | 1 | 1 | .. | 81.53 | 36.10 | [a] | Ondaz Zydis | SZ |
| | | | | | | | [a] | Zofran Zydis | AS |
| | **ONDANSETRON** | | | | | | | | |
| | **Restricted benefit** | | | | | | | | |
| | Management of nausea and vomiting associated with cytotoxic chemotherapy being used to treat malignancy which occurs within 48 hours of chemotherapy administration. | | | | | | | | |
| | Increased maximum quantities will be limited to a maximum of 7 days per chemotherapy cycle | | | | | | | | |
| | **Note** | | | | | | | | |
| | Pharmaceutical benefits that have the form ondansetron tablet (orally disintegrating) 8 mg and pharmaceutical benefits that have the form ondansetron wafer 8 mg are equivalent for the purposes of substitution. | | | | | | | | |
| 5471Y *NP* | ONDANSETRON Tablet (orally disintegrating) 8 mg, 4 | 1 | .. | .. | 37.94 | 36.10 | [a] | Ondansetron ODT-DRLA | RZ |
| | | | | | | | [a] | Onsetron ODT 8 | WQ |
| 8411Q *NP* | ondansetron 8 mg wafer, 4 | 1 | .. | .. | 37.94 | 36.10 | [a] | Ondaz Zydis | SZ |
| | | | | | | | [a] | Zofran Zydis | AS |
| | **ONDANSETRON** | | | | | | | | |
| | **Authority required (STREAMLINED)** | | | | | | | | |
| | ***3611*** | | | | | | | | |
| | Management of nausea and vomiting associated with radiotherapy being used to treat malignancy | | | | | | | | |
| 1594X *NP* | ondansetron 4 mg tablet, 10 | 1 | 1 | .. | 54.60 | 36.10 | [a] | APO-Ondansetron | TX |
| | | | | | | | [a] | Ondansetron-DRLA | RZ |
| | | | | | | | [a] | Ondaz | SZ |
| | | | | | | | [a] | Onsetron 4 | ZP |
| | | | | | | | [a] | Zilfojim 4 | DO |
| | | | | | | | [a] | Zofran | AS |
| 1596B *NP* | ondansetron 4 mg/2 mL injection, 1 x 2 mL ampoule | 1 | .. | .. | 9.02 | 10.15 | [a] | Ondansetron Alphapharm | AF |
| | | | | | | | [a] | Ondansetron-Claris | AE |
| | | | | | | | [a] | Ondansetron Kabi | PK |
| | | | | | | | [a] | Ondaz | SZ |
| | | | | | | | [a] | Onsetron | ZP |
| | | | | | | | [a] | Zofran | AS |
| 8233H *NP* | ondansetron 4 mg/5 mL oral liquid, 50 mL | ‡1 | 1 | .. | 102.17 | 36.10 | | Zofran syrup 50 mL | AS |
| 1595Y *NP* | ondansetron 8 mg tablet, 10 | 1 | 1 | .. | 81.53 | 36.10 | [a] | APO-Ondansetron | TX |

# ALIMENTARY TRACT AND METABOLISM

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | [a] | Ondansetron-DRLA | RZ |
| | | | | | | | [a] | Ondaz | SZ |
| | | | | | | | [a] | Onsetron 8 | ZP |
| | | | | | | | [a] | Zilfojim 8 | DO |
| | | | | | | | [a] | Zofran | AS |
| 1597C *NP* | ondansetron 8 mg/4 mL injection, 1 x 4 mL ampoule | 1 | .. | .. | 10.41 | 11.54 | [a] | Ondansetron Alphapharm | AF |
| | | | | | | | [a] | Ondansetron-Claris | AE |
| | | | | | | | [a] | Ondansetron Kabi | PK |
| | | | | | | | [a] | Ondaz | SZ |
| | | | | | | | [a] | Onsetron | ZP |
| | | | | | | | [a] | Zofran | AS |

**ONDANSETRON**

**Restricted benefit**

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

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

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 8224W *NP* | ondansetron 4 mg tablet, 4 | 1 | .. | .. | 26.63 | 27.76 | [a] | APO-Ondansetron | TX |
| | | | | | | | [a] | Ondansetron-DRLA | RZ |
| | | | | | | | [a] | Ondaz | SZ |
| | | | | | | | [a] | Onsetron 4 | ZP |
| | | | | | | | [a] | Zofran | AS |
| 8226Y *NP* | ondansetron 4 mg/2 mL injection, 1 x 2 mL ampoule | 1 | .. | .. | 9.02 | 10.15 | [a] | Ondansetron Alphapharm | AF |
| | | | | | | | [a] | Ondansetron-Claris | AE |
| | | | | | | | [a] | Ondansetron Kabi | PK |
| | | | | | | | [a] | Ondaz | SZ |
| | | | | | | | [a] | Onsetron | ZP |
| | | | | | | | [a] | Zofran | AS |
| 9441X *NP* | ondansetron 4 mg/5 mL oral liquid, 50 mL | ‡1 | .. | .. | 102.17 | 36.10 | | Zofran syrup 50 mL | AS |
| 8225X *NP* | ondansetron 8 mg tablet, 4 | 1 | .. | .. | 37.94 | 36.10 | [a] | APO-Ondansetron | TX |
| | | | | | | | [a] | Ondansetron-DRLA | RZ |
| | | | | | | | [a] | Ondaz | SZ |
| | | | | | | | [a] | Onsetron 8 | ZP |
| | | | | | | | [a] | Zofran | AS |
| 8227B *NP* | ondansetron 8 mg/4 mL injection, 1 x 4 mL ampoule | 1 | .. | .. | 10.41 | 11.54 | [a] | Ondansetron Alphapharm | AF |
| | | | | | | | [a] | Ondansetron-Claris | AE |
| | | | | | | | [a] | Ondansetron Kabi | PK |
| | | | | | | | [a] | Ondaz | SZ |
| | | | | | | | [a] | Onsetron | ZP |
| | | | | | | | [a] | Zofran | AS |

**PALONOSETRON**

**Restricted benefit**

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

**Note**

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

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 5295Q *NP* | palonosetron 250 microgram/5 mL injection, 1 x 5 mL vial | 1 | .. | .. | 48.07 | 36.10 | | Aloxi | TS |

**TROPISETRON**

**Restricted benefit**

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

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

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 2745L *NP* | tropisetron 5 mg capsule, 2 | 1 | .. | .. | 50.93 | 36.10 | | Navoban | NV |

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|---|
| 2746M<br>*NP* | tropisetron 5 mg/5 mL injection, 1 x 5 mL ampoule | 1 | .. | .. | 29.50 | 30.63 | [a] | Navoban | NV |
| | | | | | | | [a] | Tropisetron-AFT | AE |

## *Other antiemetics*

**APREPITANT**

**Authority required (STREAMLINED)**

***3619***

Management of nausea and vomiting associated with cytotoxic chemotherapy being used to treat malignancy, in combination with a 5HT3 antagonist and dexamethasone, where any 1 of the following chemotherapy agents are to be administered:

(a) altretamine;

(b) carmustine;

(c) cisplatin when a single dose constitutes a cycle of chemotherapy;

(d) cyclophosphamide at a dose of 1500 mg per square metre per day or greater;

(e) dacarbazine;

(f) procarbazine when a single dose constitutes a cycle of chemotherapy;

(g) streptozocin.

No more than 1 pack containing 1 x 125 mg capsule and 2 x 80 mg capsules will be authorised per cycle of cytotoxic chemotherapy

**Authority required (STREAMLINED)**

***3620***

Management of nausea and vomiting associated with cytotoxic chemotherapy being used to treat breast cancer, in combination with a 5HT3 antagonist and dexamethasone, where cyclophosphamide and an anthracycline are to be co-administered.

No more than 1 pack containing 1 x 125 mg capsule and 2 x 80 mg capsules will be authorised per cycle of cytotoxic chemotherapy

**Authority required (STREAMLINED)**

***3621***

Management of nausea and vomiting associated with moderately emetogenic cytotoxic chemotherapy being used to treat malignancy, in combination with a 5HT3 antagonist and dexamethasone on day 1, where the patient has had a prior episode of chemotherapy induced nausea or vomiting where any 1 of the following intravenous chemotherapy agents is to be administered:

(a) arsenic trioxide;

(b) azacitidine;

(c) carboplatin;

(d) cyclophosphamide at a dose of less than 1500 mg per square metre per day;

(e) cytarabine at a dose of greater than 1 g per square metre per day;

(f) dactinomycin;

(g) daunorubicin;

(h) doxorubicin;

(i) epirubicin;

(j) fotemustine;

(k) idarubicin;

(l) ifosfamide;

(m) irinotecan;

(n) melphalan;

(o) methotrexate at a dose of 250 mg to 1 g per square metre;

(p) oxaliplatin;

(q) raltitrexed.

No more than one pack containing 1 x 125 mg capsule and 2 x 80 mg capsules will be authorised per cycle of cytotoxic chemotherapy. Concomitant use of a 5HT3 antagonist should not occur with aprepitant on days 2 and 3 of any chemotherapy cycle

**Note**

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

**Note**

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

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 8808N<br>*NP* | aprepitant 125 mg capsule [1 capsule] (&) aprepitant 80 mg capsule [2 capsules], 3 | ‡1 | 5 | .. | 139.10 | 36.10 | | Emend | MK |

**APREPITANT**

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|
| | **Authority required (STREAMLINED)**<br>***4211***<br>Nausea and vomiting<br>**The Clinical criteria is:**<br>The condition must be associated with cytotoxic chemotherapy being used to treat malignancy,<br>**AND the Clinical criteria is:**<br>The treatment must be in combination with a 5-hydroxytryptamine receptor (5HT3) antagonist and dexamethasone,<br>**AND the Clinical criteria is:**<br>Patient must be scheduled to be administered a chemotherapy regimen that includes any 1 of the following agents: altretamine; carmustine; cisplatin when a single dose constitutes a cycle of chemotherapy; cyclophosphamide at a dose of 1500 mg per square metre per day or greater; dacarbazine; procarbazine when a single dose constitutes a cycle of chemotherapy; streptozocin .<br>No more than 1 capsule of aprepitant 165 mg will be authorised per cycle of cytotoxic chemotherapy. | | | | | | | |
| | **Authority required (STREAMLINED)**<br>***4215***<br>Nausea and vomiting<br>**The Clinical criteria is:**<br>The condition must be associated with cytotoxic chemotherapy being used to treat breast cancer,<br>**AND the Clinical criteria is:**<br>The treatment must be in combination with a 5-hydroxytryptamine receptor (5HT3) antagonist and dexamethasone,<br>**AND the Clinical criteria is:**<br>Patient must be scheduled to be co-administered cyclophosphamide and an anthracycline.<br>No more than 1 capsule of aprepitant 165 mg will be authorised per cycle of cytotoxic chemotherapy. | | | | | | | |
| | **Authority required (STREAMLINED)**<br>***4213***<br>Nausea and vomiting<br>**The Clinical criteria is:**<br>The condition must be associated with moderately emetogenic cytotoxic chemotherapy being used to treat malignancy,<br>**AND the Clinical criteria is:**<br>The treatment must be in combination with a 5-hydroxytryptamine receptor (5HT3) antagonist and dexamethasone on day 1 of a chemotherapy cycle,<br>**AND the Clinical criteria is:**<br>Patient must have had a prior episode of chemotherapy induced nausea or vomiting,<br>**AND the Clinical criteria is:**<br>Patient must be scheduled to be administered a chemotherapy regimen that includes any 1 of the following intravenous chemotherapy agents: arsenic trioxide; azacitidine; carboplatin; cyclophosphamide at a dose of less than 1500 mg per square metre per day; cytarabine at a dose of greater than 1 g per square metre per day; dactinomycin; daunorubicin; doxorubicin; epirubicin; fotemustine; idarubicin; ifosfamide; irinotecan; melphalan; methotrexate at a dose of 250 mg to 1 g per square metre; oxaliplatin; raltitrexed .<br>No more than 1 capsule of aprepitant 165 mg will be authorised per cycle of cytotoxic chemotherapy.<br>Concomitant use of a 5HT3 antagonist should not occur with aprepitant on days 2 and 3 of any chemotherapy cycle.<br>**Note**<br>Aprepitant is not PBS-subsidised for nausea and vomiting associated with radiotherapy being used to treat malignancy.<br>**Note**<br>No increase in the maximum quantity or number of units may be authorised.<br>**Note**<br>No increase in the maximum number of repeats may be authorised. | | | | | | | |
| 2518M<br>*NP* | aprepitant 165 mg capsule, 1 | 1 | 5 | .. | 138.00 | 36.10 | Emend | MK |
| | **PROCHLORPERAZINE**<br>**Caution**<br>Prochlorperazine may be associated with parkinsonism and tardive dyskinesia and should be used for short-term treatment only.<br>**Note**<br>As prochlorperazine may be associated with parkinsonism and tardive dyskinesia it should be used for short-term treatment only. However, authorities for increased maximum quantities and/or repeats of prochlorperazine tablets will be granted for the treatment of emesis associated with malignant disease. | | | | | | | |
| 2895J | prochlorperazine maleate 25 mg | ‡1 | 2 | .. | 20.14 | 21.27 | Stemetil | SW |

# ALIMENTARY TRACT AND METABOLISM

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|---|
| *NP* | suppository, 5 | | | | | | | | |
| 2893G *NP* | prochlorperazine maleate 5 mg tablet, 25 | 1 | .. | .. | 8.90 | 10.03 | [a] | APO-Prochlorperazine | TX |
| | | | | | | | [a] | Pharmacor Prozine 5 | CR |
| | | | | | | | [a] | ProCalm | QA |
| | | | | | | | [a] | Prochlorperazine-GA | GM |
| | | | | | | | [a] | Prochlorperazine GH | GQ |
| | | | | | | | [a] | Stemzine | AV |
| | | | | [B]3.45 | 12.35 | 10.03 | [a] | Stemetil | SW |
| 2369Q *NP* | prochlorperazine mesylate 12.5 mg/mL injection, 10 x 1 mL ampoules | 1 | .. | .. | 17.03 | 18.16 | | Stemetil | SW |
| | **PROCHLORPERAZINE** | | | | | | | | |
| | **Caution** | | | | | | | | |
| | Prochlorperazine may be associated with parkinsonism and tardive dyskinesia and should be used for short-term treatment only. | | | | | | | | |
| 5208D *DP* | prochlorperazine maleate 25 mg suppository, 5 | ‡1 | .. | .. | 20.14 | 21.27 | | Stemetil | SW |
| 5205Y *DP* | prochlorperazine maleate 5 mg tablet, 25 | 1 | .. | .. | 8.90 | 10.03 | [a] | APO-Prochlorperazine | TX |
| | | | | | | | [a] | Pharmacor Prozine 5 | CR |
| | | | | | | | [a] | ProCalm | QA |
| | | | | | | | [a] | Prochlorperazine-GA | GM |
| | | | | | | | [a] | Prochlorperazine GH | GQ |
| | | | | | | | [a] | Stemzine | AV |
| | | | | [B]3.45 | 12.35 | 10.03 | [a] | Stemetil | SW |
| 5206B *DP* | prochlorperazine mesylate 12.5 mg/mL injection, 10 x 1 mL ampoules | 1 | .. | .. | 17.03 | 18.16 | | Stemetil | SW |
| | **PROMETHAZINE** | | | | | | | | |
| 3374N *DP* | promethazine hydrochloride 50 mg/2 mL injection, 5 x 2 mL ampoules | 2 | .. | .. | *30.45 | 31.58 | | Hospira Pty Limited | HH |

## BILE AND LIVER THERAPY

### BILE THERAPY

#### *Bile acid preparations*

**URSODEOXYCHOLIC ACID**

**Authority required (STREAMLINED)**

***1700***

Primary biliary cirrhosis

**Note**

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

**Note**

Continuing Therapy Only:

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

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 8448P *NP* | ursodeoxycholic acid 250 mg capsule, 100 | 2 | 2 | .. | *372.81 | 36.10 | | Ursofalk | OA |

## LAXATIVES

### LAXATIVES

#### *Contact laxatives*

**BISACODYL**

**Restricted benefit**

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

**Restricted benefit**

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

**Restricted benefit**

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

**Restricted benefit**

Patients receiving palliative care

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|---|
| | **Restricted benefit**<br>Terminal malignant neoplasia | | | | | | | | |
| | **Restricted benefit**<br>Anorectal congenital abnormalities | | | | | | | | |
| | **Restricted benefit**<br>Megacolon | | | | | | | | |
| 1260H<br>*NP* | bisacodyl 10 mg suppository, 10 | 3 | 5 | .. | *21.15 | 22.28 | a | Petrus Bisacodyl Suppositories | PP |
| | | | | B1.50 | *22.65 | 22.28 | a | Dulcolax | BY |
| 1258F<br>*NP* | bisacodyl 10 mg suppository, 12 | 3 | 4 | .. | *18.54 | 19.67 | | Petrus Bisacodyl Suppositories | PP |
| 1259G<br>*NP* | bisacodyl 5 mg tablet: enteric, 200 tablets | 1 | 2 | .. | 14.32 | 15.45 | | Bisalax | AS |
| | | | | | | | | Lax-Tab | AE |

## *Bulk producers*

**RHAMNUS FRANGULA + STERCULIA**

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

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

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

**Restricted benefit**
Patients receiving palliative care

**Restricted benefit**
Terminal malignant neoplasia

**Restricted benefit**
Anorectal congenital abnormalities

**Restricted benefit**
Megacolon

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 1104D<br>*NP* | rhamnus frangula 80 mg/g + sterculia 620 mg/g granules, 500 g | ‡1 | 1 | .. | 26.58 | 27.71 | | Normacol Plus | NE |

## *Osmotically acting laxatives*

**LACTULOSE**

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

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

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 3064G<br>*NP* | LACTULOSE Mixture 3.34 g per 5 mL, 500 mL, 1 | ‡1 | 5 | .. | 11.35 | 12.48 | a | Actilax | AF |
| | | | | | | | a | Genlac | QA |
| | | | | | | | a | GenRx Lactulose | GX |
| | | | | | | | a | Lac-Dol | GM |
| | | | | | | | a | Lactocur | SZ |
| | | | | B1.01 | 12.36 | 12.48 | a | Duphalac | AB |

**MACROGOL-3350**

**Restricted benefit**
Constipation

**The Clinical criteria is:**

Patient must have malignant neoplasia.

**Restricted benefit**
Constipation

**The Clinical criteria is:**

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

**AND the Clinical criteria is:**

The condition must be unresponsive to other oral therapies.

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|---|
| | **Restricted benefit**<br>Constipation<br>**The Clinical criteria is:**<br>Patient must be receiving palliative care.<br>**Restricted benefit**<br>Chronic constipation<br>**The Clinical criteria is:**<br>The condition must be inadequately controlled with first line interventions such as bulk-forming agents.<br>**Restricted benefit**<br>Faecal impaction<br>**The Clinical criteria is:**<br>The condition must be inadequately controlled with first line interventions such as bulk-forming agents.<br>**Note**<br>Pharmaceutical benefits that have the form macrogol-3350 1 g/g oral liquid: powder for, 510 g and pharmaceutical benefits that have the form macrogol-3350 1 g/g oral liquid: powder for, 30 x 17 g sachets are equivalent for the purposes of substitution. | | | | | | | | |
| 2373X<br>*NP* | macrogol-3350 1 g/g oral liquid: powder for, 30 x 17 g sachets | ‡1 | 5 | .. | 20.76 | 21.89 | a | MediHealth ClearLax | ON |
| 3416T<br>*NP* | macrogol-3350 1 g/g oral liquid: powder for, 510 g | ‡1 | 5 | .. | 20.76 | 21.89 | a | OsmoLax | KY |
| | **MACROGOL-3350 + SODIUM CHLORIDE + POTASSIUM CHLORIDE + BICARBONATE**<br>**Restricted benefit**<br>Constipation in patients with malignant neoplasia<br>**Restricted benefit**<br>Chronic constipation or faecal impaction not adequately controlled with first line interventions such as bulk-forming agents<br>**Restricted benefit**<br>Paraplegic and quadriplegic patients and others with severe neurogenic impairment of bowel function not responding to other oral therapies<br>**Restricted benefit**<br>Patients receiving palliative care | | | | | | | | |
| 8612G<br>*NP* | 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 | ‡1 | 5 | .. | 20.76 | 21.89 | a | LaxaCon | GM |
| | | | | | | | a | Movicol | NE |

## *Enemas*

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | **BISACODYL**<br>**Restricted benefit**<br>Paraplegic and quadriplegic patients and others with severe neurogenic impairment of bowel function<br>**Restricted benefit**<br>Patients who are receiving long-term nursing care on account of age, infirmity or other condition in hospitals, nursing homes or residential facilities<br>**Restricted benefit**<br>For use by a patient who is receiving long-term nursing care and in respect of whom a Carer Allowance is payable as a disabled adult<br>**Restricted benefit**<br>Patients receiving palliative care<br>**Restricted benefit**<br>Terminal malignant neoplasia<br>**Restricted benefit**<br>Anorectal congenital abnormalities<br>**Restricted benefit**<br>Megacolon | | | | | | | | |
| 1263L<br>*NP* | bisacodyl 10 mg/5 mL enema, 25 x 5 mL | ‡1 | 2 | .. | 38.15 | 36.10 | | Bisalax | AS |
| | **SORBITOL + CITRATE + LAURYL SULFOACETATE SODIUM**<br>**Restricted benefit**<br>Paraplegic and quadriplegic patients and others with severe neurogenic impairment of bowel function<br>**Restricted benefit** | | | | | | | | |

# ALIMENTARY TRACT AND METABOLISM

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|---|
| | Patients who are receiving long-term nursing care on account of age, infirmity or other condition in hospitals, nursing homes or residential facilities | | | | | | | | |
| | **Restricted benefit**<br>For use by a patient who is receiving long-term nursing care and in respect of whom a Carer Allowance is payable as a disabled adult | | | | | | | | |
| | **Restricted benefit**<br>Patients receiving palliative care | | | | | | | | |
| | **Restricted benefit**<br>Terminal malignant neoplasia | | | | | | | | |
| | **Restricted benefit**<br>Anorectal congenital abnormalities | | | | | | | | |
| | **Restricted benefit**<br>Megacolon | | | | | | | | |
| 2091C<br>*NP* | sorbitol 3.125 g/5 mL + citrate sodium dihydrate 450 mg/5 mL + lauryl sulfoacetate sodium 45 mg/5 mL enema, 12 x 5 mL | 2 | 2 | .. | *32.49 | 33.62 | [a] | Micolette | AE |
| | | | | | | | [a] | Microlax | JT |

### *Other laxatives*

**GLYCEROL**

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

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

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

**Restricted benefit**
Patients receiving palliative care

**Restricted benefit**
Terminal malignant neoplasia

**Restricted benefit**
Anorectal congenital abnormalities

**Restricted benefit**
Megacolon

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 2556M<br>*NP* | glycerol 1.4 g suppository, 12 | 3 | 5 | .. | *20.10 | 21.23 | | Petrus Pharmaceuticals Pty Ltd | PP |
| 2557N<br>*NP* | glycerol 2.8 g suppository, 12 | 3 | 5 | .. | *20.61 | 21.74 | | Petrus Pharmaceuticals Pty Ltd | PP |
| 2555L<br>*NP* | glycerol 700 mg suppository, 12 | 3 | 5 | .. | *19.68 | 20.81 | | Petrus Pharmaceuticals Pty Ltd | PP |

## ANTIDIARRHEALS, INTESTINAL ANTIINFLAMMATORY/ANTIINFECTIVE AGENTS

### INTESTINAL ANTIINFECTIVES

### *Antibiotics*

**NYSTATIN**

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 1699K<br>*NP* | nystatin 500 000 international units capsule, 50 | 1 | .. | .. | 18.19 | 19.32 | | Nilstat | QA |
| 3345C<br>*DP* | nystatin 500 000 international units capsule, 50 | 1 | .. | .. | 18.19 | 19.32 | | Nilstat | QA |
| 1696G<br>*NP* | nystatin 500 000 international units tablet, 50 | 1 | .. | .. | 18.19 | 19.32 | | Nilstat | QA |
| 3342X<br>*DP* | nystatin 500 000 international units tablet, 50 | 1 | .. | .. | 18.19 | 19.32 | | Nilstat | QA |

**VANCOMYCIN**

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

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

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

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|---|
| | preferred treatment. | | | | | | | | |
| 3113W | vancomycin 125 mg capsule, 20 | 2 | .. | .. | *232.47 | 36.10 | | Vancocin | AS |
| 3114X | vancomycin 250 mg capsule, 20 | 2 | .. | .. | *440.25 | 36.10 | | Vancocin | AS |

## ELECTROLYTES WITH CARBOHYDRATES
### *Oral rehydration salt formulations*

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

**Note**

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

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 3196F *NP* | sodium chloride 470 mg + potassium chloride 300 mg + glucose monohydrate 3.56 g + sodium acid citrate 530 mg oral liquid: powder for, 10 x 4.9 g sachets | ‡1 | .. | .. | 13.12 | 14.25 | [a] | O.R.S. | AS |
| | | | | | | | [a] | Repalyte New Formulation | SW |
| | | | | | | | [a] | restore O.R.S. | GM |

## ANTIPROPULSIVES
### *Antipropulsives*

**DIPHENOXYLATE + ATROPINE SULFATE**

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 2501P *NP* | diphenoxylate hydrochloride 2.5 mg + atropine sulfate 25 microgram tablet, 20 | 1 | .. | .. | 8.68 | 9.81 | [a] | Lofenoxal | HC |
| | | | | [B]1.73 | 10.41 | 9.81 | [a] | Lomotil | BI |

**LOPERAMIDE**

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 1571Q *NP* | loperamide hydrochloride 2 mg capsule, 12 | 1 | .. | .. | 8.34 | 9.47 | [a] | Gastrex | CR |
| | | | | | | | [a] | Gastro-Stop Loperamide | AS |
| | | | | [B]0.75 | 9.09 | 9.47 | [a] | Imodium | JT |

## INTESTINAL ANTIINFLAMMATORY AGENTS
### *Corticosteroids acting locally*

**HYDROCORTISONE ACETATE**

**Restricted benefit**

Proctitis

**Restricted benefit**

Ulcerative colitis

**Note**

Continuing Therapy Only:

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

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 1502C *NP* | hydrocortisone acetate 10% (100 mg/g) enema, 21.1 g | 2 | 3 | .. | *44.09 | 36.10 | | Colifoam | AS |

**PREDNISOLONE SODIUM PHOSPHATE**

**Note**

Continuing Therapy Only:

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

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 1920C *NP* | prednisolone (as sodium phosphate) 20 mg/100 mL enema, 7 x 100 mL | 4 | 3 | .. | *211.55 | 36.10 | | Predsol | QA |

**PREDNISOLONE SODIUM PHOSPHATE**

**Restricted benefit**

Proctitis

**Restricted benefit**

Ulcerative colitis

**Note**

Continuing Therapy Only:

# ALIMENTARY TRACT AND METABOLISM

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|
| | For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners. | | | | | | | |
| 2554K *NP* | prednisolone (as sodium phosphate) 5 mg suppository, 10 | 3 | 3 | .. | *41.91 | 36.10 | Predsol | QA |

## *Aminosalicylic acid and similar agents*

**BALSALAZIDE**

**Authority required (STREAMLINED)**

***1708***

Ulcerative colitis where hypersensitivity to sulfonamides exists

**Authority required (STREAMLINED)**

***1709***

Ulcerative colitis where intolerance to sulfasalazine exists

**Note**

Not for the treatment of Crohn disease.

**Note**

Continuing Therapy Only:

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

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 8845M *NP* | balsalazide sodium 750 mg capsule, 180 | 1 | 5 | .. | 125.06 | 36.10 | Colazide | PK |

**MESALAZINE**

**Authority required (STREAMLINED)**

***1708***

Ulcerative colitis where hypersensitivity to sulfonamides exists

**Authority required (STREAMLINED)**

***1709***

Ulcerative colitis where intolerance to sulfasalazine exists

**Note**

Not for the treatment of Crohn disease.

**Note**

Continuing Therapy Only:

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

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 8599N *NP* | mesalazine 1 g granules: modified release, 100 x 1 g sachets | 1 | 5 | .. | 279.84 | 36.10 | Salofalk | OA |
| 9353G *NP* | mesalazine 1.2 g tablet: modified release, 60 tablets | 1 | 5 | .. | 221.20 | 36.10 | Mezavant | ZI |
| 9206M *NP* | mesalazine 1.5 g granules: modified release, 60 x 1.5 g sachets | 1 | 5 | .. | 245.13 | 36.10 | Salofalk | OA |
| 8598M *NP* | mesalazine 500 mg granules: modified release, 100 x 500 mg sachets | 2 | 5 | .. | *297.65 | 36.10 | Salofalk | OA |

**MESALAZINE**

**Authority required (STREAMLINED)**

***1708***

Ulcerative colitis where hypersensitivity to sulfonamides exists

**Authority required (STREAMLINED)**

***1709***

Ulcerative colitis where intolerance to sulfasalazine exists

**Authority required (STREAMLINED)**

***2268***

Crohn disease where hypersensitivity to sulfonamides exists

**Authority required (STREAMLINED)**

***2269***

Crohn disease where intolerance to sulfasalazine exists

**Note**

Continuing Therapy Only:

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

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 2234N | mesalazine 1 g granules: modified | 1 | 5 | .. | 330.88 | 36.10 | Pentasa | FP |

# ALIMENTARY TRACT AND METABOLISM

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|
| *NP* | release, 120 x 1 g sachets | | | | | | | |
| 3413P *NP* | mesalazine 1 g tablet: modified release, 60 tablets | 2 | 5 | .. | *330.89 | 36.10 | Pentasa | FP |
| 2287J *NP* | mesalazine 2 g granules: modified release, 60 x 2 g sachets | 1 | 5 | .. | 312.51 | 36.10 | Pentasa | FP |
| 1611T *NP* | mesalazine 250 mg tablet: enteric, 100 tablets | 1 | 5 | .. | 93.64 | 36.10 | Mesasal | AS |
| 8731M *NP* | mesalazine 500 mg tablet: enteric, 100 tablets | 2 | 5 | .. | *297.65 | 36.10 | Salofalk | OA |
| 2214M *NP* | mesalazine 500 mg tablet: modified release, 100 tablets | 2 | 5 | .. | *297.65 | 36.10 | Pentasa | FP |

**MESALAZINE**

**Restricted benefit**

Acute episode of mild to moderate ulcerative proctitis

**Note**

Not for the treatment of Crohn disease.

**Note**

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

**Note**

Continuing Therapy Only:

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

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 5461K *NP* | mesalazine 1 g suppository, 30 | 1 | 1 | .. | 136.60 | 36.10 | Salofalk | OA |
| 8752P *NP* | mesalazine 1 g suppository, 30 | 1 | 1 | .. | 136.60 | 36.10 | Pentasa | FP |

**MESALAZINE**

**Authority required (STREAMLINED)**

***1707***

Acute episode of mild to moderate ulcerative colitis

**Note**

Not for the treatment of Crohn disease.

**Note**

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

**Note**

Continuing Therapy Only:

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

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 8753Q *NP* | mesalazine 1 g/100 mL enema, 7 x 100 mL | 4 | 1 | .. | *336.43 | 36.10 | Pentasa | FP |
| 8768L *NP* | mesalazine 1 g/application enema, 14 applications | 4 | 1 | .. | *336.43 | 36.10 | Salofalk | OA |
| 8616L *NP* | mesalazine 2 g/60 mL enema, 7 x 60 mL | 4 | 1 | .. | *336.43 | 36.10 | Salofalk | OA |
| 8617M *NP* | mesalazine 4 g/60 mL enema, 7 x 60 mL | 4 | 1 | .. | *446.11 | 36.10 | Salofalk | OA |

**OLSALAZINE**

**Authority required (STREAMLINED)**

***1708***

Ulcerative colitis where hypersensitivity to sulfonamides exists

**Authority required (STREAMLINED)**

***1709***

Ulcerative colitis where intolerance to sulfasalazine exists

**Note**

Not for the treatment of Crohn disease.

**Note**

Continuing Therapy Only:

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

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 1728Y | olsalazine sodium 250 mg capsule, 100 | 1 | 5 | .. | 61.62 | 36.10 | Dipentum | UC |

# ALIMENTARY TRACT AND METABOLISM

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|---|
| *NP* | | | | | | | | | |
| 8086N *NP* | olsalazine sodium 500 mg tablet, 100 | 1 | 5 | .. | 103.50 | 36.10 | | Dipentum | UC |

**SULFASALAZINE**

**Note**

Continuing Therapy Only:

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

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 2096H *NP* | SULFASALAZINE Tablet 500 mg (enteric coated), 100 | 2 | 5 | .. | *54.47 | 36.10 | a | Pyralin EN | FZ |
| | | | | [B]1.96 | *56.43 | 36.10 | a | Salazopyrin-EN | PF |
| 2093E *NP* | sulfasalazine 500 mg tablet, 100 | 2 | 5 | .. | *50.49 | 36.10 | | Salazopyrin | PF |

**SULFASALAZINE**

**Restricted benefit**

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

**Note**

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

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 9209Q | SULFASALAZINE Tablet 500 mg (enteric coated), 100 | 2 | 11 | .. | *54.47 | 36.10 | a | Pyralin EN | FZ |
| | | | | [B]1.96 | *56.43 | 36.10 | a | Salazopyrin-EN | PF |
| 9208P | sulfasalazine 500 mg tablet, 100 | 2 | 11 | .. | *50.49 | 36.10 | | Salazopyrin | PF |

## DIGESTIVES, INCL. ENZYMES

DIGESTIVES, INCL. ENZYMES

### *Enzyme preparations*

**PANCREATIC EXTRACT**

**Note**

Continuing Therapy Only:

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

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 8020D *NP* | pancreatic extract 10 000 international units capsule: modified release, 100 capsules | 5 | 10 | .. | *183.88 | 36.10 | Creon 10,000 | AB |
| 8021E *NP* | pancreatic extract 25 000 international units capsule: modified release, 100 capsules | 2 | 10 | .. | *147.95 | 36.10 | Creon 25,000 | AB |
| 9412J *NP* | pancreatic extract 40 000 international units capsule: modified release, 100 capsules | 2 | 10 | .. | *230.17 | 36.10 | Creon 40,000 | AB |
| 5453B *NP* | pancreatic extract 5000 international units/100 mg granules: enteric-coated, 20 g | 3 | 10 | .. | *141.99 | 36.10 | Creon Micro | AB |

**PANCREATIC EXTRACT**

**Restricted benefit**

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

**Note**

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

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 9226N | pancreatic extract 10 000 international units capsule: modified release, 100 capsules | 5 | 21 | .. | *183.88 | 36.10 | Creon 10,000 | AB |
| 9227P | pancreatic extract 25 000 international units capsule: modified release, 100 capsules | 2 | 21 | .. | *147.95 | 36.10 | Creon 25,000 | AB |
| 9413K | pancreatic extract 40 000 international units capsule: modified release, 100 capsules | 2 | 21 | .. | *230.17 | 36.10 | Creon 40,000 | AB |
| 5454C | pancreatic extract 5000 international units/100 mg granules: enteric-coated, | 3 | 21 | .. | *141.99 | 36.10 | Creon Micro | AB |

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|
| | 20 g | | | | | | | |
| | **PANCRELIPASE**<br>**Note**<br>Continuing Therapy Only:<br>For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners. | | | | | | | |
| 8366H<br>*NP* | pancrelipase 25 000 units capsule, 100 | 2 | 10 | .. | *138.11 | 36.10 | Panzytrat 25000 | TM |
| | **PANCRELIPASE**<br>**Restricted benefit**<br>For use in patients with cystic fibrosis, and who are receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements<br>**Note**<br>No applications for increased maximum quantities and/or repeats will be authorised. | | | | | | | |
| 9229R | pancrelipase 25 000 units capsule, 100 | 2 | 21 | .. | *138.11 | 36.10 | Panzytrat 25000 | TM |

## DRUGS USED IN DIABETES

### INSULINS AND ANALOGUES

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

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | **INSULIN ASPART** | | | | | | | |
| 8571D<br>*NP* | insulin aspart 100 international units/mL injection, 1 x 10 mL vial | 5 | 2 | .. | *159.48 | 36.10 | NovoRapid | NO |
| 8435Y<br>*NP* | insulin aspart 100 international units/mL injection, 5 x 3 mL cartridges | 5 | 1 | .. | *264.43 | 36.10 | NovoRapid FlexPen | NF |
| | | | | | | | NovoRapid Penfill 3 mL | NO |
| | **INSULIN GLULISINE** | | | | | | | |
| 9224L<br>*NP* | insulin glulisine 100 international units/mL injection, 1 x 10 mL vial | 5 | 2 | .. | *159.48 | 36.10 | Apidra | SW |
| 1921D<br>*NP* | insulin glulisine 100 international units/mL injection, 5 x 3 mL cartridges | 5 | 1 | .. | *264.43 | 36.10 | Apidra | AV |
| | | | | | | | Apidra SoloStar | SW |
| | **INSULIN LISPRO** | | | | | | | |
| 8084L<br>*NP* | insulin lispro 100 international units/mL injection, 1 x 10 mL vial | 5 | 2 | .. | *159.48 | 36.10 | Humalog | LY |
| 8212F<br>*NP* | insulin lispro 100 international units/mL injection, 5 x 3 mL cartridges | 5 | 1 | .. | *264.43 | 36.10 | Humalog | LY |
| | | | | | | | Humalog KwikPen | KP |
| | **INSULIN NEUTRAL BOVINE** | | | | | | | |
| 1713E<br>*NP* | insulin neutral bovine 100 international units/mL injection, 1 x 10 mL vial | 5 | 2 | .. | *172.23 | 36.10 | Hypurin Neutral | AS |
| | **INSULIN NEUTRAL HUMAN** | | | | | | | |
| 1531N<br>*NP* | insulin neutral human 100 international units/mL injection, 1 x 10 mL vial | 5 | 2 | .. | *134.03 | 36.10 | Actrapid | NO |
| | | | | | | | Humulin R | LY |
| 1762R<br>*NP* | insulin neutral human 100 international units/mL injection, 5 x 3 mL cartridges | 5 | 1 | .. | *224.53 | 36.10 | Actrapid Penfill 3 mL | NO |
| | | | | | | | Humulin R | LY |

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

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | **INSULIN ISOPHANE BOVINE** | | | | | | | |
| 1711C<br>*NP* | insulin isophane bovine 100 international units/mL injection, 1 x 10 mL vial | 5 | 2 | .. | *172.23 | 36.10 | Hypurin Isophane | AS |
| | **INSULIN ISOPHANE HUMAN** | | | | | | | |
| 1533Q<br>*NP* | insulin isophane human 100 international units/mL injection, 1 x 10 mL vial | 5 | 2 | .. | *134.03 | 36.10 | Humulin NPH | LY |
| | | | | | | | Protaphane | NO |
| 1761Q | insulin isophane human 100 | 5 | 1 | .. | *224.53 | 36.10 | Humulin NPH | LY |

# ALIMENTARY TRACT AND METABOLISM

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|---|
| *NP* | international units/mL injection, 5 x 3 mL cartridges | | | | | | | | |
| | | | | | | | | Protaphane InnoLet | NI |
| | | | | | | | | Protaphane Penfill 3 mL | NO |

## *Insulins and analogues for injection, intermediate-acting combined with fast-acting*

**INSULIN ASPART + INSULIN ASPART PROTAMINE**

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 8609D *NP* | insulin aspart 30 international units/mL + insulin aspart protamine 70 international units/mL injection, 5 x 3 mL syringes | 5 | 1 | .. | *264.43 | 36.10 | | NovoMix 30 FlexPen | NF |
| | | | | | | | | NovoMix 30 Penfill 3 mL | NO |

**INSULIN ISOPHANE HUMAN + INSULIN NEUTRAL HUMAN**

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 1763T *NP* | insulin isophane human 70 international units/mL + insulin neutral human 30 international units/mL injection, 5 x 3 mL cartridges | 5 | 1 | .. | *224.53 | 36.10 | | Humulin 30/70 | LY |
| | | | | | | | | Mixtard 30/70 InnoLet | NI |
| | | | | | | | | Mixtard 30/70 Penfill 3 mL | NO |
| 1426C *NP* | insulin neutral human 30 international units/mL + insulin isophane human 70 international units/mL injection, 1 x 10 mL vial | 5 | 2 | .. | *134.03 | 36.10 | | Humulin 30/70 | LY |
| 2062M *NP* | insulin neutral human 50 international units/mL + insulin isophane human 50 international units/mL injection, 5 x 3 mL cartridges | 5 | 1 | .. | *224.53 | 36.10 | | Mixtard 50/50 Penfill 3 mL | NO |

**INSULIN LISPRO + INSULIN LISPRO PROTAMINE**

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 8390N *NP* | insulin lispro 25 international units/mL + insulin lispro protamine 75 international units/mL injection, 5 x 3 mL cartridges | 5 | 1 | .. | *264.43 | 36.10 | | Humalog Mix25 | LY |
| | | | | | | | | Humalog Mix25 KwikPen | KP |
| 8874C *NP* | insulin lispro 50 international units/mL + insulin lispro protamine 50 international units/mL injection, 5 x 3 mL cartridges | 5 | 1 | .. | *264.43 | 36.10 | | Humalog Mix50 | LY |
| | | | | | | | | Humalog Mix50 KwikPen | KP |

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

**INSULIN DETEMIR**

**Restricted benefit**

Type 1 diabetes

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 9040T *NP* | insulin detemir 100 international units/mL injection, 5 x 3 mL cartridges | 5 | 1 | .. | *432.93 | 36.10 | | Levemir FlexPen | NF |
| | | | | | | | | Levemir Penfill | NO |

**INSULIN GLARGINE**

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 9039R *NP* | insulin glargine 100 international units/mL injection, 5 x 3 mL cartridges | 5 | 1 | .. | *432.93 | 36.10 | | Lantus | SW |
| | | | | | | | | Lantus SoloStar | AV |

# BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS

## *Biguanides*

**METFORMIN**

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 8607B *NP* | metformin hydrochloride 1 g tablet, 90 | 1 | 5 | .. | 14.40 | 15.53 | [a] | APO-Metformin 1000 | TX |
| | | | | | | | [a] | Chem mart Metformin 1000 | CH |
| | | | | | | | [a] | Diaformin 1000 | AF |
| | | | | | | | [a] | Formet 1000 | QA |
| | | | | | | | [a] | Glucobete 1000 | DO |

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | [a] | Metformin-GA | GM |
| | | | | | | | [a] | Metformin generichealth 1000 | GQ |
| | | | | | | | [a] | Metformin Ranbaxy 1000 | RA |
| | | | | | | | [a] | Metformin Sandoz | SZ |
| | | | | | | | [a] | Pharmacor Metformin 1000 | CR |
| | | | | | | | [a] | Terry White Chemists Metformin 1000 | TW |
| | | | | [B]1.23 | 15.63 | 15.53 | [a] | Diabex 1000 | AL |
| 3439B *NP* | metformin hydrochloride 1 g tablet: modified release, 60 tablets | 1 | 5 | .. | 13.76 | 14.89 | | Diabex XR 1000 | AL |
| 2430X *NP* | metformin hydrochloride 500 mg tablet, 100 | 1 | 5 | .. | 11.08 | 12.21 | [a] | APO-Metformin 500 | TX |
| | | | | | | | [a] | Chem mart Metformin | CH |
| | | | | | | | [a] | Diaformin | AF |
| | | | | | | | [a] | Formet 500 | QA |
| | | | | | | | [a] | Formet Aspen 500 | AS |
| | | | | | | | [a] | GenRx Metformin | GX |
| | | | | | | | [a] | Glucobete 500 | DO |
| | | | | | | | [a] | Metformin 500 | CR |
| | | | | | | | [a] | Metformin-GA | GM |
| | | | | | | | [a] | Metformin generichealth | GQ |
| | | | | | | | [a] | Metformin Ranbaxy | RA |
| | | | | | | | [a] | Metformin Sandoz | SZ |
| | | | | | | | [a] | Terry White Chemists Metformin | TW |
| | | | | [B]1.20 | 12.28 | 12.21 | [a] | Diabex | AL |
| 9435N *NP* | metformin hydrochloride 500 mg tablet: modified release, 120 tablets | 1 | 5 | .. | 13.76 | 14.89 | [a] | APO-Metformin XR 500 | TX |
| | | | | | | | [a] | Chem mart Metformin XR 500 | CH |
| | | | | | | | [a] | Diabex XR | AL |
| | | | | | | | [a] | Diaformin XR | AF |
| | | | | | | | [a] | Metex XR | QA |
| | | | | | | | [a] | Terry White Chemists Metformin XR 500 | TW |
| 1801T *NP* | metformin hydrochloride 850 mg tablet, 60 | 1 | 5 | .. | 11.08 | 12.21 | [a] | APO-Metformin 850 | TX |
| | | | | | | | [a] | Chem mart Metformin | CH |
| | | | | | | | [a] | Diaformin 850 | AF |
| | | | | | | | [a] | Formet 850 | QA |
| | | | | | | | [a] | Formet Aspen 850 | AS |
| | | | | | | | [a] | GenRx Metformin | GX |
| | | | | | | | [a] | Glucobete 850 | DO |
| | | | | | | | [a] | Metformin 850 | CR |
| | | | | | | | [a] | Metformin-GA | GM |
| | | | | | | | [a] | Metformin generichealth | GQ |
| | | | | | | | [a] | Metformin Ranbaxy | RA |
| | | | | | | | [a] | Metformin Sandoz | SZ |
| | | | | | | | [a] | Terry White Chemists Metformin | TW |
| | | | | [B]0.74 | 11.82 | 12.21 | [a] | Glucophage | MQ |
| | | | | [B]1.20 | 12.28 | 12.21 | [a] | Diabex 850 | AL |

## *Sulfonamides, urea derivatives*

**GLIBENCLAMIDE**

**Caution**

Sulfonylureas may cause hypoglycaemia, particularly in the elderly.

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 2939Q *NP* | glibenclamide 5 mg tablet, 100 | 1 | 5 | .. | 11.60 | 12.73 | [a] | Glimel | AF |
| | | | | [B]1.44 | 13.04 | 12.73 | [a] | Daonil | SW |

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|---|
| | **GLICLAZIDE** | | | | | | | | |
| | **Caution** | | | | | | | | |
| | Sulfonylureas may cause hypoglycaemia, particularly in the elderly. | | | | | | | | |
| 8535F *NP* | gliclazide 30 mg tablet: modified release, 100 tablets | 1 | 5 | .. | 13.56 | 14.69 | [a] | APO-Gliclazide MR | TX |
| | | | | | | | [a] | Chem mart Gliclazide MR | CH |
| | | | | | | | [a] | Glyade MR | AF |
| | | | | | | | [a] | Oziclide MR | RA |
| | | | | | | | [a] | Terry White Chemists Gliclazide MR | TW |
| 9302N *NP* | gliclazide 60 mg tablet: modified release, 60 tablets | 1 | 5 | .. | 14.96 | 16.09 | | Diamicron 60mg MR | SE |
| 2449X *NP* | gliclazide 80 mg tablet, 100 | 1 | 5 | .. | 13.37 | 14.50 | [a] | Chem mart Gliclazide | CH |
| | | | | | | | [a] | GenRx Gliclazide | GX |
| | | | | | | | [a] | Glyade | AF |
| | | | | | | | [a] | Nidem | QA |
| | | | | | | | [a] | Terry White Chemists Gliclazide | TW |
| | **GLIMEPIRIDE** | | | | | | | | |
| | **Caution** | | | | | | | | |
| | Sulfonylureas may cause hypoglycaemia, particularly in the elderly. | | | | | | | | |
| 8450R *NP* | glimepiride 1 mg tablet, 30 | 1 | 5 | .. | 8.26 | 9.39 | [a] | APO-Glimepiride | TX |
| | | | | | | | [a] | Aylide 1 | AF |
| | | | | | | | [a] | Diapride 1 | QA |
| | | | | | | | [a] | Dimirel | AV |
| | | | | | | | [a] | Glimepiride GA 1 | GM |
| | | | | | | | [a] | Glimepiride Sandoz | SZ |
| | | | | [B]2.80 | 11.06 | 9.39 | [a] | Amaryl | SW |
| 8451T *NP* | glimepiride 2 mg tablet, 30 | 1 | 5 | .. | 9.76 | 10.89 | [a] | APO-Glimepiride | TX |
| | | | | | | | [a] | Aylide 2 | AF |
| | | | | | | | [a] | Diapride 2 | QA |
| | | | | | | | [a] | Dimirel | AV |
| | | | | | | | [a] | Glimepiride GA 2 | GM |
| | | | | | | | [a] | Glimepiride Sandoz | SZ |
| | | | | [B]2.80 | 12.56 | 10.89 | [a] | Amaryl | SW |
| 8533D *NP* | glimepiride 3 mg tablet, 30 | 1 | 5 | .. | 10.62 | 11.75 | [a] | APO-Glimepiride | TX |
| | | | | | | | [a] | Aylide 3 | AF |
| | | | | | | | [a] | Diapride 3 | QA |
| | | | | | | | [a] | Dimirel | AV |
| | | | | | | | [a] | Glimepiride GA 3 | GM |
| | | | | | | | [a] | Glimepiride Sandoz | SZ |
| | | | | [B]2.81 | 13.43 | 11.75 | [a] | Amaryl | SW |
| 8452W *NP* | glimepiride 4 mg tablet, 30 | 1 | 5 | .. | 11.53 | 12.66 | [a] | APO-Glimepiride | TX |
| | | | | | | | [a] | Aylide 4 | AF |
| | | | | | | | [a] | Diapride 4 | QA |
| | | | | | | | [a] | Dimirel | AV |
| | | | | | | | [a] | Glimepiride GA 4 | GM |
| | | | | | | | [a] | Glimepiride Sandoz | SZ |
| | | | | [B]2.81 | 14.34 | 12.66 | [a] | Amaryl | SW |
| | **GLIPIZIDE** | | | | | | | | |
| | **Caution** | | | | | | | | |
| | Sulfonylureas may cause hypoglycaemia, particularly in the elderly. | | | | | | | | |
| 2440K *NP* | glipizide 5 mg tablet, 100 | 1 | 5 | .. | 12.48 | 13.61 | [a] | Melizide | AF |
| | | | | [B]3.83 | 16.31 | 13.61 | [a] | Minidiab | PF |

***Combinations of oral blood glucose lowering drugs***

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|
| | **METFORMIN + GLIBENCLAMIDE** | | | | | | | |
| | **Caution** | | | | | | | |
| | Sulfonylureas may cause hypoglycaemia, particularly in the elderly. | | | | | | | |
| 8838E *NP* | metformin hydrochloride 250 mg + glibenclamide 1.25 mg tablet, 90 | 1 | 5 | .. | 13.98 | 15.11 | Glucovance 250mg/1.25mg | AL |
| 8810Q *NP* | metformin hydrochloride 500 mg + glibenclamide 2.5 mg tablet, 90 | 1 | 5 | .. | 14.89 | 16.02 | Glucovance 500mg/2.5mg | AL |
| 8811R *NP* | metformin hydrochloride 500 mg + glibenclamide 5 mg tablet, 90 | 1 | 5 | .. | 16.01 | 17.14 | Glucovance 500mg/5mg | AL |
| | **ROSIGLITAZONE + METFORMIN** | | | | | | | |
| | **Authority required** | | | | | | | |
| | Type 2 diabetes in a patient whose HbA1c is greater than 7% prior to initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone) or a glucagon-like peptide-1 despite treatment with metformin and where a sulfonylurea is contraindicated or not tolerated. | | | | | | | |
| | The date and level of the qualifying HbA1c must be documented in the patient's medical records at the time treatment with a gliptin, a glitazone or a glucagon-like peptide-1 is initiated. The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone or a glucagon-like peptide-1 is initiated. | | | | | | | |
| | Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances: | | | | | | | |
| | (a) clinical conditions with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or | | | | | | | |
| | (b) red cell transfusion within the previous 3 months. | | | | | | | |
| | A patient in these circumstances will be eligible for treatment where blood glucose monitoring over a 2 week period shows blood glucose levels greater than 10 mmol per L in more than 20% of tests. The results of this blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone or a glucagon-like peptide-1, must be documented in the patient's medical records | | | | | | | |
| | **Note** | | | | | | | |
| | Rosiglitazone with metformin fixed dose combination tablet is not PBS-subsidised when used in combination with a sulfonylurea (triple oral therapy) or an insulin or a dipeptidyl peptidase 4 inhibitor (gliptin) or a glucagon-like peptide-1. | | | | | | | |
| 9060W *NP* | rosiglitazone 2 mg + metformin hydrochloride 1 g tablet, 56 | 1 | 5 | .. | 65.98 | 36.10 | Avandamet | GK |
| 9059T *NP* | rosiglitazone 2 mg + metformin hydrochloride 500 mg tablet, 56 | 1 | 5 | .. | 63.74 | 36.10 | Avandamet | GK |
| 9062Y *NP* | rosiglitazone 4 mg + metformin hydrochloride 1 g tablet, 56 | 1 | 5 | .. | 95.44 | 36.10 | Avandamet | GK |
| 9061X *NP* | rosiglitazone 4 mg + metformin hydrochloride 500 mg tablet, 56 | 1 | 5 | .. | 93.20 | 36.10 | Avandamet | GK |
| | **SITAGLIPTIN + METFORMIN** | | | | | | | |
| | **Authority required (STREAMLINED)** | | | | | | | |
| | ***3543*** | | | | | | | |
| | Type 2 diabetes in a patient whose HbA1c is greater than 7% prior to initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone) or a glucagon-like peptide-1 despite treatment with metformin and where a combination of metformin and a sulfonylurea is contraindicated or not tolerated. | | | | | | | |
| | The date and level of the qualifying HbA1c must be documented in the patient's medical records at the time treatment with a gliptin, a glitazone or a glucagon-like peptide-1 is initiated. The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone or a glucagon-like peptide-1 is initiated. | | | | | | | |
| | Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances: | | | | | | | |
| | (a) clinical conditions with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or | | | | | | | |
| | (b) red cell transfusion within the previous 3 months. | | | | | | | |
| | A patient in these circumstances will be eligible for treatment where blood glucose monitoring over a 2 week period shows blood glucose levels greater than 10 mmol per L in more than 20% of tests. The results of this blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone or a glucagon-like peptide-1, must be documented in the patient's medical records | | | | | | | |
| | **Authority required (STREAMLINED)** | | | | | | | |
| | ***3149*** | | | | | | | |
| | Continuation of therapy in type 2 diabetes mellitus in a patient who has previously received and been stabilised on a PBS-subsidised regimen of oral diabetic medicines which includes metformin and sitagliptin | | | | | | | |
| | **Note** | | | | | | | |
| | Sitagliptin with metformin fixed dose combination tablet is not PBS-subsidised for use in combination with a sulfonylurea (triple oral therapy), as initial therapy or in combination with a thiazolidinedione (glitazone) or a glucagon-like peptide-1. | | | | | | | |
| 9451K *NP* | sitagliptin 50 mg + metformin hydrochloride 1 g tablet, 56 | 1 | 5 | .. | 95.44 | 36.10 | Janumet | MK |
| 9449H *NP* | sitagliptin 50 mg + metformin hydrochloride 500 mg tablet, 56 | 1 | 5 | .. | 93.20 | 36.10 | Janumet | MK |
| 9450J | sitagliptin 50 mg + metformin | 1 | 5 | .. | 94.80 | 36.10 | Janumet | MK |

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|
| *NP* | hydrochloride 850 mg tablet, 56 | | | | | | | |

**VILDAGLIPTIN + METFORMIN**

**Authority required (STREAMLINED)**

***3543***

Type 2 diabetes in a patient whose HbA1c is greater than 7% prior to initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone) or a glucagon-like peptide-1 despite treatment with metformin and where a combination of metformin and a sulfonylurea is contraindicated or not tolerated.

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

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

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

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

A patient in these circumstances will be eligible for treatment where blood glucose monitoring over a 2 week period shows blood glucose levels greater than 10 mmol per L in more than 20% of tests. The results of this blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone or a glucagon-like peptide-1, must be documented in the patient's medical records

**Authority required (STREAMLINED)**

***3686***

Continuation of therapy in type 2 diabetes mellitus in a patient who has previously received and been stabilised on a PBS-subsidised regimen of oral diabetic medicines which includes metformin and vildagliptin

**Note**

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

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 5476F *NP* | vildagliptin 50 mg + metformin hydrochloride 1 g tablet, 60 | 1 | 5 | .. | 98.70 | 36.10 | Galvumet 50/1000 | NV |
| 5474D *NP* | vildagliptin 50 mg + metformin hydrochloride 500 mg tablet, 60 | 1 | 5 | .. | 96.30 | 36.10 | Galvumet 50/500 | NV |
| 5475E *NP* | vildagliptin 50 mg + metformin hydrochloride 850 mg tablet, 60 | 1 | 5 | .. | 98.01 | 36.10 | Galvumet 50/850 | NV |

## *Alpha glucosidase inhibitors*

**ACARBOSE**

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 8189B *NP* | acarbose 100 mg tablet, 90 | 1 | 5 | .. | 45.74 | 36.10 | Glucobay 100 | BN |
| 8188Y *NP* | acarbose 50 mg tablet, 90 | 1 | 5 | .. | 34.74 | 35.87 | Glucobay 50 | BN |

## *Thiazolidinediones*

**PIOGLITAZONE**

**Authority required (STREAMLINED)**

***3540***

Dual oral combination therapy with metformin or a sulfonylurea

Type 2 diabetes, in combination with either metformin or a sulfonylurea, in a patient whose HbA1c is greater than 7% prior to initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone) or a glucagon-like peptide-1 despite treatment with either metformin or a sulfonylurea and where a combination of metformin and a sulfonylurea is contraindicated or not tolerated.

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

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

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

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

A patient in these circumstances will be eligible for treatment where blood glucose monitoring over a 2 week period shows blood glucose levels greater than 10 mmol per L in more than 20% of tests. The results of this blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone or a glucagon-like peptide-1, must be documented in the patient's medical records

**Authority required (STREAMLINED)**

***3541***

Combination therapy with insulin

Type 2 diabetes, in combination with insulin, in a patient whose HbA1c is greater than 7% prior to initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone) or a glucagon-like peptide-1 despite treatment with insulin and oral anti-diabetic agents, or insulin alone where metformin is contraindicated.

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

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|---|
| | like peptide-1 is initiated.<br>Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:<br>(a) clinical conditions with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or<br>(b) red cell transfusion within the previous 3 months.<br>A patient in these circumstances will be eligible for treatment where blood glucose monitoring over a 2 week period shows blood glucose levels greater than 10 mmol per L in more than 20% of tests. The results of this blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone or a glucagon-like peptide-1, must be documented in the patient's medical records<br>**Authority required (STREAMLINED)**<br>***3542***<br>Triple oral combination therapy with metformin and a sulfonylurea<br>Type 2 diabetes, in combination with metformin and a sulfonylurea, in a patient whose HbA1c is greater than 7% prior to initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone) or a glucagon-like peptide-1 despite treatment with maximally tolerated doses of metformin and a sulfonylurea.<br>The date and level of the qualifying HbA1c must be documented in the patient's medical records at the time treatment with a gliptin, a glitazone or a glucagon-like peptide-1 is initiated. The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone or a glucagon-like peptide-1 is initiated.<br>Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:<br>(a) clinical conditions with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or<br>(b) red cell transfusion within the previous 3 months.<br>A patient in these circumstances will be eligible for treatment where blood glucose monitoring over a 2 week period shows blood glucose levels greater than 10 mmol per L in more than 20% of tests. The results of this blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone or a glucagon-like peptide-1, must be documented in the patient's medical records<br>**Note**<br>Pioglitazone hydrochloride is not PBS-subsidised as monotherapy or in combination with a dipeptidyl peptidase 4 inhibitor (gliptin) or a glucagon-like peptide-1. | | | | | | | | |
| 8694N<br>*NP* | pioglitazone 15 mg tablet, 28 | 1 | 5 | .. | 40.93 | 36.10 | [a] | Acpio 15 | QA |
| | | | | | | | [a] | Actos | LY |
| | | | | | | | [a] | APOTEX-Pioglitazone | TX |
| | | | | | | | [a] | Chem mart Pioglitazone | CH |
| | | | | | | | [a] | Pharmacor Pioglitazone 15 | CR |
| | | | | | | | [a] | Pioglitazone-GA | GM |
| | | | | | | | [a] | Pioglitazone generichealth 15 | GQ |
| | | | | | | | [a] | Pioglitazone Sandoz | SZ |
| | | | | | | | [a] | Pizaccord | RA |
| | | | | | | | [a] | Prioten 15 | DO |
| | | | | | | | [a] | Terry White Chemists Pioglitazone | TW |
| | | | | | | | [a] | Vexazone | AF |
| 8695P<br>*NP* | pioglitazone 30 mg tablet, 28 | 1 | 5 | .. | 57.10 | 36.10 | [a] | Acpio 30 | QA |
| | | | | | | | [a] | Actos | LY |
| | | | | | | | [a] | APOTEX-Pioglitazone | TX |
| | | | | | | | [a] | Chem mart Pioglitazone | CH |
| | | | | | | | [a] | Pharmacor Pioglitazone 30 | CR |
| | | | | | | | [a] | Pioglitazone-GA | GM |
| | | | | | | | [a] | Pioglitazone generichealth 30 | GQ |
| | | | | | | | [a] | Pioglitazone Sandoz | SZ |
| | | | | | | | [a] | Pizaccord | RA |
| | | | | | | | [a] | Prioten 30 | DO |
| | | | | | | | [a] | Terry White Chemists Pioglitazone | TW |
| | | | | | | | [a] | Vexazone | AF |
| 8696Q<br>*NP* | pioglitazone 45 mg tablet, 28 | 1 | 5 | .. | 72.25 | 36.10 | [a] | Acpio 45 | QA |
| | | | | | | | [a] | Actos | LY |
| | | | | | | | [a] | APOTEX-Pioglitazone | TX |
| | | | | | | | [a] | Chem mart Pioglitazone | CH |

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|
| | | | | | | | [a] Pharmacor Pioglitazone 45 | CR |
| | | | | | | | [a] Pioglitazone-GA | GM |
| | | | | | | | [a] Pioglitazone generichealth 45 | GQ |
| | | | | | | | [a] Pioglitazone Sandoz | SZ |
| | | | | | | | [a] Pizaccord | RA |
| | | | | | | | [a] Prioten 45 | DO |
| | | | | | | | [a] Terry White Chemists Pioglitazone | TW |
| | | | | | | | [a] Vexazone | AF |

**ROSIGLITAZONE**

**Authority required**

Dual oral combination therapy with metformin or a sulfonylurea

Type 2 diabetes, in combination with either metformin or a sulfonylurea, in a patient whose HbA1c is greater than 7% prior to initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone) or a glucagon-like peptide-1 despite treatment with either metformin or a sulfonylurea and where a combination of metformin and a sulfonylurea is contraindicated or not tolerated.

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

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

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

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

A patient in these circumstances will be eligible for treatment where blood glucose monitoring over a 2 week period shows blood glucose levels greater than 10 mmol per L in more than 20% of tests. The results of this blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone or a glucagon-like peptide-1, must be documented in the patient's medical records

**Note**

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

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 8689H *NP* | rosiglitazone 4 mg tablet, 28 | 1 | 5 | .. | 61.36 | 36.10 | Avandia | GK |
| 8690J *NP* | rosiglitazone 8 mg tablet, 28 | 1 | 5 | .. | 90.81 | 36.10 | Avandia | GK |

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

**LINAGLIPTIN**

**Authority required (STREAMLINED)**

***3540***

Dual oral combination therapy with metformin or a sulfonylurea

Type 2 diabetes, in combination with either metformin or a sulfonylurea, in a patient whose HbA1c is greater than 7% prior to initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone) or a glucagon-like peptide-1 despite treatment with either metformin or a sulfonylurea and where a combination of metformin and a sulfonylurea is contraindicated or not tolerated.

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

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

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

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

A patient in these circumstances will be eligible for treatment where blood glucose monitoring over a 2 week period shows blood glucose levels greater than 10 mmol per L in more than 20% of tests. The results of this blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone or a glucagon-like peptide-1, must be documented in the patient's medical records

**Note**

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

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 3387G *NP* | linagliptin 5 mg tablet, 30 | 1 | 5 | .. | 96.82 | 36.10 | Trajenta | BY |

**SAXAGLIPTIN**

**Authority required (STREAMLINED)**

***3540***

Dual oral combination therapy with metformin or a sulfonylurea

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|
| | Type 2 diabetes, in combination with either metformin or a sulfonylurea, in a patient whose HbA1c is greater than 7% prior to initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone) or a glucagon-like peptide-1 despite treatment with either metformin or a sulfonylurea and where a combination of metformin and a sulfonylurea is contraindicated or not tolerated.<br>The date and level of the qualifying HbA1c must be documented in the patient's medical records at the time treatment with a gliptin, a glitazone or a glucagon-like peptide-1 is initiated. The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone or a glucagon-like peptide-1 is initiated.<br>Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:<br>(a) clinical conditions with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or<br>(b) red cell transfusion within the previous 3 months.<br>A patient in these circumstances will be eligible for treatment where blood glucose monitoring over a 2 week period shows blood glucose levels greater than 10 mmol per L in more than 20% of tests. The results of this blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone or a glucagon-like peptide-1, must be documented in the patient's medical records<br>**Note**<br>Saxagliptin is not PBS-subsidised for use in combination with metformin and a sulfonylurea (triple oral therapy), as monotherapy or in combination with a thiazolidinedione (glitazone) or a glucagon-like peptide-1. | | | | | | | |
| 8983T<br>*NP* | saxagliptin 5 mg tablet, 28 | 1 | 5 | .. | 90.81 | 36.10 | Onglyza | BQ |
| | **SIMVASTATIN + SITAGLIPTIN**<br>**Authority required (STREAMLINED)**<br>***4183***<br>Diabetes mellitus type 2 and hypercholesterolaemia<br>**The Clinical criteria is:**<br>Patient must meet the criteria set out in the General Statement for Lipid-Lowering Drugs,<br>**AND the Clinical criteria is:**<br>The treatment must be in combination with metformin; OR<br>The treatment must be in combination with a sulfonylurea,<br>**AND the Clinical criteria is:**<br>Patient must have a contraindication to a combination of metformin and a sulfonylurea; OR<br>Patient must not have tolerated a combination of metformin and a sulfonylurea,<br>**AND the Clinical criteria is:**<br>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) or a glucagon-like peptide-1 despite treatment with either metformin or a sulfonylurea; OR<br>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 or a glucagon-like peptide-1 despite treatment with either metformin or a sulfonylurea.<br>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 or a glucagon-like peptide-1 is initiated.<br>The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone or a glucagon-like peptide-1 is or was initiated.<br>Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:<br>(a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or<br>(b) Had red cell transfusion within the previous 3 months.<br>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 or a glucagon-like peptide-1, must be documented in the patient's medical records.<br>**Note**<br>The treatment must not be in combination with a thiazolidinedione (glitazone) or glucagon-like peptide-1. | | | | | | | |
| 2391W<br>*NP* | simvastatin 10 mg + sitagliptin 100 mg tablet: film-coated, 28 | 1 | 5 | .. | 94.70 | 36.10 | Juvicor | MK |
| 2377D<br>*NP* | simvastatin 20 mg + sitagliptin 100 mg tablet: film-coated, 28 | 1 | 5 | .. | 96.40 | 36.10 | Juvicor | MK |
| 2383K<br>*NP* | simvastatin 40 mg + sitagliptin 100 mg tablet: film-coated, 28 | 1 | 5 | .. | 98.84 | 36.10 | Juvicor | MK |
| | **SITAGLIPTIN**<br>**Authority required (STREAMLINED)**<br>***3540***<br>Dual oral combination therapy with metformin or a sulfonylurea<br>Type 2 diabetes, in combination with either metformin or a sulfonylurea, in a patient whose HbA1c is greater than 7% prior to initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone) or a glucagon-like peptide-1 despite treatment with either metformin or a | | | | | | | |

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | Brand Name and Manufacturer | |
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| | sulfonylurea and where a combination of metformin and a sulfonylurea is contraindicated or not tolerated.<br>The date and level of the qualifying HbA1c must be documented in the patient's medical records at the time treatment with a gliptin, a glitazone or a glucagon-like peptide-1 is initiated. The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone or a glucagon-like peptide-1 is initiated.<br>Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:<br>(a) clinical conditions with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or<br>(b) red cell transfusion within the previous 3 months.<br>A patient in these circumstances will be eligible for treatment where blood glucose monitoring over a 2 week period shows blood glucose levels greater than 10 mmol per L in more than 20% of tests. The results of this blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone or a glucagon-like peptide-1, must be documented in the patient's medical records<br>**Note**<br>Sitagliptin is not PBS-subsidised for use in combination with metformin and a sulfonylurea (triple oral therapy), as monotherapy or in combination with a thiazolidinedione (glitazone) or a glucagon-like peptide-1. | | | | | | | |
| 9182G<br>*NP* | sitagliptin 100 mg tablet, 28 | 1 | 5 | .. | 90.81 | 36.10 | Januvia | MK |
| 9180E<br>*NP* | sitagliptin 25 mg tablet, 28 | 1 | 5 | .. | 90.81 | 36.10 | Januvia | MK |
| 9181F<br>*NP* | sitagliptin 50 mg tablet, 28 | 1 | 5 | .. | 90.81 | 36.10 | Januvia | MK |
| | **VILDAGLIPTIN**<br>**Authority required (STREAMLINED)**<br>***3540***<br>Dual oral combination therapy with metformin or a sulfonylurea<br>Type 2 diabetes, in combination with either metformin or a sulfonylurea, in a patient whose HbA1c is greater than 7% prior to initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone) or a glucagon-like peptide-1 despite treatment with either metformin or a sulfonylurea and where a combination of metformin and a sulfonylurea is contraindicated or not tolerated.<br>The date and level of the qualifying HbA1c must be documented in the patient's medical records at the time treatment with a gliptin, a glitazone or a glucagon-like peptide-1 is initiated. The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone or a glucagon-like peptide-1 is initiated.<br>Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:<br>(a) clinical conditions with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or<br>(b) red cell transfusion within the previous 3 months.<br>A patient in these circumstances will be eligible for treatment where blood glucose monitoring over a 2 week period shows blood glucose levels greater than 10 mmol per L in more than 20% of tests. The results of this blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone or a glucagon-like peptide-1, must be documented in the patient's medical records<br>**Note**<br>Vildagliptin is not PBS-subsidised for use in combination with metformin and a sulfonylurea (triple oral therapy), as monotherapy or in combination with a thiazolidinedione (glitazone) or a glucagon-like peptide-1. | | | | | | | |
| 3415R<br>*NP* | vildagliptin 50 mg tablet, 60 | 1 | 5 | .. | 96.82 | 36.10 | Galvus | NV |

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

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | **EXENATIDE**<br>**Authority required (STREAMLINED)**<br>***3540***<br>Dual oral combination therapy with metformin or a sulfonylurea<br>Type 2 diabetes, in combination with either metformin or a sulfonylurea, in a patient whose HbA1c is greater than 7% prior to initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone) or a glucagon-like peptide-1 despite treatment with either metformin or a sulfonylurea and where a combination of metformin and a sulfonylurea is contraindicated or not tolerated.<br>The date and level of the qualifying HbA1c must be documented in the patient's medical records at the time treatment with a gliptin, a glitazone or a glucagon-like peptide-1 is initiated. The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone or a glucagon-like peptide-1 is initiated.<br>Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:<br>(a) clinical conditions with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or<br>(b) red cell transfusion within the previous 3 months.<br>A patient in these circumstances will be eligible for treatment where blood glucose monitoring over a 2 week period shows blood glucose levels greater than 10 mmol per L in more than 20% of tests. The results of this blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone or a glucagon-like peptide-1, must be documented in the patient's medical records<br>**Authority required (STREAMLINED)**<br>***3542*** | | | | | | | |

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|---|
| | Triple oral combination therapy with metformin and a sulfonylurea | | | | | | | | |
| | Type 2 diabetes, in combination with metformin and a sulfonylurea, in a patient whose HbA1c is greater than 7% prior to initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone) or a glucagon-like peptide-1 despite treatment with maximally tolerated doses of metformin and a sulfonylurea. | | | | | | | | |
| | The date and level of the qualifying HbA1c must be documented in the patient's medical records at the time treatment with a gliptin, a glitazone or a glucagon-like peptide-1 is initiated. The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone or a glucagon-like peptide-1 is initiated. | | | | | | | | |
| | Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances: | | | | | | | | |
| | (a) clinical conditions with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or | | | | | | | | |
| | (b) red cell transfusion within the previous 3 months. | | | | | | | | |
| | A patient in these circumstances will be eligible for treatment where blood glucose monitoring over a 2 week period shows blood glucose levels greater than 10 mmol per L in more than 20% of tests. The results of this blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone or a glucagon-like peptide-1, must be documented in the patient's medical records | | | | | | | | |
| | **Note**<br>Exenatide is not PBS-subsidised as monotherapy or in combination with an insulin, a thiazolidinedione (glitazone) or a dipeptidyl peptidase 4 inhibitor (gliptin). | | | | | | | | |
| | **Note**<br>Special Pricing Arrangements apply. | | | | | | | | |
| 3424F<br>*NP* | exenatide 10 microgram/40 microlitre injection, 60 unit doses | 1 | 5 | .. | 176.60 | 36.10 | | Byetta 10 microgram | BQ |
| 3423E<br>*NP* | exenatide 5 microgram/20 microlitre injection, 60 unit doses | 1 | 5 | .. | 176.60 | 36.10 | | Byetta 5 microgram | BQ |

## VITAMINS

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

#### *Vitamin D and analogues*

**CALCITRIOL**

**Authority required (STREAMLINED)**
***1165***
Hypocalcaemia due to renal disease

**Authority required (STREAMLINED)**
***1166***
Hypoparathyroidism

**Authority required (STREAMLINED)**
***1167***
Hypophosphataemic rickets

**Authority required (STREAMLINED)**
***1467***
Vitamin D-resistant rickets

**Authority required (STREAMLINED)**
***2636***
Treatment for established osteoporosis in patients with fracture due to minimal trauma. The fracture must have been demonstrated radiologically and the year of plain x-ray or CT-scan or MRI scan must be documented in the patient's medical records when treatment is initiated.

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

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 2502Q<br>*NP* | calcitriol 0.25 microgram capsule, 100 | 1 | 3 | .. | 34.16 | 35.29 | [a] | Calciprox | GN |
| | | | | | | | [a] | Calcitriol-GA | GM |
| | | | | | | | [a] | Calcitriol Sandoz | SZ |
| | | | | | | | [a] | GenRx Calcitriol | GX |
| | | | | | | | [a] | Kosteo | QA |
| | | | | | | | [a] | Rocaltrol | RO |
| | | | | | | | [a] | Sical | AF |

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

#### *Vitamin B1, plain*

**THIAMINE**

**Authority required (STREAMLINED)**
***2384***

# ALIMENTARY TRACT AND METABOLISM

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|---|
| | Prophylaxis of thiamine deficiency in an Aboriginal or a Torres Strait Islander person | | | | | | | | |
| 1070H *NP* | thiamine hydrochloride 100 mg tablet, 100 | 1 | 2 | .. | 10.32 | 11.45 | | Betavit | PP |

## MINERAL SUPPLEMENTS

### CALCIUM

#### *Calcium*

**CALCIUM**

**Authority required (STREAMLINED)**

***2212***

Hyperphosphataemia associated with chronic renal failure

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 3116B *NP* | CALCIUM Tablet (chewable) 500 mg (as carbonate), 60 | 4 | 1 | .. | *33.43 | 34.56 | | Cal-Sup | IA |
| 3117C *NP* | CALCIUM Tablet 600 mg (as carbonate), 240 | 1 | 1 | .. | 22.41 | 23.54 | | Calci-Tab 600 | AE |

### POTASSIUM

#### *Potassium*

**POTASSIUM CHLORIDE**

**Note**

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

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 2642C *NP* | potassium chloride 600 mg (8 mmol potassium) tablet: modified release, 100 tablets | 2 | 1 | .. | *13.09 | 14.22 | a | Duro-K | NM |
| | | | | [B]2.94 | *16.03 | 14.22 | a | Slow-K | NV |
| 1841X *NP* | potassium chloride 600 mg (8 mmol potassium) tablet: modified release, 200 tablets | 1 | 1 | .. | 13.08 | 14.21 | a | Span-K | AS |

**POTASSIUM CHLORIDE + POTASSIUM BICARBONATE + POTASSIUM CARBONATE**

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 3012M *NP* | potassium chloride 595 mg + potassium bicarbonate 384 mg + potassium carbonate 152 mg (total potassium 14 mmol) tablet: effervescent, 60 | 1 | 1 | .. | 15.35 | 16.48 | | Chlorvescent | AS |

### OTHER MINERAL SUPPLEMENTS

#### *Magnesium*

**MAGNESIUM ASPARTATE DIHYDRATE**

**Authority required**

Hypomagnesaemia in an Aboriginal or a Torres Strait Islander person

**Authority required**

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

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 5146W *NP* | magnesium aspartate dihydrate 500 mg (equivalent to 37.4 mg of magnesium) tablet, 50 | 1 | 5 | .. | 13.91 | 15.04 | | MagMin (PBS) | BB |
| | | | | | | | | Mag-Sup | PP |

## ANABOLIC AGENTS FOR SYSTEMIC USE

### ANABOLIC STEROIDS

#### *Estren derivatives*

**NANDROLONE DECANOATE**

**Authority required**

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

**Authority required**

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

**Authority required**

Monotherapy for osteoporosis, where other treatment is contraindicated and where specialist advice confirms that this is the only suitable

# ALIMENTARY TRACT AND METABOLISM

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|
| | treatment option for the patient. Specialist advice need only be obtained for the first authority approval | | | | | | | |
| | **Authority required**<br>Patients receiving PBS-subsidised therapy with this drug for osteoporosis prior to 1 February 2004 | | | | | | | |
| | **Authority required**<br>Patients on long-term treatment with corticosteroids | | | | | | | |
| | **Note**<br>Monotherapy for the treatment of osteoporosis does not exclude calcium supplementation. | | | | | | | |
| 1671Y | nandrolone decanoate 50 mg/mL injection, 1 x 1 mL syringe | 1 | 7 | .. | 21.41 | 22.54 | Deca-Durabolin | MK |

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|

# BLOOD AND BLOOD FORMING ORGANS

## ANTITHROMBOTIC AGENTS

### ANTITHROMBOTIC AGENTS

#### *Vitamin K antagonists*

**WARFARIN**

**Caution**

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

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 2843P *NP* | warfarin sodium 1 mg tablet, 50 | 1 | 2 | .. | 12.62 | 13.75 | Coumadin | QA |
| | | | | | | | Marevan | FM |
| 2209G *NP* | warfarin sodium 2 mg tablet, 50 | 1 | 2 | .. | 12.98 | 14.11 | Coumadin | QA |
| 2844Q *NP* | warfarin sodium 3 mg tablet, 50 | 1 | 2 | .. | 12.90 | 14.03 | Marevan | FM |
| 2211J *NP* | warfarin sodium 5 mg tablet, 50 | 1 | 2 | .. | 14.24 | 15.37 | Coumadin | QA |
| | | | | | | | Marevan | FM |

#### *Heparin group*

**DALTEPARIN SODIUM**

**Restricted benefit**

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

**Note**

No applications for increased maximum quantities will be authorised.

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 8959M *NP* | DALTEPARIN SODIUM (Low Molecular Weight Heparin Sodium-porcine mucous) Injection 15,000 units (anti-Xa) in 0.6 mL single dose pre-filled syringe, 10 | 3 | 5 | .. | *414.96 | 36.10 | Fragmin | PF |
| 8960N *NP* | DALTEPARIN SODIUM (Low Molecular Weight Heparin Sodium-porcine mucous) Injection 18,000 units (anti-Xa) in 0.72 mL single dose pre-filled syringe, 10 | 3 | 5 | .. | *493.80 | 36.10 | Fragmin | PF |
| 8957K *NP* | dalteparin sodium 10 000 anti-Xa international units/mL injection, 10 x 1 mL syringes | 3 | 5 | .. | *255.27 | 36.10 | Fragmin | PF |
| 8958L *NP* | dalteparin sodium 12 500 anti-Xa international units/0.5 mL injection, 10 x 0.5 mL syringes | 3 | 5 | .. | *349.92 | 36.10 | Fragmin | PF |
| 8956J *NP* | dalteparin sodium 7500 anti-Xa international units/0.75 mL injection, 10 x 0.75 mL syringes | 3 | 5 | .. | *192.51 | 36.10 | Fragmin | PF |

**DALTEPARIN SODIUM**

**Restricted benefit**

Haemodialysis

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 1229Q *NP* | dalteparin sodium 10 000 anti-Xa international units/mL injection, 10 x 1 mL syringes | 2 | 3 | .. | *175.77 | 36.10 | Fragmin | PF |
| 1296F *NP* | dalteparin sodium 12 500 anti-Xa international units/0.5 mL injection, 10 x 0.5 mL syringes | 2 | 3 | .. | *241.49 | 36.10 | Fragmin | PF |
| 8641T *NP* | dalteparin sodium 2500 anti-Xa international units/0.2 mL injection, 10 x 0.2 mL syringes | 2 | 3 | .. | *104.95 | 36.10 | Fragmin | PF |
| 8642W *NP* | dalteparin sodium 5000 anti-Xa international units/0.2 mL injection, 10 x 0.2 mL syringes | 2 | 3 | .. | *109.09 | 36.10 | Fragmin | PF |
| 8643X *NP* | dalteparin sodium 7500 anti-Xa international units/0.75 mL injection, 10 x 0.75 mL syringes | 2 | 3 | .. | *130.55 | 36.10 | Fragmin | PF |

# BLOOD AND BLOOD FORMING ORGANS

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|
| | **DALTEPARIN SODIUM** | | | | | | | |
| 8269F *NP* | dalteparin sodium 10 000 anti-Xa international units/mL injection, 10 x 1 mL syringes | 1 | 1 | .. | 91.20 | 36.10 | Fragmin | PF |
| 5445N *NP* | dalteparin sodium 12 500 anti-Xa international units/0.5 mL injection, 10 x 0.5 mL syringes | 1 | 1 | .. | 125.90 | 36.10 | Fragmin | PF |
| 8603T *NP* | dalteparin sodium 2500 anti-Xa international units/0.2 mL injection, 10 x 0.2 mL syringes | 2 | .. | .. | *104.95 | 36.10 | Fragmin | PF |
| 2816F *NP* | dalteparin sodium 5000 anti-Xa international units/0.2 mL injection, 10 x 0.2 mL syringes | 2 | .. | .. | *109.09 | 36.10 | Fragmin | PF |
| 8271H *NP* | dalteparin sodium 7500 anti-Xa international units/0.75 mL injection, 10 x 0.75 mL syringes | 1 | 1 | .. | 68.59 | 36.10 | Fragmin | PF |
| | **ENOXAPARIN SODIUM**<br>**Restricted benefit**<br>Haemodialysis | | | | | | | |
| 5435C *NP* | enoxaparin sodium 100 mg/mL injection, 10 x 1 mL syringes | 2 | 3 | .. | *211.29 | 36.10 | Clexane | SW |
| 8716R *NP* | enoxaparin sodium 20 mg/0.2 mL injection, 10 x 0.2 mL syringes | 2 | 3 | .. | *104.95 | 36.10 | Clexane | SW |
| 9196B *NP* | enoxaparin sodium 40 mg/0.4 mL injection, 10 x 0.4 mL ampoules | 2 | 3 | .. | *109.09 | 36.10 | Clexane | SW |
| 8639Q *NP* | enoxaparin sodium 40 mg/0.4 mL injection, 10 x 0.4 mL syringes | 2 | 3 | .. | *109.09 | 36.10 | Clexane | SW |
| 8640R *NP* | enoxaparin sodium 60 mg/0.6 mL injection, 10 x 0.6 mL syringes | 2 | 3 | .. | *153.15 | 36.10 | Clexane | SW |
| 5434B *NP* | enoxaparin sodium 80 mg/0.8 mL injection, 10 x 0.8 mL syringes | 2 | 3 | .. | *175.19 | 36.10 | Clexane | SW |
| | **ENOXAPARIN SODIUM** | | | | | | | |
| 8264Y *NP* | enoxaparin sodium 100 mg/mL injection, 10 x 1 mL syringes | 1 | 1 | .. | 109.29 | 36.10 | Clexane | SW |
| 8558K *NP* | enoxaparin sodium 20 mg/0.2 mL injection, 10 x 0.2 mL syringes | 2 | .. | .. | *104.95 | 36.10 | Clexane | SW |
| 9195Y *NP* | enoxaparin sodium 40 mg/0.4 mL injection, 10 x 0.4 mL ampoules | 2 | .. | .. | *109.09 | 36.10 | Clexane | SW |
| 8510X *NP* | enoxaparin sodium 40 mg/0.4 mL injection, 10 x 0.4 mL syringes | 2 | .. | .. | *109.09 | 36.10 | Clexane | SW |
| 8262W *NP* | enoxaparin sodium 60 mg/0.6 mL injection, 10 x 0.6 mL syringes | 1 | 1 | .. | 79.89 | 36.10 | Clexane | SW |
| 8263X *NP* | enoxaparin sodium 80 mg/0.8 mL injection, 10 x 0.8 mL syringes | 1 | 1 | .. | 90.91 | 36.10 | Clexane | SW |
| | **HEPARIN SODIUM** | | | | | | | |
| 1076P *NP* | heparin sodium 35 000 international units/35 mL injection, 1 x 35 mL vial | 12 | 5 | .. | *380.43 | 36.10 | Hospira Pty Limited | HH |
| 1466E *NP* | heparin sodium 5000 international units/0.2 mL injection, 5 x 0.2 mL ampoules | 1 | 5 | .. | 19.31 | 20.44 | Hospira Pty Limited | HH |
| 1463B *NP* | heparin sodium 5000 international units/5 mL injection, 50 x 5 mL ampoules | 1 | 5 | .. | 71.73 | 36.10 | Pfizer Australia Pty Ltd | PF |

## *Platelet aggregation inhibitors excl. heparin*

**ABCIXIMAB**
**Authority required (STREAMLINED)**
***1716***
Patients undergoing percutaneous coronary balloon angioplasty

**Authority required (STREAMLINED)**
***1717***
Patients undergoing percutaneous coronary atherectomy

**Authority required (STREAMLINED)**
***1718***

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|---|
| | Patients undergoing percutaneous coronary stent placement | | | | | | | | |
| 8048N | abciximab 10 mg/5 mL injection, 1 x 5 mL vial | 3 | .. | .. | *1453.32 | 36.10 | | ReoPro | LY |
| | **ASPIRIN** | | | | | | | | |
| 8202Q *NP* | aspirin 100 mg tablet, 112 | 1 | 1 | .. | 7.99 | 9.12 | [a] | Mayne Pharma Aspirin | YT |
| | | | | | | | [a] | Spren 100 | QA |
| | | | | [B]2.32 | 10.31 | 9.12 | [a] | Astrix | YN |
| 1010E *NP* | aspirin 300 mg tablet: effervescent, 96 | 1 | 1 | .. | 8.38 | 9.51 | | Solprin | RC |

**ASPIRIN + CLOPIDOGREL**

**Authority required (STREAMLINED)**

***3880***

Treatment of acute coronary syndrome (myocardial infarction or unstable angina)

**Authority required (STREAMLINED)**

***3219***

Treatment following cardiac stent insertion

**Authority required (STREAMLINED)**

***1722***

Prevention of recurrence of myocardial infarction or unstable angina in patients with a history of symptomatic cardiac ischaemic events while on therapy with low-dose aspirin

**Note**

Not for prophylaxis of DVT or peripheral arterial disease.

**Note**

Shared Care Model:

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

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 9296G *NP* | aspirin 100 mg + clopidogrel 75 mg tablet, 30 | 1 | 5 | .. | 75.08 | 36.10 | [a] | APO-Clopidogrel/Aspirin 75/100 | TX |
| | | | | | | | [a] | Chem mart Clopidogrel/Aspirin 75/100 | CH |
| | | | | | | | [a] | Clopidogrel Winthrop plus aspirin | WA |
| | | | | | | | [a] | CoPlavix | SW |
| | | | | | | | [a] | DuoCover | AV |
| | | | | | | | [a] | Terry White Chemists Clopidogrel/Aspirin 75/100 | TW |

**CLOPIDOGREL**

**Authority required (STREAMLINED)**

***4166***

Acute coronary syndrome (myocardial infarction or unstable angina)

**The Clinical criteria is:**

The treatment must be in combination with aspirin.

**Authority required (STREAMLINED)**

***4165***

Cardiac stent insertion

**The Clinical criteria is:**

The treatment must be in combination with aspirin,

**AND the Clinical criteria is:**

The treatment must follow insertion of a cardiac stent.

**Note**

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

**Note**

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

**Note**

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|---|
| | **Shared Care Model**: | | | | | | | | |
| | For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners. | | | | | | | | |
| 2275R *NP* | clopidogrel 75 mg tablet, 28 | 1 | 5 | .. | 31.94 | 33.07 | [a] | Clopidogrel-GA | GM |
| | | | | | | | [a] | Clovix 75 | QA |
| 9317J *NP* | clopidogrel 75 mg tablet, 28 | 1 | 5 | .. | 31.94 | 33.07 | [a] | APO-Clopidogrel | TX |
| | | | | | | | [a] | Clopidogrel Winthrop | WA |
| | | | | | | | [a] | Iscover | AV |
| | | | | | | | [a] | Plavix | SW |
| | **CLOPIDOGREL**<br>**Authority required (STREAMLINED)**<br>***1723***<br>Prevention of recurrence of myocardial infarction or unstable angina in patients where low-dose aspirin poses an unacceptable risk of gastrointestinal bleeding | | | | | | | | |
| | **Authority required (STREAMLINED)**<br>***1724***<br>Prevention of recurrence of myocardial infarction or unstable angina in patients where there is a history of anaphylaxis, urticaria or asthma within 4 hours of ingestion of aspirin, other salicylates, or NSAIDs | | | | | | | | |
| | **Authority required (STREAMLINED)**<br>***1719***<br>Prevention of recurrence of ischaemic stroke or transient cerebral ischaemic events in patients with a history of symptomatic cerebrovascular ischaemic episodes while on therapy with low-dose aspirin | | | | | | | | |
| | **Authority required (STREAMLINED)**<br>***1720***<br>Prevention of recurrence of ischaemic stroke or transient cerebral ischaemic events in patients where low-dose aspirin poses an unacceptable risk of gastrointestinal bleeding | | | | | | | | |
| | **Authority required (STREAMLINED)**<br>***1721***<br>Prevention of recurrence of ischaemic stroke or transient cerebral ischaemic events in patients where there is a history of anaphylaxis, urticaria or asthma within 4 hours of ingestion of aspirin, other salicylates, or NSAIDs | | | | | | | | |
| | **Authority required (STREAMLINED)**<br>***1722***<br>Prevention of recurrence of myocardial infarction or unstable angina in patients with a history of symptomatic cardiac ischaemic events while on therapy with low-dose aspirin | | | | | | | | |
| | **Note**<br>Not for prophylaxis of DVT or peripheral arterial disease. | | | | | | | | |
| | **Note**<br>Pharmaceutical benefits that have the forms clopidogrel tablet 75 mg, clopidogrel tablet 75 mg (as besilate) and clopidogrel tablet 75 mg (as hydrogen sulfate) are equivalent for the purposes of substitution. | | | | | | | | |
| | **Note**<br>Shared Care Model:<br>For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners. | | | | | | | | |
| 5436D *NP* | clopidogrel 75 mg tablet, 28 | 1 | 5 | .. | 31.94 | 33.07 | [a] | Clopidogrel-DRLA | RZ |
| 8358X *NP* | clopidogrel 75 mg tablet, 28 | 1 | 5 | .. | 31.94 | 33.07 | [a] | APO-Clopidogrel | TX |
| | | | | | | | [a] | Chem mart Clopidogrel | CH |
| | | | | | | | [a] | Clopidogrel RBX | RA |
| | | | | | | | [a] | Clopidogrel Sandoz | SZ |
| | | | | | | | [a] | Clopidogrel Winthrop | WA |
| | | | | | | | [a] | Iscover | AV |
| | | | | | | | [a] | Piax | AF |
| | | | | | | | [a] | Plavicor 75 | CR |
| | | | | | | | [a] | Plavix | SW |
| | | | | | | | [a] | Terry White Chemists Clopidogrel | TW |
| | **CLOPIDOGREL**<br>**Authority required (STREAMLINED)** | | | | | | | | |

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|---|
| | ***1719*** | | | | | | | | |
| | Prevention of recurrence of ischaemic stroke or transient cerebral ischaemic events in patients with a history of symptomatic cerebrovascular ischaemic episodes while on therapy with low-dose aspirin | | | | | | | | |
| | **Authority required (STREAMLINED)** | | | | | | | | |
| | ***1720*** | | | | | | | | |
| | Prevention of recurrence of ischaemic stroke or transient cerebral ischaemic events in patients where low-dose aspirin poses an unacceptable risk of gastrointestinal bleeding | | | | | | | | |
| | **Authority required (STREAMLINED)** | | | | | | | | |
| | ***1721*** | | | | | | | | |
| | Prevention of recurrence of ischaemic stroke or transient cerebral ischaemic events in patients where there is a history of anaphylaxis, urticaria or asthma within 4 hours of ingestion of aspirin, other salicylates, or NSAIDs | | | | | | | | |
| | **Authority required (STREAMLINED)** | | | | | | | | |
| | ***1722*** | | | | | | | | |
| | Prevention of recurrence of myocardial infarction or unstable angina in patients with a history of symptomatic cardiac ischaemic events while on therapy with low-dose aspirin | | | | | | | | |
| | **Authority required (STREAMLINED)** | | | | | | | | |
| | ***1723*** | | | | | | | | |
| | Prevention of recurrence of myocardial infarction or unstable angina in patients where low-dose aspirin poses an unacceptable risk of gastrointestinal bleeding | | | | | | | | |
| | **Authority required (STREAMLINED)** | | | | | | | | |
| | ***1724*** | | | | | | | | |
| | Prevention of recurrence of myocardial infarction or unstable angina in patients where there is a history of anaphylaxis, urticaria or asthma within 4 hours of ingestion of aspirin, other salicylates, or NSAIDs | | | | | | | | |
| | **Note** | | | | | | | | |
| | Not for prophylaxis of DVT or peripheral arterial disease. | | | | | | | | |
| | **Note** | | | | | | | | |
| | Pharmaceutical benefits that have the forms clopidogrel tablet 75 mg, clopidogrel tablet 75 mg (as besilate) and clopidogrel tablet 75 mg (as hydrogen sulfate) are equivalent for the purposes of substitution. | | | | | | | | |
| | **Note** | | | | | | | | |
| | Shared Care Model: | | | | | | | | |
| | For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners. | | | | | | | | |
| 9354H *NP* | clopidogrel 75 mg tablet, 28 | 1 | 5 | .. | 31.94 | 33.07 | [a] | Clopidogrel Actavis | TA |
| | | | | | | | [a] | Clopidogrel-GA | GM |
| | | | | | | | [a] | Clopidogrel GH | GQ |
| | | | | | | | [a] | Clovix 75 | QA |
| | | | | | | | [a] | STADA Clopidogrel | TD |
| | **DIPYRIDAMOLE** | | | | | | | | |
| | **Restricted benefit** | | | | | | | | |
| | Prevention of recurrence of ischaemic stroke or transient cerebral ischaemic events as adjunctive therapy with low-dose aspirin | | | | | | | | |
| | **Restricted benefit** | | | | | | | | |
| | Prevention of recurrence of ischaemic stroke or transient cerebral ischaemic events where low-dose aspirin poses an unacceptable risk of gastrointestinal bleeding | | | | | | | | |
| | **Restricted benefit** | | | | | | | | |
| | Prevention of recurrence of ischaemic stroke or transient cerebral ischaemic events where there is a history of anaphylaxis, urticaria or asthma within 4 hours of ingestion of aspirin, other salicylates, or NSAIDs | | | | | | | | |
| | **Note** | | | | | | | | |
| | Shared Care Model: | | | | | | | | |
| | For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners. | | | | | | | | |
| 8335Q *NP* | dipyridamole 200 mg capsule: modified release, 60 capsules | 1 | 5 | .. | 37.17 | 36.10 | | Persantin SR | BY |
| | **DIPYRIDAMOLE + ASPIRIN** | | | | | | | | |
| | **Restricted benefit** | | | | | | | | |
| | Prevention of recurrence of ischaemic stroke or transient cerebral ischaemic events | | | | | | | | |
| | **Note** | | | | | | | | |
| | Shared Care Model: | | | | | | | | |
| | For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised | | | | | | | | |

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|
| | arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners. | | | | | | | |
| 8382E *NP* | dipyridamole 200 mg + aspirin 25 mg capsule: modified release, 60 capsules | 1 | 5 | .. | 37.40 | 36.10 | Asasantin SR | BY |
| | **EPTIFIBATIDE** | | | | | | | |
| | **Authority required (STREAMLINED)** | | | | | | | |
| | ***1884*** | | | | | | | |
| | Patients undergoing non-urgent percutaneous intervention with intracoronary stenting | | | | | | | |
| 8683B | eptifibatide 20 mg/10 mL injection, 1 x 10 mL vial | 2 | .. | .. | *262.75 | 36.10 | Integrilin | MK |
| 8684C | eptifibatide 75 mg/100 mL injection, 1 x 100 mL vial | 3 | .. | .. | *1020.57 | 36.10 | Integrilin | MK |
| | **PRASUGREL** | | | | | | | |
| | **Authority required (STREAMLINED)** | | | | | | | |
| | ***3208*** | | | | | | | |
| | Treatment of acute coronary syndrome (myocardial infarction or unstable angina) managed by percutaneous coronary intervention in combination with aspirin | | | | | | | |
| | **Note** | | | | | | | |
| | Shared Care Model: | | | | | | | |
| | For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners. | | | | | | | |
| 9496T *NP* | prasugrel 10 mg tablet, 28 | 1 | 5 | .. | 106.64 | 36.10 | Effient | LY |
| 9495R *NP* | prasugrel 5 mg tablet, 28 | 1 | 5 | .. | 96.64 | 36.10 | Effient | LY |
| | **TICAGRELOR** | | | | | | | |
| | **Authority required (STREAMLINED)** | | | | | | | |
| | ***3879*** | | | | | | | |
| | Treatment of acute coronary syndrome (myocardial infarction or unstable angina) in combination with aspirin | | | | | | | |
| | **Note** | | | | | | | |
| | Shared Care Model: | | | | | | | |
| | For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners. | | | | | | | |
| 1418P *NP* | TICAGRELOR Tablet 90 mg, 56 | 1 | 5 | .. | 149.21 | 36.10 | Brilinta | AP |
| | **TICLOPIDINE** | | | | | | | |
| | **Authority required (STREAMLINED)** | | | | | | | |
| | ***1719*** | | | | | | | |
| | Prevention of recurrence of ischaemic stroke or transient cerebral ischaemic events in patients with a history of symptomatic cerebrovascular ischaemic episodes while on therapy with low-dose aspirin | | | | | | | |
| | **Authority required (STREAMLINED)** | | | | | | | |
| | ***1720*** | | | | | | | |
| | Prevention of recurrence of ischaemic stroke or transient cerebral ischaemic events in patients where low-dose aspirin poses an unacceptable risk of gastrointestinal bleeding | | | | | | | |
| | **Authority required (STREAMLINED)** | | | | | | | |
| | ***1721*** | | | | | | | |
| | Prevention of recurrence of ischaemic stroke or transient cerebral ischaemic events in patients where there is a history of anaphylaxis, urticaria or asthma within 4 hours of ingestion of aspirin, other salicylates, or NSAIDs | | | | | | | |
| | **Authority required (STREAMLINED)** | | | | | | | |
| | ***1260*** | | | | | | | |
| | Patients established on this drug as a pharmaceutical benefit prior to 1 November 1999 | | | | | | | |
| | **Caution** | | | | | | | |
| | Severe neutropenia is common in the early months of therapy. Haematological monitoring should be undertaken at commencement and every two weeks in the first four months of therapy. | | | | | | | |
| | **Note** | | | | | | | |
| | Shared Care Model: | | | | | | | |
| | For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners. | | | | | | | |
| 2095G *NP* | ticlopidine hydrochloride 250 mg tablet, 60 | 1 | 5 | .. | 122.14 | 36.10 | Tilodene | AF |

# BLOOD AND BLOOD FORMING ORGANS

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|
| | **TIROFIBAN**<br>**Authority required (STREAMLINED)**<br>***1729***<br>Patients with high risk unstable angina who have new transient or persistent ST-T ischaemic changes and anginal pain lasting longer than 20 minutes<br>**Authority required (STREAMLINED)**<br>***1730***<br>Patients with high risk unstable angina who have new transient or persistent ST-T ischaemic changes and repetitive episodes of angina at rest or during minimal exercise in the previous 12 hours<br>**Authority required (STREAMLINED)**<br>***1275***<br>Patients with non-Q-wave myocardial infarction<br>**Note**<br>Shared Care Model:<br>For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners. | | | | | | | |
| 8350L<br>*NP* | tirofiban 12.5 mg/50 mL injection, 1 x 50 mL vial | 1 | 2 | .. | 363.32 | 36.10 | Aggrastat | AS |

## *Enzymes*

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | **RETEPLASE**<br>**Restricted benefit**<br>Treatment of acute myocardial infarction within 6 hours of onset of attack<br>**Note**<br>Shared Care Model:<br>For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners. | | | | | | | |
| 8253J<br>*NP* | reteplase 10 units (17.4 mg) injection [2 x 10 units vials] (&) inert substance diluent [2 x 10 mL syringes], 1 pack | ‡1 | .. | .. | 2067.17 | 36.10 | Rapilysin 10 U | TA |
| | **TENECTEPLASE**<br>**Restricted benefit**<br>Treatment of acute myocardial infarction within 12 hours of onset of attack<br>**Note**<br>Shared Care Model:<br>For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners. | | | | | | | |
| 8527T<br>*NP* | tenecteplase 10 000 international units (50 mg) injection [1 x 50 mg vial] (&) inert substance diluent [1 x 10 mL vial], 1 pack | 1 | .. | .. | 2057.27 | 36.10 | Metalyse | BY |
| 8526R<br>*NP* | tenecteplase 8000 international units (40 mg) injection [1 x 40 mg vial] (&) inert substance diluent [1 x 8 mL vial], 1 pack | 1 | .. | .. | 1960.97 | 36.10 | Metalyse | BY |

## *Direct thrombin inhibitors*

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | **BIVALIRUDIN**<br>**Authority required (STREAMLINED)**<br>***3075***<br>A patient undergoing percutaneous coronary intervention | | | | | | | |
| 8844L | bivalirudin 250 mg injection, 1 x 250 mg vial | 1 | .. | .. | 671.96 | 36.10 | Angiomax | XM |
| | **DABIGATRAN**<br>**Authority required**<br>Prevention of venous thromboembolism in a patient undergoing total hip replacement who requires up to 30 days supply to complete a course of treatment<br>**Note**<br>No applications for increased maximum quantities and/or repeats will be authorised.<br>**Note**<br>Shared Care Model:<br>For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised | | | | | | | |

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|
| | arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners. | | | | | | | |
| 9321N *NP* | DABIGATRAN ETEXILATE Capsule 110 mg (as mesilate), 60 | 1 | .. | .. | 96.12 | 36.10 | Pradaxa | BY |
| 9320M *NP* | DABIGATRAN ETEXILATE Capsule 75 mg (as mesilate), 60 | 1 | .. | .. | 120.88 | 36.10 | Pradaxa | BY |

**DABIGATRAN**

**Authority required**

Prevention of venous thromboembolism in a patient undergoing total hip replacement who requires up to 20 days supply to complete a course of treatment

**Note**

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

**Note**

Shared Care Model:

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

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 9319L *NP* | dabigatran etexilate 110 mg capsule, 10 | 2 | 1 | .. | *37.81 | 36.10 | Pradaxa | BY |
| 9318K *NP* | dabigatran etexilate 75 mg capsule, 10 | 2 | 1 | .. | *45.75 | 36.10 | Pradaxa | BY |

**DABIGATRAN**

**Authority required**

Prevention of venous thromboembolism in a patient undergoing total knee replacement who requires up to 10 days of therapy

**Note**

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

**Note**

Shared Care Model:

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

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 9323Q *NP* | dabigatran etexilate 110 mg capsule, 10 | 2 | .. | .. | *37.81 | 36.10 | Pradaxa | BY |
| 9322P *NP* | dabigatran etexilate 75 mg capsule, 10 | 2 | .. | .. | *45.75 | 36.10 | Pradaxa | BY |

## *Other antithrombotic agents*

**APIXABAN**

**Authority required**

Prevention of venous thromboembolism in a patient undergoing total knee replacement who requires up to 10 days of therapy

**Authority required**

Prevention of venous thromboembolism in a patient undergoing total hip replacement who requires up to 10 days supply to complete a course of treatment

**Note**

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

**Note**

Shared Care Model:

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

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 5500L *NP* | apixaban 2.5 mg tablet, 20 | 1 | .. | .. | 100.98 | 36.10 | Eliquis | BQ |

**APIXABAN**

**Authority required**

Prevention of venous thromboembolism in a patient undergoing total knee replacement who requires up to 15 days of therapy

**Authority required**

Prevention of venous thromboembolism in a patient undergoing total hip replacement who requires up to 15 days supply to complete a course of treatment

**Note**

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

**Note**

Shared Care Model:

# BLOOD AND BLOOD FORMING ORGANS

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|---|---|---|---|---|---|---|---|---|
| | For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners. | | | | | | | |
| 5054B *NP* | apixaban 2.5 mg tablet, 30 | 1 | .. | .. | 148.16 | 36.10 | Eliquis | BQ |
| | **APIXABAN** | | | | | | | |
| | **Authority required** | | | | | | | |
| | Prevention of venous thromboembolism in a patient undergoing total hip replacement who requires up to 30 days supply to complete a course of treatment | | | | | | | |
| | **Note** | | | | | | | |
| | No applications for increased maximum quantities and/or repeats will be authorised. | | | | | | | |
| | **Note** | | | | | | | |
| | Shared Care Model: | | | | | | | |
| | For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners. | | | | | | | |
| 5061J *NP* | apixaban 2.5 mg tablet, 60 | 1 | .. | .. | 281.94 | 36.10 | Eliquis | BQ |
| | **FONDAPARINUX** | | | | | | | |
| | **Authority required (STREAMLINED)** | | | | | | | |
| | ***2005*** | | | | | | | |
| | Prevention of venous thromboembolic events in patients undergoing major hip surgery | | | | | | | |
| | **Authority required (STREAMLINED)** | | | | | | | |
| | ***2006*** | | | | | | | |
| | Prevention of venous thromboembolic events in patients undergoing total knee replacement | | | | | | | |
| | **Note** | | | | | | | |
| | No applications for increased maximum quantities and/or repeats will be authorised. | | | | | | | |
| | **Note** | | | | | | | |
| | Shared Care Model: | | | | | | | |
| | For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners. | | | | | | | |
| 8775W *NP* | FONDAPARINUX SODIUM Injection 2.5 mg in 0.5 mL single dose pre-filled syringe, 2 | 3.5 | .. | .. | *140.75 | 36.10 | Arixtra | GK |
| | **RIVAROXABAN** | | | | | | | |
| | **Authority required** | | | | | | | |
| | Prevention of venous thromboembolism in a patient undergoing total hip replacement who requires up to 30 days of therarpy | | | | | | | |
| | **Note** | | | | | | | |
| | No applications for increased maximum quantities and/or repeats will be authorised. | | | | | | | |
| | **Note** | | | | | | | |
| | Shared Care Model: | | | | | | | |
| | For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners. | | | | | | | |
| 9467G *NP* | RIVAROXABAN Tablet 10 mg, 30 | 1 | .. | .. | 101.01 | 36.10 | Xarelto | BN |
| | **RIVAROXABAN** | | | | | | | |
| | **Authority required** | | | | | | | |
| | Prevention of venous thromboembolism in a patient undergoing total hip replacement who requires up to 20 days supply to complete a course of treatment | | | | | | | |
| | **Note** | | | | | | | |
| | No applications for increased maximum quantities and/or repeats will be authorised. | | | | | | | |
| | **Note** | | | | | | | |
| | Shared Care Model: | | | | | | | |
| | For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners. | | | | | | | |
| 9465E *NP* | rivaroxaban 10 mg tablet, 10 | 1 | 1 | .. | 39.52 | 36.10 | Xarelto | BN |
| | **RIVAROXABAN** | | | | | | | |
| | **Authority required** | | | | | | | |

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|
| | Prevention of venous thromboembolism in a patient undergoing total knee replacement who requires up to 10 days of therapy<br>**Note**<br>No applications for increased maximum quantities and/or repeats will be authorised.<br>**Note**<br>Shared Care Model:<br>For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners. | | | | | | | |
| 9468H<br>*NP* | rivaroxaban 10 mg tablet, 10 | 1 | .. | .. | 39.52 | 36.10 | Xarelto | BN |
| | **RIVAROXABAN**<br>**Authority required**<br>Prevention of venous thromboembolism in a patient undergoing total hip replacement who requires up to 30 days supply to complete a course of treatment<br>**Note**<br>No applications for increased maximum quantities and/or repeats will be authorised.<br>**Note**<br>Shared Care Model:<br>For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners. | | | | | | | |
| 9466F<br>*NP* | rivaroxaban 10 mg tablet, 15 | 1 | 1 | .. | 54.03 | 36.10 | Xarelto | BN |
| | **RIVAROXABAN**<br>**Authority required**<br>Prevention of venous thromboembolism in a patient undergoing total knee replacement who requires up to 15 days of therapy<br>**Note**<br>No applications for increased maximum quantities and/or repeats will be authorised.<br>**Note**<br>Shared Care Model:<br>For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners. | | | | | | | |
| 9469J<br>*NP* | rivaroxaban 10 mg tablet, 15 | 1 | .. | .. | 54.03 | 36.10 | Xarelto | BN |
| | **RIVAROXABAN**<br>**Authority required (STREAMLINED)**<br>***4269***<br>Prevention of stroke or systemic embolism<br>**The Clinical criteria is:**<br>Patient must have non-valvular atrial fibrillation,<br>**AND the Clinical criteria is:**<br>Patient must have one or more risk factors for developing stroke or systemic embolism.<br>Risk factors for developing stroke or systemic ischaemic embolism are:<br>(i) Prior stroke (ischaemic or unknown type), transient ischaemic attack or non-central nervous system (CNS) systemic embolism;<br>(ii) age 75 years or older;<br>(iii) hypertension;<br>(iv) diabetes mellitus;<br>(v) heart failure and/or left ventricular ejection fraction 35% or less.<br>**Note**<br>**Shared Care Model**:<br>For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.<br>**Note**<br>No increase in the maximum quantity or number of units may be authorised.<br>**Note**<br>No increase in the maximum number of repeats may be authorised.<br>**Note** | | | | | | | |

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|
| | Special Pricing Arrangements apply. | | | | | | | |
| 2691P<br>*NP* | rivaroxaban 15 mg tablet, 28 | 1 | 5 | .. | 94.72 | 36.10 | Xarelto | BN |

**RIVAROXABAN**

**Authority required (STREAMLINED)**

***4098***

Deep vein thrombosis

Treatment Phase: Initial treatment

**The Clinical criteria is:**

Patient must have confirmed acute symptomatic deep vein thrombosis,

**AND the Clinical criteria is:**

Patient must not have symptomatic pulmonary embolism.

**Note**

**Shared Care Model**:

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

**Note**

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

**Note**

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

**Authority required (STREAMLINED)**

***4260***

Pulmonary embolism

Treatment Phase: Initial treatment

**The Clinical criteria is:**

Patient must have confirmed acute symptomatic pulmonary embolism.

**Note**

**Shared Care Model**:

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

**Note**

No 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.

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 2160Q<br>*NP* | rivaroxaban 15 mg tablet, 42 | 1 | .. | .. | 138.76 | 36.10 | Xarelto | BN |

**RIVAROXABAN**

**Authority required (STREAMLINED)**

***4099***

Deep vein thrombosis

Treatment Phase: Continuing treatment

**The Clinical criteria is:**

Patient must have confirmed acute symptomatic deep vein thrombosis,

**AND the Clinical criteria is:**

Patient must not have symptomatic pulmonary embolism.

**Note**

**Shared Care Model**:

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

**Note**

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

**Note**

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

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|
| | **Authority required (STREAMLINED)**<br>***4132***<br>Prevention of recurrent venous thromboembolism<br>Treatment Phase: Continuing treatment<br>**The Clinical criteria is:**<br>Patient must have a history of venous thromboembolism.<br>**Note**<br>**Shared Care Model**:<br>For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.<br>**Note**<br>No increase in the maximum quantity or number of units may be authorised.<br>**Note**<br>No increase in the maximum number of repeats may be authorised.<br>**Authority required (STREAMLINED)**<br>***4268***<br>Pulmonary embolism<br>Treatment Phase: Continuing treatment<br>**The Clinical criteria is:**<br>Patient must have confirmed acute symptomatic pulmonary embolism.<br>**Note**<br>**Shared Care Model**:<br>For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.<br>**Note**<br>No increase in the maximum quantity or number of units may be authorised.<br>**Note**<br>No increase in the maximum number of repeats may be authorised.<br>**Note**<br>Special Pricing Arrangements apply.<br>**Authority required (STREAMLINED)**<br>***4269***<br>Prevention of stroke or systemic embolism<br>**The Clinical criteria is:**<br>Patient must have non-valvular atrial fibrillation,<br>**AND the Clinical criteria is:**<br>Patient must have one or more risk factors for developing stroke or systemic embolism.<br>Risk factors for developing stroke or systemic ischaemic embolism are:<br>(i) Prior stroke (ischaemic or unknown type), transient ischaemic attack or non-central nervous system (CNS) systemic embolism;<br>(ii) age 75 years or older;<br>(iii) hypertension;<br>(iv) diabetes mellitus;<br>(v) heart failure and/or left ventricular ejection fraction 35% or less.<br>**Note**<br>**Shared Care Model**:<br>For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.<br>**Note**<br>No increase in the maximum quantity or number of units may be authorised.<br>**Note**<br>No increase in the maximum number of repeats may be authorised.<br>**Note**<br>Special Pricing Arrangements apply. | | | | | | | |
| 2268J<br>*NP* | rivaroxaban 20 mg tablet, 28 | 1 | 5 | .. | 94.72 | 36.10 | Xarelto | BN |

# BLOOD AND BLOOD FORMING ORGANS

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|---|---|---|---|---|---|---|---|---|---|

## ANTIHEMORRHAGICS

### ANTIFIBRINOLYTICS

#### *Amino acids*

**TRANEXAMIC ACID**

**Note**

Shared Care Model:

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

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 2180R *NP* | tranexamic acid 500 mg tablet, 100 | 1 | 2 | .. | 51.89 | 36.10 | | Cyklokapron | PF |

## ANTIANEMIC PREPARATIONS

### IRON PREPARATIONS

#### *Iron bivalent, oral preparations*

**FERROUS FUMARATE**

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 8985X *NP* | ferrous fumarate 200 mg (equivalent to 65.7 mg of elemental iron) tablet, 60 | 1 | 1 | .. | 11.83 | 12.96 | | Ferro-tab | AE |

**FERROUS SULFATE**

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 8815Y *NP* | ferrous sulfate 30 mg/mL (equivalent to 6 mg/mL elemental iron) oral liquid, 250 mL | ‡1 | 2 | .. | 19.56 | 20.69 | | Ferro-Liquid | AE |

#### *Iron trivalent, parenteral preparations*

**IRON POLYMALTOSE**

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 2593L *NP* | iron (as polymaltose) 100 mg/2 mL injection, 5 x 2 mL ampoules | 1 | .. | .. | 38.78 | 36.10 | [a] | Ferrosig | SI |
| | | | | | | | [a] | Ferrum H | AS |

**IRON SUCROSE**

**Authority required (STREAMLINED)**

***2070***

Iron deficiency anaemia, in combination with either epoetin alfa or darbepoetin alfa, in patients undergoing chronic haemodialysis who have had a documented hypersensitivity reaction to iron polymaltose and in whom continued intravenous iron therapy is appropriate

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 8807M *NP* | iron (as sucrose) 100 mg/5 mL injection, 5 x 5 mL vials | 1 | .. | .. | 139.69 | 36.10 | | Venofer | AS |

#### *Iron in combination with folic acid*

**FERROUS FUMARATE + FOLIC ACID**

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 9011G *NP* | ferrous fumarate 310 mg (equivalent to 100 mg elemental iron) + folic acid 350 microgram tablet, 60 | 1 | 1 | .. | 13.00 | 14.13 | | Ferro-f-tab | AE |

### VITAMIN B12 AND FOLIC ACID

#### *Vitamin B12 (cyanocobalamin and analogues)*

**HYDROXOCOBALAMIN**

**Restricted benefit**

Pernicious anaemia

**Restricted benefit**

Proven vitamin B12 deficiencies other than pernicious anaemia

**Restricted benefit**

Anaemias associated with vitamin B12 deficiency

**The Clinical criteria is:**

Patient must have had a gastrectomy,

**AND the Clinical criteria is:**

The treatment must be for prophylaxis.

**Note**

One injection of hydroxocobalamin 1 mg every three months provides appropriate maintenance therapy in vitamin B12 deficiencies.

# BLOOD AND BLOOD FORMING ORGANS

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|---|---|---|---|---|---|---|---|---|---|
| | **Note** | | | | | | | | |
| | Pharmaceutical benefits that have the form hydroxocobalamin injection 1 mg (as acetate) in 1 mL and pharmaceutical benefits that have the form hydroxocobalamin injection 1 mg (as chloride) in 1 mL are equivalent for the purposes of substitution. | | | | | | | | |
| 2162T *NP* | hydroxocobalamin 1 mg/mL injection, 3 x 1 mL ampoules | 1 | .. | .. | 13.58 | 14.71 | a | Vita-B12 | GH |
| 9048F *NP* | hydroxocobalamin 1 mg/mL injection, 3 x 1 mL ampoules | 1 | .. | .. | 13.58 | 14.71 | a | Hydroxo-B12 | AS |
| | | | | | | | a | Neo-B12 | HH |

## *Folic acid and derivatives*

**FOLIC ACID**

**Note**

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

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 1437P *NP* | folic acid 5 mg tablet, 100 | 2 | 1 | .. | *14.23 | 15.36 | | Megafol 5 | AF |

**FOLIC ACID**

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 2958Q *NP* | folic acid 500 microgram tablet, 100 | 2 | .. | .. | *12.81 | 13.94 | a | Foltabs 500 | PP |
| | | | | | | | a | Megafol 0.5 | AF |

# BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS

## BLOOD AND RELATED PRODUCTS

### *Blood substitutes and plasma protein fractions*

**GELATIN-SUCCINYLATED**

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 8444K *NP* | gelatin-succinylated 20 g/500 mL injection, 1 x 500 mL bag | 3 | .. | .. | *45.96 | 36.10 | | Gelofusine | BR |

**PENTASTARCH + SODIUM CHLORIDE**

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 9487H *NP* | HYDROXYETHYL STARCH 130/0.4 I.V. infusion 30 g per 500 mL, 500 mL, 1 | 3 | .. | .. | *45.96 | 36.10 | | Voluven 6% | PK |

## I.V. SOLUTIONS

### *Solutions for parenteral nutrition*

**GLUCOSE**

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 9445D *NP* | glucose 10% (50 g/500 mL) injection, 1 x 500 mL bag | 5 | 1 | .. | *18.08 | 19.21 | | Fresenius Kabi Australia Pty Limited | PK |
| 9474P *NP* | glucose 5% (12.5 g/250 mL) injection, 1 x 250 mL bag | 5 | 1 | .. | *23.88 | 25.01 | a | B. Braun Australia Pty Ltd | BR |
| | | | | | | | a | Glucose 5% Freeflex | PK |
| 5005K *DP* | glucose 5% (25 g/500 mL) injection, 1 x 500 mL bag | 5 | .. | .. | *18.08 | 19.21 | a | B. Braun Australia Pty Ltd | BR |
| | | | | | | | a | Fresenius Kabi Australia Pty Limited | PK |
| 9444C *NP* | glucose 5% (25 g/500 mL) injection, 1 x 500 mL bag | 5 | 1 | .. | *18.08 | 19.21 | a | B. Braun Australia Pty Ltd | BR |
| | | | | | | | a | Fresenius Kabi Australia Pty Limited | PK |
| 2245E *NP* | glucose 5% (50 g/1000 mL) injection, 1 x 1000 mL bag | 5 | 1 | .. | *23.03 | 24.16 | a | B. Braun Australia Pty Ltd | BR |
| | | | | | | | a | Baxter Healthcare Pty Ltd | BX |
| | | | | | | | a | Fresenius Kabi Australia Pty Limited | PK |
| 5106R *DP* | glucose 5% (50 g/1000 mL) injection, 1 x 1000 mL bag | 5 | .. | .. | *23.03 | 24.16 | a | B. Braun Australia Pty Ltd | BR |
| | | | | | | | a | Baxter Healthcare Pty Ltd | BX |
| | | | | | | | a | Fresenius Kabi Australia Pty Limited | PK |

### *Solutions affecting the electrolyte balance*

**LACTATE + SODIUM CHLORIDE + POTASSIUM CHLORIDE + CALCIUM CHLORIDE DIHYDRATE**

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 9416N *NP* | lactate sodium 0.322% (1.61 g/500 mL) + sodium chloride 0.6% (3 g/500 mL) + potassium chloride 0.04% (200 mg/500 | 5 | 1 | .. | *13.03 | 14.16 | a | B. Braun Australia Pty Ltd | BR |

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|---|
| | mL) + calcium chloride dihydrate 0.027% (135 mg/500 mL) injection, 1 x 500 mL bag | | | | | | | | |
| | | | | | | | [a] | Fresenius Kabi Australia Pty Limited | PK |
| 2286H *NP* | lactate sodium 0.322% (3.22 g/1000 mL) + sodium chloride 0.6% (6 g/1000 mL) + potassium chloride 0.04% (400 mg/1000 mL) + calcium chloride dihydrate 0.027% (270 mg/1000 mL) injection, 1 x 1000 mL bag | 5 | 1 | .. | *15.73 | 16.86 | [a] | B. Braun Australia Pty Ltd | BR |
| | | | | | | | [a] | Baxter Healthcare Pty Ltd | BX |
| | | | | | | | [a] | Fresenius Kabi Australia Pty Limited | PK |
| | **SODIUM CHLORIDE** | | | | | | | | |
| 9473N *NP* | sodium chloride 0.9% (2.25 g/250 mL) injection, 1 x 250 mL bag | 5 | 1 | .. | *16.58 | 17.71 | [a] | B. Braun Australia Pty Ltd | BR |
| | | | | | | | [a] | Sodium Chloride 0.9% Freeflex | PK |
| 5021G *DP* | sodium chloride 0.9% (4.5 g/500 mL) injection, 1 x 500 mL bag | 5 | .. | .. | *13.23 | 14.36 | [a] | B. Braun Australia Pty Ltd | BR |
| | | | | | | | [a] | Fresenius Kabi Australia Pty Limited | PK |
| 9392H *NP* | sodium chloride 0.9% (4.5 g/500 mL) injection, 1 x 500 mL bag | 5 | 1 | .. | *13.23 | 14.36 | [a] | B. Braun Australia Pty Ltd | BR |
| | | | | | | | [a] | Fresenius Kabi Australia Pty Limited | PK |
| 2264E *NP* | sodium chloride 0.9% (9 g/1000 mL) injection, 1 x 1000 mL bag | 5 | 1 | .. | *16.13 | 17.26 | [a] | B. Braun Australia Pty Ltd | BR |
| | | | | | | | [a] | Baxter Healthcare Pty Ltd | BX |
| | | | | | | | [a] | Fresenius Kabi Australia Pty Limited | PK |
| 5212H *DP* | sodium chloride 0.9% (9 g/1000 mL) injection, 1 x 1000 mL bag | 5 | .. | .. | *16.13 | 17.26 | [a] | B. Braun Australia Pty Ltd | BR |
| | | | | | | | [a] | Baxter Healthcare Pty Ltd | BX |
| | | | | | | | [a] | Fresenius Kabi Australia Pty Limited | PK |
| 2260Y *NP* | sodium chloride 3% (30 g/1000 mL) injection, 1 x 1000 mL bag | 2 | 1 | .. | *12.33 | 13.46 | | Baxter Healthcare Pty Ltd | BX |
| 5213J *DP* | sodium chloride 3% (30 g/1000 mL) injection, 1 x 1000 mL bag | 2 | .. | .. | *12.33 | 13.46 | | Baxter Healthcare Pty Ltd | BX |
| | **SODIUM CHLORIDE + GLUCOSE** | | | | | | | | |
| 2281C *NP* | sodium chloride 0.18% (1.8 g/1000 mL) + glucose 4% (40 g/1000 mL) injection, 1 x 1000 mL bag | 5 | 1 | .. | *23.73 | 24.86 | | Baxter Healthcare Pty Ltd | BX |
| 5214K *DP* | sodium chloride 0.18% (1.8 g/1000 mL) + glucose 4% (40 g/1000 mL) injection, 1 x 1000 mL bag | 5 | .. | .. | *23.73 | 24.86 | | Baxter Healthcare Pty Ltd | BX |
| 2279Y *NP* | sodium chloride 0.225% (1.125 g/500 mL) + glucose 3.75% (18.75 g/500 mL) injection, 1 x 500 mL bag | 5 | 1 | .. | *28.98 | 30.11 | | Baxter Healthcare Pty Ltd | BX |
| 5215L *DP* | sodium chloride 0.225% (1.125 g/500 mL) + glucose 3.75% (18.75 g/500 mL) injection, 1 x 500 mL bag | 5 | .. | .. | *28.98 | 30.11 | | Baxter Healthcare Pty Ltd | BX |
| 2278X *NP* | sodium chloride 0.45% (2.25 g/500 mL) + glucose 2.5% (12.5 g/500 mL) injection, 1 x 500 mL bag | 5 | 1 | .. | *28.98 | 30.11 | | Baxter Healthcare Pty Ltd | BX |
| 5216M *DP* | sodium chloride 0.45% (2.25 g/500 mL) + glucose 2.5% (12.5 g/500 mL) injection, 1 x 500 mL bag | 5 | .. | .. | *28.98 | 30.11 | | Baxter Healthcare Pty Ltd | BX |
| | **SODIUM CHLORIDE + POTASSIUM CHLORIDE + CALCIUM CHLORIDE DIHYDRATE** | | | | | | | | |
| 2266G *NP* | sodium chloride 8.6 g/1000 mL + potassium chloride 300 mg/1000 mL + calcium chloride dihydrate 330 mg/1000 mL injection, 1 x 1000 mL bag | 4 | 1 | .. | *30.23 | 31.36 | | Baxter Healthcare Pty Ltd | BX |

# BLOOD AND BLOOD FORMING ORGANS

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|
| | **SODIUM GLUCONATE + SODIUM CHLORIDE + POTASSIUM CHLORIDE + MAGNESIUM CHLORIDE + SODIUM ACETATE TRIHYDRATE + GLUCOSE** | | | | | | | |
| 3199J<br>*NP* | sodium gluconate 5.02 g/1000 mL + sodium chloride 5.26 g/1000 mL + potassium chloride 370 mg/1000 mL + magnesium chloride 300 mg/1000 mL + sodium acetate trihydrate 3.68 g/1000 mL + glucose 5% (50 g/1000 mL) injection, 1 x 1000 mL bag | 2 | 1 | .. | *22.17 | 23.30 | Plasma-Lyte 148 | BX |

## OTHER HEMATOLOGICAL AGENTS

## OTHER HEMATOLOGICAL AGENTS

### *Drugs used in hereditary angioedema*

**ICATIBANT**

**Authority required**

Initial supply for anticipated emergency treatment of an acute attack of hereditary angioedema in a patient with confirmed diagnosis of C1-esterase inhibitor deficiency who has been assessed to be at significant risk of an acute attack of hereditary angioedema by or in consultation with a clinical immunologist, respiratory physician, specialist allergist or general physician experienced in the management of patients with hereditary angioedema.

The name of the specialist consulted must be provided at the time of application for initial supply.

The name of the Approved Pathology Authority and date of the diagnosing pathology test must be included in the authority application

**Authority required**

Continuing supply for anticipated emergency treatment of an acute attack of hereditary angioedema, where the patient has previously been issued with an authority prescription for this drug

**Note**

Icatibant should be provided in the framework of a comprehensive hereditary angioedema prophylaxis program and an emergency Action Plan including training in recognition of the symptoms of hereditary angioedema and the self-administration of icatibant. (For further information see the Australasian Society of Clinical Immunology and Allergy website at www.allergy.org.au)

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 1976B | ICATIBANT Injection 30 mg (as acetate) in 3 mL single use pre-filled syringe, 1 | 1 | 1 | .. | 2571.57 | 36.10 | Firazyr | ZI |

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|---|

# CARDIOVASCULAR SYSTEM

## CARDIAC THERAPY

### CARDIAC GLYCOSIDES

#### *Digitalis glycosides*

**DIGOXIN**

**Note**

Shared Care Model:

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

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 1322N *NP* | digoxin 250 microgram tablet, 100 | 1 | 1 | .. | 10.92 | 12.05 | a | Sigmaxin | FM |
| | | | | B2.94 | 13.86 | 12.05 | a | Lanoxin | QA |
| 3164M *NP* | digoxin 50 microgram/mL oral liquid, 60 mL | 2 | 3 | .. | *41.33 | 36.10 | | Lanoxin | QA |
| 2605D *NP* | digoxin 62.5 microgram tablet, 200 | 1 | 1 | .. | 10.63 | 11.76 | a | Sigmaxin-PG | FM |
| | | | | B2.95 | 13.58 | 11.76 | a | Lanoxin-PG | QA |

### ANTIARRHYTHMICS, CLASS I AND III

#### *Antiarrhythmics, class Ia*

**DISOPYRAMIDE**

**Note**

Shared Care Model:

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

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 2923W *NP* | disopyramide 100 mg capsule, 100 | 1 | 5 | .. | 29.34 | 30.47 | | Rythmodan | SW |
| 2924X *NP* | disopyramide 150 mg capsule, 100 | 1 | 5 | .. | 46.72 | 36.10 | | Rythmodan | SW |

#### *Antiarrhythmics, class Ib*

**LIGNOCAINE**

**Note**

Shared Care Model:

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

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 2875H *NP* | lignocaine hydrochloride anhydrous 2% (100 mg/5 mL) injection, 5 x 5 mL ampoules | 1 | .. | .. | 37.54 | 36.10 | | Pfizer Australia Pty Ltd | PF |
| 2876J *NP* | lignocaine hydrochloride anhydrous 500 mg/5 mL injection, 10 x 5 mL ampoules | 1 | .. | .. | 29.80 | 30.93 | | Xylocard 500 | AP |

**LIGNOCAINE**

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 5142P *DP* | lignocaine hydrochloride anhydrous 2% (100 mg/5 mL) injection, 5 x 5 mL ampoules | 1 | .. | .. | 37.54 | 36.10 | | Pfizer Australia Pty Ltd | PF |

#### *Antiarrhythmics, class Ic*

**FLECAINIDE**

**Restricted benefit**

Serious supra-ventricular cardiac arrhythmias

**Restricted benefit**

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

**Caution**

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

**Note**

Shared Care Model:

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

# CARDIOVASCULAR SYSTEM

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|---|
| 1090J *NP* | flecainide acetate 100 mg tablet, 60 | 1 | 5 | .. | 44.90 | 36.10 | [a] | Flecatab | AF |
| | | | | | | | [a] | Tambocor | IA |
| 1088G *NP* | flecainide acetate 50 mg tablet, 60 | 1 | 5 | .. | 37.94 | 36.10 | | Tambocor | IA |

## *Antiarrhythmics, class III*

**AMIODARONE**

**Restricted benefit**

Severe cardiac arrhythmias

**Caution**

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

Regular monitoring of hepatic and thyroid function is recommended.

**Note**

Shared Care Model:

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

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 2344J *NP* | amiodarone hydrochloride 100 mg tablet, 30 | 1 | 5 | .. | 13.25 | 14.38 | [a] | Amiodarone Sandoz | SZ |
| | | | | | | | [a] | Aratac 100 | AF |
| | | | | | | | [a] | Cordarone X 100 | SW |
| 2343H *NP* | amiodarone hydrochloride 200 mg tablet, 30 | 1 | 5 | .. | 18.43 | 19.56 | [a] | Amiodarone Sandoz | SZ |
| | | | | | | | [a] | Aratac 200 | AF |
| | | | | | | | [a] | Chem mart Amiodarone | CH |
| | | | | | | | [a] | Cordarone X 200 | SW |
| | | | | | | | [a] | GenRx Amiodarone | GX |
| | | | | | | | [a] | Rithmik 200 | QA |
| | | | | | | | [a] | Terry White Chemists Amiodarone | TW |

**SOTALOL**

**Restricted benefit**

Severe cardiac arrhythmias

**Note**

Shared Care Model:

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

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 2043M *NP* | sotalol hydrochloride 160 mg tablet, 60 | 1 | 5 | .. | 18.26 | 19.39 | [a] | Cardol | AF |
| | | | | | | | [a] | Chem mart Sotalol | CH |
| | | | | | | | [a] | GenRx Sotalol | GX |
| | | | | | | | [a] | Solavert | QA |
| | | | | | | | [a] | Sotalol Sandoz | SZ |
| | | | | | | | [a] | Terry White Chemists Sotalol | TW |
| | | | | [B]4.26 | 22.52 | 19.39 | [a] | Sotacor | FM |
| 8398B *NP* | sotalol hydrochloride 80 mg tablet, 60 | 1 | 5 | .. | 12.05 | 13.18 | [a] | GenRx Sotalol | GX |
| | | | | | | | [a] | Solavert | QA |
| | | | | | | | [a] | Sotalol Sandoz | SZ |
| | | | | [B]4.26 | 16.31 | 13.18 | [a] | Sotacor | FM |

# CARDIAC STIMULANTS EXCL. CARDIAC GLYCOSIDES

## *Adrenergic and dopaminergic agents*

**ADRENALINE**

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 1016L *NP* | adrenaline 1 in 1000 (1 mg/mL) injection, 5 x 1 mL ampoules | 1 | 1 | .. | 20.55 | 21.68 | | Link Medical Products Pty Ltd | LM |
| 5004J *DP* | adrenaline 1 in 1000 (1 mg/mL) injection, 5 x 1 mL ampoules | 1 | .. | .. | 20.55 | 21.68 | | Link Medical Products Pty Ltd | LM |

**ADRENALINE**

**Authority required**

Initial sole PBS-subsidised supply for anticipated emergency treatment of acute allergic reactions with anaphylaxis in a patient who has been

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|---|
| | assessed to be at significant risk of anaphylaxis by, or in consultation with, a clinical immunologist, allergist, paediatrician or respiratory physician. The name of the specialist consulted must be provided at the time of application for initial supply | | | | | | | | |
| | **Authority required**<br>Initial sole PBS-subsidised supply for anticipated emergency treatment of acute allergic reactions with anaphylaxis in a patient who has been discharged from hospital or an emergency department after treatment with adrenaline for acute allergic reaction with anaphylaxis | | | | | | | | |
| | **Authority required**<br>Continuing sole PBS-subsidised supply for anticipated emergency treatment of acute allergic reactions with anaphylaxis, where the patient has previously been issued with an authority prescription for this drug | | | | | | | | |
| | **Caution**<br>EpiPen and Anapen products have different administration techniques and should not be prescribed to the same patient without training in their use. | | | | | | | | |
| | **Note**<br>The auto-injector should be provided in the framework of a comprehensive anaphylaxis prevention program and an emergency action plan including training in recognition of the symptoms of anaphylaxis and the use of the auto-injector device. (For further information see the Australasian Society of Clinical Immunology and Allergy website at www.allergy.org.au.) | | | | | | | | |
| | **Note**<br>Authority approvals will be limited to a maximum quantity of 2 auto-injectors (Anapen or EpiPen) at any one time.<br>No repeats will be issued. | | | | | | | | |
| 3408J<br>*NP* | adrenaline 150 microgram/0.3 mL injection, 1 x 0.3 mL syringe | 1 | .. | .. | 106.21 | 36.10 | | Anapen Junior | LM |
| 8697R<br>*NP* | adrenaline 150 microgram/0.3 mL injection, 1 x 0.3 mL syringe | 1 | .. | .. | 106.21 | 36.10 | | EpiPen Jr. | AL |
| 3409K<br>*NP* | adrenaline 300 microgram/0.3 mL injection, 1 x 0.3 mL syringe | 1 | .. | .. | 106.21 | 36.10 | | Anapen | LM |
| 8698T<br>*NP* | adrenaline 300 microgram/0.3 mL injection, 1 x 0.3 mL syringe | 1 | .. | .. | 106.21 | 36.10 | | EpiPen | AL |

## VASODILATORS USED IN CARDIAC DISEASES

### *Organic nitrates*

**GLYCERYL TRINITRATE**

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 1516T<br>*NP* | glyceryl trinitrate 10 mg/24 hours patch, 30 | 1 | 5 | .. | 34.02 | 35.15 | | Transiderm-Nitro 50 | NV |
| 8011P<br>*NP* | glyceryl trinitrate 10 mg/24 hours patch, 30 | 1 | 5 | .. | 34.02 | 35.15 | | Nitro-Dur 10 | MK |
| 8028M<br>*NP* | glyceryl trinitrate 10 mg/24 hours patch, 30 | 1 | 5 | .. | 34.02 | 35.15 | | Minitran 10 | IA |
| 8026K<br>*NP* | glyceryl trinitrate 15 mg/24 hours patch, 30 | 1 | 5 | .. | 34.02 | 35.15 | | Nitro-Dur 15 | MK |
| 8119H<br>*NP* | glyceryl trinitrate 15 mg/24 hours patch, 30 | 1 | 5 | .. | 34.02 | 35.15 | | Minitran 15 | IA |
| 1515R<br>*NP* | glyceryl trinitrate 5 mg/24 hours patch, 30 | 1 | 5 | .. | 27.53 | 28.66 | | Transiderm-Nitro 25 | NV |
| 8010N<br>*NP* | glyceryl trinitrate 5 mg/24 hours patch, 30 | 1 | 5 | .. | 27.53 | 28.66 | | Nitro-Dur 5 | MK |
| 8027L<br>*NP* | glyceryl trinitrate 5 mg/24 hours patch, 30 | 1 | 5 | .. | 27.53 | 28.66 | | Minitran 5 | IA |
| 1459T<br>*NP* | glyceryl trinitrate 600 microgram tablet: sublingual, 100 tablets | ‡1 | 5 | .. | 15.04 | 16.17 | a | Lycinate | FM |
| | | | | [B]2.94 | 17.98 | 16.17 | a | Anginine Stabilised | QA |
| 5108W<br>*DP* | glyceryl trinitrate 600 microgram tablet: sublingual, 100 tablets | ‡1 | .. | .. | 15.04 | 16.17 | a | Lycinate | FM |
| | | | | [B]2.94 | 17.98 | 16.17 | a | Anginine Stabilised | QA |

**GLYCERYL TRINITRATE**

**Note**
The spray should not be inhaled.

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 8171C<br>*NP* | glyceryl trinitrate 400 microgram/actuation spray, 200 actuations | ‡1 | 5 | .. | 20.34 | 21.47 | | Nitrolingual Pumpspray | SW |

**ISOSORBIDE DINITRATE**

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 2588F<br>*NP* | isosorbide dinitrate 5 mg tablet: sublingual, 100 | 2 | 2 | .. | *14.77 | 15.90 | | Isordil Sublingual | QA |

**ISOSORBIDE MONONITRATE**

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 8273K | isosorbide mononitrate 120 mg tablet: | 1 | 5 | .. | 18.28 | 19.41 | a | Monodur 120 mg | PM |

# CARDIOVASCULAR SYSTEM

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|---|
| *NP* | modified release, 30 tablets | | | | | | | | |
| | | | | [B]3.75 | 22.03 | 19.41 | [a] | Imdur 120 mg | AP |
| 1558B | isosorbide mononitrate 60 mg tablet: | 1 | 5 | .. | 11.55 | 12.68 | [a] | Chem mart Isosorbide Mononitrate | CH |
| *NP* | modified release, 30 tablets | | | | | | [a] | Duride | AF |
| | | | | | | | [a] | GenRx Isosorbide Mononitrate | GX |
| | | | | | | | [a] | Imtrate 60 mg | GM |
| | | | | | | | [a] | Isomonit | SZ |
| | | | | | | | [a] | Terry White Chemists Isosorbide Mononitrate | TW |
| | | | | [B]2.75 | 14.30 | 12.68 | [a] | Monodur 60 mg | PM |
| | | | | [B]3.75 | 15.30 | 12.68 | [a] | Imdur Durule | AP |

### *Other vasodilators used in cardiac diseases*

**NICORANDIL**

**Note**

Shared Care Model:

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

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 8228C | nicorandil 10 mg tablet, 60 | ‡1 | 5 | .. | 24.35 | 25.48 | | Ikorel | SW |
| *NP* | | | | | | | | | |
| 8229D | nicorandil 20 mg tablet, 60 | ‡1 | 5 | .. | 31.47 | 32.60 | | Ikorel | SW |
| *NP* | | | | | | | | | |

**PERHEXILINE**

**Authority required (STREAMLINED)**

***1023***

Angina not responding to other therapy

**Caution**

Regular monitoring of drug serum levels is recommended.

**Note**

Shared Care Model:

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

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 1822X | perhexiline maleate 100 mg tablet, 100 | 1 | 5 | .. | 62.83 | 36.10 | | Pexsig | QA |
| *NP* | | | | | | | | | |

## ANTIHYPERTENSIVES

### ANTIADRENERGIC AGENTS, CENTRALLY ACTING

### *Methyldopa*

**METHYLDOPA**

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 1629R | methyldopa 250 mg tablet, 100 | 1 | 5 | .. | 14.08 | 15.21 | [a] | Hydopa | AF |
| *NP* | | | | | | | | | |
| | | | | [B]3.54 | 17.62 | 15.21 | [a] | Aldomet | AS |

### *Imidazoline receptor agonists*

**CLONIDINE**

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 3145M | clonidine hydrochloride 100 microgram tablet, 100 | 1 | 5 | .. | 29.09 | 30.22 | | Catapres 100 | BY |
| *NP* | | | | | | | | | |
| 3141H | clonidine hydrochloride 150 microgram tablet, 100 | 1 | 5 | .. | 37.65 | 36.10 | | Catapres | BY |
| *NP* | | | | | | | | | |

**MOXONIDINE**

**Restricted benefit**

Hypertension in patients receiving concurrent antihypertensive therapy

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 9019Q | moxonidine 200 microgram tablet, 30 | 1 | 5 | .. | 19.74 | 20.87 | | Physiotens | AB |
| *NP* | | | | | | | | | |
| 9020R | moxonidine 400 microgram tablet, 30 | 1 | 5 | .. | 28.99 | 30.12 | | Physiotens | AB |
| *NP* | | | | | | | | | |

### ANTIADRENERGIC AGENTS, PERIPHERALLY ACTING

### *Alpha-adrenoreceptor antagonists*

# CARDIOVASCULAR SYSTEM

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|---|
| | **PRAZOSIN** | | | | | | | | |
| 1479W *NP* | prazosin 1 mg tablet, 100 | 1 | 5 | .. | 11.58 | 12.71 | [a] | APO-Prazosin | TX |
| | | | | | | | [a] | Chem mart Prazosin | CH |
| | | | | | | | [a] | Minipress | PF |
| | | | | | | | [a] | Terry White Chemists Prazosin | TW |
| 1480X *NP* | prazosin 2 mg tablet, 100 | 1 | 5 | .. | 14.51 | 15.64 | [a] | APO-Prazosin | TX |
| | | | | | | | [a] | Chem mart Prazosin | CH |
| | | | | | | | [a] | Minipress | PF |
| | | | | | | | [a] | Terry White Chemists Prazosin | TW |
| 1478T *NP* | prazosin 5 mg tablet, 100 | 1 | 5 | .. | 20.78 | 21.91 | [a] | APO-Prazosin | TX |
| | | | | | | | [a] | Chem mart Prazosin | CH |
| | | | | | | | [a] | Minipress | PF |
| | | | | | | | [a] | Terry White Chemists Prazosin | TW |

## ARTERIOLAR SMOOTH MUSCLE, AGENTS ACTING ON

### *Hydrazinophthalazine derivatives*

**HYDRALAZINE**

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 1640H *NP* | hydralazine hydrochloride 25 mg tablet, 100 | 2 | 2 | .. | *17.51 | 18.64 | | Alphapress 25 | AF |
| 1639G *NP* | hydralazine hydrochloride 50 mg tablet, 100 | 2 | 2 | .. | *19.23 | 20.36 | | Alphapress 50 | AF |

### *Pyrimidine derivatives*

**MINOXIDIL**

**Authority required (STREAMLINED)**

***2759***

Severe refractory hypertension. Treatment must be initiated by a consultant physician

**Note**

Continuing Therapy Only:

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

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 2313R *NP* | minoxidil 10 mg tablet, 100 | 1 | 5 | .. | 60.48 | 36.10 | | Loniten | PF |

## DIURETICS

## LOW-CEILING DIURETICS, THIAZIDES

### *Thiazides, plain*

**HYDROCHLOROTHIAZIDE**

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 1484D *NP* | hydrochlorothiazide 25 mg tablet, 100 | 1 | 1 | .. | 21.45 | 22.58 | | Dithiazide | PL |

## LOW-CEILING DIURETICS, EXCL. THIAZIDES

### *Sulfonamides, plain*

**CHLORTHALIDONE**

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 1585K *NP* | chlorthalidone 25 mg tablet, 50 | 2 | 1 | .. | *17.79 | 18.92 | | Hygroton 25 | LM |

**INDAPAMIDE**

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 8532C *NP* | indapamide hemihydrate 1.5 mg tablet: modified release, 90 tablets | 1 | 1 | .. | 19.51 | 20.64 | | Natrilix SR | SE |
| 2436F *NP* | indapamide hemihydrate 2.5 mg tablet, 90 | 1 | 1 | .. | 15.46 | 16.59 | [a] | Chem mart Indapamide | CH |
| | | | | | | | [a] | Dapa-Tabs | AF |
| | | | | | | | [a] | GenRx Indapamide | GX |
| | | | | | | | [a] | Indapamide-GA | GM |
| | | | | | | | [a] | Indapamide Sandoz | SZ |
| | | | | | | | [a] | Insig | QA |

# CARDIOVASCULAR SYSTEM

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | [a] | Terry White Chemists Indapamide | TW |
| | | | | [B]4.11 | 19.57 | 16.59 | [a] | Natrilix | SE |

## HIGH-CEILING DIURETICS

### *Sulfonamides, plain*

**FRUSEMIDE**

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 2411X *NP* | frusemide 10 mg/mL oral liquid, 30 mL | ‡1 | 3 | .. | 17.27 | 18.40 | | Lasix | SW |
| 2413B *NP* | frusemide 20 mg/2 mL injection, 5 x 2 mL ampoules | 1 | .. | .. | 9.83 | 10.96 | [a] | Frusemide-Claris | AE |
| | | | | | | | [a] | Frusemide Sandoz | SZ |
| | | | | | | | [a] | Lasix | SW |
| 2412Y *NP* | frusemide 40 mg tablet, 100 | 1 | 1 | .. | 8.53 | 9.66 | [a] | APO-Frusemide | TX |
| | | | | | | | [a] | Chem mart Frusemide | CH |
| | | | | | | | [a] | Frusax | GN |
| | | | | | | | [a] | Frusemide Sandoz | SZ |
| | | | | | | | [a] | Frusid | GM |
| | | | | | | | [a] | GenRx Frusemide | GX |
| | | | | | | | [a] | Terry White Chemists Frusemide | TW |
| | | | | | | | [a] | Uremide | AF |
| | | | | | | | | Urex | FM |
| | | | | [B]2.40 | 10.93 | 9.66 | [a] | Lasix | SW |
| 2415D *NP* | frusemide 500 mg tablet, 50 | 1 | 3 | .. | 16.45 | 17.58 | | Urex-Forte | FM |

**FRUSEMIDE**

**Note**

For item codes 2414C and 1810G, pharmaceutical benefits that have the form tablet 20 mg are equivalent for the purposes of substitution.

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 2414C *NP* | frusemide 20 mg tablet, 100 | 1 | 1 | .. | 8.71 | 9.84 | [a] | APO-Frusemide | TX |
| | | | | | | | [a] | Chem mart Frusemide | CH |
| | | | | | | | [a] | Frusid | GM |
| | | | | | | | [a] | GenRx Frusemide | GX |
| | | | | | | | [a] | Terry White Chemists Frusemide | TW |
| 1810G *NP* | frusemide 20 mg tablet, 50 | 2 | 1 | .. | *8.71 | 9.84 | [a] | Urex-M | FM |
| | | | | [B]1.92 | *10.63 | 9.84 | [a] | Lasix-M | SW |

### *Aryloxyacetic acid derivatives*

**ETHACRYNIC ACID**

**Restricted benefit**

Patients hypersensitive to other oral diuretics

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 8748K *NP* | ethacrynic acid 25 mg tablet, 100 | 2 | 1 | .. | *197.51 | 36.10 | | Edecrin | FK |

## POTASSIUM-SPARING AGENTS

### *Aldosterone antagonists*

**EPLERENONE**

**Authority required (STREAMLINED)**

***2637***

Heart failure with a left ventricular ejection fraction of 40% or less occurring within 3 to 14 days following an acute myocardial infarction. Treatment with eplerenone must be commenced within 14 days of an acute myocardial infarction.

The date of the acute myocardial infarction and the date of initiation of eplerenone treatment must be documented in the patient's medical records when PBS-subsidised treatment is initiated

**Caution**

Serum electrolytes should be checked regularly.

**Note**

Continuing Therapy Only:

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

# CARDIOVASCULAR SYSTEM

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|---|
| 8879H *NP* | eplerenone 25 mg tablet, 30 | 1 | 5 | .. | 112.98 | 36.10 | | Inspra | PF |
| 8880J *NP* | eplerenone 50 mg tablet, 30 | 1 | 5 | .. | 112.98 | 36.10 | | Inspra | PF |
| | **SPIRONOLACTONE** | | | | | | | | |
| | **Caution** | | | | | | | | |
| | Serum electrolytes should be checked regularly. | | | | | | | | |
| | **Caution** | | | | | | | | |
| | Appropriate contraceptive measures should be taken by women of child-bearing age in whom spironolactone therapy has been initiated. | | | | | | | | |
| 2340E *NP* | spironolactone 100 mg tablet, 100 | 1 | 5 | .. | 29.33 | 30.46 | a | Spiractin 100 | AF |
| | | | | [B]2.40 | 31.73 | 30.46 | a | Aldactone | PF |
| 2339D *NP* | spironolactone 25 mg tablet, 100 | 1 | 5 | .. | 12.40 | 13.53 | a | Spiractin 25 | AF |
| | | | | [B]1.75 | 14.15 | 13.53 | a | Aldactone | PF |

## DIURETICS AND POTASSIUM-SPARING AGENTS IN COMBINATION

### *Low-ceiling diuretics and potassium-sparing agents*

**HYDROCHLOROTHIAZIDE + AMILORIDE**

**Caution**

Serum electrolytes should be checked regularly.

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 1486F *NP* | hydrochlorothiazide 50 mg + amiloride hydrochloride 5 mg tablet, 50 | 2 | 1 | .. | *13.71 | 14.84 | | Moduretic | AS |

**HYDROCHLOROTHIAZIDE + TRIAMTERENE**

**Caution**

Serum electrolytes should be checked regularly.

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 1280J *NP* | hydrochlorothiazide 25 mg + triamterene 50 mg tablet, 100 | 1 | 1 | .. | 13.10 | 14.23 | | Hydrene 25/50 | AF |

## PERIPHERAL VASODILATORS

## PERIPHERAL VASODILATORS

### *Other peripheral vasodilators*

**PHENOXYBENZAMINE**

**Restricted benefit**

Phaeochromocytoma

**Restricted benefit**

Neurogenic urinary retention

**Note**

Continuing Therapy Only:

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

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 1862B *NP* | phenoxybenzamine hydrochloride 10 mg capsule, 100 | 1 | 5 | .. | 67.58 | 36.10 | | Dibenyline | GH |
| 9286R *NP* | phenoxybenzamine hydrochloride 10 mg capsule, 100 | ‡1 | 5 | .. | 1164.68 | 36.10 | | Dibenzyline | BZ |
| 1166J *NP* | phenoxybenzamine hydrochloride 10 mg capsule, 30 | 3 | 5 | .. | *205.11 | 36.10 | | Dibenyline | GH |

## BETA BLOCKING AGENTS

## BETA BLOCKING AGENTS

### *Beta blocking agents, non-selective*

**OXPRENOLOL**

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 2942W *NP* | oxprenolol hydrochloride 20 mg tablet, 100 | 1 | 5 | .. | 28.08 | 29.21 | | Corbeton 20 | AF |
| 2961W *NP* | oxprenolol hydrochloride 40 mg tablet, 100 | 1 | 5 | .. | 48.45 | 36.10 | | Corbeton 40 | AF |

**PINDOLOL**

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 3065H | pindolol 15 mg tablet, 50 | 1 | 5 | .. | 11.23 | 12.36 | a | Barbloc 15 | AF |

# CARDIOVASCULAR SYSTEM

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|---|
| *NP* | | | | | | | | | |
| | | | | [B]1.70 | 12.93 | 12.36 | [a] | Visken 15 | NV |
| 3062E | pindolol 5 mg tablet, 100 | 1 | 5 | .. | 33.57 | 34.70 | | Barbloc 5 | AF |
| *NP* | | | | | | | | | |
| | **PROPRANOLOL** | | | | | | | | |
| 2565B | propranolol hydrochloride 10 mg tablet, 100 | 1 | 5 | .. | 10.40 | 11.53 | | Deralin 10 | AF |
| *NP* | | | | | | | | | |
| | | | | [B]3.75 | 14.15 | 11.53 | | Inderal | AP |
| 2899N | propranolol hydrochloride 160 mg tablet, 50 | 1 | 5 | .. | 11.22 | 12.35 | | Deralin 160 | AF |
| *NP* | | | | | | | | | |
| 2566C | propranolol hydrochloride 40 mg tablet, 100 | 1 | 5 | .. | 10.77 | 11.90 | | Deralin 40 | AF |
| *NP* | | | | | | | | | |
| | | | | [B]3.75 | 14.52 | 11.90 | | Inderal | AP |

## *Beta blocking agents, selective*

**ATENOLOL**

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 1081X | atenolol 50 mg tablet, 30 | 1 | 5 | .. | 8.55 | 9.68 | [a] | APO-Atenolol | TX |
| *NP* | | | | | | | | | |
| | | | | | | | [a] | Atenolol-GA | GN |
| | | | | | | | [a] | Atenolol GH | GQ |
| | | | | | | | [a] | Atenolol Sandoz | SZ |
| | | | | | | | [a] | Chem mart Atenolol | CH |
| | | | | | | | [a] | Noten | AF |
| | | | | | | | [a] | Tenolten 50 | DO |
| | | | | | | | [a] | Tensig | QA |
| | | | | | | | [a] | Terry White Chemists Atenolol | TW |
| | | | | [B]2.85 | 11.40 | 9.68 | [a] | Tenormin | AP |

**ATENOLOL**
**Restricted benefit**
For a patient who is unable to take a solid dose form of atenolol.

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 2243C | atenolol 50 mg/10 mL oral liquid, 300 mL | ‡1 | 5 | .. | 27.65 | 28.78 | | Atenolol-AFT | AE |
| *NP* | | | | | | | | | |

**BISOPROLOL**
**Authority required (STREAMLINED)**
***3234***
Moderate to severe heart failure in a patient stabilised on conventional therapy which must include an ACE inhibitor or Angiotensin II antagonist, if tolerated

**Note**
Continuing Therapy Only:

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

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 8606Y | bisoprolol fumarate 10 mg tablet, 28 | 1 | 5 | .. | 58.96 | 36.10 | [a] | APO-Bisoprolol | TX |
| *NP* | | | | | | | | | |
| | | | | | | | [a] | Beprol 10 | DO |
| | | | | | | | [a] | Bicard 10 | QA |
| | | | | | | | [a] | Bicor | AL |
| | | | | | | | [a] | Biso 10 | WQ |
| | | | | | | | [a] | Bisoprolol GH | GQ |
| | | | | | | | [a] | Bisoprolol Sandoz | SZ |
| | | | | | | | [a] | Bispro 10 | AF |
| | | | | | | | [a] | Chem mart Bisoprolol | CH |
| | | | | | | | [a] | Terry White Chemists Bisoprolol | TW |
| 8604W | bisoprolol fumarate 2.5 mg tablet, 28 | 1 | 5 | .. | 41.58 | 36.10 | [a] | APO-Bisoprolol | TX |
| *NP* | | | | | | | | | |
| | | | | | | | [a] | Beprol 2.5 | DO |
| | | | | | | | [a] | Bicard 2.5 | QA |
| | | | | | | | [a] | Bicor | AL |
| | | | | | | | [a] | Biso 2.5 | WQ |
| | | | | | | | [a] | Bisoprolol GH | GQ |
| | | | | | | | [a] | Bisoprolol Sandoz | SZ |

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | [a] | Bispro 2.5 | AF |
| | | | | | | | [a] | Chem mart Bisoprolol | CH |
| | | | | | | | [a] | Terry White Chemists Bisoprolol | TW |
| 8605X *NP* | bisoprolol fumarate 5 mg tablet, 28 | 1 | 5 | .. | 49.18 | 36.10 | [a] | APO-Bisoprolol | TX |
| | | | | | | | [a] | Beprol 5 | DO |
| | | | | | | | [a] | Bicard 5 | QA |
| | | | | | | | [a] | Bicor | AL |
| | | | | | | | [a] | Biso 5 | WQ |
| | | | | | | | [a] | Bisoprolol GH | GQ |
| | | | | | | | [a] | Bisoprolol Sandoz | SZ |
| | | | | | | | [a] | Bispro 5 | AF |
| | | | | | | | [a] | Chem mart Bisoprolol | CH |
| | | | | | | | [a] | Terry White Chemists Bisoprolol | TW |

**METOPROLOL SUCCINATE**

**Authority required (STREAMLINED)**

***3234***

Moderate to severe heart failure in a patient stabilised on conventional therapy which must include an ACE inhibitor or Angiotensin II antagonist, if tolerated

**Note**

Continuing Therapy Only:

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

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 8735R *NP* | METOPROLOL SUCCINATE Tablet 190 mg (controlled release), 30 | 1 | 5 | .. | 109.81 | 36.10 | | Toprol-XL 190 | AP |
| 8732N *NP* | METOPROLOL SUCCINATE Tablet 23.75 mg (controlled release), 15 | 1 | .. | .. | 21.25 | 22.38 | | Toprol-XL 23.75 | AP |
| 8733P *NP* | METOPROLOL SUCCINATE Tablet 47.5 mg (controlled release), 30 | 1 | 5 | .. | 72.67 | 36.10 | | Toprol-XL 47.5 | AP |
| 8734Q *NP* | METOPROLOL SUCCINATE Tablet 95 mg (controlled release), 30 | 1 | 5 | .. | 89.17 | 36.10 | | Toprol-XL 95 | AP |

**METOPROLOL TARTRATE**

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 1325R *NP* | METOPROLOL TARTRATE Tablet 100 mg, 60 | 1 | 5 | .. | 10.51 | 11.64 | [b] | Chem mart Metoprolol | CH |
| | | | | | | | [b] | GenRx Metoprolol | GX |
| | | | | | | | [b] | Metohexal | SZ |
| | | | | | | | [b] | Metrol 100 | QA |
| | | | | | | | [b] | Minax 100 | AF |
| | | | | | | | [b] | Terry White Chemists Metoprolol | TW |
| | | | | | | | [a] | APO-Metoprolol | TX |
| | | | | [B]2.22 | 12.73 | 11.64 | [a] | Lopresor 100 | NV |
| | | | | [B]3.76 | 14.27 | 11.64 | [b] | Betaloc | AP |
| 1324Q *NP* | METOPROLOL TARTRATE Tablet 50 mg, 100 | 1 | 5 | .. | 9.65 | 10.78 | [a] | APO-Metoprolol | TX |
| | | | | | | | [b] | Chem mart Metoprolol | CH |
| | | | | | | | [b] | GenRx Metoprolol | GX |
| | | | | | | | [b] | Metohexal | SZ |
| | | | | | | | [b] | Metrol 50 | QA |
| | | | | | | | [b] | Minax 50 | AF |
| | | | | | | | [b] | Terry White Chemists Metoprolol | TW |
| | | | | [B]2.26 | 11.91 | 10.78 | [a] | Lopresor 50 | NV |
| | | | | [B]3.77 | 13.42 | 10.78 | [b] | Betaloc | AP |

**NEBIVOLOL**

**Authority required (STREAMLINED)**

***3234***

Moderate to severe heart failure in a patient stabilised on conventional therapy which must include an ACE inhibitor or Angiotensin II antagonist, if tolerated

**Note**

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|---|
| | Continuing Therapy Only: | | | | | | | | |
| | For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners. | | | | | | | | |
| 9316H *NP* | nebivolol 1.25 mg tablet, 28 | 2 | 5 | .. | *50.83 | 36.10 | | Nebilet | FK |
| 9312D *NP* | nebivolol 10 mg tablet, 28 | 1 | 5 | .. | 68.23 | 36.10 | | Nebilet | FK |
| 9311C *NP* | nebivolol 5 mg tablet, 28 | 1 | 5 | .. | 61.15 | 36.10 | | Nebilet | FK |

## *Alpha and beta blocking agents*

**CARVEDILOL**

**Authority required (STREAMLINED)**

***3234***

Moderate to severe heart failure in a patient stabilised on conventional therapy which must include an ACE inhibitor or Angiotensin II antagonist, if tolerated

**Authority required (STREAMLINED)**

***1735***

Patients receiving this drug as a pharmaceutical benefit prior to 1 August 2002

**Note**

Continuing Therapy Only:

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

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 8257N *NP* | carvedilol 12.5 mg tablet, 60 | 1 | 5 | .. | 35.38 | 36.10 | [a] | APO-Carvedilol | TX |
| | | | | | | | [a] | Carvedilol generichealth | GQ |
| | | | | | | | [a] | Carvedilol Sandoz | SZ |
| | | | | | | | [a] | Chem mart Carvedilol 12.5 mg | CH |
| | | | | | | | [a] | Dicarz | AF |
| | | | | | | | [a] | Dilatrend 12.5 | RO |
| | | | | | | | [a] | GN-Carvedilol | GM |
| | | | | | | | [a] | Terry White Chemists Carvedilol 12.5 mg | TW |
| | | | | | | | [a] | Vedilol 12.5 | QA |
| | | | | | | | [a] | Volirop 12.5 | DO |
| 8258P *NP* | carvedilol 25 mg tablet, 60 | 1 | 5 | .. | 42.39 | 36.10 | [a] | APO-Carvedilol | TX |
| | | | | | | | [a] | Carvedilol generichealth | GQ |
| | | | | | | | [a] | Carvedilol Sandoz | SZ |
| | | | | | | | [a] | Chem mart Carvedilol 25 mg | CH |
| | | | | | | | [a] | Dicarz | AF |
| | | | | | | | [a] | Dilatrend 25 | RO |
| | | | | | | | [a] | GN-Carvedilol | GM |
| | | | | | | | [a] | Terry White Chemists Carvedilol 25 mg | TW |
| | | | | | | | [a] | Vedilol 25 | QA |
| | | | | | | | [a] | Volirop 25 | DO |
| 8255L *NP* | carvedilol 3.125 mg tablet, 30 | 1 | .. | .. | 11.49 | 12.62 | [a] | APO-Carvedilol | TX |
| | | | | | | | [a] | Chem mart Carvedilol 3.125 mg | CH |
| | | | | | | | [a] | Dilatrend 3.125 | RO |
| | | | | | | | [a] | GN-Carvedilol | GM |
| | | | | | | | [a] | Terry White Chemists Carvedilol 3.125 mg | TW |
| | | | | | | | [a] | Vedilol 3.125 | QA |
| | | | | | | | [a] | Volirop 3.125 | DO |
| 8256M *NP* | carvedilol 6.25 mg tablet, 60 | 1 | 5 | .. | 29.63 | 30.76 | [a] | APO-Carvedilol | TX |
| | | | | | | | [a] | Carvedilol generichealth | GQ |

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | [a] | Carvedilol Sandoz | SZ |
| | | | | | | | [a] | Chem mart Carvedilol 6.25 mg | CH |
| | | | | | | | [a] | Dicarz | AF |
| | | | | | | | [a] | Dilatrend 6.25 | RO |
| | | | | | | | [a] | GN-Carvedilol | GM |
| | | | | | | | [a] | Terry White Chemists Carvedilol 6.25 mg | TW |
| | | | | | | | [a] | Vedilol 6.25 | QA |
| | | | | | | | [a] | Volirop 6.25 | DO |
| | **LABETALOL** | | | | | | | | |
| 1566K *NP* | labetalol hydrochloride 100 mg tablet, 100 | 1 | 5 | .. | 15.49 | 16.62 | [a] | Presolol 100 | AF |
| | | | | [B]3.13 | 18.62 | 16.62 | [a] | Trandate | QA |
| 1567L *NP* | labetalol hydrochloride 200 mg tablet, 100 | 1 | 5 | .. | 21.21 | 22.34 | [a] | Presolol 200 | AF |
| | | | | [B]3.14 | 24.35 | 22.34 | [a] | Trandate | QA |

## CALCIUM CHANNEL BLOCKERS

### SELECTIVE CALCIUM CHANNEL BLOCKERS WITH MAINLY VASCULAR EFFECTS

#### *Dihydropyridine derivatives*

**AMLODIPINE**

**Note**

Pharmaceutical benefits that have the form amlodipine tablet 10 mg (as besylate) and pharmaceutical benefits that have the form amlodipine tablet 10 mg (as maleate) are equivalent for the purposes of substitution.

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 2752W *NP* | amlodipine 10 mg tablet, 30 | 1 | 5 | .. | 11.92 | 13.05 | [a] | Amlo 10 | QA |
| | | | | | | | [a] | Amlodipine-DRLA | RZ |
| | | | | | | | [a] | Amlodipine-GA | GM |
| | | | | | | | [a] | Amlodipine generichealth | GQ |
| | | | | | | | [a] | Amlodipine Pfizer | FZ |
| | | | | | | | [a] | Amlodipine Sandoz | SZ |
| | | | | | | | [a] | APO-Amlodipine | TX |
| | | | | | | | [a] | Auro-Amlodipine 10 | DO |
| | | | | | | | [a] | Chem mart Amlodipine | CH |
| | | | | | | | [a] | Nordip | AF |
| | | | | | | | [a] | Norvapine | GN |
| | | | | | | | [a] | Ozlodip | RA |
| | | | | | | | [a] | Terry White Chemists Amlodipine | TW |
| | | | | [B]5.50 | 17.42 | 13.05 | [a] | Norvasc | PF |

**AMLODIPINE**

**Note**

Pharmaceutical benefits that have the form amlodipine tablet 5 mg (as besylate) and pharmaceutical benefits that have the form amlodipine tablet 5 mg (as maleate) are equivalent for the purposes of substitution.

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 2751T *NP* | amlodipine 5 mg tablet, 30 | 1 | 5 | .. | 9.64 | 10.77 | [a] | Amlo 5 | QA |
| | | | | | | | [a] | Amlodipine-DRLA | RZ |
| | | | | | | | [a] | Amlodipine-GA | GM |
| | | | | | | | [a] | Amlodipine generichealth | GQ |
| | | | | | | | [a] | Amlodipine Pfizer | FZ |
| | | | | | | | [a] | Amlodipine Sandoz | SZ |
| | | | | | | | [a] | APO-Amlodipine | TX |
| | | | | | | | [a] | Auro-Amlodipine 5 | DO |
| | | | | | | | [a] | Chem mart Amlodipine | CH |
| | | | | | | | [a] | Nordip | AF |
| | | | | | | | [a] | Norvapine | GN |
| | | | | | | | [a] | Ozlodip | RA |
| | | | | | | | [a] | Terry White Chemists Amlodipine | TW |

# CARDIOVASCULAR SYSTEM

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|---|
| | | | | [B]3.75 | 13.39 | 10.77 | [a] | Norvasc | PF |
| | **FELODIPINE** | | | | | | | | |
| 2367N<br>*NP* | felodipine 10 mg tablet: modified release, 30 tablets | 1 | 5 | .. | 20.12 | 21.25 | [a] | Felodil XR 10 | QA |
| | | | | | | | [a] | Felodur ER 10 mg | TX |
| | | | | | | | [a] | Fendex ER | AF |
| | | | | [B]4.08 | 24.20 | 21.25 | [a] | Plendil ER | AP |
| 2361G<br>*NP* | felodipine 2.5 mg tablet: modified release, 30 tablets | 1 | 5 | .. | 11.82 | 12.95 | [a] | Felodur ER 2.5 mg | TX |
| | | | | | | | [a] | Fendex ER | AF |
| | | | | [B]4.06 | 15.88 | 12.95 | [a] | Plendil ER | AP |
| 2366M<br>*NP* | felodipine 5 mg tablet: modified release, 30 tablets | 1 | 5 | .. | 14.08 | 15.21 | [a] | Felodil XR 5 | QA |
| | | | | | | | [a] | Felodur ER 5 mg | TX |
| | | | | | | | [a] | Fendex ER | AF |
| | | | | [B]4.07 | 18.15 | 15.21 | [a] | Plendil ER | AP |
| | **LERCANIDIPINE** | | | | | | | | |
| 8534E<br>*NP* | lercanidipine hydrochloride 10 mg tablet, 28 | 1 | 5 | .. | 11.02 | 12.15 | [a] | APO-Lercanidipine | TX |
| | | | | | | | [a] | Chem mart Lercanidipine | CH |
| | | | | | | | [a] | Ledip | RA |
| | | | | | | | [a] | Lercadip | GM |
| | | | | | | | [a] | Lercan | QA |
| | | | | | | | [a] | Lercanidipine GH | GQ |
| | | | | | | | [a] | Lercanidipine Sandoz | SZ |
| | | | | | | | [a] | Terry White Chemists Lercanidipine | TW |
| | | | | | | | [a] | Zircol | AF |
| | | | | [B]2.66 | 13.68 | 12.15 | [a] | Zanidip | AB |
| 8679T<br>*NP* | lercanidipine hydrochloride 20 mg tablet, 28 | 1 | 5 | .. | 13.97 | 15.10 | [a] | APO-Lercanidipine | TX |
| | | | | | | | [a] | Chem mart Lercanidipine | CH |
| | | | | | | | [a] | Ledip | RA |
| | | | | | | | [a] | Lercadip | GM |
| | | | | | | | [a] | Lercan | QA |
| | | | | | | | [a] | Lercanidipine GH | GQ |
| | | | | | | | [a] | Lercanidipine Sandoz | SZ |
| | | | | | | | [a] | Terry White Chemists Lercanidipine | TW |
| | | | | | | | [a] | Zircol | AF |
| | | | | [B]2.65 | 16.62 | 15.10 | [a] | Zanidip | AB |
| | **NIFEDIPINE** | | | | | | | | |
| 1694E<br>*NP* | nifedipine 10 mg tablet, 60 | 1 | 5 | .. | 13.86 | 14.99 | [a] | Adefin 10 | AF |
| | | | | [B]0.95 | 14.81 | 14.99 | [a] | Adalat 10 | BN |
| 1695F<br>*NP* | nifedipine 20 mg tablet, 60 | 1 | 5 | .. | 15.53 | 16.66 | [a] | Adefin 20 | AF |
| | | | | | | | [a] | GenRx Nifedipine | GX |
| | | | | | | | [a] | Nifehexal | SZ |
| | | | | [B]1.76 | 17.29 | 16.66 | [a] | Adalat 20 | BN |
| 8610E<br>*NP* | nifedipine 20 mg tablet: modified release, 30 tablets | 1 | 5 | .. | 15.89 | 17.02 | | Adalat Oros 20mg | BN |
| 1906H<br>*NP* | nifedipine 30 mg tablet: modified release, 30 tablets | 1 | 5 | .. | 16.64 | 17.77 | [a] | Addos XR 30 | QA |
| | | | | | | | [a] | Adefin XL 30 | AF |
| | | | | | | | [a] | APO-Nifedipine XR | TX |
| | | | | [B]2.03 | 18.67 | 17.77 | [a] | Adalat Oros 30 | BN |
| 1907J<br>*NP* | nifedipine 60 mg tablet: modified release, 30 tablets | 1 | 5 | .. | 19.19 | 20.32 | [a] | Addos XR 60 | QA |
| | | | | | | | [a] | Adefin XL 60 | AF |
| | | | | | | | [a] | APO-Nifedipine XR | TX |

# CARDIOVASCULAR SYSTEM

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|---|---|---|---|---|---|---|---|---|---|
| | | | | [B]2.24 | 21.43 | 20.32 | [a] | Adalat Oros 60 | BN |

## SELECTIVE CALCIUM CHANNEL BLOCKERS WITH DIRECT CARDIAC EFFECTS

### *Phenylalkylamine derivatives*

**VERAPAMIL**

**Caution**

The myocardial depressant effects of this drug and of beta-blocking drugs are additive.

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 1254B *NP* | verapamil hydrochloride 120 mg tablet, 100 | 1 | 5 | .. | 19.07 | 20.20 | | Isoptin | AB |
| 2206D *NP* | verapamil hydrochloride 160 mg capsule: modified release, 30 capsules | 1 | 5 | .. | 12.36 | 13.49 | | Veracaps SR | QA |
| 2208F *NP* | verapamil hydrochloride 180 mg tablet: modified release, 30 tablets | 1 | 5 | .. | 13.56 | 14.69 | [a] | Cordilox 180 SR | KN |
| | | | | [B]3.50 | 17.06 | 14.69 | [a] | Isoptin 180 SR | AB |
| 2207E *NP* | verapamil hydrochloride 240 mg capsule: modified release, 30 capsules | 1 | 5 | .. | 15.96 | 17.09 | | Veracaps SR | QA |
| 1241H *NP* | verapamil hydrochloride 240 mg tablet: modified release, 30 tablets | 1 | 5 | .. | 15.88 | 17.01 | [a] | Cordilox SR | KN |
| | | | | [B]3.50 | 19.38 | 17.01 | [a] | Isoptin SR | AB |
| 1248Q *NP* | verapamil hydrochloride 40 mg tablet, 100 | 1 | 5 | .. | 11.47 | 12.60 | [a] | Anpec 40 | AF |
| | | | | [B]0.73 | 12.20 | 12.60 | [a] | Isoptin | AB |
| 1250T *NP* | verapamil hydrochloride 80 mg tablet, 100 | 1 | 5 | .. | 15.22 | 16.35 | [a] | Anpec 80 | AF |
| | | | | [B]0.71 | 15.93 | 16.35 | [a] | Isoptin | AB |

### *Benzothiazepine derivatives*

**DILTIAZEM**

**Caution**

The myocardial depressant effects of this drug and of beta-blocking drugs are additive.

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 1312C *NP* | diltiazem hydrochloride 180 mg capsule: modified release, 30 capsules | 1 | 5 | .. | 15.28 | 16.41 | [a] | Cardizem CD | SW |
| | | | | | | | [a] | Chem mart Diltiazem CD | CH |
| | | | | | | | [a] | Diltiazem Sandoz CD | SZ |
| | | | | | | | [a] | GenRx Diltiazem CD | GX |
| | | | | | | | [a] | Terry White Chemists Diltiazem CD | TW |
| | | | | | | | [a] | Vasocardol CD | AV |
| 1313D *NP* | diltiazem hydrochloride 240 mg capsule: modified release, 30 capsules | 1 | 5 | .. | 18.31 | 19.44 | [a] | Cardizem CD | SW |
| | | | | | | | [a] | Chem mart Diltiazem CD | CH |
| | | | | | | | [a] | Diltiazem Sandoz CD | SZ |
| | | | | | | | [a] | GenRx Diltiazem CD | GX |
| | | | | | | | [a] | Terry White Chemists Diltiazem CD | TW |
| | | | | | | | [a] | Vasocardol CD | AV |
| 8480H *NP* | diltiazem hydrochloride 360 mg capsule: modified release, 30 capsules | 1 | 5 | .. | 21.95 | 23.08 | [a] | Cardizem CD | SW |
| | | | | | | | [a] | Diltiazem Sandoz CD | SZ |
| | | | | | | | [a] | Vasocardol CD | AV |
| 1335G *NP* | diltiazem hydrochloride 60 mg tablet, 90 | 1 | 5 | .. | 14.43 | 15.56 | [a] | Cardizem | SW |
| | | | | | | | [a] | Chem mart Diltiazem | CH |
| | | | | | | | [a] | Coras | AF |
| | | | | | | | [a] | Diltiazem Sandoz | SZ |
| | | | | | | | [a] | Dilzem 60 mg | GM |
| | | | | | | | [a] | GenRx Diltiazem | GX |
| | | | | | | | [a] | Terry White Chemists Diltiazem | TW |
| | | | | | | | [a] | Vasocardol | AV |

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|---|---|---|---|---|---|---|---|---|---|
| | AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM | | | | | | | | |
| | **ACE INHIBITORS, PLAIN** | | | | | | | | |
| | ***ACE inhibitors, plain*** | | | | | | | | |
| | **CAPTOPRIL** | | | | | | | | |
| | **Caution** | | | | | | | | |
| | Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero. | | | | | | | | |
| 1147J | captopril 12.5 mg tablet, 90 | 1 | 5 | .. | 12.84 | 13.97 | a | Captopril Sandoz | SZ |
| *NP* | | | | | | | a | GenRx Captopril | GX |
| | | | | | | | a | Zedace | AF |
| 1148K | captopril 25 mg tablet, 90 | 1 | 5 | .. | 15.61 | 16.74 | a | Captopril Sandoz | SZ |
| *NP* | | | | | | | a | GenRx Captopril | GX |
| | | | | | | | a | Zedace | AF |
| | | | | B5.20 | 20.81 | 16.74 | a | Capoten | QA |
| 1149L | captopril 50 mg tablet, 90 | 1 | 5 | .. | 24.35 | 25.48 | a | Captopril Sandoz | SZ |
| *NP* | | | | | | | a | GenRx Captopril | GX |
| | | | | | | | a | Zedace | AF |
| | | | | B4.04 | 28.39 | 25.48 | a | Capoten | QA |
| | **CAPTOPRIL** | | | | | | | | |
| | **Restricted benefit** | | | | | | | | |
| | For patients unable to take a solid dose form of an ACE inhibitor | | | | | | | | |
| | **Caution** | | | | | | | | |
| | Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero. | | | | | | | | |
| 8760C | captopril 5 mg/mL oral liquid, 95 mL | ‡1 | 5 | .. | 112.03 | 36.10 | | Capoten | QA |
| *NP* | | | | | | | | | |
| | **ENALAPRIL** | | | | | | | | |
| | **Caution** | | | | | | | | |
| | Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero. | | | | | | | | |
| 1368B | enalapril maleate 10 mg tablet, 30 | 1 | 5 | .. | 12.56 | 13.69 | a | Acetec | AL |
| *NP* | | | | | | | a | Auspril | QA |
| | | | | | | | a | Chem mart Enalapril | CH |
| | | | | | | | a | Enalapril-GA | GM |
| | | | | | | | a | Enalapril generichealth | GQ |
| | | | | | | | a | Enalapril Sandoz | SZ |
| | | | | | | | a | GenRx Enalapril | GX |
| | | | | | | | a | Terry White Chemists Enalapril | TW |
| | | | | B3.78 | 16.34 | 13.69 | a | Renitec | MK |
| 1369C | enalapril maleate 20 mg tablet, 30 | 1 | 5 | .. | 14.20 | 15.33 | a | Acetec | AL |
| *NP* | | | | | | | a | Auspril | QA |
| | | | | | | | a | Chem mart Enalapril | CH |
| | | | | | | | a | Enalapril-GA | GM |
| | | | | | | | a | Enalapril generichealth | GQ |
| | | | | | | | a | Enalapril Sandoz | SZ |
| | | | | | | | a | GenRx Enalapril | GX |
| | | | | | | | a | Terry White Chemists Enalapril | TW |
| | | | | B3.78 | 17.98 | 15.33 | a | Renitec 20 | MK |
| 1370D | enalapril maleate 5 mg tablet, 30 | 1 | 5 | .. | 10.24 | 11.37 | a | Acetec | AL |
| *NP* | | | | | | | a | Auspril | QA |
| | | | | | | | a | Chem mart Enalapril | CH |
| | | | | | | | a | Enalapril-GA | GM |
| | | | | | | | a | Enalapril generichealth | GQ |
| | | | | | | | a | Enalapril Sandoz | SZ |
| | | | | | | | a | GenRx Enalapril | GX |

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|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | [a] | Terry White Chemists Enalapril | TW |
| | | | | [B]3.77 | 14.01 | 11.37 | [a] | Renitec M | MK |
| | **FOSINOPRIL** | | | | | | | | |
| | **Caution** | | | | | | | | |
| | Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero. | | | | | | | | |
| 1182F *NP* | fosinopril sodium 10 mg tablet, 30 | 1 | 5 | .. | 14.47 | 15.60 | [a] | Fosipril 10 | QA |
| | | | | | | | [a] | GenRx Fosinopril | GX |
| | | | | | | | [a] | Monace 10 | AF |
| | | | | | | | [a] | Monopril | BQ |
| 1183G *NP* | fosinopril sodium 20 mg tablet, 30 | 1 | 5 | .. | 18.36 | 19.49 | [a] | Fosipril 20 | QA |
| | | | | | | | [a] | GenRx Fosinopril | GX |
| | | | | | | | [a] | Monace 20 | AF |
| | | | | | | | [a] | Monopril | BQ |
| | **LISINOPRIL** | | | | | | | | |
| | **Caution** | | | | | | | | |
| | Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero. | | | | | | | | |
| 2457H *NP* | lisinopril 10 mg tablet, 30 | 1 | 5 | .. | 13.09 | 14.22 | [a] | APO-Lisinopril | TX |
| | | | | | | | [a] | Chem mart Lisinopril | CH |
| | | | | | | | [a] | Fibsol 10 | QA |
| | | | | | | | [a] | Lisinopril-DRLA | RZ |
| | | | | | | | [a] | Lisinopril-GA | GN |
| | | | | | | | [a] | Lisinopril generichealth | GQ |
| | | | | | | | [a] | Lisinopril Sandoz | SZ |
| | | | | | | | [a] | Terry White Chemists Lisinopril | TW |
| | | | | | | | [a] | Zinopril 10 | AL |
| | | | | [B]2.96 | 16.05 | 14.22 | [a] | Zestril | AP |
| | | | | [B]2.97 | 16.06 | 14.22 | [a] | Prinivil 10 | MK |
| 2458J *NP* | lisinopril 20 mg tablet, 30 | 1 | 5 | .. | 14.78 | 15.91 | [a] | APO-Lisinopril | TX |
| | | | | | | | [a] | Chem mart Lisinopril | CH |
| | | | | | | | [a] | Fibsol 20 | QA |
| | | | | | | | [a] | Lisinopril-DRLA | RZ |
| | | | | | | | [a] | Lisinopril-GA | GN |
| | | | | | | | [a] | Lisinopril generichealth | GQ |
| | | | | | | | [a] | Lisinopril Sandoz | SZ |
| | | | | | | | [a] | Terry White Chemists Lisinopril | TW |
| | | | | | | | [a] | Zinopril 20 | AL |
| | | | | [B]2.96 | 17.74 | 15.91 | [a] | Prinivil 20 | MK |
| | | | | | | | [a] | Zestril | AP |
| 2456G *NP* | lisinopril 5 mg tablet, 30 | 1 | 5 | .. | 10.94 | 12.07 | [a] | APO-Lisinopril | TX |
| | | | | | | | [a] | Chem mart Lisinopril | CH |
| | | | | | | | [a] | Fibsol 5 | QA |
| | | | | | | | [a] | Lisinopril-DRLA | RZ |
| | | | | | | | [a] | Lisinopril-GA | GN |
| | | | | | | | [a] | Lisinopril generichealth | GQ |
| | | | | | | | [a] | Lisinopril Sandoz | SZ |
| | | | | | | | [a] | Terry White Chemists Lisinopril | TW |
| | | | | | | | [a] | Zinopril 5 | AL |
| | | | | [B]2.96 | 13.90 | 12.07 | [a] | Zestril | AP |
| | **PERINDOPRIL** | | | | | | | | |
| | **Caution** | | | | | | | | |
| | Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero. | | | | | | | | |
| | **Note** | | | | | | | | |
| | Pharmaceutical benefits that have the form perindopril erbumine tablet 8 mg and pharmaceutical benefits that have the form perindopril arginine | | | | | | | | |

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|---|---|---|---|---|---|---|---|---|---|
| | tablet 10 mg are equivalent for the purposes of substitution. | | | | | | | | |
| 9008D<br>*NP* | perindopril arginine 10 mg tablet, 30 | 1 | 5 | .. | 18.60 | 19.73 | [a] | Coversyl 10mg | SE |
| 8704D<br>*NP* | perindopril erbumine 8 mg tablet, 30 | 1 | 5 | .. | 18.60 | 19.73 | [a] | APO-Perindopril | TX |
| | | | | | | | [a] | Chem mart Perindopril | CH |
| | | | | | | | [a] | GenRx Perindopril | GX |
| | | | | | | | [a] | Idaprex 8 | SZ |
| | | | | | | | [a] | Indopril 8 | QA |
| | | | | | | | [a] | Indosyl Mono 8 | FM |
| | | | | | | | [a] | Ozapace | RA |
| | | | | | | | [a] | Perindo | AF |
| | | | | | | | [a] | Perindopril-DP | GN |
| | | | | | | | [a] | Perindopril-GA | GM |
| | | | | | | | [a] | Perindopril generichealth | GQ |
| | | | | | | | [a] | Terry White Chemists Perindopril | TW |
| | **PERINDOPRIL**<br>**Caution**<br>Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.<br>**Note**<br>Pharmaceutical benefits that have the form perindopril erbumine tablet 2 mg and pharmaceutical benefits that have the form perindopril arginine tablet 2.5 mg are equivalent for the purposes of substitution. | | | | | | | | |
| 9006B<br>*NP* | perindopril arginine 2.5 mg tablet, 30 | 1 | 5 | .. | 10.80 | 11.93 | [a] | Coversyl 2.5mg | SE |
| 3050M<br>*NP* | perindopril erbumine 2 mg tablet, 30 | 1 | 5 | .. | 10.80 | 11.93 | [a] | APO-Perindopril | TX |
| | | | | | | | [a] | Chem mart Perindopril | CH |
| | | | | | | | [a] | GenRx Perindopril | GX |
| | | | | | | | [a] | Idaprex 2 | SZ |
| | | | | | | | [a] | Indopril 2 | QA |
| | | | | | | | [a] | Indosyl Mono 2 | FM |
| | | | | | | | [a] | Ozapace | RA |
| | | | | | | | [a] | Perindo | AF |
| | | | | | | | [a] | Perindopril-DP | GN |
| | | | | | | | [a] | Perindopril-GA | GM |
| | | | | | | | [a] | Perindopril generichealth | GQ |
| | | | | | | | [a] | Terry White Chemists Perindopril | TW |
| | **PERINDOPRIL**<br>**Caution**<br>Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.<br>**Note**<br>Pharmaceutical benefits that have the form perindopril erbumine tablet 4 mg and pharmaceutical benefits that have the form perindopril arginine tablet 5 mg are equivalent for the purposes of substitution. | | | | | | | | |
| 9007C<br>*NP* | perindopril arginine 5 mg tablet, 30 | 1 | 5 | .. | 14.45 | 15.58 | [a] | Coversyl 5mg | SE |
| 3051N<br>*NP* | perindopril erbumine 4 mg tablet, 30 | 1 | 5 | .. | 14.45 | 15.58 | [a] | APO-Perindopril | TX |
| | | | | | | | [a] | Chem mart Perindopril | CH |
| | | | | | | | [a] | GenRx Perindopril | GX |
| | | | | | | | [a] | Idaprex 4 | SZ |
| | | | | | | | [a] | Indopril 4 | QA |
| | | | | | | | [a] | Indosyl Mono 4 | FM |
| | | | | | | | [a] | Ozapace | RA |
| | | | | | | | [a] | Perindo | AF |
| | | | | | | | [a] | Perindopril-DP | GN |
| | | | | | | | [a] | Perindopril-GA | GM |
| | | | | | | | [a] | Perindopril generichealth | GQ |

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|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | [a] | Terry White Chemists Perindopril | TW |
| | **QUINAPRIL**<br>**Caution**<br>Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero. | | | | | | | | |
| 1969P<br>*NP* | quinapril 10 mg tablet, 30 | 1 | 5 | .. | 13.09 | 14.22 | [a] | Acquin 10 | QA |
| | | | | | | | [a] | Acquin Aspen 10 | AS |
| | | | | | | | [a] | APO-Quinapril | TX |
| | | | | | | | [a] | Aquinafil | GN |
| | | | | | | | [a] | Qpril 10 | AF |
| | | | | | | | [a] | Quinapril generichealth | GQ |
| | | | | | | | [a] | Quinapril Pfizer | FZ |
| | | | | [B]1.64 | 14.73 | 14.22 | [a] | Accupril | PF |
| 1970Q<br>*NP* | quinapril 20 mg tablet, 30 | 1 | 5 | .. | 14.63 | 15.76 | [a] | Acquin 20 | QA |
| | | | | | | | [a] | Acquin Aspen 20 | AS |
| | | | | | | | [a] | APO-Quinapril | TX |
| | | | | | | | [a] | Aquinafil | GN |
| | | | | | | | [a] | Qpril 20 | AF |
| | | | | | | | [a] | Quinapril-GA | GM |
| | | | | | | | [a] | Quinapril generichealth | GQ |
| | | | | | | | [a] | Quinapril Pfizer | FZ |
| | | | | | | | [a] | Quinapril Sandoz | SZ |
| | | | | [B]1.64 | 16.27 | 15.76 | [a] | Accupril | PF |
| 1968N<br>*NP* | quinapril 5 mg tablet, 30 | 1 | 5 | .. | 11.16 | 12.29 | [a] | Acquin 5 | QA |
| | | | | | | | [a] | Acquin Aspen 5 | AS |
| | | | | | | | [a] | APO-Quinapril | TX |
| | | | | | | | [a] | Aquinafil | GN |
| | | | | | | | [a] | Qpril 5 | AF |
| | | | | | | | [a] | Quinapril generichealth | GQ |
| | | | | | | | [a] | Quinapril Pfizer | FZ |
| | | | | | | | [a] | Quinapril Sandoz | SZ |
| | | | | [B]1.62 | 12.78 | 12.29 | [a] | Accupril | PF |
| | **RAMIPRIL**<br>**Caution**<br>Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.<br>**Note**<br>Pharmaceutical benefits that have the form ramipril tablet 1.25 mg and pharmaceutical benefits that have the form ramipril capsule 1.25 mg are equivalent for the purposes of substitution. | | | | | | | | |
| 9120B<br>*NP* | ramipril 1.25 mg capsule, 30 | 1 | 5 | .. | 9.08 | 10.21 | [a] | APO-Ramipril | TX |
| | | | | | | | [a] | Chem mart Ramipril | CH |
| | | | | | | | [a] | Ramipril-GA | GM |
| | | | | | | | [a] | Ramipril generichealth | GQ |
| | | | | | | | [a] | Terry White Chemists Ramipril | TW |
| | | | | | | | [a] | Tryzan Caps 1.25 | AF |
| 1944H<br>*NP* | ramipril 1.25 mg tablet, 30 | 1 | 5 | .. | 9.08 | 10.21 | [a] | APO-Ramipril | TX |
| | | | | | | | [a] | Chem mart Ramipril | CH |
| | | | | | | | [a] | Prilace 1.25 | QA |
| | | | | | | | [a] | Ramace 1.25 mg | AV |
| | | | | | | | [a] | Ramipril Sandoz | SZ |
| | | | | | | | [a] | Ramipril Winthrop | WA |
| | | | | | | | [a] | Terry White Chemists Ramipril | TW |
| | | | | | | | [a] | Tritace 1.25 mg | SW |
| | | | | | | | [a] | Tryzan Tabs 1.25 | AF |
| | | | | | | | [a] | Vascalace 1.25 | DO |

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|---|
| | **RAMIPRIL**<br>**Caution**<br>Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.<br>**Note**<br>Pharmaceutical benefits that have the form ramipril tablet 10 mg and pharmaceutical benefits that have the form ramipril capsule 10 mg are equivalent for the purposes of substitution. | | | | | | | | |
| 8470T<br>*NP* | ramipril 10 mg capsule, 30 | 1 | 5 | .. | 14.57 | 15.70 | [a] | APO-Ramipril | TX |
| | | | | | | | [a] | Chem mart Ramipril | CH |
| | | | | | | | [a] | GenRx Ramipril | GX |
| | | | | | | | [a] | Pharmacor Ramipril 10 | CR |
| | | | | | | | [a] | Prilace 10 | QA |
| | | | | | | | [a] | Ramace 10 mg | AV |
| | | | | | | | [a] | Ramipril-GA | GM |
| | | | | | | | [a] | Ramipril generichealth | GQ |
| | | | | | | | [a] | Ramipril Sandoz | SZ |
| | | | | | | | [a] | Ramipril Winthrop | WA |
| | | | | | | | [a] | Terry White Chemists Ramipril | TW |
| | | | | | | | [a] | Tritace 10 mg | SW |
| | | | | | | | [a] | Tryzan Caps 10 | AF |
| 1316G<br>*NP* | ramipril 10 mg tablet, 30 | 1 | 5 | .. | 14.57 | 15.70 | [a] | APO-Ramipril | TX |
| | | | | | | | [a] | Chem mart Ramipril | CH |
| | | | | | | | [a] | Ramipril Sandoz | SZ |
| | | | | | | | [a] | Terry White Chemists Ramipril | TW |
| | | | | | | | [a] | Tritace | SW |
| | | | | | | | [a] | Tryzan Tabs 10 | AF |
| | | | | | | | [a] | Vascalace 10 | DO |
| | **RAMIPRIL**<br>**Caution**<br>Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.<br>**Note**<br>Pharmaceutical benefits that have the form ramipril tablet 2.5 mg and pharmaceutical benefits that have the form ramipril capsule 2.5 mg are equivalent for the purposes of substitution. | | | | | | | | |
| 9121C<br>*NP* | ramipril 2.5 mg capsule, 30 | 1 | 5 | .. | 10.22 | 11.35 | [a] | APO-Ramipril | TX |
| | | | | | | | [a] | Chem mart Ramipril | CH |
| | | | | | | | [a] | Ramipril-GA | GM |
| | | | | | | | [a] | Ramipril generichealth | GQ |
| | | | | | | | [a] | Terry White Chemists Ramipril | TW |
| | | | | | | | [a] | Tryzan Caps 2.5 | AF |
| 1945J<br>*NP* | ramipril 2.5 mg tablet, 30 | 1 | 5 | .. | 10.22 | 11.35 | [a] | APO-Ramipril | TX |
| | | | | | | | [a] | Chem mart Ramipril | CH |
| | | | | | | | [a] | Prilace 2.5 | QA |
| | | | | | | | [a] | Ramace 2.5 mg | AV |
| | | | | | | | [a] | Ramipril Sandoz | SZ |
| | | | | | | | [a] | Ramipril Winthrop | WA |
| | | | | | | | [a] | Terry White Chemists Ramipril | TW |
| | | | | | | | [a] | Tritace 2.5 mg | SW |
| | | | | | | | [a] | Tryzan Tabs 2.5 | AF |
| | | | | | | | [a] | Vascalace 2.5 | DO |
| | **RAMIPRIL**<br>**Caution**<br>Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero. | | | | | | | | |
| 8668F<br>*NP* | ramipril 2.5 mg tablet [7 tablets] (&)<br>ramipril 5 mg tablet [21 tablets] (&) | ‡1 | .. | .. | 14.00 | 15.13 | | Tritace Titration Pack | SW |

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|---|---|---|---|---|---|---|---|---|---|
| | ramipril 10 mg capsule [10 capsules], 1 pack | | | | | | | | |
| | **RAMIPRIL** | | | | | | | | |
| | **Caution** | | | | | | | | |
| | Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero. | | | | | | | | |
| | **Note** | | | | | | | | |
| | Pharmaceutical benefits that have the form ramipril tablet 5 mg and pharmaceutical benefits that have the form ramipril capsule 5 mg are equivalent for the purposes of substitution. | | | | | | | | |
| 9122D *NP* | ramipril 5 mg capsule, 30 | 1 | 5 | .. | 11.13 | 12.26 | [a] | APO-Ramipril | TX |
| | | | | | | | [a] | Chem mart Ramipril | CH |
| | | | | | | | [a] | Pharmacor Ramipril 5 | CR |
| | | | | | | | [a] | Ramipril-GA | GM |
| | | | | | | | [a] | Ramipril generichealth | GQ |
| | | | | | | | [a] | Terry White Chemists Ramipril | TW |
| | | | | | | | [a] | Tryzan Caps 5 | AF |
| 1946K *NP* | ramipril 5 mg tablet, 30 | 1 | 5 | .. | 11.13 | 12.26 | [a] | APO-Ramipril | TX |
| | | | | | | | [a] | Chem mart Ramipril | CH |
| | | | | | | | [a] | Prilace 5 | QA |
| | | | | | | | [a] | Ramace 5 mg | AV |
| | | | | | | | [a] | Ramipril Sandoz | SZ |
| | | | | | | | [a] | Ramipril Winthrop | WA |
| | | | | | | | [a] | Terry White Chemists Ramipril | TW |
| | | | | | | | [a] | Tritace 5 mg | SW |
| | | | | | | | [a] | Tryzan Tabs 5 | AF |
| | | | | | | | [a] | Vascalace 5 | DO |
| | **TRANDOLAPRIL** | | | | | | | | |
| | **Caution** | | | | | | | | |
| | Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero. | | | | | | | | |
| 2792Y *NP* | trandolapril 1 mg capsule, 28 | 1 | 5 | .. | 11.77 | 12.90 | [a] | APO-Trandolapril | TX |
| | | | | | | | [a] | Dolapril 1 | QA |
| | | | | | | | [a] | Tranalpha | AF |
| | | | | | | | [a] | Trandolapril-DP | GN |
| | | | | | | | [a] | Trandolapril generichealth | GQ |
| | | | | [B]1.28 | 13.05 | 12.90 | [a] | Gopten | AB |
| 2793B *NP* | trandolapril 2 mg capsule, 28 | 1 | 5 | .. | 12.84 | 13.97 | [a] | APO-Trandolapril | TX |
| | | | | | | | [a] | Dolapril 2 | QA |
| | | | | | | | [a] | Tranalpha | AF |
| | | | | | | | [a] | Trandolapril-DP | GN |
| | | | | | | | [a] | Trandolapril generichealth | GQ |
| | | | | [B]2.69 | 15.53 | 13.97 | [a] | Gopten | AB |
| 8758Y *NP* | trandolapril 4 mg capsule, 28 | 1 | 5 | .. | 18.28 | 19.41 | [a] | APO-Trandolapril | TX |
| | | | | | | | [a] | Dolapril 4 | QA |
| | | | | | | | [a] | Tranalpha | AF |
| | | | | | | | [a] | Trandolapril-DP | GN |
| | | | | | | | [a] | Trandolapril generichealth | GQ |
| | | | | [B]2.69 | 20.97 | 19.41 | [a] | Gopten | AB |
| 2791X *NP* | trandolapril 500 microgram capsule, 28 | 1 | 5 | .. | 8.57 | 9.70 | [a] | APO-Trandolapril | TX |
| | | | | | | | [a] | Dolapril 0.5 | QA |
| | | | | | | | [a] | Tranalpha | AF |
| | | | | | | | [a] | Trandolapril-DP | GN |
| | | | | | | | [a] | Trandolapril generichealth | GQ |

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|---|---|---|---|---|---|---|---|---|---|
| | | | | [B]1.23 | 9.80 | 9.70 | [a] | Gopten | AB |

## ACE INHIBITORS, COMBINATIONS
### *ACE inhibitors and diuretics*

**ENALAPRIL + HYDROCHLOROTHIAZIDE**

**Restricted benefit**

Hypertension in a patient who is not adequately controlled with either of the drugs in the combination

**Caution**

Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 8477E *NP* | enalapril maleate 20 mg + hydrochlorothiazide 6 mg tablet, 30 | 1 | 5 | .. | 27.81 | 28.94 | [a] | Enalapril/HCT Sandoz | SZ |
| | | | | | | | [a] | Renitec Plus 20/6 | MK |

**FOSINOPRIL + HYDROCHLOROTHIAZIDE**

**Restricted benefit**

Hypertension in a patient who is not adequately controlled with either of the drugs in the combination

**Caution**

Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 8400D *NP* | fosinopril sodium 10 mg + hydrochlorothiazide 12.5 mg tablet, 30 | 1 | 5 | .. | 21.53 | 22.66 | [a] | APO-Fosinopril HCTZ 10/12.5 | TX |
| | | | | | | | [a] | Fosinopril/HCTZ-GA 10/12.5 | GM |
| | | | | | | | [a] | Hyforil | RA |
| | | | | | | | [a] | Monoplus 10/12.5 | BQ |
| 8401E *NP* | fosinopril sodium 20 mg + hydrochlorothiazide 12.5 mg tablet, 30 | 1 | 5 | .. | 28.51 | 29.64 | [a] | APO-Fosinopril HCTZ 20/12.5 | TX |
| | | | | | | | [a] | Fosetic 20/12.5 | ZP |
| | | | | | | | [a] | Fosinopril/HCTZ-GA 20/12.5 | GM |
| | | | | | | | [a] | Hyforil | RA |
| | | | | | | | [a] | Monoplus 20/12.5 | BQ |

**PERINDOPRIL + INDAPAMIDE**

**Caution**

Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 2190G *NP* | perindopril arginine 2.5 mg + indapamide hemihydrate 0.625 mg tablet, 30 | 1 | 5 | .. | 15.21 | 16.34 | | Coversyl Plus LD 2.5mg/0.625mg | SE |

**PERINDOPRIL + INDAPAMIDE**

**Restricted benefit**

Hypertension in a patient who is not adequately controlled with either of the drugs in the combination

**Caution**

Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

**Note**

Pharmaceutical benefits that have the form perindopril with indapamide hemihydrate tablet (containing 4 mg perindopril erbumine-1.25 mg indapamide hemihydrate) and pharmaceutical benefits that have the form perindopril with indapamide hemihydrate tablet (containing 5 mg perindopril arginine-1.25 mg indapamide hemihydrate) are equivalent for the purposes of substitution.

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 2845R *NP* | perindopril arginine 5 mg + indapamide hemihydrate 1.25 mg tablet, 30 | 1 | 5 | .. | 25.90 | 27.03 | [a] | Coversyl Plus 5mg/1.25mg | SE |
| 8449Q *NP* | perindopril erbumine 4 mg + indapamide hemihydrate 1.25 mg tablet, 30 | 1 | 5 | .. | 25.90 | 27.03 | [a] | Chem mart Perindopril/ Indapamide 4/1.25 | CH |
| | | | | | | | [a] | GenRx Perindopril/ Indapamide 4/1.25 | GX |
| | | | | | | | [a] | Idaprex Combi 4/1.25 | SZ |
| | | | | | | | [a] | Indosyl Combi 4/1.25 | QA |
| | | | | | | | [a] | Perindo Combi 4/1.25 | AF |
| | | | | | | | [a] | Perindopril/ Indapamide GH 4/1.25 | GQ |
| | | | | | | | [a] | Terry White Chemists Perindopril/ Indapamide 4/1.25 | TW |

**QUINAPRIL + HYDROCHLOROTHIAZIDE**

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|---|
| | **Restricted benefit**<br>Hypertension in a patient who is not adequately controlled with either of the drugs in the combination | | | | | | | | |
| | **Caution**<br>Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero. | | | | | | | | |
| 8589C<br>*NP* | quinapril 10 mg + hydrochlorothiazide 12.5 mg tablet, 30 | 1 | 5 | .. | 15.32 | 16.45 | | Accuretic 10/12.5mg | PF |
| 8590D<br>*NP* | quinapril 20 mg + hydrochlorothiazide 12.5 mg tablet, 30 | 1 | 5 | .. | 16.85 | 17.98 | | Accuretic 20/12.5mg | PF |

## *ACE inhibitors and calcium channel blockers*

**AMLODIPINE + PERINDOPRIL**

**Restricted benefit**
Hypertension in a patient who is not adequately controlled with either of the drugs in the combination

**Restricted benefit**
Stable coronary heart disease in a patient who is stabilised on treatment with perindopril and amlodipine at the same doses

**Caution**
Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

**Note**
Treatment should not be initiated with this combination.

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 9349C<br>*NP* | amlodipine 10 mg + perindopril arginine 10 mg tablet, 30 | 1 | 5 | .. | 40.47 | 36.10 | [a] | Coveram 10/10 | SE |
| | | | | | | | [a] | Reaptan 10/10 | RX |
| 9347Y<br>*NP* | amlodipine 10 mg + perindopril arginine 5 mg tablet, 30 | 1 | 5 | .. | 34.66 | 35.79 | [a] | Coveram 5/10 | SE |
| | | | | | | | [a] | Reaptan 5/10 | RX |
| 9348B<br>*NP* | amlodipine 5 mg + perindopril arginine 10 mg tablet, 30 | 1 | 5 | .. | 33.15 | 34.28 | [a] | Coveram 10/5 | SE |
| | | | | | | | [a] | Reaptan 10/5 | RX |
| 9346X<br>*NP* | amlodipine 5 mg + perindopril arginine 5 mg tablet, 30 | 1 | 5 | .. | 27.32 | 28.45 | [a] | Coveram 5/5 | SE |
| | | | | | | | [a] | Reaptan 5/5 | RX |

**LERCANIDIPINE + ENALAPRIL**

**Restricted benefit**
Hypertension in a patient who is not adequately controlled with either of the drugs in the combination

**Caution**
Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 9144G<br>*NP* | lercanidipine hydrochloride 10 mg + enalapril maleate 10 mg tablet, 28 | 1 | 5 | .. | 16.55 | 17.68 | Zan-Extra 10/10 | AB |
| 9145H<br>*NP* | lercanidipine hydrochloride 10 mg + enalapril maleate 20 mg tablet, 28 | 1 | 5 | .. | 18.08 | 19.21 | Zan-Extra 10/20 | AB |

**RAMIPRIL + FELODIPINE**

**Restricted benefit**
Hypertension in a patient who is not adequately controlled with either of the drugs in the combination

**Caution**
Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 2626F<br>*NP* | ramipril 2.5 mg + felodipine 2.5 mg tablet: modified release, 30 tablets | 1 | 5 | .. | 15.39 | 16.52 | Triasyn 2.5/2.5 | SW |
| 2629J<br>*NP* | ramipril 5 mg + felodipine 5 mg tablet: modified release, 30 tablets | 1 | 5 | .. | 18.59 | 19.72 | Triasyn 5.0/5.0 | SW |

**TRANDOLAPRIL + VERAPAMIL**

**Restricted benefit**
Hypertension in a patient who is not adequately controlled with either of the drugs in the combination

**Caution**
Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

**Caution**
The myocardial depressant effects of verapamil hydrochloride and of beta-blocking drugs are additive.

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 9387C<br>*NP* | trandolapril 2 mg + verapamil hydrochloride 180 mg tablet: modified release, 28 tablets | 1 | 5 | .. | 19.31 | 20.44 | Tarka 2/180 | AB |
| 2857J | trandolapril 4 mg + verapamil | 1 | 5 | .. | 26.90 | 28.03 | Tarka 4/240 | AB |

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|---|---|---|---|---|---|---|---|---|---|
| *NP* | hydrochloride 240 mg tablet: modified release, 28 tablets | | | | | | | | |

## ANGIOTENSIN II ANTAGONISTS, PLAIN

### *Angiotensin II antagonists, plain*

**CANDESARTAN**

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 8297Q *NP* | candesartan cilexetil 16 mg tablet, 30 | 1 | 5 | .. | 25.52 | 26.65 | [a] | Adesan | AF |
| | | | | | | | [a] | APO-Candesartan | TX |
| | | | | | | | [a] | Atacand | AP |
| | | | | | | | [a] | Candesartan Aspen 16 | QA |
| | | | | | | | [a] | Candesartan-GA | GM |
| | | | | | | | [a] | Candesartan GH | GQ |
| | | | | | | | [a] | Candesartan Sandoz | SZ |
| | | | | | | | [a] | STADA Candesartan | TD |
| 8889W *NP* | candesartan cilexetil 32 mg tablet, 30 | 1 | 5 | .. | 29.47 | 30.60 | [a] | Adesan | AF |
| | | | | | | | [a] | APO-Candesartan | TX |
| | | | | | | | [a] | Atacand | AP |
| | | | | | | | [a] | Candesartan Aspen 32 | QA |
| | | | | | | | [a] | Candesartan-GA | GM |
| | | | | | | | [a] | Candesartan GH | GQ |
| | | | | | | | [a] | Candesartan Sandoz | SZ |
| | | | | | | | [a] | STADA Candesartan | TD |
| 8295N *NP* | candesartan cilexetil 4 mg tablet, 30 | 1 | 5 | .. | 8.75 | 9.88 | [a] | Adesan | AF |
| | | | | | | | [a] | APO-Candesartan | TX |
| | | | | | | | [a] | Atacand | AP |
| | | | | | | | [a] | Candesartan Aspen 4 | QA |
| | | | | | | | [a] | Candesartan-GA | GM |
| | | | | | | | [a] | Candesartan GH | GQ |
| | | | | | | | [a] | Candesartan Sandoz | SZ |
| | | | | | | | [a] | STADA Candesartan | TD |
| 8296P *NP* | candesartan cilexetil 8 mg tablet, 30 | 1 | 5 | .. | 12.94 | 14.07 | [a] | Adesan | AF |
| | | | | | | | [a] | APO-Candesartan | TX |
| | | | | | | | [a] | Atacand | AP |
| | | | | | | | [a] | Candesartan Aspen 8 | QA |
| | | | | | | | [a] | Candesartan-GA | GM |
| | | | | | | | [a] | Candesartan GH | GQ |
| | | | | | | | [a] | Candesartan Sandoz | SZ |
| | | | | | | | [a] | STADA Candesartan | TD |

**EPROSARTAN**

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 8397Y *NP* | eprosartan 400 mg tablet, 28 | 2 | 5 | [T]2.96 | *23.81 | 21.98 | | Teveten | AB |
| 8447N *NP* | eprosartan 600 mg tablet, 28 | 1 | 5 | [T]1.69 | 26.13 | 25.57 | | Teveten | AB |

**EPROSARTAN**

**Authority required**
Adverse effects occurring with all of the base-priced drugs

**Authority required**
Drug interactions occurring with all of the base-priced drugs

**Authority required**
Drug interactions expected to occur with all of the base-priced drugs

**Authority required**
Transfer to a base-priced drug would cause patient confusion resulting in problems with compliance

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 8951D *NP* | eprosartan 400 mg tablet, 28 | 2 | 5 | .. | *23.81 | 24.94 | | Teveten | AB |
| 5491B *NP* | eprosartan 600 mg tablet, 28 | 1 | 5 | .. | 26.13 | 27.26 | | Teveten | AB |

**IRBESARTAN**

# CARDIOVASCULAR SYSTEM

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|---|
| 8247C<br>*NP* | irbesartan 150 mg tablet, 30 | 1 | 5 | .. | 16.28 | 17.41 | [a] | Abisart | AF |
| | | | | | | | [a] | APO-Irbesartan | TX |
| | | | | | | | [a] | Avapro | AV |
| | | | | | | | [a] | Chem mart Irbesartan | CH |
| | | | | | | | [a] | Irbesartan-DRLA | RZ |
| | | | | | | | [a] | Irbesartan-GA | GM |
| | | | | | | | [a] | Irbesartan RBX | RA |
| | | | | | | | [a] | Irbesartan Sandoz | SZ |
| | | | | | | | [a] | Irbesartan Winthrop | WA |
| | | | | | | | [a] | Irbesat GH | GQ |
| | | | | | | | [a] | Karbesat 150 | QA |
| | | | | | | | [a] | Karvea | SW |
| | | | | | | | [a] | STADA Irbesartan | TD |
| | | | | | | | [a] | Terry White Chemists Irbesartan | TW |
| 8248D<br>*NP* | irbesartan 300 mg tablet, 30 | 1 | 5 | .. | 25.89 | 27.02 | [a] | Abisart | AF |
| | | | | | | | [a] | APO-Irbesartan | TX |
| | | | | | | | [a] | Avapro | AV |
| | | | | | | | [a] | Chem mart Irbesartan | CH |
| | | | | | | | [a] | Irbesartan-DRLA | RZ |
| | | | | | | | [a] | Irbesartan-GA | GM |
| | | | | | | | [a] | Irbesartan RBX | RA |
| | | | | | | | [a] | Irbesartan Sandoz | SZ |
| | | | | | | | [a] | Irbesartan Winthrop | WA |
| | | | | | | | [a] | Irbesat GH | GQ |
| | | | | | | | [a] | Karbesat 300 | QA |
| | | | | | | | [a] | Karvea | SW |
| | | | | | | | [a] | STADA Irbesartan | TD |
| | | | | | | | [a] | Terry White Chemists Irbesartan | TW |
| 8246B<br>*NP* | irbesartan 75 mg tablet, 30 | 1 | 5 | .. | 13.38 | 14.51 | [a] | Abisart | AF |
| | | | | | | | [a] | APO-Irbesartan | TX |
| | | | | | | | [a] | Avapro | AV |
| | | | | | | | [a] | Chem mart Irbesartan | CH |
| | | | | | | | [a] | Irbesartan-DRLA | RZ |
| | | | | | | | [a] | Irbesartan-GA | GM |
| | | | | | | | [a] | Irbesartan RBX | RA |
| | | | | | | | [a] | Irbesartan Sandoz | SZ |
| | | | | | | | [a] | Irbesartan Winthrop | WA |
| | | | | | | | [a] | Irbesat GH | GQ |
| | | | | | | | [a] | Karbesat 75 | QA |
| | | | | | | | [a] | Karvea | SW |
| | | | | | | | [a] | STADA Irbesartan | TD |
| | | | | | | | [a] | Terry White Chemists Irbesartan | TW |
| | **LOSARTAN** | | | | | | | | |
| 5452Y<br>*NP* | losartan potassium 25 mg tablet, 30 | 1 | 5 | .. | 12.92 | 14.05 | | Cozavan | AF |
| 8203R<br>*NP* | losartan potassium 50 mg tablet, 30 | 2 | 5 | .. | *24.61 | 25.74 | | Cozavan | AF |
| | **OLMESARTAN MEDOXOMIL** | | | | | | | | |
| 2147B<br>*NP* | olmesartan medoxomil 20 mg tablet, 30 | 1 | 5 | [T]2.51 | 18.33 | 16.95 | | Olmetec | MK |
| 2148C<br>*NP* | olmesartan medoxomil 40 mg tablet, 30 | 1 | 5 | [T]2.51 | 28.63 | 27.25 | | Olmetec | MK |

**OLMESARTAN MEDOXOMIL**

**Authority required**

Adverse effects occurring with all of the base-priced drugs

**Authority required**

# CARDIOVASCULAR SYSTEM

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|---|
| | Drug interactions occurring with all of the base-priced drugs | | | | | | | | |
| | **Authority required** | | | | | | | | |
| | Drug interactions expected to occur with all of the base-priced drugs | | | | | | | | |
| | **Authority required** | | | | | | | | |
| | Transfer to a base-priced drug would cause patient confusion resulting in problems with compliance | | | | | | | | |
| 5492C | olmesartan medoxomil 20 mg tablet, 30 | 1 | 5 | .. | 18.33 | 19.46 | | Olmetec | MK |
| *NP* | | | | | | | | | |
| 5493D | olmesartan medoxomil 40 mg tablet, 30 | 1 | 5 | .. | 28.63 | 29.76 | | Olmetec | MK |
| *NP* | | | | | | | | | |
| | **TELMISARTAN** | | | | | | | | |
| | **Authority required** | | | | | | | | |
| | Adverse effects occurring with all of the base-priced drugs | | | | | | | | |
| | **Authority required** | | | | | | | | |
| | Drug interactions occurring with all of the base-priced drugs | | | | | | | | |
| | **Authority required** | | | | | | | | |
| | Drug interactions expected to occur with all of the base-priced drugs | | | | | | | | |
| | **Authority required** | | | | | | | | |
| | Transfer to a base-priced drug would cause patient confusion resulting in problems with compliance | | | | | | | | |
| 5494E | telmisartan 40 mg tablet, 28 | 1 | 5 | .. | 15.65 | 16.78 | | Micardis | BY |
| *NP* | | | | | | | | | |
| 5495F | telmisartan 80 mg tablet, 28 | 1 | 5 | .. | 28.02 | 29.15 | | Micardis | BY |
| *NP* | | | | | | | | | |
| | **TELMISARTAN** | | | | | | | | |
| 8355R | telmisartan 40 mg tablet, 28 | 1 | 5 | T2.50 | 15.65 | 14.28 | | Micardis | BY |
| *NP* | | | | | | | | | |
| 8356T | telmisartan 80 mg tablet, 28 | 1 | 5 | T2.50 | 28.02 | 26.65 | | Micardis | BY |
| *NP* | | | | | | | | | |
| | **VALSARTAN** | | | | | | | | |
| 9370E | valsartan 160 mg tablet, 28 | 1 | 5 | .. | 19.98 | 21.11 | | Diovan | NV |
| *NP* | | | | | | | | | |
| 9368C | valsartan 40 mg tablet, 28 | 1 | .. | .. | 13.79 | 14.92 | | Diovan | NV |
| *NP* | | | | | | | | | |
| 9369D | valsartan 80 mg tablet, 28 | 1 | 5 | .. | 17.04 | 18.17 | | Diovan | NV |
| *NP* | | | | | | | | | |
| | **VALSARTAN** | | | | | | | | |
| | **Note** | | | | | | | | |
| | No applications for increased maximum quantities and/or repeats will be authorised for the 320 mg tablet. | | | | | | | | |
| 9371F | valsartan 320 mg tablet, 28 | 1 | 5 | .. | 23.73 | 24.86 | | Diovan | NV |
| *NP* | | | | | | | | | |

## ANGIOTENSIN II ANTAGONISTS, COMBINATIONS

### *Angiotensin II antagonists and diuretics*

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | **CANDESARTAN + HYDROCHLOROTHIAZIDE** | | | | | | | | |
| | **Restricted benefit** | | | | | | | | |
| | Hypertension in a patient who is not adequately controlled with either of the drugs in the combination | | | | | | | | |
| 8504N | candesartan cilexetil 16 mg + hydrochlorothiazide 12.5 mg tablet, 30 | 1 | 5 | .. | 27.39 | 28.52 | a | Adesan HCT 16/12.5 | AF |
| *NP* | | | | | | | a | APO-Candesartan HCTZ 16/12.5 | TX |
| | | | | | | | a | Atacand Plus 16/12.5 | AP |
| | | | | | | | a | Candesartan Combi Aspen 16/12.5 | QA |
| | | | | | | | a | Candesartan HCT GH 16/12.5 | GQ |
| | | | | | | | a | Candesartan HCTZ-GA 16/12.5 | GM |
| | | | | | | | a | STADA Candesartan HCT 16/12.5 | TD |
| 9314F | candesartan cilexetil 32 mg + hydrochlorothiazide 12.5 mg tablet, 30 | 1 | 5 | .. | 31.33 | 32.46 | a | APO-Candesartan HCTZ 32/12.5 | TX |
| *NP* | | | | | | | a | Atacand Plus 32/12.5 | AP |

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|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | [a] | Candesartan Combi Aspen 32/12.5 | QA |
| | | | | | | | [a] | Candesartan HCT GH 32/12.5 | GQ |
| | | | | | | | [a] | Candesartan HCTZ-GA 32/12.5 | GM |
| | | | | | | | [a] | STADA Candesartan HCT 32/12.5 | TD |
| 9315G *NP* | candesartan cilexetil 32 mg + hydrochlorothiazide 25 mg tablet, 30 | 1 | 5 | .. | 33.21 | 34.34 | [a] | APO-Candesartan HCTZ 32/25 | TX |
| | | | | | | | [a] | Atacand Plus 32/25 | AP |
| | | | | | | | [a] | Candesartan Combi Aspen 32/25 | QA |
| | | | | | | | [a] | Candesartan HCT GH 32/25 | GQ |
| | | | | | | | [a] | Candesartan HCTZ-GA 32/25 | GM |
| | | | | | | | [a] | STADA Candesartan HCT 32/25 | TD |
| | **EPROSARTAN + HYDROCHLOROTHIAZIDE**<br>**Restricted benefit**<br>Hypertension in a patient who is not adequately controlled with either of the drugs in the combination | | | | | | | | |
| 8624X *NP* | eprosartan 600 mg + hydrochlorothiazide 12.5 mg tablet, 28 | 1 | 5 | .. | 26.51 | 27.64 | | Teveten Plus 600/12.5 | AB |
| | **IRBESARTAN + HYDROCHLOROTHIAZIDE**<br>**Restricted benefit**<br>Hypertension in a patient who is not adequately controlled with either of the drugs in the combination | | | | | | | | |
| 8404H *NP* | irbesartan 150 mg + hydrochlorothiazide 12.5 mg tablet, 30 | 1 | 5 | .. | 18.14 | 19.27 | [a] | Abisart HCT 150/12.5 | AF |
| | | | | | | | [a] | APO-Irbesartan HCTZ | TX |
| | | | | | | | [a] | Avapro HCT 150/12.5 | AV |
| | | | | | | | [a] | Chem mart Irbesartan HCTZ | CH |
| | | | | | | | [a] | Irbesartan/HCT Sandoz | SZ |
| | | | | | | | [a] | Irbesartan/HCTZ RBX 150/12.5 | RA |
| | | | | | | | [a] | Irbesartan HCT Winthrop 150/12.5 | WA |
| | | | | | | | [a] | Irbesartan HCTZ-GA 150/12.5 | GM |
| | | | | | | | [a] | Irbesatzide GH 150/12.5 | GQ |
| | | | | | | | [a] | Karvezide 150/12.5 | SW |
| | | | | | | | [a] | KSART HCT 150/12.5 | QA |
| | | | | | | | [a] | STADA Irbesartan HCT 150/12.5 | TD |
| | | | | | | | [a] | Terry White Chemists Irbesartan HCTZ | TW |
| 8405J *NP* | irbesartan 300 mg + hydrochlorothiazide 12.5 mg tablet, 30 | 1 | 5 | .. | 27.77 | 28.90 | [a] | Abisart HCT 300/12.5 | AF |
| | | | | | | | [a] | APO-Irbesartan HCTZ | TX |
| | | | | | | | [a] | Avapro HCT 300/12.5 | AV |
| | | | | | | | [a] | Chem mart Irbesartan HCTZ | CH |
| | | | | | | | [a] | Irbesartan/HCT Sandoz | SZ |
| | | | | | | | [a] | Irbesartan/HCTZ RBX 300/12.5 | RA |
| | | | | | | | [a] | Irbesartan HCT Winthrop 300/12.5 | WA |
| | | | | | | | [a] | Irbesartan HCTZ-GA 300/12.5 | GM |
| | | | | | | | [a] | Irbesatzide GH 300/12.5 | GQ |
| | | | | | | | [a] | Karvezide 300/12.5 | SW |
| | | | | | | | [a] | KSART HCT 300/12.5 | QA |
| | | | | | | | [a] | STADA Irbesartan HCT | TD |

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|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | 300/12.5 | |
| | | | | | | | [a] | Terry White Chemists Irbesartan HCTZ | TW |
| 2136K *NP* | irbesartan 300 mg + hydrochlorothiazide 25 mg tablet, 30 | 1 | 5 | .. | 29.64 | 30.77 | [a] | Abisart HCT 300/25 | AF |
| | | | | | | | [a] | APO-Irbesartan HCTZ | TX |
| | | | | | | | [a] | Avapro HCT 300/25 | AV |
| | | | | | | | [a] | Chem mart Irbesartan HCTZ | CH |
| | | | | | | | [a] | Irbesartan/HCT Sandoz | SZ |
| | | | | | | | [a] | Irbesartan/HCTZ RBX 300/25 | RA |
| | | | | | | | [a] | Irbesartan HCT Winthrop 300/25 | WA |
| | | | | | | | [a] | Irbesartan HCTZ-GA 300/25 | GM |
| | | | | | | | [a] | Irbesatzide GH 300/25 | GQ |
| | | | | | | | [a] | Karvezide 300/25 | SW |
| | | | | | | | [a] | KSART HCT 300/25 | QA |
| | | | | | | | [a] | STADA Irbesartan HCT 300/25 | TD |
| | | | | | | | [a] | Terry White Chemists Irbesartan HCTZ | TW |
| | **OLMESARTAN MEDOXOMIL + HYDROCHLOROTHIAZIDE** | | | | | | | | |
| | **Restricted benefit** | | | | | | | | |
| | Hypertension in a patient who is not adequately controlled with either of the drugs in the combination | | | | | | | | |
| 2161R *NP* | olmesartan medoxomil 20 mg + hydrochlorothiazide 12.5 mg tablet, 30 | 1 | 5 | .. | 18.03 | 19.16 | | Olmetec Plus | MK |
| 2166B *NP* | olmesartan medoxomil 40 mg + hydrochlorothiazide 12.5 mg tablet, 30 | 1 | 5 | .. | 28.33 | 29.46 | | Olmetec Plus | MK |
| 2170F *NP* | olmesartan medoxomil 40 mg + hydrochlorothiazide 25 mg tablet, 30 | 1 | 5 | .. | 30.57 | 31.70 | | Olmetec Plus | MK |
| | **TELMISARTAN + HYDROCHLOROTHIAZIDE** | | | | | | | | |
| | **Restricted benefit** | | | | | | | | |
| | Hypertension in a patient who is not adequately controlled with either of the drugs in the combination | | | | | | | | |
| 8622T *NP* | telmisartan 40 mg + hydrochlorothiazide 12.5 mg tablet, 28 | 1 | 5 | .. | 14.89 | 16.02 | [a] | Micardis Plus 40/12.5 mg | BY |
| | | | | | | | [a] | Pritor Plus 40/12.5 mg | FI |
| 8623W *NP* | telmisartan 80 mg + hydrochlorothiazide 12.5 mg tablet, 28 | 1 | 5 | .. | 27.27 | 28.40 | [a] | Micardis Plus 80/12.5 mg | BY |
| | | | | | | | [a] | Pritor Plus 80/12.5 mg | FI |
| 9381R *NP* | telmisartan 80 mg + hydrochlorothiazide 25 mg tablet, 28 | 1 | 5 | .. | 29.01 | 30.14 | [a] | Micardis Plus 80/25 mg | BY |
| | | | | | | | [a] | Pritor Plus 80/25 mg | FI |
| | **VALSARTAN + HYDROCHLOROTHIAZIDE** | | | | | | | | |
| | **Restricted benefit** | | | | | | | | |
| | Hypertension in a patient who is not adequately controlled with either of the drugs in the combination | | | | | | | | |
| 9373H *NP* | valsartan 160 mg + hydrochlorothiazide 12.5 mg tablet, 28 | 1 | 5 | .. | 22.06 | 23.19 | | Co-Diovan 160/12.5 | NV |
| 9374J *NP* | valsartan 160 mg + hydrochlorothiazide 25 mg tablet, 28 | 1 | 5 | .. | 24.13 | 25.26 | | Co-Diovan 160/25 | NV |
| 9372G *NP* | valsartan 80 mg + hydrochlorothiazide 12.5 mg tablet, 28 | 1 | 5 | .. | 19.12 | 20.25 | | Co-Diovan 80/12.5 | NV |
| | **VALSARTAN + HYDROCHLOROTHIAZIDE** | | | | | | | | |
| | **Restricted benefit** | | | | | | | | |
| | Hypertension in a patient who is not adequately controlled with either of the drugs in the combination | | | | | | | | |
| | **Note** | | | | | | | | |
| | No applications for increased maximum quantities and/or repeats will be authorised for the tablets containing 320 mg valsartan. | | | | | | | | |
| 9481B *NP* | valsartan 320 mg + hydrochlorothiazide 12.5 mg tablet, 28 | 1 | 5 | .. | 25.81 | 26.94 | | Co-Diovan 320/12.5 | NV |
| 9482C *NP* | valsartan 320 mg + hydrochlorothiazide 25 mg tablet, 28 | 1 | 5 | .. | 27.88 | 29.01 | | Co-Diovan 320/25 | NV |

# CARDIOVASCULAR SYSTEM

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|---|---|---|---|---|---|---|---|---|---|
| | **AMLODIPINE + VALSARTAN** | | | | | | | | |
| | **Restricted benefit** | | | | | | | | |
| | Hypertension in a patient who is not adequately controlled with either of the drugs in the combination | | | | | | | | |
| 9377M *NP* | amlodipine 10 mg + valsartan 160 mg tablet, 28 | 1 | 5 | .. | 28.85 | 29.98 | | Exforge 10/160 | NV |
| 5460J *NP* | amlodipine 10 mg + valsartan 320 mg tablet, 28 | 1 | 5 | .. | 32.68 | 33.81 | | Exforge 10/320 | NV |
| 9376L *NP* | amlodipine 5 mg + valsartan 160 mg tablet, 28 | 1 | 5 | .. | 25.31 | 26.44 | | Exforge 5/160 | NV |
| 5459H *NP* | amlodipine 5 mg + valsartan 320 mg tablet, 28 | 1 | 5 | .. | 29.15 | 30.28 | | Exforge 5/320 | NV |
| 9375K *NP* | amlodipine 5 mg + valsartan 80 mg tablet, 28 | 1 | 5 | .. | 22.24 | 23.37 | [a] | Exforge 5/80 | NV |
| | | | | | | | [a] | Valsartan/Amlodipine Sandoz 80/5 | NM |
| | **OLMESARTAN MEDOXOMIL + AMLODIPINE** | | | | | | | | |
| | **Restricted benefit** | | | | | | | | |
| | Hypertension in a patient who is not adequately controlled with either of the drugs in the combination | | | | | | | | |
| 5292M *NP* | olmesartan medoxomil 20 mg + amlodipine 5 mg tablet, 30 | 1 | 5 | .. | 18.83 | 19.96 | | Sevikar 20/5 | MK |
| 5294P *NP* | olmesartan medoxomil 40 mg + amlodipine 10 mg tablet, 30 | 1 | 5 | .. | 31.41 | 32.54 | | Sevikar 40/10 | MK |
| 5293N *NP* | olmesartan medoxomil 40 mg + amlodipine 5 mg tablet, 30 | 1 | 5 | .. | 29.14 | 30.27 | | Sevikar 40/5 | MK |
| | **TELMISARTAN + AMLODIPINE** | | | | | | | | |
| | **Restricted benefit** | | | | | | | | |
| | Hypertension in a patient who is not adequately controlled with either of the drugs in the combination | | | | | | | | |
| 8979N *NP* | telmisartan 40 mg + amlodipine 10 mg tablet, 28 | 1 | 5 | .. | 18.08 | 19.21 | | Twynsta | BY |
| 8978M *NP* | telmisartan 40 mg + amlodipine 5 mg tablet, 28 | 1 | 5 | .. | 15.97 | 17.10 | | Twynsta | BY |
| 8981Q *NP* | telmisartan 80 mg + amlodipine 10 mg tablet, 28 | 1 | 5 | .. | 30.46 | 31.59 | | Twynsta | BY |
| 8980P *NP* | telmisartan 80 mg + amlodipine 5 mg tablet, 28 | 1 | 5 | .. | 28.34 | 29.47 | | Twynsta | BY |

## *Angiotensin II antagonists, other combinations*

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | **AMLODIPINE + VALSARTAN + HYDROCHLOROTHIAZIDE** | | | | | | | | |
| | **Restricted benefit** | | | | | | | | |
| | Hypertension in a patient who is not adequately controlled with any two of the drugs in the combination | | | | | | | | |
| 5287G *NP* | amlodipine 10 mg + valsartan 160 mg + hydrochlorothiazide 12.5 mg tablet, 28 | 1 | 5 | .. | 30.58 | 31.71 | | Exforge HCT 10/160/12.5 | NV |
| 5288H *NP* | amlodipine 10 mg + valsartan 160 mg + hydrochlorothiazide 25 mg tablet, 28 | 1 | 5 | .. | 32.32 | 33.45 | | Exforge HCT 10/160/25 | NV |
| 5289J *NP* | amlodipine 10 mg + valsartan 320 mg + hydrochlorothiazide 25 mg tablet, 28 | 1 | 5 | .. | 36.19 | 36.10 | | Exforge HCT 10/320/25 | NV |
| 5285E *NP* | amlodipine 5 mg + valsartan 160 mg + hydrochlorothiazide 12.5 mg tablet, 28 | 1 | 5 | .. | 27.04 | 28.17 | [a] | Exforge HCT 5/160/12.5 | NV |
| | | | | | | | [a] | Valsartan/Amlodipine/ HCT Sandoz 160/5/12.5 | NM |
| 5286F *NP* | amlodipine 5 mg + valsartan 160 mg + hydrochlorothiazide 25 mg tablet, 28 | 1 | 5 | .. | 28.79 | 29.92 | | Exforge HCT 5/160/25 | NV |

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|---|---|---|---|---|---|---|---|

# GENERAL STATEMENT FOR LIPID-LOWERING DRUGS PRESCRIBED AS PHARMACEUTICAL BENEFITS

Use the following criteria to determine patient eligibility for subsidisation under the PBS for the following drugs:

- atorvastatin calcium
- fluvastatin sodium
- pravastatin sodium
- rosuvastatin calcium
- simvastatin
- fenofibrate
- gemfibrozil

**By writing a PBS prescription, the prescriber is certifying the patient satisfies the qualifying criteria set out below and the use is in accordance with the registered indications which differ between agents in this class - refer to the current Product Information for details. Note also that patients already established on a particular lipid-lowering drug, where use satisfies the PBS qualifying criteria, but is outside the registered indications for that drug, are not required to switch to another drug in the class to retain PBS eligibility.**

Patients in very high risk categories (see below) may commence drug therapy with statins or fibrates immediately (ie simultaneously with an appropriate diet). For all other patients, dietary therapy should be trialled prior to initiation of drug therapy.

Dietary therapy should be continued concurrently with pharmacological therapy and should be reviewed on at least an annual basis.

Patients identified as being in one of the following very high risk categories may commence drug therapy with statins or fibrates at any cholesterol level:

- coronary heart disease which has become symptomatic
- cerebrovascular disease which has become symptomatic
- peripheral vascular disease which has become symptomatic
- diabetes mellitus with microalbuminuria (defined as urinary albumin excretion rate of >20mcg/min or urinary albumin to creatinine ratio of > 2.5 for males, > 3.5 for females)
- diabetes mellitus in Aboriginal or Torres Strait Islander patients
- diabetes mellitus in patients aged 60 years or more
- family history of coronary heart disease which has become symptomatic before the age of 55 years in two or more first degree relatives
- family history of coronary heart disease which has become symptomatic before the age of 45 years in one or more first degree relatives

**If your patient is not identified as being in any of the above very high risk categories, then use the flow-chart and table below to determine whether your patient satisfies the following criteria for subsidisation under the PBS. Document how the patient meets each of these steps in the patient record. Lipid levels must be measured at an accredited laboratory.**

# CARDIOVASCULAR SYSTEM

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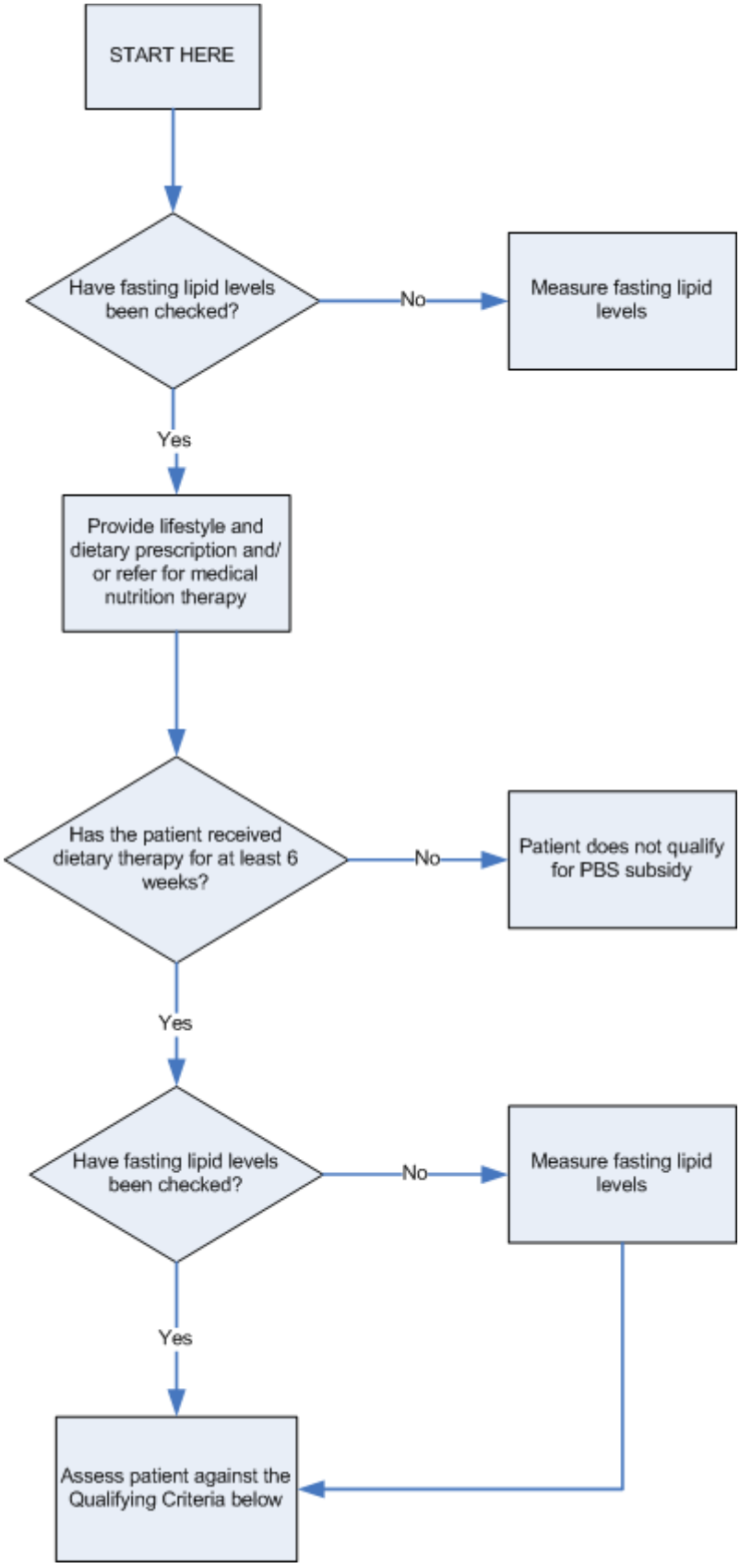
|---|---|---|---|---|---|---|---|



# CARDIOVASCULAR SYSTEM

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|---|

**POST-DIETARY QUALIFYING CRITERIA**

Dietary therapy should be continued concurrently with pharmacological therapy and should be reviewed on at least an annual basis.

| PATIENT CATEGORY | LIPID LEVELS FOR PBS SUBSIDY |
|---|---|
| Patients with diabetes mellitus not otherwise included | total cholesterol > 5.5 mmol/L |
| Aboriginal or Torres Strait Islander patients<br>Patients with hypertension | total cholesterol > 6.5 mmol/L<br>or<br>total cholesterol > 5.5 mmol/L and<br>HDL cholesterol < 1 mmol/L |
| Patients with HDL cholesterol < 1 mmol/L | total cholesterol > 6.5 mmol/L |
| Patients with familial hypercholesterolaemia identified by:<br>• DNA mutation; or<br>• tendon xanthomas in the patient or their first or second degree relative<br>Patients with:<br>• family history of coronary heart disease which has become symptomatic before the age of 60 years in one or more first degree relatives; or<br>• family history of coronary heart disease which has become symptomatic before the age of 50 years in one or more second degree relatives | If aged 18 years or less at treatment initiation:<br>LDL cholesterol > 4 mmol/L<br>If aged more than 18 years at treatment initiation:<br>LDL cholesterol > 5 mmol/L<br>or<br>total cholesterol > 6.5 mmol/L<br>or<br>total cholesterol > 5.5 mmol/L and<br>HDL cholesterol < 1 mmol/L |
| Patients not eligible under the above:<br>• men aged 35 to 75 years<br>• post-menopausal women aged up to 75 years | total cholesterol > 7.5 mmol/L<br>or<br>triglyceride > 4 mmol/L |
| Patients not otherwise included | total cholesterol > 9 mmol/L<br>or<br>triglyceride > 8 mmol/L |

## LIPID MODIFYING AGENTS, PLAIN
### *HMG CoA reductase inhibitors*

**ATORVASTATIN**
**Restricted benefit**
For use in patients that meet the criteria set out in the General Statement for Lipid-Lowering Drugs

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 8213G<br>*NP* | atorvastatin 10 mg tablet, 30 | 1 | 5 | .. | 29.65 | 30.78 | [a] | APO-Atorvastatin | TX |
| | | | | | | | [a] | Atorvachol | GM |
| | | | | | | | [a] | Atorvastatin GH | GQ |
| | | | | | | | [a] | Atorvastatin Pfizer | FZ |
| | | | | | | | [a] | Atorvastatin Sandoz | SZ |
| | | | | | | | [a] | Atorvastatin SCP 10 | RZ |
| | | | | | | | [a] | Atorvastatin SZ | HX |
| | | | | | | | [a] | Chem mart Atorvastatin | CH |
| | | | | | | | [a] | Lipitor | PF |
| | | | | | | | [a] | Lorstat 10 | AF |
| | | | | | | | [a] | STADA Atorvastatin | TD |
| | | | | | | | [a] | Terry White Chemists Atorvastatin | TW |
| | | | | | | | [a] | Torvastat 10 | QA |
| | | | | | | | [a] | Trovas | RA |

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|---|
| 8214H | atorvastatin 20 mg tablet, 30 | 1 | 5 | .. | 40.61 | 36.10 | a | APO-Atorvastatin | TX |
| *NP* | | | | | | | a | Atorvachol | GM |
| | | | | | | | a | Atorvastatin GH | GQ |
| | | | | | | | a | Atorvastatin Pfizer | FZ |
| | | | | | | | a | Atorvastatin Sandoz | SZ |
| | | | | | | | a | Atorvastatin SCP 20 | RZ |
| | | | | | | | a | Atorvastatin SZ | HX |
| | | | | | | | a | Chem mart Atorvastatin | CH |
| | | | | | | | a | Lipitor | PF |
| | | | | | | | a | Lorstat 20 | AF |
| | | | | | | | a | STADA Atorvastatin | TD |
| | | | | | | | a | Terry White Chemists Atorvastatin | TW |
| | | | | | | | a | Torvastat 20 | QA |
| | | | | | | | a | Trovas | RA |
| 8215J | atorvastatin 40 mg tablet, 30 | 1 | 5 | .. | 52.73 | 36.10 | a | APO-Atorvastatin | TX |
| *NP* | | | | | | | a | Atorvachol | GM |
| | | | | | | | a | Atorvastatin GH | GQ |
| | | | | | | | a | Atorvastatin Pfizer | FZ |
| | | | | | | | a | Atorvastatin Sandoz | SZ |
| | | | | | | | a | Atorvastatin SCP 40 | RZ |
| | | | | | | | a | Atorvastatin SZ | HX |
| | | | | | | | a | Chem mart Atorvastatin | CH |
| | | | | | | | a | Lipitor | PF |
| | | | | | | | a | Lorstat 40 | AF |
| | | | | | | | a | STADA Atorvastatin | TD |
| | | | | | | | a | Terry White Chemists Atorvastatin | TW |
| | | | | | | | a | Torvastat 40 | QA |
| | | | | | | | a | Trovas | RA |
| 8521L | atorvastatin 80 mg tablet, 30 | 1 | 5 | .. | 72.05 | 36.10 | a | APO-Atorvastatin | TX |
| *NP* | | | | | | | a | Atorvachol | GM |
| | | | | | | | a | Atorvastatin GH | GQ |
| | | | | | | | a | Atorvastatin Pfizer | FZ |
| | | | | | | | a | Atorvastatin Sandoz | SZ |
| | | | | | | | a | Atorvastatin SCP 80 | RZ |
| | | | | | | | a | Atorvastatin SZ | HX |
| | | | | | | | a | Chem mart Atorvastatin | CH |
| | | | | | | | a | Lipitor | PF |
| | | | | | | | a | Lorstat 80 | AF |
| | | | | | | | a | STADA Atorvastatin | TD |
| | | | | | | | a | Terry White Chemists Atorvastatin | TW |
| | | | | | | | a | Torvastat 80 | QA |
| | | | | | | | a | Trovas | RA |

**ATORVASTATIN**

**Restricted benefit**

For use in patients who meet the criteria set out in the General Statement for Lipid-Lowering Drugs, and who are receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements

**Note**

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

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 9230T | atorvastatin 10 mg tablet, 30 | 1 | 11 | .. | 29.65 | 30.78 | a | APO-Atorvastatin | TX |
| | | | | | | | a | Atorvachol | GM |
| | | | | | | | a | Atorvastatin GH | GQ |
| | | | | | | | a | Atorvastatin Pfizer | FZ |
| | | | | | | | a | Atorvastatin Sandoz | SZ |
| | | | | | | | a | Atorvastatin SCP 10 | RZ |
| | | | | | | | a | Atorvastatin SZ | HX |
| | | | | | | | a | Chem mart Atorvastatin | CH |

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | [a] | Lipitor | PF |
| | | | | | | | [a] | Lorstat 10 | AF |
| | | | | | | | [a] | STADA Atorvastatin | TD |
| | | | | | | | [a] | Terry White Chemists Atorvastatin | TW |
| | | | | | | | [a] | Torvastat 10 | QA |
| | | | | | | | [a] | Trovas | RA |
| 9231W | atorvastatin 20 mg tablet, 30 | 1 | 11 | .. | 40.61 | 36.10 | [a] | APO-Atorvastatin | TX |
| | | | | | | | [a] | Atorvachol | GM |
| | | | | | | | [a] | Atorvastatin GH | GQ |
| | | | | | | | [a] | Atorvastatin Pfizer | FZ |
| | | | | | | | [a] | Atorvastatin Sandoz | SZ |
| | | | | | | | [a] | Atorvastatin SCP 20 | RZ |
| | | | | | | | [a] | Atorvastatin SZ | HX |
| | | | | | | | [a] | Chem mart Atorvastatin | CH |
| | | | | | | | [a] | Lipitor | PF |
| | | | | | | | [a] | Lorstat 20 | AF |
| | | | | | | | [a] | STADA Atorvastatin | TD |
| | | | | | | | [a] | Terry White Chemists Atorvastatin | TW |
| | | | | | | | [a] | Torvastat 20 | QA |
| | | | | | | | [a] | Trovas | RA |
| 9232X | atorvastatin 40 mg tablet, 30 | 1 | 11 | .. | 52.73 | 36.10 | [a] | APO-Atorvastatin | TX |
| | | | | | | | [a] | Atorvachol | GM |
| | | | | | | | [a] | Atorvastatin GH | GQ |
| | | | | | | | [a] | Atorvastatin Pfizer | FZ |
| | | | | | | | [a] | Atorvastatin Sandoz | SZ |
| | | | | | | | [a] | Atorvastatin SCP 40 | RZ |
| | | | | | | | [a] | Atorvastatin SZ | HX |
| | | | | | | | [a] | Chem mart Atorvastatin | CH |
| | | | | | | | [a] | Lipitor | PF |
| | | | | | | | [a] | Lorstat 40 | AF |
| | | | | | | | [a] | STADA Atorvastatin | TD |
| | | | | | | | [a] | Terry White Chemists Atorvastatin | TW |
| | | | | | | | [a] | Torvastat 40 | QA |
| | | | | | | | [a] | Trovas | RA |
| 9233Y | atorvastatin 80 mg tablet, 30 | 1 | 11 | .. | 72.05 | 36.10 | [a] | APO-Atorvastatin | TX |
| | | | | | | | [a] | Atorvachol | GM |
| | | | | | | | [a] | Atorvastatin GH | GQ |
| | | | | | | | [a] | Atorvastatin Pfizer | FZ |
| | | | | | | | [a] | Atorvastatin Sandoz | SZ |
| | | | | | | | [a] | Atorvastatin SCP 80 | RZ |
| | | | | | | | [a] | Atorvastatin SZ | HX |
| | | | | | | | [a] | Chem mart Atorvastatin | CH |
| | | | | | | | [a] | Lipitor | PF |
| | | | | | | | [a] | Lorstat 80 | AF |
| | | | | | | | [a] | STADA Atorvastatin | TD |
| | | | | | | | [a] | Terry White Chemists Atorvastatin | TW |
| | | | | | | | [a] | Torvastat 80 | QA |
| | | | | | | | [a] | Trovas | RA |
| | **FLUVASTATIN**<br>**Restricted benefit**<br>For use in patients that meet the criteria set out in the General Statement for Lipid-Lowering Drugs | | | | | | | | |
| 8023G<br>*NP* | fluvastatin 20 mg capsule, 28 | 1 | 5 | .. | 25.67 | 26.80 | [a] | Lescol | NV |
| | | | | [B]3.09 | 28.76 | 26.80 | [a] | Vastin | NM |
| 8024H<br>*NP* | fluvastatin 40 mg capsule, 28 | 1 | 5 | .. | 29.98 | 31.11 | [a] | Lescol | NV |
| | | | | [B]3.38 | 33.36 | 31.11 | [a] | Vastin | NM |
| 2863Q<br>*NP* | fluvastatin 80 mg tablet: modified release, 28 tablets | 1 | 5 | .. | 45.63 | 36.10 | | Lescol XL | NV |

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|---|
| | **FLUVASTATIN** | | | | | | | | |
| | **Restricted benefit** | | | | | | | | |
| | For use in patients who meet the criteria set out in the General Statement for Lipid-Lowering Drugs, and who are receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements | | | | | | | | |
| | **Note** | | | | | | | | |
| | No applications for increased maximum quantities and/or repeats will be authorised. | | | | | | | | |
| 9234B | fluvastatin 20 mg capsule, 28 | 1 | 11 | .. | 25.67 | 26.80 | a | Lescol | NV |
| | | | | B3.09 | 28.76 | 26.80 | a | Vastin | NM |
| 9235C | fluvastatin 40 mg capsule, 28 | 1 | 11 | .. | 29.98 | 31.11 | a | Lescol | NV |
| | | | | B3.38 | 33.36 | 31.11 | a | Vastin | NM |
| 9236D | fluvastatin 80 mg tablet: modified release, 28 tablets | 1 | 11 | .. | 45.63 | 36.10 | | Lescol XL | NV |
| | **PRAVASTATIN** | | | | | | | | |
| | **Restricted benefit** | | | | | | | | |
| | For use in patients that meet the criteria set out in the General Statement for Lipid-Lowering Drugs | | | | | | | | |
| 2833D | pravastatin sodium 10 mg tablet, 30 | 1 | 5 | .. | 11.38 | 12.51 | a | APO-Pravastatin | TX |
| *NP* | | | | | | | a | Chem mart Pravastatin | CH |
| | | | | | | | a | Cholstat 10 | AF |
| | | | | | | | a | Lipostat 10 | QA |
| | | | | | | | a | Pharmacor Pravastat 10 | CR |
| | | | | | | | a | Pravastatin Actavis 10 | TA |
| | | | | | | | a | Pravastatin-GA 10 | GM |
| | | | | | | | a | Pravastatin generichealth | GQ |
| | | | | | | | a | Pravastatin Sandoz | SZ |
| | | | | | | | a | Terry White Chemists Pravastatin | TW |
| | | | | B2.64 | 14.02 | 12.51 | a | Pravachol | FM |
| 2834E | pravastatin sodium 20 mg tablet, 30 | 1 | 5 | .. | 14.17 | 15.30 | a | APO-Pravastatin | TX |
| *NP* | | | | | | | a | Chem mart Pravastatin | CH |
| | | | | | | | a | Cholstat 20 | AF |
| | | | | | | | a | Cholvastin | RA |
| | | | | | | | a | Lipostat 20 | QA |
| | | | | | | | a | Pharmacor Pravastat 20 | CR |
| | | | | | | | a | Pravastatin Actavis 20 | TA |
| | | | | | | | a | Pravastatin-GA 20 | GM |
| | | | | | | | a | Pravastatin generichealth | GQ |
| | | | | | | | a | Pravastatin Sandoz | SZ |
| | | | | | | | a | Terry White Chemists Pravastatin | TW |
| | | | | B2.64 | 16.81 | 15.30 | a | Pravachol | FM |
| 8197K | pravastatin sodium 40 mg tablet, 30 | 1 | 5 | .. | 18.37 | 19.50 | a | APO-Pravastatin | TX |
| *NP* | | | | | | | a | Chem mart Pravastatin | CH |
| | | | | | | | a | Cholstat 40 | AF |
| | | | | | | | a | Cholvastin | RA |
| | | | | | | | a | Lipostat 40 | QA |
| | | | | | | | a | Pharmacor Pravastat 40 | CR |
| | | | | | | | a | Pravastatin Actavis 40 | TA |
| | | | | | | | a | Pravastatin-GA 40 | GM |
| | | | | | | | a | Pravastatin generichealth | GQ |
| | | | | | | | a | Pravastatin Sandoz | SZ |
| | | | | | | | a | Terry White Chemists Pravastatin | TW |
| | | | | B2.82 | 21.19 | 19.50 | a | Pravachol | FM |
| 8829Q | pravastatin sodium 80 mg tablet, 30 | 1 | 5 | .. | 24.69 | 25.82 | a | APO-Pravastatin | TX |
| *NP* | | | | | | | a | Chem mart Pravastatin | CH |

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | [a] | Lipostat 80 | QA |
| | | | | | | | [a] | Pravastatin-GA 80 | GM |
| | | | | | | | [a] | Pravastatin generichealth | GQ |
| | | | | | | | [a] | Pravastatin Sandoz | SZ |
| | | | | | | | [a] | Terry White Chemists Pravastatin | TW |
| | | | | [B]2.80 | 27.49 | 25.82 | [a] | Pravachol | FM |
| | **PRAVASTATIN**<br>**Restricted benefit**<br>For use in patients who meet the criteria set out in the General Statement for Lipid-Lowering Drugs, and who are receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements<br>**Note**<br>No applications for increased maximum quantities and/or repeats will be authorised. | | | | | | | | |
| 9237E | pravastatin sodium 10 mg tablet, 30 | 1 | 11 | .. | 11.38 | 12.51 | [a] | APO-Pravastatin | TX |
| | | | | | | | [a] | Chem mart Pravastatin | CH |
| | | | | | | | [a] | Cholstat 10 | AF |
| | | | | | | | [a] | Lipostat 10 | QA |
| | | | | | | | [a] | Pharmacor Pravastat 10 | CR |
| | | | | | | | [a] | Pravastatin Actavis 10 | TA |
| | | | | | | | [a] | Pravastatin-GA 10 | GM |
| | | | | | | | [a] | Pravastatin generichealth | GQ |
| | | | | | | | [a] | Pravastatin Sandoz | SZ |
| | | | | | | | [a] | Terry White Chemists Pravastatin | TW |
| | | | | [B]2.64 | 14.02 | 12.51 | [a] | Pravachol | FM |
| 9238F | pravastatin sodium 20 mg tablet, 30 | 1 | 11 | .. | 14.17 | 15.30 | [a] | APO-Pravastatin | TX |
| | | | | | | | [a] | Chem mart Pravastatin | CH |
| | | | | | | | [a] | Cholstat 20 | AF |
| | | | | | | | [a] | Cholvastin | RA |
| | | | | | | | [a] | Lipostat 20 | QA |
| | | | | | | | [a] | Pharmacor Pravastat 20 | CR |
| | | | | | | | [a] | Pravastatin Actavis 20 | TA |
| | | | | | | | [a] | Pravastatin-GA 20 | GM |
| | | | | | | | [a] | Pravastatin generichealth | GQ |
| | | | | | | | [a] | Pravastatin Sandoz | SZ |
| | | | | | | | [a] | Terry White Chemists Pravastatin | TW |
| | | | | [B]2.64 | 16.81 | 15.30 | [a] | Pravachol | FM |
| 9239G | pravastatin sodium 40 mg tablet, 30 | 1 | 11 | .. | 18.37 | 19.50 | [a] | APO-Pravastatin | TX |
| | | | | | | | [a] | Chem mart Pravastatin | CH |
| | | | | | | | [a] | Cholstat 40 | AF |
| | | | | | | | [a] | Cholvastin | RA |
| | | | | | | | [a] | Lipostat 40 | QA |
| | | | | | | | [a] | Pharmacor Pravastat 40 | CR |
| | | | | | | | [a] | Pravastatin Actavis 40 | TA |
| | | | | | | | [a] | Pravastatin-GA 40 | GM |
| | | | | | | | [a] | Pravastatin generichealth | GQ |
| | | | | | | | [a] | Pravastatin Sandoz | SZ |
| | | | | | | | [a] | Terry White Chemists Pravastatin | TW |
| | | | | [B]2.82 | 21.19 | 19.50 | [a] | Pravachol | FM |
| 9240H | pravastatin sodium 80 mg tablet, 30 | 1 | 11 | .. | 24.69 | 25.82 | [a] | APO-Pravastatin | TX |
| | | | | | | | [a] | Chem mart Pravastatin | CH |
| | | | | | | | [a] | Lipostat 80 | QA |
| | | | | | | | [a] | Pravastatin-GA 80 | GM |
| | | | | | | | [a] | Pravastatin generichealth | GQ |
| | | | | | | | [a] | Pravastatin Sandoz | SZ |
| | | | | | | | [a] | Terry White Chemists | TW |

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | Pravastatin | |
| | | | | [B]2.80 | 27.49 | 25.82 | [a] | Pravachol | FM |
| | **ROSUVASTATIN**<br>**Restricted benefit**<br>For use in patients who meet the criteria set out in the General Statement for Lipid-Lowering Drugs<br>**The Clinical criteria is:**<br>Patient must be receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements.<br>**Note**<br>No increase in the maximum quantity or number of units may be authorised.<br>**Note**<br>No increase in the maximum number of repeats may be authorised. | | | | | | | | |
| 2584B | rosuvastatin 10 mg tablet, 30 | 1 | 11 | .. | 43.90 | 36.10 | [a] | Cavstat | AF |
| | | | | | | | [a] | Crestor | AP |
| | | | | | | | [a] | Rosuvastatin Actavis 10 | WQ |
| | | | | | | | [a] | Rosuvastatin GH | GQ |
| 2609H | rosuvastatin 20 mg tablet, 30 | 1 | 11 | .. | 57.96 | 36.10 | [a] | Cavstat | AF |
| | | | | | | | [a] | Crestor | AP |
| | | | | | | | [a] | Rosuvastatin Actavis 20 | WQ |
| | | | | | | | [a] | Rosuvastatin GH | GQ |
| 2636R | rosuvastatin 40 mg tablet, 30 | 1 | 11 | .. | 79.84 | 36.10 | [a] | Cavstat | AF |
| | | | | | | | [a] | Crestor | AP |
| | | | | | | | [a] | Rosuvastatin Actavis 40 | WQ |
| | | | | | | | [a] | Rosuvastatin GH | GQ |
| 2590H | rosuvastatin 5 mg tablet, 30 | 1 | 11 | .. | 32.31 | 33.44 | [a] | Cavstat | AF |
| | | | | | | | [a] | Crestor | AP |
| | | | | | | | [a] | Rosuvastatin Actavis 5 | WQ |
| | | | | | | | [a] | Rosuvastatin GH | GQ |
| | **ROSUVASTATIN**<br>**Restricted benefit**<br>For use in patients who meet the criteria set out in the General Statement for Lipid-Lowering Drugs | | | | | | | | |
| 2628H<br>*NP* | rosuvastatin 10 mg tablet, 30 | 1 | 5 | .. | 43.90 | 36.10 | [a] | Cavstat | AF |
| | | | | | | | [a] | Crestor | AP |
| | | | | | | | [a] | Rosuvastatin Actavis 10 | WQ |
| | | | | | | | [a] | Rosuvastatin GH | GQ |
| 2606E<br>*NP* | rosuvastatin 5 mg tablet, 30 | 1 | 5 | .. | 32.31 | 33.44 | [a] | Cavstat | AF |
| | | | | | | | [a] | Crestor | AP |
| | | | | | | | [a] | Rosuvastatin Actavis 5 | WQ |
| | | | | | | | [a] | Rosuvastatin GH | GQ |
| | **ROSUVASTATIN**<br>**Restricted benefit**<br>For use in patients who meet the criteria set out in the General Statement for Lipid-Lowering Drugs<br>**The Clinical criteria is:**<br>Patient must be receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements,<br>**AND the Clinical criteria is:**<br>The treatment must not be prescribed for hypercholesterolaemia if the patient has heterozygous familial hypercholesterolaemia.<br>**Note**<br>No increase in the maximum quantity or number of units may be authorised.<br>**Note**<br>No increase in the maximum number of repeats may be authorised. | | | | | | | | |
| 3403D | rosuvastatin 10 mg tablet, 30 | 1 | 11 | .. | 43.90 | 36.10 | [a] | APO-Rosuvastatin | TX |
| | | | | | | | [a] | Cavstat | AF |
| | | | | | | | [a] | Chem mart Rosuvastatin | CH |
| | | | | | | | [a] | Crestor | AP |

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | [a] | Rostor 10 | DO |
| | | | | | | | [a] | Rosuvastatin Actavis 10 | WQ |
| | | | | | | | [a] | Rosuvastatin GH | GQ |
| | | | | | | | [a] | Rosuvastatin RBX | RA |
| | | | | | | | [a] | Rosuvastatin Sandoz | SZ |
| | | | | | | | [a] | Terry White Chemists Rosuvastatin | TW |
| 3404E | rosuvastatin 20 mg tablet, 30 | 1 | 11 | .. | 57.96 | 36.10 | [a] | APO-Rosuvastatin | TX |
| | | | | | | | [a] | Cavstat | AF |
| | | | | | | | [a] | Chem mart Rosuvastatin | CH |
| | | | | | | | [a] | Crestor | AP |
| | | | | | | | [a] | Rostor 20 | DO |
| | | | | | | | [a] | Rosuvastatin Actavis 20 | WQ |
| | | | | | | | [a] | Rosuvastatin GH | GQ |
| | | | | | | | [a] | Rosuvastatin RBX | RA |
| | | | | | | | [a] | Rosuvastatin Sandoz | SZ |
| | | | | | | | [a] | Terry White Chemists Rosuvastatin | TW |
| 3405F | rosuvastatin 40 mg tablet, 30 | 1 | 11 | .. | 79.84 | 36.10 | [a] | APO-Rosuvastatin | TX |
| | | | | | | | [a] | Cavstat | AF |
| | | | | | | | [a] | Chem mart Rosuvastatin | CH |
| | | | | | | | [a] | Crestor | AP |
| | | | | | | | [a] | Rostor 40 | DO |
| | | | | | | | [a] | Rosuvastatin Actavis 40 | WQ |
| | | | | | | | [a] | Rosuvastatin GH | GQ |
| | | | | | | | [a] | Rosuvastatin RBX | RA |
| | | | | | | | [a] | Rosuvastatin Sandoz | SZ |
| | | | | | | | [a] | Terry White Chemists Rosuvastatin | TW |
| 3402C | rosuvastatin 5 mg tablet, 30 | 1 | 11 | .. | 32.31 | 33.44 | [a] | APO-Rosuvastatin | TX |
| | | | | | | | [a] | Cavstat | AF |
| | | | | | | | [a] | Chem mart Rosuvastatin | CH |
| | | | | | | | [a] | Crestor | AP |
| | | | | | | | [a] | Rostor 5 | DO |
| | | | | | | | [a] | Rosuvastatin Actavis 5 | WQ |
| | | | | | | | [a] | Rosuvastatin GH | GQ |
| | | | | | | | [a] | Rosuvastatin RBX | RA |
| | | | | | | | [a] | Rosuvastatin Sandoz | SZ |
| | | | | | | | [a] | Terry White Chemists Rosuvastatin | TW |
| | **ROSUVASTATIN**<br>**Restricted benefit**<br>For use in patients who meet the criteria set out in the General Statement for Lipid-Lowering Drugs<br>**The Clinical criteria is:**<br>The treatment must not be prescribed for hypercholesterolaemia if the patient has heterozygous familial hypercholesterolaemia. | | | | | | | | |
| 9043Y<br>*NP* | rosuvastatin 10 mg tablet, 30 | 1 | 5 | .. | 43.90 | 36.10 | [a] | APO-Rosuvastatin | TX |
| | | | | | | | [a] | Cavstat | AF |
| | | | | | | | [a] | Chem mart Rosuvastatin | CH |
| | | | | | | | [a] | Crestor | AP |
| | | | | | | | [a] | Rostor 10 | DO |
| | | | | | | | [a] | Rosuvastatin Actavis 10 | WQ |
| | | | | | | | [a] | Rosuvastatin GH | GQ |
| | | | | | | | [a] | Rosuvastatin RBX | RA |
| | | | | | | | [a] | Rosuvastatin Sandoz | SZ |
| | | | | | | | [a] | Terry White Chemists Rosuvastatin | TW |
| 9042X<br>*NP* | rosuvastatin 5 mg tablet, 30 | 1 | 5 | .. | 32.31 | 33.44 | [a] | APO-Rosuvastatin | TX |

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | [a] | Cavstat | AF |
| | | | | | | | [a] | Chem mart Rosuvastatin | CH |
| | | | | | | | [a] | Crestor | AP |
| | | | | | | | [a] | Rostor 5 | DO |
| | | | | | | | [a] | Rosuvastatin Actavis 5 | WQ |
| | | | | | | | [a] | Rosuvastatin GH | GQ |
| | | | | | | | [a] | Rosuvastatin RBX | RA |
| | | | | | | | [a] | Rosuvastatin Sandoz | SZ |
| | | | | | | | [a] | Terry White Chemists Rosuvastatin | TW |
| | **ROSUVASTATIN**<br>**Restricted benefit**<br>For use in patients who meet the criteria set out in the General Statement for Lipid-Lowering Drugs | | | | | | | | |
| 2574L<br>*NP* | rosuvastatin 20 mg tablet, 30 | 1 | 5 | .. | 57.96 | 36.10 | [a] | Cavstat | AF |
| | | | | | | | [a] | Crestor | AP |
| | | | | | | | [a] | Rosuvastatin Actavis 20 | WQ |
| | | | | | | | [a] | Rosuvastatin GH | GQ |
| | **ROSUVASTATIN**<br>**Restricted benefit**<br>For use in patients who meet the criteria set out in the General Statement for Lipid-Lowering Drugs<br>**The Clinical criteria is:**<br>The treatment must not be prescribed for hypercholesterolaemia if the patient has heterozygous familial hypercholesterolaemia. | | | | | | | | |
| 9044B<br>*NP* | rosuvastatin 20 mg tablet, 30 | 1 | 5 | .. | 57.96 | 36.10 | [a] | APO-Rosuvastatin | TX |
| | | | | | | | [a] | Cavstat | AF |
| | | | | | | | [a] | Chem mart Rosuvastatin | CH |
| | | | | | | | [a] | Crestor | AP |
| | | | | | | | [a] | Rostor 20 | DO |
| | | | | | | | [a] | Rosuvastatin Actavis 20 | WQ |
| | | | | | | | [a] | Rosuvastatin GH | GQ |
| | | | | | | | [a] | Rosuvastatin RBX | RA |
| | | | | | | | [a] | Rosuvastatin Sandoz | SZ |
| | | | | | | | [a] | Terry White Chemists Rosuvastatin | TW |
| | **ROSUVASTATIN**<br>**Restricted benefit**<br>For use in patients who meet the criteria set out in the General Statement for Lipid-Lowering Drugs | | | | | | | | |
| 2594M<br>*NP* | rosuvastatin 40 mg tablet, 30 | 1 | 5 | .. | 79.84 | 36.10 | [a] | Cavstat | AF |
| | | | | | | | [a] | Crestor | AP |
| | | | | | | | [a] | Rosuvastatin Actavis 40 | WQ |
| | | | | | | | [a] | Rosuvastatin GH | GQ |
| | **ROSUVASTATIN**<br>**Restricted benefit**<br>For use in patients who meet the criteria set out in the General Statement for Lipid-Lowering Drugs<br>**The Clinical criteria is:**<br>The treatment must not be prescribed for hypercholesterolaemia if the patient has heterozygous familial hypercholesterolaemia. | | | | | | | | |
| 9045C<br>*NP* | rosuvastatin 40 mg tablet, 30 | 1 | 5 | .. | 79.84 | 36.10 | [a] | APO-Rosuvastatin | TX |
| | | | | | | | [a] | Cavstat | AF |
| | | | | | | | [a] | Chem mart Rosuvastatin | CH |
| | | | | | | | [a] | Crestor | AP |
| | | | | | | | [a] | Rostor 40 | DO |
| | | | | | | | [a] | Rosuvastatin Actavis 40 | WQ |
| | | | | | | | [a] | Rosuvastatin GH | GQ |
| | | | | | | | [a] | Rosuvastatin RBX | RA |

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | [a] | Rosuvastatin Sandoz | SZ |
| | | | | | | | [a] | Terry White Chemists Rosuvastatin | TW |
| | **SIMVASTATIN**<br>**Restricted benefit**<br>For use in patients that meet the criteria set out in the General Statement for Lipid-Lowering Drugs | | | | | | | | |
| 2011W<br>*NP* | simvastatin 10 mg tablet, 30 | 1 | 5 | .. | 10.97 | 12.10 | [a] | APO-Simvastatin | TX |
| | | | | | | | [a] | Auro-Simvastatin 10 | DO |
| | | | | | | | [a] | Chem mart Simvastatin | CH |
| | | | | | | | [a] | GenRx Simvastatin | GX |
| | | | | | | | [a] | Ransim | RA |
| | | | | | | | [a] | Simvacor 10 | CR |
| | | | | | | | [a] | Simvar 10 | QA |
| | | | | | | | [a] | Simvastatin-DP | GM |
| | | | | | | | [a] | Simvastatin-DRLA | RZ |
| | | | | | | | [a] | Simvastatin-GA 10 | GN |
| | | | | | | | [a] | Simvastatin generichealth | GQ |
| | | | | | | | [a] | Simvastatin Sandoz | SZ |
| | | | | | | | [a] | Simvastatin-Spirit 10 | ZP |
| | | | | | | | [a] | Terry White Chemists Simvastatin | TW |
| | | | | | | | [a] | Zimstat | AF |
| | | | | [B]1.85 | 12.82 | 12.10 | [a] | Lipex 10 | FR |
| | | | | | | | [a] | Zocor | MK |
| 2012X<br>*NP* | simvastatin 20 mg tablet, 30 | 1 | 5 | .. | 12.89 | 14.02 | [a] | APO-Simvastatin | TX |
| | | | | | | | [a] | Auro-Simvastatin 20 | DO |
| | | | | | | | [a] | Chem mart Simvastatin | CH |
| | | | | | | | [a] | Ransim | RA |
| | | | | | | | [a] | Simvacor 20 | CR |
| | | | | | | | [a] | Simvar 20 | QA |
| | | | | | | | [a] | Simvastatin-DP | GM |
| | | | | | | | [a] | Simvastatin-DRLA | RZ |
| | | | | | | | [a] | Simvastatin-GA 20 | GN |
| | | | | | | | [a] | Simvastatin generichealth | GQ |
| | | | | | | | [a] | Simvastatin Sandoz | SZ |
| | | | | | | | [a] | Simvastatin-Spirit 20 | ZP |
| | | | | | | | [a] | Terry White Chemists Simvastatin | TW |
| | | | | | | | [a] | Zimstat | AF |
| | | | | [B]1.82 | 14.71 | 14.02 | [a] | Lipex 20 | FR |
| | | | | | | | [a] | Zocor | MK |
| 8173E<br>*NP* | simvastatin 40 mg tablet, 30 | 1 | 5 | .. | 15.63 | 16.76 | [a] | APO-Simvastatin | TX |
| | | | | | | | [a] | Auro-Simvastatin 40 | DO |
| | | | | | | | [a] | Chem mart Simvastatin | CH |
| | | | | | | | [a] | Ransim | RA |
| | | | | | | | [a] | Simvacor 40 | CR |
| | | | | | | | [a] | Simvar 40 | QA |
| | | | | | | | [a] | Simvastatin-DP | GM |
| | | | | | | | [a] | Simvastatin-DRLA | RZ |
| | | | | | | | [a] | Simvastatin-GA 40 | GN |
| | | | | | | | [a] | Simvastatin generichealth | GQ |
| | | | | | | | [a] | Simvastatin Sandoz | SZ |
| | | | | | | | [a] | Simvastatin-Spirit 40 | ZP |
| | | | | | | | [a] | Terry White Chemists Simvastatin | TW |
| | | | | | | | [a] | Zimstat | AF |
| | | | | [B]1.84 | 17.47 | 16.76 | [a] | Lipex 40 | FR |
| | | | | | | | [a] | Zocor | MK |

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|---|
| 2013Y | simvastatin 5 mg tablet, 30 | 1 | 5 | .. | 9.77 | 10.90 | a | Simvastatin Sandoz | SZ |
| *NP* | | | | | | | a | Zimstat | AF |
| | | | | [B]1.84 | 11.61 | 10.90 | a | Zocor | MK |
| 8313M | simvastatin 80 mg tablet, 30 | 1 | 5 | .. | 19.57 | 20.70 | a | APO-Simvastatin | TX |
| *NP* | | | | | | | a | Auro-Simvastatin 80 | DO |
| | | | | | | | a | Chem mart Simvastatin | CH |
| | | | | | | | a | Ransim | RA |
| | | | | | | | a | Simvacor 80 | CR |
| | | | | | | | a | Simvar 80 | QA |
| | | | | | | | a | Simvastatin-DP | GM |
| | | | | | | | a | Simvastatin-DRLA | RZ |
| | | | | | | | a | Simvastatin-GA 80 | GN |
| | | | | | | | a | Simvastatin generichealth | GQ |
| | | | | | | | a | Simvastatin Sandoz | SZ |
| | | | | | | | a | Simvastatin-Spirit 80 | ZP |
| | | | | | | | a | Terry White Chemists Simvastatin | TW |
| | | | | | | | a | Zimstat | AF |
| | | | | [B]1.84 | 21.41 | 20.70 | a | Lipex 80 | FR |
| | | | | | | | a | Zocor | MK |
| | **SIMVASTATIN**<br>**Restricted benefit**<br>For use in patients who meet the criteria set out in the General Statement for Lipid-Lowering Drugs, and who are receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements<br>**Note**<br>No applications for increased maximum quantities and/or repeats will be authorised. | | | | | | | | |
| 9242K | simvastatin 10 mg tablet, 30 | 1 | 11 | .. | 10.97 | 12.10 | a | APO-Simvastatin | TX |
| | | | | | | | a | Auro-Simvastatin 10 | DO |
| | | | | | | | a | Chem mart Simvastatin | CH |
| | | | | | | | a | GenRx Simvastatin | GX |
| | | | | | | | a | Ransim | RA |
| | | | | | | | a | Simvacor 10 | CR |
| | | | | | | | a | Simvar 10 | QA |
| | | | | | | | a | Simvastatin-DP | GM |
| | | | | | | | a | Simvastatin-DRLA | RZ |
| | | | | | | | a | Simvastatin-GA 10 | GN |
| | | | | | | | a | Simvastatin generichealth | GQ |
| | | | | | | | a | Simvastatin Sandoz | SZ |
| | | | | | | | a | Simvastatin-Spirit 10 | ZP |
| | | | | | | | a | Terry White Chemists Simvastatin | TW |
| | | | | | | | a | Zimstat | AF |
| | | | | [B]1.85 | 12.82 | 12.10 | a | Lipex 10 | FR |
| | | | | | | | a | Zocor | MK |
| 9243L | simvastatin 20 mg tablet, 30 | 1 | 11 | .. | 12.89 | 14.02 | a | APO-Simvastatin | TX |
| | | | | | | | a | Auro-Simvastatin 20 | DO |
| | | | | | | | a | Chem mart Simvastatin | CH |
| | | | | | | | a | Ransim | RA |
| | | | | | | | a | Simvacor 20 | CR |
| | | | | | | | a | Simvar 20 | QA |
| | | | | | | | a | Simvastatin-DP | GM |
| | | | | | | | a | Simvastatin-DRLA | RZ |
| | | | | | | | a | Simvastatin-GA 20 | GN |
| | | | | | | | a | Simvastatin generichealth | GQ |
| | | | | | | | a | Simvastatin Sandoz | SZ |
| | | | | | | | a | Simvastatin-Spirit 20 | ZP |
| | | | | | | | a | Terry White Chemists | TW |

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | Simvastatin | |
| | | | | | | | [a] | Zimstat | AF |
| | | | | [B]1.82 | 14.71 | 14.02 | [a] | Lipex 20 | FR |
| | | | | | | | [a] | Zocor | MK |
| 9244M | simvastatin 40 mg tablet, 30 | 1 | 11 | .. | 15.63 | 16.76 | [a] | APO-Simvastatin | TX |
| | | | | | | | [a] | Auro-Simvastatin 40 | DO |
| | | | | | | | [a] | Chem mart Simvastatin | CH |
| | | | | | | | [a] | Ransim | RA |
| | | | | | | | [a] | Simvacor 40 | CR |
| | | | | | | | [a] | Simvar 40 | QA |
| | | | | | | | [a] | Simvastatin-DP | GM |
| | | | | | | | [a] | Simvastatin-DRLA | RZ |
| | | | | | | | [a] | Simvastatin-GA 40 | GN |
| | | | | | | | [a] | Simvastatin generichealth | GQ |
| | | | | | | | [a] | Simvastatin Sandoz | SZ |
| | | | | | | | [a] | Simvastatin-Spirit 40 | ZP |
| | | | | | | | [a] | Terry White Chemists Simvastatin | TW |
| | | | | | | | [a] | Zimstat | AF |
| | | | | [B]1.84 | 17.47 | 16.76 | [a] | Lipex 40 | FR |
| | | | | | | | [a] | Zocor | MK |
| 9241J | simvastatin 5 mg tablet, 30 | 1 | 11 | .. | 9.77 | 10.90 | [a] | Simvastatin Sandoz | SZ |
| | | | | | | | [a] | Zimstat | AF |
| | | | | [B]1.84 | 11.61 | 10.90 | [a] | Zocor | MK |
| 9245N | simvastatin 80 mg tablet, 30 | 1 | 11 | .. | 19.57 | 20.70 | [a] | APO-Simvastatin | TX |
| | | | | | | | [a] | Auro-Simvastatin 80 | DO |
| | | | | | | | [a] | Chem mart Simvastatin | CH |
| | | | | | | | [a] | Ransim | RA |
| | | | | | | | [a] | Simvacor 80 | CR |
| | | | | | | | [a] | Simvar 80 | QA |
| | | | | | | | [a] | Simvastatin-DP | GM |
| | | | | | | | [a] | Simvastatin-DRLA | RZ |
| | | | | | | | [a] | Simvastatin-GA 80 | GN |
| | | | | | | | [a] | Simvastatin generichealth | GQ |
| | | | | | | | [a] | Simvastatin Sandoz | SZ |
| | | | | | | | [a] | Simvastatin-Spirit 80 | ZP |
| | | | | | | | [a] | Terry White Chemists Simvastatin | TW |
| | | | | | | | [a] | Zimstat | AF |
| | | | | [B]1.84 | 21.41 | 20.70 | [a] | Lipex 80 | FR |
| | | | | | | | [a] | Zocor | MK |

## *Fibrates*

**FENOFIBRATE**

**Restricted benefit**

For use in patients that meet the criteria set out in the General Statement for Lipid-Lowering Drugs

**Note**

The risk of serious muscle toxicity is increased if fenofibrate is used concomitantly with HMG CoA reductase inhibitors or other fibrates. Such combination therapy should be used with caution in patients with severe combined dyslipidaemia and high cardiovascular risk without any history of muscular disease and patients monitored closely for chronic signs of muscle toxicity.

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 9023X *NP* | fenofibrate 145 mg tablet, 30 | 1 | 5 | .. | 41.96 | 36.10 | | Lipidil | AB |
| 9022W *NP* | fenofibrate 48 mg tablet, 60 | 1 | 5 | .. | 30.26 | 31.39 | | Lipidil | AB |

**FENOFIBRATE**

**Restricted benefit**

For use in patients who meet the criteria set out in the General Statement for Lipid-Lowering Drugs, and who are receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements

**Note**

The risk of serious muscle toxicity is increased if fenofibrate is used concomitantly with HMG CoA reductase inhibitors or other fibrates. Such

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|---|
| | combination therapy should be used with caution in patients with severe combined dyslipidaemia and high cardiovascular risk without any history of muscular disease and patients monitored closely for chronic signs of muscle toxicity. | | | | | | | | |
| | **Note**<br>No applications for increased maximum quantities and/or repeats will be authorised. | | | | | | | | |
| 9247Q | fenofibrate 145 mg tablet, 30 | 1 | 11 | .. | 41.96 | 36.10 | | Lipidil | AB |
| 9246P | fenofibrate 48 mg tablet, 60 | 1 | 11 | .. | 30.26 | 31.39 | | Lipidil | AB |
| | **GEMFIBROZIL**<br>**Restricted benefit**<br>For use in patients that meet the criteria set out in the General Statement for Lipid-Lowering Drugs | | | | | | | | |
| | **Note**<br>The risk of serious muscle toxicity is increased if gemfibrozil is used concomitantly with HMG CoA reductase inhibitors or other fibrates. Such combination therapy should be used with caution in patients with severe combined dyslipidaemia and high cardiovascular risk without any history of muscular disease and patients monitored closely for chronic signs of muscle toxicity. | | | | | | | | |
| 1453L<br>*NP* | gemfibrozil 600 mg tablet, 60 | 1 | 5 | .. | 19.41 | 20.54 | [a] | Ausgem | QA |
| | | | | | | | [a] | Chem mart Gemfibrozil | CH |
| | | | | | | | [a] | Gemfibrozil-GA | GM |
| | | | | | | | [a] | Gemhexal | SZ |
| | | | | | | | [a] | GenRx Gemfibrozil | GX |
| | | | | | | | [a] | Jezil | GN |
| | | | | | | | [a] | Lipigem | AF |
| | | | | | | | [a] | Terry White Chemists Gemfibrozil | TW |
| | | | | [B]1.62 | 21.03 | 20.54 | [a] | Lopid | PF |
| | **GEMFIBROZIL**<br>**Restricted benefit**<br>For use in patients who meet the criteria set out in the General Statement for Lipid-Lowering Drugs, and who are receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements | | | | | | | | |
| | **Note**<br>The risk of serious muscle toxicity is increased if gemfibrozil is used concomitantly with HMG CoA reductase inhibitors or other fibrates. Such combination therapy should be used with caution in patients with severe combined dyslipidaemia and high cardiovascular risk without any history of muscular disease and patients monitored closely for chronic signs of muscle toxicity. | | | | | | | | |
| | **Note**<br>No applications for increased maximum quantities and/or repeats will be authorised. | | | | | | | | |
| 9248R | gemfibrozil 600 mg tablet, 60 | 1 | 11 | .. | 19.41 | 20.54 | [a] | Ausgem | QA |
| | | | | | | | [a] | Chem mart Gemfibrozil | CH |
| | | | | | | | [a] | Gemfibrozil-GA | GM |
| | | | | | | | [a] | Gemhexal | SZ |
| | | | | | | | [a] | GenRx Gemfibrozil | GX |
| | | | | | | | [a] | Jezil | GN |
| | | | | | | | [a] | Lipigem | AF |
| | | | | | | | [a] | Terry White Chemists Gemfibrozil | TW |
| | | | | [B]1.62 | 21.03 | 20.54 | [a] | Lopid | PF |
| | ***Bile acid sequestrants*** | | | | | | | | |
| | **CHOLESTYRAMINE** | | | | | | | | |
| 2967E<br>*NP* | cholestyramine 4 g oral liquid: powder for, 50 x 4.7 g sachets | 2 | 5 | .. | *72.15 | 36.10 | | Questran Lite | QA |
| | **CHOLESTYRAMINE**<br>**Restricted benefit**<br>For use in patients who are receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements | | | | | | | | |
| | **Note**<br>No applications for increased maximum quantities and/or repeats will be authorised. | | | | | | | | |
| 9249T | cholestyramine 4 g oral liquid: powder for, 50 x 4.7 g sachets | 2 | 11 | .. | *72.15 | 36.10 | | Questran Lite | QA |
| | **COLESTIPOL HYDROCHLORIDE** | | | | | | | | |
| 1224K | colestipol hydrochloride 5 g granules, | ‡1 | 5 | .. | 85.25 | 36.10 | | Colestid | PF |

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|
| *NP* | 120 x 5 g sachets | | | | | | | |

**COLESTIPOL HYDROCHLORIDE**

**Restricted benefit**

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

**Note**

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

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 9250W | colestipol hydrochloride 5 g granules, 120 x 5 g sachets | ‡1 | 11 | .. | 85.25 | 36.10 | Colestid | PF |

## *Other lipid modifying agents*

**EZETIMIBE**

**Authority required (STREAMLINED)**

***3724***

Treatment, in conjunction with dietary therapy and exercise, for co-administration with an HMG CoA reductase inhibitor (statin) in patients whose cholesterol levels are inadequately controlled with a statin and who have coronary heart disease. Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated

**Authority required (STREAMLINED)**

***3725***

Treatment, in conjunction with dietary therapy and exercise, for co-administration with an HMG CoA reductase inhibitor (statin) in patients whose cholesterol levels are inadequately controlled with a statin and who have diabetes mellitus. Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated

**Authority required (STREAMLINED)**

***3726***

Treatment, in conjunction with dietary therapy and exercise, for co-administration with an HMG CoA reductase inhibitor (statin) in patients whose cholesterol levels are inadequately controlled with a statin and who have peripheral vascular disease. Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated

**Authority required (STREAMLINED)**

***3727***

Treatment, in conjunction with dietary therapy and exercise, for co-administration with an HMG CoA reductase inhibitor (statin) in patients whose cholesterol levels are inadequately controlled with a statin and who have heterozygous familial hypercholesterolaemia. Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the

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cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated

**Authority required (STREAMLINED)**

***3728***

Treatment, in conjunction with dietary therapy and exercise, for co-administration with an HMG CoA reductase inhibitor (statin) in patients whose cholesterol levels are inadequately controlled with a statin and who have symptomatic cerebrovascular disease. Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated

**Authority required (STREAMLINED)**

***3729***

Treatment, in conjunction with dietary therapy and exercise, for co-administration with an HMG CoA reductase inhibitor (statin) in patients whose cholesterol levels are inadequately controlled with a statin and who have family history of coronary heart disease. Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated

**Authority required (STREAMLINED)**

***3730***

Treatment, in conjunction with dietary therapy and exercise, for co-administration with an HMG CoA reductase inhibitor (statin) in patients whose cholesterol levels are inadequately controlled with a statin and who have hypertension. Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated

**Authority required (STREAMLINED)**

***1989***

Patients eligible for PBS-subsidised lipid-lowering medication (according to the criteria set out in the General Statement for Lipid-Lowering Drugs) where treatment with an HMG CoA reductase inhibitor (statin) is contraindicated

**Authority required (STREAMLINED)**

***3731***

Patients eligible for PBS-subsidised lipid-lowering medication (according to the criteria set out in the General Statement for Lipid-Lowering Drugs) where treatment with an HMG CoA reductase inhibitor (statin) must be discontinued or reduced because the patient developed a clinically important product-related adverse event during treatment with a statin.

A clinically important product-related adverse event is defined as follows:

(i) Severe myalgia (muscle symptoms without creatine kinase elevation) which is proven to be temporally associated with statin treatment; or

(ii) Myositis (clinically important creatine kinase elevation, with or without muscle symptoms) demonstrated by results twice the upper limit of

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normal on a single reading or a rising pattern on consecutive measurements and which is unexplained by other causes; or

(iii) Unexplained, persistent elevations of serum transaminases (greater than 3 times the upper limit of normal) during treatment with a statin

**Authority required (STREAMLINED)**

***1991***

Homozygous sitosterolaemia

**Authority required (STREAMLINED)**

***2438***

Patients with homozygous familial hypercholesterolaemia who are eligible for PBS-subsidised lipid-lowering medication (according to the criteria set out in the General Statement for Lipid-Lowering Drugs), in combination with an HMG CoA reductase inhibitor (statin)

**Note**

Continuing Therapy Only:

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

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|---|---|---|---|---|---|---|---|---|
| 8757X *NP* | ezetimibe 10 mg tablet, 30 | 1 | 5 | .. | 71.18 | 36.10 | Ezetrol | MK |

## LIPID MODIFYING AGENTS, COMBINATIONS

### *HMG CoA reductase inhibitors in combination with other lipid modifying agents*

**EZETIMIBE + SIMVASTATIN**

**Authority required (STREAMLINED)**

***4068***

Hypercholesterolaemia

**The Clinical criteria is:**

The treatment must be in conjunction with dietary therapy and exercise,

**AND the Clinical criteria is:**

Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin),

**AND the Clinical criteria is:**

Patient must have coronary heart disease.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

**Authority required (STREAMLINED)**

***4085***

Hypercholesterolaemia

**The Clinical criteria is:**

The treatment must be in conjunction with dietary therapy and exercise,

**AND the Clinical criteria is:**

Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin),

**AND the Clinical criteria is:**

Patient must have diabetes mellitus.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which

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shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

**Authority required (STREAMLINED)**

***4086***

Hypercholesterolaemia

**The Clinical criteria is:**

The treatment must be in conjunction with dietary therapy and exercise,

**AND the Clinical criteria is:**

Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin),

**AND the Clinical criteria is:**

Patient must have peripheral vascular disease.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

**Authority required (STREAMLINED)**

***4069***

Hypercholesterolaemia

**The Clinical criteria is:**

The treatment must be in conjunction with dietary therapy and exercise,

**AND the Clinical criteria is:**

Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin),

**AND the Clinical criteria is:**

Patient must have heterozygous familial hypercholesterolaemia.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

**Authority required (STREAMLINED)**

***4096***

Hypercholesterolaemia

**The Clinical criteria is:**

The treatment must be in conjunction with dietary therapy and exercise,

**AND the Clinical criteria is:**

Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin),

**AND the Clinical criteria is:**

Patient must have symptomatic cerebrovascular disease.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a

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maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

**Authority required (STREAMLINED)**

***4120***

Hypercholesterolaemia

**The Clinical criteria is:**

The treatment must be in conjunction with dietary therapy and exercise,

**AND the Clinical criteria is:**

Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin),

**AND the Clinical criteria is:**

Patient must have a family history of coronary heart disease.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

**Authority required (STREAMLINED)**

***4121***

Hypercholesterolaemia

**The Clinical criteria is:**

The treatment must be in conjunction with dietary therapy and exercise,

**AND the Clinical criteria is:**

Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin),

**AND the Clinical criteria is:**

Patient must have hypertension.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

**Authority required (STREAMLINED)**

***4097***

Hypercholesterolaemia

**The Clinical criteria is:**

Patient must have homozygous familial hypercholesterolaemia,

**AND the Clinical criteria is:**

Patient must be eligible for PBS-subsidised lipid-lowering medication (according to the criteria set out in the General Statement for Lipid-Lowering Drugs).

**Authority required (STREAMLINED)**

***4147***

Hypercholesterolaemia

**The Clinical criteria is:**

Patient must be eligible for PBS-subsidised lipid-lowering medication (according to the criteria set out in the General Statement for Lipid-Lowering Drugs),

**AND the Clinical criteria is:**

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| | Patient must have developed a clinically important product-related adverse event during treatment with an HMG CoA reductase inhibitor (statin) necessitating a reduction in the statin dose.<br>A clinically important product-related adverse event is defined as follows:<br>(i) Severe myalgia (muscle symptoms without creatine kinase elevation) which is proven to be temporally associated with statin treatment; or<br>(ii) Myositis (clinically important creatine kinase elevation, with or without muscle symptoms) demonstrated by results twice the upper limit of normal on a single reading or a rising pattern on consecutive measurements and which is unexplained by other causes; or<br>(iii) Unexplained, persistent elevations of serum transaminases (greater than 3 times the upper limit of normal) during treatment with a statin.<br>**Note**<br>**Continuing Therapy Only:**<br>For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners. | | | | | | | |
| 9483D<br>*NP* | ezetimibe 10 mg + simvastatin 10 mg tablet, 30 | 1 | 5 | .. | 89.00 | 36.10 | Vytorin | MK |
| 9484E<br>*NP* | ezetimibe 10 mg + simvastatin 20 mg tablet, 30 | 1 | 5 | .. | 96.80 | 36.10 | Vytorin | MK |

**EZETIMIBE + SIMVASTATIN**

**Authority required (STREAMLINED)**

***4068***

Hypercholesterolaemia

**The Clinical criteria is:**

The treatment must be in conjunction with dietary therapy and exercise,

**AND the Clinical criteria is:**

Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin),

**AND the Clinical criteria is:**

Patient must have coronary heart disease.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

**Authority required (STREAMLINED)**

***4085***

Hypercholesterolaemia

**The Clinical criteria is:**

The treatment must be in conjunction with dietary therapy and exercise,

**AND the Clinical criteria is:**

Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin),

**AND the Clinical criteria is:**

Patient must have diabetes mellitus.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

**Authority required (STREAMLINED)**

***4086***

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | Brand Name and Manufacturer |
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Hypercholesterolaemia

**The Clinical criteria is:**

The treatment must be in conjunction with dietary therapy and exercise,

**AND the Clinical criteria is:**

Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin),

**AND the Clinical criteria is:**

Patient must have peripheral vascular disease.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

**Authority required (STREAMLINED)**

***4069***

Hypercholesterolaemia

**The Clinical criteria is:**

The treatment must be in conjunction with dietary therapy and exercise,

**AND the Clinical criteria is:**

Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin),

**AND the Clinical criteria is:**

Patient must have heterozygous familial hypercholesterolaemia.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

**Authority required (STREAMLINED)**

***4096***

Hypercholesterolaemia

**The Clinical criteria is:**

The treatment must be in conjunction with dietary therapy and exercise,

**AND the Clinical criteria is:**

Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin),

**AND the Clinical criteria is:**

Patient must have symptomatic cerebrovascular disease.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|

**Authority required (STREAMLINED)**

***4120***

Hypercholesterolaemia

**The Clinical criteria is:**

The treatment must be in conjunction with dietary therapy and exercise,

**AND the Clinical criteria is:**

Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin),

**AND the Clinical criteria is:**

Patient must have a family history of coronary heart disease.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

**Authority required (STREAMLINED)**

***4121***

Hypercholesterolaemia

**The Clinical criteria is:**

The treatment must be in conjunction with dietary therapy and exercise,

**AND the Clinical criteria is:**

Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin),

**AND the Clinical criteria is:**

Patient must have hypertension.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

**Authority required (STREAMLINED)**

***4097***

Hypercholesterolaemia

**The Clinical criteria is:**

Patient must have homozygous familial hypercholesterolaemia,

**AND the Clinical criteria is:**

Patient must be eligible for PBS-subsidised lipid-lowering medication (according to the criteria set out in the General Statement for Lipid-Lowering Drugs).

**Note**

**Continuing Therapy Only:**

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

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 8881K *NP* | ezetimibe 10 mg + simvastatin 40 mg tablet, 30 | 1 | 5 | .. | 108.06 | 36.10 | Vytorin | MK |
| 8882L *NP* | ezetimibe 10 mg + simvastatin 80 mg tablet, 30 | 1 | 5 | .. | 124.18 | 36.10 | Vytorin | MK |

## *HMG CoA reductase inhibitors, other combinations*

**AMLODIPINE + ATORVASTATIN**

# CARDIOVASCULAR SYSTEM

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|---|
| | **Restricted benefit**<br>For use in patients who have hypertension and/or angina and who meet the criteria set out in the General Statement for Lipid-Lowering Drugs, and who are currently receiving treatment with a dihydropyridine calcium channel blocker | | | | | | | | |
| | **Restricted benefit**<br>For use in patients who have hypertension and/or angina and who meet the criteria set out in the General Statement for Lipid-Lowering Drugs, and whose blood pressure and/or angina is inadequately controlled with other classes of antihypertensive and/or anti-anginal agent, and in whom adjunctive therapy with a dihydropyridine calcium channel blocker would be appropriate | | | | | | | | |
| | **Restricted benefit**<br>For use in patients who have hypertension and/or angina and who meet the criteria set out in the General Statement for Lipid-Lowering Drugs, and who are intolerant of the side effects of other classes of antihypertensive and/or anti-anginal agent, and in whom replacement therapy with a dihydropyridine calcium channel blocker would be appropriate | | | | | | | | |
| 9053L<br>*NP* | amlodipine 10 mg + atorvastatin 10 mg tablet, 30 | 1 | 5 | .. | 45.51 | 36.10 | [a] | Cadatin 10/10 | FZ |
| | | | | | | | [a] | Caduet 10/10 | PF |
| 9054M<br>*NP* | amlodipine 10 mg + atorvastatin 20 mg tablet, 30 | 1 | 5 | .. | 58.41 | 36.10 | [a] | Cadatin 10/20 | FZ |
| | | | | | | | [a] | Caduet 10/20 | PF |
| 9055N<br>*NP* | amlodipine 10 mg + atorvastatin 40 mg tablet, 30 | 1 | 5 | .. | 76.10 | 36.10 | [a] | Cadatin 10/40 | FZ |
| | | | | | | | [a] | Caduet 10/40 | PF |
| 9056P<br>*NP* | amlodipine 10 mg + atorvastatin 80 mg tablet, 30 | 1 | 5 | .. | 102.30 | 36.10 | [a] | Cadatin 10/80 | FZ |
| | | | | | | | [a] | Caduet 10/80 | PF |
| 9049G<br>*NP* | amlodipine 5 mg + atorvastatin 10 mg tablet, 30 | 1 | 5 | .. | 42.21 | 36.10 | [a] | Cadatin 5/10 | FZ |
| | | | | | | | [a] | Caduet 5/10 | PF |
| 9050H<br>*NP* | amlodipine 5 mg + atorvastatin 20 mg tablet, 30 | 1 | 5 | .. | 54.90 | 36.10 | [a] | Cadatin 5/20 | FZ |
| | | | | | | | [a] | Caduet 5/20 | PF |
| 9051J<br>*NP* | amlodipine 5 mg + atorvastatin 40 mg tablet, 30 | 1 | 5 | .. | 72.47 | 36.10 | [a] | Cadatin 5/40 | FZ |
| | | | | | | | [a] | Caduet 5/40 | PF |
| 9052K<br>*NP* | amlodipine 5 mg + atorvastatin 80 mg tablet, 30 | 1 | 5 | .. | 98.67 | 36.10 | [a] | Cadatin 5/80 | FZ |
| | | | | | | | [a] | Caduet 5/80 | PF |

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|

# DERMATOLOGICALS

## ANTIFUNGALS FOR DERMATOLOGICAL USE

### ANTIFUNGALS FOR TOPICAL USE

#### *Antibiotics*

**NYSTATIN**

**Authority required (STREAMLINED)**

***2354***

Treatment of a fungal or a yeast infection in an Aboriginal or a Torres Strait Islander person

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 1698J *NP* | nystatin 100 000 international units/g cream, 15 g | 2 | 3 | .. | *18.77 | 19.90 | Mycostatin | FM |

#### *Imidazole and triazole derivatives*

**KETOCONAZOLE**

**Authority required (STREAMLINED)**

***2354***

Treatment of a fungal or a yeast infection in an Aboriginal or a Torres Strait Islander person

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 9025B *NP* | ketoconazole 1% (10 mg/g) application, 100 mL | ‡1 | 1 | .. | 17.81 | 18.94 | Nizoral 1% | JT |
| 1574W *NP* | ketoconazole 2% (20 mg/g) application, 60 mL | ‡1 | 1 | .. | 18.52 | 19.65 | Nizoral 2% | JT |
| 9024Y *NP* | ketoconazole 2% (20 mg/g) cream, 30 g | ‡1 | 2 | .. | 23.33 | 24.46 | Nizoral 2% Cream | JT |

**MICONAZOLE**

**Authority required (STREAMLINED)**

***2354***

Treatment of a fungal or a yeast infection in an Aboriginal or a Torres Strait Islander person

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 9031H *NP* | miconazole 2% (20 mg/mL) lotion, 30 mL | ‡1 | 2 | .. | 19.68 | 20.81 | Daktarin | JT |
| 9026C *NP* | miconazole nitrate 2% (20 mg/g) cream, 15 g | 2 | 3 | .. | *16.11 | 17.24 | Daktarin | JT |
| 9027D *NP* | miconazole nitrate 2% (20 mg/g) cream, 30 g | ‡1 | 2 | .. | 15.00 | 16.13 | Daktarin | JT |
| 9028E *NP* | miconazole nitrate 2% (20 mg/g) cream, 70 g | ‡1 | 1 | .. | 17.00 | 18.13 | Daktarin | JT |
| 9029F *NP* | miconazole nitrate 2% (20 mg/g) powder: dusting, 30 g | ‡1 | 2 | .. | 15.77 | 16.90 | Daktarin | JT |
| 9030G *NP* | miconazole nitrate 2% (20 mg/mL) lotion, 30 g | ‡1 | 2 | .. | 16.93 | 18.06 | Daktarin | JT |

#### *Other antifungals for topical use*

**TERBINAFINE**

**Authority required (STREAMLINED)**

***2354***

Treatment of a fungal or a yeast infection in an Aboriginal or a Torres Strait Islander person

**Authority required (STREAMLINED)**

***3243***

Treatment of a fungal or a yeast infection in a patient aged up to 18 years inclusive

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 9160D *NP* | terbinafine hydrochloride 1% (10 mg/g) cream, 15 g | 2 | 3 | .. | *37.57 | 36.10 | Lamisil | NC |

### ANTIFUNGALS FOR SYSTEMIC USE

#### *Antifungals for systemic use*

**GRISEOFULVIN**

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 1460W *NP* | griseofulvin 125 mg tablet, 100 | 1 | 2 | .. | 26.08 | 27.21 | Grisovin | QA |
| 2982Y *NP* | griseofulvin 500 mg tablet, 28 | 1 | 2 | .. | 27.20 | 28.33 | Grisovin 500 | QA |

**TERBINAFINE**

**Authority required**

# DERMATOLOGICALS

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|---|
| | Treatment of a dermatophyte infection in an Aboriginal or a Torres Strait Islander person where topical treatment has failed | | | | | | | | |
| | **Authority required** | | | | | | | | |
| | Treatment of a dermatophyte infection in a patient aged up to 18 years inclusive where topical treatment and griseofulvin have failed | | | | | | | | |
| 2285G *NP* | terbinafine 250 mg tablet, 42 | 1 | .. | .. | 53.50 | 36.10 | [a] | GenRx Terbinafine | GX |
| | | | | | | | [a] | Lamisil (Novartis Pharmaceuticals Australia Pty Limited) | NV |
| | | | | | | | [a] | Pharmacy Choice Terbinafine | RI |
| | | | | | | | [a] | Sebifin 250 | RA |
| | | | | | | | [a] | Tamsil | QA |
| | | | | | | | [a] | Terbinafine-DRLA | RZ |
| | | | | | | | [a] | Terbinafine-GA | GM |
| | | | | | | | [a] | Terbinafine Sandoz | SZ |
| | | | | | | | [a] | Tinasil | AF |
| | **TERBINAFINE** | | | | | | | | |
| | **Authority required** | | | | | | | | |
| | Proximal or extensive (greater than 80% nail involvement) onychomycosis due to dermatophyte infection where topical treatment has failed. This infection must be proven by microscopy or culture and confirmed by an Approved Pathology Authority. The date of the pathology report must be provided at the time of application and must not be more than 12 months old | | | | | | | | |
| | **Note** | | | | | | | | |
| | No applications for increased maximum quantities and/or repeats will be authorised. | | | | | | | | |
| 2804N *NP* | terbinafine 250 mg tablet, 42 | 1 | 1 | .. | 53.50 | 36.10 | [a] | GenRx Terbinafine | GX |
| | | | | | | | [a] | Lamisil (Novartis Pharmaceuticals Australia Pty Limited) | NV |
| | | | | | | | [a] | Pharmacy Choice Terbinafine | RI |
| | | | | | | | [a] | Sebifin 250 | RA |
| | | | | | | | [a] | Tamsil | QA |
| | | | | | | | [a] | Terbinafine-DRLA | RZ |
| | | | | | | | [a] | Terbinafine-GA | GM |
| | | | | | | | [a] | Terbinafine Sandoz | SZ |
| | | | | | | | [a] | Tinasil | AF |

## ANTIPSORIATICS

### ANTIPSORIATICS FOR TOPICAL USE

#### *Tars*

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | **COAL TAR PREPARED** | | | | | | | | |
| 8864M *NP* | coal tar prepared 1% (10 mg/g) lotion, 100 mL | ‡1 | 2 | .. | 33.29 | 34.42 | | Exorex | GM |

#### *Other antipsoriatics for topical use*

**BETAMETHASONE DIPROPIONATE + CALCIPOTRIOL**

**Restricted benefit**

Chronic stable plaque type psoriasis vulgaris of the scalp in a patient who is not adequately controlled with either calcipotriol or potent topical corticosteroid monotherapy

**Note**

Continuing Therapy Only:

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

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 5276Q *NP* | betamethasone (as dipropionate) 0.05% + calcipotriol 0.005% gel, 30 g | ‡1 | 1 | .. | 42.10 | 36.10 | | Daivobet 50/500 gel | LO |

**BETAMETHASONE DIPROPIONATE + CALCIPOTRIOL**

**Restricted benefit**

Chronic stable plaque type psoriasis vulgaris in a patient who is not adequately controlled with either calcipotriol or potent topical corticosteroid monotherapy

**Note**

# DERMATOLOGICALS

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|---|
| | Continuing Therapy Only: | | | | | | | | |
| | For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners. | | | | | | | | |
| 9494Q *NP* | betamethasone (as dipropionate) 0.05% + calcipotriol 0.005% ointment, 30 g | ‡1 | 1 | .. | 42.10 | 36.10 | | Daivobet | LO |

**CALCIPOTRIOL**
**Restricted benefit**
Chronic stable plaque type psoriasis vulgaris

**Note**
Continuing Therapy Only:

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

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 2080L *NP* | calcipotriol 0.005% (50 microgram/g) cream, 30 g | ‡1 | 1 | .. | 28.27 | 29.40 | | Daivonex | LO |

## ANTIPSORIATICS FOR SYSTEMIC USE
### *Retinoids for treatment of psoriasis*

**ACITRETIN**
**Authority required (STREAMLINED)**
***1366***
Severe intractable psoriasis

**Authority required (STREAMLINED)**
***1363***
Severe forms of disorders of keratinisation

**Caution**
This drug is a potent teratogen—pregnancy should be avoided for at least two years after cessation of therapy.

**Note**
Care must be taken to comply with the provisions of State/Territory law when prescribing acitretin.

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 2019G | acitretin 10 mg capsule, 100 | 1 | 2 | .. | 205.98 | 36.10 | | Neotigason | TA |
| 2020H | acitretin 25 mg capsule, 100 | 1 | 2 | .. | 393.42 | 36.10 | | Neotigason | TA |

## ANTIBIOTICS AND CHEMOTHERAPEUTICS FOR DERMATOLOGICAL USE

## CHEMOTHERAPEUTICS FOR TOPICAL USE
### *Sulfonamides*

**SULFADIAZINE SILVER**
**Restricted benefit**
Prevention and treatment of infection in partial or full skin thickness loss due to burns

**Restricted benefit**
Prevention and treatment of infection in partial or full skin thickness loss due to epidermolysis bullosa

**Restricted benefit**
Stasis ulcers

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 9479X *NP* | sulfadiazine silver 1% (10 mg/g) cream, 50 g | ‡1 | .. | .. | 19.36 | 20.49 | | Flamazine | SN |

## CORTICOSTEROIDS, DERMATOLOGICAL PREPARATIONS

## CORTICOSTEROIDS, PLAIN
### *Corticosteroids, weak (group I)*

**HYDROCORTISONE ACETATE**
**Restricted benefit**
Treatment of corticosteroid-responsive dermatoses

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 2887Y *NP* | hydrocortisone acetate 1% (10 mg/g) cream, 30 g | ‡1 | 1 | .. | 9.10 | 10.23 | a | Cortic-DS 1% | FM |
| | | | | [B]2.69 | 11.79 | 10.23 | a | Sigmacort | QA |
| 5111B *DP* | hydrocortisone acetate 1% (10 mg/g) cream, 30 g | ‡1 | .. | .. | 9.10 | 10.23 | a | Cortic-DS 1% | FM |
| | | | | [B]2.69 | 11.79 | 10.23 | a | Sigmacort | QA |
| 2881P | hydrocortisone acetate 1% (10 mg/g) | ‡1 | 1 | .. | 8.77 | 9.90 | a | Cortic-DS 1% | FM |

# DERMATOLOGICALS

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|---|
| *NP* | cream, 50 g | | | | | | | | |
| | | | | [B]2.70 | 11.47 | 9.90 | [a] | Sigmacort | QA |
| 5113D | hydrocortisone acetate 1% (10 mg/g) | ‡1 | .. | .. | 8.77 | 9.90 | [a] | Cortic-DS 1% | FM |
| *DP* | cream, 50 g | | | | | | | | |
| | | | | [B]2.70 | 11.47 | 9.90 | [a] | Sigmacort | QA |
| 2888B | hydrocortisone acetate 1% (10 mg/g) | ‡1 | 1 | .. | 9.10 | 10.23 | [a] | Cortic-DS 1% | FM |
| *NP* | ointment, 30 g | | | | | | | | |
| | | | | [B]2.69 | 11.79 | 10.23 | [a] | Sigmacort | QA |
| 5112C | hydrocortisone acetate 1% (10 mg/g) | ‡1 | .. | .. | 9.10 | 10.23 | [a] | Cortic-DS 1% | FM |
| *DP* | ointment, 30 g | | | | | | | | |
| | | | | [B]2.69 | 11.79 | 10.23 | [a] | Sigmacort | QA |
| 2882Q | hydrocortisone acetate 1% (10 mg/g) | ‡1 | 1 | .. | 8.77 | 9.90 | [a] | Cortic-DS 1% | FM |
| *NP* | ointment, 50 g | | | | | | | | |
| | | | | [B]2.70 | 11.47 | 9.90 | [a] | Sigmacort | QA |
| 5114E | hydrocortisone acetate 1% (10 mg/g) | ‡1 | .. | .. | 8.77 | 9.90 | [a] | Cortic-DS 1% | FM |
| *DP* | ointment, 50 g | | | | | | | | |
| | | | | [B]2.70 | 11.47 | 9.90 | [a] | Sigmacort | QA |

## *Corticosteroids, moderately potent (group II)*

**TRIAMCINOLONE**

**Restricted benefit**

Treatment of corticosteroid-responsive dermatoses

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 2117K | triamcinolone acetonide 0.02% (200 | 2 | .. | .. | *14.61 | 15.74 | [a] | Tricortone | FM |
| *NP* | microgram/g) cream, 100 g | | | | | | | | |
| | | | | [B]3.78 | *18.39 | 15.74 | [a] | Aristocort 0.02% | QA |
| 2118L | triamcinolone acetonide 0.02% (200 | 2 | .. | .. | *14.61 | 15.74 | [a] | Tricortone | FM |
| *NP* | microgram/g) ointment, 100 g | | | | | | | | |
| | | | | [B]3.78 | *18.39 | 15.74 | [a] | Aristocort 0.02% | QA |

## *Corticosteroids, potent (group III)*

**BETAMETHASONE DIPROPIONATE**

**Restricted benefit**

Treatment of corticosteroid-responsive dermatoses

**Note**

Continuing Therapy Only:

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

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 1115Q | betamethasone (as dipropionate) 0.05% | ‡1 | 1 | .. | 13.35 | 14.48 | [a] | Eleuphrat | FR |
| *NP* | (500 microgram/g) cream, 15 g | | | | | | | | |
| | | | | [B]2.45 | 15.80 | 14.48 | [a] | Diprosone | MK |
| 1119X | betamethasone (as dipropionate) 0.05% | ‡1 | 1 | .. | 13.35 | 14.48 | [a] | Eleuphrat | FR |
| *NP* | (500 microgram/g) ointment, 15 g | | | | | | | | |
| | | | | [B]2.45 | 15.80 | 14.48 | [a] | Diprosone | MK |

**BETAMETHASONE VALERATE**

**Restricted benefit**

Treatment of corticosteroid-responsive dermatoses

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 2812B | betamethasone (as valerate) 0.02% (200 | 2 | .. | .. | *24.43 | 25.56 | [b] | Antroquoril | FR |
| *NP* | microgram/g) cream, 100 g | | | | | | | | |
| | | | | | | | [a] | Cortival 1/5 | FM |
| | | | | [B]2.46 | *26.89 | 25.56 | [b] | Celestone-M | MK |
| | | | | [B]6.88 | *31.31 | 25.56 | [a] | Betnovate 1/5 | QA |

**BETAMETHASONE VALERATE**

**Restricted benefit**

Treatment of corticosteroid-responsive dermatoses

**Note**

Continuing Therapy Only:

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

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 2813C | betamethasone (as valerate) 0.05% (500 | ‡1 | 1 | .. | 8.62 | 9.75 | [a] | Cortival 1/2 | FM |
| *NP* | microgram/g) cream, 15 g | | | | | | | | |
| | | | | [B]2.94 | 11.56 | 9.75 | [a] | Betnovate 1/2 | QA |

# DERMATOLOGICALS

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|---|
| | **METHYLPREDNISOLONE**<br>**Restricted benefit**<br>Treatment of corticosteroid-responsive dermatoses<br>**Note**<br>Continuing Therapy Only:<br>For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners. | | | | | | | | |
| 8054X<br>*NP* | methylprednisolone aceponate 0.1% (1 mg/g) cream, 15 g | ‡1 | .. | .. | 14.19 | 15.32 | | Advantan | CS |
| 8055Y<br>*NP* | methylprednisolone aceponate 0.1% (1 mg/g) ointment, 15 g | ‡1 | .. | .. | 14.19 | 15.32 | | Advantan | CS |
| 8128T<br>*NP* | methylprednisolone aceponate 0.1% (1 mg/g) ointment, 15 g | ‡1 | .. | .. | 14.19 | 15.32 | | Advantan | CS |
| | **METHYLPREDNISOLONE**<br>**Restricted benefit**<br>Eczema<br>**Note**<br>Continuing Therapy Only:<br>For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners. | | | | | | | | |
| 8618N<br>*NP* | methylprednisolone aceponate 0.1% (1 mg/g) lotion, 20 g | ‡1 | .. | .. | 14.86 | 15.99 | | Advantan | CS |
| | **MOMETASONE**<br>**Restricted benefit**<br>Treatment of corticosteroid-responsive dermatoses<br>**Note**<br>Continuing Therapy Only:<br>For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners. | | | | | | | | |
| 1913Q<br>*NP* | mometasone furoate 0.1% (1 mg/g) cream, 15 g | ‡1 | .. | .. | 12.92 | 14.05 | a | Novasone | FR |
| | | | | [B]2.90 | 15.82 | 14.05 | a | Elocon | MK |
| 8043H<br>*NP* | mometasone furoate 0.1% (1 mg/g) lotion, 30 mL | ‡1 | .. | .. | 16.54 | 17.67 | a | Novasone | FR |
| | | | | | | | a | Zatamil | EO |
| | | | | [B]2.91 | 19.45 | 17.67 | a | Elocon | MK |
| 1915T<br>*NP* | mometasone furoate 0.1% (1 mg/g) ointment, 15 g | ‡1 | .. | .. | 12.92 | 14.05 | a | Novasone | FR |
| | | | | | | | a | Zatamil | EO |
| | | | | [B]2.90 | 15.82 | 14.05 | a | Elocon | MK |

## ANTI-ACNE PREPARATIONS

### ANTI-ACNE PREPARATIONS FOR TOPICAL USE

#### *Retinoids for topical use in acne*

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | **ADAPALENE + BENZOYL PEROXIDE**<br>**Restricted benefit**<br>Acute treatment, in combination with an oral antibiotic, of severe acne vulgaris | | | | | | | | |
| 8954G | adapalene 0.1% (1 mg/g) + benzoyl peroxide 2.5% (25 mg/g) gel, 30 g | ‡1 | 1 | .. | 37.14 | 36.10 | | Epiduo | GA |
| | **ADAPALENE + BENZOYL PEROXIDE**<br>**Restricted benefit**<br>Maintenance treatment of severe acne vulgaris<br>**Note**<br>Continuing Therapy Only:<br>For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners. | | | | | | | | |
| 8955H | adapalene 0.1% (1 mg/g) + benzoyl | ‡1 | 3 | .. | 37.14 | 36.10 | | Epiduo | GA |

# DERMATOLOGICALS

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|---|
| *NP* | peroxide 2.5% (25 mg/g) gel, 30 g | | | | | | | | |

## ANTI-ACNE PREPARATIONS FOR SYSTEMIC USE

### *Retinoids for treatment of acne*

**ISOTRETINOIN**

**Authority required (STREAMLINED)**

***1354***

Severe cystic acne not responsive to other therapy

**Caution**

This drug causes birth defects. Isotretinoin has been reported to cause other frequent and potentially serious toxicity.

**Note**

Care must be taken to comply with the provisions of State/Territory law when prescribing isotretinoin.

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 2591J | isotretinoin 10 mg capsule, 60 | 1 | 3 | .. | 57.87 | 36.10 | [a] | APO-Isotretinoin | TX |
| | | | | | | | [a] | Oratane | GM |
| | | | | | | | [a] | Roaccutane | RO |
| | | | | | | | [a] | Rocta 10 | QA |
| 2592K | isotretinoin 20 mg capsule, 60 | 1 | 3 | .. | 86.49 | 36.10 | [a] | APO-Isotretinoin | TX |
| | | | | | | | [a] | GenRx Isotretinoin | GX |
| | | | | | | | [a] | Oratane | GM |
| | | | | | | | [a] | Roaccutane | RO |
| | | | | | | | [a] | Rocta 20 | QA |
| 2549E | isotretinoin 40 mg capsule, 30 | 1 | 3 | .. | 78.70 | 36.10 | | Oratane | GM |

## OTHER DERMATOLOGICAL PREPARATIONS

## OTHER DERMATOLOGICAL PREPARATIONS

### *Agents for dermatitis, excluding corticosteroids*

**PIMECROLIMUS**

**Authority required**

Treatment of facial or eyelid atopic dermatitis in patients aged at least 3 months with 1 or more of the following contraindications to topical corticosteroids:

(i) perioral dermatitis;

(ii) periorbital dermatitis;

(iii) rosacea;

(iv) epidermal atrophy;

(v) dermal atrophy;

(vi) allergy to topical corticosteroids;

(vii) cataracts;

(viii) glaucoma;

(ix) raised intraocular pressure

**Authority required**

Short-term (up to 3 weeks) intermittent treatment of atopic dermatitis of the face or eyelids in patients aged at least 3 months who fail to achieve satisfactory disease control with intermittent topical corticosteroid therapy, and where more than 3 months have passed since the initial diagnosis of atopic dermatitis.

Failure to achieve satisfactory disease control with intermittent topical corticosteroid therapy is manifest by:

(i) failure of the facial skin to clear despite at least 2 weeks of topical hydrocortisone 1% applied every day; or

(ii) failure of the facial skin to clear despite at least 1 week of a moderate or potent topical corticosteroid applied every day; or

(iii) clearing of the facial skin with at least 2 weeks of topical hydrocortisone 1% applied every day, but almost immediate and significant flare in facial disease (within 48 hours) upon stopping topical corticosteroids, occurring on at least 2 consecutive occasions; or

(iv) clearing of the facial skin with at least 1 week of a moderate or potent topical corticosteroid applied every day, but almost immediate and significant flare in facial disease (within 48 hours) upon stopping topical corticosteroids, occurring on at least 2 consecutive occasions

**Note**

No applications for increased maximum quantities and/or repeats will be authorised. Only 1 authority application per 6 months, per patient, will be authorised.

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 8802G | pimecrolimus 1% (10 mg/g) cream, 15 g | ‡1 | 1 | .. | 34.00 | 35.13 | | Elidel | HM |

### *Other dermatologicals*

**DAPSONE**

# DERMATOLOGICALS

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|---|
| | **Note**<br>Shared Care Model:<br>For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners. | | | | | | | | |
| 1272Y<br>*NP* | dapsone 100 mg tablet, 100 | 1 | 1 | .. | 114.05 | 36.10 | | Link Medical Products Pty Ltd | LM |
| 8801F<br>*NP* | dapsone 25 mg tablet, 100 | 1 | 1 | .. | 100.79 | 36.10 | | Link Medical Products Pty Ltd | LM |
| | **IMIQUIMOD**<br>**Authority required**<br>Superficial basal cell carcinoma<br>**The Clinical criteria is:**<br>The condition must be previously untreated,<br>**AND the Clinical criteria is:**<br>The condition must be confirmed by biopsy,<br>**AND the Clinical criteria is:**<br>Patient must have normal immune function,<br>**AND the Clinical criteria is:**<br>The condition must not be suitable for treatment with cryotherapy; OR<br>The condition must not be suitable for treatment with curettage with diathermy; OR<br>The condition must not be suitable for treatment with surgical excision,<br>**AND the Clinical criteria is:**<br>Patient must require topical drug therapy.<br>The date of the pathology report and name of the Approved Pathology Authority must be provided at the time of application.<br>**Note**<br>The patient or carer must be able to understand and administer the imiquimod dosing regimen.<br>**Note**<br>No increase in the maximum quantity or number of units may be authorised.<br>**Note**<br>No increase in the maximum number of repeats may be authorised.<br>**Note**<br>Treatment of recurrent (previously treated) lesions will not be authorised.<br>**Note**<br>Pharmaceutical benefits that have the form imiquimod single use sachets and pharmaceutical benefits that have the form imiquimod multi-use pump are equivalent for the purposes of substitution. | | | | | | | | |
| 2546B | imiquimod 5% (12.5 mg/250 mg) cream, 12 x 250 mg sachets | 1 | 1 | .. | 135.59 | 36.10 | [a] | Aldara | IA |
| | | | | | | | [a] | APO-Imiquimod | TX |
| 2637T | imiquimod 5% cream, 2 x 2 g pump packs | 1 | 1 | .. | 135.59 | 36.10 | [a] | Aldara Pump | IA |

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|---|

# GENITO URINARY SYSTEM AND SEX HORMONES

## OTHER GYNECOLOGICALS

### OXYTOCICS

#### *Prostaglandins*

**MISOPROSTOL**

**Authority required**

Termination of an intra-uterine pregnancy

**The Treatment criteria is:**

Must be treated by a prescriber who is registered with the MS 2 Step Prescribing Program,

**AND the Clinical criteria is:**

The condition must be an intra-uterine pregnancy of up to 49 days of gestation,

**AND the Clinical criteria is:**

The treatment must be in sequential combination with mifepristone 200 mg.

An authority prescription for mifepristone 200 mg tablet must be sought at the time of authority application.

**Note**

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

**Note**

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

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 2672P | misoprostol 200 microgram tablet, 4 | 1 | 1 | .. | 7.95 | 9.08 | | GyMiso | XH |

### CONTRACEPTIVES FOR TOPICAL USE

#### *Intrauterine contraceptives*

**LEVONORGESTREL**

**Restricted benefit**

Contraception

**Restricted benefit**

Idiopathic menorrhagia where oral treatments are ineffective

**Restricted benefit**

Idiopathic menorrhagia where oral treatments are contraindicated

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 8633J *NP* | levonorgestrel 52 mg drug delivery system: intrauterine, 1 system | 1 | .. | .. | 266.43 | 36.10 | | Mirena | BN |

### OTHER GYNECOLOGICALS

#### *Prolactine inhibitors*

**BROMOCRIPTINE**

**Restricted benefit**

Acromegaly

**Restricted benefit**

Parkinson's disease

**Restricted benefit**

Pathological hyperprolactinaemia where surgery is not indicated

**Restricted benefit**

Pathological hyperprolactinaemia where surgery has already been used with incomplete resolution

**Restricted benefit**

Pathological hyperprolactinaemia where radiotherapy is not indicated

**Restricted benefit**

Pathological hyperprolactinaemia where radiotherapy has already been used with incomplete resolution

**Note**

Care should be taken when treating patients with advanced age and significant cognitive impairment with dopamine agonists.

**Note**

For item codes 1443Y and 1559C, pharmaceutical benefits that have the form tablet 2.5 mg (base) are equivalent for the purposes of substitution.

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 1443Y | bromocriptine 2.5 mg tablet, 30 | 2 | 5 | .. | *31.63 | 32.76 | [a] | Parlodel | NV |
| 1559C | bromocriptine 2.5 mg tablet, 60 | 1 | 5 | .. | 31.63 | 32.76 | [a] | Kripton 2.5 | AF |

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|---|
| | **BROMOCRIPTINE**<br>**Restricted benefit**<br>Prevention of the onset of lactation in the puerperium for medical reasons | | | | | | | | |
| 1444B<br>*NP* | bromocriptine 2.5 mg tablet, 30 | 1 | .. | .. | 19.13 | 20.26 | [a] | Kripton 2.5 | AF |
| | | | | | | | [a] | Parlodel | NV |
| | **BROMOCRIPTINE**<br>**Restricted benefit**<br>Acromegaly<br>**Restricted benefit**<br>Parkinson's disease<br>**Restricted benefit**<br>Pathological hyperprolactinaemia where surgery is not indicated<br>**Restricted benefit**<br>Pathological hyperprolactinaemia where surgery has already been used with incomplete resolution<br>**Restricted benefit**<br>Pathological hyperprolactinaemia where radiotherapy is not indicated<br>**Restricted benefit**<br>Pathological hyperprolactinaemia where radiotherapy has already been used with incomplete resolution<br>**Note**<br>Care should be taken when treating patients with advanced age and significant cognitive impairment with dopamine agonists. | | | | | | | | |
| 1446D | bromocriptine 5 mg capsule, 60 | 1 | 5 | .. | 48.49 | 36.10 | | Kripton 5 | AF |
| | **CABERGOLINE**<br>**Restricted benefit**<br>Prevention of the onset of lactation in the puerperium for medical reasons | | | | | | | | |
| 8115D<br>*NP* | cabergoline 500 microgram tablet, 2 | 1 | .. | .. | 21.99 | 23.12 | [a] | Dostan | GM |
| | | | | | | | [a] | Dostinex | PF |
| | **CABERGOLINE**<br>**Authority required (STREAMLINED)**<br>***2659***<br>Pathological hyperprolactinaemia where surgery is not indicated<br>**Authority required (STREAMLINED)**<br>***2660***<br>Pathological hyperprolactinaemia where surgery has already been used with incomplete resolution<br>**Authority required (STREAMLINED)**<br>***2661***<br>Pathological hyperprolactinaemia where radiotherapy is not indicated<br>**Authority required (STREAMLINED)**<br>***2662***<br>Pathological hyperprolactinaemia where radiotherapy has already been used with incomplete resolution | | | | | | | | |
| 8114C | cabergoline 500 microgram tablet, 8 | 1 | 5 | .. | 65.44 | 36.10 | [a] | Dostan | GM |
| | | | | | | | [a] | Dostinex | PF |
| | | | | | | | [a] | Tinexa | QA |
| | **QUINAGOLIDE**<br>**Authority required (STREAMLINED)**<br>***2659***<br>Pathological hyperprolactinaemia where surgery is not indicated<br>**Authority required (STREAMLINED)**<br>***2660***<br>Pathological hyperprolactinaemia where surgery has already been used with incomplete resolution<br>**Authority required (STREAMLINED)**<br>***2661***<br>Pathological hyperprolactinaemia where radiotherapy is not indicated<br>**Authority required (STREAMLINED)**<br>***2662*** | | | | | | | | |

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|---|
| | Pathological hyperprolactinaemia where radiotherapy has already been used with incomplete resolution | | | | | | | | |
| 8860H | quinagolide 25 microgram tablet [3 tablets] (&) quinagolide 50 microgram tablet [3 tablets], 6 | ‡1 | .. | .. | 11.68 | 12.81 | | Norprolac | FP |
| 8822H | quinagolide 75 microgram tablet, 30 | 1 | 5 | .. | 55.00 | 36.10 | | Norprolac | FP |

## SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM

### HORMONAL CONTRACEPTIVES FOR SYSTEMIC USE

#### *Progestogens and estrogens, fixed combinations*

**ETHINYLOESTRADIOL + NORETHISTERONE**

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 2775C *NP* | ethinyloestradiol 35 microgram + norethisterone 1 mg tablet [84] (&) inert substance tablet [28], 112 [4 x 28] | 1 | 2 | .. | 16.67 | 17.80 | a | Norimin-1 28 Day | FZ |
| | | | | B7.67 | 24.34 | 17.80 | a | Brevinor-1 | PF |
| 2774B *NP* | ethinyloestradiol 35 microgram + norethisterone 500 microgram tablet [84] (&) inert substance tablet [28], 112 [4 x 28] | 1 | 2 | .. | 16.67 | 17.80 | a | Norimin 28 Day | FZ |
| | | | | B7.67 | 24.34 | 17.80 | a | Brevinor | PF |

**LEVONORGESTREL + ETHINYLOESTRADIOL**

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 2416E *NP* | levonorgestrel 100 microgram + ethinyloestradiol 20 microgram tablet [84 tablets] (&) inert substance tablet [28 tablets], 112 [4 x 28 tablets] | 1 | 2 | .. | 15.51 | 16.64 | | Femme-Tab ED 20/100 | AE |
| 1456P *NP* | levonorgestrel 125 microgram + ethinyloestradiol 50 microgram tablet [84 tablets] (&) inert substance tablet [28 tablets], 112 [4 x 28 tablets] | 1 | 2 | .. | 15.51 | 16.64 | | Microgynon 50 ED | BN |
| 1394J *NP* | levonorgestrel 150 microgram + ethinyloestradiol 30 microgram tablet [84 tablets] (&) inert substance tablet [28 tablets], 112 [4 x 28 tablets] | 1 | 2 | .. | 15.51 | 16.64 | a | Femme-Tab ED 30/150 | AE |
| | | | | | | | a | Levlen ED | SY |
| | | | | | | | b | Monofeme 28 | FZ |
| | | | | B11.37 | 26.88 | 16.64 | b | Nordette 28 | PF |
| | | | | B11.41 | 26.92 | 16.64 | a | Microgynon 30 ED | BN |

**MESTRANOL + NORETHISTERONE**

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 3179H *NP* | inert substance tablet [28] (&) mestranol 50 microgram + norethisterone 1 mg tablet [84], 112 [4 x 28] | 1 | 2 | .. | 16.67 | 17.80 | | Norinyl-1/28 | PF |

#### *Progestogens and estrogens, sequential preparations*

**ETHINYLOESTRADIOL + NORETHISTERONE**

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 2776D *NP* | ethinyloestradiol 35 microgram + norethisterone 500 microgram tablet [48] (&) ethinyloestradiol 35 microgram + norethisterone 1 mg tablet [36] (&) inert substance tablet [28], 112 [4 x 28] | 1 | 2 | .. | 16.67 | 17.80 | | Improvil 28 Day | FZ |

**LEVONORGESTREL + ETHINYLOESTRADIOL**

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 1392G *NP* | levonorgestrel 50 microgram + ethinyloestradiol 30 microgram tablet [24 tablets] (&) levonorgestrel 75 microgram + ethinyloestradiol 40 microgram tablet [20 tablets] (&) levonorgestrel 125 microgram + ethinyloestradiol 30 microgram tablet [40 tablets] (&) inert substance tablet [28 tablets], 112 [4 x 28 tablets] | 1 | 2 | .. | 15.51 | 16.64 | b | Trifeme 28 | FZ |
| | | | | | | | a | Logynon ED | SY |
| | | | | B11.37 | 26.88 | 16.64 | b | Triphasil 28 | PF |
| | | | | B11.41 | 26.92 | 16.64 | a | Triquilar ED | BN |

#### *Progestogens*

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|---|
| | **ETONOGESTREL** | | | | | | | | |
| 8487Q<br>*NP,MW* | etonogestrel 68 mg implant, 1 | 1 | .. | .. | 216.13 | 36.10 | | Implanon NXT | MK |
| | **LEVONORGESTREL** | | | | | | | | |
| 2913H<br>*NP,MW* | levonorgestrel 30 microgram tablet, 112 [4 x 28 tablets] | 1 | 2 | .. | 17.53 | 18.66 | | Microlut 28 | BN |
| | **MEDROXYPROGESTERONE** | | | | | | | | |
| 3118D<br>*NP* | medroxyprogesterone acetate 150 mg/mL injection, 1 x 1 mL vial | 1 | 1 | .. | 21.50 | 22.63 | a | Depo-Ralovera | FZ |
| | | | | B3.20 | 24.70 | 22.63 | a | Depo-Provera | PF |
| | **NORETHISTERONE** | | | | | | | | |
| 1967M<br>*NP* | norethisterone 350 microgram tablet, 112 [4 x 28] | 1 | 2 | .. | 16.67 | 17.80 | | Micronor | JC |
| | | | | | | | a | Locilan 28 Day | FZ |
| | | | | B3.90 | 20.57 | 17.80 | a | Noriday 28 Day | PF |

## ANDROGENS

### *3-oxoandrosten (4) derivatives*

**TESTOSTERONE**

**Authority required**

Androgen deficiency in males with established pituitary or testicular disorders

**Authority required**

Androgen deficiency in males 40 years and older who do not have established pituitary or testicular disorders other than aging, confirmed by at least 2 morning blood samples taken on different mornings. Androgen deficiency is confirmed by testosterone less than 8 nmol per L, or 8-15 nmol per L with high LH (greater than 1.5 times the upper limit of the eugonadal reference range for young men)

**Authority required**

Micropenis, pubertal induction, or constitutional delay of growth or puberty, in males under 18 years of age

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 8830R | testosterone 1% (50 mg/5 g) gel, 30 x 5 g sachets | ‡1 | 5 | .. | 95.33 | 36.10 | | Testogel | BN |
| 8098F | testosterone 100 mg implant, 1 | 6 | .. | .. | *209.79 | 36.10 | | Merck Sharp & Dohme (Australia) Pty Ltd | MK |
| 2341F | testosterone 2% (30 mg/1.5 mL actuation) transdermal solution, 60 actuations | ‡1 | 5 | .. | 82.66 | 36.10 | | Axiron | LY |
| 8460G | testosterone 2.5 mg/24 hours patch, 60 | ‡1 | 5 | .. | 96.05 | 36.10 | | Androderm | GM |
| 8099G | testosterone 200 mg implant, 1 | 3 | .. | .. | *209.76 | 36.10 | | Merck Sharp & Dohme (Australia) Pty Ltd | MK |
| 8619P | testosterone 5 mg/24 hours patch, 30 | ‡1 | 5 | .. | 96.05 | 36.10 | | Androderm | GM |

**TESTOSTERONE ENANTHATE**

**Authority required**

Androgen deficiency in males with established pituitary or testicular disorders

**Authority required**

Androgen deficiency in males 40 years and older who do not have established pituitary or testicular disorders other than aging, confirmed by at least 2 morning blood samples taken on different mornings. Androgen deficiency is confirmed by testosterone less than 8 nmol per L, or 8-15 nmol per L with high LH (greater than 1.5 times the upper limit of the eugonadal reference range for young men)

**Authority required**

Micropenis, pubertal induction, or constitutional delay of growth or puberty, in males under 18 years of age

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 2114G | testosterone enanthate 250 mg/mL injection, 3 x 1 mL syringes | 1 | 3 | .. | 33.69 | 34.82 | | Primoteston Depot | BN |

**TESTOSTERONE UNDECANOATE**

**Authority required**

Androgen deficiency in males with established pituitary or testicular disorders

**Authority required**

Androgen deficiency in males 40 years and older who do not have established pituitary or testicular disorders other than aging, confirmed by at least 2 morning blood samples taken on different mornings. Androgen deficiency is confirmed by testosterone less than 8 nmol per L, or 8-15 nmol per L with high LH (greater than 1.5 times the upper limit of the eugonadal reference range for young men)

**Authority required**

Micropenis, pubertal induction, or constitutional delay of growth or puberty, in males under 18 years of age

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 9004X | testosterone undecanoate 1 g/4 mL | 1 | 1 | .. | 147.62 | 36.10 | | Reandron 1000 | BN |

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|
| | injection, 1 x 4 mL ampoule | | | | | | | |
| 2115H | testosterone undecanoate 40 mg capsule, 60 | 1 | 5 | .. | 37.74 | 36.10 | Andriol Testocaps | MK |

## ESTROGENS

### *Natural and semisynthetic estrogens, plain*

**OESTRADIOL**

**Note**

Oestradiol should be used in conjunction with an oral progestogen in women with an intact uterus.

**Note**

Continuing Therapy Only:

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

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 8286D *NP* | oestradiol 0.1% (1 mg/g) gel, 28 x 1 g sachets | ǂ1 | 5 | .. | 17.30 | 18.43 | Sandrena | AS |
| 8126Q *NP* | oestradiol 100 microgram/24 hours patch, 4 | ǂ1 | 5 | .. | 19.34 | 20.47 | Climara 100 | BN |
| 8312L *NP* | oestradiol 100 microgram/24 hours patch, 8 | ǂ1 | 5 | .. | 19.34 | 20.47 | Estraderm MX 100 | NV |
| 8765H *NP* | oestradiol 100 microgram/24 hours patch, 8 | ǂ1 | 5 | .. | 19.34 | 20.47 | Estradot 100 | NV |
| 8485N *NP* | oestradiol 25 microgram/24 hours patch, 4 | ǂ1 | 5 | .. | 17.30 | 18.43 | Climara 25 | BN |
| 8311K *NP* | oestradiol 25 microgram/24 hours patch, 8 | ǂ1 | 5 | .. | 17.30 | 18.43 | Estraderm MX 25 | NV |
| 8761D *NP* | oestradiol 25 microgram/24 hours patch, 8 | ǂ1 | 5 | .. | 17.30 | 18.43 | Estradot 25 | NV |
| 8762E *NP* | oestradiol 37.5 microgram/24 hours patch, 8 | ǂ1 | 5 | .. | 17.30 | 18.43 | Estradot 37.5 | NV |
| 8125P *NP* | oestradiol 50 microgram/24 hours patch, 4 | ǂ1 | 5 | .. | 17.30 | 18.43 | Climara 50 | BN |
| 8140K *NP* | oestradiol 50 microgram/24 hours patch, 8 | ǂ1 | 5 | .. | 17.30 | 18.43 | Estraderm MX 50 | NV |
| 8763F *NP* | oestradiol 50 microgram/24 hours patch, 8 | ǂ1 | 5 | .. | 17.30 | 18.43 | Estradot 50 | NV |
| 8486P *NP* | oestradiol 75 microgram/24 hours patch, 4 | ǂ1 | 5 | .. | 19.34 | 20.47 | Climara 75 | BN |
| 8764G *NP* | oestradiol 75 microgram/24 hours patch, 8 | ǂ1 | 5 | .. | 19.34 | 20.47 | Estradot 75 | NV |

**OESTRADIOL**

**Note**

Continuing Therapy Only:

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

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 8274L *NP* | oestradiol 2 mg tablet, 56 | 1 | 2 | .. | 13.76 | 14.89 | Zumenon | AB |
| 1742Q *NP* | oestradiol 25 microgram pessary: modified release, 15 | ǂ1 | 2 | .. | 26.99 | 28.12 | Vagifem | NO |
| 1663M *NP* | oestradiol valerate 1 mg tablet, 56 | 1 | 2 | .. | 11.89 | 13.02 | Progynova | BN |
| 1664N *NP* | oestradiol valerate 2 mg tablet, 56 | 1 | 2 | .. | 14.11 | 15.24 | Progynova | BN |

**OESTRIOL**

**Note**

Continuing Therapy Only:

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

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 1781R *NP* | oestriol 0.1% (1 mg/g) cream, 15 g | ǂ1 | 1 | .. | 19.30 | 20.43 | Ovestin | MK |
| 1771F *NP* | oestriol 500 microgram pessary, 15 | ǂ1 | 2 | .. | 21.47 | 22.60 | Ovestin Ovula | MK |

## PROGESTOGENS

### *Pregnen (4) derivatives*

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|---|
| | **MEDROXYPROGESTERONE** | | | | | | | | |
| | **Restricted benefit** | | | | | | | | |
| | Endometriosis | | | | | | | | |
| 2722G | medroxyprogesterone acetate 10 mg tablet, 100 | 1 | 2 | .. | 32.97 | 34.10 | a | Ralovera | FZ |
| | | | | [B]1.95 | 34.92 | 34.10 | a | Provera | PF |
| | **MEDROXYPROGESTERONE** | | | | | | | | |
| | **Note** | | | | | | | | |
| | Continuing Therapy Only: | | | | | | | | |
| | For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners. | | | | | | | | |
| 2321E *NP* | medroxyprogesterone acetate 10 mg tablet, 30 | 1 | 2 | .. | 14.53 | 15.66 | a | Medroxyprogesterone Sandoz | SZ |
| | | | | | | | a | Ralovera | FZ |
| | | | | [B]1.96 | 16.49 | 15.66 | a | Provera | PF |
| 2323G *NP* | medroxyprogesterone acetate 5 mg tablet, 56 | 1 | 2 | .. | 14.90 | 16.03 | a | Ralovera | FZ |
| | | | | [B]1.95 | 16.85 | 16.03 | a | Provera | PF |

### *Estren derivatives*

**NORETHISTERONE**

**Note**

Continuing Therapy Only:

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

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 2993M *NP* | norethisterone 5 mg tablet, 30 | 1 | 2 | .. | 32.17 | 33.30 | | Primolut N | BN |

## PROGESTOGENS AND ESTROGENS IN COMBINATION

### *Progestogens and estrogens, fixed combinations*

**NORETHISTERONE ACETATE + OESTRADIOL**

**Note**

Continuing Therapy Only:

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

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 8427M *NP* | oestradiol 50 microgram/24 hours + norethisterone acetate 140 microgram/24 hours patch, 8 | ‡1 | 5 | .. | 19.34 | 20.47 | | Estalis continuous 50/140 | NV |
| 8428N *NP* | oestradiol 50 microgram/24 hours + norethisterone acetate 250 microgram/24 hours patch, 8 | ‡1 | 5 | .. | 19.34 | 20.47 | | Estalis continuous 50/250 | NV |

### *Progestogens and estrogens, sequential preparations*

**OESTRADIOL (&) NORETHISTERONE ACETATE + OESTRADIOL**

**Note**

Continuing Therapy Only:

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

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 8425K *NP* | oestradiol 50 microgram/24 hours patch [4 patches] (&) oestradiol 50 microgram/24 hours + norethisterone acetate 140 microgram/24 hours patch [4 patches], 8 | ‡1 | 5 | .. | 19.34 | 20.47 | | Estalis sequi 50/140 | NV |
| 8426L *NP* | oestradiol 50 microgram/24 hours patch [4 patches] (&) oestradiol 50 microgram/24 hours + norethisterone acetate 250 microgram/24 hours patch [4 patches], 8 | ‡1 | 5 | .. | 19.34 | 20.47 | | Estalis sequi 50/250 | NV |

**OESTRADIOL (&) OESTRADIOL + DYDROGESTERONE**

**Note**

Continuing Therapy Only:

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|
| | For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners. | | | | | | | |
| 8244X *NP* | oestradiol 2 mg tablet [14 tablets] (&) oestradiol 2 mg + dydrogesterone 10 mg tablet [14 tablets], 28 | ‡1 | 5 | .. | 18.97 | 20.10 | Femoston 2/10 | AB |

## GONADOTROPINS AND OTHER OVULATION STIMULANTS

### *Gonadotropins*

**FOLLITROPIN ALFA**

**Restricted benefit**

Anovulatory infertility

**Restricted benefit**

For the treatment of infertility in males due to hypogonadotrophic hypogonadism, following failure of 6 months' treatment with human chorionic gonadotrophin to achieve adequate spermatogenesis. Combined treatment with HCG must be given

**Note**

Except in cases of hypopituitarism or primary amenorrhoea, the patient should have been adequately treated with clomiphene citrate and/or gonadorelin and failed to have conceived.

Women who have had apparent ovulation induced by other agents and have failed to conceive should have laparoscopic evidence that there is no other impediment to conception.

Oligomenorrhoea should have been present for at least twelve months or amenorrhoea for at least six months prior to treatment.

Patients with hyperprolactinaemia should have had appropriate surgical or medical treatment prior to treatment.

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 8713N | follitropin alfa 300 international units / 0.5 mL (21.84 microgram/0.5 mL) injection, 1 x 0.5 mL cartridge | 3 | 5 | .. | *493.71 | 36.10 | Gonal-f Pen | SG |
| 8714P | follitropin alfa 450 international units / 0.75 mL (32.76 microgram/0.75 mL) injection, 1 x 0.75 mL cartridge | 3 | 5 | .. | *737.28 | 36.10 | Gonal-f Pen | SG |
| 8715Q | follitropin alfa 900 international units / 1.5 mL (65.52 microgram/1.5 mL) injection, 1 x 1.5 mL cartridge | 2 | 5 | .. | *980.81 | 36.10 | Gonal-f Pen | SG |

**FOLLITROPIN BETA**

**Restricted benefit**

Anovulatory infertility

**Restricted benefit**

For the treatment of infertility in males due to hypogonadotrophic hypogonadism, following failure of 6 months' treatment with human chorionic gonadotrophin to achieve adequate spermatogenesis. Combined treatment with HCG must be given

**Note**

Except in cases of hypopituitarism or primary amenorrhoea, the patient should have been adequately treated with clomiphene citrate and/or gonadorelin and failed to have conceived.

Women who have had apparent ovulation induced by other agents and have failed to conceive should have laparoscopic evidence that there is no other impediment to conception.

Oligomenorrhoea should have been present for at least twelve months or amenorrhoea for at least six months prior to treatment.

Patients with hyperprolactinaemia should have had appropriate surgical or medical treatment prior to treatment.

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 8565T | follitropin beta 300 international units/0.36 mL injection, 1 x 0.36 mL cartridge | 3 | 5 | .. | *509.82 | 36.10 | Puregon 300 IU/0.36 mL | MK |
| 8566W | follitropin beta 600 international units/0.72 mL injection, 1 x 0.72 mL cartridge | 2 | 5 | .. | *661.27 | 36.10 | Puregon 600 IU/0.72 mL | MK |
| 8871X | follitropin beta 900 international units/1.08 mL injection, 1 x 1.08 mL cartridge | 2 | 5 | .. | *979.79 | 36.10 | Puregon 900 IU/1.08 mL | MK |

**GONADOTROPHIN CHORIONIC HUMAN**

**Restricted benefit**

Anovulatory infertility

**Restricted benefit**

For the treatment of infertility in males due to hypogonadotrophic hypogonadism

**Restricted benefit**

For the treatment of infertility in males associated with isolated luteinising hormone deficiency

**Restricted benefit**

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|---|
| | For the treatment of males who have combined deficiency of human growth hormone and gonadotrophins and in whom the absence of secondary sexual characteristics indicates a lag in maturation<br>**Restricted benefit**<br>For the treatment of boys over the age of 16 years who show clinical evidence of hypogonadism or delayed puberty. Treatment must not extend beyond 6 months<br>**Note**<br>Except in cases of hypopituitarism or primary amenorrhoea, the patient should have been adequately treated with clomiphene citrate and/or gonadorelin and failed to have conceived.<br>Women who have had apparent ovulation induced by other agents and have failed to conceive should have laparoscopic evidence that there is no other impediment to conception.<br>Oligomenorrhoea should have been present for at least twelve months or amenorrhoea for at least six months prior to treatment.<br>Patients with hyperprolactinaemia should have had appropriate surgical or medical treatment prior to treatment. | | | | | | | | |
| 1581F | gonadotrophin chorionic human 1500 international units injection [3 x 1500 international units ampoules] (&) inert substance diluent [3 x 1 mL ampoules], 1 pack | 1 | 5 | .. | 53.68 | 36.10 | | Pregnyl | MK |

### *Ovulation stimulants, synthetic*

**CLOMIPHENE**
**Restricted benefit**
Anovulatory infertility

**Restricted benefit**
Patients undergoing in-vitro fertilisation

**Note**
Care must be taken to comply with the provisions of State/Territory law when prescribing clomiphene citrate.

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 1211R | clomiphene citrate 50 mg tablet, 10 | 1 | 5 | .. | 34.72 | 35.85 | [a] | Clomid | SW |
| | | | | | | | [a] | Serophene | SG |

## ANTIANDROGENS

### *Antiandrogens, plain*

**CYPROTERONE**
**Authority required (STREAMLINED)**
***1014***
Advanced carcinoma of the prostate

**Authority required (STREAMLINED)**
***1404***
To reduce drive in sexual deviations in males

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 8019C | cyproterone acetate 100 mg tablet, 50 | 1 | 5 | .. | 116.22 | 36.10 | [a] | Cyprocur 100 | QA |
| | | | | | | | [a] | Cyprohexal | SZ |
| | | | | | | | [a] | Cyprostat-100 | SY |
| | | | | | | | [a] | Cyproterone Sandoz | HX |
| | | | | | | | [a] | GenRx Cyproterone Acetate | GX |
| | | | | | | | [a] | Procur 100 | GM |
| | | | | [B]1.11 | 117.33 | 36.10 | [a] | Androcur-100 | BN |
| 1270W | cyproterone acetate 50 mg tablet, 50 | 2 | 5 | .. | *147.33 | 36.10 | [a] | Cyprocur 50 | QA |
| | | | | | | | [a] | Cyprohexal | SZ |
| | | | | | | | [a] | Cyprone | AF |
| | | | | | | | [a] | Cyprostat | SY |
| | | | | | | | [a] | Cyproterone Sandoz | HX |
| | | | | | | | [a] | GenRx Cyproterone Acetate | GX |
| | | | | | | | [a] | Procur | GM |
| | | | | [B]2.64 | *149.97 | 36.10 | [a] | Androcur | BN |

**CYPROTERONE**
**Authority required (STREAMLINED)**
***1230***
Moderate to severe androgenisation in non-pregnant women (acne alone is not a sufficient indication of androgenisation)

**Caution**

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|---|
| | This drug should not be used during pregnancy as it may result in feminisation of the male foetus. | | | | | | | | |
| 1269T | cyproterone acetate 50 mg tablet, 20 | 1 | 5 | .. | 36.05 | 36.10 | [a] | Cyprocur 50 | QA |
| | | | | | | | [a] | Cyprohexal | SZ |
| | | | | | | | [a] | Cyprone | AF |
| | | | | | | | [a] | Cyprostat | SY |
| | | | | | | | [a] | Cyproterone Sandoz | HX |
| | | | | | | | [a] | GenRx Cyproterone Acetate | GX |
| | | | | | | | [a] | Procur | GM |
| | | | | [B]2.86 | 38.91 | 36.10 | [a] | Androcur | BN |

## OTHER SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM

### *Antigonadotropins and similar agents*

**DANAZOL**

**Authority required (STREAMLINED)**

***1090***

Endometriosis, visually proven

**Authority required (STREAMLINED)**

***1151***

Hereditary angio-oedema

**Authority required (STREAMLINED)**

***2639***

Short-term treatment (up to 6 months) of intractable primary menorrhagia (Treatment of this indication is limited to 6 months. See Australian Product Information)

**Authority required (STREAMLINED)**

***2640***

Short-term treatment (up to 6 months) of severe benign (fibrocystic) breast disease or mastalgia associated with severe symptomatic benign breast disease in patients refractory to other treatments (Treatment of this indication is limited to 6 months. See Australian Product Information)

**Caution**

Pregnancy must be excluded prior to administration of this drug.

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 1285P | danazol 100 mg capsule, 100 | 1 | 5 | .. | 58.79 | 36.10 | Azol 100 | AF |
| 1287R | danazol 200 mg capsule, 100 | 1 | 5 | .. | 87.18 | 36.10 | Azol 200 | AF |

**GESTRINONE**

**Authority required (STREAMLINED)**

***3652***

Short-term treatment (up to 6 months) of visually proven endometriosis (only 1 course of not more than 6 months' therapy may be prescribed)

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 8015W | gestrinone 2.5 mg capsule, 8 | 1 | 5 | .. | 82.02 | 36.10 | Dimetriose | SW |

### *Antiprogestogens*

**MIFEPRISTONE**

**Authority required**

Termination of an intra-uterine pregnancy

**The Treatment criteria is:**

Must be treated by a prescriber who is registered with the MS 2 Step Prescribing Program,

**AND the Clinical criteria is:**

The condition must be an intra-uterine pregnancy of up to 49 days of gestation,

**AND the Clinical criteria is:**

The treatment must be in sequential combination with misoprostol 800 micrograms.

An authority prescription for misoprostol 200 microgram tablets must be sought at the time of authority application.

**Note**

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

**Note**

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

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 2710P | mifepristone 200 mg tablet, 1 | 1 | .. | .. | 320.09 | 36.10 | Mifepristone Linepharma | XH |

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|---|
| | **UROLOGICALS** | | | | | | | | |
| | **OTHER UROLOGICALS, INCL. ANTISPASMODICS** | | | | | | | | |
| | ***Urinary antispasmodics*** | | | | | | | | |
| | **OXYBUTYNIN**<br>**Restricted benefit**<br>Detrusor overactivity in a patient who cannot tolerate oral oxybutynin, or who cannot swallow oral oxybutynin | | | | | | | | |
| 9454N<br>*NP* | oxybutynin 3.9 mg/24 hours patch, 8 | ‡1 | 5 | .. | 35.44 | 36.10 | | Oxytrol | GM |
| | **OXYBUTYNIN**<br>**Restricted benefit**<br>Detrusor overactivity | | | | | | | | |
| 8039D<br>*NP* | oxybutynin hydrochloride 5 mg tablet, 100 | 1 | 5 | .. | 14.59 | 15.72 | [a] | Ditropan | SW |
| | | | | | | | [a] | Oxybutynin Sandoz | SZ |
| | | | | | | | [a] | Oxybutynin Winthrop | WA |
| | **PROPANTHELINE**<br>**Restricted benefit**<br>Detrusor overactivity | | | | | | | | |
| 1953T<br>*NP* | propantheline bromide 15 mg tablet, 100 | 2 | 5 | .. | *26.67 | 27.80 | | Pro-Banthine | QA |
| | ***Other urologicals*** | | | | | | | | |
| | **BICARBONATE** | | | | | | | | |
| 9470K<br>*NP* | sodium bicarbonate 840 mg capsule, 100 | 1 | 2 | .. | 14.21 | 15.34 | | Sodibic | AS |
| | **PHENOXYBENZAMINE**<br>**Restricted benefit**<br>Phaeochromocytoma | | | | | | | | |
| | **Restricted benefit**<br>Neurogenic urinary retention | | | | | | | | |
| | **Note**<br>Continuing Therapy Only:<br>For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners. | | | | | | | | |
| 1862B<br>*NP* | phenoxybenzamine hydrochloride 10 mg capsule, 100 | 1 | 5 | .. | 67.58 | 36.10 | | Dibenyline | GH |
| 9286R<br>*NP* | phenoxybenzamine hydrochloride 10 mg capsule, 100 | ‡1 | 5 | .. | 1164.68 | 36.10 | | Dibenzyline | BZ |
| 1166J<br>*NP* | phenoxybenzamine hydrochloride 10 mg capsule, 30 | 3 | 5 | .. | *205.11 | 36.10 | | Dibenyline | GH |
| | **DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY** | | | | | | | | |
| | ***Alpha-adrenoreceptor antagonists*** | | | | | | | | |
| | **DUTASTERIDE + TAMSULOSIN**<br>**Authority required (STREAMLINED)**<br>***3687***<br>Treatment of lower urinary tract symptoms due to benign prostatic hyperplasia where treatment has been initiated by a urologist | | | | | | | | |
| | **Note**<br>Continuing Therapy Only:<br>For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners. | | | | | | | | |
| 5490Y<br>*NP* | dutasteride 500 microgram + tamsulosin hydrochloride 400 microgram capsule: modified release, 30 capsules | 1 | 5 | .. | 35.50 | 36.10 | | Duodart 500ug/400ug | GK |
| | ***Testosterone-5-alpha reductase inhibitors*** | | | | | | | | |
| | **DUTASTERIDE**<br>**Authority required (STREAMLINED)** | | | | | | | | |

# GENITO URINARY SYSTEM AND SEX HORMONES

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|
| | ***3667*** | | | | | | | |
| | Treatment, in combination with an alpha-antagonist, of lower urinary tract symptoms due to benign prostatic hyperplasia where treatment is initiated by a urologist | | | | | | | |
| | **Note** | | | | | | | |
| | Continuing Therapy Only: | | | | | | | |
| | For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners. | | | | | | | |
| 5468T<br>*NP* | dutasteride 500 microgram capsule, 30 | 1 | 5 | .. | 30.64 | 31.77 | Avodart | GK |

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|

# SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS

## PITUITARY AND HYPOTHALAMIC HORMONES AND ANALOGUES

### ANTERIOR PITUITARY LOBE HORMONES AND ANALOGUES

#### *ACTH*

**TETRACOSACTRIN**

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 2832C | tetracosactrin 1 mg/mL injection: modified release, 1 x 1 mL ampoule | 5 | 5 | .. | *71.48 | 36.10 | Synacthen Depot 1 mg/1 mL | NV |

#### *Thyrotropin*

**THYROTROPIN ALFA**

**Authority required (STREAMLINED)**

***3193***

Ablation of thyroid remnant tissue, in combination with radioactive iodine, in a post thyroidectomy patient without known metastatic disease

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 2700D | thyrotropin alfa 900 microgram injection, 2 x 900 microgram vials | 1 | .. | .. | 1901.63 | 36.10 | Thyrogen | GZ |

### POSTERIOR PITUITARY LOBE HORMONES

#### *Vasopressin and analogues*

**DESMOPRESSIN**

**Authority required (STREAMLINED)**

***2641***

Primary nocturnal enuresis in patients aged 6 years or older who are refractory to an enuresis alarm

**Authority required (STREAMLINED)**

***2642***

Primary nocturnal enuresis in patients aged 6 years or older for whom an enuresis alarm is contraindicated. The reason that an alarm is contraindicated must be documented in the patient's medical records when treatment is initiated

**Note**

Not to be used in preference to enuresis alarms.

Desmopressin nasal spray may be associated with an increased risk of hyponatraemia compared to the oral formulations.

**Note**

Only one application per six months will be authorised for the wafers. No more than twice the maximum quantity for the 120 micrograms wafers and no applications for increased maximum quantities for the 240 micrograms wafers will be authorised.

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 9398P *NP* | desmopressin 120 microgram wafer: sublingual, 30 | 1 | 5 | .. | 71.06 | 36.10 | Minirin Melt | FP |
| 8975J *NP* | desmopressin 240 microgram wafer: sublingual, 30 | 1 | 5 | .. | 116.15 | 36.10 | Minirin Melt | FP |

**DESMOPRESSIN**

**Authority required (STREAMLINED)**

***1678***

Cranial diabetes insipidus

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 8711L | desmopressin acetate 10 microgram/actuation nasal spray, 60 actuations | 2 | 5 | .. | *161.25 | 36.10 | Minirin Nasal Spray | FP |
| 2129C | desmopressin acetate 100 microgram/mL nasal drops, 2.5 mL | 5 | 5 | .. | *161.38 | 36.10 | Minirin | FP |
| 8662X | desmopressin acetate 200 microgram tablet, 30 | 3 | 5 | .. | *180.12 | 36.10 | Minirin | FP |

**DESMOPRESSIN**

**Authority required (STREAMLINED)**

***2641***

Primary nocturnal enuresis in patients aged 6 years or older who are refractory to an enuresis alarm

**Authority required (STREAMLINED)**

***2642***

Primary nocturnal enuresis in patients aged 6 years or older for whom an enuresis alarm is contraindicated. The reason that an alarm is contraindicated must be documented in the patient's medical records when treatment is initiated

# SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|
| | **Note**<br>Not to be used in preference to enuresis alarms.<br>Desmopressin nasal spray may be associated with an increased risk of hyponatraemia compared to the oral formulations. | | | | | | | |
| 8712M<br>*NP* | desmopressin acetate 10 microgram/actuation nasal spray, 60 actuations | ‡1 | 5 | .. | 83.94 | 36.10 | Minirin Nasal Spray | FP |
| | **DESMOPRESSIN**<br>**Authority required (STREAMLINED)**<br>***2641***<br>Primary nocturnal enuresis in patients aged 6 years or older who are refractory to an enuresis alarm | | | | | | | |
| | **Authority required (STREAMLINED)**<br>***2642***<br>Primary nocturnal enuresis in patients aged 6 years or older for whom an enuresis alarm is contraindicated. The reason that an alarm is contraindicated must be documented in the patient's medical records when treatment is initiated<br>**Note**<br>Not to be used in preference to enuresis alarms.<br>Desmopressin nasal spray may be associated with an increased risk of hyponatraemia compared to the oral formulations.<br>**Note**<br>Only one application per six months with no more than twice the maximum quantity will be authorised for the tablets. | | | | | | | |
| 8663Y<br>*NP* | desmopressin acetate 200 microgram tablet, 30 | 1 | 5 | .. | 64.46 | 36.10 | Minirin | FP |

## HYPOTHALAMIC HORMONES

### *Gonadotropin-releasing hormones*

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | **NAFARELIN**<br>**Authority required**<br>Initial treatment (up to 6 months) of visually proven endometriosis<br>**Authority required**<br>Subsequent treatment (up to 6 months) of visually proven endometriosis, where 2 years or more have elapsed since the end of the previous course and where a recent bone density assessment has been made. The date of the assessment must be provided | | | | | | | |
| 2962X | nafarelin 2 mg/mL nasal spray, 60 actuations | ‡1 | 5 | .. | 132.00 | 36.10 | Synarel | PF |

## CORTICOSTEROIDS FOR SYSTEMIC USE

## CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN

### *Mineralocorticoids*

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | **FLUDROCORTISONE ACETATE**<br>**Note**<br>Continuing Therapy Only:<br>For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners. | | | | | | | |
| 1433K<br>*NP* | fludrocortisone acetate 100 microgram tablet, 100 | 2 | 1 | .. | *46.71 | 36.10 | Florinef | QA |

### *Glucocorticoids*

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | **BETAMETHASONE ACETATE + BETAMETHASONE SODIUM PHOSPHATE**<br>**Restricted benefit**<br>Alopecia areata<br>**Restricted benefit**<br>For local intra-articular or peri-articular infiltration<br>**Restricted benefit**<br>Granulomata, dermal<br>**Restricted benefit**<br>Keloid<br>**Restricted benefit**<br>Lichen planus hypertrophic<br>**Restricted benefit**<br>Lichen simplex chronicus | | | | | | | |

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|---|
| | **Restricted benefit**<br>Lupus erythematosus, chronic discoid | | | | | | | | |
| | **Restricted benefit**<br>Necrobiosis lipoidica | | | | | | | | |
| | **Restricted benefit**<br>Uveitis | | | | | | | | |
| | **Note**<br>Shared Care Model:<br>For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners. | | | | | | | | |
| 2694T<br>*NP* | betamethasone acetate 3 mg/mL + betamethasone sodium phosphate 3.9 mg/mL injection, 5 x 1 mL ampoules | 1 | .. | .. | 25.21 | 26.34 | | Celestone Chronodose | MK |
| | **BETAMETHASONE ACETATE + BETAMETHASONE SODIUM PHOSPHATE**<br>**Restricted benefit**<br>For local intra-articular or peri-articular infiltration | | | | | | | | |
| | **Restricted benefit**<br>Keloid | | | | | | | | |
| | **Restricted benefit**<br>Lichen planus hypertrophic | | | | | | | | |
| 5034Y<br>*DP* | betamethasone acetate 3 mg/mL + betamethasone sodium phosphate 3.9 mg/mL injection, 5 x 1 mL ampoules | 1 | .. | .. | 25.21 | 26.34 | | Celestone Chronodose | MK |
| | **CORTISONE**<br>**Note**<br>Continuing Therapy Only:<br>For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners. | | | | | | | | |
| 1247P<br>*NP* | cortisone acetate 25 mg tablet, 60 | 1 | 4 | .. | 17.95 | 19.08 | | Cortate | AS |
| 1246N<br>*NP* | cortisone acetate 5 mg tablet, 50 | 1 | 4 | .. | 15.51 | 16.64 | | Cortate | AS |
| | **DEXAMETHASONE**<br>**Note**<br>Shared Care Model:<br>For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners. | | | | | | | | |
| 2507Y<br>*NP* | DEXAMETHASONE Tablet 4 mg, 30 | 1 | 4 | .. | 12.61 | 13.74 | | Dexmethsone | AS |
| 1292B<br>*NP* | DEXAMETHASONE Tablet 500 micrograms, 30 | 1 | 4 | .. | 9.05 | 10.18 | | Dexmethsone | AS |
| | **DEXAMETHASONE SODIUM PHOSPHATE**<br>**Note**<br>Shared Care Model:<br>For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners. | | | | | | | | |
| 2509C<br>*NP* | DEXAMETHASONE SODIUM PHOSPHATE Injection equivalent to 4 mg dexamethasone phosphate in 1 mL, 5 | 1 | .. | .. | 15.00 | 16.13 | [a] | Dexmethsone | AS |
| | | | | | | | [a] | Hospira Pty Limited | HH |
| 1291Y<br>*NP* | DEXAMETHASONE SODIUM PHOSPHATE Injection equivalent to 8 mg dexamethasone phosphate in 2 mL, 5 | 1 | 1 | .. | 21.83 | 22.96 | [a] | Dexmethsone | AS |
| | | | | | | | [a] | Hospira Pty Limited | HH |
| | **HYDROCORTISONE**<br>**Note**<br>Continuing Therapy Only:<br>For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been | | | | | | | | |

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|---|
| | initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners. | | | | | | | | |
| 1500Y *NP* | hydrocortisone 20 mg tablet, 60 | 1 | 4 | .. | 30.37 | 31.50 | | Hysone 20 | AF |
| 1499X *NP* | hydrocortisone 4 mg tablet, 50 | 1 | 4 | .. | 23.26 | 24.39 | | Hysone 4 | AF |
| | **HYDROCORTISONE SODIUM SUCCINATE** | | | | | | | | |
| 1501B *NP* | hydrocortisone (as sodium succinate) 100 mg injection [1 x 100 mg vial] (&) inert substance diluent [1 x 2 mL vial], 1 pack | 2 | .. | .. | *16.73 | 17.86 | | Solu-Cortef | PF |
| 3096Y *NP* | hydrocortisone (as sodium succinate) 250 mg injection [1 x 250 mg vial] (&) inert substance diluent [1 x 2 mL vial], 1 pack | 1 | .. | .. | 15.75 | 16.88 | | Solu-Cortef | PF |
| | **HYDROCORTISONE SODIUM SUCCINATE**<br>**Restricted benefit**<br>For use in a hospital | | | | | | | | |
| 1510L *NP* | hydrocortisone (as sodium succinate) 100 mg injection [1 x 100 mg vial] (&) inert substance diluent [1 x 2 mL vial], 1 pack | 6 | .. | .. | *36.93 | 36.10 | | Solu-Cortef | PF |
| 5118J *DP* | hydrocortisone (as sodium succinate) 100 mg injection [1 x 100 mg vial] (&) inert substance diluent [1 x 2 mL vial], 1 pack | 6 | .. | .. | *36.93 | 36.10 | | Solu-Cortef | PF |
| 1511M *NP* | hydrocortisone (as sodium succinate) 250 mg injection [1 x 250 mg vial] (&) inert substance diluent [1 x 2 mL vial], 1 pack | 6 | .. | .. | *58.95 | 36.10 | | Solu-Cortef | PF |
| 5119K *DP* | hydrocortisone (as sodium succinate) 250 mg injection [1 x 250 mg vial] (&) inert substance diluent [1 x 2 mL vial], 1 pack | 6 | .. | .. | *58.95 | 36.10 | | Solu-Cortef | PF |
| | **METHYLPREDNISOLONE**<br>**Note**<br>Pharmaceutical benefits that have the form methylprednisolone powder for injection 1 g (as sodium succinate) and pharmaceutical benefits that have the form methylprednisolone powder for injection 1 g (as sodium succinate) with diluent are equivalent for the purposes of substitution. | | | | | | | | |
| 8834Y *NP* | methylprednisolone 1 g injection [1 x 1 g vial] (&) inert substance diluent [1 x 16 mL vial], 1 pack | 1 | .. | .. | 79.90 | 36.10 | [a] | Solu-Medrol | PF |
| 5264C *NP* | methylprednisolone Powder for injection 1 g (as sodium succinate), 1 | 1 | .. | .. | 79.90 | 36.10 | [a] | Methylpred | AS |
| | | | | | | | [a] | Methylprednisolone Alphapharm | AF |
| | **METHYLPREDNISOLONE**<br>**Note**<br>Pharmaceutical benefits that have the form methylprednisolone powder for injection 40 mg (as sodium succinate) and pharmaceutical benefits that have the form methylprednisolone powder for injection 40 mg (as sodium succinate) with diluent are equivalent for the purposes of substitution. | | | | | | | | |
| 2981X *NP* | methylprednisolone 40 mg injection [5 x 40 mg vials] (&) inert substance diluent [5 x 1 mL vials], 1 pack | 1 | .. | .. | 30.68 | 31.81 | [a] | Solu-Medrol | PF |
| 5263B *NP* | methylprednisolone Powder for injection 40 mg (as sodium succinate), 5 | 1 | .. | .. | 30.68 | 31.81 | [a] | Methylpred | AS |
| | **METHYLPREDNISOLONE**<br>**Restricted benefit**<br>For local intra-articular or peri-articular infiltration | | | | | | | | |
| 1928L *NP* | methylprednisolone acetate 40 mg/mL injection, 5 x 1 mL vials | 1 | .. | .. | 21.59 | 22.72 | [a] | Depo-Nisolone | FZ |
| | | | | [B]0.96 | 22.55 | 22.72 | [a] | Depo-Medrol | PF |
| 5148Y *DP* | methylprednisolone acetate 40 mg/mL injection, 5 x 1 mL vials | 1 | .. | .. | 21.59 | 22.72 | [a] | Depo-Nisolone | FZ |
| | | | | [B]0.96 | 22.55 | 22.72 | [a] | Depo-Medrol | PF |

# SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|---|
| | **PREDNISOLONE** | | | | | | | | |
| 3152X | prednisolone 1 mg tablet, 100 | 1 | 4 | .. | 8.54 | 9.67 | a | Predsolone | LN |
| *NP* | | | | | | | | | |
| | | | | [B]0.44 | 8.98 | 9.67 | a | Panafcortelone | AS |
| 1916W | prednisolone 25 mg tablet, 30 | 1 | 4 | .. | 10.34 | 11.47 | | Panafcortelone | AS |
| *NP* | | | | | | | | | |
| | | | | | | | | Solone | VT |
| 1917X | prednisolone 5 mg tablet, 60 | 1 | 4 | .. | 8.68 | 9.81 | | Panafcortelone | AS |
| *NP* | | | | | | | | | |
| | | | | | | | | Solone | VT |
| | **PREDNISOLONE SODIUM PHOSPHATE** | | | | | | | | |
| 8285C | prednisolone (as sodium phosphate) 5 mg/mL oral liquid, 30 mL | ‡1 | 5 | .. | 14.91 | 16.04 | a | PredMix | LN |
| *NP* | | | | | | | | | |
| | | | | [B]2.36 | 17.27 | 16.04 | a | Redipred | AS |
| | **PREDNISONE** | | | | | | | | |
| 1934T | prednisone 1 mg tablet, 100 | 1 | 4 | .. | 9.07 | 10.20 | a | Predsone | LN |
| *NP* | | | | | | | | | |
| | | | | [B]0.60 | 9.67 | 10.20 | a | Panafcort | AS |
| 1936X | prednisone 25 mg tablet, 30 | 1 | 4 | .. | 11.62 | 12.75 | | Panafcort | AS |
| *NP* | | | | | | | | | |
| | | | | | | | | Sone | VT |
| 1935W | prednisone 5 mg tablet, 60 | 1 | 4 | .. | 9.39 | 10.52 | | Panafcort | AS |
| *NP* | | | | | | | | | |
| | | | | | | | | Sone | VT |
| | **TRIAMCINOLONE** | | | | | | | | |
| | **Restricted benefit** | | | | | | | | |
| | Alopecia areata | | | | | | | | |
| | **Restricted benefit** | | | | | | | | |
| | For local intra-articular or peri-articular infiltration | | | | | | | | |
| | **Restricted benefit** | | | | | | | | |
| | Granulomata, dermal | | | | | | | | |
| | **Restricted benefit** | | | | | | | | |
| | Keloid | | | | | | | | |
| | **Restricted benefit** | | | | | | | | |
| | Lichen planus hypertrophic | | | | | | | | |
| | **Restricted benefit** | | | | | | | | |
| | Lichen simplex chronicus | | | | | | | | |
| | **Restricted benefit** | | | | | | | | |
| | Lupus erythematosus, chronic discoid | | | | | | | | |
| | **Restricted benefit** | | | | | | | | |
| | Necrobiosis lipoidica | | | | | | | | |
| | **Restricted benefit** | | | | | | | | |
| | Psoriasis | | | | | | | | |
| | **Note** | | | | | | | | |
| | Shared Care Model: | | | | | | | | |
| | For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners. | | | | | | | | |
| 2990J | triamcinolone acetonide 10 mg/mL injection, 5 x 1 mL ampoules | 1 | .. | .. | 25.21 | 26.34 | | Kenacort-A10 | QA |
| *NP* | | | | | | | | | |
| | **TRIAMCINOLONE** | | | | | | | | |
| | **Restricted benefit** | | | | | | | | |
| | For local intra-articular or peri-articular infiltration | | | | | | | | |
| | **Restricted benefit** | | | | | | | | |
| | Keloid | | | | | | | | |
| | **Restricted benefit** | | | | | | | | |
| | Lichen planus hypertrophic | | | | | | | | |
| 5233K | triamcinolone acetonide 10 mg/mL | 1 | .. | .. | 25.21 | 26.34 | | Kenacort-A10 | QA |

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|---|
| *DP* | injection, 5 x 1 mL ampoules | | | | | | | | |

## THYROID THERAPY

### THYROID PREPARATIONS

#### *Thyroid hormones*

**LIOTHYRONINE**

**Authority required (STREAMLINED)**

***1219***

Management of patients with thyroid cancer

**Authority required (STREAMLINED)**

***1858***

Replacement therapy for hypothyroid patients who have documented intolerance to thyroxine sodium

**Authority required (STREAMLINED)**

***1859***

Replacement therapy for hypothyroid patients who have documented resistance to thyroxine sodium

**Authority required (STREAMLINED)**

***1182***

Initiation of thyroid therapy in severely hypothyroid patients

**Note**

Continuing Therapy Only:

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

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 2318B *NP* | liothyronine sodium 20 microgram tablet, 100 | 1 | 2 | .. | 83.74 | 36.10 | | Tertroxin | QA |

**THYROXINE**

**Note**

Continuing Therapy Only:

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

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 2175L *NP* | thyroxine sodium 100 microgram tablet, 200 | 1 | 1 | .. | 24.19 | 25.32 | a | Eutroxsig | FM |
| | | | | B2.21 | 26.40 | 25.32 | a | Oroxine | QA |
| 2173J *NP* | thyroxine sodium 200 microgram tablet, 200 | 1 | 1 | .. | 27.22 | 28.35 | a | Eutroxsig | FM |
| | | | | B2.21 | 29.43 | 28.35 | a | Oroxine | QA |
| 2174K *NP* | thyroxine sodium 50 microgram tablet, 200 | 1 | 1 | .. | 23.58 | 24.71 | a | Eutroxsig | FM |
| | | | | B2.20 | 25.78 | 24.71 | a | Oroxine | QA |
| 9287T *NP* | thyroxine sodium 75 microgram tablet, 200 | 1 | 1 | .. | 24.23 | 25.36 | a | Eutroxsig | FM |
| | | | | B2.27 | 26.50 | 25.36 | a | Oroxine | QA |

### ANTITHYROID PREPARATIONS

#### *Thiouracils*

**PROPYLTHIOURACIL**

**Note**

Continuing Therapy Only:

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

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 1955X *NP* | propylthiouracil 50 mg tablet, 100 | 2 | 2 | .. | *49.85 | 36.10 | | PTU | PL |

#### *Sulfur-containing imidazole derivatives*

**CARBIMAZOLE**

**Note**

Continuing Therapy Only:

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

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 1153Q *NP* | carbimazole 5 mg tablet, 100 | 2 | 2 | .. | *31.25 | 32.38 | | Neo-Mercazole | LM |

# SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|
| **PANCREATIC HORMONES** | | | | | | | | |
| **GLYCOGENOLYTIC HORMONES** | | | | | | | | |
| ***Glycogenolytic hormones*** | | | | | | | | |
| | **GLUCAGON HYDROCHLORIDE** | | | | | | | |
| 1449G *NP* | glucagon hydrochloride 1 mg injection [1 x 1 mg vial] (&) inert substance diluent [1 x 1 mL syringe], 1 pack | 1 | 1 | .. | 49.31 | 36.10 | GlucaGen Hypokit | NO |
| 5105Q *DP* | glucagon hydrochloride 1 mg injection [1 x 1 mg vial] (&) inert substance diluent [1 x 1 mL syringe], 1 pack | 1 | .. | .. | 49.31 | 36.10 | GlucaGen Hypokit | NO |
| **CALCIUM HOMEOSTASIS** | | | | | | | | |
| **PARATHYROID HORMONES AND ANALOGUES** | | | | | | | | |
| ***Parathyroid hormones and analogues*** | | | | | | | | |

**TERIPARATIDE**

**Authority required**

Severe established osteoporosis

Treatment Phase: Initial treatment

**The Treatment criteria is:**

Must be treated by a specialist; OR

Must be treated by a consultant physician,

**AND the Clinical criteria is:**

Patient must be at very high risk of fracture,

**AND the Clinical criteria is:**

Patient must have a bone mineral density (BMD) T-score of -3.0 or less,

**AND the Clinical criteria is:**

Patient must have had 2 or more fractures due to minimal trauma,

**AND the Clinical criteria is:**

Patient must have experienced at least 1 symptomatic new fracture after at least 12 months continuous therapy with an anti-resorptive agent at adequate doses,

**AND the Clinical criteria is:**

The treatment must be the sole PBS-subsidised agent,

**AND the Clinical criteria is:**

The treatment must not exceed a lifetime maximum of 18 months therapy.

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

If treatment with anti-resorptive therapy is contraindicated according to the relevant TGA-approved Product Information, details of the contraindication must be provided at the time of application.

If an intolerance of a severity necessitating permanent treatment withdrawal develops during the relevant period of use of one anti-resorptive agent, alternate anti-resorptive agents must be trialled so that the patient achieves the minimum requirement of 12 months continuous therapy. Details must be provided at the time of application.

Anti-resorptive therapies for osteoporosis and their adequate doses which will be accepted for the purposes of administering this restriction are alendronate sodium 10 mg per day or 70 mg once weekly, risedronate sodium 5 mg per day or 35 mg once weekly or 150 mg once monthly, raloxifene hydrochloride 60 mg per day (women only), denosumab 60 mg once every 6 months, strontium ranelate 2 g per day and zoledronic acid 5 mg per annum.

Details of prior anti-resorptive therapy, fracture history including the date(s), site(s), the symptoms associated with the fracture(s) which developed after at least 12 months continuous anti-resorptive therapy and the score of the qualifying BMD measurement must be provided at the time of application.

**Note**

Details of accepted toxicities including severity can be found on the Department of Human Services website at www.humanservices.gov.au.

**Note**

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

**Note**

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|---|---|---|---|---|---|---|---|---|

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

**Note**
Special Pricing Arrangements apply.

**Authority required**
Severe established osteoporosis

Treatment Phase: Continuing treatment

**The Clinical criteria is:**

Patient must have previously been issued with an authority prescription for this drug,

**AND the Clinical criteria is:**

The treatment must not exceed a lifetime maximum of 18 months therapy.

**Note**
Up to a maximum of 18 pens will be reimbursed through the PBS.

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

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

**Note**
Special Pricing Arrangements apply.

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 9411H | teriparatide 20 microgram/dose injection, 1 x 2.4 mL cartridge | 1 | 5 | .. | 438.58 | 36.10 | Forteo | LY |

## ANTI-PARATHYROID AGENTS

### *Calcitonin preparations*

**SALCATONIN**
**Authority required (STREAMLINED)**
***3256***
Symptomatic Paget disease of bone

**Authority required (STREAMLINED)**
***1412***
Treatment initiated in a hospital (in-patient or out-patient) of hypercalcaemia

**Note**
The maximum quantities for salcatonin shown represent the number of individual ampoules and NOT multiples of the manufacturer's packs. The pack size for both strengths is five ampoules.

**Note**
Continuing Therapy Only:

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

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 2997R *NP* | salcatonin 100 international units/mL injection, 5 x 1 mL ampoules | 3 | 5 | .. | *161.34 | 36.10 | Miacalcic 100 | NV |
| 2995P *NP* | salcatonin 50 international units/mL injection, 5 x 1 mL ampoules | 6 | 5 | .. | *207.87 | 36.10 | Miacalcic 50 | NV |

### *Other anti-parathyroid agents*

**CINACALCET**
**Authority required (STREAMLINED)**
***3673***
Maintenance therapy, following initiation and stabilisation of treatment with cinacalcet, of a patient with chronic kidney disease on dialysis who has a decrease of at least 30% in iPTH concentrations after 6 months treatment

**Authority required (STREAMLINED)**
***3672***
Maintenance therapy, following initiation and stabilisation of treatment with cinacalcet, of a patient with chronic kidney disease on dialysis who has iPTH greater than 15 pmol per L and an (adjusted) serum calcium concentration of less than 2.6 mmol per L after 6 months treatment

**Note**
During the titration phase, intact PTH should be monitored 4 weekly (measured at least 12 hours post dose) and dose titrated until an appropriate iPTH concentration is achieved. During the titration phase, approval will be limited to sufficient supply for 4 weeks treatment at a time, with doses between 30 and 180 mg per day according to the patient's response and tolerability.

During the maintenance phase, approval will be limited to provide sufficient quantity for 4 weeks treatment up to a maximum of 6 months supply for doses between 30 and 180 mg per day according to the patient's response and tolerability. Intact PTH should be monitored quarterly (measured at least 12 hours post dose) and dose adjusted as necessary to maintain an appropriate iPTH concentration.

# SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|
| | **Note**<br>Special Pricing Arrangements apply. | | | | | | | |
| | **Note**<br>Shared Care Model:<br>For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners. | | | | | | | |
| 9157Y<br>*NP* | cinacalcet 30 mg tablet, 28 | 1 | 5 | .. | 343.81 | 36.10 | Sensipar | AN |
| 9158B<br>*NP* | cinacalcet 60 mg tablet, 28 | 1 | 5 | .. | 670.53 | 36.10 | Sensipar | AN |
| 9159C<br>*NP* | cinacalcet 90 mg tablet, 28 | 1 | 5 | .. | 1002.48 | 36.10 | Sensipar | AN |

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|---|
| | **ANTIINFECTIVES FOR SYSTEMIC USE** | | | | | | | | |
| | ANTIBACTERIALS FOR SYSTEMIC USE | | | | | | | | |
| | **TETRACYCLINES** | | | | | | | | |
| | ***Tetracyclines*** | | | | | | | | |
| | **DOXYCYCLINE** | | | | | | | | |
| | **Restricted benefit** | | | | | | | | |
| | Urethritis | | | | | | | | |
| 2715X<br>*NP* | doxycycline 100 mg capsule: modified release, 21 capsules | 1 | .. | .. | 11.20 | 12.33 | a | Mayne Pharma Doxycycline | YT |
| | | | | B6.56 | 17.76 | 12.33 | a | Doryx | YN |
| | **DOXYCYCLINE** | | | | | | | | |
| | **Restricted benefit** | | | | | | | | |
| | Pelvic inflammatory disease | | | | | | | | |
| 2703G<br>*NP* | doxycycline 100 mg capsule: modified release, 7 capsules | 4 | .. | .. | *12.71 | 13.84 | a | Mayne Pharma Doxycycline | YT |
| | | | | B11.20 | *23.91 | 13.84 | a | Doryx | YN |
| | **DOXYCYCLINE** | | | | | | | | |
| 2708M<br>*NP* | doxycycline 100 mg capsule: modified release, 7 capsules | 1 | 1 | .. | 8.15 | 9.28 | a | Mayne Pharma Doxycycline | YT |
| | | | | B2.80 | 10.95 | 9.28 | a | Doryx | YN |
| 3322W<br>*DP* | doxycycline 100 mg capsule: modified release, 7 capsules | 1 | .. | .. | 8.15 | 9.28 | a | Mayne Pharma Doxycycline | YT |
| | | | | B2.80 | 10.95 | 9.28 | a | Doryx | YN |
| | **DOXYCYCLINE** | | | | | | | | |
| | **Restricted benefit** | | | | | | | | |
| | Urethritis | | | | | | | | |
| | **Note** | | | | | | | | |
| | Pharmaceutical benefits that have the form doxycycline tablet 100 mg (as hydrochloride) and pharmaceutical benefits that have the form doxycycline tablet 100 mg (as monohydrate) are equivalent for the purposes of substitution. | | | | | | | | |
| 1800R<br>*NP* | doxycycline 100 mg tablet, 21 | 1 | .. | .. | 11.20 | 12.33 | a | GenRx Doxycycline | GX |
| 2714W<br>*NP* | doxycycline 100 mg tablet, 7 | 3 | .. | .. | *11.19 | 12.32 | a | Doxsig | QA |
| | | | | | | | a | Doxy-100 | GM |
| | | | | | | | a | Doxylin 100 | AF |
| 9108J<br>*NP* | doxycycline 100 mg tablet, 7 | 3 | .. | .. | *11.19 | 12.32 | a | Chem mart Doxycycline | CH |
| | | | | | | | a | Doxycycline Sandoz | HX |
| | | | | | | | a | Doxyhexal | SZ |
| | | | | | | | a | Terry White Chemists Doxycycline | TW |
| | **DOXYCYCLINE** | | | | | | | | |
| | **Restricted benefit** | | | | | | | | |
| | Pelvic inflammatory disease | | | | | | | | |
| | **Note** | | | | | | | | |
| | Pharmaceutical benefits that have the form doxycycline tablet 100 mg (as hydrochloride) and pharmaceutical benefits that have the form doxycycline tablet 100 mg (as monohydrate) are equivalent for the purposes of substitution. | | | | | | | | |
| 2702F<br>*NP* | doxycycline 100 mg tablet, 7 | 4 | .. | .. | *12.71 | 13.84 | a | Doxsig | QA |
| | | | | | | | a | Doxy-100 | GM |
| | | | | | | | a | Doxylin 100 | AF |
| 9107H<br>*NP* | doxycycline 100 mg tablet, 7 | 4 | .. | .. | *12.71 | 13.84 | a | Chem mart Doxycycline | CH |
| | | | | | | | a | Doxycycline Sandoz | HX |
| | | | | | | | a | Doxyhexal | SZ |
| | | | | | | | a | GenRx Doxycycline | GX |
| | | | | | | | a | Terry White Chemists | TW |

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | Doxycycline | |
| | **DOXYCYCLINE**<br>**Note**<br>Pharmaceutical benefits that have the form doxycycline tablet 100 mg (as hydrochloride) and pharmaceutical benefits that have the form doxycycline tablet 100 mg (as monohydrate) are equivalent for the purposes of substitution. | | | | | | | | |
| 2709N<br>*NP* | doxycycline 100 mg tablet, 7 | 1 | 1 | .. | 8.15 | 9.28 | [a] | Doxsig | QA |
| | | | | | | | [a] | Doxy-100 | GM |
| | | | | | | | [a] | Doxylin 100 | AF |
| 3321T<br>*DP* | doxycycline 100 mg tablet, 7 | 1 | .. | .. | 8.15 | 9.28 | [a] | Doxsig | QA |
| | | | | | | | [a] | Doxy-100 | GM |
| | | | | | | | [a] | Doxylin 100 | AF |
| 5082L<br>*DP* | doxycycline 100 mg tablet, 7 | 1 | .. | .. | 8.15 | 9.28 | [a] | Chem mart Doxycycline | CH |
| | | | | | | | [a] | Doxycycline Sandoz | HX |
| | | | | | | | [a] | Doxyhexal | SZ |
| | | | | | | | [a] | GenRx Doxycycline | GX |
| | | | | | | | [a] | Terry White Chemists Doxycycline | TW |
| 9105F<br>*NP* | doxycycline 100 mg tablet, 7 | 1 | 1 | .. | 8.15 | 9.28 | [a] | Chem mart Doxycycline | CH |
| | | | | | | | [a] | Doxycycline Sandoz | HX |
| | | | | | | | [a] | Doxyhexal | SZ |
| | | | | | | | [a] | GenRx Doxycycline | GX |
| | | | | | | | [a] | Terry White Chemists Doxycycline | TW |
| | **DOXYCYCLINE**<br>**Restricted benefit**<br>Bronchiectasis in patients aged 8 years or older<br>**Restricted benefit**<br>Chronic bronchitis in patients aged 8 years or older<br>**Restricted benefit**<br>Severe acne | | | | | | | | |
| 2707L<br>*NP* | doxycycline 50 mg capsule: modified release, 25 capsules | 1 | 5 | .. | 9.33 | 10.46 | [a] | Mayne Pharma Doxycycline | YT |
| | | | | [B]4.72 | 14.05 | 10.46 | [a] | Doryx | YN |
| | **DOXYCYCLINE**<br>**Restricted benefit**<br>Bronchiectasis in patients aged 8 years or older<br>**Restricted benefit**<br>Chronic bronchitis in patients aged 8 years or older<br>**Restricted benefit**<br>Severe acne<br>**Note**<br>Pharmaceutical benefits that have the form doxycycline tablet 50 mg (as hydrochloride) and pharmaceutical benefits that have the form doxycycline tablet 50 mg (as monohydrate) are equivalent for the purposes of substitution. | | | | | | | | |
| 2711Q<br>*NP* | doxycycline 50 mg tablet, 25 | 1 | 5 | .. | 9.33 | 10.46 | [a] | Doxy-50 | GM |
| | | | | | | | [a] | Doxylin 50 | AF |
| | | | | [B]1.95 | 11.28 | 10.46 | [a] | Vibra-Tabs | PF |
| 9106G<br>*NP* | doxycycline 50 mg tablet, 25 | 1 | 5 | .. | 9.33 | 10.46 | [a] | Chem mart Doxycycline | CH |
| | | | | | | | [a] | Doxyhexal | SZ |
| | | | | | | | [a] | Frakas | QA |
| | | | | | | | [a] | GenRx Doxycycline | GX |
| | | | | | | | [a] | Terry White Chemists Doxycycline | TW |
| | **MINOCYCLINE**<br>**Restricted benefit** | | | | | | | | |

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|---|
| | Severe acne not responding to other tetracyclines | | | | | | | | |
| | **Caution** | | | | | | | | |
| | There are concerns about the incidence of benign intracranial hypertension associated with this drug. | | | | | | | | |
| | **Note** | | | | | | | | |
| | No applications for increased maximum quantities and/or repeats will be authorised. | | | | | | | | |
| 1616C *NP* | minocycline 50 mg tablet, 60 | 1 | 5 | .. | 15.26 | 16.39 | a | Akamin 50 | AF |
| | | | | B1.89 | 17.15 | 16.39 | a | Minomycin-50 | QA |

## BETA-LACTAM ANTIBACTERIALS, PENICILLINS

### *Penicillins with extended spectrum*

**AMOXYCILLIN**

**Restricted benefit**

Acute exacerbations of chronic bronchitis

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 8581P *NP* | amoxycillin 1 g tablet, 14 | 1 | 1 | .. | 8.78 | 9.91 | a | Amoxycillin Sandoz | BG |
| | | | | B0.58 | 9.36 | 9.91 | a | Maxamox | SZ |

**AMOXYCILLIN**

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 1888J *NP* | amoxycillin 100 mg/mL oral liquid: powder for, 20 mL | ‡1 | 1 | S0.61 | #14.09 | 14.96 | | Amoxil | AS |
| 3310F *DP* | amoxycillin 100 mg/mL oral liquid: powder for, 20 mL | ‡1 | .. | S0.61 | #14.09 | 14.96 | | Amoxil | AS |
| 1886G *NP* | amoxycillin 125 mg/5 mL oral liquid: powder for, 100 mL | ‡1 | 1 | .. | #10.19 | 11.67 | a | Alphamox 125 | AF |
| | | | | | | | a | Amoxycillin Sandoz | SZ |
| | | | | | | | a | Bgramin | GM |
| | | | | | | | a | Chem mart Amoxycillin | CH |
| | | | | | | | a | GenRx Amoxycillin | GX |
| | | | | | | | a | Ranmoxy | RA |
| | | | | | | | a | Terry White Chemists Amoxycillin | TW |
| | | | | B0.72 | #10.91 | 11.67 | a | Amoxil | AS |
| 3302T *DP* | amoxycillin 125 mg/5 mL oral liquid: powder for, 100 mL | ‡1 | .. | .. | #10.19 | 11.67 | a | Alphamox 125 | AF |
| | | | | | | | a | Amoxycillin Sandoz | SZ |
| | | | | | | | a | Bgramin | GM |
| | | | | | | | a | Chem mart Amoxycillin | CH |
| | | | | | | | a | GenRx Amoxycillin | GX |
| | | | | | | | a | Ranmoxy | RA |
| | | | | | | | a | Terry White Chemists Amoxycillin | TW |
| | | | | B0.72 | #10.91 | 11.67 | a | Amoxil | AS |
| 1884E *NP,MW* | amoxycillin 250 mg capsule, 20 | 1 | 1 | .. | 7.68 | 8.81 | a | Alphamox 250 | AF |
| | | | | | | | a | Amoxycillin-GA | GM |
| | | | | | | | a | Amoxycillin Ranbaxy | RA |
| | | | | | | | a | Amoxycillin Sandoz | SZ |
| | | | | | | | a | APO-Amoxycillin | TX |
| | | | | | | | a | Chem mart Amoxycillin | CH |
| | | | | | | | a | Cilamox | QA |
| | | | | | | | a | Terry White Chemists Amoxycillin | TW |
| | | | | | | | a | Yomax 250 | DO |
| | | | | B0.71 | 8.39 | 8.81 | a | Amoxil | AS |
| 3301R *DP* | amoxycillin 250 mg capsule, 20 | 1 | .. | .. | 7.68 | 8.81 | a | Alphamox 250 | AF |
| | | | | | | | a | Amoxycillin-GA | GM |
| | | | | | | | a | Amoxycillin Ranbaxy | RA |
| | | | | | | | a | Amoxycillin Sandoz | SZ |
| | | | | | | | a | APO-Amoxycillin | TX |
| | | | | | | | a | Chem mart Amoxycillin | CH |
| | | | | | | | a | Cilamox | QA |
| | | | | | | | a | Terry White Chemists | TW |

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|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | Amoxycillin | |
| | | | | | | | [a] | Yomax 250 | DO |
| | | | | [B]0.71 | 8.39 | 8.81 | [a] | Amoxil | AS |
| 1887H *NP* | amoxycillin 250 mg/5 mL oral liquid: powder for, 100 mL | ‡1 | 1 | .. | #10.60 | 12.08 | [a] | Alphamox 250 | AF |
| | | | | | | | [a] | Amoxycillin Sandoz | SZ |
| | | | | | | | [a] | Bgramin | GM |
| | | | | | | | [a] | Chem mart Amoxycillin | CH |
| | | | | | | | [a] | Cilamox | QA |
| | | | | | | | [a] | GenRx Amoxycillin | GX |
| | | | | | | | [a] | Ranmoxy | RA |
| | | | | | | | [a] | Terry White Chemists Amoxycillin | TW |
| | | | | [B]0.70 | #11.30 | 12.08 | [a] | Amoxil Forte | AS |
| 3393N *DP* | amoxycillin 250 mg/5 mL oral liquid: powder for, 100 mL | ‡1 | .. | .. | #10.60 | 12.08 | [a] | Alphamox 250 | AF |
| | | | | | | | [a] | Amoxycillin Sandoz | SZ |
| | | | | | | | [a] | Bgramin | GM |
| | | | | | | | [a] | Chem mart Amoxycillin | CH |
| | | | | | | | [a] | Cilamox | QA |
| | | | | | | | [a] | GenRx Amoxycillin | GX |
| | | | | | | | [a] | Ranmoxy | RA |
| | | | | | | | [a] | Terry White Chemists Amoxycillin | TW |
| | | | | [B]0.70 | #11.30 | 12.08 | [a] | Amoxil Forte | AS |
| 1889K *NP,MW* | amoxycillin 500 mg capsule, 20 | 1 | 1 | .. | 8.72 | 9.85 | [a] | Alphamox 500 | AF |
| | | | | | | | [a] | Amoxycillin-GA | GM |
| | | | | | | | [a] | Amoxycillin generichealth 500 | GQ |
| | | | | | | | [a] | Amoxycillin Ranbaxy | RA |
| | | | | | | | [a] | Amoxycillin Sandoz | SZ |
| | | | | | | | [a] | APO-Amoxycillin | TX |
| | | | | | | | [a] | Chem mart Amoxycillin | CH |
| | | | | | | | [a] | Cilamox | QA |
| | | | | | | | [a] | Terry White Chemists Amoxycillin | TW |
| | | | | | | | [a] | Yomax 500 | DO |
| | | | | [B]0.72 | 9.44 | 9.85 | [a] | Amoxil | AS |
| 3300Q *DP* | amoxycillin 500 mg capsule, 20 | 1 | .. | .. | 8.72 | 9.85 | [a] | Alphamox 500 | AF |
| | | | | | | | [a] | Amoxycillin-GA | GM |
| | | | | | | | [a] | Amoxycillin generichealth 500 | GQ |
| | | | | | | | [a] | Amoxycillin Ranbaxy | RA |
| | | | | | | | [a] | Amoxycillin Sandoz | SZ |
| | | | | | | | [a] | APO-Amoxycillin | TX |
| | | | | | | | [a] | Chem mart Amoxycillin | CH |
| | | | | | | | [a] | Cilamox | QA |
| | | | | | | | [a] | Terry White Chemists Amoxycillin | TW |
| | | | | | | | [a] | Yomax 500 | DO |
| | | | | [B]0.72 | 9.44 | 9.85 | [a] | Amoxil | AS |
| 5225B *DP* | amoxycillin 500 mg/5 mL oral liquid: powder for, 100 mL | ‡1 | .. | .. | #12.08 | 13.56 | | Maxamox | SZ |
| 8705E *NP* | amoxycillin 500 mg/5 mL oral liquid: powder for, 100 mL | ‡1 | 1 | .. | #12.08 | 13.56 | | Maxamox | SZ |

**AMOXYCILLIN**

**Authority required**

Treatment of infections suspected or proven to be due to a susceptible organism in patients who require a liquid formulation and in whom the syrup formulations are unsuitable

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 9714G *NP* | amoxycillin 100 mg/mL oral liquid: powder for, 20 mL | ‡1 | 1 | .. | #14.09 | 15.57 | | Amoxil | AS |

**AMPICILLIN**

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|---|
| 2977Q *NP* | ampicillin 1 g injection, 5 x 1 g vials | 1 | 1 | .. | 13.90 | 15.03 | [a] | Aspen Ampicyn | AS |
| | | | | | | | [a] | Austrapen | LN |
| | | | | | | | [a] | Ibimicyn | WQ |
| 3314K *DP* | ampicillin 1 g injection, 5 x 1 g vials | 1 | .. | .. | 13.90 | 15.03 | [a] | Aspen Ampicyn | AS |
| | | | | | | | [a] | Austrapen | LN |
| | | | | | | | [a] | Ibimicyn | WQ |
| 2390T *NP* | ampicillin 500 mg injection, 5 x 500 mg vials | 1 | 1 | .. | 11.06 | 12.19 | [a] | Austrapen | LN |
| | | | | | | | [a] | Ibimicyn | WQ |
| 3313J *DP* | ampicillin 500 mg injection, 5 x 500 mg vials | 1 | .. | .. | 11.06 | 12.19 | [a] | Austrapen | LN |
| | | | | | | | [a] | Ibimicyn | WQ |

## *Beta-lactamase sensitive penicillins*

**BENZATHINE BENZYLPENICILLIN**

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 2267H *NP* | BENZATHINE BENZYLPENICILLIN Injection 900 mg in 2.3 mL single use pre-filled syringe, 10 | 1 | .. | .. | 293.32 | 36.10 | | Bicillin L-A | PF |
| 5027N *DP* | BENZATHINE BENZYLPENICILLIN Injection 900 mg in 2.3 mL single use pre-filled syringe, 10 | 1 | .. | .. | 293.32 | 36.10 | | Bicillin L-A | PF |

**BENZYLPENICILLIN**

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 2647H *NP* | benzylpenicillin 3 g injection, 1 x 3 g vial | 10 | .. | .. | *79.23 | 36.10 | | BenPen | CS |
| 3399X *DP* | benzylpenicillin 3 g injection, 1 x 3 g vial | 10 | .. | .. | *79.23 | 36.10 | | BenPen | CS |
| 1775K *NP,MW* | benzylpenicillin 600 mg injection, 1 x 600 mg vial | 10 | 1 | .. | *49.53 | 36.10 | | BenPen | CS |
| 3398W *DP* | benzylpenicillin 600 mg injection, 1 x 600 mg vial | 10 | .. | .. | *49.53 | 36.10 | | BenPen | CS |

**PHENOXYMETHYLPENICILLIN**

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 5024K *DP* | phenoxymethylpenicillin 125 mg/5 mL oral liquid: powder for, 100 mL | 2 | .. | .. | *#17.01 | 18.49 | | Phenoxymethyl-penicillin-AFT | AE |
| 8976K *NP* | phenoxymethylpenicillin 125 mg/5 mL oral liquid: powder for, 100 mL | 2 | 1 | .. | *#17.01 | 18.49 | | Phenoxymethyl-penicillin-AFT | AE |
| 5012T *DP* | phenoxymethylpenicillin 150 mg/5 mL oral liquid, 100 mL | 2 | .. | .. | *21.81 | 22.94 | [a] | Cilicaine V | FM |
| | | | | [B]1.90 | *23.71 | 22.94 | [a] | Abbocillin-V | QA |
| 9143F *NP* | phenoxymethylpenicillin 150 mg/5 mL oral liquid, 100 mL | 2 | 1 | .. | *21.81 | 22.94 | [a] | Cilicaine V | FM |
| | | | | [B]1.90 | *23.71 | 22.94 | [a] | Abbocillin-V | QA |
| 1789E *NP* | phenoxymethylpenicillin 250 mg capsule, 50 | 1 | .. | .. | 11.37 | 12.50 | [a] | Cilicaine VK | FM |
| | | | | | | | [a] | Cilopen VK | GM |
| | | | | | | | | LPV | VT |
| 3363B *DP* | phenoxymethylpenicillin 250 mg capsule, 50 | 1 | .. | .. | 11.37 | 12.50 | [a] | Cilicaine VK | FM |
| | | | | | | | [a] | Cilopen VK | GM |
| | | | | | | | | LPV | VT |
| 1787C *NP* | phenoxymethylpenicillin 250 mg tablet, 25 | 2 | .. | .. | *11.53 | 12.66 | | Abbocillin-VK Filmtab | QA |
| 3360W *DP* | phenoxymethylpenicillin 250 mg tablet, 25 | 2 | .. | .. | *11.53 | 12.66 | | Abbocillin-VK Filmtab | QA |
| 5029Q *DP* | phenoxymethylpenicillin 250 mg/5 mL oral liquid: powder for, 100 mL | 2 | .. | .. | *#19.57 | 21.05 | | Phenoxymethyl-penicillin-AFT | AE |
| 8977L *NP* | phenoxymethylpenicillin 250 mg/5 mL oral liquid: powder for, 100 mL | 2 | 1 | .. | *#19.57 | 21.05 | | Phenoxymethyl-penicillin-AFT | AE |
| 2965C *NP* | phenoxymethylpenicillin 500 mg capsule, 50 | 1 | .. | .. | 13.68 | 14.81 | | LPV | VT |
| | | | | | | | [a] | Cilicaine VK | FM |
| | | | | | | | [a] | Cilopen VK | GM |
| 3364C *DP* | phenoxymethylpenicillin 500 mg capsule, 50 | 1 | .. | .. | 13.68 | 14.81 | | LPV | VT |
| | | | | | | | [a] | Cilicaine VK | FM |

# ANTIINFECTIVES FOR SYSTEMIC USE

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | [a] | Cilopen VK | GM |
| 3028J *NP* | phenoxymethylpenicillin 500 mg tablet, 25 | 2 | .. | .. | *13.87 | 15.00 | | Abbocillin-VK Filmtab | QA |
| 3361X *DP* | phenoxymethylpenicillin 500 mg tablet, 25 | 2 | .. | .. | *13.87 | 15.00 | | Abbocillin-VK Filmtab | QA |
| | **PHENOXYMETHYLPENICILLIN** | | | | | | | | |
| | **Restricted benefit** | | | | | | | | |
| | Prophylaxis of recurrent streptococcal infections (including rheumatic fever) | | | | | | | | |
| 1705R *NP* | phenoxymethylpenicillin 250 mg capsule, 50 | 1 | 5 | .. | 11.37 | 12.50 | [a] | Cilicaine VK | FM |
| | | | | | | | [a] | Cilopen VK | GM |
| | | | | | | | | LPV | VT |
| 1703P *NP* | phenoxymethylpenicillin 250 mg tablet, 25 | 2 | 5 | .. | *11.53 | 12.66 | | Abbocillin-VK Filmtab | QA |
| | **PROCAINE PENICILLIN** | | | | | | | | |
| 1794K *NP* | procaine penicillin 1.5 g/3.4 mL injection, 5 x 3.4 mL syringes | 1 | .. | .. | 92.43 | 36.10 | | Cilicaine | QA |
| 3371K *DP* | procaine penicillin 1.5 g/3.4 mL injection, 5 x 3.4 mL syringes | 1 | .. | .. | 92.43 | 36.10 | | Cilicaine | QA |
| | ***Beta-lactamase resistant penicillins*** | | | | | | | | |
| | **DICLOXACILLIN** | | | | | | | | |
| | **Restricted benefit** | | | | | | | | |
| | Serious staphylococcal infections | | | | | | | | |
| 5096F *DP* | dicloxacillin 250 mg capsule, 24 | 1 | .. | .. | 12.31 | 13.44 | | Distaph 250 | AF |
| 8121K *NP,MW* | dicloxacillin 250 mg capsule, 24 | 1 | .. | .. | 12.31 | 13.44 | | Distaph 250 | AF |
| 5097G *DP* | dicloxacillin 500 mg capsule, 24 | 1 | .. | .. | 16.62 | 17.75 | [a] | Diclocil | BQ |
| | | | | | | | [a] | Distaph 500 | AF |
| 8122L *NP,MW* | dicloxacillin 500 mg capsule, 24 | 1 | .. | .. | 16.62 | 17.75 | [a] | Diclocil | BQ |
| | | | | | | | [a] | Distaph 500 | AF |
| | **FLUCLOXACILLIN** | | | | | | | | |
| | **Caution** | | | | | | | | |
| | Severe cholestatic hepatitis has been reported with this drug. Significant risk factors are age, particularly greater than 55 years, and duration of treatment longer than 14 days. | | | | | | | | |
| 1525G *NP* | flucloxacillin 1 g injection, 5 x 1 g vials | 1 | 1 | .. | 14.36 | 15.49 | [a] | Flubiclox | WQ |
| | | | | | | | [a] | Flucil | AS |
| | | | | | | | [a] | Hospira Pty Limited | HH |
| 5095E *DP* | flucloxacillin 1 g injection, 5 x 1 g vials | 1 | .. | .. | 14.36 | 15.49 | [a] | Flubiclox | WQ |
| | | | | | | | [a] | Flucil | AS |
| | | | | | | | [a] | Hospira Pty Limited | HH |
| 1524F *NP* | flucloxacillin 500 mg injection, 5 x 500 mg vials | 1 | .. | .. | 11.56 | 12.69 | [a] | Flubiclox | WQ |
| | | | | | | | [a] | Flucil | AS |
| 5094D *DP* | flucloxacillin 500 mg injection, 5 x 500 mg vials | 1 | .. | .. | 11.56 | 12.69 | [a] | Flubiclox | WQ |
| | | | | | | | [a] | Flucil | AS |
| | **FLUCLOXACILLIN** | | | | | | | | |
| | **Restricted benefit** | | | | | | | | |
| | Serious staphylococcal infections | | | | | | | | |
| | **Caution** | | | | | | | | |
| | Severe cholestatic hepatitis has been reported with this drug. Significant risk factors are age, particularly greater than 55 years, and duration of treatment longer than 14 days. | | | | | | | | |
| 5257Q *DP* | flucloxacillin 125 mg/5 mL oral liquid: powder for, 100 mL | ‡1 | .. | .. | #16.30 | 17.78 | | Flucil | LN |
| 9149M *NP* | flucloxacillin 125 mg/5 mL oral liquid: powder for, 100 mL | ‡1 | .. | .. | #16.30 | 17.78 | | Flucil | LN |

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|---|
| 1526H<br>*NP,MW* | flucloxacillin 250 mg capsule, 24 | 1 | .. | .. | 11.40 | 12.53 | [a] | Flopen | AS |
| | | | | | | | [a] | Staphylex 250 | AF |
| 5090X<br>*DP* | flucloxacillin 250 mg capsule, 24 | 1 | .. | .. | 11.40 | 12.53 | [a] | Flopen | AS |
| | | | | | | | [a] | Staphylex 250 | AF |
| 5258R<br>*DP* | flucloxacillin 250 mg/5 mL oral liquid: powder for, 100 mL | ‡1 | .. | .. | #19.83 | 21.31 | | Flucil | LN |
| 9150N<br>*NP* | flucloxacillin 250 mg/5 mL oral liquid: powder for, 100 mL | ‡1 | .. | .. | #19.83 | 21.31 | | Flucil | LN |
| 1527J<br>*NP,MW* | flucloxacillin 500 mg capsule, 24 | 1 | .. | .. | 16.62 | 17.75 | [a] | Flopen | AS |
| | | | | | | | [a] | Staphylex 500 | AF |
| 5091Y<br>*DP* | flucloxacillin 500 mg capsule, 24 | 1 | .. | .. | 16.62 | 17.75 | [a] | Flopen | AS |
| | | | | | | | [a] | Staphylex 500 | AF |

## *Combinations of penicillins, incl. beta-lactamase inhibitors*

**AMOXYCILLIN + CLAVULANIC ACID**

**Restricted benefit**

Infections where resistance to amoxycillin is suspected

**Restricted benefit**

Infections where resistance to amoxycillin is proven

**Caution**

Hepatotoxicity has been reported with this drug.

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 1892N<br>*NP* | amoxycillin 125 mg/5 mL + clavulanic acid 31.25 mg/5 mL oral liquid: powder for, 75 mL | ‡1 | 1 | .. | #11.07 | 12.55 | [a] | Clamoxyl | AL |
| | | | | | | | [a] | Curam | SZ |
| | | | | | | | [a] | GA-Amclav 125/31.25 | GM |
| | | | | [B]3.00 | #14.07 | 12.55 | [a] | Augmentin | AS |
| 5009P<br>*DP* | amoxycillin 125 mg/5 mL + clavulanic acid 31.25 mg/5 mL oral liquid: powder for, 75 mL | ‡1 | .. | .. | #11.07 | 12.55 | [a] | Clamoxyl | AL |
| | | | | | | | [a] | Curam | SZ |
| | | | | | | | [a] | GA-Amclav 125/31.25 | GM |
| | | | | [B]3.00 | #14.07 | 12.55 | [a] | Augmentin | AS |
| 5011R<br>*DP* | amoxycillin 400 mg/5 mL + clavulanic acid 57 mg/5 mL oral liquid: powder for, 60 mL | ‡1 | .. | .. | #11.85 | 13.33 | [a] | Clamoxyl Duo 400 | AL |
| | | | | | | | [a] | Curam Duo | SZ |
| | | | | | | | [a] | GA-Amclav Forte 400/57 | GM |
| | | | | [B]4.21 | #16.06 | 13.33 | [a] | Augmentin Duo 400 | AS |
| 8319W<br>*NP* | amoxycillin 400 mg/5 mL + clavulanic acid 57 mg/5 mL oral liquid: powder for, 60 mL | ‡1 | 1 | .. | #11.85 | 13.33 | [a] | Clamoxyl Duo 400 | AL |
| | | | | | | | [a] | Curam Duo | SZ |
| | | | | | | | [a] | GA-Amclav Forte 400/57 | GM |
| | | | | [B]4.21 | #16.06 | 13.33 | [a] | Augmentin Duo 400 | AS |
| 1891M<br>*NP,MW* | amoxycillin 500 mg + clavulanic acid 125 mg tablet, 10 | 1 | 1 | .. | 9.60 | 10.73 | [a] | Amoxycillin/ Clavulanic Acid 500/125 generichealth | GQ |
| | | | | | | | [a] | APO-Amoxycillin/ Clavulanic Acid 500/125 | TX |
| | | | | | | | [a] | Clamoxyl Duo | AL |
| | | | | | | | [a] | Curam Duo 500/125 | SZ |
| | | | | | | | [a] | GA-Amclav 500/125 | GM |
| | | | | | | | [a] | Moxiclav Duo 500/125 | QA |
| | | | | | | | [a] | Pharmacor AmoxyClav 500/125 | CR |
| | | | | [B]4.14 | 13.74 | 10.73 | [a] | Augmentin Duo | AS |
| 5008N<br>*DP* | amoxycillin 500 mg + clavulanic acid 125 mg tablet, 10 | 1 | .. | .. | 9.60 | 10.73 | [a] | Amoxycillin/ Clavulanic Acid 500/125 | GQ |

# ANTIINFECTIVES FOR SYSTEMIC USE

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | generichealth | |
| | | | | | | | [a] | APO-Amoxycillin/ Clavulanic Acid 500/125 | TX |
| | | | | | | | [a] | Clamoxyl Duo | AL |
| | | | | | | | [a] | Curam Duo 500/125 | SZ |
| | | | | | | | [a] | GA-Amclav 500/125 | GM |
| | | | | | | | [a] | Moxiclav Duo 500/125 | QA |
| | | | | | | | [a] | Pharmacor AmoxyClav 500/125 | CR |
| | | | | [B]4.14 | 13.74 | 10.73 | [a] | Augmentin Duo | AS |
| 5006L *DP* | amoxycillin 875 mg + clavulanic acid 125 mg tablet, 10 | 1 | .. | .. | 10.85 | 11.98 | [a] | Amoxycillin/ Clavulanic Acid 875/125 generichealth | GQ |
| | | | | | | | [a] | APO-Amoxycillin and Clavulanic Acid | TX |
| | | | | | | | [a] | Chem mart Amoxycillin and Clavulanic Acid | CH |
| | | | | | | | [a] | Clamoxyl Duo forte | AL |
| | | | | | | | [a] | Curam Duo Forte 875/125 | SZ |
| | | | | | | | [a] | GA-Amclav Forte 875/125 | GM |
| | | | | | | | [a] | GenRx Amoxycillin and Clavulanic Acid | GX |
| | | | | | | | [a] | Moxiclav Duo Forte 875/125 | QA |
| | | | | | | | [a] | Pharmacor AmoxyClav 875/125 | CR |
| | | | | | | | [a] | Terry White Chemists Amoxycillin and Clavulanic Acid | TW |
| | | | | [B]5.21 | 16.06 | 11.98 | [a] | Augmentin Duo forte | AS |
| 8254K *NP* | amoxycillin 875 mg + clavulanic acid 125 mg tablet, 10 | 1 | 1 | .. | 10.85 | 11.98 | [a] | Amoxycillin/ Clavulanic Acid 875/125 generichealth | GQ |
| | | | | | | | [a] | APO-Amoxycillin and Clavulanic Acid | TX |
| | | | | | | | [a] | Chem mart Amoxycillin and Clavulanic Acid | CH |
| | | | | | | | [a] | Clamoxyl Duo forte | AL |
| | | | | | | | [a] | Curam Duo Forte 875/125 | SZ |
| | | | | | | | [a] | GA-Amclav Forte 875/125 | GM |
| | | | | | | | [a] | GenRx Amoxycillin and Clavulanic Acid | GX |
| | | | | | | | [a] | Moxiclav Duo Forte 875/125 | QA |
| | | | | | | | [a] | Pharmacor AmoxyClav 875/125 | CR |
| | | | | | | | [a] | Terry White Chemists Amoxycillin and Clavulanic Acid | TW |
| | | | | [B]5.21 | 16.06 | 11.98 | [a] | Augmentin Duo forte | AS |

**TICARCILLIN + CLAVULANIC ACID**

**Restricted benefit**

Infections where positive bacteriological evidence confirms that this antibiotic is an appropriate therapeutic agent

**Restricted benefit**

Septicaemia, suspected

**Restricted benefit**

Septicaemia, proven

**Note**

Shared Care Model:

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

# ANTIINFECTIVES FOR SYSTEMIC USE

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|---|
| 2179Q<br>*NP* | ticarcillin 3 g + clavulanic acid 100 mg injection, 10 x 3.1 g vials | 1 | .. | .. | 163.53 | 36.10 | | Timentin | AS |
| | **TICARCILLIN + CLAVULANIC ACID**<br>**Restricted benefit**<br>Infections where positive bacteriological evidence confirms that this antibiotic is an appropriate therapeutic agent | | | | | | | | |
| 5230G<br>*DP* | ticarcillin 3 g + clavulanic acid 100 mg injection, 10 x 3.1 g vials | 1 | .. | .. | 163.53 | 36.10 | | Timentin | AS |

## OTHER BETA-LACTAM ANTIBACTERIALS

### *First-generation cephalosporins*

**CEPHALEXIN**

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 3094W<br>*NP* | cephalexin 125 mg/5 mL oral liquid: powder for, 100 mL | ‡1 | 1 | .. | #10.78 | 12.26 | [a] | APO-Cephalexin | TX |
| | | | | | | | [a] | Cefalexin Sandoz | SZ |
| | | | | | | | [a] | Chem mart Cephalexin | CH |
| | | | | | | | [a] | Cilex | GM |
| | | | | | | | [a] | Ialex | LN |
| | | | | | | | [a] | Ibilex 125 | AF |
| | | | | | | | [a] | Terry White Chemists Cephalexin | TW |
| | | | | [B]3.74 | #14.52 | 12.26 | [a] | Keflex | AS |
| 3319Q<br>*DP* | cephalexin 125 mg/5 mL oral liquid: powder for, 100 mL | ‡1 | .. | .. | #10.78 | 12.26 | [a] | APO-Cephalexin | TX |
| | | | | | | | [a] | Cefalexin Sandoz | SZ |
| | | | | | | | [a] | Chem mart Cephalexin | CH |
| | | | | | | | [a] | Cilex | GM |
| | | | | | | | [a] | Ialex | LN |
| | | | | | | | [a] | Ibilex 125 | AF |
| | | | | | | | [a] | Terry White Chemists Cephalexin | TW |
| | | | | [B]3.74 | #14.52 | 12.26 | [a] | Keflex | AS |
| 3058Y<br>*NP,MW* | cephalexin 250 mg capsule, 20 | 1 | 1 | .. | 7.92 | 9.05 | [a] | Cefalexin Sandoz | SZ |
| | | | | | | | [a] | Cephalexin generichealth | GQ |
| | | | | | | | [a] | Chem mart Cephalexin | CH |
| | | | | | | | [a] | Cilex | GM |
| | | | | | | | [a] | GenRx Cephalexin | GX |
| | | | | | | | [a] | Ialex | LN |
| | | | | | | | [a] | Ibilex 250 | AF |
| | | | | | | | [a] | Pharmacor Cephalexin 250 | CR |
| | | | | | | | [a] | Rancef | RA |
| | | | | | | | [a] | Terry White Chemists Cephalexin | TW |
| | | | | [B]3.38 | 11.30 | 9.05 | [a] | Keflex | AS |
| 3317N<br>*DP* | cephalexin 250 mg capsule, 20 | 1 | .. | .. | 7.92 | 9.05 | [a] | Cefalexin Sandoz | SZ |
| | | | | | | | [a] | Cephalexin generichealth | GQ |
| | | | | | | | [a] | Chem mart Cephalexin | CH |
| | | | | | | | [a] | Cilex | GM |
| | | | | | | | [a] | GenRx Cephalexin | GX |
| | | | | | | | [a] | Ialex | LN |
| | | | | | | | [a] | Ibilex 250 | AF |
| | | | | | | | [a] | Pharmacor Cephalexin 250 | CR |
| | | | | | | | [a] | Rancef | RA |
| | | | | | | | [a] | Terry White Chemists Cephalexin | TW |
| | | | | [B]3.38 | 11.30 | 9.05 | [a] | Keflex | AS |
| 3095X<br>*NP* | cephalexin 250 mg/5 mL oral liquid: powder for, 100 mL | ‡1 | 1 | .. | #11.53 | 13.01 | [a] | APO-Cephalexin | TX |
| | | | | | | | [a] | Cefalexin Sandoz | SZ |
| | | | | | | | [a] | Chem mart Cephalexin | CH |

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|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | [a] | Cilex | GM |
| | | | | | | | [a] | Ialex | LN |
| | | | | | | | [a] | Ibilex 250 | AF |
| | | | | | | | [a] | Terry White Chemists Cephalexin | TW |
| | | | | [B]4.80 | #16.33 | 13.01 | [a] | Keflex | AS |
| 3320R<br>*DP* | cephalexin 250 mg/5 mL oral liquid: powder for, 100 mL | ‡1 | .. | .. | #11.53 | 13.01 | [a] | APO-Cephalexin | TX |
| | | | | | | | [a] | Cefalexin Sandoz | SZ |
| | | | | | | | [a] | Chem mart Cephalexin | CH |
| | | | | | | | [a] | Cilex | GM |
| | | | | | | | [a] | Ialex | LN |
| | | | | | | | [a] | Ibilex 250 | AF |
| | | | | | | | [a] | Terry White Chemists Cephalexin | TW |
| | | | | [B]4.80 | #16.33 | 13.01 | [a] | Keflex | AS |
| 3119E<br>*NP,MW* | cephalexin 500 mg capsule, 20 | 1 | 1 | .. | 8.93 | 10.06 | [a] | Cefalexin Sandoz | SZ |
| | | | | | | | [a] | Cephalexin generichealth | GQ |
| | | | | | | | [a] | Chem mart Cephalexin | CH |
| | | | | | | | [a] | Cilex | GM |
| | | | | | | | [a] | GenRx Cephalexin | GX |
| | | | | | | | [a] | Ialex | LN |
| | | | | | | | [a] | Ibilex 500 | AF |
| | | | | | | | [a] | Pharmacor Cephalexin 500 | CR |
| | | | | | | | [a] | Rancef | RA |
| | | | | | | | [a] | Terry White Chemists Cephalexin | TW |
| | | | | [B]4.83 | 13.76 | 10.06 | [a] | Keflex | AS |
| 3318P<br>*DP* | cephalexin 500 mg capsule, 20 | 1 | .. | .. | 8.93 | 10.06 | [a] | Cefalexin Sandoz | SZ |
| | | | | | | | [a] | Cephalexin generichealth | GQ |
| | | | | | | | [a] | Chem mart Cephalexin | CH |
| | | | | | | | [a] | Cilex | GM |
| | | | | | | | [a] | GenRx Cephalexin | GX |
| | | | | | | | [a] | Ialex | LN |
| | | | | | | | [a] | Ibilex 500 | AF |
| | | | | | | | [a] | Pharmacor Cephalexin 500 | CR |
| | | | | | | | [a] | Rancef | RA |
| | | | | | | | [a] | Terry White Chemists Cephalexin | TW |
| | | | | [B]4.83 | 13.76 | 10.06 | [a] | Keflex | AS |
| | **CEPHALEXIN**<br>**<u>Authority required (STREAMLINED)</u>**<br>***4243***<br>Prophylaxis of urinary tract infection | | | | | | | | |
| 2655R | cephalexin 250 mg capsule, 20 | 2 | 2 | .. | *9.21 | 10.34 | [a] | Cefalexin Sandoz | SZ |
| | | | | | | | [a] | Cephalexin generichealth | GQ |
| | | | | | | | [a] | Chem mart Cephalexin | CH |
| | | | | | | | [a] | Cilex | GM |
| | | | | | | | [a] | GenRx Cephalexin | GX |
| | | | | | | | [a] | Ialex | LN |
| | | | | | | | [a] | Ibilex 250 | AF |
| | | | | | | | [a] | Pharmacor Cephalexin 250 | CR |
| | | | | | | | [a] | Rancef | RA |
| | | | | | | | [a] | Terry White Chemists Cephalexin | TW |
| | | | | [B]6.76 | *15.97 | 10.34 | [a] | Keflex | AS |

# ANTIINFECTIVES FOR SYSTEMIC USE

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|---|---|---|---|---|---|---|---|---|---|
| | **CEPHALOTHIN** | | | | | | | | |
| 2964B<br>*NP* | cephalothin 1 g injection, 10 x 1 g vials | 1 | 1 | .. | 23.09 | 24.22 | [a] | Cefalotin Sandoz | SZ |
| | | | | | | | [a] | Hospira Pty Limited | HH |
| 3376Q<br>*DP* | cephalothin 1 g injection, 10 x 1 g vials | 1 | .. | .. | 23.09 | 24.22 | [a] | Cefalotin Sandoz | SZ |
| | | | | | | | [a] | Hospira Pty Limited | HH |
| | **CEPHAZOLIN**<br>**Restricted benefit**<br>Infections where positive bacteriological evidence confirms that this antibiotic is an appropriate therapeutic agent<br>**Restricted benefit**<br>Septicaemia, suspected<br>**Restricted benefit**<br>Septicaemia, proven<br>**Note**<br>For item codes 1257E and 1797N, pharmaceutical benefits that have the form powder for injection 1 g are equivalent for the purposes of substitution.<br>**Note**<br>Shared Care Model:<br>For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners. | | | | | | | | |
| 1257E<br>*NP* | cephazolin 1 g injection, 10 x 1 g vials | 1 | .. | .. | 26.24 | 27.37 | [a] | Cefazolin Sandoz | SZ |
| | | | | | | | [a] | Cephazolin Alphapharm | AF |
| | | | | | | | [a] | Kefzol | AS |
| 1797N<br>*NP* | cephazolin 1 g injection, 5 x 1 g vials | 2 | .. | .. | *26.25 | 27.38 | [a] | Cefazolin-AFT | AE |
| | | | | | | | [a] | Hospira Pty Limited | HH |
| | **CEPHAZOLIN**<br>**Restricted benefit**<br>Cellulitis<br>**Note**<br>For item codes 5478H and 1799Q, pharmaceutical benefits that have the form powder for injection 1 g are equivalent for the purposes of substitution. | | | | | | | | |
| 5478H<br>*NP* | cephazolin 1 g injection, 10 x 1 g vials | 1 | .. | .. | 26.24 | 27.37 | [a] | Cefazolin Sandoz | SZ |
| | | | | | | | [a] | Cephazolin Alphapharm | AF |
| | | | | | | | [a] | Kefzol | AS |
| 1799Q<br>*NP* | cephazolin 1 g injection, 5 x 1 g vials | 2 | .. | .. | *26.25 | 27.38 | [a] | Cefazolin-AFT | AE |
| | | | | | | | [a] | Hospira Pty Limited | HH |
| | **CEPHAZOLIN**<br>**Restricted benefit**<br>Cellulitis | | | | | | | | |
| 5479J<br>*NP* | cephazolin 2 g injection, 1 x 2 g vial | 10 | .. | .. | *50.23 | 36.10 | [a] | Cefazolin Sandoz | SZ |
| | | | | | | | [a] | Cephazolin Alphapharm | AF |
| 5477G<br>*NP* | cephazolin 500 mg injection, 5 x 500 mg vials | 2 | .. | .. | *21.37 | 22.50 | [a] | Cefazolin-AFT | AE |
| | | | | | | | [a] | Hospira Pty Limited | HH |
| | **CEPHAZOLIN**<br>**Restricted benefit**<br>Infections where positive bacteriological evidence confirms that this antibiotic is an appropriate therapeutic agent<br>**Restricted benefit**<br>Septicaemia, suspected<br>**Restricted benefit**<br>Septicaemia, proven<br>**Note** | | | | | | | | |

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|---|
| | Shared Care Model: | | | | | | | | |
| | For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners. | | | | | | | | |
| 9326W<br>*NP* | cephazolin 2 g injection, 1 x 2 g vial | 10 | .. | .. | *50.23 | 36.10 | [a] | Cefazolin Sandoz | SZ |
| | | | | | | | [a] | Cephazolin Alphapharm | AF |
| 1256D<br>*NP* | cephazolin 500 mg injection, 5 x 500 mg vials | 2 | .. | .. | *21.37 | 22.50 | [a] | Cefazolin-AFT | AE |
| | | | | | | | [a] | Hospira Pty Limited | HH |

## *Second-generation cephalosporins*

**CEFACLOR**

**Caution**

Serum sickness-like reactions have been reported with this drug, especially in children.

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 2460L | cefaclor 125 mg/5 mL oral liquid: powder for, 100 mL | ‡1 | 1 | .. | #12.29 | 13.77 | [a] | Aclor 125 | QA |
| | | | | | | | [a] | Chem mart Cefaclor | CH |
| | | | | | | | [a] | GenRx Cefaclor | GX |
| | | | | | | | [a] | Keflor | AF |
| | | | | | | | [a] | Terry White Chemists Cefaclor | TW |
| | | | | [B]4.26 | #16.55 | 13.77 | [a] | Ceclor | AS |
| 5046N<br>*DP* | cefaclor 125 mg/5 mL oral liquid: powder for, 100 mL | ‡1 | .. | .. | #12.29 | 13.77 | [a] | Aclor 125 | QA |
| | | | | | | | [a] | Chem mart Cefaclor | CH |
| | | | | | | | [a] | GenRx Cefaclor | GX |
| | | | | | | | [a] | Keflor | AF |
| | | | | | | | [a] | Terry White Chemists Cefaclor | TW |
| | | | | [B]4.26 | #16.55 | 13.77 | [a] | Ceclor | AS |
| 2461M | cefaclor 250 mg/5 mL oral liquid: powder for, 75 mL | ‡1 | 1 | .. | #12.52 | 14.00 | [a] | Aclor 250 | QA |
| | | | | | | | [a] | Chem mart Cefaclor | CH |
| | | | | | | | [a] | GenRx Cefaclor | GX |
| | | | | | | | [a] | Keflor | AF |
| | | | | | | | [a] | Terry White Chemists Cefaclor | TW |
| | | | | [B]4.48 | #17.00 | 14.00 | [a] | Ceclor | AS |
| 5047P<br>*DP* | cefaclor 250 mg/5 mL oral liquid: powder for, 75 mL | ‡1 | .. | .. | #12.52 | 14.00 | [a] | Aclor 250 | QA |
| | | | | | | | [a] | Chem mart Cefaclor | CH |
| | | | | | | | [a] | GenRx Cefaclor | GX |
| | | | | | | | [a] | Keflor | AF |
| | | | | | | | [a] | Terry White Chemists Cefaclor | TW |
| | | | | [B]4.48 | #17.00 | 14.00 | [a] | Ceclor | AS |
| 1169M | cefaclor 375 mg tablet: modified release, 10 tablets | 1 | 1 | .. | 10.97 | 12.10 | [a] | Cefaclor-GA | GN |
| | | | | | | | [a] | Cefaclor GH | GQ |
| | | | | | | | [a] | Chem mart Cefaclor CD | CH |
| | | | | | | | [a] | GenRx Cefaclor CD | GX |
| | | | | | | | [a] | Karlor CD | LN |
| | | | | | | | [a] | Keflor CD | AF |
| | | | | | | | [a] | Ozcef | RA |
| | | | | | | | [a] | Terry White Chemists Cefaclor CD | TW |
| | | | | [B]5.46 | 16.43 | 12.10 | [a] | Ceclor CD | AS |
| 5045M<br>*DP* | cefaclor 375 mg tablet: modified release, 10 tablets | 1 | .. | .. | 10.97 | 12.10 | [a] | Cefaclor-GA | GN |
| | | | | | | | [a] | Cefaclor GH | GQ |
| | | | | | | | [a] | Chem mart Cefaclor CD | CH |
| | | | | | | | [a] | GenRx Cefaclor CD | GX |
| | | | | | | | [a] | Karlor CD | LN |
| | | | | | | | [a] | Keflor CD | AF |
| | | | | | | | [a] | Ozcef | RA |

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | [a] | Terry White Chemists Cefaclor CD | TW |
| | | | | [B]5.46 | 16.43 | 12.10 | [a] | Ceclor CD | AS |
| | **CEFUROXIME** | | | | | | | | |
| 2002J *DP* | CEFUROXIME AXETIL Powder for oral suspension 125 mg (base) per 5 mL, 70 mL, 1 | ‡1 | .. | .. | #19.66 | 21.14 | | Zinnat | AS |
| 5499K | CEFUROXIME AXETIL Powder for oral suspension 125 mg (base) per 5 mL, 70 mL, 1 | ‡1 | 1 | .. | #19.66 | 21.14 | | Zinnat | AS |
| 5052X *DP* | cefuroxime 250 mg tablet, 14 | 1 | .. | .. | 18.83 | 19.96 | | Zinnat | AS |
| 8292K | cefuroxime 250 mg tablet, 14 | 1 | 1 | .. | 18.83 | 19.96 | | Zinnat | AS |

## *Third-generation cephalosporins*

**CEFOTAXIME**

**Restricted benefit**

Infections where positive bacteriological evidence confirms that this antibiotic is an appropriate therapeutic agent

**Restricted benefit**

Septicaemia, suspected

**Restricted benefit**

Septicaemia, proven

**Note**

For item codes 1085D and 1758M, pharmaceutical benefits that have the form powder for injection 1 g are equivalent for the purposes of substitution.

**Note**

Shared Care Model:

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

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 1758M *NP* | CEFOTAXIME Powder for injection 1 g, 10 | 1 | .. | .. | 23.08 | 24.21 | [a] | Hospira Pty Limited | HH |
| 1085D *NP* | cefotaxime 1 g injection, 1 x 1 g vial | 10 | .. | .. | *23.03 | 24.16 | [a] | Cefotaxime Sandoz | SZ |

**CEFOTAXIME**

**Restricted benefit**

Infections where positive bacteriological evidence confirms that this antibiotic is an appropriate therapeutic agent

**Note**

For item codes 5048Q and 1768C, pharmaceutical benefits that have the form powder for injection 1 g are equivalent for the purposes of substitution.

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 1768C *DP* | CEFOTAXIME Powder for injection 1 g, 10 | 1 | .. | .. | 23.08 | 24.21 | [a] | Hospira Pty Limited | HH |
| 5048Q *DP* | cefotaxime 1 g injection, 1 x 1 g vial | 10 | .. | .. | *23.03 | 24.16 | [a] | Cefotaxime Sandoz | SZ |

**CEFOTAXIME**

**Restricted benefit**

Infections where positive bacteriological evidence confirms that this antibiotic is an appropriate therapeutic agent

**Restricted benefit**

Septicaemia, suspected

**Restricted benefit**

Septicaemia, proven

**Note**

For item codes 1086E and 1759N, pharmaceutical benefits that have the form powder for injection 2 g are equivalent for the purposes of substitution.

**Note**

Shared Care Model:

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

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 1759N *NP* | CEFOTAXIME Powder for injection 2 g, 10 | 1 | .. | .. | 36.92 | 36.10 | [a] | Hospira Pty Limited | HH |
| 1086E | cefotaxime 2 g injection, 1 x 2 g vial | 10 | .. | .. | *36.83 | 36.10 | [a] | Cefotaxime Sandoz | SZ |

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|---|
| *NP* | | | | | | | | | |
| | **CEFOTAXIME**<br>**Restricted benefit**<br>Infections where positive bacteriological evidence confirms that this antibiotic is an appropriate therapeutic agent<br>**Note**<br>For item codes 5049R and 1769D, pharmaceutical benefits that have the form powder for injection 2 g are equivalent for the purposes of substitution. | | | | | | | | |
| 1769D<br>*DP* | CEFOTAXIME Powder for injection 2 g, 10 | 1 | .. | .. | 36.92 | 36.10 | a | Hospira Pty Limited | HH |
| 5049R<br>*DP* | cefotaxime 2 g injection, 1 x 2 g vial | 10 | .. | .. | *36.83 | 36.10 | a | Cefotaxime Sandoz | SZ |
| | **CEFTRIAXONE**<br>**Restricted benefit**<br>Infections where positive bacteriological evidence confirms that this antibiotic is an appropriate therapeutic agent<br>**Restricted benefit**<br>Septicaemia, suspected<br>**Restricted benefit**<br>Septicaemia, proven<br>**Note**<br>For item codes 1784X and 1788D, pharmaceutical benefits that have the form powder for injection 1 g are equivalent for the purposes of substitution.<br>**Note**<br>Shared Care Model:<br>For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners. | | | | | | | | |
| 1788D<br>*NP* | CEFTRIAXONE Powder for injection 1 g, 5 | 1 | .. | .. | 21.53 | 22.66 | a | Ceftriaxone Alphapharm | AF |
| | | | | | | | a | Max Pharma Ceftriaxone | GQ |
| 1784X<br>*NP* | ceftriaxone 1 g injection, 1 x 1 g vial | 5 | .. | .. | *21.53 | 22.66 | a | Ceftriaxone-AFT | AE |
| | | | | | | | a | Ceftriaxone ICP | PP |
| | | | | | | | a | Ceftriaxone Sandoz | SZ |
| | | | | | | | a | DBL Ceftriaxone | HH |
| | | | | | | | a | Rocephin | RO |
| | **CEFTRIAXONE**<br>**Restricted benefit**<br>Infections where positive bacteriological evidence confirms that this antibiotic is an appropriate therapeutic agent<br>**Restricted benefit**<br>Septicaemia, suspected<br>**Restricted benefit**<br>Septicaemia, proven<br>**Note**<br>Shared Care Model:<br>For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners. | | | | | | | | |
| 1785Y<br>*NP* | ceftriaxone 2 g injection, 1 x 2 g vial | 5 | .. | .. | *34.28 | 35.41 | a | Ceftriaxone-AFT | AE |
| | | | | | | | a | Ceftriaxone Alphapharm | AF |
| | | | | | | | a | Ceftriaxone ICP | PP |
| | | | | | | | a | Ceftriaxone Sandoz | SZ |
| | | | | | | | a | DBL Ceftriaxone | HH |
| | | | | | | | a | Rocephin | RO |
| 1783W<br>*NP* | ceftriaxone 500 mg injection, 1 x 500 mg vial | 5 | .. | .. | *16.18 | 17.31 | a | Ceftriaxone-AFT | AE |
| | | | | | | | a | Ceftriaxone ICP | PP |
| | **CEFTRIAXONE**<br>**Restricted benefit** | | | | | | | | |

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|---|
| | Gonorrhoea | | | | | | | | |
| 9058R<br>*NP* | ceftriaxone 500 mg injection, 1 x 500 mg vial | 1 | .. | .. | 8.54 | 9.67 | [a] | Ceftriaxone-AFT | AE |
| | | | | | | | [a] | Ceftriaxone ICP | PP |

### *Fourth-generation cephalosporins*

**CEFEPIME**
**Authority required**
Treatment of febrile neutropenia

**Note**
Shared Care Model:

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

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 8315P<br>*NP* | CEFEPIME Powder for injection 1 g (as hydrochloride), 1 | 10 | .. | .. | *110.03 | 36.10 | [a] | Cefepime Sandoz | SZ |
| | | | | | | | [a] | DBL Cefepime | HH |
| | | | | | | | [a] | Omegapharm Pty Ltd | OE |
| 8316Q<br>*NP* | CEFEPIME Powder for injection 2 g (as hydrochloride), 1 | 10 | .. | .. | *203.53 | 36.10 | [a] | Cefepime Sandoz | SZ |
| | | | | | | | [a] | DBL Cefepime | HH |
| | | | | | | | [a] | Omegapharm Pty Ltd | OE |

## SULFONAMIDES AND TRIMETHOPRIM

### *Trimethoprim and derivatives*

**TRIMETHOPRIM**
**Authority required (STREAMLINED)**
***4243***
Prophylaxis of urinary tract infection

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 2666H | trimethoprim 300 mg tablet, 7 | 2 | 2 | .. | *10.55 | 11.68 | [a] | Alprim | AF |
| | | | | [B]3.78 | *14.33 | 11.68 | [a] | Triprim | QA |

**TRIMETHOPRIM**

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 2922T<br>*NP* | trimethoprim 300 mg tablet, 7 | 1 | 1 | .. | 8.59 | 9.72 | [a] | Alprim | AF |
| | | | | [B]1.89 | 10.48 | 9.72 | [a] | Triprim | QA |

### *Combinations of sulfonamides and trimethoprim, incl. derivatives*

**TRIMETHOPRIM + SULFAMETHOXAZOLE**
**Caution**
There is an increased risk of severe adverse reactions with this combination in the elderly.

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 2951H<br>*NP* | trimethoprim 160 mg + sulfamethoxazole 800 mg tablet, 10 | 1 | 1 | .. | 9.45 | 10.58 | [a] | Bactrim DS | RO |
| | | | | | | | [a] | Resprim Forte | AF |
| | | | | [B]1.46 | 10.91 | 10.58 | [a] | Septrin Forte | QA |
| 3390K<br>*DP* | trimethoprim 160 mg + sulfamethoxazole 800 mg tablet, 10 | 1 | .. | .. | 9.45 | 10.58 | [a] | Bactrim DS | RO |
| | | | | | | | [a] | Resprim Forte | AF |
| | | | | [B]1.46 | 10.91 | 10.58 | [a] | Septrin Forte | QA |
| 3103H<br>*NP* | trimethoprim 40 mg/5 mL + sulfamethoxazole 200 mg/5 mL oral liquid, 100 mL | ‡1 | 1 | .. | 9.14 | 10.27 | | Bactrim | RO |
| | | | | [B]1.79 | 10.93 | 10.27 | | Septrin | QA |
| 3391L<br>*DP* | trimethoprim 40 mg/5 mL + sulfamethoxazole 200 mg/5 mL oral liquid, 100 mL | ‡1 | .. | .. | 9.14 | 10.27 | | Bactrim | RO |
| | | | | [B]1.79 | 10.93 | 10.27 | | Septrin | QA |

## MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS

### *Macrolides*

**AZITHROMYCIN**
**Restricted benefit**
Trachoma

**Note**

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|---|
| | No applications for increased maximum quantities and/or repeats will be authorised. | | | | | | | | |
| 8201P *NP* | azithromycin 200 mg/5 mL oral liquid: powder for, 15 mL | ‡1 | .. | .. | #21.39 | 22.87 | | Zithromax | PF |
| 8336R *NP* | azithromycin 500 mg tablet, 2 | 1 | 2 | .. | 21.30 | 22.43 | [a] | APO-Azithromycin | TX |
| | | | | | | | [a] | Azithromycin Sandoz | SZ |
| | | | | | | | [a] | Chem mart Azithromycin | CH |
| | | | | | | | [a] | Terry White Chemists Azithromycin | TW |
| | | | | | | | [a] | Zithromax | PF |
| | | | | | | | [a] | Zitrocin | GM |
| | **AZITHROMYCIN**<br>**Restricted benefit**<br>Uncomplicated urethritis due to Chlamydia trachomatis<br>**Restricted benefit**<br>Uncomplicated cervicitis due to Chlamydia trachomatis<br>**Note**<br>No applications for increased maximum quantities and/or repeats will be authorised. | | | | | | | | |
| 8200N *NP* | azithromycin 500 mg tablet, 2 | 1 | .. | .. | 21.30 | 22.43 | [a] | APO-Azithromycin | TX |
| | | | | | | | [a] | Azithromycin Sandoz | SZ |
| | | | | | | | [a] | Chem mart Azithromycin | CH |
| | | | | | | | [a] | Terry White Chemists Azithromycin | TW |
| | | | | | | | [a] | Zithromax | PF |
| | | | | | | | [a] | Zitrocin | GM |
| | **CLARITHROMYCIN** | | | | | | | | |
| 8318T *NP* | clarithromycin 250 mg tablet, 14 | 1 | 1 | .. | 10.74 | 11.87 | [a] | APO-Clarithromycin | TX |
| | | | | | | | [a] | Chem mart Clarithromycin | CH |
| | | | | | | | [a] | Clarac | GM |
| | | | | | | | [a] | Clarihexal | SZ |
| | | | | | | | [a] | Clarithro 250 | QA |
| | | | | | | | [a] | Kalixocin | AF |
| | | | | | | | [a] | Terry White Chemists Clarithromycin | TW |
| | | | | [B]1.28 | 12.02 | 11.87 | [a] | Klacid | AB |
| | **CLARITHROMYCIN**<br>**Restricted benefit**<br>Bordetella pertussis<br>**Restricted benefit**<br>Atypical mycobacterial infections | | | | | | | | |
| 9192T *NP* | clarithromycin 250 mg/5 mL oral liquid: powder for, 50 mL | ‡1 | .. | .. | #27.78 | 29.26 | | Klacid | AB |
| | **ERYTHROMYCIN** | | | | | | | | |
| 1404X *NP* | erythromycin 250 mg capsule: enteric, 25 | 1 | 1 | .. | 10.90 | 12.03 | [a] | Mayne Pharma Erythromycin | YT |
| | | | | [B]2.91 | 13.81 | 12.03 | [a] | Eryc | YN |
| 3325B *DP* | erythromycin 250 mg capsule: enteric, 25 | 1 | .. | .. | 10.90 | 12.03 | [a] | Mayne Pharma Erythromycin | YT |
| | | | | [B]2.91 | 13.81 | 12.03 | [a] | Eryc | YN |
| | **ERYTHROMYCIN ETHYLSUCCINATE** | | | | | | | | |
| 2424N *NP* | erythromycin (as ethylsuccinate) 200 mg/5 mL oral liquid: powder for, 100 mL | ‡1 | 1 | .. | #14.77 | 16.25 | [a] | E-Mycin 200 | AF |
| | | | | [B]2.71 | #17.48 | 16.25 | [a] | E.E.S. 200 | LM |
| 3334L *DP* | erythromycin (as ethylsuccinate) 200 mg/5 mL oral liquid: powder for, 100 | ‡1 | .. | .. | #14.77 | 16.25 | [a] | E-Mycin 200 | AF |

# ANTIINFECTIVES FOR SYSTEMIC USE

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|---|
| | mL | | | | | | | | |
| | | | | [B]2.71 | #17.48 | 16.25 | [a] | E.E.S. 200 | LM |
| 2750R *NP* | erythromycin (as ethylsuccinate) 400 mg tablet, 25 | 1 | 1 | .. | 12.27 | 13.40 | [a] | E-Mycin | AF |
| | | | | [B]2.67 | 14.94 | 13.40 | [a] | E.E.S. 400 Filmtab | LM |
| 3336N *DP* | erythromycin (as ethylsuccinate) 400 mg tablet, 25 | 1 | .. | .. | 12.27 | 13.40 | [a] | E-Mycin | AF |
| | | | | [B]2.67 | 14.94 | 13.40 | [a] | E.E.S. 400 Filmtab | LM |
| 2428T *NP* | erythromycin (as ethylsuccinate) 400 mg/5 mL oral liquid: powder for, 100 mL | ‡1 | 1 | .. | #16.28 | 17.76 | [a] | E-Mycin 400 | AF |
| | | | | [B]2.73 | #19.01 | 17.76 | [a] | E.E.S. Granules | LM |
| 3337P *DP* | erythromycin (as ethylsuccinate) 400 mg/5 mL oral liquid: powder for, 100 mL | ‡1 | .. | .. | #16.28 | 17.76 | [a] | E-Mycin 400 | AF |
| | | | | [B]2.73 | #19.01 | 17.76 | [a] | E.E.S. Granules | LM |
| | **ERYTHROMYCIN LACTOBIONATE** | | | | | | | | |
| 1397M *NP* | erythromycin (as lactobionate) 1 g injection, 1 x 1 g vial | 5 | .. | .. | *196.68 | 36.10 | | Erythrocin-I.V. | LM |
| 5088T *DP* | erythromycin (as lactobionate) 1 g injection, 1 x 1 g vial | 5 | .. | .. | *196.68 | 36.10 | | Erythrocin-I.V. | LM |
| | **ROXITHROMYCIN** | | | | | | | | |
| 1760P *NP* | roxithromycin 150 mg tablet, 10 | 1 | 1 | .. | 9.30 | 10.43 | [a] | APO-Roxithromycin | TX |
| | | | | | | | [a] | Biaxsig | AV |
| | | | | | | | [a] | Chem mart Roxithromycin | CH |
| | | | | | | | [a] | Roxar 150 | QA |
| | | | | | | | [a] | Roximycin | AF |
| | | | | | | | [a] | Roxithromycin-GA | GM |
| | | | | | | | [a] | Roxithromycin Sandoz | SZ |
| | | | | | | | [a] | Terry White Chemists Roxithromycin | TW |
| | | | | [B]2.09 | 11.39 | 10.43 | [a] | Rulide | SW |
| 5260W *DP* | roxithromycin 150 mg tablet, 10 | 1 | .. | .. | 9.30 | 10.43 | [a] | APO-Roxithromycin | TX |
| | | | | | | | [a] | Biaxsig | AV |
| | | | | | | | [a] | Chem mart Roxithromycin | CH |
| | | | | | | | [a] | Roxar 150 | QA |
| | | | | | | | [a] | Roximycin | AF |
| | | | | | | | [a] | Roxithromycin-GA | GM |
| | | | | | | | [a] | Roxithromycin Sandoz | SZ |
| | | | | | | | [a] | Terry White Chemists Roxithromycin | TW |
| | | | | [B]2.09 | 11.39 | 10.43 | [a] | Rulide | SW |
| 5261X *DP* | roxithromycin 300 mg tablet, 5 | 1 | .. | .. | 9.30 | 10.43 | [a] | APO-Roxithromycin | TX |
| | | | | | | | [a] | Biaxsig | AV |
| | | | | | | | [a] | Chem mart Roxithromycin | CH |
| | | | | | | | [a] | Roxar 300 | QA |
| | | | | | | | [a] | Roximycin | AF |
| | | | | | | | [a] | Roxithromycin-GA | GM |
| | | | | | | | [a] | Roxithromycin Sandoz | SZ |
| | | | | | | | [a] | Terry White Chemists Roxithromycin | TW |
| | | | | [B]2.09 | 11.39 | 10.43 | [a] | Rulide | SW |
| 8016X *NP* | roxithromycin 300 mg tablet, 5 | 1 | 1 | .. | 9.30 | 10.43 | [a] | APO-Roxithromycin | TX |
| | | | | | | | [a] | Biaxsig | AV |
| | | | | | | | [a] | Chem mart Roxithromycin | CH |
| | | | | | | | [a] | Roxar 300 | QA |
| | | | | | | | [a] | Roximycin | AF |

# ANTIINFECTIVES FOR SYSTEMIC USE

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | [a] | Roxithromycin-GA | GM |
| | | | | | | | [a] | Roxithromycin Sandoz | SZ |
| | | | | | | | [a] | Terry White Chemists Roxithromycin | TW |
| | | | | [B]2.09 | 11.39 | 10.43 | [a] | Rulide | SW |
| 5259T *DP* | roxithromycin 50 mg tablet: dispersible, 10 | 1 | .. | .. | 13.10 | 14.23 | | Rulide D | SW |
| 8129W *NP* | roxithromycin 50 mg tablet: dispersible, 10 | 1 | 1 | .. | 13.10 | 14.23 | | Rulide D | SW |

### *Lincosamides*

**CLINDAMYCIN**
**Restricted benefit**
Gram-positive coccal infections where these cannot be safely and effectively treated with a penicillin

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 3138E *NP,MW* | clindamycin 150 mg capsule, 24 | 1 | .. | .. | 19.96 | 21.09 | [a] | Cleocin | FZ |
| | | | | [B]1.37 | 21.33 | 21.09 | [a] | Dalacin C | PF |
| 5057E *DP* | clindamycin 150 mg capsule, 24 | 1 | .. | .. | 19.96 | 21.09 | [a] | Cleocin | FZ |
| | | | | [B]1.37 | 21.33 | 21.09 | [a] | Dalacin C | PF |

**LINCOMYCIN**

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 2530E *NP,MW* | lincomycin 600 mg/2 mL injection, 5 x 2 mL vials | 1 | .. | .. | 159.20 | 36.10 | | Lincocin | PF |
| 5144R *DP* | lincomycin 600 mg/2 mL injection, 5 x 2 mL vials | 1 | .. | .. | 159.20 | 36.10 | | Lincocin | PF |

## AMINOGLYCOSIDE ANTIBACTERIALS

### *Other aminoglycosides*

**GENTAMICIN**

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 2824P *NP* | gentamicin 80 mg/2 mL injection, 10 x 2 mL ampoules | 1 | 1 | .. | 19.88 | 21.01 | | Pfizer Australia Pty Ltd | PF |

**TOBRAMYCIN**
**Authority required (STREAMLINED)**
***3842***
Management of a proven Pseudomonas aeruginosa infection in a patient with cystic fibrosis

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

**Note**
Special Pricing Arrangements apply.

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 5442K | tobramycin 300 mg/5 mL inhalation: solution, 56 x 5 mL ampoules | 1 | 2 | .. | 2137.57 | 36.10 | | Tobi | NV |

**TOBRAMYCIN**
**Restricted benefit**
Systemic treatment of Pseudomonas aeruginosa infection in a patient with cystic fibrosis

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 9480Y *NP* | tobramycin 500 mg/5 mL injection, 10 x 5 mL vials | 1 | 1 | .. | 357.58 | 36.10 | | Tobra-Day | PL |

**TOBRAMYCIN**
**Restricted benefit**
Infections where positive bacteriological evidence confirms that this antibiotic is an appropriate therapeutic agent

**Restricted benefit**
Septicaemia, suspected

**Restricted benefit**
Septicaemia, proven

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 1356J *NP* | tobramycin 80 mg/2 mL injection, 5 x 2 mL vials | 2 | 1 | .. | *65.23 | 36.10 | | Hospira Pty Limited | HH |
| 8872Y *NP* | tobramycin Injection 80 mg (base) in 2 mL (without preservative), 5 | 2 | 1 | .. | *65.23 | 36.10 | | Pfizer Australia Pty Ltd | PF |

## QUINOLONE ANTIBACTERIALS

### *Fluoroquinolones*

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|---|
| | **CIPROFLOXACIN**<br>**Authority required**<br>Respiratory tract infection proven or suspected to be caused by Pseudomonas aeruginosa in severely immunocompromised patients<br>**Authority required**<br>Bacterial gastroenteritis in severely immunocompromised patients<br>**Authority required**<br>Treatment of infections proven to be due to Pseudomonas aeruginosa or other gram-negative bacteria resistant to all other oral antimicrobials<br>**Authority required**<br>Treatment of joint and bone infections, epididymo-orchitis, prostatitis or perichondritis of the pinna, suspected or proven to be caused by gram-negative bacteria or gram-positive bacteria resistant to all other appropriate antimicrobials<br>**Authority required**<br>Gonorrhoea | | | | | | | | |
| 1208N<br>*NP* | ciprofloxacin 250 mg tablet, 14 | 1 | .. | .. | 14.71 | 15.84 | [a] | C-Flox 250 | AL |
| | | | | | | | [a] | Cifran | RA |
| | | | | | | | [a] | Ciprofloxacin-DRLA | RZ |
| | | | | | | | [a] | Ciprofloxacin Sandoz | SZ |
| | | | | | | | [a] | Ciprol 250 | QA |
| | | | | | | | [a] | GenRx Ciprofloxacin | GX |
| | | | | [B]0.60 | 15.31 | 15.84 | [a] | Ciproxin 250 | BN |
| | **CIPROFLOXACIN**<br>**Authority required**<br>Respiratory tract infection proven or suspected to be caused by Pseudomonas aeruginosa in severely immunocompromised patients<br>**Authority required**<br>Bacterial gastroenteritis in severely immunocompromised patients<br>**Authority required**<br>Treatment of infections proven to be due to Pseudomonas aeruginosa or other gram-negative bacteria resistant to all other oral antimicrobials<br>**Authority required**<br>Treatment of joint and bone infections, epididymo-orchitis, prostatitis or perichondritis of the pinna, suspected or proven to be caused by gram-negative bacteria or gram-positive bacteria resistant to all other appropriate antimicrobials | | | | | | | | |
| 1209P<br>*NP* | ciprofloxacin 500 mg tablet, 14 | 1 | .. | .. | 22.44 | 23.57 | [a] | C-Flox 500 | AL |
| | | | | | | | [a] | Cifran | RA |
| | | | | | | | [a] | Ciprofloxacin 500 | CR |
| | | | | | | | [a] | Ciprofloxacin-BW | GQ |
| | | | | | | | [a] | Ciprofloxacin-DRLA | RZ |
| | | | | | | | [a] | Ciprofloxacin-GA | GM |
| | | | | | | | [a] | Ciprofloxacin Sandoz | SZ |
| | | | | | | | [a] | Ciprol 500 | QA |
| | | | | | | | [a] | GenRx Ciprofloxacin | GX |
| | | | | | | | [a] | Loxip 500 | DO |
| | | | | [B]0.61 | 23.05 | 23.57 | [a] | Ciproxin 500 | BN |
| 1210Q<br>*NP* | ciprofloxacin 750 mg tablet, 14 | 1 | .. | .. | 30.47 | 31.60 | [a] | C-Flox 750 | AL |
| | | | | | | | [a] | Cifran | RA |
| | | | | | | | [a] | Ciprofloxacin 750 | CR |
| | | | | | | | [a] | Ciprofloxacin-BW | GQ |
| | | | | | | | [a] | Ciprofloxacin-DRLA | RZ |
| | | | | | | | [a] | Ciprofloxacin-GA | GM |
| | | | | | | | [a] | Ciprofloxacin Sandoz | SZ |
| | | | | | | | [a] | Ciprol 750 | QA |
| | | | | | | | [a] | GenRx Ciprofloxacin | GX |
| | | | | | | | [a] | Loxip 750 | DO |
| | | | | [B]0.60 | 31.07 | 31.60 | [a] | Ciproxin 750 | BN |
| | **NORFLOXACIN**<br>**Authority required**<br>Acute bacterial enterocolitis<br>**Authority required** | | | | | | | | |

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|---|
| | Complicated urinary tract infection | | | | | | | | |
| 3010K<br>*NP* | norfloxacin 400 mg tablet, 14 | 1 | 1 | .. | 12.74 | 13.87 | [a] | GenRx Norfloxacin | GX |
| | | | | | | | [a] | Norfloxacin-GA | GM |
| | | | | | | | [a] | Norfloxacin Sandoz | SZ |
| | | | | | | | [a] | Nufloxib | AF |
| | | | | | | | [a] | Roxin | QA |
| | | | | [B]3.27 | 16.01 | 13.87 | [a] | Noroxin | MK |

## OTHER ANTIBACTERIALS

### *Glycopeptide antibacterials*

**VANCOMYCIN**
**Restricted benefit**
Prophylaxis of endocarditis in patients hypersensitive to penicillin

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 2269K | vancomycin 1 g injection, 1 x 1 g vial | 1 | .. | .. | 11.69 | 12.82 | [a] | Hospira Pty Limited | HH |
| | | | | | | | [a] | Vancomycin Alphapharm | AF |
| | | | | | | | [a] | Vancomycin Sandoz | SZ |
| | | | | | | | [a] | Vycin IV | WQ |
| 5083M<br>*DP* | vancomycin 1 g injection, 1 x 1 g vial | 1 | .. | .. | 11.69 | 12.82 | [a] | Hospira Pty Limited | HH |
| | | | | | | | [a] | Vancomycin Alphapharm | AF |
| | | | | | | | [a] | Vancomycin Sandoz | SZ |
| | | | | | | | [a] | Vycin IV | WQ |
| 3130R | vancomycin 500 mg injection, 1 x 500 mg vial | 2 | .. | .. | *11.67 | 12.80 | [a] | Hospira Pty Limited | HH |
| | | | | | | | [a] | Vancocin CP | AS |
| | | | | | | | [a] | Vancomycin Alphapharm | AF |
| | | | | | | | [a] | Vancomycin Sandoz | SZ |
| | | | | | | | [a] | Vycin IV | WQ |
| 3323X<br>*DP* | vancomycin 500 mg injection, 1 x 500 mg vial | 2 | .. | .. | *11.67 | 12.80 | [a] | Hospira Pty Limited | HH |
| | | | | | | | [a] | Vancocin CP | AS |
| | | | | | | | [a] | Vancomycin Alphapharm | AF |
| | | | | | | | [a] | Vancomycin Sandoz | SZ |
| | | | | | | | [a] | Vycin IV | WQ |

**VANCOMYCIN**
**Restricted benefit**
Endophthalmitis

**Restricted benefit**
Use initiated in a hospital for infections where vancomycin is an appropriate antibiotic

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 2270L | vancomycin 1 g injection, 1 x 1 g vial | 3 | .. | .. | *21.81 | 22.94 | [a] | Hospira Pty Limited | HH |
| | | | | | | | [a] | Vancomycin Alphapharm | AF |
| | | | | | | | [a] | Vancomycin Sandoz | SZ |
| | | | | | | | [a] | Vycin IV | WQ |
| 3131T | vancomycin 500 mg injection, 1 x 500 mg vial | 5 | .. | .. | *19.23 | 20.36 | [a] | Hospira Pty Limited | HH |
| | | | | | | | [a] | Vancocin CP | AS |
| | | | | | | | [a] | Vancomycin Alphapharm | AF |
| | | | | | | | [a] | Vancomycin Sandoz | SZ |
| | | | | | | | [a] | Vycin IV | WQ |

### *Steroid antibacterials*

**FUSIDATE**
**Restricted benefit**
For use in combination with another antibiotic in the treatment of proven serious staphylococcal infections

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 2312Q | fusidate sodium 250 mg tablet, 36 | 1 | 1 | .. | 91.10 | 36.10 | | Fucidin | CS |

### *Imidazole derivatives*

# ANTIINFECTIVES FOR SYSTEMIC USE

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|---|
| | **METRONIDAZOLE** | | | | | | | | |
| 1636D<br>*NP* | metronidazole 200 mg tablet, 21 | 1 | 1 | .. | 8.09 | 9.22 | [a] | Metrogyl 200 | AF |
| | | | | | | | [a] | Metronide 200 | AV |
| | | | | [B]2.30 | 10.39 | 9.22 | [a] | Flagyl | SW |
| 3339R<br>*DP* | metronidazole 200 mg tablet, 21 | 1 | .. | .. | 8.09 | 9.22 | [a] | Metrogyl 200 | AF |
| | | | | | | | [a] | Metronide 200 | AV |
| | | | | [B]2.30 | 10.39 | 9.22 | [a] | Flagyl | SW |
| 1630T<br>*NP* | metronidazole 200 mg/5 mL oral liquid, 100 mL | ‡1 | .. | .. | 19.03 | 20.16 | | Flagyl S | SW |
| 3341W<br>*DP* | metronidazole 200 mg/5 mL oral liquid, 100 mL | ‡1 | .. | .. | 19.03 | 20.16 | | Flagyl S | SW |
| 1642K<br>*NP* | metronidazole 500 mg suppository, 10 | ‡1 | .. | .. | 23.37 | 24.50 | | Flagyl | SW |
| 5157K<br>*DP* | metronidazole 500 mg suppository, 10 | ‡1 | .. | .. | 23.37 | 24.50 | | Flagyl | SW |
| | **METRONIDAZOLE**<br>**Restricted benefit**<br>Treatment of anaerobic infections | | | | | | | | |
| 1621H<br>*NP* | metronidazole 400 mg tablet, 21 | 1 | 1 | .. | 10.06 | 11.19 | [a] | Metrogyl 400 | AF |
| | | | | | | | [a] | Metronide 400 | AV |
| | | | | [B]2.30 | 12.36 | 11.19 | [a] | Flagyl | SW |
| 5155H<br>*DP* | metronidazole 400 mg tablet, 21 | 1 | .. | .. | 10.06 | 11.19 | [a] | Metrogyl 400 | AF |
| | | | | | | | [a] | Metronide 400 | AV |
| | | | | [B]2.30 | 12.36 | 11.19 | [a] | Flagyl | SW |
| | **METRONIDAZOLE**<br>**Restricted benefit**<br>Prophylaxis to prevent infection<br>**The Clinical criteria is:**<br>Patient must be undergoing large bowel surgery.<br>**Restricted benefit**<br>Acute anaerobic sepsis<br>**The Treatment criteria is:**<br>Must be treated in a hospital.<br>**Note**<br>Pharmaceutical benefits that have the forms metronidazole 500 mg/100 mL (0.5%) injection, 1 x 100 mL bag, metronidazole 500 mg/100 mL (0.5%) injection, 10 x 100 mL bags and metronidazole 500 mg/100 mL (0.5%) injection, 5 x 100 mL bags are equivalent for the purposes of substitution. | | | | | | | | |
| 1638F<br>*NP* | metronidazole 500 mg/100 mL (0.5%) injection, 1 x 100 mL bag | 10 | .. | .. | *33.53 | 34.66 | [a] | Baxter Healthcare Pty Ltd | BX |
| 1821W<br>*NP* | metronidazole 500 mg/100 mL (0.5%) injection, 10 x 100 mL bags | 1 | .. | .. | 33.59 | 34.72 | [a] | DBL Metronidazole Intravenous Infusion | HH |
| 2277W<br>*NP* | metronidazole 500 mg/100 mL (0.5%) injection, 5 x 100 mL bags | 2 | .. | .. | *33.59 | 34.72 | [a] | Metronidazole-Claris | AE |
| | **METRONIDAZOLE**<br>**Restricted benefit**<br>Acute anaerobic sepsis<br>**The Treatment criteria is:**<br>Must be treated in a hospital.<br>**Note**<br>Pharmaceutical benefits that have the forms metronidazole 500 mg/100 mL (0.5%) injection, 1 x 100 mL bag, metronidazole 500 mg/100 mL (0.5%) injection, 10 x 100 mL bags and metronidazole 500 mg/100 mL (0.5%) injection, 5 x 100 mL bags are equivalent for the purposes of substitution. | | | | | | | | |
| 5154G<br>*DP* | metronidazole 500 mg/100 mL (0.5%) injection, 1 x 100 mL bag | 10 | .. | .. | *33.53 | 34.66 | [a] | Baxter Healthcare Pty Ltd | BX |
| 1832K<br>*DP* | metronidazole 500 mg/100 mL (0.5%) injection, 10 x 100 mL bags | 1 | .. | .. | 33.59 | 34.72 | [a] | DBL Metronidazole Intravenous Infusion | HH |
| 2298Y<br>*DP* | metronidazole 500 mg/100 mL (0.5%) injection, 5 x 100 mL bags | 2 | .. | .. | *33.59 | 34.72 | [a] | Metronidazole-Claris | AE |

# ANTIINFECTIVES FOR SYSTEMIC USE

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|---|
| | **TINIDAZOLE** | | | | | | | | |
| 1465D<br>*NP* | tinidazole 500 mg tablet, 4 | 1 | .. | .. | 11.00 | 12.13 | [a] | Simplotan | FZ |
| | | | | [B]2.42 | 13.42 | 12.13 | [a] | Fasigyn | PF |

## *Nitrofuran derivatives*

**NITROFURANTOIN**
**Caution**
Nitrofurantoin may cause peripheral neuritis and severe pulmonary reactions.

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 1693D<br>*NP,MW* | nitrofurantoin 100 mg capsule, 30 | 1 | 1 | .. | 30.81 | 31.94 | | Macrodantin | PF |
| 1692C<br>*NP,MW* | nitrofurantoin 50 mg capsule, 30 | 1 | 1 | .. | 23.87 | 25.00 | | Macrodantin | PF |

## *Other antibacterials*

**HEXAMINE HIPPURATE**

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 3124K<br>*NP* | hexamine hippurate 1 g tablet, 100 | 1 | 5 | .. | 43.46 | 36.10 | | Hiprex | IA |

ANTIMYCOTICS FOR SYSTEMIC USE

# ANTIMYCOTICS FOR SYSTEMIC USE

## *Imidazole derivatives*

**KETOCONAZOLE**
**Authority required (STREAMLINED)**
***3606***
Symptomatic genital candidiasis recurring after treatment of at least 2 episodes with topical therapy

**Caution**
Hepatotoxicity has been reported with ketoconazole.

**Note**
Shared Care Model:

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

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 1573T<br>*NP* | ketoconazole 200 mg tablet, 10 | 1 | .. | .. | 18.99 | 20.12 | | Nizoral | JC |

**KETOCONAZOLE**
**Authority required (STREAMLINED)**
***3604***
Oral candidiasis in severely immunocompromised persons where topical therapy has failed

**Authority required (STREAMLINED)**
***3605***
Systemic or deep mycoses where other forms of therapy have failed

**Caution**
Hepatotoxicity has been reported with ketoconazole.

**Note**
Shared Care Model:

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

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 1572R<br>*NP* | ketoconazole 200 mg tablet, 30 | 1 | 5 | .. | 43.39 | 36.10 | | Nizoral | JC |

## *Triazole derivatives*

**FLUCONAZOLE**
**Authority required (STREAMLINED)**
***3615***
Treatment of cryptococcal meningitis

**Authority required (STREAMLINED)**
***3616***
Maintenance therapy in patients with cryptococcal meningitis and immunosuppression

**Authority required (STREAMLINED)**

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|---|
| | ***3613***<br>Treatment of oropharyngeal candidiasis in immunosuppressed patients<br>**Authority required (STREAMLINED)** | | | | | | | | |
| | ***3614***<br>Treatment of oesophageal candidiasis in immunosuppressed patients<br>**Authority required (STREAMLINED)** | | | | | | | | |
| | ***3617***<br>Prophylaxis of oropharyngeal candidiasis in immunosuppressed patients<br>**Authority required (STREAMLINED)** | | | | | | | | |
| | ***3618***<br>Treatment of serious and life-threatening candida infections<br>**Note**<br>Shared Care Model:<br>For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners. | | | | | | | | |
| 1472L<br>*NP* | fluconazole 100 mg capsule, 28 | 1 | 5 | .. | 57.81 | 36.10 | [a] | Diflucan | PF |
| | | | | | | | [a] | Dizole 100 | AF |
| | | | | | | | [a] | Fluconazole Sandoz | SZ |
| | | | | | | | [a] | Ozole | RA |
| 1473M<br>*NP* | fluconazole 100 mg/50 mL injection, 1 x 50 mL vial | 7 | .. | .. | *91.54 | 36.10 | [a] | Diflucan | PF |
| | | | | | | | [a] | Fluconazole-Claris | AE |
| | | | | | | | [a] | Fluconazole Hexal | HX |
| | | | | | | | [a] | Fluconazole Sandoz | SZ |
| 1475P<br>*NP* | fluconazole 200 mg capsule, 28 | 1 | 5 | .. | 106.33 | 36.10 | [a] | APO-Fluconazole | TX |
| | | | | | | | [a] | Diflucan | PF |
| | | | | | | | [a] | Dizole 200 | AF |
| | | | | | | | [a] | Fluconazole Sandoz | SZ |
| | | | | | | | [a] | Fluzole 200 | QA |
| | | | | | | | [a] | Ozole | RA |
| 1474N<br>*NP* | fluconazole 200 mg/100 mL injection, 1 x 100 mL vial | 7 | .. | .. | *166.58 | 36.10 | [a] | Baxter Healthcare Pty Ltd | BX |
| | | | | | | | [a] | Diflucan | PF |
| | | | | | | | [a] | Fluconazole Alphapharm | AF |
| | | | | | | | [a] | Fluconazole-Claris | AE |
| | | | | | | | [a] | Fluconazole Hexal | HX |
| | | | | | | | [a] | Fluconazole Sandoz | SZ |
| 1757L<br>*NP* | fluconazole 400 mg/200 mL injection, 1 x 200 mL bag | 1 | .. | .. | 43.82 | 36.10 | [a] | Baxter Healthcare Pty Ltd | BX |
| | | | | | | | [a] | Fluconazole Alphapharm | AF |
| 1471K<br>*NP* | fluconazole 50 mg capsule, 28 | 1 | 5 | .. | 34.10 | 35.23 | [a] | Diflucan | PF |
| | | | | | | | [a] | Dizole 50 | AF |
| | | | | | | | [a] | Fluconazole Sandoz | SZ |
| | | | | | | | [a] | Ozole | RA |
| | **FLUCONAZOLE**<br>**Authority required**<br>Treatment of cryptococcal meningitis in a patient unable to take a solid dose form of fluconazole | | | | | | | | |
| | **Authority required**<br>Maintenance therapy in a patient with cryptococcal meningitis and immunosuppression unable to take a solid dose form of fluconazole | | | | | | | | |
| | **Authority required**<br>Treatment of oropharyngeal candidiasis in an immunosuppressed patient unable to take a solid dose form of fluconazole | | | | | | | | |
| | **Authority required**<br>Treatment of oesophageal candidiasis in an immunosuppressed patient unable to take a solid dose form of fluconazole | | | | | | | | |
| | **Authority required**<br>Prophylaxis of oropharyngeal candidiasis in an immunosuppressed patient unable to take a solid dose form of fluconazole | | | | | | | | |
| | **Authority required** | | | | | | | | |

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|
| | Treatment of serious and life-threatening candida infections in a patient unable to take a solid dose form of fluconazole | | | | | | | |
| | **Note**<br>Shared Care Model:<br>For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners. | | | | | | | |
| 5446P<br>*NP* | fluconazole 50 mg/5 mL oral liquid: powder for, 35 mL | 1 | .. | .. | #58.10 | 36.10 | Diflucan | PF |
| | **ITRACONAZOLE**<br>**Authority required (STREAMLINED)**<br>***3607***<br>Systemic aspergillosis | | | | | | | |
| | **Authority required (STREAMLINED)**<br>***3608***<br>Systemic sporotrichosis | | | | | | | |
| | **Authority required (STREAMLINED)**<br>***3609***<br>Systemic histoplasmosis | | | | | | | |
| | **Authority required (STREAMLINED)**<br>***3610***<br>Treatment and maintenance therapy in patients with AIDS who have disseminated pulmonary histoplasmosis infection | | | | | | | |
| | **Authority required (STREAMLINED)**<br>***3612***<br>Treatment and maintenance therapy in patients with AIDS who have chronic pulmonary histoplasmosis infection | | | | | | | |
| | **Authority required (STREAMLINED)**<br>***3613***<br>Treatment of oropharyngeal candidiasis in immunosuppressed patients | | | | | | | |
| | **Authority required (STREAMLINED)**<br>***3614***<br>Treatment of oesophageal candidiasis in immunosuppressed patients | | | | | | | |
| | **Note**<br>Shared Care Model:<br>For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners. | | | | | | | |
| 8196J<br>*NP* | itraconazole 100 mg capsule, 60 | 1 | 5 | .. | 247.00 | 36.10 | Sporanox | JC |
| | **POSACONAZOLE**<br>**Authority required**<br>Treatment of invasive aspergillosis in patients intolerant to, or with disease refractory to, alternative therapy | | | | | | | |
| | **Authority required**<br>Treatment of fusariosis, zygomycosis, coccidioidomycosis, chromoblastomycosis and mycetoma in patients intolerant to, or with disease refractory to, alternative therapy | | | | | | | |
| | **Authority required**<br>Prophylaxis of invasive fungal infections, including both yeasts and moulds, in a patient who is at high risk of developing these infections, defined as follows:<br>(1) Neutropenia<br>Patients with anticipated neutropenia (an absolute neutrophil count of less than 500 cells per cubic millimetre) for at least 10 days, who are receiving chemotherapy for acute myelogenous leukaemia or myelodysplastic syndrome.<br>Treatment should continue until recovery of the neutrophil count to at least 500 cells per cubic millimetre.<br>Patients who have had a previous invasive fungal infection should have secondary prophylaxis during subsequent episodes of neutropenia.<br>(2) Graft versus host disease (GVHD)<br>Patients with acute GVHD grades II to IV or extensive chronic GVHD, who are receiving intensive immunosuppressive therapy after allogeneic haematopoietic stem cell transplant.<br>No more than 6 months therapy per episode will be PBS-subsidised | | | | | | | |
| | **Note**<br>Application for an increased maximum quantity to allow for up to 1 month's treatment and repeats sufficient for up to 6 months' treatment may be authorised. | | | | | | | |
| | **Note** | | | | | | | |

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|
| | Shared Care Model:<br>For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners. | | | | | | | |
| 9360P<br>*NP* | posaconazole 40 mg/mL oral liquid, 105 mL | 1 | .. | .. | 733.47 | 36.10 | Noxafil | MK |
| | **VORICONAZOLE**<br>**Authority required**<br>For the treatment and maintenance therapy of definite or probable invasive aspergillosis in immunocompromised patients<br>**Authority required**<br>For the treatment and maintenance therapy of serious fungal infections caused by Scedosporium species or Fusarium species<br>**Authority required**<br>For the treatment and maintenance therapy of serious Candida infections where the causative species is not susceptible to fluconazole<br>**Authority required**<br>For the treatment and maintenance therapy of serious Candida infections where treatment with fluconazole has failed<br>**Authority required**<br>For the treatment and maintenance therapy of serious Candida infections where treatment with fluconazole is not tolerated<br>**Authority required**<br>For the treatment and maintenance therapy of other serious invasive mycosis<br>**Note**<br>Shared Care Model:<br>For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners. | | | | | | | |
| 9364W<br>*NP* | voriconazole 200 mg tablet, 56 | 1 | 2 | .. | 2631.29 | 36.10 | Vfend | PF |
| 9363T<br>*NP* | voriconazole 50 mg tablet, 56 | 1 | 2 | .. | 701.08 | 36.10 | Vfend | PF |
| | **VORICONAZOLE**<br>**Authority required**<br>For the treatment and maintenance therapy of definite or probable invasive aspergillosis in immunocompromised patients<br>**Authority required**<br>For the treatment and maintenance therapy of serious fungal infections caused by Scedosporium species or Fusarium species<br>**Authority required**<br>For the treatment and maintenance therapy of serious Candida infections where the causative species is not susceptible to fluconazole<br>**Authority required**<br>For the treatment and maintenance therapy of serious Candida infections where treatment with fluconazole has failed<br>**Authority required**<br>For the treatment and maintenance therapy of serious Candida infections where treatment with fluconazole is not tolerated<br>**Authority required**<br>For the treatment and maintenance therapy of other serious invasive mycosis<br>**Note**<br>Application for an increased maximum quantity to allow for up to 1 month's treatment and repeats sufficient for up to 6 months' treatment may be authorised.<br>**Note**<br>Shared Care Model:<br>For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners. | | | | | | | |
| 9452L<br>*NP* | voriconazole 40 mg/mL oral liquid: powder for, 70 mL | 1 | .. | .. | #703.70 | 36.10 | Vfend | PF |

## ANTIMYCOBACTERIALS

### DRUGS FOR TREATMENT OF TUBERCULOSIS

#### *Hydrazides*

**ISONIAZID**

**Note**

Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|---|
| | arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners. | | | | | | | | |
| 1554T *NP* | isoniazid 100 mg tablet, 100 | 1 | 2 | .. | 21.70 | 22.83 | | Fawns and McAllan Proprietary Limited | FM |

## DRUGS FOR TREATMENT OF LEPRA

### *Drugs for treatment of lepra*

**DAPSONE**

**Note**

Shared Care Model:

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

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 1272Y *NP* | dapsone 100 mg tablet, 100 | 1 | 1 | .. | 114.05 | 36.10 | | Link Medical Products Pty Ltd | LM |
| 8801F *NP* | dapsone 25 mg tablet, 100 | 1 | 1 | .. | 100.79 | 36.10 | | Link Medical Products Pty Ltd | LM |

**RIFAMPICIN**

**Restricted benefit**

Prophylaxis of meningococcal disease in close contacts and carriers

**Restricted benefit**

Prophylactic treatment of contacts of patients with Haemophilus influenzae type B

**Note**

Shared Care Model:

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

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 8025J *NP* | rifampicin 100 mg/5 mL oral liquid, 60 mL | ‡1 | .. | .. | 28.78 | 29.91 | | Rifadin | SW |
| 1981G *NP* | rifampicin 150 mg capsule, 10 | 1 | .. | .. | 38.99 | 36.10 | | Rimycin 150 | AF |
| 1984K *NP* | rifampicin 300 mg capsule, 10 | 1 | .. | .. | 21.40 | 22.53 | | Rimycin 300 | AF |

**RIFAMPICIN**

**Authority required**

Leprosy in adults

**Note**

Shared Care Model:

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

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 1982H *NP* | rifampicin 150 mg capsule, 100 | 1 | .. | .. | 306.01 | 36.10 | | Rimycin 150 | AF |
| 1983J *NP* | rifampicin 300 mg capsule, 100 | 1 | .. | .. | 147.85 | 36.10 | | Rimycin 300 | AF |

# ANTIVIRALS FOR SYSTEMIC USE

## DIRECT ACTING ANTIVIRALS

### *Nucleosides and nucleotides excl. reverse transcriptase inhibitors*

**ACICLOVIR**

**Authority required (STREAMLINED)**

***3632***

Moderate to severe initial genital herpes. Microbiological confirmation of diagnosis (viral culture, antigen detection or nucleic acid amplification by PCR) is desirable but need not delay treatment

**Note**

Aciclovir 200 mg is not PBS-subsidised for chickenpox, herpes zoster or herpes simplex infections other than genital herpes.

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

**Note**

For item codes 1003T and 1555W, pharmaceutical benefits that have the form tablet 200 mg are equivalent for the purposes of substitution.

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 1003T *NP* | aciclovir 200 mg tablet, 25 | 2 | .. | .. | *45.65 | 36.10 | [a] | Acihexal | SZ |
| | | | | | | | [a] | Acyclo-V 200 | AF |

# ANTIINFECTIVES FOR SYSTEMIC USE

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | [a] | Lovir | GM |
| | | | | [B]2.36 | *48.01 | 36.10 | [a] | Zovirax 200 mg | GK |
| 1555W<br>*NP* | aciclovir 200 mg tablet, 50 | 1 | .. | .. | 45.64 | 36.10 | [a] | GenRx Aciclovir | GX |
| | **ACICLOVIR**<br>**Authority required (STREAMLINED)**<br>***3633***<br>Episodic treatment or suppressive therapy of moderate to severe recurrent genital herpes. Microbiological confirmation of diagnosis (viral culture, antigen detection or nucleic acid amplification by PCR) is required but need not delay treatment<br>**Note**<br>Aciclovir 200 mg is not PBS-subsidised for chickenpox, herpes zoster or herpes simplex infections other than genital herpes. | | | | | | | | | |
| 1007B<br>*NP* | aciclovir 200 mg tablet, 90 | 1 | 5 | .. | 74.97 | 36.10 | [a] | Aciclovir 200 | CR |
| | | | | | | | [a] | Aciclovir GH | GQ |
| | | | | | | | [a] | Acihexal | SZ |
| | | | | | | | [a] | Acyclo-V 200 | AF |
| | | | | | | | [a] | Chem mart Aciclovir | CH |
| | | | | | | | [a] | GenRx Aciclovir | GX |
| | | | | | | | [a] | Lovir | GM |
| | | | | | | | [a] | Ozvir | RA |
| | | | | | | | [a] | Terry White Chemists Aciclovir | TW |
| | | | | [B]1.91 | 76.88 | 36.10 | [a] | Zovirax 200 mg | GK |
| | **ACICLOVIR**<br>**Authority required (STREAMLINED)**<br>***3630***<br>Patients with advanced HIV disease (CD4 cell counts of less than 150 million per litre) | | | | | | | | |
| 8234J<br>*NP* | aciclovir 800 mg tablet, 120 | 1 | 5 | .. | 282.31 | 36.10 | [a] | Acihexal | SZ |
| | | | | | | | [a] | Acyclo-V 800 | AF |
| | **ACICLOVIR**<br>**Authority required (STREAMLINED)**<br>***3622***<br>Treatment of patients with herpes zoster within 72 hours of the onset of the rash<br>**Authority required (STREAMLINED)**<br>***3631***<br>Herpes zoster ophthalmicus<br>**Note**<br>Aciclovir is effective only if commenced within 72 hours of onset of rash.<br>Aciclovir 800 mg is not PBS-subsidised for herpes simplex or chickenpox.<br>**Note**<br>No applications for repeats will be authorised. | | | | | | | | |
| 1052J<br>*NP* | aciclovir 800 mg tablet, 35 | 1 | .. | .. | 89.31 | 36.10 | [a] | Aciclovir 800 | CR |
| | | | | | | | [a] | Acihexal | SZ |
| | | | | | | | [a] | Acyclo-V 800 | AF |
| | | | | | | | [a] | GenRx Aciclovir | GX |
| | | | | [B]0.93 | 90.24 | 36.10 | [a] | Zovirax 800 mg | GK |
| | **FAMCICLOVIR**<br>**Authority required (STREAMLINED)**<br>***3624***<br>Episodic treatment of moderate to severe recurrent genital herpes. Microbiological confirmation of diagnosis (viral culture, antigen detection or nucleic acid amplification by PCR) is required but need not delay treatment<br>**Note**<br>Famciclovir 125 mg is not PBS-subsidised for chickenpox, herpes zoster or herpes simplex infections other than genital herpes. | | | | | | | | |
| 8092X<br>*NP* | famciclovir 125 mg tablet, 40 | 1 | 1 | .. | 132.09 | 36.10 | [a] | APO-Famciclovir | TX |
| | | | | | | | [a] | Ezovir | AF |
| | | | | | | | [a] | Famciclovir-GA | GM |

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | [a] | Famvir | NV |
| | | | | | | | [a] | Favic 125 | QA |
| | **FAMCICLOVIR**<br>**Authority required (STREAMLINED)**<br>***3624***<br>Episodic treatment of moderate to severe recurrent genital herpes. Microbiological confirmation of diagnosis (viral culture, antigen detection or nucleic acid amplification by PCR) is required but need not delay treatment<br>**Note**<br>Famciclovir 250 mg is not PBS-subsidised for chickenpox or herpes simplex infections other than genital herpes. | | | | | | | | |
| 2274Q<br>*NP* | famciclovir 250 mg tablet, 20 | 1 | 1 | .. | 132.10 | 36.10 | [a] | APO-Famciclovir | TX |
| | | | | | | | [a] | Ezovir | AF |
| | | | | | | | [a] | Famciclovir-GA | GM |
| | | | | | | | [a] | Famciclovir Sandoz | SZ |
| | | | | | | | [a] | Famvir | NV |
| | | | | | | | [a] | Favic 250 | QA |
| | **FAMCICLOVIR**<br>**Authority required (STREAMLINED)**<br>***3622***<br>Treatment of patients with herpes zoster within 72 hours of the onset of the rash<br>**Note**<br>Famciclovir is effective only if commenced within 72 hours of onset of rash.<br>Famciclovir 250 mg is not PBS-subsidised for chickenpox or herpes simplex infections other than genital herpes.<br>**Note**<br>No applications for repeats will be authorised. | | | | | | | | |
| 8002E<br>*NP* | famciclovir 250 mg tablet, 21 | 1 | .. | .. | 138.37 | 36.10 | [a] | APO-Famciclovir | TX |
| | | | | | | | [a] | Ezovir | AF |
| | | | | | | | [a] | Famciclovir-GA | GM |
| | | | | | | | [a] | Famciclovir generichealth 250 | GQ |
| | | | | | | | [a] | Famciclovir Sandoz | SZ |
| | | | | | | | [a] | Famlo | RA |
| | | | | | | | [a] | Famvir | NV |
| | | | | | | | [a] | Favic 250 | QA |
| | **FAMCICLOVIR**<br>**Authority required (STREAMLINED)**<br>***3623***<br>Suppressive therapy of moderate to severe recurrent genital herpes. Microbiological confirmation of diagnosis (viral culture, antigen detection or nucleic acid amplification by PCR) is required but need not delay treatment<br>**Note**<br>Famciclovir 250 mg is not PBS-subsidised for chickenpox or herpes simplex infections other than genital herpes. | | | | | | | | |
| 8217L<br>*NP* | famciclovir 250 mg tablet, 56 | 1 | 5 | .. | 343.99 | 36.10 | [a] | APO-Famciclovir | TX |
| | | | | | | | [a] | Ezovir | AF |
| | | | | | | | [a] | Famciclovir-GA | GM |
| | | | | | | | [a] | Famciclovir generichealth 250 | GQ |
| | | | | | | | [a] | Famciclovir Sandoz | SZ |
| | | | | | | | [a] | Famlo | RA |
| | | | | | | | [a] | Famvir | NV |
| | | | | | | | [a] | Favic 250 | QA |
| | **FAMCICLOVIR**<br>**Authority required (STREAMLINED)**<br>***3625***<br>Treatment of immunocompromised patients with herpes zoster within 72 hours of the onset of the rash<br>**Note**<br>Famciclovir is effective only if commenced within 72 hours of onset of rash.<br>Famciclovir 500 mg is not PBS-subsidised for chickenpox. | | | | | | | | |

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|---|
| | Famciclovir 500 mg is not PBS-subsidised for herpes zoster, genital herpes or other herpes simplex infections in immunocompetent patients. | | | | | | | | |
| | **Note**<br>No applications for repeats will be authorised. | | | | | | | | |
| 8897G<br>*NP* | famciclovir 500 mg tablet, 30 | 1 | .. | .. | 194.82 | 36.10 | [a] | APO-Famciclovir | TX |
| | | | | | | | [a] | Chem mart Famciclovir | CH |
| | | | | | | | [a] | Famciclovir Sandoz | SZ |
| | | | | | | | [a] | Famvir | NV |
| | | | | | | | [a] | Favic 500 | QA |
| | | | | | | | [a] | Terry White Chemists Famciclovir | TW |
| | **FAMCICLOVIR**<br>**Authority required (STREAMLINED)**<br>***3626***<br>Episodic treatment or suppressive therapy of moderate to severe recurrent genital herpes in immunocompromised patients. Microbiological confirmation of diagnosis (viral culture, antigen detection or nucleic acid amplification by PCR) is required but need not delay treatment | | | | | | | | |
| | **Authority required (STREAMLINED)**<br>***3627***<br>Episodic treatment of moderate to severe recurrent oral or labial herpes in a patient with HIV infection and a CD4 cell count of less than 500 million per litre. Microbiological confirmation of diagnosis (viral culture, antigen detection or nucleic acid amplification by PCR) is required but need not delay treatment | | | | | | | | |
| | **Authority required (STREAMLINED)**<br>***3628***<br>Suppressive therapy of moderate to severe recurrent oral or labial herpes in a patient with HIV infection and a CD4 cell count of less than 150 million per litre. Microbiological confirmation of diagnosis (viral culture, antigen detection or nucleic acid amplification by PCR) is required but need not delay treatment | | | | | | | | |
| | **Authority required (STREAMLINED)**<br>***3629***<br>Suppressive therapy of moderate to severe recurrent oral or labial herpes in a patient with HIV infection and other opportunistic infections or AIDS defining tumours. Microbiological confirmation of diagnosis (viral culture, antigen detection or nucleic acid amplification by PCR) is required but need not delay treatment | | | | | | | | |
| | **Note**<br>Famciclovir 500 mg is not PBS-subsidised for chickenpox. | | | | | | | | |
| | Famciclovir 500 mg is not PBS-subsidised for herpes zoster, genital herpes or other herpes simplex infections in immunocompetent patients. | | | | | | | | |
| 8896F<br>*NP* | famciclovir 500 mg tablet, 56 | 1 | 5 | .. | 343.98 | 36.10 | [a] | APO-Famciclovir | TX |
| | | | | | | | [a] | Auro-Famciclovir 500 | DO |
| | | | | | | | [a] | Chem mart Famciclovir | CH |
| | | | | | | | [a] | Ezovir | AF |
| | | | | | | | [a] | Famciclovir-GA | GM |
| | | | | | | | [a] | Famciclovir generichealth 500 | GQ |
| | | | | | | | [a] | Famciclovir Sandoz | SZ |
| | | | | | | | [a] | Famvir | NV |
| | | | | | | | [a] | Favic 500 | QA |
| | | | | | | | [a] | Terry White Chemists Famciclovir | TW |
| | **VALACICLOVIR**<br>**Authority required (STREAMLINED)**<br>***3632***<br>Moderate to severe initial genital herpes. Microbiological confirmation of diagnosis (viral culture, antigen detection or nucleic acid amplification by PCR) is desirable but need not delay treatment | | | | | | | | |
| | **Note**<br>Valaciclovir 500 mg is not PBS-subsidised for chickenpox or herpes simplex infections other than genital herpes. | | | | | | | | |
| | **Note**<br>No applications for increased maximum quantities and/or repeats will be authorised. | | | | | | | | |
| 8133C<br>*NP* | valaciclovir 500 mg tablet, 10 | 2 | .. | .. | *105.99 | 36.10 | [a] | APO-Valaciclovir | TX |
| | | | | | | | [a] | Chem mart Valaciclovir | CH |
| | | | | | | | [a] | Terry White Chemists Valaciclovir | TW |

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | [a] | Vaclovir | AF |
| | | | | | | | [a] | Valaciclovir GA | GN |
| | | | | | | | [a] | Valaciclovir Sandoz | SZ |
| | | | | | | | [a] | Valnir | QA |
| | | | | | | | [a] | Valtrex | AS |
| | | | | | | | [a] | Zelitrex | GM |
| | **VALACICLOVIR**<br>**Authority required (STREAMLINED)**<br>***3623***<br>Suppressive therapy of moderate to severe recurrent genital herpes. Microbiological confirmation of diagnosis (viral culture, antigen detection or nucleic acid amplification by PCR) is required but need not delay treatment<br>**Note**<br>Valaciclovir 500 mg is not PBS-subsidised for chickenpox or herpes simplex infections other than genital herpes. | | | | | | | | |
| 5480K<br>*NP* | valaciclovir 500 mg tablet, 30 | 1 | 5 | .. | 155.66 | 36.10 | [a] | APO-Valaciclovir | TX |
| | | | | | | | [a] | Chem mart Valaciclovir | CH |
| | | | | | | | [a] | Shilova 500 | DO |
| | | | | | | | [a] | Terry White Chemists Valaciclovir | TW |
| | | | | | | | [a] | Vaclovir | AF |
| | | | | | | | [a] | Valaciclovir GA | GN |
| | | | | | | | [a] | Valaciclovir generichealth | GQ |
| | | | | | | | [a] | Valaciclovir RBX | RA |
| | | | | | | | [a] | Valaciclovir SZ | HX |
| | | | | | | | [a] | Valacor 500 | CR |
| | | | | | | | [a] | Valnir | QA |
| | | | | | | | [a] | Valtrex | AS |
| | | | | | | | [a] | Zelitrex | GM |
| | **VALACICLOVIR**<br>**Authority required (STREAMLINED)**<br>***3624***<br>Episodic treatment of moderate to severe recurrent genital herpes. Microbiological confirmation of diagnosis (viral culture, antigen detection or nucleic acid amplification by PCR) is required but need not delay treatment<br>**Note**<br>Valaciclovir 500 mg is not PBS-subsidised for chickenpox or herpes simplex infections other than genital herpes. | | | | | | | | |
| 8134D<br>*NP* | valaciclovir 500 mg tablet, 30 | 1 | 5 | .. | 155.66 | 36.10 | [a] | APO-Valaciclovir | TX |
| | | | | | | | [a] | Chem mart Valaciclovir | CH |
| | | | | | | | [a] | Shilova 500 | DO |
| | | | | | | | [a] | Terry White Chemists Valaciclovir | TW |
| | | | | | | | [a] | Vaclovir | AF |
| | | | | | | | [a] | Valaciclovir GA | GN |
| | | | | | | | [a] | Valaciclovir generichealth | GQ |
| | | | | | | | [a] | Valaciclovir RBX | RA |
| | | | | | | | [a] | Valaciclovir Sandoz | SZ |
| | | | | | | | [a] | Valaciclovir SZ | HX |
| | | | | | | | [a] | Valacor 500 | CR |
| | | | | | | | [a] | Valnir | QA |
| | | | | | | | [a] | Valtrex | AS |
| | | | | | | | [a] | Zelitrex | GM |
| | **VALACICLOVIR**<br>**Authority required (STREAMLINED)**<br>***3622***<br>Treatment of patients with herpes zoster within 72 hours of the onset of the rash<br>**Authority required (STREAMLINED)**<br>***3631***<br>Herpes zoster ophthalmicus<br>**Note** | | | | | | | | |

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|---|
| | Valaciclovir is effective only if commenced within 72 hours of onset of rash. | | | | | | | | |
| | Valaciclovir 500 mg is not PBS-subsidised for chickenpox or herpes simplex infections other than genital herpes. | | | | | | | | |
| | **Note**<br>No applications for repeats will be authorised. | | | | | | | | |
| 8064K<br>*NP* | valaciclovir 500 mg tablet, 42 | 1 | .. | .. | 214.30 | 36.10 | [a] | APO-Valaciclovir | TX |
| | | | | | | | [a] | Chem mart Valaciclovir | CH |
| | | | | | | | [a] | Terry White Chemists Valaciclovir | TW |
| | | | | | | | [a] | Vaclovir | AF |
| | | | | | | | [a] | Valaciclovir GA | GN |
| | | | | | | | [a] | Valaciclovir generichealth | GQ |
| | | | | | | | [a] | Valaciclovir RBX | RA |
| | | | | | | | [a] | Valaciclovir Sandoz | SZ |
| | | | | | | | [a] | Valacor 500 | CR |
| | | | | | | | [a] | Valnir | QA |
| | | | | | | | [a] | Valtrex | AS |
| | | | | | | | [a] | Zelitrex | GM |

## VACCINES

### BACTERIAL VACCINES

#### *Pneumococcal vaccines*

**PNEUMOCOCCAL PURIFIED CAPSULAR POLYSACCHARIDES**

**Restricted benefit**
Splenectomised persons over 2 years of age

**Restricted benefit**
Persons with Hodgkin's disease

**Restricted benefit**
Persons at high risk of pneumococcal infections

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 1903E<br>*NP* | pneumococcal purified capsular polysaccharides 25 microgram/0.5 mL injection, 1 x 0.5 mL vial | 1 | .. | .. | 46.34 | 36.10 | | Pneumovax 23 | CS |

#### *Tetanus vaccines*

**DIPHTHERIA TOXOID + TETANUS TOXOID**

**Note**
For immunisation of adults and children aged greater than or equal to 8 years.

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 8783G<br>*NP* | diphtheria toxoid 2 international units/0.5 mL + tetanus toxoid 20 international units/0.5 mL injection, 5 x 0.5 mL syringes | 1 | .. | .. | 75.55 | 36.10 | | ADT Booster | CS |

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|---|
| | **ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS** | | | | | | | | |
| | ANTINEOPLASTIC AGENTS | | | | | | | | |
| | **ALKYLATING AGENTS** | | | | | | | | |
| | ***Nitrogen mustard analogues*** | | | | | | | | |
| | **CHLORAMBUCIL** | | | | | | | | |
| 1163F | chlorambucil 2 mg tablet, 25 | 4 | 2 | .. | *138.19 | 36.10 | | Leukeran | AS |
| | **CYCLOPHOSPHAMIDE** | | | | | | | | |
| 1266P | cyclophosphamide 50 mg tablet, 50 | 1 | 2 | .. | 31.50 | 32.63 | | Cycloblastin | PF |
| | **MELPHALAN** | | | | | | | | |
| 2547C | melphalan 2 mg tablet, 25 | 1 | 1 | .. | 51.10 | 36.10 | | Alkeran | AS |
| | ***Alkyl sulfonates*** | | | | | | | | |
| | **BUSULFAN** | | | | | | | | |
| 1128J | busulfan 2 mg tablet, 100 | 1 | .. | .. | 86.47 | 36.10 | | Myleran | AS |
| | ***Nitrosoureas*** | | | | | | | | |
| | **CARMUSTINE** | | | | | | | | |
| | **Restricted benefit** | | | | | | | | |
| | Glioblastoma multiforme, suspected or confirmed, at the time of initial surgery | | | | | | | | |
| | **Note** | | | | | | | | |
| | Carmustine is not PBS-subsidised for use in conjunction with PBS-subsidised temozolomide. | | | | | | | | |
| 8898H | carmustine 7.7 mg implant, 8 | ‡1 | .. | .. | 17539.53 | 36.10 | | Gliadel | OA |
| | ***Other alkylating agents*** | | | | | | | | |
| | **TEMOZOLOMIDE** | | | | | | | | |
| | **Authority required** | | | | | | | | |
| | Recurrence of anaplastic astrocytoma following standard therapy | | | | | | | | |
| | **Authority required** | | | | | | | | |
| | Recurrence of glioblastoma multiforme following standard therapy | | | | | | | | |
| | **Authority required** | | | | | | | | |
| | Glioblastoma multiforme following radiotherapy | | | | | | | | |
| 8380C | temozolomide 100 mg capsule, 5 | 1 | 5 | .. | 504.25 | 36.10 | [a] | Astromide | WQ |
| | | | | | | | [a] | Orion Temozolomide | ON |
| | | | | | | | [a] | Temizole 100 | QA |
| | | | | | | | [a] | Temodal | MK |
| 9362R | temozolomide 140 mg capsule, 5 | 1 | 5 | .. | 683.70 | 36.10 | [a] | Astromide | WQ |
| | | | | | | | [a] | Orion Temozolomide | ON |
| | | | | | | | [a] | Temizole 140 | QA |
| | | | | | | | [a] | Temodal | MK |
| 2438H | temozolomide 180 mg capsule, 5 | 1 | 5 | .. | 895.94 | 36.10 | [a] | Astromide | WQ |
| | | | | | | | [a] | Temodal | MK |
| 8379B | temozolomide 20 mg capsule, 5 | 1 | 5 | .. | 132.29 | 36.10 | [a] | Astromide | WQ |
| | | | | | | | [a] | Orion Temozolomide | ON |
| | | | | | | | [a] | Temizole 20 | QA |
| | | | | | | | [a] | Temodal | MK |
| 8381D | temozolomide 250 mg capsule, 5 | 1 | 5 | .. | 1204.07 | 36.10 | [a] | Astromide | WQ |
| | | | | | | | [a] | Orion Temozolomide | ON |
| | | | | | | | [a] | Temizole 250 | QA |
| | | | | | | | [a] | Temodal | MK |
| 8378Y | temozolomide 5 mg capsule, 5 | 1 | 5 | .. | 49.99 | 36.10 | [a] | Astromide | WQ |
| | | | | | | | [a] | Orion Temozolomide | ON |
| | | | | | | | [a] | Temizole 5 | QA |
| | | | | | | | [a] | Temodal | MK |
| | **TEMOZOLOMIDE** | | | | | | | | |
| | **Authority required** | | | | | | | | |

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|---|
| | Glioblastoma multiforme concomitantly with radiotherapy | | | | | | | | |
| | **Note**<br>Temozolomide is not PBS-subsidised for use in conjunction with PBS-subsidised carmustine. | | | | | | | | |
| | **Note**<br>No applications for increased repeats will be authorised. | | | | | | | | |
| 8821G | temozolomide 100 mg capsule, 5 | 3 | 2 | .. | *1499.49 | 36.10 | [a] | Astromide | WQ |
| | | | | | | | [a] | Orion Temozolomide | ON |
| | | | | | | | [a] | Temizole 100 | QA |
| | | | | | | | [a] | Temodal | MK |
| 9361Q | temozolomide 140 mg capsule, 5 | 3 | 2 | .. | *2029.71 | 36.10 | [a] | Astromide | WQ |
| | | | | | | | [a] | Orion Temozolomide | ON |
| | | | | | | | [a] | Temizole 140 | QA |
| | | | | | | | [a] | Temodal | MK |
| 8820F | temozolomide 20 mg capsule, 5 | 3 | 2 | .. | *367.35 | 36.10 | [a] | Astromide | WQ |
| | | | | | | | [a] | Orion Temozolomide | ON |
| | | | | | | | [a] | Temizole 20 | QA |
| | | | | | | | [a] | Temodal | MK |
| 8819E | temozolomide 5 mg capsule, 5 | 3 | 2 | .. | *134.88 | 36.10 | [a] | Astromide | WQ |
| | | | | | | | [a] | Orion Temozolomide | ON |
| | | | | | | | [a] | Temizole 5 | QA |
| | | | | | | | [a] | Temodal | MK |

## ANTIMETABOLITES

### *Folic acid analogues*

**METHOTREXATE**

**Note**
For item codes 2395C and 1818Q, pharmaceutical benefits that have the form injection 50 mg in 2 mL are equivalent for the purposes of substitution.

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 1818Q | METHOTREXATE Injection 50 mg in 2 mL, 1 | 5 | 5 | .. | *24.98 | 26.11 | [a] | Methaccord | WQ |
| 2395C | methotrexate 50 mg/2 mL injection, 5 x 2 mL vials | 1 | 5 | .. | 25.00 | 26.13 | [a] | Hospira Pty Limited | HH |
| | | | | | | | [a] | Pfizer Australia Pty Ltd | PF |

**METHOTREXATE**

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 2272N | methotrexate 10 mg tablet, 15 | 1 | 3 | .. | 20.55 | 21.68 | | Methoblastin | PF |
| 1622J | methotrexate 2.5 mg tablet, 30 | 1 | 5 | .. | 13.33 | 14.46 | [a] | Hospira Pty Limited | HH |
| | | | | | | | [a] | Methoblastin | PF |
| 2396D | methotrexate 5 mg/2 mL injection, 5 x 2 mL vials | 1 | .. | .. | 25.38 | 26.51 | | Hospira Pty Limited | HH |

**METHOTREXATE**
**Restricted benefit**
For patients requiring doses greater than 20 mg per week

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 1623K | methotrexate 10 mg tablet, 50 | 1 | 2 | .. | 51.45 | 36.10 | | Methoblastin | PF |

### *Purine analogues*

**FLUDARABINE**
**Authority required**
B-cell chronic lymphocytic leukaemia in combination with cyclophosphamide where the patient has advanced disease (Binet Stage B or C) or evidence of progressive Stage A disease.

Stage A progressive disease is defined by at least one of the following: persistent rise in lymphocyte count with doubling time less than 12 months; a downward trend in haemoglobin or platelets, or both; more than 50% increase in the size of liver, spleen, or lymph nodes, or appearance of these signs if not previously present; constitutional symptoms attributable to disease.

The diagnosis of chronic lymphocytic leukaemia (CLL) must have been established based on:

(a) a lymphocytosis, with more than 5,000 million lymphocytes per L in the peripheral blood; and

(b) a clonal population of B-cells (CD5/CD19) documented by flow cytometry

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 9184J | fludarabine phosphate 10 mg tablet, 20 | 1 | 5 | .. | 936.91 | 36.10 | | Fludara | GZ |

**MERCAPTOPURINE**

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 1598D | mercaptopurine 50 mg tablet, 25 | 4 | 2 | .. | *252.15 | 36.10 | | Purinethol | AS |

# ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|
| | **THIOGUANINE** | | | | | | | |
| 1233X | thioguanine 40 mg tablet, 25 | 1 | 1 | .. | 198.87 | 36.10 | Lanvis | AS |

## *Pyrimidine analogues*

**CAPECITABINE**

**Authority required**

Advanced breast cancer after failure of prior therapy which includes a taxane and an anthracycline

**Authority required**

Advanced breast cancer where therapy with a taxane and/or an anthracycline is contraindicated

**Authority required**

Advanced breast cancer in combination with docetaxel after failure of prior anthracycline-containing chemotherapy

**Authority required**

Treatment of advanced or metastatic colorectal cancer

**Authority required**

Adjuvant treatment of stage III (Dukes C) colon cancer, following complete resection of the primary tumour either as:

(a) monotherapy; or

(b) in combination with oxaliplatin

**Authority required**

Advanced (Stage III or IV) oesophago-gastric cancer, previously untreated, in combination with a cisplatin-based regimen, in a patient with a WHO performance status of 2 or less

**Note**

In the adjuvant setting, the recommended treatment duration is 24 weeks.

Capecitabine is not PBS-subsidised for the treatment of patients with stage II (Dukes B) colon cancer.

Capecitabine is not PBS-subsidised for the adjuvant treatment of patients with rectal cancer.

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 8361C | capecitabine 150 mg tablet, 60 | 1 | 2 | .. | 124.14 | 36.10 | Xeloda | RO |
| 8362D | capecitabine 500 mg tablet, 120 | 1 | 2 | .. | 695.38 | 36.10 | Xeloda | RO |

# PLANT ALKALOIDS AND OTHER NATURAL PRODUCTS

## *Vinca alkaloids and analogues*

**VINORELBINE**

**Authority required**

Advanced breast cancer

**The Clinical criteria is:**

Patient must have failed standard prior therapy, which includes an anthracycline.

**Authority required**

Locally advanced or metastatic non-small cell lung cancer

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 9009E | vinorelbine 20 mg capsule, 1 | 20 | 2 | .. | *1579.43 | 36.10 | Navelbine | FB |
| 9010F | vinorelbine 30 mg capsule, 1 | 16 | 2 | .. | *1887.43 | 36.10 | Navelbine | FB |

## *Podophyllotoxin derivatives*

**ETOPOSIDE**

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 1389D | etoposide 100 mg capsule, 10 | 1 | .. | .. | 390.94 | 36.10 | Vepesid | BQ |
| 1396L | etoposide 50 mg capsule, 20 | 1 | .. | .. | 445.15 | 36.10 | Vepesid | BQ |

# CYTOTOXIC ANTIBIOTICS AND RELATED SUBSTANCES

## *Anthracyclines and related substances*

**IDARUBICIN**

**Restricted benefit**

Acute myelogenous leukaemia

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 2448W | idarubicin hydrochloride 10 mg capsule, 1 | 3 | .. | .. | *494.70 | 36.10 | Zavedos | PF |
| 2446R | idarubicin hydrochloride 5 mg capsule, 1 | 3 | .. | .. | *267.81 | 36.10 | Zavedos | PF |

# OTHER ANTINEOPLASTIC AGENTS

## *Protein kinase inhibitors*

**DASATINIB**

**Authority required**

Initial treatment, as the sole PBS-subsidised therapy, of a patient in the chronic phase of chronic myeloid leukaemia expressing the Philadelphia

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|

chromosome or the transcript, BCR-ABL tyrosine kinase, and who has a primary diagnosis of chronic myeloid leukaemia.

Applications under this restriction will be limited to provide patients with a maximum of 18 months of therapy with dasatinib, imatinib or nilotinib from the date the first application for initial treatment was approved.

Patients should be commenced on a dose of dasatinib of at least 100 mg (base) daily. Continuing therapy is dependent on patients demonstrating a response to dasatinib therapy following the initial 18 months of treatment and at 12 monthly intervals thereafter.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Chronic Myeloid Leukaemia - Chronic Phase, First Line - Supporting Information form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and

(3) a pathology cytogenetic report conducted on peripheral blood or bone marrow supporting the diagnosis of chronic myeloid leukaemia to confirm eligibility for treatment, or a qualitative PCR report documenting the presence of the BCR-ABL transcript in either peripheral blood or bone marrow; and

(4) a signed patient acknowledgement form

**Authority required**

Continuing treatment, as the sole PBS-subsidised therapy, of a patient who has received initial PBS-subsidised treatment with dasatinib for the chronic phase of chronic myeloid leukaemia and who has demonstrated either a major cytogenetic response or less than 1% BCR-ABL level in the blood.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) demonstration of continued response to treatment as evidenced by either:

(a) major cytogenetic response [see Note explaining requirements]. Where this has been supplied within the previous 12 months, only the date of the relevant pathology report need be provided; or

(b) a peripheral blood level of BCR-ABL of less than 1% on the international scale [see Note explaining requirements]. Where this has been supplied within the previous 12 months, only the date of the relevant pathology report need be provided

**Note**

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

Prescribing information (including Authority Application forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Applications for authority to prescribe dasatinib should be forwarded to:

Medicare Australia

Prior Written Approval of Specialised Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

**Note**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of tyrosine kinase inhibitors (TKI) agents for the chronic phase of chronic myeloid leukaemia. Where the term TKI agent appears in the following notes and restrictions it refers to imatinib mesylate, dasatinib or nilotinib.

Patients are eligible for PBS-subsidised treatment with only one TKI agent at any one time and must not be receiving concomitant interferon alfa therapy. Eligible patients may only swap between TKI agents if they have not failed prior PBS-subsidised treatment with that agent.

1. Initial treatment - imatinib mesylate, dasatinib and nilotinib

From 1 April 2012, under the PBS, a patient will be able to be prescribed any of imatinib mesylate, dasatinib or nilotinib within the initial 18 month treatment period, as long as only one agent is used at a time and providing the patient has not failed to respond to any one of these TKIs.

During the initial 18 month treatment period, switching between approved first-line agents may only occur for reasons of intolerance, not failure of response.

2. Continuing treatment with imatinib mesylate - first-line

First continuing applications are to be written and must include a pathology report demonstrating the patient has responded to the initial course of treatment.

Second and subsequent authority applications for continuing therapy with imatinib mesylate may be made on the telephone by contacting Medicare Australia on 1800 700 720 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Patients must maintain a major cytogenetic response or have a peripheral blood BCR-ABL of less than 1% to receive continuing therapy.

3. Continuing treatment with dasatinib or nilotinib - first-line

All continuing applications are to be written and must include a pathology report demonstrating the patient has responded to PBS-subsidised treatment as follows:

(i) within 18 months of the commencement of treatment, at which time patients in whom a major cytogenetic response or peripheral blood BCR-ABL level of less than 1% has been demonstrated may receive authorisation for a further 12 months of treatment; and

(ii) at no greater than 12 month intervals thereafter, to demonstrate that the major cytogenetic response or peripheral blood BCR-ABL level of less

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|

than 1% has been sustained.

4. For imatinib mesylate, dasatinib and nilotinib

During continuing therapy beyond the initial 18 month treatment period, switching between approved first-line agents may only occur for reason of intolerance. Where there is failure of response, switching may only occur through application for prescription of second-line agents.

Where a patient has previously received PBS-subsidised treatment with imatinib mesylate, dasatinib or nilotinib no approval will be granted for PBS-subsidised re-treatment in the chronic phase of chronic myeloid leukaemia, where that patient has at any time failed to meet the response criteria whilst on that TKI agent.

5. Authority approval requirements.

Response criteria to initial treatment with imatinib mesylate, dasatinib or nilotinib:

For the purposes of assessing response to PBS-subsidised treatment with imatinib mesylate, dasatinib or nilotinib either cytogenetic analysis indicating the number of Philadelphia positive [t (9;22)] cells in the bone marrow measured by standard karyotyping, or quantitative PCR indicating the relative level of BCR-ABL transcript in the peripheral blood using the international scale, must be submitted. For bone marrow analyses, where the standard karyotyping is not informative for technical reasons, a cytogenetic analysis performed on the bone marrow by the use of fluorescence in situ hybridisation (FISH) with BCR-ABL specific probe must be submitted. The cytogenetic or peripheral blood quantitative PCR analyses must be submitted within 18 months of the commencement of treatment with imatinib mesylate, dasatinib or nilotinib (patients in whom a major cytogenetic response or peripheral blood BCR-ABL level of less than 1% is demonstrable by 18 months are eligible to receive continuing treatment with that agent).

6. Definitions of response.

A major cytogenetic response is defined as less than 35% Philadelphia positive bone marrow cells.

A peripheral blood BCR-ABL level of less than 1% on the international scale (Blood 108: 28-37, 2006) also indicates a response, at least the biological equivalent of a major cytogenetic response.

7. Definitions of loss of response.

Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph positive cells on bone marrow biopsy), during ongoing tyrosine kinase inhibitor (TKI) therapy.

Loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing consecutively in value by at least 5 fold to a level of greater than 0.1% confirmed on a subsequent test), during ongoing tyrosine kinase inhibitor therapy.

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 1416M | dasatinib 100 mg tablet, 30 | 1 | 5 | .. | 5004.01 | 36.10 | Sprycel | BQ |
| 1354G | dasatinib 20 mg tablet, 60 | 1 | 5 | .. | 3095.66 | 36.10 | Sprycel | BQ |
| 1381Q | dasatinib 50 mg tablet, 60 | 1 | 5 | .. | 5004.01 | 36.10 | Sprycel | BQ |
| 1415L | dasatinib 70 mg tablet, 60 | 1 | 5 | .. | 6160.40 | 36.10 | Sprycel | BQ |

**DASATINIB**

**Authority required**

Initial treatment, as the sole PBS-subsidised therapy, of a patient with chronic myeloid leukaemia in any disease phase who has failed an adequate trial of imatinib or nilotinib as first-line treatment.

Failure of an adequate trial of imatinib or nilotinib is defined as:

(i) Lack of response to initial imatinib or nilotinib therapy, defined as either:

— failure to achieve a haematological response after a minimum of 3 months therapy with imatinib or nilotinib for patients initially treated in chronic phase; or

— failure to achieve any cytogenetic response after a minimum of 6 months therapy with imatinib or nilotinib for patients initially treated in chronic phase as demonstrated on bone marrow biopsy by presence of greater than 95% Philadelphia chromosome positive cells; or

— failure to achieve a major cytogenetic response or a peripheral blood BCR-ABL level of less than 1% after a minimum of 12 months therapy with imatinib or nilotinib; OR

(ii) Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph positive cells on bone marrow biopsy), during ongoing imatinib or nilotinib therapy; OR

(iii) Loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing consecutively in value by at least 5 fold to a level of greater than 0.1% confirmed on a subsequent test), during ongoing imatinib or nilotinib therapy; OR

(iv) Development of accelerated phase or blast crisis in a patient previously prescribed imatinib or nilotinib for any phase of chronic myeloid leukaemia.

Accelerated phase is defined by the presence of 1 or more of the following:

(1) Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 15% but less than 30%; or

(2) Percentage of blasts plus promyelocytes in the peripheral blood or bone marrow greater than or equal to 30%, provided that blast count is less than 30%; or

(3) Peripheral basophils greater than or equal to 20%; or

(4) Progressive splenomegaly to a size greater than or equal to 10 cm below the left costal margin to be confirmed on 2 occasions at least 4 weeks apart, or a greater than or equal to 50% increase in size below the left costal margin over 4 weeks; or

(5) Karyotypic evolution (chromosomal abnormalities in addition to a single Philadelphia chromosome); OR

Blast crisis is defined as either:

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|

(1) Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 30%; or

(2) Extramedullary involvement other than spleen and liver; OR

(v) Disease progression (defined as a greater than or equal to 50% increase in peripheral white blood cell count, blast count, basophils or platelets) during first-line imatinib or nilotinib therapy in patients with accelerated phase or blast crisis chronic myeloid leukaemia.

Patients should be commenced on a dose of dasatinib of at least 100 mg (base) daily. Continuing therapy is dependent on patients demonstrating a major cytogenetic response to dasatinib therapy or a peripheral blood BCR-ABL level of less than 1% within 18 months and thereafter at 12 monthly intervals.

Applications for authorisation must be in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Chronic Myeloid Leukaemia - Second and Third Line - Supporting Information Form; and

(c) a signed patient acknowledgement; and

(d) a bone marrow biopsy pathology report demonstrating the patient has active chronic myeloid leukaemia, either manifest as cytogenetic evidence of the Philadelphia chromosome, or RT-PCR level of BCR-ABL transcript greater than 0.1% on the international scale. (The date of the relevant pathology report needs to be provided); and

(e) where there has been a loss of response to imatinib or nilotinib, a copy of the current confirming pathology report(s) from an Approved Pathology Authority or details of the dates of assessment in the case of progressive splenomegaly or extramedullary involvement

**Authority required**

Continuing treatment, as the sole PBS-subsidised therapy, of a patient who has received initial PBS-subsidised treatment with dasatinib for chronic myeloid leukaemia, and who has demonstrated either a major cytogenetic response, or less than 1% BCR-ABL level in the blood, to dasatinib in the preceding 18 months and thereafter at 12 monthly intervals.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Chronic Myeloid Leukaemia - Second and Third Line - Application Form for continuing treatment; and

(3) demonstration of continued response to treatment as evidenced by either:

(a) major cytogenetic response [see Note explaining definitions of response]. Where this has been supplied within the previous 12 months (or 18 months for the initial supply), only the date of the relevant pathology report needs to be provided; or

(b) a peripheral blood level of BCR-ABL of less than 1% on the international scale [see Note explaining definitions of response]. Where this has been supplied within the previous 12 months (or 18 months for the initial supply), only the date of the relevant pathology report needs to be provided

**Note**

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

Prescribing information (including Authority Application forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Applications for authority to prescribe dasatinib should be forwarded to:

Medicare Australia

Prior Written Approval of Specialised Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

**Note**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of tyrosine kinase inhibitors (TKI) agents for all phases of chronic myeloid leukaemia. Where the term TKI agent appears in the following notes and restrictions it refers to dasatinib or nilotinib. Imatinib mesylate is not approved for use in second or third line treatment.

Patients are eligible for PBS-subsidised treatment with only one of dasatinib or nilotinib at any one time and must not be receiving concomitant interferon alfa therapy. Eligible patients may only swap between these agents if they have not failed prior PBS-subsidised treatment with that agent.

Nilotinib is not approved for patients in blast crisis.

1. Initial second line treatment

From 1 April 2012, under the PBS, a patient will be able to be prescribed either dasatinib or nilotinib within the initial 18 month treatment period as second-line therapy, as long as only one agent is approved at a time and providing the patient did not fail that drug as first-line therapy.

During the initial 18 month treatment period, switching between approved second-line agents may only occur for reasons of intolerance, not failure of response.

2. Initial third line treatment

Third-line treatment with a TKI can only be approved when imatinib is used for first-line treatment. Patients will only be approved for PBS-subsidised treatment with one third-line agent.

From 1 April 2012, under the PBS, a patient will be able to be prescribed either dasatinib or nilotinib providing the patient did not fail that drug as first or second line therapy and for nilotinib the patient is not in blast crisis.

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|
| | 3. Continuing treatment for second and third line treatment<br>All continuing applications are to be written and must include a pathology report demonstrating the patient has responded to PBS-subsidised treatment as follows:<br>(i) within 18 months of the commencement of treatment, at which time patients in whom a major cytogenetic response or peripheral blood BCR-ABL level of less than 1% has been demonstrated may receive authorisation for a further 12 months of treatment; and<br>(ii) at no greater than 12 month intervals thereafter, to demonstrate that the major cytogenetic response or peripheral blood BCR-ABL level of less than 1% has been sustained.<br>During second line continuing treatment beyond the initial 18 month treatment period, switching between approved second line TKI agents may only occur for reason of intolerance. Where there is failure of response, switching may only occur through application for prescription of a third line agent.<br>4. Authority approval requirements.<br>Response criteria to initial treatment with dasatinib or nilotinib:<br>For the purposes of assessing response to PBS-subsidised treatment with dasatinib or nilotinib, either cytogenetic analysis indicating the number of Philadelphia positive [t (9;22)] cells in the bone marrow measured by standard karyotyping, or quantitative PCR indicating the relative level of BCR-ABL transcript in the peripheral blood using the international scale, must be submitted. For bone marrow analyses, where the standard karyotyping is not informative for technical reasons, a cytogenetic analysis performed on the bone marrow by the use of fluorescence in situ hybridisation (FISH) with BCR-ABL specific probe must be submitted. The cytogenetic or peripheral blood quantitative PCR analyses must be submitted within 18 months of the commencement of treatment with dasatinib or nilotinib (patients in whom a major cytogenetic response or peripheral blood BCR-ABL level of less than 1% is demonstrable by 18 months are eligible to receive continuing treatment with that agent).<br>5. Definitions of response.<br>A major cytogenetic response is defined as less than 35% Philadelphia positive bone marrow cells.<br>A peripheral blood BCR-ABL level of less than 1% on the international scale (Blood 108: 28-37, 2006) also indicates a response, at least the biological equivalent of a major cytogenetic response.<br>6. Definitions of loss of response.<br>Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph positive cells on bone marrow biopsy), during ongoing tyrosine kinase inhibitor (TKI) therapy.<br>Loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing consecutively in value by at least 5 fold to a level of greater than 0.1% confirmed on a subsequent test), during ongoing tyrosine kinase inhibitor therapy. | | | | | | | |
| 9342Q | dasatinib 100 mg tablet, 30 | 1 | 5 | .. | 5004.01 | 36.10 | Sprycel | BQ |
| 2478K | dasatinib 20 mg tablet, 60 | 1 | 5 | .. | 3095.66 | 36.10 | Sprycel | BQ |
| 2482P | dasatinib 50 mg tablet, 60 | 1 | 5 | .. | 5004.01 | 36.10 | Sprycel | BQ |
| 2485T | dasatinib 70 mg tablet, 60 | 1 | 5 | .. | 6160.40 | 36.10 | Sprycel | BQ |

**DASATINIB**

**Authority required**

Initial treatment, as monotherapy, of a patient with acute lymphoblastic leukaemia (ALL) bearing the Philadelphia chromosome or expressing the transcript, BCR-ABL, who has failed treatment with chemotherapy AND imatinib and where appropriate, allogeneic haemopoietic stem cell transplantation.

Failure of treatment is defined as either:

(i) Failure to achieve a complete morphological and cytogenetic remission after a minimum of 2 months treatment with intensive chemotherapy and imatinib;

(ii) Morphological or cytogenetic relapse of leukaemia after achieving a complete remission induced by chemotherapy and imatinib;

(iii) Morphological or cytogenetic relapse or persistence of leukaemia after allogeneic haemopoietic stem cell transplantation.

Patients must have active leukaemia, as defined by presence on current pathology assessments of either morphological infiltration of the bone marrow (greater than 5% lymphoblasts) or cerebrospinal fluid or other sites; OR the presence of cells bearing the Philadelphia chromosome on cytogenetic or FISH analysis in the bone marrow of patients in morphological remission.

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

(a) a completed authority prescription form; and

(b) a completed Acute Lymphoblastic Leukaemia Dasatinib PBS Authority Application - Supporting Information Form; and

(c) a signed patient acknowledgement; and

(d) a pathology report demonstrating that the patient has active acute lymphoblastic leukaemia, either manifest as cytogenetic evidence of the Philadelphia chromosome, or morphological evidence of acute lymphoblastic leukaemia plus qualitative RT-PCR evidence of BCR-ABL transcript. The date of the relevant pathology report(s) need(s) to be provided

**Authority required**

Initial treatment, as monotherapy, of a patient with acute lymphoblastic leukaemia bearing the Philadelphia chromosome or expressing the transcript, BCR-ABL, who has been treated prior to 1 December 2007 and has failed treatment with chemotherapy and where appropriate, allogeneic haemopoietic stem cell transplantation.

Patients must have active leukaemia, as defined by presence on current pathology assessments of either morphological infiltration of the bone marrow (greater than 5% lymphoblasts) or cerebrospinal fluid or other sites; OR the presence of cells bearing the Philadelphia chromosome on

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cytogenetic or FISH analysis in the bone marrow of patients in morphological remission.

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

(a) a completed authority prescription form; and

(b) a completed Acute Lymphoblastic Leukaemia Dasatinib PBS Authority Application - Supporting Information Form; and

(c) a signed patient acknowledgement; and

(d) a pathology report demonstrating that the patient has active acute lymphoblastic leukaemia, either manifest as cytogenetic evidence of the Philadelphia chromosome, or morphological evidence of acute lymphoblastic leukaemia plus qualitative RT-PCR evidence of BCR-ABL transcript. The date of the relevant pathology report(s) need(s) to be provided

**Authority required**

Continuing treatment, as monotherapy, of a patient with acute lymphoblastic leukaemia bearing the Philadelphia chromosome or expressing the transcript, BCR-ABL, where the patient has previously been issued with an authority prescription for dasatinib and does not have progressive disease.

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

**Note**

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

Prescribing information (including Authority Application forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Applications for authority to prescribe dasatinib should be forwarded to:

Medicare Australia

Prior Written Approval of Specialised Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

**Note**

Dasatinib will only be subsidised for patients with acute lymphoblastic leukaemia who are not receiving concomitant PBS-subsidised imatinib mesylate and who are not appropriate for an allogeneic haemopoietic stem cell transplant.

**Note**

No applications for increased repeats will be authorised.

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 9343R | dasatinib 100 mg tablet, 30 | 1 | 2 | .. | 5004.01 | 36.10 | Sprycel | BQ |
| 9125G | dasatinib 20 mg tablet, 60 | 1 | 2 | .. | 3095.66 | 36.10 | Sprycel | BQ |
| 9126H | dasatinib 50 mg tablet, 60 | 1 | 2 | .. | 5004.01 | 36.10 | Sprycel | BQ |
| 9127J | dasatinib 70 mg tablet, 60 | 1 | 2 | .. | 6160.40 | 36.10 | Sprycel | BQ |

**ERLOTINIB**

**Authority required**

Initial PBS-subsidised treatment, as monotherapy, in a patient with locally advanced or metastatic (stage IIIB or IV) non-small cell lung cancer with a WHO performance status of 3 or less, after prior treatment with platinum-based chemotherapy, where:

(1) (a) disease progression has occurred following treatment with docetaxel or pemetrexed; or

(b) treatment with docetaxel and pemetrexed is either contraindicated or cannot be tolerated; and

(2) further cytotoxic chemotherapy is not appropriate

**Authority required**

Continuing PBS-subsidised treatment, as monotherapy, in a patient with locally advanced or metastatic (stage IIIB or IV) non-small cell lung cancer who has previously been issued with an authority prescription for this drug and who does not have progressive disease

**Note**

Special Pricing Arrangements apply.

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 9167L | erlotinib 100 mg tablet, 30 | 1 | 3 | .. | 2703.55 | 36.10 | Tarceva | RO |
| 9168M | erlotinib 150 mg tablet, 30 | 1 | 3 | .. | 3309.87 | 36.10 | Tarceva | RO |
| 9166K | erlotinib 25 mg tablet, 30 | 1 | 3 | .. | 794.40 | 36.10 | Tarceva | RO |

**GEFITINIB**

**Authority required**

Initial PBS-subsidised treatment, as monotherapy, of locally advanced or metastatic non-small cell lung cancer in patients with a WHO performance status of 2 or less, where:

(1) disease progression has occurred following treatment with at least 1 chemotherapy agent; and

(2) there is evidence that the patient has an activating mutation(s) of the epidermal growth factor receptor (EGFR) gene in tumour material

**Authority required**

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|
| | Continuing PBS-subsidised treatment, as monotherapy, of locally advanced or metastatic non-small cell lung cancer in patients with a WHO performance status of 2 or less, where the patient has previously been issued with an authority prescription for gefitinib | | | | | | | |
| 8769M | gefitinib 250 mg tablet, 30 | 1 | 3 | .. | 3851.57 | 36.10 | Iressa | AP |

**IMATINIB**

**Authority required**

Adjuvant treatment of a patient at high risk of recurrence following complete resection of primary gastrointestinal stromal tumour (GIST) which has been histologically confirmed by the detection of CD117 on immunohistochemical staining, at a dose not exceeding 400 mg per day for a period of 12 months.

High risk of recurrence is defined as:

Primary GIST greater than 5 cm with a mitotic count of greater than 5/50 high power fields (HPF); or

Primary GIST greater than 10 cm with any mitotic rate; or

Primary GIST with a mitotic count of greater than 10/50 HPF.

(Prognosis definition based on the Australian and New Zealand consensus approach to best practice management, see Zalcberg et al. Asia-Pacific Journal of Clinical Oncology 2008: 4.4: 188-98.)

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Imatinib Mesylate (Glivec) PBS Authority Application for Use in Adjuvant Treatment of Gastrointestinal Stromal Tumour - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) a copy of a pathology report from an Approved Pathology Authority supporting the diagnosis of a gastrointestinal stromal tumour and confirming the presence of CD117 on immunohistochemical staining; and

(ii) a copy of the pathology report must include the size and mitotic rate of the tumour, and the date of tumour resection must be documented, which must not be more than 3 months prior to the date of this application

**Authority required**

Initial treatment of a patient who was receiving adjuvant imatinib mesylate for gastrointestinal stromal tumour (GIST) prior to 1 September 2011 and who meets the PBS eligibility criteria for adjuvant treatment with imatinib mesylate of a patient at high risk of recurrence following complete resection of primary GIST. The patient is eligible to receive sufficient imatinib at a dose of 400 mg per day to complete 12 months of combined PBS-subsidised and non-PBS-subsidised therapy.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Imatinib Mesylate (Glivec) PBS Authority Application for Use in Adjuvant Treatment of Gastrointestinal Stromal Tumour - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) a copy of a pathology report from an Approved Pathology Authority supporting the diagnosis of a gastrointestinal stromal tumour and confirming the presence of CD117 on immunohistochemical staining; and

(ii) a copy of the pathology report must include the size and mitotic rate of the tumour, and the date of tumour resection must be documented

**Note**

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

Prescribing information (including Authority Application forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe imatinib mesylate should be forwarded to:

Medicare Australia

Prior Written Approval of Specialised Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

For the following diseases, written authority is required at initiation and for continuation:

Dermatofibrosarcoma protuberans;

Hypereosinophilic syndrome;

Chronic eosinophilic leukaemia;

Myelodysplastic or myeloproliferative disorder;

Aggressive systemic mastocytosis with eosinophilia.

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 5443L | imatinib 100 mg tablet, 60 | 1 | 5 | .. | 2005.19 | 36.10 | Glivec | NV |
| 5444M | imatinib 400 mg tablet, 30 | 1 | 5 | .. | 3863.81 | 36.10 | Glivec | NV |

**IMATINIB**

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|
| | **Authority required**<br>Initial PBS-subsidised treatment, for up to 3 months, of a patient with a metastatic or unresectable malignant gastrointestinal stromal tumour which has been histologically confirmed by the detection of CD117 on immunohistochemical staining.<br>Patients must commence treatment at a dose not exceeding 400 mg per day for at least 3 months. Authority prescriptions for a higher dose will not be approved during this initial 3 month treatment period.<br>Applications for authorisation must be in writing and must include:<br>(1) a completed authority prescription form; and<br>(2) a completed Imatinib Mesylate (Glivec) PBS Authority Application for Use in the Treatment of Metastatic or Unresectable Gastrointestinal Stromal Tumour - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:<br>(i) a copy of a pathology report from an Approved Pathology Authority supporting the diagnosis of a gastrointestinal stromal tumour and confirming the presence of CD117 on immunohistochemical staining; and<br>(ii) a copy of the most recent (within 2 months of the application) computed tomography (CT) scan, magnetic resonance imaging (MRI) or ultrasound assessment of the tumour(s), including whether or not there is evidence of metastatic disease; and<br>(iii) where the application for authority to prescribe is being sought on the basis of an unresectable tumour, written evidence in support of that claim must be provided<br>**Authority required**<br>Continuing PBS-subsidised treatment, at a dose of up to 600 mg per day, of a patient with a metastatic or unresectable malignant gastrointestinal stromal tumour who has previously been issued with an authority prescription for this drug.<br>Applications for continuing treatment may be made by telephone (1800 700 270, hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).<br>Patients who have failed to respond or are intolerant to imatinib are no longer eligible to receive PBS-subsidised imatinib<br>**Note**<br>Any queries concerning the arrangements to prescribe imatinib mesylate may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).<br>Prescribing information (including Authority Application forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.<br>Written applications for authority to prescribe imatinib mesylate should be forwarded to:<br>Medicare Australia<br>Prior Written Approval of Specialised Drugs<br>Reply Paid 9826<br>GPO Box 9826<br>HOBART TAS 7001<br>For the following diseases, written authority is required at initiation and for continuation:<br>Dermatofibrosarcoma protuberans;<br>Hypereosinophilic syndrome;<br>Chronic eosinophilic leukaemia;<br>Myelodysplastic or myeloproliferative disorder;<br>Aggressive systemic mastocytosis with eosinophilia.<br>**Note**<br>Patients with metastatic/unresectable disease who achieve a response to treatment at an imatinib dose of 400 mg per day should be continued at this dose and assessed for response at regular intervals. Patients who fail to achieve a response to 400 mg per day may have their dose increased to 600 mg per day. Authority applications for doses higher than 600 mg per day will not be approved.<br>A response to treatment is defined as a decrease from baseline in the sum of the products of the perpendicular diameters of all measurable lesions of 50% or greater. (Response definition based on the Southwest Oncology Group standard criteria, see Demetri et al. N Engl J Med 2002; 347: 472-80.)<br>**Note**<br>No applications for increased repeats will be authorised. | | | | | | | |
| 9111M | imatinib 100 mg tablet, 60 | 1 | 2 | .. | 2005.19 | 36.10 | Glivec | NV |
| 9112N | imatinib 400 mg tablet, 30 | 1 | 2 | .. | 3863.81 | 36.10 | Glivec | NV |
| | **IMATINIB**<br>**Authority required**<br>Initial treatment, as the sole PBS-subsidised therapy, of a patient in the chronic phase of chronic myeloid leukaemia expressing the Philadelphia chromosome or the transcript, BCR-ABL tyrosine kinase, and who has a primary diagnosis of chronic myeloid leukaemia.<br>Applications under this restriction will be limited to provide patients with a maximum of 18 months of therapy with dasatinib, imatinib or nilotinib from the date the first application for initial treatment was approved.<br>Patients should be commenced on a dose of imatinib mesylate of 400 mg (base) daily. Continuing therapy is dependent on patients demonstrating a response to imatinib mesylate therapy following the initial 18 months of treatment and at 12 monthly intervals thereafter. | | | | | | | |

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | Brand Name and Manufacturer |
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Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Chronic Myeloid Leukaemia - Chronic Phase, First Line - Supporting Information form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and

(3) a pathology cytogenetic report conducted on peripheral blood or bone marrow supporting the diagnosis of chronic myeloid leukaemia to confirm eligibility for treatment, or a qualitative PCR report documenting the presence of the BCR-ABL transcript in either peripheral blood or bone marrow; and

(4) a signed patient acknowledgement form

**Authority required**

Continuing treatment, as the sole PBS-subsidised therapy, of a patient who has received initial PBS-subsidised treatment with imatinib mesylate for the chronic phase of chronic myeloid leukaemia and who has demonstrated either a major cytogenetic response or less than 1% BCR-ABL level in the blood.

First continuing applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) demonstration of a response to treatment as evidenced by either:

(a) major cytogenetic response [see Note explaining requirements]; or

(b) a peripheral blood level of BCR-ABL of less than 1% on the international scale [see Note explaining requirements].

Second and subsequent authority applications for continuing therapy with imatinib mesylate may be made on the telephone by contacting Medicare Australia on 1800 700 720 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Patients must maintain a major cytogenetic response or have a peripheral blood BCR-ABL of less than 1% to receive continuing therapy

**Note**

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

Prescribing information (including Authority Application forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe imatinib mesylate should be forwarded to:

Medicare Australia

Prior Written Approval of Specialised Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

For the following diseases, written authority is required at initiation and for continuation:

Dermatofibrosarcoma protuberans;

Hypereosinophilic syndrome;

Chronic eosinophilic leukaemia;

Myelodysplastic or myeloproliferative disorder;

Aggressive systemic mastocytosis with eosinophilia.

**Note**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of tyrosine kinase inhibitors (TKI) agents for the chronic phase of chronic myeloid leukaemia. Where the term TKI agent appears in the following notes and restrictions it refers to imatinib mesylate, dasatinib or nilotinib.

Patients are eligible for PBS-subsidised treatment with only one TKI agent at any one time and must not be receiving concomitant interferon alfa therapy. Eligible patients may only swap between TKI agents if they have not failed prior PBS-subsidised treatment with that agent.

1. Initial treatment - imatinib mesylate, dasatinib and nilotinib

From 1 April 2012, under the PBS, a patient will be able to be prescribed any of imatinib mesylate, dasatinib or nilotinib within the initial 18 month treatment period, as long as only one agent is used at a time and providing the patient has not failed to respond to any one of these TKIs.

During the initial 18 month treatment period, switching between approved first-line agents may only occur for reasons of intolerance, not failure of response.

2. Continuing treatment with imatinib mesylate - first-line

First continuing applications are to be written and must include a pathology report demonstrating the patient has responded to the initial course of treatment.

Second and subsequent authority applications for continuing therapy with imatinib mesylate may be made on the telephone by contacting Medicare Australia on 1800 700 720 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Patients must maintain a major cytogenetic response or have a peripheral blood BCR-ABL of less than 1% to receive continuing therapy.

3. Continuing treatment with dasatinib or nilotinib - first-line

All continuing applications are to be written and must include a pathology report demonstrating the patient has responded to PBS-subsidised

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| | treatment as follows: | | | | | | | |
| | (i) within 18 months of the commencement of treatment, at which time patients in whom a major cytogenetic response or peripheral blood BCR-ABL level of less than 1% has been demonstrated may receive authorisation for a further 12 months of treatment; and | | | | | | | |
| | (ii) at no greater than 12 month intervals thereafter, to demonstrate that the major cytogenetic response or peripheral blood BCR-ABL level of less than 1% has been sustained. | | | | | | | |
| | 4. For imatinib mesylate, dasatinib and nilotinib | | | | | | | |
| | During continuing therapy beyond the initial 18 month treatment period, switching between approved first-line agents may only occur for reason of intolerance. Where there is failure of response, switching may only occur through application for prescription of second-line agents. | | | | | | | |
| | Where a patient has previously received PBS-subsidised treatment with imatinib mesylate, dasatinib or nilotinib no approval will be granted for PBS-subsidised re-treatment in the chronic phase of chronic myeloid leukaemia, where that patient has at any time failed to meet the response criteria whilst on that TKI agent. | | | | | | | |
| | 5. Authority approval requirements. | | | | | | | |
| | Response criteria to initial treatment with imatinib mesylate, dasatinib or nilotinib: | | | | | | | |
| | For the purposes of assessing response to PBS-subsidised treatment with imatinib mesylate, dasatinib or nilotinib either cytogenetic analysis indicating the number of Philadelphia positive [t (9;22)] cells in the bone marrow measured by standard karyotyping, or quantitative PCR indicating the relative level of BCR-ABL transcript in the peripheral blood using the international scale, must be submitted. For bone marrow analyses, where the standard karyotyping is not informative for technical reasons, a cytogenetic analysis performed on the bone marrow by the use of fluorescence in situ hybridisation (FISH) with BCR-ABL specific probe must be submitted. The cytogenetic or peripheral blood quantitative PCR analyses must be submitted within 18 months of the commencement of treatment with imatinib mesylate, dasatinib or nilotinib (patients in whom a major cytogenetic response or peripheral blood BCR-ABL level of less than 1% is demonstrable by 18 months are eligible to receive continuing treatment with that agent). | | | | | | | |
| | 6. Definitions of response. | | | | | | | |
| | A major cytogenetic response is defined as less than 35% Philadelphia positive bone marrow cells. | | | | | | | |
| | A peripheral blood BCR-ABL level of less than 1% on the international scale (Blood 108: 28-37, 2006) also indicates a response, at least the biological equivalent of a major cytogenetic response. | | | | | | | |
| | 7. Definitions of loss of response. | | | | | | | |
| | Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph positive cells on bone marrow biopsy), during ongoing tyrosine kinase inhibitor (TKI) therapy. | | | | | | | |
| | Loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing consecutively in value by at least 5 fold to a level of greater than 0.1% confirmed on a subsequent test), during ongoing tyrosine kinase inhibitor therapy. | | | | | | | |
| 9113P | imatinib 100 mg tablet, 60 | 1 | 5 | .. | 2005.19 | 36.10 | Glivec | NV |
| 9114Q | imatinib 400 mg tablet, 30 | 1 | 5 | .. | 3863.81 | 36.10 | Glivec | NV |

**IMATINIB**

**Authority required**

Treatment of patients in the accelerated phase of chronic myeloid leukaemia expressing the Philadelphia chromosome or the transcript, bcr-abl tyrosine kinase, and who have a primary diagnosis of chronic myeloid leukaemia. Progress to the accelerated phase is defined by the presence of 1 or more of the following:

(1) Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 15% but less than 30%; or

(2) Percentage of blasts plus promyelocytes in the peripheral blood or bone marrow greater than or equal to 30%; or

(3) Peripheral basophils greater than or equal to 20%; or

(4) Progressive splenomegaly to a size greater than or equal to 10 cm below the left costal margin to be confirmed on 2 occasions at least 4 weeks apart, or a greater than or equal to 50% increase in size below the left costal margin over 4 weeks; or

(5) Karyotypic evolution (chromosomal abnormalities in addition to a single Philadelphia chromosome).

Applications for authorisation must be in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Imatinib Mesylate (Glivec) PBS Authority Application for Use in the Treatment of Chronic Myeloid Leukaemia - Supporting Information form, stating which of the above criteria are satisfied by the patient; and

(c) a copy of the confirming pathology report from an Approved Pathology Authority in the case of criteria (1), (2), (3) and (5) above, or details of the dates of assessments in the case of progressive splenomegaly

**Authority required**

Treatment of patients in the blast phase of chronic myeloid leukaemia expressing the Philadelphia chromosome or the transcript, bcr-abl tyrosine kinase, and who have a primary diagnosis of chronic myeloid leukaemia. Progress to myeloid blast crisis is defined as either:

(1) Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 30%; or

(2) Extramedullary involvement other than spleen and liver.

Applications for authorisation must be in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Imatinib Mesylate (Glivec) PBS Authority Application for Use in the Treatment of Chronic Myeloid Leukaemia - Supporting

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| | Information form, stating which of the above criteria are satisfied by the patient; and<br>(c) a copy of the confirming pathology report from an Approved Pathology Authority in the case of criterion (1) above, or details of the date of assessment in the case of extramedullary involvement<br>**Authority required**<br>Continuing treatment of patients with chronic myeloid leukaemia expressing the Philadelphia chromosome or the transcript, bcr-abl tyrosine kinase, where the patient has previously received PBS-subsidised treatment with imatinib mesylate of the accelerated phase of chronic myeloid leukaemia<br>**Authority required**<br>Continuing treatment of patients with chronic myeloid leukaemia expressing the Philadelphia chromosome or the transcript, bcr-abl tyrosine kinase, where the patient has previously received PBS-subsidised treatment with imatinib mesylate of the blast phase of chronic myeloid leukaemia<br>**Note**<br>Any queries concerning the arrangements to prescribe imatinib mesylate may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).<br>Prescribing information (including Authority Application forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.<br>Written applications for authority to prescribe imatinib mesylate should be forwarded to:<br>Medicare Australia<br>Prior Written Approval of Specialised Drugs<br>Reply Paid 9826<br>GPO Box 9826<br>HOBART TAS 7001<br>For the following diseases, written authority is required at initiation and for continuation:<br>Dermatofibrosarcoma protuberans;<br>Hypereosinophilic syndrome;<br>Chronic eosinophilic leukaemia;<br>Myelodysplastic or myeloproliferative disorder;<br>Aggressive systemic mastocytosis with eosinophilia.<br>**Note**<br>No applications for increased repeats will be authorised. | | | | | | | |
| 9115R | imatinib 100 mg tablet, 60 | 1 | 2 | .. | 2005.19 | 36.10 | Glivec | NV |
| 9116T | imatinib 400 mg tablet, 30 | 1 | 2 | .. | 3863.81 | 36.10 | Glivec | NV |
| | **IMATINIB**<br>**Authority required**<br>Initial treatment in combination with chemotherapy as induction or consolidation of a newly diagnosed patient with acute lymphoblastic leukaemia (ALL) bearing the Philadelphia chromosome or expressing the transcript, BCR-ABL.<br>The first authority application must be made in writing and must include:<br>(a) a completed authority prescription form; and<br>(b) a completed Acute Lymphoblastic Leukaemia Imatinib PBS Authority Application - Supporting Information Form; and<br>(c) a pathology cytogenetic report conducted on peripheral blood or bone marrow supporting the diagnosis of acute lymphoblastic leukaemia to confirm eligibility for treatment, with either cytogenetic evidence of the Philadelphia chromosome, or a qualitative PCR report documenting the presence of the BCR-ABL transcript in either peripheral blood or bone marrow. (The date of the relevant pathology report needs to be provided); and<br>(d) a signed patient acknowledgement<br>**Authority required**<br>Initial treatment of a patient with acute lymphoblastic leukaemia bearing the Philadelphia chromosome or expressing the transcript BCR-ABL who was previously treated with imatinib mesylate under the Imatinib Compassionate Program and who meets all the PBS criteria.<br>The first authority application must be made in writing and must include:<br>(a) a completed authority prescription form; and<br>(b) a completed Acute Lymphoblastic Leukaemia Imatinib PBS Authority Application - Supporting Information Form; and<br>(c) a pathology cytogenetic report conducted on peripheral blood or bone marrow supporting the diagnosis of acute lymphoblastic leukaemia to confirm eligibility for treatment, with either cytogenetic evidence of the Philadelphia chromosome, or a qualitative PCR report documenting the presence of the BCR-ABL transcript in either peripheral blood or bone marrow. (The date of the relevant pathology report needs to be provided); and<br>(d) a signed patient acknowledgement<br>**Authority required**<br>Continuing treatment in combination with chemotherapy as maintenance of first complete remission of patients with acute lymphoblastic leukaemia bearing the Philadelphia chromosome or expressing the transcript, BCR-ABL. | | | | | | | |

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|---|---|---|---|---|---|---|---|---|
| | Authority applications for continuing treatment may be made by telephone to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). | | | | | | | |
| | Imatinib mesylate is available with a lifetime maximum of 24 months for continuing treatment with imatinib mesylate therapy for patients with acute lymphoblastic leukaemia reimbursed through the PBS. | | | | | | | |
| | Any queries concerning the arrangements to prescribe imatinib mesylate beyond 24 months may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) | | | | | | | |
| | **Note**<br>Any queries concerning the arrangements to prescribe imatinib mesylate may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). | | | | | | | |
| | Prescribing information (including Authority Application forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au. | | | | | | | |
| | Written applications for authority to prescribe imatinib mesylate should be forwarded to: | | | | | | | |
| | Medicare Australia | | | | | | | |
| | Prior Written Approval of Specialised Drugs | | | | | | | |
| | Reply Paid 9826 | | | | | | | |
| | GPO Box 9826 | | | | | | | |
| | HOBART TAS 7001 | | | | | | | |
| | For the following diseases, written authority is required at initiation and for continuation: | | | | | | | |
| | Dermatofibrosarcoma protuberans; | | | | | | | |
| | Hypereosinophilic syndrome; | | | | | | | |
| | Chronic eosinophilic leukaemia; | | | | | | | |
| | Myelodysplastic or myeloproliferative disorder; | | | | | | | |
| | Aggressive systemic mastocytosis with eosinophilia. | | | | | | | |
| | **Note**<br>Allogeneic stem cell transplantation is the preferred therapy for eligible patients achieving a complete remission of Philadelphia positive acute lymphoblastic leukaemia. | | | | | | | |
| | **Note**<br>No applications for increased repeats will be authorised. | | | | | | | |
| 9123E | imatinib 100 mg tablet, 60 | 1 | 2 | .. | 2005.19 | 36.10 | Glivec | NV |
| 9124F | imatinib 400 mg tablet, 30 | 1 | 2 | .. | 3863.81 | 36.10 | Glivec | NV |
| | **IMATINIB** | | | | | | | |
| | **Authority required**<br>Initial PBS-subsidised treatment of a patient with unresectable, locally recurrent or metastatic dermatofibrosarcoma protuberans. | | | | | | | |
| | Maximum dose: 800 mg per day. | | | | | | | |
| | (1) Where the application for authority to prescribe is being sought on the basis of unresectable tumour, written evidence in support of that claim must be provided; and | | | | | | | |
| | (2) Where the application for authority to prescribe is being sought on the basis of locally recurrent disease, the site of the local recurrence must be specified; and | | | | | | | |
| | (3) Where the application for authority to prescribe is being sought on the basis of metastatic disease, the site(s) of metastatic disease must be provided. | | | | | | | |
| | Applications for authorisation for initial treatment must be made in writing and must include: | | | | | | | |
| | (a) a completed authority prescription form; and | | | | | | | |
| | (b) a completed Rare Diseases Imatinib PBS Authority Application - Supporting Information Form; and | | | | | | | |
| | (c) a signed patient acknowledgement | | | | | | | |
| | **Authority required**<br>Continuing PBS-subsidised treatment of a patient with unresectable, locally recurrent or metastatic dermatofibrosarcoma protuberans who has previously been issued with an authority prescription for imatinib and who has demonstrated a response, but whose disease remains unresectable. | | | | | | | |
| | Maximum dose: 800 mg per day. | | | | | | | |
| | Applications for authorisation must be made in writing and must include: | | | | | | | |
| | (a) a completed authority prescription form; and | | | | | | | |
| | (b) a completed Rare Diseases Imatinib PBS Authority Application - Supporting Information Form; and | | | | | | | |
| | (c) a statement that the disease has not progressed on imatinib therapy | | | | | | | |
| | **Note**<br>Any queries concerning the arrangements to prescribe imatinib mesylate may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). | | | | | | | |

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|
| | Prescribing information (including Authority Application forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au. | | | | | | | |
| | Written applications for authority to prescribe imatinib mesylate should be forwarded to: | | | | | | | |
| | Medicare Australia | | | | | | | |
| | Prior Written Approval of Specialised Drugs | | | | | | | |
| | Reply Paid 9826 | | | | | | | |
| | GPO Box 9826 | | | | | | | |
| | HOBART TAS 7001 | | | | | | | |
| | For the following diseases, written authority is required at initiation and for continuation: | | | | | | | |
| | Dermatofibrosarcoma protuberans; | | | | | | | |
| | Hypereosinophilic syndrome; | | | | | | | |
| | Chronic eosinophilic leukaemia; | | | | | | | |
| | Myelodysplastic or myeloproliferative disorder; | | | | | | | |
| | Aggressive systemic mastocytosis with eosinophilia. | | | | | | | |
| | **Note** | | | | | | | |
| | No applications for increased repeats will be authorised. | | | | | | | |
| 9172R | imatinib 100 mg tablet, 60 | 1 | 2 | .. | 2005.19 | 36.10 | Glivec | NV |
| 9173T | imatinib 400 mg tablet, 30 | 1 | 2 | .. | 3863.81 | 36.10 | Glivec | NV |

**IMATINIB**

**Authority required**

Initial PBS-subsidised treatment of a patient with hypereosinophilic syndrome or chronic eosinophilic leukaemia requiring treatment and confirmed to carry the FIP1L1-PDGFRA fusion gene.

Maximum dose: 400 mg per day.

Applications for authorisation for initial treatment must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Rare Diseases Imatinib PBS Authority Application - Supporting Information Form; and

(c) a copy of the pathology report confirming the presence of the FIP1L1-PDGFRA fusion gene; and

(d) a copy of the full blood examination report confirming the presence of hypereosinophilic syndrome or chronic eosinophilic leukaemia; and

(e) details of organ involvement requiring treatment, including a copy of the radiology, nuclear medicine, respiratory function or anatomical pathology reports as appropriate; and

(f) a signed patient acknowledgement

**Authority required**

Continuing PBS-subsidised treatment of a patient with hypereosinophilic syndrome or chronic eosinophilic leukaemia who has previously been issued with an authority prescription for imatinib and who has achieved and maintained a complete haematological response.

Maximum dose: 400 mg per day.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Rare Diseases Imatinib PBS Authority Application - Supporting Information Form; and

(c) a copy of the full blood examination report which demonstrates a complete haematological response, with a normal eosinophil count; and

(d) a statement that the disease has not progressed on imatinib therapy

**Note**

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

Prescribing information (including Authority Application forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe imatinib mesylate should be forwarded to:

Medicare Australia

Prior Written Approval of Specialised Drugs

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For the following diseases, written authority is required at initiation and for continuation:

Dermatofibrosarcoma protuberans;

Hypereosinophilic syndrome;

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|
| | Chronic eosinophilic leukaemia;<br>Myelodysplastic or myeloproliferative disorder;<br>Aggressive systemic mastocytosis with eosinophilia.<br>**Note**<br>No applications for increased repeats will be authorised. | | | | | | | |
| 9174W | imatinib 100 mg tablet, 60 | 1 | 2 | .. | 2005.19 | 36.10 | Glivec | NV |
| 9175X | imatinib 400 mg tablet, 30 | 1 | 2 | .. | 3863.81 | 36.10 | Glivec | NV |

**IMATINIB**

**Authority required**

Initial PBS-subsidised treatment of a patient with a myelodysplastic or myeloproliferative disorder where:

(1) there is confirmed evidence of a platelet-derived growth factor receptor (PDGFR) gene re-arrangement either by standard karyotyping, or FISH or PDGFRB fusion gene transcript; and

(2) the patient has previously failed an adequate trial of one or more of the following conventional therapies:

— cytarabine;

— etoposide;

— hydroxyurea.

Maximum dose: 400 mg per day.

Applications for authorisation for initial treatment must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Rare Diseases Imatinib PBS Authority Application - Supporting Information Form; and

(c) a copy of the pathology report confirming the platelet-derived growth factor receptor (PDGFR) gene re-arrangement; and

(d) a copy of the bone marrow biopsy report which demonstrates the presence of a myelodysplastic or myeloproliferative disorder; and

(e) details of the prior therapy trialled and the response; and

(f) a signed patient acknowledgement

**Authority required**

Continuing PBS-subsidised treatment of a patient with a PDGFRB fusion gene-positive myelodysplastic or myeloproliferative disorder who has previously been issued with an authority prescription for imatinib and who has demonstrated a complete haematological response.

Maximum dose: 400 mg per day.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Rare Diseases Imatinib PBS Authority Application - Supporting Information Form; and

(c) a copy of the full blood examination report which demonstrates a complete haematological response; and

(d) a statement that the disease has not progressed on imatinib therapy

**Note**

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

Prescribing information (including Authority Application forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe imatinib mesylate should be forwarded to:

Medicare Australia

Prior Written Approval of Specialised Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

For the following diseases, written authority is required at initiation and for continuation:

Dermatofibrosarcoma protuberans;

Hypereosinophilic syndrome;

Chronic eosinophilic leukaemia;

Myelodysplastic or myeloproliferative disorder;

Aggressive systemic mastocytosis with eosinophilia.

**Note**

No applications for increased repeats will be authorised.

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 9176Y | imatinib 100 mg tablet, 60 | 1 | 2 | .. | 2005.19 | 36.10 | Glivec | NV |

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|
| 9177B | imatinib 400 mg tablet, 30 | 1 | 2 | .. | 3863.81 | 36.10 | Glivec | NV |

**IMATINIB**

**Authority required**

Initial PBS-subsidised treatment of a patient with aggressive systemic mastocytosis with eosinophilia where:

(1) there is confirmed evidence of the FIP1L1-PDGFRA fusion gene; and

(2) the patient has previously failed an adequate trial of one or more of the following conventional therapies:

— corticosteroids;

— hydroxyurea.

Maximum dose: 400 mg per day.

Applications for authorisation for initial treatment must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Rare Diseases Imatinib PBS Authority Application - Supporting Information Form; and

(c) a copy of the pathology report confirming the presence of the FIP1L1-PDGFRA fusion gene; and

(d) a copy of the bone marrow biopsy report and/or other tissue biopsy report confirming the diagnosis of aggressive systemic mastocytosis and a copy of the full blood examination report demonstrating eosinophilia; and

(e) details of symptomatic organ involvement requiring treatment, including a copy of the radiology, nuclear medicine, respiratory function or anatomical pathology reports as appropriate; and

(f) details of prior treatment trialled and the response; and

(g) a signed patient acknowledgement

**Authority required**

Continuing PBS-subsidised treatment of a patient with aggressive systemic mastocytosis confirmed to carry the FIP1L1-PDGFRA fusion gene, who has previously been issued with an authority prescription for imatinib and who has demonstrated a complete haematological response.

Maximum dose: 400 mg per day.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Rare Diseases Imatinib PBS Authority Application - Supporting Information Form; and

(c) a copy of the full blood examination report which demonstrates a complete haematological response; and

(d) a statement that the disease has not progressed on imatinib therapy

**Note**

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

Prescribing information (including Authority Application forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe imatinib mesylate should be forwarded to:

Medicare Australia

Prior Written Approval of Specialised Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

For the following diseases, written authority is required at initiation and for continuation:

Dermatofibrosarcoma protuberans;

Hypereosinophilic syndrome;

Chronic eosinophilic leukaemia;

Myelodysplastic or myeloproliferative disorder;

Aggressive systemic mastocytosis with eosinophilia.

**Note**

No applications for increased repeats will be authorised.

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 9178C | imatinib 100 mg tablet, 60 | 1 | 2 | .. | 2005.19 | 36.10 | Glivec | NV |
| 9179D | imatinib 400 mg tablet, 30 | 1 | 2 | .. | 3863.81 | 36.10 | Glivec | NV |

**LAPATINIB**

**Authority required**

Initial treatment, in combination with capecitabine, of a patient with HER2 positive metastatic breast cancer (equivalent to Stage IIIC or Stage IV) who has received prior therapy with a taxane, for at least 3 cycles, and whose disease has progressed despite treatment with trastuzumab for

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | Brand Name and Manufacturer | |
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metastatic disease.

Authority applications for initial treatment must be made in writing and must include:

(a) a completed authority prescription form;

(b) a pathology report demonstrating HER2 positivity has been demonstrated by in situ hybridisation (ISH);

(c) date of last treatment with a taxane and total number of cycles;

(d) a signed patient acknowledgment;

(e) dates of treatment with trastuzumab; and

(f) date of demonstration of progression whilst on treatment with trastuzumab

**Authority required**

Continuing treatment, in combination with capecitabine, of a patient with HER2 positive metastatic breast cancer who has previously received treatment with PBS-subsidised lapatinib and who does not have progressive disease.

Authority applications must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a statement from the prescribing doctor that the disease has not progressed

**Note**

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

Lapatinib should not be used in patients with a left ventricular ejection fraction (LVEF) of less than 45% or with symptomatic heart failure. Cardiac function must be tested by a suitable method including, for example, ECHO or MUGA, prior to seeking the initial authority approval and then at 3 monthly intervals during treatment.

Lapatinib is not PBS-subsidised when used in combination with Commonwealth-subsidised trastuzumab.

If disease progression occurs, the prescribing doctor must contact Medicare Australia within one week on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) and lapatinib treatment must be ceased immediately.

**Note**

Treatment with trastuzumab for metastatic disease is defined as trastuzumab administered alone or in combination with chemotherapy for at least 6 weeks at standard doses.

If treatment with a taxane is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of the accepted toxicities, including severity, can be found on the Medicare Australia website [www.medicareaustralia.gov.au].

**Note**

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

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 9148L | lapatinib 250 mg tablet, 70 | 2 | 2 | .. | *3387.67 | 36.10 | Tykerb | GK |

**NILOTINIB**

**Authority required**

Initial treatment, as the sole PBS-subsidised therapy, of a patient in the chronic phase of chronic myeloid leukaemia expressing the Philadelphia chromosome or the transcript, BCR-ABL tyrosine kinase, and who has a primary diagnosis of chronic myeloid leukaemia.

Applications under this restriction will be limited to provide patients with a maximum of 18 months of therapy with dasatinib, imatinib or nilotinib from the date the first application for initial treatment was approved.

Patients should be commenced on a dose of nilotinib of 300 mg twice daily. Continuing therapy is dependent on patients demonstrating a response to nilotinib therapy following the initial 18 months of treatment and at 12 monthly intervals thereafter.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Chronic Myeloid Leukaemia - Chronic Phase, First Line - Supporting Information form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and

(3) a pathology cytogenetic report conducted on peripheral blood or bone marrow supporting the diagnosis of chronic myeloid leukaemia to confirm eligibility for treatment, or a qualitative PCR report documenting the presence of the BCR-ABL transcript in either peripheral blood or bone marrow; and

(4) a signed patient acknowledgement form

**Authority required**

Continuing treatment, as the sole PBS-subsidised therapy, of a patient who has received initial PBS-subsidised treatment with nilotinib for the chronic phase of chronic myeloid leukaemia and who has demonstrated either a major cytogenetic response or less than 1% BCR-ABL level in the blood.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

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(2) demonstration of continued response to treatment as evidenced by either:

(a) major cytogenetic response [see Note explaining requirements]. Where this has been supplied within the previous 12 months, only the date of the relevant pathology report need be provided; or

(b) a peripheral blood level of BCR-ABL of less than 1% on the international scale [see Note explaining requirements]. Where this has been supplied within the previous 12 months, only the date of the relevant pathology report need be provided

**Note**

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

Prescribing information (including Authority Application forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Applications for authority to prescribe nilotinib should be forwarded to:

Medicare Australia

Prior Written Approval of Specialised Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

**Note**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of tyrosine kinase inhibitors (TKI) agents for the chronic phase of chronic myeloid leukaemia. Where the term TKI agent appears in the following notes and restrictions it refers to imatinib mesylate, dasatinib or nilotinib.

Patients are eligible for PBS-subsidised treatment with only one TKI agent at any one time and must not be receiving concomitant interferon alfa therapy. Eligible patients may only swap between TKI agents if they have not failed prior PBS-subsidised treatment with that agent.

1. Initial treatment - imatinib mesylate, dasatinib and nilotinib

From 1 April 2012, under the PBS, a patient will be able to be prescribed any of imatinib mesylate, dasatinib or nilotinib within the initial 18 month treatment period, as long as only one agent is used at a time and providing the patient has not failed to respond to any one of these TKIs.

During the initial 18 month treatment period, switching between approved first-line agents may only occur for reasons of intolerance, not failure of response.

2. Continuing treatment with imatinib mesylate - first-line

First continuing applications are to be written and must include a pathology report demonstrating the patient has responded to the initial course of treatment.

Second and subsequent authority applications for continuing therapy with imatinib mesylate may be made on the telephone by contacting Medicare Australia on 1800 700 720 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Patients must maintain a major cytogenetic response or have a peripheral blood BCR-ABL of less than 1% to receive continuing therapy.

3. Continuing treatment with dasatinib or nilotinib - first-line

All continuing applications are to be written and must include a pathology report demonstrating the patient has responded to PBS-subsidised treatment as follows:

(i) within 18 months of the commencement of treatment, at which time patients in whom a major cytogenetic response or peripheral blood BCR-ABL level of less than 1% has been demonstrated may receive authorisation for a further 12 months of treatment; and

(ii) at no greater than 12 month intervals thereafter, to demonstrate that the major cytogenetic response or peripheral blood BCR-ABL level of less than 1% has been sustained.

4. For imatinib mesylate, dasatinib and nilotinib

During continuing therapy beyond the initial 18 month treatment period, switching between approved first-line agents may only occur for reason of intolerance. Where there is failure of response, switching may only occur through application for prescription of second-line agents.

Where a patient has previously received PBS-subsidised treatment with imatinib mesylate, dasatinib or nilotinib no approval will be granted for PBS-subsidised re-treatment in the chronic phase of chronic myeloid leukaemia, where that patient has at any time failed to meet the response criteria whilst on that TKI agent.

5. Authority approval requirements.

Response criteria to initial treatment with imatinib mesylate, dasatinib or nilotinib:

For the purposes of assessing response to PBS-subsidised treatment with imatinib mesylate, dasatinib or nilotinib either cytogenetic analysis indicating the number of Philadelphia positive [t (9;22)] cells in the bone marrow measured by standard karyotyping, or quantitative PCR indicating the relative level of BCR-ABL transcript in the peripheral blood using the international scale, must be submitted. For bone marrow analyses, where the standard karyotyping is not informative for technical reasons, a cytogenetic analysis performed on the bone marrow by the use of fluorescence in situ hybridisation (FISH) with BCR-ABL specific probe must be submitted. The cytogenetic or peripheral blood quantitative PCR analyses must be submitted within 18 months of the commencement of treatment with imatinib mesylate, dasatinib or nilotinib (patients in whom a major cytogenetic response or peripheral blood BCR-ABL level of less than 1% is demonstrable by 18 months are eligible to receive continuing treatment with that agent).

6. Definitions of response.

A major cytogenetic response is defined as less than 35% Philadelphia positive bone marrow cells.

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|---|---|---|---|---|---|---|---|---|
| | A peripheral blood BCR-ABL level of less than 1% on the international scale (Blood 108: 28-37, 2006) also indicates a response, at least the biological equivalent of a major cytogenetic response.<br>7. Definitions of loss of response.<br>Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph positive cells on bone marrow biopsy), during ongoing tyrosine kinase inhibitor (TKI) therapy.<br>Loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing consecutively in value by at least 5 fold to a level of greater than 0.1% confirmed on a subsequent test), during ongoing tyrosine kinase inhibitor therapy. | | | | | | | |
| 1309X | NILOTINIB Capsule 150 mg (as hydrochloride monohydrate), 120 | 1 | 5 | .. | 4468.08 | 36.10 | Tasigna | NV |

**NILOTINIB**

**Authority required**

Initial treatment, as the sole PBS-subsidised therapy, of a patient with chronic myeloid leukaemia in chronic or accelerated phase who has failed an adequate trial of imatinib or dasatinib as first-line treatment.

Failure of an adequate trial of imatinib or dasatinib is defined as:

(i) Lack of response to initial imatinib or dasatinib therapy, defined as either:

— failure to achieve a haematological response after a minimum of 3 months therapy with imatinib or dasatinib for patients initially treated in chronic phase; or

— failure to achieve any cytogenetic response after a minimum of 6 months therapy with imatinib or dasatinib for patients initially treated in chronic phase as demonstrated on bone marrow biopsy by presence of greater than 95% Philadelphia chromosome positive cells; or

— failure to achieve a major cytogenetic response or a peripheral blood BCR-ABL level of less than 1% after a minimum of 12 months therapy with imatinib or dasatinib; OR

(ii) Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph positive cells on bone marrow biopsy), during ongoing imatinib or dasatinib therapy; OR

(iii) Loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing consecutively in value by at least 5 fold to a level of greater than 0.1% confirmed on a subsequent test), during ongoing imatinib or dasatinib therapy; OR

(iv) Development of accelerated phase in a patient previously prescribed imatinib or dasatinib for the chronic phase of chronic myeloid leukaemia.

Accelerated phase is defined by the presence of 1 or more of the following:

(1) Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 15% but less than 30%; or

(2) Percentage of blasts plus promyelocytes in the peripheral blood or bone marrow greater than or equal to 30%, provided that blast count is less than 30%; or

(3) Peripheral basophils greater than or equal to 20%; or

(4) Progressive splenomegaly to a size greater than or equal to 10 cm below the left costal margin to be confirmed on 2 occasions at least 4 weeks apart, or a greater than or equal to 50% increase in size below the left costal margin over 4 weeks; or

(5) Karyotypic evolution (chromosomal abnormalities in addition to a single Philadelphia chromosome); OR

(v) Disease progression (defined as a greater than or equal to 50% increase in peripheral white blood cell count, blast count, basophils or platelets) during first-line imatinib or dasatinib therapy in patients with accelerated phase chronic myeloid leukaemia, provided that blast crisis has been excluded on bone marrow biopsy.

Patients should be commenced on a dose of nilotinib of 400 mg twice daily. Continuing therapy is dependent on patients demonstrating a major cytogenetic response to nilotinib therapy or a peripheral blood BCR-ABL level of less than 1% within 18 months and thereafter at 12 monthly intervals.

Applications for authorisation must be in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Chronic Myeloid Leukaemia - Second and Third Line - Supporting Information Form; and

(c) a signed patient acknowledgement; and

(d) a bone marrow biopsy pathology report demonstrating the patient has active chronic myeloid leukaemia, either manifest as cytogenetic evidence of the Philadelphia chromosome, or RT-PCR level of BCR-ABL transcript greater than 0.1% on the international scale. (The date of the relevant pathology report needs to be provided); and

(e) where there has been a loss of response to imatinib or dasatinib, a copy of the current confirming pathology report(s) from an Approved Pathology Authority or details of the dates of assessment in the case of progressive splenomegaly or extramedullary involvement

**Authority required**

Continuing treatment, as the sole PBS-subsidised therapy, of a patient who has received initial PBS-subsidised treatment with nilotinib for chronic myeloid leukaemia, and who has demonstrated either a major cytogenetic response, or less than 1% BCR-ABL level in the blood, to dasatinib in the preceding 18 months and thereafter at 12 monthly intervals.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Chronic Myeloid Leukaemia - Second and Third Line - Application Form for continuing treatment; and

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(3) demonstration of continued response to treatment as evidenced by either:

(a) major cytogenetic response [see Note explaining definitions of response]. Where this has been supplied within the previous 12 months (or 18 months for the initial supply), only the date of the relevant pathology report needs to be provided; or

(b) a peripheral blood level of BCR-ABL of less than 1% on the international scale [see Note explaining definitions of response]. Where this has been supplied within the previous 12 months (or 18 months for the initial supply), only the date of the relevant pathology report needs to be provided

**Note**

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

Prescribing information (including Authority Application forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Applications for authority to prescribe nilotinib should be forwarded to:

Medicare Australia

Prior Written Approval of Specialised Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

**Note**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of tyrosine kinase inhibitors (TKI) agents for all phases of chronic myeloid leukaemia. Where the term TKI agent appears in the following notes and restrictions it refers to dasatinib or nilotinib. Imatinib mesylate is not approved for use in second or third line treatment.

Patients are eligible for PBS-subsidised treatment with only one of dasatinib or nilotinib at any one time and must not be receiving concomitant interferon alfa therapy. Eligible patients may only swap between these agents if they have not failed prior PBS-subsidised treatment with that agent.

Nilotinib is not approved for patients in blast crisis.

1. Initial second line treatment

From 1 April 2012, under the PBS, a patient will be able to be prescribed either dasatinib or nilotinib within the initial 18 month treatment period as second-line therapy, as long as only one agent is approved at a time and providing the patient did not fail that drug as first-line therapy.

During the initial 18 month treatment period, switching between approved second-line agents may only occur for reasons of intolerance, not failure of response.

2. Initial third line treatment

Third-line treatment with a TKI can only be approved when imatinib is used for first-line treatment. Patients will only be approved for PBS-subsidised treatment with one third-line agent.

From 1 April 2012, under the PBS, a patient will be able to be prescribed either dasatinib or nilotinib providing the patient did not fail that drug as first or second line therapy and for nilotinib the patient is not in blast crisis.

3. Continuing treatment for second and third line treatment

All continuing applications are to be written and must include a pathology report demonstrating the patient has responded to PBS-subsidised treatment as follows:

(i) within 18 months of the commencement of treatment, at which time patients in whom a major cytogenetic response or peripheral blood BCR-ABL level of less than 1% has been demonstrated may receive authorisation for a further 12 months of treatment; and

(ii) at no greater than 12 month intervals thereafter, to demonstrate that the major cytogenetic response or peripheral blood BCR-ABL level of less than 1% has been sustained.

During second line continuing treatment beyond the initial 18 month treatment period, switching between approved second line TKI agents may only occur for reason of intolerance. Where there is failure of response, switching may only occur through application for prescription of a third line agent.

4. Authority approval requirements.

Response criteria to initial treatment with dasatinib or nilotinib:

For the purposes of assessing response to PBS-subsidised treatment with dasatinib or nilotinib, either cytogenetic analysis indicating the number of Philadelphia positive [t (9;22)] cells in the bone marrow measured by standard karyotyping, or quantitative PCR indicating the relative level of BCR-ABL transcript in the peripheral blood using the international scale, must be submitted. For bone marrow analyses, where the standard karyotyping is not informative for technical reasons, a cytogenetic analysis performed on the bone marrow by the use of fluorescence in situ hybridisation (FISH) with BCR-ABL specific probe must be submitted. The cytogenetic or peripheral blood quantitative PCR analyses must be submitted within 18 months of the commencement of treatment with dasatinib or nilotinib (patients in whom a major cytogenetic response or peripheral blood BCR-ABL level of less than 1% is demonstrable by 18 months are eligible to receive continuing treatment with that agent).

5. Definitions of response.

A major cytogenetic response is defined as less than 35% Philadelphia positive bone marrow cells.

A peripheral blood BCR-ABL level of less than 1% on the international scale (Blood 108: 28-37, 2006) also indicates a response, at least the biological equivalent of a major cytogenetic response.

6. Definitions of loss of response.

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|
| | Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph positive cells on bone marrow biopsy), during ongoing tyrosine kinase inhibitor (TKI) therapy. | | | | | | | |
| | Loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing consecutively in value by at least 5 fold to a level of greater than 0.1% confirmed on a subsequent test), during ongoing tyrosine kinase inhibitor therapy. | | | | | | | |
| 9171Q | NILOTINIB Capsule 200 mg (as hydrochloride monohydrate), 120 | 1 | 5 | .. | 5872.35 | 36.10 | Tasigna | NV |

**PAZOPANIB**

**Authority required**

Stage IV clear cell variant renal cell carcinoma (RCC)

Treatment Phase: Continuing treatment beyond 3 months

**The Clinical criteria is:**

Patient must have previously been issued with an authority prescription for pazopanib,

**AND the Clinical criteria is:**

Patient must have stable or responding disease according to the Response Evaluation Criteria In Solid Tumours (RECIST),

**AND the Clinical criteria is:**

Patient must require dose adjustment,

**AND the Clinical criteria is:**

The treatment must be the sole PBS-subsidised tyrosine kinase inhibitor therapy for this condition.

**Note**

Patients who have progressive disease with pazopanib are no longer eligible for PBS-subsidised pazopanib.

**Note**

Patients who have progressive disease on sunitinib are not eligible to receive PBS-subsidised pazopanib.

**Note**

Response Evaluation Criteria In Solid Tumours (RECIST) is defined as follows:

Complete response (CR) is disappearance of all target lesions.

Partial response (PR) is a 30% decrease in the sum of the longest diameter of target lesions.

Progressive disease (PD) is a 20% increase in the sum of the longest diameter of target lesions.

Stable disease (SD) is small changes that do not meet above criteria.

**Note**

Special Pricing Arrangements apply.

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 2232L | pazopanib 200 mg tablet, 30 | 1 | 5 | .. | 1256.46 | 36.10 | Votrient | GK |
| 2201W | pazopanib 400 mg tablet, 30 | 1 | 5 | .. | 2410.21 | 36.10 | Votrient | GK |

**PAZOPANIB**

**Authority required**

Stage IV clear cell variant renal cell carcinoma (RCC)

Treatment Phase: Initial treatment

**The Clinical criteria is:**

Patient must meet the Memorial Sloan Kettering Cancer Centre (MSKCC) low to intermediate risk group criteria,

**AND the Clinical criteria is:**

Patient must have a WHO performance status of 2 or less,

**AND the Clinical criteria is:**

The treatment must be the sole PBS-subsidised tyrosine kinase inhibitor therapy for this condition.

Patients who have progressive disease on sunitinib are not eligible to receive PBS-subsidised pazopanib.

**Note**

Patients who have developed intolerance to sunitinib of a severity necessitating permanent treatment withdrawal are eligible to receive PBS-subsidised pazopanib.

**Note**

Patients who have progressive disease with pazopanib are no longer eligible for PBS-subsidised pazopanib.

**Note**

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

**Note**

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

**Note**

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|
| | Special Pricing Arrangements apply. | | | | | | | |
| 2029T | pazopanib 200 mg tablet, 90 | 1 | 2 | .. | 3542.03 | 36.10 | Votrient | GK |
| 2030W | pazopanib 400 mg tablet, 60 | 1 | 2 | .. | 4673.85 | 36.10 | Votrient | GK |

**PAZOPANIB**

**Authority required**

Stage IV clear cell variant renal cell carcinoma (RCC)

Treatment Phase: Continuing treatment beyond 3 months

**The Clinical criteria is:**

Patient must have previously been issued with an authority prescription for pazopanib,

**AND the Clinical criteria is:**

Patient must have stable or responding disease according to the Response Evaluation Criteria In Solid Tumours (RECIST),

**AND the Clinical criteria is:**

The treatment must be the sole PBS-subsidised tyrosine kinase inhibitor therapy for this condition.

**Note**

Patients who have progressive disease with pazopanib are no longer eligible for PBS-subsidised pazopanib.

**Note**

Patients who have progressive disease on sunitinib are not eligible to receive PBS-subsidised pazopanib.

**Note**

Response Evaluation Criteria In Solid Tumours (RECIST) is defined as follows:

Complete response (CR) is disappearance of all target lesions.

Partial response (PR) is a 30% decrease in the sum of the longest diameter of target lesions.

Progressive disease (PD) is a 20% increase in the sum of the longest diameter of target lesions.

Stable disease (SD) is small changes that do not meet above criteria.

**Note**

Special Pricing Arrangements apply.

**Authority required**

Stage IV clear cell variant renal cell carcinoma (RCC)

Treatment Phase: Initial treatment

**The Clinical criteria is:**

Patient must have been receiving treatment with pazopanib prior to 1 October 2012,

**AND the Clinical criteria is:**

The treatment must be the sole PBS-subsidised tyrosine kinase inhibitor therapy for this condition.

**Note**

Patients who have progressive disease with pazopanib are no longer eligible for PBS-subsidised pazopanib.

**Note**

Special Pricing Arrangements apply.

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 2034C | pazopanib 200 mg tablet, 90 | 1 | 5 | .. | 3542.03 | 36.10 | Votrient | GK |
| 2035D | pazopanib 400 mg tablet, 60 | 1 | 5 | .. | 4673.85 | 36.10 | Votrient | GK |

**SORAFENIB**

**Authority required (STREAMLINED)**

***4230***

Advanced Barcelona Clinic Liver Cancer Stage C hepatocellular carcinoma

Treatment Phase: Initial

**The Clinical criteria is:**

The treatment must be the sole PBS-subsidised therapy for this condition,

**AND the Clinical criteria is:**

Patient must have a WHO performance status of 2 or less,

**AND the Clinical criteria is:**

Patient must have Child Pugh class A.

**Authority required (STREAMLINED)**

***4234***

Advanced Barcelona Clinic Liver Cancer Stage C hepatocellular carcinoma

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|
| | Treatment Phase: Continuing<br>**The Clinical criteria is:**<br>The treatment must be the sole PBS-subsidised therapy for this condition,<br>**AND the Clinical criteria is:**<br>Patient must have previously been treated with PBS-subsidised sorafenib,<br>**AND the Clinical criteria is:**<br>Patient must not have progressive disease.<br>**Note**<br>Sorafenib is not PBS-subsidised for adjunctive treatment after resection, ablation or chemoembolization.<br>Sorafenib is not PBS-subsidised for maintenance therapy after disease progression.<br>**Note**<br>No increase in the maximum quantity or number of units may be authorised.<br>**Note**<br>No increase in the maximum number of repeats may be authorised.<br>**Note**<br>Special Pricing Arrangements apply. | | | | | | | |
| 9380Q | sorafenib 200 mg tablet, 60 | 2 | 2 | .. | *6457.29 | 36.10 | Nexavar | BN |
| | **SUNITINIB**<br>**Authority required**<br>Stage IV clear cell variant renal cell carcinoma (RCC)<br>Treatment Phase: Initial treatment<br>**The Clinical criteria is:**<br>Patient must meet the Memorial Sloan Kettering Cancer Centre (MSKCC) low to intermediate risk group criteria,<br>**AND the Clinical criteria is:**<br>Patient must have a WHO performance status of 2 or less,<br>**AND the Clinical criteria is:**<br>The treatment must be the sole PBS-subsidised tyrosine kinase inhibitor therapy for this condition.<br>Patients who have developed progressive disease on pazopanib are not eligible to receive PBS-subsidised sunitinib.<br>**Note**<br>Patients who have developed intolerance to pazopanib of a severity necessitating permanent treatment withdrawal are eligible to receive PBS-subsidised sunitinib.<br>**Note**<br>Patients who have progressive disease with sunitinib are no longer eligible for PBS-subsidised sunitinib.<br>**Note**<br>No increase in the maximum quantity or number of units may be authorised.<br>**Note**<br>No increase in the maximum number of repeats may be authorised.<br>**Note**<br>Special Pricing Arrangements apply. | | | | | | | |
| 9417P | sunitinib 12.5 mg capsule, 28 | 1 | 1 | .. | 1834.41 | 36.10 | Sutent | PF |
| 9418Q | sunitinib 25 mg capsule, 28 | 1 | 1 | .. | 3521.97 | 36.10 | Sutent | PF |
| 9419R | sunitinib 50 mg capsule, 28 | 1 | 1 | .. | 6897.65 | 36.10 | Sutent | PF |
| | **SUNITINIB**<br>**Authority required**<br>Stage IV clear cell variant renal cell carcinoma (RCC)<br>Treatment Phase: Continuing treatment beyond 3 months<br>**The Clinical criteria is:**<br>Patient must have previously been issued with an authority prescription for sunitinib,<br>**AND the Clinical criteria is:**<br>Patient must have stable or responding disease according to the Response Evaluation Criteria In Solid Tumours (RECIST),<br>**AND the Clinical criteria is:**<br>The treatment must be the sole PBS-subsidised tyrosine kinase inhibitor therapy for this condition.<br>**Note** | | | | | | | |

# ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|
| | Patients who have progressive disease with sunitinib are no longer eligible for PBS-subsidised sunitinib. | | | | | | | |
| | **Note**<br>Patients who have developed progressive disease on pazopanib are not eligible to receive PBS-subsidised sunitinib. | | | | | | | |
| | **Note**<br>Response Evaluation Criteria In Solid Tumours (RECIST) is defined as follows:<br>Complete response (CR) is disappearance of all target lesions.<br>Partial response (PR) is a 30% decrease in the sum of the longest diameter of target lesions.<br>Progressive disease (PD) is a 20% increase in the sum of the longest diameter of target lesions.<br>Stable disease (SD) is small changes that do not meet above criteria. | | | | | | | |
| | **Note**<br>Special Pricing Arrangements apply. | | | | | | | |
| 9420T | sunitinib 12.5 mg capsule, 28 | 1 | 3 | .. | 1834.41 | 36.10 | Sutent | PF |
| 9421W | sunitinib 25 mg capsule, 28 | 1 | 3 | .. | 3521.97 | 36.10 | Sutent | PF |
| 9422X | sunitinib 50 mg capsule, 28 | 1 | 3 | .. | 6897.65 | 36.10 | Sutent | PF |
| | **SUNITINIB**<br>**Authority required**<br>Initial PBS-subsidised treatment as monotherapy of a patient with WHO performance status of 2 or less with a metastatic or unresectable malignant gastrointestinal stromal tumour after failure of imatinib mesylate treatment due to resistance or intolerance.<br>Applications for authorisation must be in writing and must include:<br>(1) a completed authority prescription form; and<br>(2) a completed Sunitinib Malate (Sutent) PBS Authority Application for Use in the Treatment of Gastrointestinal Stromal Tumour - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and<br>(3) a signed patient acknowledgement.<br>Patients who have failed to respond or are intolerant to imatinib are no longer eligible to receive PBS-subsidised imatinib | | | | | | | |
| | **Authority required**<br>Continuing PBS-subsidised treatment as monotherapy of a patient with WHO performance status of 2 or less with a metastatic or unresectable malignant gastrointestinal stromal tumour who has previously been issued with an authority prescription for sunitinib and who does not have progressive disease.<br>Applications for continuing treatment may be made by telephone (1800 700 270, hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).<br>Patients who have failed to respond or who are intolerant to imatinib are no longer eligible to receive PBS-subsidised imatinib.<br>Patients who have progressive disease on sunitinib are no longer eligible for PBS-subsidised sunitinib | | | | | | | |
| | **Note**<br>Any queries concerning the arrangements to prescribe sunitinib malate may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).<br>Prescribing information (including Authority Application forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.<br>Any queries concerning patients who are enrolled on the Sunitinib Compassionate Program may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).<br>Written applications for authority to prescribe sunitinib malate should be forwarded to:<br>Medicare Australia<br>Prior Written Approval of Specialised Drugs<br>Reply Paid 9826<br>GPO Box 9826<br>HOBART TAS 7001<br>Sunitinib malate is not PBS-subsidised for the treatment of patients with resectable malignant gastrointestinal stromal tumours. | | | | | | | |
| | **Note**<br>No applications for increased maximum quantities and/or repeats will be authorised. | | | | | | | |
| | **Note**<br>Special Pricing Arrangements apply. | | | | | | | |
| 9488J | sunitinib 12.5 mg capsule, 28 | 1 | 1 | .. | 1834.41 | 36.10 | Sutent | PF |
| 9489K | sunitinib 25 mg capsule, 28 | 1 | 1 | .. | 3521.97 | 36.10 | Sutent | PF |
| 9490L | sunitinib 50 mg capsule, 28 | 1 | 1 | .. | 6897.65 | 36.10 | Sutent | PF |
| | ***Other antineoplastic agents*** | | | | | | | |
| | **HYDROXYUREA** | | | | | | | |
| 3093T | hydroxyurea 500 mg capsule, 100 | 1 | .. | .. | 76.67 | 36.10 | Hydrea | BQ |

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|
| | **ENDOCRINE THERAPY** | | | | | | | |
| | **HORMONES AND RELATED AGENTS** | | | | | | | |
| | ***Progestogens*** | | | | | | | |
| | **MEDROXYPROGESTERONE**<br>**Restricted benefit**<br>Hormone-dependent breast cancer<br>**Restricted benefit**<br>Endometrial cancer | | | | | | | |
| 2725K | medroxyprogesterone acetate 100 mg tablet, 100 | 1 | 2 | .. | 90.59 | 36.10 | Provera | PF |
| 2316X | medroxyprogesterone acetate 200 mg tablet, 60 | 1 | 2 | .. | 102.00 | 36.10 | Provera | PF |
| 2727M | medroxyprogesterone acetate 250 mg tablet, 60 | 1 | 2 | .. | 125.86 | 36.10 | Provera | PF |
| | **MEDROXYPROGESTERONE**<br>**Restricted benefit**<br>Hormone-dependent advanced breast cancer | | | | | | | |
| 2728N | medroxyprogesterone acetate 500 mg tablet, 30 | 1 | 2 | .. | 126.09 | 36.10 | Provera | PF |
| | **MEGESTROL**<br>**Restricted benefit**<br>Hormone-dependent advanced breast cancer | | | | | | | |
| 2734X | megestrol acetate 160 mg tablet, 30 | 1 | 2 | .. | 83.60 | 36.10 | Megace | QA |
| | ***Gonadotropin releasing hormone analogues*** | | | | | | | |
| | **GOSERELIN**<br>**Authority required (STREAMLINED)**<br>***3229***<br>Locally advanced (equivalent to stage C) or metastatic (equivalent to stage D) carcinoma of the prostate | | | | | | | |
| 8093Y | goserelin 10.8 mg implant, 1 | 1 | 1 | .. | 1108.97 | 36.10 | Zoladex 10.8 Implant | AP |
| | **GOSERELIN**<br>**Authority required**<br>Locally advanced (equivalent to stage C) or metastatic (equivalent to stage D) carcinoma of the prostate<br>**Authority required**<br>Hormone-dependent locally advanced (equivalent to stage III) or metastatic (equivalent to stage IV) breast cancer in pre-menopausal women<br>**Authority required**<br>Short-term treatment (up to 6 months) of visually proven endometriosis (only 1 course of not more than 6 months' therapy will be authorised)<br>**Authority required**<br>Hormone-dependent breast cancer as an alternative to adjuvant chemotherapy in peri- or pre-menopausal women | | | | | | | |
| 1454M | goserelin 3.6 mg implant, 1 | 1 | 5 | .. | 333.21 | 36.10 | Zoladex Implant | AP |
| | **GOSERELIN (&) BICALUTAMIDE**<br>**Authority required (STREAMLINED)**<br>***3239***<br>Metastatic (equivalent to stage D) prostatic carcinoma in patients for whom a combination of an antiandrogen and a GnRH (LH-RH) agonist is required<br>**Note**<br>No applications for increased maximum quantities and/or repeats will be authorised. | | | | | | | |
| 9065D | goserelin 10.8 mg implant [1 implant] (&) bicalutamide 50 mg tablet [28 tablets], 1 pack | ‡1 | .. | .. | 1248.50 | 36.10 | ZolaCos CP 10.8/50(28) | AP |
| 9066E | goserelin 10.8 mg implant [1 implant] (&) bicalutamide 50 mg tablet [84 tablets], 1 pack | ‡1 | 1 | .. | 1527.58 | 36.10 | ZolaCos CP 10.8/50(84) | AP |
| 9064C | goserelin 3.6 mg implant [1 implant] (&) bicalutamide 50 mg tablet [28 tablets], 1 pack | ‡1 | 5 | .. | 477.58 | 36.10 | ZolaCos CP 3.6/50 | AP |

# ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|
| | **LEUPRORELIN** | | | | | | | |
| | **Authority required (STREAMLINED)** | | | | | | | |
| | ***3229*** | | | | | | | |
| | Locally advanced (equivalent to stage C) or metastatic (equivalent to stage D) carcinoma of the prostate | | | | | | | |
| 8708H | leuprorelin acetate 22.5 mg injection: modified release [1 syringe] (&) inert substance diluent [1 syringe], 1 pack | 1 | 1 | .. | 1108.97 | 36.10 | Eligard 3 month | HH |
| 8876E | leuprorelin acetate 22.5 mg injection: modified release [1 x 22.5 mg syringe] (&) inert substance diluent [1 x 2 mL syringe], 1 pack | 1 | 1 | .. | 1108.97 | 36.10 | Lucrin Depot 3 Month PDS | VE |
| 8709J | leuprorelin acetate 30 mg injection: modified release [1 syringe] (&) inert substance diluent [1 syringe], 1 pack | 1 | 1 | .. | 1451.54 | 36.10 | Eligard 4 month | HH |
| 8877F | leuprorelin acetate 30 mg injection: modified release [1 x 30 mg syringe] (&) inert substance diluent [1 x 2 mL syringe], 1 pack | 1 | 1 | .. | 1451.54 | 36.10 | Lucrin Depot 4 Month PDS | VE |
| 8859G | leuprorelin acetate 45 mg injection: modified release [1 syringe] (&) inert substance diluent [1 syringe], 1 pack | 1 | .. | .. | 2124.19 | 36.10 | Eligard 6 month | HH |
| 8707G | leuprorelin acetate 7.5 mg injection: modified release [1 syringe] (&) inert substance diluent [1 syringe], 1 pack | 1 | 5 | .. | 420.41 | 36.10 | Eligard 1 month | HH |
| 8875D | leuprorelin acetate 7.5 mg injection: modified release [1 x 7.5 mg syringe] (&) inert substance diluent [1 x 2 mL syringe], 1 pack | 1 | 5 | .. | 420.41 | 36.10 | Lucrin Depot 7.5mg PDS | VE |
| | **TRIPTORELIN** | | | | | | | |
| | **Authority required (STREAMLINED)** | | | | | | | |
| | ***3229*** | | | | | | | |
| | Locally advanced (equivalent to stage C) or metastatic (equivalent to stage D) carcinoma of the prostate | | | | | | | |
| 9379P | triptorelin 11.25 mg injection [1 x 11.25 mg vial] (&) inert substance diluent [1 x 2 mL ampoule], 1 pack | 1 | 1 | .. | 1108.97 | 36.10 | Diphereline | IS |
| 5297T | triptorelin 22.5 mg injection [1 x 22.5 mg vial] (&) inert substance diluent [1 x 2 mL ampoule], 1 pack | 1 | .. | .. | 2124.19 | 36.10 | Diphereline | IS |
| 9378N | triptorelin 3.75 mg injection [1 x 3.75 mg vial] (&) inert substance diluent [1 x 2 mL ampoule], 1 pack | 1 | 5 | .. | 420.41 | 36.10 | Diphereline | IS |

## HORMONE ANTAGONISTS AND RELATED AGENTS

### *Anti-estrogens*

**TAMOXIFEN**

**Restricted benefit**

Treatment of hormone-dependent breast cancer

**Note**

This drug is not PBS-subsidised for primary prevention of breast cancer.

**Note**

Shared Care Model:

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

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 2109B | tamoxifen 10 mg tablet, 60 | 1 | 5 | .. | 27.36 | 28.49 | Genox 10 | AF |
| *NP* | | | | | | | | |

**TAMOXIFEN**

**Restricted benefit**

Treatment of hormone-dependent breast cancer

**Note**

This drug is not PBS-subsidised for primary prevention of breast cancer.

**Note**

For item codes 2110C and 1880Y, pharmaceutical benefits that have the form tablet 20 mg (base) are equivalent for the purposes of substitution.

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|---|
| | **Note**<br>Shared Care Model:<br>For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners. | | | | | | | | |
| 1880Y<br>*NP* | tamoxifen 20 mg tablet, 30 | 2 | 5 | [B]2.24 | *44.63 | 36.10 | [a] | Nolvadex-D | AP |
| 2110C<br>*NP* | tamoxifen 20 mg tablet, 60 | 1 | 5 | .. | 42.40 | 36.10 | [a] | Genox 20 | AF |
| | | | | | | | [a] | GenRx Tamoxifen | GX |
| | | | | | | | [a] | Tamosin | QA |
| | | | | | | | [a] | Tamoxen 20 mg | GM |
| | | | | | | | [a] | Tamoxifen Sandoz | SZ |
| | **TOREMIFENE**<br>**Restricted benefit**<br>Treatment of hormone-dependent metastatic breast cancer in post-menopausal patients<br>**Note**<br>This drug is not PBS-subsidised for primary prevention of breast cancer. | | | | | | | | |
| 8216K | toremifene 60 mg tablet, 30 | 1 | 5 | .. | 73.95 | 36.10 | | Fareston | MK |

## *Anti-androgens*

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | **BICALUTAMIDE**<br>**Authority required (STREAMLINED)**<br>***3674***<br>Metastatic (equivalent to stage D) prostatic carcinoma in combination with GnRH (LH-RH) analogue therapy<br>**Note**<br>No applications for increased maximum quantities and/or repeats will be authorised.<br>**Note**<br>Shared Care Model:<br>For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners. | | | | | | | | |
| 8094B<br>*NP* | bicalutamide 50 mg tablet, 28 | 1 | 5 | .. | 151.85 | 36.10 | [a] | APO-Bicalutamide | TX |
| | | | | | | | [a] | Bicalutamide-GA | GM |
| | | | | | | | [a] | Calutex | QA |
| | | | | | | | [a] | Cosamide | AF |
| | | | | | | | [a] | Cosudex | AP |
| | **CYPROTERONE**<br>**Authority required (STREAMLINED)**<br>***1014***<br>Advanced carcinoma of the prostate<br>**Authority required (STREAMLINED)**<br>***1404***<br>To reduce drive in sexual deviations in males | | | | | | | | |
| 8019C | cyproterone acetate 100 mg tablet, 50 | 1 | 5 | .. | 116.22 | 36.10 | [a] | Cyprocur 100 | QA |
| | | | | | | | [a] | Cyprohexal | SZ |
| | | | | | | | [a] | Cyprostat-100 | SY |
| | | | | | | | [a] | Cyproterone Sandoz | HX |
| | | | | | | | [a] | GenRx Cyproterone Acetate | GX |
| | | | | | | | [a] | Procur 100 | GM |
| | | | | [B]1.11 | 117.33 | 36.10 | [a] | Androcur-100 | BN |
| 1270W | cyproterone acetate 50 mg tablet, 50 | 2 | 5 | .. | *147.33 | 36.10 | [a] | Cyprocur 50 | QA |
| | | | | | | | [a] | Cyprohexal | SZ |
| | | | | | | | [a] | Cyprone | AF |
| | | | | | | | [a] | Cyprostat | SY |
| | | | | | | | [a] | Cyproterone Sandoz | HX |
| | | | | | | | [a] | GenRx Cyproterone Acetate | GX |
| | | | | | | | [a] | Procur | GM |
| | | | | [B]2.64 | *149.97 | 36.10 | [a] | Androcur | BN |

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|---|
| | **FLUTAMIDE**<br>**Authority required (STREAMLINED)**<br>***3674***<br>Metastatic (equivalent to stage D) prostatic carcinoma in combination with GnRH (LH-RH) analogue therapy<br>**Note**<br>No applications for increased maximum quantities and/or repeats will be authorised.<br>**Note**<br>Shared Care Model:<br>For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners. | | | | | | | | |
| 1417N<br>*NP* | flutamide 250 mg tablet, 100 | 1 | 5 | .. | 201.90 | 36.10 | | Flutamin | AF |
| | **NILUTAMIDE**<br>**Authority required (STREAMLINED)**<br>***3675***<br>Locally advanced (equivalent to stage C) or metastatic (equivalent to stage D) prostatic carcinoma, in combination with GnRH (LH-RH) analogue therapy<br>**Authority required (STREAMLINED)**<br>***3300***<br>Locally advanced (equivalent to stage C) or metastatic (equivalent to stage D) prostatic carcinoma, in conjunction with surgical orchidectomy<br>**Note**<br>Shared Care Model:<br>For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners. | | | | | | | | |
| 8131Y<br>*NP* | nilutamide 150 mg tablet, 30 | 1 | 5 | .. | 236.77 | 36.10 | | Anandron | SW |

## *Aromatase inhibitors*

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|---|
| | **ANASTROZOLE**<br>**Restricted benefit**<br>Treatment of hormone-dependent breast cancer in post-menopausal women<br>**Note**<br>This drug is not PBS-subsidised for primary prevention of breast cancer.<br>This drug is not PBS-subsidised for adjuvant hormonal treatment of early breast cancer extended beyond 5 years.<br>**Note**<br>Shared Care Model:<br>For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners. | | | | | | | | |
| 8179L<br>*NP* | anastrozole 1 mg tablet, 30 | 1 | 5 | .. | 152.59 | 36.10 | [a] | Anastrol | QA |
| | | | | | | | [a] | Anastrozole-DRLA | RZ |
| | | | | | | | [a] | Anastrozole-GA | GM |
| | | | | | | | [a] | Anastrozole GH | GQ |
| | | | | | | | [a] | Anastrozole RBX | RA |
| | | | | | | | [a] | Anastrozole Sandoz | SZ |
| | | | | | | | [a] | Anzole | WQ |
| | | | | | | | [a] | APO-Anastrozole | TX |
| | | | | | | | [a] | Arianna | AF |
| | | | | | | | [a] | Arimidex | AP |
| | | | | | | | [a] | Chem mart Anastrozole | CH |
| | | | | | | | [a] | Pharmacor Anastrozole 1 | CR |
| | | | | | | | [a] | Pharmacy Choice Anastrozole | RI |
| | | | | | | | [a] | STADA Anastrozole | TD |
| | | | | | | | [a] | Terry White Chemists Anastrozole | TW |
| | **EXEMESTANE**<br>**Restricted benefit** | | | | | | | | |

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|---|
| | Treatment of hormone-dependent advanced breast cancer in post-menopausal women with disease progression following treatment with tamoxifen citrate | | | | | | | | |
| | **Restricted benefit**<br>Treatment of hormone-dependent early breast cancer in post-menopausal women following a minimum of 2 years' treatment with tamoxifen citrate | | | | | | | | |
| | **Note**<br>This drug is not PBS-subsidised for primary prevention of breast cancer.<br>This drug is not PBS-subsidised for adjuvant hormonal treatment of early breast cancer extended beyond 5 years, i.e. a patient who has received 2 years of tamoxifen therapy may only receive 3 years of PBS-subsidised treatment with exemestane. | | | | | | | | |
| | **Note**<br>Shared Care Model:<br>For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners. | | | | | | | | |
| 8506Q<br>*NP* | exemestane 25 mg tablet, 30 | 1 | 5 | .. | 152.59 | 36.10 | [a] | APO-Exemestane | TX |
| | | | | | | | [a] | Aromasin | PF |
| | | | | | | | [a] | Exaccord | RA |
| | | | | | | | [a] | Exemestane-GA | GM |
| | | | | | | | [a] | Exemestane Pfizer | FZ |
| | | | | | | | [a] | Exemestane Sandoz | SZ |
| | **LETROZOLE**<br>**Restricted benefit**<br>Treatment of hormone-dependent advanced breast cancer in post-menopausal women | | | | | | | | |
| | **Restricted benefit**<br>Treatment of hormone-dependent early breast cancer in post-menopausal women | | | | | | | | |
| | **Restricted benefit**<br>Extended adjuvant treatment of hormone-dependent early breast cancer in post-menopausal women commencing within 6 months of ceasing treatment with tamoxifen citrate | | | | | | | | |
| | **Note**<br>This drug is not PBS-subsidised for primary prevention of breast cancer.<br>This drug is not PBS-subsidised for adjuvant hormonal treatment of early breast cancer extended beyond 5 years.<br>This drug is not PBS-subsidised for extended adjuvant early breast cancer treatment where the total duration of letrozole (or any other aromatase inhibitor) treatment extends beyond 5 years. | | | | | | | | |
| | **Note**<br>Shared Care Model:<br>For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners. | | | | | | | | |
| 8245Y<br>*NP* | letrozole 2.5 mg tablet, 30 | 1 | 5 | .. | 152.59 | 36.10 | [a] | APO-Letrozole | TX |
| | | | | | | | [a] | Chem mart Letrozole | CH |
| | | | | | | | [a] | Femara 2.5 mg | NV |
| | | | | | | | [a] | Femolet | AF |
| | | | | | | | [a] | Fera | QA |
| | | | | | | | [a] | Letrozole Actavis | TA |
| | | | | | | | [a] | Letrozole-DRLA | RZ |
| | | | | | | | [a] | Letrozole-GA | GM |
| | | | | | | | [a] | Letrozole generichealth | GQ |
| | | | | | | | [a] | Letrozole RBX | RA |
| | | | | | | | [a] | Letrozole Sandoz | SZ |
| | | | | | | | [a] | Lezole | WQ |
| | | | | | | | [a] | Pharmacor Letrozole 2.5 | CR |
| | | | | | | | [a] | Pharmacy Choice Letrozole | RI |
| | | | | | | | [a] | STADA Letrozole | TD |
| | | | | | | | [a] | Terry White Chemists Letrozole | TW |

## *Other hormone antagonists and related agents*

**ABIRATERONE**

# ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|
| | **Authority required**<br>Castration resistant metastatic carcinoma of the prostate<br>**The Clinical criteria is:**<br>The treatment must be in combination with prednisone or prednisolone,<br>**AND the Clinical criteria is:**<br>The treatment must not be used in combination with chemotherapy,<br>**AND the Clinical criteria is:**<br>Patient must have failed treatment with docetaxel due to resistance or intolerance,<br>**AND the Clinical criteria is:**<br>Patient must have a WHO performance status of 2 or less,<br>**AND the Clinical criteria is:**<br>Patient must not receive PBS-subsidised abiraterone if progressive disease develops while on abiraterone.<br>**Note**<br>Patients who have received PBS-subsidised abiraterone or cabazitaxel are not eligible for PBS-subsidised docetaxel.<br>**Note**<br>Special Pricing Arrangements apply. | | | | | | | |
| 2698B | abiraterone acetate 250 mg tablet, 120 | 1 | 2 | .. | 3600.11 | 36.10 | Zytiga | JC |
| | **DEGARELIX**<br>**Authority required (STREAMLINED)**<br>***3229***<br>Locally advanced (equivalent to stage C) or metastatic (equivalent to stage D) carcinoma of the prostate<br>**Note**<br>No applications for increased maximum quantities and/or repeats will be authorised for the 120 mg powder for injection. | | | | | | | |
| 5456E | degarelix 120 mg injection: subcutaneous infusion [2 x 120 mg vials] (&) inert substance diluent [2 x 3 mL vials], 1 pack | ‡1 | .. | .. | 438.93 | 36.10 | Firmagon 120mg | FP |
| | **DEGARELIX**<br>**Authority required (STREAMLINED)**<br>***3229***<br>Locally advanced (equivalent to stage C) or metastatic (equivalent to stage D) carcinoma of the prostate | | | | | | | |
| 5455D | degarelix 80 mg injection: subcutaneous infusion [1 x 80 mg vial] (&) inert substance diluent [1 x 4.2 mL vial], 1 pack | 1 | 5 | .. | 420.41 | 36.10 | Firmagon 80mg | FP |

## IMMUNOSTIMULANTS

## IMMUNOSTIMULANTS

### *Interferons*

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | **INTERFERON ALFA-2A**<br>**Authority required**<br>Hairy cell leukaemia<br>**Authority required**<br>Myeloproliferative disease with excessive thrombocytosis<br>**Caution**<br>Treatment with interferon alfa has been associated with depression and suicide in some patients. Patients with a history of suicidal ideation or depressive illness should be warned of the risks. Psychiatric status during therapy should be monitored. | | | | | | | |
| 8180M | interferon alfa-2a 3 million international units/0.5 mL injection, 1 x 0.5 mL syringe | 15 | 4 | .. | *506.43 | 36.10 | Roferon-A | RO |
| | **INTERFERON ALFA-2A**<br>**Authority required**<br>Low grade non-Hodgkin's lymphoma with clinical features suggestive of a poor prognosis, in combination with anthracycline-based chemotherapy<br>**Caution**<br>Treatment with interferon alfa has been associated with depression and suicide in some patients. Patients with a history of suicidal ideation or | | | | | | | |

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|
| | depressive illness should be warned of the risks. Psychiatric status during therapy should be monitored. | | | | | | | |
| 8181N | interferon alfa-2a 3 million international units/0.5 mL injection, 1 x 0.5 mL syringe | 15 | 5 | .. | *506.43 | 36.10 | Roferon-A | RO |
| 8182P | interferon alfa-2a 4.5 million international units/0.5 mL injection, 1 x 0.5 mL syringe | 5 | 5 | .. | *264.93 | 36.10 | Roferon-A | RO |
| 8183Q | interferon alfa-2a 6 million international units/0.5 mL injection, 1 x 0.5 mL syringe | 5 | 5 | .. | *344.93 | 36.10 | Roferon-A | RO |
| 8184R | interferon alfa-2a 9 million international units/0.5 mL injection, 1 x 0.5 mL syringe | 5 | 5 | .. | *506.33 | 36.10 | Roferon-A | RO |
| | **INTERFERON ALFA-2A** | | | | | | | |
| | **Authority required** | | | | | | | |
| | Myeloproliferative disease with excessive thrombocytosis | | | | | | | |
| | **Caution** | | | | | | | |
| | Treatment with interferon alfa has been associated with depression and suicide in some patients. Patients with a history of suicidal ideation or depressive illness should be warned of the risks. Psychiatric status during therapy should be monitored. | | | | | | | |
| 8551C | interferon alfa-2a 4.5 million international units/0.5 mL injection, 1 x 0.5 mL syringe | 5 | 4 | .. | *264.93 | 36.10 | Roferon-A | RO |
| 8552D | interferon alfa-2a 6 million international units/0.5 mL injection, 1 x 0.5 mL syringe | 5 | 4 | .. | *344.93 | 36.10 | Roferon-A | RO |
| 8553E | interferon alfa-2a 9 million international units/0.5 mL injection, 1 x 0.5 mL syringe | 5 | 4 | .. | *506.33 | 36.10 | Roferon-A | RO |
| | **INTERFERON ALFA-2B** | | | | | | | |
| | **Authority required** | | | | | | | |
| | Maintenance treatment of multiple myeloma once remission has been achieved with chemotherapy | | | | | | | |
| | **Authority required** | | | | | | | |
| | Low grade non-Hodgkin's lymphoma with clinical features suggestive of a poor prognosis, in combination with anthracycline-based chemotherapy | | | | | | | |
| | **Caution** | | | | | | | |
| | Treatment with interferon alfa has been associated with depression and suicide in some patients. Patients with a history of suicidal ideation or depressive illness should be warned of the risks. Psychiatric status during therapy should be monitored. | | | | | | | |
| 8348J | interferon alfa-2b 18 million international units/1.2 mL injection, 1 x 1.2 mL cartridge | 3 | 5 | .. | *606.24 | 36.10 | Intron A Redipen | MK |
| 8476D | interferon alfa-2b 30 million international units/1.2 mL injection, 1 x 1.2 mL cartridge | 3 | 5 | .. | *1005.96 | 36.10 | Intron A Redipen | MK |
| | **INTERFERON ALFA-2B** | | | | | | | |
| | **Authority required** | | | | | | | |
| | Hairy cell leukaemia | | | | | | | |
| | **Caution** | | | | | | | |
| | Treatment with interferon alfa has been associated with depression and suicide in some patients. Patients with a history of suicidal ideation or depressive illness should be warned of the risks. Psychiatric status during therapy should be monitored. | | | | | | | |
| 8572E | interferon alfa-2b 18 million international units/1.2 mL injection, 1 x 1.2 mL cartridge | 3 | 4 | .. | *606.24 | 36.10 | Intron A Redipen | MK |
| | **INTERFERON BETA-1A** | | | | | | | |
| | **Authority required** | | | | | | | |
| | Initial treatment of clinically definite relapsing-remitting multiple sclerosis in ambulatory (without assistance or support) patients who have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to the multiple sclerosis, in the preceding 2 years. The diagnosis must be confirmed by magnetic resonance imaging of the brain and/or spinal cord and the date of the scan included in the authority application, unless the authority application is accompanied by written certification provided by a radiologist that an MRI scan is contraindicated because of the risk of physical (not psychological) injury to the patient. The authority will be limited to the maximum quantity and number of repeats indicated in the schedule | | | | | | | |
| | **Authority required** | | | | | | | |
| | Continuing treatment of clinically definite relapsing-remitting multiple sclerosis in patients previously issued with an authority prescription for this drug who do not show continuing progression of disability while on treatment with this drug and who have demonstrated compliance with, and an | | | | | | | |

# ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|---|
| | ability to tolerate, this therapy. Authorities will be limited to the maximum quantity and number of repeats indicated in the schedule | | | | | | | | |
| 8968B | INTERFERON BETA-1a Injection 44 micrograms (12,000,000 i.u.) in 0.5 mL single dose autoinjector, 12 | 1 | 5 | .. | 1056.98 | 36.10 | | Rebif 44 | SG |
| 8289G | interferon beta-1a 30 microgram (6 million international units) injection [4 x 30 microgram vials] (&) inert substance diluent [4 x 1.1 mL syringes], 1 pack | 1 | 5 | .. | 1056.98 | 36.10 | | Avonex | BD |
| 8805K | interferon beta-1a 30 microgram/0.5 mL (6 million international units) injection, 4 x 0.5 mL syringes | 1 | 5 | .. | 1056.98 | 36.10 | | Avonex | BD |
| 8403G | interferon beta-1a 44 microgram/0.5 mL (12 million international units) injection, 12 x 0.5 mL syringes | 1 | 5 | .. | 1056.98 | 36.10 | | Rebif 44 | SG |
| 9332E | interferon beta-1a 44 microgram/0.5 mL (12 million international units) injection, 4 x 1.5 mL cartridges | 1 | 5 | .. | 1056.98 | 36.10 | | Rebif 44 | SG |
| | **INTERFERON BETA-1B** | | | | | | | | |
| | **Authority required** | | | | | | | | |
| | Initial treatment of clinically definite relapsing-remitting multiple sclerosis in ambulatory (without assistance or support) patients who have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to the multiple sclerosis, in the preceding 2 years. The diagnosis must be confirmed by magnetic resonance imaging of the brain and/or spinal cord and the date of the scan included in the authority application, unless the authority application is accompanied by written certification provided by a radiologist that an MRI scan is contraindicated because of the risk of physical (not psychological) injury to the patient. The authority will be limited to the maximum quantity and number of repeats indicated in the schedule | | | | | | | | |
| | **Authority required** | | | | | | | | |
| | Continuing treatment of clinically definite relapsing-remitting multiple sclerosis in patients previously issued with an authority prescription for this drug who do not show continuing progression of disability while on treatment with this drug and who have demonstrated compliance with, and an ability to tolerate, this therapy. Authorities will be limited to the maximum quantity and number of repeats indicated in the schedule | | | | | | | | |
| 8101J | interferon beta-1b 8 million international units (250 microgram) injection [15 x 250 microgram vials] (&) inert substance diluent [15 x 1.2 mL syringes], 1 pack | 1 | 5 | .. | 1001.02 | 36.10 | [a] | Betaferon | BN |
| | | | | | | | [a] | Extavia | NV |

## *Other immunostimulants*

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | **BACILLUS CALMETTE AND GUERIN-CONNAUGHT STRAIN** | | | | | | | | |
| | **Restricted benefit** | | | | | | | | |
| | Treatment of carcinoma in situ of the urinary bladder | | | | | | | | |
| 1140B | Bacillus Calmette and Guerin-Connaught strain 660 million colony forming units injection [1 x 81 mg vial] (&) inert substance diluent [1 x 3 mL vial], 1 pack | 3 | 1 | .. | *460.08 | 36.10 | | ImmuCyst | SW |
| | **BACILLUS CALMETTE AND GUERIN-TICE STRAIN** | | | | | | | | |
| | **Restricted benefit** | | | | | | | | |
| | Primary and relapsing superficial urothelial carcinoma of the bladder | | | | | | | | |
| 1131M | Bacillus Calmette and Guerin-Tice strain 500 million colony forming units injection, 3 x 500 million colony forming units vials | 1 | 1 | .. | 556.60 | 36.10 | | OncoTICE | MK |
| | **GLATIRAMER ACETATE** | | | | | | | | |
| | **Authority required** | | | | | | | | |
| | Initial treatment of clinically definite relapsing-remitting multiple sclerosis in ambulatory (without assistance or support) patients who have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to the multiple sclerosis, in the preceding 2 years. The diagnosis must be confirmed by magnetic resonance imaging of the brain and/or spinal cord and the date of the scan included in the authority application, unless the authority application is accompanied by written certification provided by a radiologist that an MRI scan is contraindicated because of the risk of physical (not psychological) injury to the patient. The authority will be limited to the maximum quantity and number of repeats indicated in the schedule | | | | | | | | |
| | **Authority required** | | | | | | | | |
| | Continuing treatment of clinically definite relapsing-remitting multiple sclerosis in patients previously issued with an authority prescription for this drug who do not show continuing progression of disability while on treatment with this drug and who have demonstrated compliance with, and an ability to tolerate, this therapy. Authorities will be limited to the maximum quantity and number of repeats indicated in the schedule | | | | | | | | |

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|
| 8726G | glatiramer acetate 20 mg/mL injection, 28 x 1 mL syringes | 1 | 5 | .. | 1092.86 | 36.10 | Copaxone | CS |



## IMMUNOSUPPRESSANTS

### *Selective immunosuppressants*

**ABATACEPT**

**Authority required**

Initial 1 (new patient or patient re-commencing after a break of more than 24 months)

Initial PBS-subsidised treatment with abatacept, in combination with methotrexate at a dose of at least 7.5 mg weekly, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of adults who:

(a) have severe active rheumatoid arthritis; and

(b) have received no PBS-subsidised treatment with a bDMARD for this condition in the previous 24 months; and

(c) have failed, in the 24 months immediately prior to the date of application, to achieve an adequate response to at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs), which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be:

— hydroxychloroquine at a dose of at least 200 mg daily; or

— leflunomide at a dose of at least 10 mg daily; or

— sulfasalazine at a dose of at least 2 g daily.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, then the 6 months of intensive DMARD treatment must include at least 3 months continuous treatment with each of at least 2 of the DMARDs:

— hydroxychloroquine at a dose of at least 200 mg daily; and/or

— leflunomide at a dose of at least 10 mg daily; and/or

— sulfasalazine at a dose of at least 2 g daily.

The application must include details of the contraindication or intolerance to methotrexate. Details of the toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose can be found on the Medicare Australia website [www.medicareaustralia.gov.au]. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

If 3 or more of methotrexate, hydroxychloroquine, leflunomide and sulfasalazine are contraindicated according to the relevant TGA-approved product information or cannot be tolerated at the doses specified above, then one or more of the following DMARDs may be used in place of these agents in order to satisfy the requirement for a trial of 6 months of intensive DMARD therapy with at least 2 DMARDs taken continuously for at least 3 months each:

— azathioprine at a dose of at least 1 mg/kg per day; and/or

— cyclosporin at a dose of at least 2 mg/kg/day; and/or

— sodium aurothiomalate at a dose of 50 mg weekly.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances. Details of the toxicities, including severity, which will be accepted as a reason for substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial can be found on the Medicare Australia website [www.medicareaustralia.gov.au].

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

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance and dose for each DMARD must be provided in the authority application. Details of the toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy can be found on the Medicare Australia website [www.medicareaustralia.gov.au].

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

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L;

AND either

(i) a total active joint count of at least 20 active (swollen and tender) joints; or

(ii) at least 4 active joints from the following list of major joints:

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

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

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

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|

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

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

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

(1) completed authority prescription form(s); and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and

(3) a signed patient acknowledgement.

A maximum of 16 weeks of treatment will be authorised under this restriction.

Initial treatment with an I.V. loading dose: Two completed authority prescriptions must be submitted with the initial application. One prescription must be for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription must be written for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats.

Initial treatment with no loading dose: One completed authority prescription must be submitted with the initial application. The prescription must be written with a maximum quantity of 4 and up to 3 repeats. Where fewer than 3 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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

Patients who fail to demonstrate a response to treatment with abatacept under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition

**Authority required**

Initial 2 (change or re-commencement after break of less than 24 months)

Initial course of PBS-subsidised treatment with abatacept, in combination with methotrexate at a dose of at least 7.5 mg weekly, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of adults who:

(a) have a documented history of severe active rheumatoid arthritis; and

(b) have received prior PBS-subsidised bDMARD treatment for this condition and are eligible to receive further bDMARD therapy.

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

(1) completed authority prescription form(s); and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].

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

A maximum of 16 weeks of treatment will be authorised under this restriction.

Initial treatment with an I.V. loading dose: Two completed authority prescriptions must be submitted with the initial application. One prescription must be for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription must be written for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats.

Initial treatment with no loading dose: One completed authority prescription must be submitted with the initial application. The prescription must be written with a maximum quantity of 4 and up to 3 repeats.

Where fewer than 3 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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

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

Patients who fail to demonstrate a response to treatment with abatacept under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition

**Note**

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

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|

Further prescribing information (including Authority Application Forms) is on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe abatacept should be forwarded to:

Medicare Australia

Prior Written Approval of Specialised Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

**Note**

TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

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

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

PBS-subsidised abatacept, golimumab, infliximab and rituximab must be used in combination with methotrexate at a dose of at least 7.5 mg weekly. Where a patient cannot tolerate 7.5 mg of methotrexate weekly, they are eligible to receive PBS-subsidised adalimumab, certolizumab pegol, etanercept and tocilizumab.

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

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:

— a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,

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

— once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact Medicare Australia on 1800 700 270.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or

(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or

(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or

(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

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

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab and tocilizumab, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

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

Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to Medicare Australia within 4 weeks.

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

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|

Abatacept patients:

Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients:

A further application may be submitted to Medicare Australia 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.

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

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

Assessments of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Rituximab patients:

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.

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

(2) Swapping therapy.

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

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

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

Abatacept patients:

Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

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

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

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

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

**Note**

(3) Baseline measurements to determine response.

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

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

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

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|---|---|---|---|---|---|---|---|---|
| | DMARD therapy. | | | | | | | |
| | **Note** | | | | | | | |
| | No applications for increased maximum quantities and/or repeats will be authorised. | | | | | | | |
| | **Note** | | | | | | | |
| | Special Pricing Arrangements apply. | | | | | | | |
| 1220F | abatacept 125 mg/mL injection, 4 x 1 mL syringes | 1 | 3 | .. | 1754.12 | 36.10 | Orencia | BQ |

**ABATACEPT**

**Authority required**

Continuing treatment

Continuing PBS-subsidised treatment with abatacept, in combination with methotrexate at a dose of at least 7.5 mg weekly, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of adults:

(a) who have a documented history of severe active rheumatoid arthritis; and

(b) who have demonstrated an adequate response to treatment with abatacept; and

(c) whose most recent course of PBS-subsidised bDMARD treatment was with abatacept.

An adequate response to treatment is defined as:

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

AND either of the following:

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

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

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

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

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

(1) a completed authority prescription form; and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].

A maximum of 24 weeks of treatment will be approved under this restriction.

Where fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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

Patients who fail to demonstrate a response to treatment with abatacept under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition

**Note**

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

Further prescribing information (including Authority Application Forms) is on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe abatacept should be forwarded to:

Medicare Australia

Prior Written Approval of Specialised Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

**Note**

TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

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

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

PBS-subsidised abatacept, golimumab, infliximab and rituximab must be used in combination with methotrexate at a dose of at least 7.5 mg weekly.

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|

Where a patient cannot tolerate 7.5 mg of methotrexate weekly, they are eligible to receive PBS-subsidised adalimumab, certolizumab pegol, etanercept and tocilizumab.

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

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:

— a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,

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

— once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact Medicare Australia on 1800 700 270.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or

(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or

(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or

(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

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

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab and tocilizumab, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

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

Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to Medicare Australia within 4 weeks.

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

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

Abatacept patients:

Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients:

A further application may be submitted to Medicare Australia 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.

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

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

Assessments of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|
| | Rituximab patients: | | | | | | | |
| | A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction. | | | | | | | |
| | Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD. | | | | | | | |
| | (2) Swapping therapy. | | | | | | | |
| | Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled. | | | | | | | |
| | Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent. | | | | | | | |
| | A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug. | | | | | | | |
| | Abatacept patients: | | | | | | | |
| | Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation. | | | | | | | |
| | In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment. | | | | | | | |
| | To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction. | | | | | | | |
| | PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period. | | | | | | | |
| | To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing. | | | | | | | |
| | **Note** | | | | | | | |
| | (3) Baseline measurements to determine response. | | | | | | | |
| | Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and Medicare Australia will assess response according to these revised baseline measurements. | | | | | | | |
| | To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. | | | | | | | |
| | Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. | | | | | | | |
| | **Note** | | | | | | | |
| | No applications for increased maximum quantities and/or repeats will be authorised. | | | | | | | |
| | **Note** | | | | | | | |
| | Special Pricing Arrangements apply. | | | | | | | |
| 1221G | abatacept 125 mg/mL injection, 4 x 1 mL syringes | 1 | 5 | .. | 1754.12 | 36.10 | Orencia | BQ |
| | **EVEROLIMUS** | | | | | | | |
| | **Authority required** | | | | | | | |
| | Maintenance therapy, following initiation and stabilisation of treatment with everolimus and where therapy remains under the supervision and direction of the transplant unit reviewing that patient, of patients with renal transplants. The name of the specialised transplant unit reviewing treatment and the date of the latest review at the specialised transplant unit must be included in the authority application | | | | | | | |
| | **Authority required** | | | | | | | |
| | Maintenance therapy, following initiation and stabilisation of treatment with everolimus and where therapy remains under the supervision and direction of the transplant unit reviewing that patient, of patients with cardiac transplants. The name of the specialised transplant unit reviewing treatment and the date of the latest review at the specialised transplant unit must be included in the authority application | | | | | | | |

# ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|---|
| | **Caution**<br>Careful monitoring of patients is mandatory. | | | | | | | | |
| 9352F | everolimus 1 mg tablet, 60 | 2 | 3 | .. | *2068.97 | 36.10 | | Certican | NV |
| 8840G | everolimus 250 microgram tablet, 60 | 1 | 3 | .. | 283.00 | 36.10 | | Certican | NV |
| 8841H | everolimus 500 microgram tablet, 60 | 1 | 3 | .. | 544.04 | 36.10 | | Certican | NV |
| 8842J | everolimus 750 microgram tablet, 60 | 2 | 3 | .. | *1578.83 | 36.10 | | Certican | NV |
| | **FINGOLIMOD**<br>**Authority required**<br>Initial treatment, as monotherapy, of clinically definite relapsing-remitting multiple sclerosis in an ambulatory (without assistance or support) patient who has experienced at least 2 documented attacks of neurological dysfunction, believed to be due to the multiple sclerosis, in the preceding 2 years. The diagnosis must be confirmed by magnetic resonance imaging of the brain and/or spinal cord and the date of the scan included in the authority application, unless the authority application is accompanied by written certification provided by a radiologist that an MRI scan is contraindicated because of the risk of physical (not psychological) injury to the patient. The authority will be limited to the maximum quantity and number of repeats indicated in the schedule<br>**Authority required**<br>Continuing treatment, as monotherapy, of clinically definite relapsing-remitting multiple sclerosis in a patient previously issued with an authority prescription for this drug who does not show continuing progression of disability while on treatment with this drug and who has demonstrated compliance with, and an ability to tolerate, this therapy. Authorities will be limited to the maximum quantity and number of repeats indicated in the schedule<br>**Note**<br>Special Pricing Arrangements apply. | | | | | | | | |
| 5262Y | fingolimod 500 microgram capsule, 28 | 1 | 5 | .. | 2313.19 | 36.10 | | Gilenya | NV |
| | **LEFLUNOMIDE**<br>**Authority required (STREAMLINED)**<br>***2682***<br>Treatment of severe active psoriatic arthritis where other disease modifying anti-rheumatic drugs (including methotrexate) are ineffective and/or inappropriate. Treatment must be initiated by a physician<br>**Caution**<br>Leflunomide is a category X drug and must not be given to pregnant women. Pregnancy should be avoided for two years after cessation of therapy, unless special wash-out procedures are carried out. | | | | | | | | |
| 5449T | leflunomide 10 mg tablet, 30 | 1 | 5 | .. | 65.95 | 36.10 | [a] | Arabloc | AV |
| | | | | | | | [a] | Arava | SW |
| 5450W | leflunomide 20 mg tablet, 30 | 1 | 5 | .. | 96.95 | 36.10 | [a] | Arabloc | AV |
| | | | | | | | [a] | Arava | SW |
| | **LEFLUNOMIDE**<br>**Authority required (STREAMLINED)**<br>***2644***<br>Treatment of severe active rheumatoid arthritis where other disease modifying anti-rheumatic drugs (including methotrexate) are ineffective and/or inappropriate. Treatment must be initiated by a physician<br>**Caution**<br>Leflunomide is a category X drug and must not be given to pregnant women. Pregnancy should be avoided for two years after cessation of therapy, unless special wash-out procedures are carried out. | | | | | | | | |
| 8374R | leflunomide 10 mg tablet, 30 | 1 | 5 | .. | 65.95 | 36.10 | [a] | APO-Leflunomide | TX |
| | | | | | | | [a] | Arabloc | AV |
| | | | | | | | [a] | Arava | SW |
| | | | | | | | [a] | Leflunomide-GA | GM |
| | | | | | | | [a] | Lunava 10 | ZP |
| 8375T | leflunomide 20 mg tablet, 30 | 1 | 5 | .. | 96.95 | 36.10 | [a] | APO-Leflunomide | TX |
| | | | | | | | [a] | Arabloc | AV |
| | | | | | | | [a] | Arava | SW |
| | | | | | | | [a] | Leflunomide-GA | GM |
| | | | | | | | [a] | Lunava 20 | ZP |
| | **LEFLUNOMIDE**<br>**Authority required (STREAMLINED)**<br>***2643***<br>Initial treatment of severe active rheumatoid arthritis where other disease modifying anti-rheumatic drugs (including methotrexate) are ineffective and/or inappropriate. Treatment must be initiated by a physician<br>**Authority required (STREAMLINED)**<br>***2681*** | | | | | | | | |

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | | Brand Name and Manufacturer | |
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| | Initial treatment of severe active psoriatic arthritis where other disease modifying anti-rheumatic drugs (including methotrexate) are ineffective and/or inappropriate. Treatment must be initiated by a physician | | | | | | | | |
| | **Caution**<br>Leflunomide is a category X drug and must not be given to pregnant women. Pregnancy should be avoided for two years after cessation of therapy, unless special wash-out procedures are carried out. | | | | | | | | |
| | **Note**<br>No applications for increased maximum quantities and/or repeats will be authorised. | | | | | | | | |
| 8373Q | leflunomide 100 mg tablet [3 tablets] (&) leflunomide 20 mg tablet [30 tablets], 33 | ‡1 | .. | .. | 149.27 | 36.10 | | Arava | SW |
| | **MYCOPHENOLATE**<br>**Authority required**<br>WHO Class III, IV or V lupus nephritis<br>Treatment Phase: Maintenance<br>**The Clinical criteria is:**<br>The condition must be proven by biopsy,<br>**AND the Clinical criteria is:**<br>Patient must have received initiation treatment,<br>**AND the Clinical criteria is:**<br>The treatment must be under the supervision and direction of a nephrologist reviewing the patient.<br>The name of the nephrologist reviewing treatment and the date of the latest review, which must be within the last 12 months, must be included in the authority application.<br>**Caution**<br>Careful monitoring of patients is mandatory. | | | | | | | | |
| 2150E | mycophenolate 180 mg tablet: enteric, 120 tablets | 1 | 5 | .. | 225.39 | 36.10 | | Myfortic | NV |
| 2193K | mycophenolate 360 mg tablet: enteric, 120 tablets | 1 | 5 | .. | 426.14 | 36.10 | | Myfortic | NV |
| | **MYCOPHENOLATE**<br>**Authority required**<br>Maintenance therapy, following initiation and stabilisation of treatment with mycophenolate sodium and where therapy remains under the supervision and direction of the transplant unit reviewing that patient, of patients with renal transplants. The name of the specialised transplant unit reviewing treatment and the date of the latest review at the specialised transplant unit must be included in the authority application<br>**Caution**<br>Careful monitoring of patients is mandatory. | | | | | | | | |
| 8652J | mycophenolate 180 mg tablet: enteric, 120 tablets | 1 | 3 | .. | 225.39 | 36.10 | | Myfortic | NV |
| 8653K | mycophenolate 360 mg tablet: enteric, 120 tablets | 1 | 3 | .. | 426.14 | 36.10 | | Myfortic | NV |
| | **MYCOPHENOLATE**<br>**Authority required**<br>Maintenance therapy, following initiation and stabilisation of treatment with mycophenolate mofetil and where therapy remains under the supervision and direction of the transplant unit reviewing that patient, of patients with renal transplants. The name of the specialised transplant unit reviewing treatment and the date of the latest review at the specialised transplant unit must be included in the authority application<br>**Authority required**<br>Maintenance therapy, following initiation and stabilisation of treatment with mycophenolate mofetil and where therapy remains under the supervision and direction of the transplant unit reviewing that patient, of patients with cardiac transplants. The name of the specialised transplant unit reviewing treatment and the date of the latest review at the specialised transplant unit must be included in the authority application<br>**Caution**<br>Careful monitoring of patients is mandatory.<br>**Note**<br>For item codes 8649F and 1836P, pharmaceutical benefits that have the form capsule 250 mg are equivalent for the purposes of substitution. | | | | | | | | |
| 1836P | mycophenolate Capsule 250 mg, 50 | 6 | 3 | .. | *528.63 | 36.10 | [a] | Ceptolate | AF |
| 8649F | mycophenolate mofetil 250 mg capsule, 100 | 3 | 3 | .. | *528.60 | 36.10 | [a] | APO-Mycophenolate | TX |
| | | | | | | | [a] | CellCept | RO |
| | | | | | | | [a] | Imulate | QA |
| | | | | | | | [a] | Mycophenolate Sandoz | SZ |

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | | Brand Name and Manufacturer | |
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| | | | | | | | [a] | Pharmacor Mycophenolate 250 | CR |

**MYCOPHENOLATE**

**Authority required**

Maintenance therapy, following initiation and stabilisation of treatment with mycophenolate mofetil and where therapy remains under the supervision and direction of the transplant unit reviewing that patient, of patients with renal transplants. The name of the specialised transplant unit reviewing treatment and the date of the latest review at the specialised transplant unit must be included in the authority application

**Authority required**

Maintenance therapy, following initiation and stabilisation of treatment with mycophenolate mofetil and where therapy remains under the supervision and direction of the transplant unit reviewing that patient, of patients with cardiac transplants. The name of the specialised transplant unit reviewing treatment and the date of the latest review at the specialised transplant unit must be included in the authority application

**Caution**

Careful monitoring of patients is mandatory.

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 8651H | mycophenolate mofetil 1 g/5 mL oral liquid: powder for, 165 mL | ‡1 | 3 | .. | #290.15 | 36.10 | | CellCept | RO |
| 8650G | mycophenolate mofetil 500 mg tablet, 50 | 3 | 3 | .. | *528.57 | 36.10 | [a] | APO-Mycophenolate | TX |
| | | | | | | | [a] | CellCept | RO |
| | | | | | | | [a] | Ceptolate | AF |
| | | | | | | | [a] | Imulate | QA |
| | | | | | | | [a] | Mycophenolate Sandoz | SZ |
| | | | | | | | [a] | Pharmacor Mycophenolate 500 | CR |

**SIROLIMUS**

**Authority required**

Maintenance therapy, following initiation and stabilisation of treatment with sirolimus and where therapy remains under the supervision and direction of the transplant unit reviewing that patient, of patients with renal transplants. The name of the specialised transplant unit reviewing treatment and the date of the latest review at the specialised transplant unit must be included in the authority application

**Caution**

Careful monitoring of patients is mandatory.

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 8724E | sirolimus 1 mg tablet, 100 | 1 | 3 | .. | 815.46 | 36.10 | | Rapamune | PF |
| 8725F | sirolimus 1 mg/mL oral liquid, 60 mL | ‡1 | 3 | .. | 529.95 | 36.10 | | Rapamune | PF |
| 8833X | sirolimus 2 mg tablet, 100 | 1 | 3 | .. | 1583.90 | 36.10 | | Rapamune | PF |
| 8984W | sirolimus 500 microgram tablet, 100 | 1 | 3 | .. | 413.50 | 36.10 | | Rapamune | PF |

## *Tumor necrosis factor alpha (TNF-) inhibitors*

**ADALIMUMAB**

**Authority required**

Initial 1 (new patient or patient recommencing after a break of more than 12 months).

Initial treatment, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of a patient aged 18 years or older who:

(a) has a documented history of juvenile idiopathic arthritis with onset prior to the age of 18 years; AND

(b) has received no PBS-subsidised treatment with a bDMARD for this condition in the previous 12 months; and

(c) has failed to achieve an adequate response to at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs), which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be:

— hydroxychloroquine at a dose of at least 200 mg daily; or

— leflunomide at a dose of at least 10 mg daily; or

— sulfasalazine at a dose of at least 2 g daily.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, then the 6 months of intensive DMARD treatment must include at least 3 months continuous treatment with each of at least 2 of the DMARDs:

— hydroxychloroquine at a dose of at least 200 mg daily; and/or

— leflunomide at a dose of at least 10 mg daily; and/or

— sulfasalazine at a dose of at least 2 g daily.

The application must include details of the contraindication or intolerance to methotrexate. Details of the toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose can be found on the Medicare Australia website [www.medicareaustralia.gov.au]. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

If 3 or more of methotrexate, hydroxychloroquine, leflunomide and sulfasalazine are contraindicated according to the relevant TGA-approved

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product information or cannot be tolerated at the doses specified above, then one or more of the following DMARDs may be used in place of these agents in order to satisfy the requirement for a trial of 6 months of intensive DMARD therapy with at least 2 DMARDs taken continuously for at least 3 months each:

— azathioprine at a dose of at least 1 mg/kg per day; and/or

— cyclosporin at a dose of at least 2 mg/kg per day; and/or

— sodium aurothiomalate at a dose of 50 mg weekly.

The application must include details of the DMARDs trialed, their doses and duration of treatment, and all relevant contraindications and/or intolerances. Details of the toxicities, including severity, which will be accepted as a reason for substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial can be found on the Medicare Australia website [www.medicareaustralia.gov.au].

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

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance and dose for each DMARD must be provided in the authority application. Details of the toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy can be found on the Medicare Australia website [www.medicareaustralia.gov.au].

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

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either

(i) an active joint count of at least 20 active (swollen and tender) joints; or

(ii) at least 4 active joints from the following list:

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

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

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

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

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

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

(1) a completed authority prescription form; and

(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and

(3) a signed patient acknowledgement.

A maximum of 16 weeks of treatment will be authorised under this restriction.

Where fewer than 3 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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

If a patient fails to respond to treatment 3 times (twice with one agent and once with the other) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle. A patient may re-trial adalimumab after a minimum of 5 years have elapsed between the date of the last approval for PBS-subsidised bDMARD therapy in the last treatment cycle and the date of the first application under a new treatment cycle

**Authority required**

Initial 2 (change or re-commencement after break of less than 12 months).

Initial PBS-subsidised treatment with adalimumab by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of a patient aged 18 years or older who:

(a) has a documented history of juvenile idiopathic arthritis with onset prior to the age of 18 years; AND

(b) in this treatment cycle, has received prior PBS-subsidised treatment with adalimumab or etanercept for this condition; and

(c) has not failed PBS-subsidised therapy with adalimumab for this condition more than once in the current treatment cycle.

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

(a) a completed authority prescription form; and

(b) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].

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

A maximum of 16 weeks of treatment will be authorised under this restriction.

Where fewer than 3 repeats are requested at the time of the initial authority application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment with adalimumab may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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

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

Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to that particular course of bDMARD.

If a patient fails to respond to treatment 3 times (twice with one agent and once with the other) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle. A patient may re-trial adalimumab after a minimum of 5 years have elapsed between the date of the last approval for PBS-subsidised bDMARD therapy in the last treatment cycle and the date of the first application under a new treatment cycle

**Note**

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

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe adalimumab should be forwarded to:

Medicare Australia

Prior Written Approval of Specialised Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

**Note**

TREATMENT OF ADULT PATIENTS WITH A HISTORY OF JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab and etanercept for a patient over 18 years who has a history of juvenile idiopathic arthritis with onset prior to the age of 18 years. Where the term bDMARD appears in the following NOTES and restrictions, it refers to adalimumab and etanercept only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 2 bDMARDs at any one time.

From 1 November 2010, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to the alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

— continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy, and

— fail to respond, or to sustain a response to one PBS-subsidised bDMARD twice and the other PBS-subsidised bDMARD once only.

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

A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 November 2010 is considered to be in their first cycle as of 1 November 2010. A patient who has had a break in bDMARD treatment of at least 12 months immediately prior to making a new application, on or after 1 November 2010, will commence a new treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 12 months may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 12 months must commence a new treatment cycle. The length of the break in therapy is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

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

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 November 2010.

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | Brand Name and Manufacturer | |
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| | (a) Initial treatment.<br>Applications for initial treatment should be made where:<br>(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or<br>(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 12 months (Initial 1); or<br>(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<br>(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 12 months in PBS-subsidised therapy with that agent (Initial 2).<br>Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.<br>A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.<br>Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.<br>For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.<br>(b) Continuing treatment.<br>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.<br>A patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.<br>It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.<br>Assessments of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.<br>Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.<br>(2) Swapping therapy.<br>Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to the alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count and ESR/CRP) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 12 months.<br>A patient may trial the 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 twice within the current treatment cycle.<br>To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.<br>To avoid confusion, an application for a patient who wishes to swap to the alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.<br>(3) Baseline measurements to determine response.<br>Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and Medicare Australia will assess response according to the revised baseline measurement.<br>(4) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.<br>A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 12 months, must requalify for treatment under the Initial 1 treatment restriction.<br>(5) Patients 'grandfathered' onto PBS-subsidised treatment with adalimumab.<br>A patient who commenced treatment with adalimumab for severe active juvenile idiopathic arthritis prior to 1 March 2010 and who continues to receive treatment at the time of application, may qualify for treatment under the initial 'grandfather' treatment restriction.<br>A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment with adalimumab will be authorised under this criterion.<br>Following completion of the initial PBS-subsidised course, further applications for treatment with adalimumab will be assessed under the continuing treatment restriction.<br>'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must qualify for initial treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 12 month break in PBS-subsidised therapy' above for further details. | | | | | | | |
| 5282B | adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL cartridges | 1 | 3 | .. | 1774.57 | 36.10 | Humira | VE |

# ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | Brand Name and Manufacturer | |
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| 5281Y | adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes | 1 | 3 | .. | 1774.57 | 36.10 | Humira | VE |

**ADALIMUMAB**

**Authority required**

Initial 3 ('grandfather' patients).

Initial PBS-subsidised supply for continuing treatment, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of a patient aged 18 years or older who:

(a) has a documented history of severe active juvenile idiopathic arthritis with onset prior to the age of 18 years; and

(b) was receiving treatment with adalimumab prior to 1 March 2010; and

(c) has demonstrated a response as specified in the criteria for continuing PBS-subsidised treatment with adalimumab; and

(d) is receiving treatment with adalimumab at the time of application.

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

(1) a completed authority prescription form; and

(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and

(3) a signed patient acknowledgement.

A maximum of 24 weeks of treatment with adalimumab will be approved under this criterion.

Where fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

The same indices of disease severity used to establish baseline at the commencement of treatment with a bDMARD must be used for assessment of all continuing applications.

The assessment of the patient's response to a continuing course of therapy must be made within 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled in order to ensure continuity of treatment for those patients who meet the continuation criterion.

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

**Authority required**

Continuing treatment.

Continuing PBS-subsidised treatment, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of a patient aged 18 years or older:

(a) who has a documented history of severe active juvenile idiopathic arthritis with onset prior to the age of 18 years; and

(b) who has demonstrated an adequate response to treatment with adalimumab; and

(c) whose most recent course of PBS-subsidised bDMARD treatment was with adalimumab.

An adequate response to treatment is defined as:

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

AND either of the following:

(i) an active joint count of fewer than 10 active (swollen and tender) joints; or

(ii) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or

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

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

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

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

(1) a completed authority prescription form; and

(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].

A maximum of 24 weeks of treatment will be approved under this restriction.

Where fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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

If a patient fails to respond to treatment 3 times (twice with one agent and once with the other) they will not be eligible to receive further PBS-

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subsidised bDMARD therapy in this treatment cycle. A patient may re-trial adalimumab after a minimum of 5 years have elapsed between the date of the last approval for PBS-subsidised bDMARD therapy in the last treatment cycle and the date of the first application under a new treatment cycle

**Note**

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

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe adalimumab should be forwarded to:

Medicare Australia

Prior Written Approval of Specialised Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

**Note**

TREATMENT OF ADULT PATIENTS WITH A HISTORY OF JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab and etanercept for a patient over 18 years who has a history of juvenile idiopathic arthritis with onset prior to the age of 18 years. Where the term bDMARD appears in the following NOTES and restrictions, it refers to adalimumab and etanercept only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 2 bDMARDs at any one time.

From 1 November 2010, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to the alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

— continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy, and

— fail to respond, or to sustain a response to one PBS-subsidised bDMARD twice and the other PBS-subsidised bDMARD once only.

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

A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 November 2010 is considered to be in their first cycle as of 1 November 2010. A patient who has had a break in bDMARD treatment of at least 12 months immediately prior to making a new application, on or after 1 November 2010, will commence a new treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 12 months may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 12 months must commence a new treatment cycle. The length of the break in therapy is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

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

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 November 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or

(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 12 months (Initial 1); or

(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or

(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 12 months in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

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

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

For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

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

A patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to

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sustain the response.

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

Assessments of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

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

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to the alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count and ESR/CRP) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 12 months.

A patient may trial the 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 twice within the current treatment cycle.

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

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

(3) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and Medicare Australia will assess response according to the revised baseline measurement.

(4) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 12 months, must requalify for treatment under the Initial 1 treatment restriction.

(5) Patients 'grandfathered' onto PBS-subsidised treatment with adalimumab.

A patient who commenced treatment with adalimumab for severe active juvenile idiopathic arthritis prior to 1 March 2010 and who continues to receive treatment at the time of application, may qualify for treatment under the initial 'grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment with adalimumab will be authorised under this criterion.

Following completion of the initial PBS-subsidised course, further applications for treatment with adalimumab will be assessed under the continuing treatment restriction.

'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must qualify for initial treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 12 month break in PBS-subsidised therapy' above for further details.

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| 5284D | adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL cartridges | 1 | 5 | .. | 1774.57 | 36.10 | Humira | VE |
| 5283C | adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes | 1 | 5 | .. | 1774.57 | 36.10 | Humira | VE |

**ADALIMUMAB**

**Authority required**

Initial 1

Initial treatment of complex refractory FISTULISING CROHN DISEASE.

Initial PBS-subsidised treatment with adalimumab by a gastroenterologist or a consultant physician as specified in the NOTE below, of a patient with complex refractory fistulising Crohn disease who:

(a) has confirmed Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician as specified in the NOTE below; and

(b) has an externally draining enterocutaneous or rectovaginal fistula; and

(c) has signed a patient acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criteria for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

Authority applications must be made in writing and must include:

(a) two completed authority prescription forms; and

(b) a completed Fistulising Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

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(i) a completed current Fistula Assessment Form including the date of assessment of the patient's condition; and

(ii) a signed patient acknowledgement.

The most recent fistula assessment must be no more than 1 month old at the time of application.

A maximum of 16 weeks treatment will be authorised under this criterion.

Two completed authority prescriptions must be submitted with every initial application for adalimumab. One prescription must be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats. The second prescription must be written for 2 doses of 40 mg and 2 repeats. Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment with adalimumab may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

An assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of therapy so that there is adequate time for a response to be demonstrated.

This assessment must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with adalimumab.

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised adalimumab treatment

**Authority required**

Initial 2

Change or re-commencement of treatment of complex refractory FISTULISING CROHN DISEASE.

Initial PBS-subsidised treatment with adalimumab of complex refractory fistulising Crohn disease by a gastroenterologist or a consultant physician as specified in the NOTE below, of a patient with complex refractory fistulising Crohn disease who:

(a) has a documented history of complex refractory fistulising Crohn disease; and

(b) in this treatment cycle, has received prior PBS-subsidised treatment with adalimumab or infliximab for a draining enterocutaneous or rectovaginal fistula; and

(c) has not failed PBS-subsidised therapy with adalimumab for this condition more than once in the current treatment cycle.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

To demonstrate a response to treatment the application must be accompanied by the results of the most recent course of TNF-alfa antagonist therapy within the time frames specified in the relevant restriction.

Where the most recent course of PBS-subsidised TNF-alfa antagonist treatment was approved under an initial treatment restriction, the patient must have been assessed for response to that course following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

If the response assessment to the previous course of TNF-alfa antagonist treatment is not submitted as detailed above, the patient will be deemed to have failed therapy with that particular course of TNF-alfa antagonist.

Authority applications must be made in writing and must include:

(a) two completed authority prescription forms; and

(b) a completed Fistulising Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) a completed current Fistula Assessment Form including the date of assessment of the patient's condition; and

details of prior TNF-alfa antagonist treatment including details of date and duration of treatment.

The most recent fistula assessment must be no more than 1 month old at the time of application.

A maximum of 16 weeks treatment will be authorised under this criterion.

Two completed authority prescriptions must be submitted with every initial application for adalimumab. One prescription must be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats. The second prescription must be written for 2 doses of 40 mg and 2 repeats. Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment with adalimumab may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

An assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of therapy so that there is adequate time for a response to be demonstrated.

This assessment must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with adalimumab.

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised adalimumab treatment

**Note**

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

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe adalimumab should be forwarded to:

Medicare Australia

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**Note**

TREATMENT OF COMPLEX REFRACTORY FISTULISING CROHN DISEASE

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab and infliximab for patients with complex refractory fistulising Crohn disease. Where the term 'tumour necrosis factor (TNF) alfa antagonist' appears in the following NOTES and restrictions, it refers to adalimumab and infliximab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 2 TNF-alfa antagonists at any 1 time.

From 1 April 2011, under the PBS, all patients will be able to commence a treatment cycle where they may trial each PBS-subsidised TNF-alfa antagonist without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a TNF-alfa antagonist while they continue to show a response to therapy.

A patient who received PBS-subsidised TNF-alfa antagonist treatment prior to 1 April 2011 is considered to be in their first cycle as of 1 April 2011.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised TNF-alfa antagonist more than twice.

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

A patient who has failed fewer than 3 trials of TNF-alfa antagonists in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of TNF-alfa antagonists in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

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

(1) How to prescribe PBS-subsidised TNF-alfa antagonist therapy after 1 April 2011.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised TNF-alfa antagonist treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or

(ii) a patient has received prior PBS-subsidised (initial or continuing) TNF-alfa antagonist therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to re-commence treatment with a specific TNF-alfa antagonist following a break in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and 14 weeks of therapy for infliximab.

From 1 April 2011, a patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.

For second and subsequent courses of PBS-subsidised TNF-alfa antagonist treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

Adalimumab only: Two completed authority prescriptions must be submitted with every initial application for adalimumab. One prescription must be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats. The second prescription must be written for 2 doses of 40 mg and 2 repeats.

(b) Continuing treatment.

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

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted TNF-alfa

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antagonist supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised TNF-alfa antagonist is approved, a patient may swap if eligible to the alternate TNF-alfa antagonist within the same treatment cycle.

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

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

To avoid confusion, an application for a patient who wishes to swap to the alternate TNF-alfa antagonist should be accompanied by the approved authority prescription or remaining repeats for the TNF-alfa antagonist the patient is ceasing.

(3) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements submitted with the first authority application for a TNF-alfa antagonist. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and Medicare Australia will assess response according to these revised baseline measurements.

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

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised TNF-alfa antagonist therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity.

(5) Patients 'grandfathered' onto PBS-subsidised treatment with adalimumab or infliximab.

A patient who commenced treatment with adalimumab for complex refractory fistulising Crohn disease prior to 4 November 2010 or infliximab prior to 1 March 2010 and who continues to receive treatment at the time of application, may qualify for treatment under the initial 'grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment with adalimumab or infliximab will be authorised under this criterion.

Following completion of the initial PBS-subsidised course, further applications for treatment with adalimumab or infliximab will be assessed under the continuing treatment restriction.

'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must requalify for initial treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' above for further details.

**Note**

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

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| 8965W | adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL cartridges | 1 | 2 | .. | 1774.57 | 36.10 | Humira | VE |
| 8963R | adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes | 1 | 2 | .. | 1774.57 | 36.10 | Humira | VE |
| 8962Q | adalimumab 40 mg/0.8 mL injection, 6 x 0.8 mL cartridges | 1 | .. | .. | 5036.57 | 36.10 | Humira | VE |
| 8961P | adalimumab 40 mg/0.8 mL injection, 6 x 0.8 mL syringes | 1 | .. | .. | 5036.57 | 36.10 | Humira | VE |

**ADALIMUMAB**

**Authority required**

Initial 3 (grandfather)

Initial PBS-subsidised treatment of complex refractory FISTULISING CROHN DISEASE in a patient who has previously received non-PBS-subsidised therapy with adalimumab.

Initial PBS-subsidised supply for continuing treatment with adalimumab by a gastroenterologist, a consultant physician as specified in the NOTE below, or other consultant physician in consultation with a gastroenterologist of a patient who satisfies the following criteria:

(a) has a documented history of complex refractory fistulising Crohn disease and was receiving treatment with adalimumab prior to 4 November 2010; and

(b) had a draining enterocutaneous or rectovaginal fistula(e) prior to commencing treatment with adalimumab; and

(c) has signed a patient acknowledgement indicating that they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criteria for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and

(d) is receiving treatment with adalimumab at the time of application; and

(e) has demonstrated or sustained an adequate response to treatment with adalimumab.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or

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consultant physicians [general medicine specialising in gastroenterology (code 82)].

An adequate response to adalimumab treatment is defined as:

(a) a decrease from baseline in the number of open draining fistulae of greater than or equal to 50%; and/or

(b) a marked reduction in drainage of all fistula(e) from baseline, together with less pain and induration as reported by the patient.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Fistulising Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) a completed current and baseline Fistula Assessment form including the date of assessment of the patient's condition; and

(ii) a signed patient acknowledgement.

The current fistula assessment must be no more than 1 month old at the time of application.

The baseline fistula assessment must be from immediately prior to commencing treatment with adalimumab.

An assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criteria.

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with adalimumab.

A maximum of 24 weeks treatment will be approved under this criterion.

Where fewer than 5 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Patients may qualify for PBS-subsidised treatment under this restriction once only

**Authority required**

Continuing treatment of complex refractory FISTULISING CROHN DISEASE.

Continuing PBS-subsidised treatment with adalimumab by a gastroenterologist, a consultant physician as specified in the NOTE below or other consultant physician in consultation with a gastroenterologist, of a patient who:

(a) has a documented history of complex refractory fistulising Crohn disease; and

(b) has demonstrated or sustained an adequate response to treatment with adalimumab.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

An adequate response is defined as:

(a) a decrease from baseline in the number of open draining fistulae of greater than or equal to 50%; and/or

(b) a marked reduction in drainage of all fistula(e) from baseline, together with less pain and induration as reported by the patient.

Authority applications must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Fistulising Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes a completed Fistula Assessment form including the date of the assessment of the patient's condition.

The fistula assessment must be no more than 1 month old at the time of application.

If the application is the first application for continuing treatment with adalimumab, an assessment of the patient's response must be made following a minimum of 12 weeks after the first dose so that there is adequate time for a response to be demonstrated.

An assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criteria.

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with adalimumab.

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

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

Where fewer than 5 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday)

**Note**

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

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

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Written applications for authority to prescribe adalimumab should be forwarded to:

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**Note**

TREATMENT OF COMPLEX REFRACTORY FISTULISING CROHN DISEASE

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab and infliximab for patients with complex refractory fistulising Crohn disease. Where the term 'tumour necrosis factor (TNF) alfa antagonist' appears in the following NOTES and restrictions, it refers to adalimumab and infliximab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 2 TNF-alfa antagonists at any 1 time.

From 1 April 2011, under the PBS, all patients will be able to commence a treatment cycle where they may trial each PBS-subsidised TNF-alfa antagonist without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a TNF-alfa antagonist while they continue to show a response to therapy.

A patient who received PBS-subsidised TNF-alfa antagonist treatment prior to 1 April 2011 is considered to be in their first cycle as of 1 April 2011.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised TNF-alfa antagonist more than twice.

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

A patient who has failed fewer than 3 trials of TNF-alfa antagonists in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of TNF-alfa antagonists in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

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

(1) How to prescribe PBS-subsidised TNF-alfa antagonist therapy after 1 April 2011.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised TNF-alfa antagonist treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or

(ii) a patient has received prior PBS-subsidised (initial or continuing) TNF-alfa antagonist therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to re-commence treatment with a specific TNF-alfa antagonist following a break in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and 14 weeks of therapy for infliximab.

From 1 April 2011, a patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.

For second and subsequent courses of PBS-subsidised TNF-alfa antagonist treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

Adalimumab only: Two completed authority prescriptions must be submitted with every initial application for adalimumab. One prescription must be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats. The second prescription must be written for 2 doses of 40 mg and 2 repeats.

(b) Continuing treatment.

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

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

Assessments of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

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| | Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.<br>(2) Swapping therapy.<br>Once initial treatment with the first PBS-subsidised TNF-alfa antagonist is approved, a patient may swap if eligible to the alternate TNF-alfa antagonist within the same treatment cycle.<br>A patient may trial the alternate TNF-alfa antagonist at any time, regardless of whether they are receiving therapy (initial or continuing) with a TNF-alfa antagonist at the time of the application. However, they cannot swap to a particular TNF-alfa antagonist if they have failed to respond to prior treatment with that drug two times within the same treatment cycle.<br>To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.<br>To avoid confusion, an application for a patient who wishes to swap to the alternate TNF-alfa antagonist should be accompanied by the approved authority prescription or remaining repeats for the TNF-alfa antagonist the patient is ceasing.<br>(3) Baseline measurements to determine response.<br>Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements submitted with the first authority application for a TNF-alfa antagonist. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and Medicare Australia will assess response according to these revised baseline measurements.<br>(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.<br>A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised TNF-alfa antagonist therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity.<br>(5) Patients 'grandfathered' onto PBS-subsidised treatment with adalimumab or infliximab.<br>A patient who commenced treatment with adalimumab for complex refractory fistulising Crohn disease prior to 4 November 2010 or infliximab prior to 1 March 2010 and who continues to receive treatment at the time of application, may qualify for treatment under the initial 'grandfather' treatment restriction.<br>A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment with adalimumab or infliximab will be authorised under this criterion.<br>Following completion of the initial PBS-subsidised course, further applications for treatment with adalimumab or infliximab will be assessed under the continuing treatment restriction.<br>'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must requalify for initial treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' above for further details.<br>**Note**<br>No applications for increased maximum quantities and/or repeats will be authorised. | | | | | | | |
| 8966X | adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL cartridges | 1 | 5 | .. | 1774.57 | 36.10 | Humira | VE |
| 8964T | adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes | 1 | 5 | .. | 1774.57 | 36.10 | Humira | VE |
| | **ADALIMUMAB**<br>**Authority required**<br>Initial 1 (new patient or patient re-commencing after a break of more than 24 months)<br>Initial PBS-subsidised treatment with adalimumab, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of adults who:<br>(a) have severe active rheumatoid arthritis; and<br>(b) have received no PBS-subsidised treatment with a bDMARD for this condition in the previous 24 months; and<br>(c) have failed, in the 24 months immediately prior to the date of application, to achieve an adequate response to at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs), which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be:<br>— hydroxychloroquine at a dose of at least 200 mg daily; or<br>— leflunomide at a dose of at least 10 mg daily; or<br>— sulfasalazine at a dose of at least 2 g daily.<br>If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, then the 6 months of intensive DMARD treatment must include at least 3 months continuous treatment with each of at least 2 of the DMARDs:<br>— hydroxychloroquine at a dose of at least 200 mg daily; and/or<br>— leflunomide at a dose of at least 10 mg daily; and/or<br>— sulfasalazine at a dose of at least 2 g daily.<br>The application must include details of the contraindication or intolerance to methotrexate. Details of the toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose can be found on the Medicare Australia website [www.medicareaustralia.gov.au]. The maximum tolerated dose of methotrexate must | | | | | | | |

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be documented in the application, if applicable.

If 3 or more of methotrexate, hydroxychloroquine, leflunomide and sulfasalazine are contraindicated according to the relevant TGA-approved product information or cannot be tolerated at the doses specified above, then one or more of the following DMARDs may be used in place of these agents in order to satisfy the requirement for a trial of 6 months of intensive DMARD therapy with at least 2 DMARDs taken continuously for at least 3 months each:

— azathioprine at a dose of at least 1 mg/kg per day; and/or

— cyclosporin at a dose of at least 2 mg/kg/day; and/or

— sodium aurothiomalate at a dose of 50 mg weekly.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances. Details of the toxicities, including severity, which will be accepted as a reason for substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial can be found on the Medicare Australia website [www.medicareaustralia.gov.au].

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

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance and dose for each DMARD must be provided in the authority application. Details of the toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy can be found on the Medicare Australia website [www.medicareaustralia.gov.au].

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

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L;

AND either

(i) a total active joint count of at least 20 active (swollen and tender) joints; or

(ii) at least 4 active joints from the following list of major joints:

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

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

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

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

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

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

(1) a completed authority prescription form; and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and

(3) a signed patient acknowledgement.

A maximum of 16 weeks of treatment will be authorised under this restriction.

Where fewer than 3 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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

Patients who fail to demonstrate a response to treatment with adalimumab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition

**Authority required**

Initial 2 (change or re-commencement after break of less than 24 months)

Initial course of PBS-subsidised treatment with adalimumab, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of adults who:

(a) have a documented history of severe active rheumatoid arthritis; and

(b) have received prior PBS-subsidised bDMARD treatment for this condition and are eligible to receive further bDMARD therapy.

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

(1) a completed authority prescription form; and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].

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

A maximum of 16 weeks of treatment will be authorised under this restriction.

Where fewer than 3 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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

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

Patients who fail to demonstrate a response to treatment with adalimumab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition

**Note**

TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

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

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

PBS-subsidised abatacept, golimumab, infliximab and rituximab must be used in combination with methotrexate at a dose of at least 7.5 mg weekly. Where a patient cannot tolerate 7.5 mg of methotrexate weekly, they are eligible to receive PBS-subsidised adalimumab, certolizumab pegol, etanercept and tocilizumab.

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

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:

— a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,

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

— once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact Medicare Australia on 1800 700 270.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or

(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or

(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or

(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

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

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab

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and tocilizumab, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

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

Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to Medicare Australia within 4 weeks.

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

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

Abatacept patients:

Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients:

A further application may be submitted to Medicare Australia 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.

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

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

Assessments of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Rituximab patients:

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.

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

(2) Swapping therapy.

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

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

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

Abatacept patients:

Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

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

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

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

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

**Note**

(3) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint

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| | count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and Medicare Australia will assess response according to these revised baseline measurements.<br>To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.<br>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.<br>**Note**<br>Any queries concerning the arrangements to prescribe adalimumab may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).<br>Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.<br>Written applications for authority to prescribe adalimumab should be forwarded to:<br>Medicare Australia<br>Prior Written Approval of Specialised Drugs<br>Reply Paid 9826<br>GPO Box 9826<br>HOBART TAS 7001<br>**Note**<br>No applications for increased maximum quantities and/or repeats will be authorised.<br>Applications for treatment with adalimumab where the dosing frequency exceeds 40 mg per fortnight will not be approved.<br>**Note**<br>Special Pricing Arrangements apply. | | | | | | | |
| 9099X | adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL cartridges | 1 | 3 | .. | 1774.57 | 36.10 | Humira | VE |
| 8737W | adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes | 1 | 3 | .. | 1774.57 | 36.10 | Humira | VE |
| | **ADALIMUMAB**<br>**Authority required**<br>Continuing treatment<br>Continuing PBS-subsidised treatment with adalimumab, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of adults:<br>(a) who have a documented history of severe active rheumatoid arthritis; and<br>(b) who have demonstrated an adequate response to treatment with adalimumab; and<br>(c) whose most recent course of PBS-subsidised bDMARD treatment was with adalimumab.<br>An adequate response to treatment is defined as:<br>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;<br>AND either of the following:<br>(i) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or<br>(ii) a reduction in the number of the following major active joints, from at least 4, by at least 50%:<br>— elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or<br>— 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).<br>The authority application must be made in writing and must include:<br>(1) a completed authority prescription form; and<br>(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].<br>A maximum of 24 weeks of treatment will be approved under this restriction.<br>Where fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). | | | | | | | |

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

Patients who fail to demonstrate a response to treatment with adalimumab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition

**Note**

TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

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

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

PBS-subsidised abatacept, golimumab, infliximab and rituximab must be used in combination with methotrexate at a dose of at least 7.5 mg weekly. Where a patient cannot tolerate 7.5 mg of methotrexate weekly, they are eligible to receive PBS-subsidised adalimumab, certolizumab pegol, etanercept and tocilizumab.

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

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:

— a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,

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

— once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact Medicare Australia on 1800 700 270.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or

(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or

(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or

(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

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

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab and tocilizumab, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

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

Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to Medicare Australia within 4 weeks.

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

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

Abatacept patients:

Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no

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repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients:

A further application may be submitted to Medicare Australia 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.

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

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

Assessments of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Rituximab patients:

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.

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

(2) Swapping therapy.

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

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

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

Abatacept patients:

Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

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

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

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

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

**Note**

(3) Baseline measurements to determine response.

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

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

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

**Note**

Any queries concerning the arrangements to prescribe adalimumab may be directed to Medicare Australia on 1800 700 270 (hours of operation 8

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| | a.m. to 5 p.m. EST Monday to Friday). | | | | | | | |
| | Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au. | | | | | | | |
| | Written applications for authority to prescribe adalimumab should be forwarded to: | | | | | | | |
| | Medicare Australia | | | | | | | |
| | Prior Written Approval of Specialised Drugs | | | | | | | |
| | Reply Paid 9826 | | | | | | | |
| | GPO Box 9826 | | | | | | | |
| | HOBART TAS 7001 | | | | | | | |
| | **Note** | | | | | | | |
| | No applications for increased maximum quantities and/or repeats will be authorised. | | | | | | | |
| | Applications for treatment with adalimumab where the dosing frequency exceeds 40 mg per fortnight will not be approved. | | | | | | | |
| | **Note** | | | | | | | |
| | Special Pricing Arrangements apply. | | | | | | | |
| 9100Y | adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL cartridges | 1 | 5 | .. | 1774.57 | 36.10 | Humira | VE |
| 8741C | adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes | 1 | 5 | .. | 1774.57 | 36.10 | Humira | VE |
| | **ADALIMUMAB** | | | | | | | |
| | **Authority required** | | | | | | | |
| | Initial 1 | | | | | | | |
| | Initial PBS-subsidised treatment with adalimumab, by a rheumatologist or clinical immunologist with expertise in the management of psoriatic arthritis, of adults who: | | | | | | | |
| | (1) have severe active psoriatic arthritis; and | | | | | | | |
| | (2) have received no prior PBS-subsidised biological treatment for this condition in this Treatment Cycle; and | | | | | | | |
| | (3) have failed to achieve an adequate response to: | | | | | | | |
| | (a) methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months; and | | | | | | | |
| | (b) sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months; or | | | | | | | |
| | (c) leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months. | | | | | | | |
| | If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application. | | | | | | | |
| | If intolerance to treatment develops during the relevant period of use, which is of a severity to necessitate permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of acceptable toxicities, including severity, can be found on the Medicare Australia website (www.medicareaustralia.gov.au). | | | | | | | |
| | The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application: | | | | | | | |
| | an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either | | | | | | | |
| | (i) an active joint count of at least 20 active (swollen and tender) joints; or | | | | | | | |
| | (ii) at least 4 active joints from the following list of major joints: | | | | | | | |
| | — elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or | | | | | | | |
| | — shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). | | | | | | | |
| | If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. | | | | | | | |
| | The authority application must be made in writing and must include: | | | | | | | |
| | (1) a completed authority prescription form; and | | | | | | | |
| | (2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and | | | | | | | |
| | (3) a signed patient acknowledgement. | | | | | | | |
| | A maximum of 16 weeks treatment will be authorised under this restriction. | | | | | | | |
| | Where fewer than 3 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). | | | | | | | |
| | The assessment of the patient's response to the initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted to Medicare Australia no later than 4 weeks from the cessation of that treatment course. If the response assessment is not submitted | | | | | | | |

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within these timeframes, the patient will be deemed to have failed this course of treatment.

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

**Authority required**

Initial 2

Initial PBS-subsidised treatment with adalimumab, by a rheumatologist or clinical immunologist with expertise in the management of psoriatic arthritis, of adults who:

(1) have a documented history of severe active psoriatic arthritis; and

(2) have received prior PBS-subsidised biological treatment for this condition in this Treatment Cycle and are eligible to receive further biological therapy; and

(3) have not failed treatment with adalimumab during the current Treatment Cycle.

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

A maximum of 16 weeks treatment will be authorised under this restriction.

Where fewer than 3 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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

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

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

(1) a completed authority prescription form; and

(2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].

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

**Note**

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

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe adalimumab should be forwarded to:

Medicare Australia

Prior Written Approval of Specialised Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

**Note**

TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS

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

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological agents at any 1 time. Where the term 'biological agents' appears in the following NOTES and restrictions, it only refers to adalimumab, etanercept, golimumab and infliximab.

From 1 August 2006, all patients will be able to commence a 'Biological Treatment Cycle' (Cycle), where they may trial biological agents without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

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

Once patients have either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological therapy before they are eligible to commence another Cycle [further details

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

The 5-year break in therapy will be measured from the date the last approval for PBS-subsidised treatment was granted in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Cycle.

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

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

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

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

How to prescribe biological agents for the treatment of severe active psoriatic arthritis after 1 August 2010.

(1) Initial treatment.

Applications for initial treatment should be made where:

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

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

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

All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 16 weeks of therapy for all agents except for infliximab, for which a maximum of 22 weeks will be authorised. It is recommended that patients be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological agent supply.

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

Grandfather patients — golimumab only.

Applications for patients who commenced treatment with golimumab prior to 1 March 2010 may apply for initial PBS-subsidised treatment as continuing therapy under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with any biological agent prior to PBS listing of that agent.

Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment for all agents. Approval will be based on the criteria included in the relevant restriction.

(2) Continuing treatment.

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

Patients must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.

(3) Swapping therapy.

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

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

Patients may alternate between therapy with any biological agent of their choice (1 at a time) providing:

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

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

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

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

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

(4) Baseline measurements to determine response.

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

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| | To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.<br>(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.<br>Patients who wish to trial a second or subsequent treatment Cycle following a break in PBS-subsidised biological therapy of at least 5 years, must re-qualify for initial treatment with respect to both the indices of disease severity. Patients must have received treatment with methotrexate and sulfasalazine or leflunomide, at an adequate dose, for a minimum of 3 months at the time the ESR or CRP levels and the active joint counts are measured.<br>**Note**<br>No applications for increased maximum quantities and/or repeats will be authorised.<br>Applications for treatment with adalimumab where the dosing frequency exceeds 40 mg per fortnight will not be approved. | | | | | | | |
| 9101B | adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL cartridges | 1 | 3 | .. | 1774.57 | 36.10 | Humira | VE |
| 9033K | adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes | 1 | 3 | .. | 1774.57 | 36.10 | Humira | VE |
| | **ADALIMUMAB**<br>**Authority required**<br>Continuing treatment<br>Continuing PBS-subsidised treatment with adalimumab, by a rheumatologist or clinical immunologist with expertise in the management of psoriatic arthritis, of adults:<br>(1) who have a documented history of severe active psoriatic arthritis; and<br>(2) whose most recent course of PBS-subsidised biological agent for this condition in the current Treatment Cycle was with adalimumab; and<br>(3) who, at the time of application, demonstrate an adequate response to treatment with adalimumab.<br>An adequate response to treatment with adalimumab is defined as:<br>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:<br>(i) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or<br>(ii) a reduction in the number of the following major active joints, from at least 4, by at least 50%:<br>— elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or<br>— 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).<br>The authority application must be made in writing and must include:<br>(1) a completed authority prescription form; and<br>(2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].<br>A maximum of 24 weeks of treatment will be approved under this restriction.<br>Where fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).<br>All applications for continuing treatment with adalimumab must include a measurement of response to the prior course of therapy. This assessment must be provided to Medicare Australia no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with adalimumab, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with the initial treatment course.<br>Patients who fail to demonstrate a response to treatment with adalimumab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug, in this Treatment Cycle. Patients may re-trial adalimumab after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle<br>**Note**<br>Any queries concerning the arrangements to prescribe adalimumab may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).<br>Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.<br>Written applications for authority to prescribe adalimumab should be forwarded to:<br>Medicare Australia<br>Prior Written Approval of Specialised Drugs<br>Reply Paid 9826 | | | | | | | |

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HOBART TAS 7001

**Note**

TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS

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

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological agents at any 1 time. Where the term 'biological agents' appears in the following NOTES and restrictions, it only refers to adalimumab, etanercept, golimumab and infliximab.

From 1 August 2006, all patients will be able to commence a 'Biological Treatment Cycle' (Cycle), where they may trial biological agents without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

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

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

The 5-year break in therapy will be measured from the date the last approval for PBS-subsidised treatment was granted in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Cycle.

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

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

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

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

How to prescribe biological agents for the treatment of severe active psoriatic arthritis after 1 August 2010.

(1) Initial treatment.

Applications for initial treatment should be made where:

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

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

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

All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 16 weeks of therapy for all agents except for infliximab, for which a maximum of 22 weeks will be authorised. It is recommended that patients be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological agent supply.

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

Grandfather patients — golimumab only.

Applications for patients who commenced treatment with golimumab prior to 1 March 2010 may apply for initial PBS-subsidised treatment as continuing therapy under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with any biological agent prior to PBS listing of that agent.

Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment for all agents. Approval will be based on the criteria included in the relevant restriction.

(2) Continuing treatment.

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

Patients must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.

(3) Swapping therapy.

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

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| | 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.<br>Patients may alternate between therapy with any biological agent of their choice (1 at a time) providing:<br>(i) they have not received PBS-subsidised treatment with that particular biological agent previously; or<br>(ii) they have demonstrated an adequate response to that particular biological agent if they have previously trialled it on the PBS; or<br>(iii) they have not previously failed to respond to treatment 3 times in this Treatment Cycle.<br>To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.<br>To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the biological agent the patient is ceasing.<br>(4) Baseline measurements to determine response.<br>Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements of the indices of disease severity submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment authority is submitted within a treatment Cycle and Medicare Australia will assess response according to these revised baseline measurements.<br>To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.<br>(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.<br>Patients who wish to trial a second or subsequent treatment Cycle following a break in PBS-subsidised biological therapy of at least 5 years, must re-qualify for initial treatment with respect to both the indices of disease severity. Patients must have received treatment with methotrexate and sulfasalazine or leflunomide, at an adequate dose, for a minimum of 3 months at the time the ESR or CRP levels and the active joint counts are measured.<br>**Note**<br>No applications for increased maximum quantities and/or repeats will be authorised.<br>Applications for treatment with adalimumab where the dosing frequency exceeds 40 mg per fortnight will not be approved. | | | | | | | |
| 9102C | adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL cartridges | 1 | 5 | .. | 1774.57 | 36.10 | Humira | VE |
| 9034L | adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes | 1 | 5 | .. | 1774.57 | 36.10 | Humira | VE |
| | **ADALIMUMAB**<br>**Authority required**<br>Initial 1 (new patients)<br>Initial PBS-subsidised treatment with adalimumab, by a rheumatologist, of an adult with active ankylosing spondylitis who has radiographically (plain X-ray) confirmed Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis and who has not received any PBS-subsidised treatment with either adalimumab, etanercept, golimumab or infliximab in this treatment cycle; AND<br>(a) who has at least 2 of the following:<br>(i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; or<br>(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) [for further information on the BASMI please refer to the Medicare Australia website at www.medicareaustralia.gov.au]; or<br>(iii) limitation of chest expansion relative to normal values for age and gender [for chest expansion normal values please refer to the Medicare Australia website at www.medicareaustralia.gov.au]; AND<br>(b) who has 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.<br>The application must include details of the NSAIDs trialled, their doses and duration of treatment. If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used.<br>If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication.<br>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. Details of the toxicities, including severity, which will be accepted for the purposes of administering this restriction can be found on the Medicare Australia website [www.medicareaustralia.gov.au].<br>For details on the appropriate minimum exercise program that will be accepted for the purposes of administering this restriction, please refer to the Medicare Australia website at www.medicareaustralia.gov.au.<br>The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of the initial application:<br>(a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale; AND | | | | | | | |

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(b) an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 10 mg per L.

The BASDAI must be determined at the completion of the 3 month NSAID and exercise trial, but prior to ceasing NSAID treatment. The BASDAI must be no more than 1 month old at the time of initial application.

Both ESR and CRP measures should be provided with the initial treatment application and both must be no more than 1 month old. If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reason this criterion cannot be satisfied.

Authority applications 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 [www.medicareaustralia.gov.au] which must include the following:

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

(ii) a completed BASDAI Assessment Form [www.medicareaustralia.gov.au]; and

(iii) a completed Exercise Program Self Certification Form included in the supporting information form; and

(iv) a signed patient acknowledgment form.

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

A maximum of 16 weeks of treatment with adalimumab will be approved under this criterion.

Where fewer than 3 repeats are initially requested with the authority prescription, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone.

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

**Authority required**

Initial 2 (change or re-commencement for all patients)

Initial PBS-subsidised treatment with adalimumab, by a rheumatologist, of an adult with a documented history of active ankylosing spondylitis who, in this treatment cycle, has received prior PBS-subsidised TNF-alfa antagonist treatment for this condition and is eligible to receive further TNF-alfa antagonist therapy, and has not failed PBS-subsidised therapy with adalimumab in the current treatment cycle.

Where the most recent course of PBS-subsidised TNF-alfa antagonist treatment was approved under either of the initial treatment restrictions (i.e. for patients with no prior PBS-subsidised TNF-alfa antagonist therapy or, under this restriction, for patients who have received previous PBS-subsidised TNF-alfa antagonist 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 Medicare Australia 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 adalimumab treatment was approved under the continuing treatment criteria, patients must have been assessed for response, and the assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Authority applications 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 [www.medicareaustralia.gov.au].

A maximum of 16 weeks of treatment with adalimumab will be approved under this criterion.

Where fewer than 3 repeats are initially requested with the authority prescription, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone.

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

**Note**

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

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe adalimumab should be forwarded to:

Medicare Australia

Prior Written Approval of Specialised Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

**Note**

TREATMENT OF ADULT PATIENTS WITH ACTIVE ANKYLOSING SPONDYLITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept, golimumab and

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infliximab for adult patients with active ankylosing spondylitis. Where the term 'tumour necrosis factor (TNF) alfa antagonist' appears in the following NOTES and restrictions, it refers to adalimumab, etanercept, golimumab and infliximab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 4 TNF-alfa antagonists at any 1 time.

From 1 March 2007, under the PBS, all patients will be able to commence a treatment cycle where they may trial PBS-subsidised TNF-alfa antagonists without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a TNF-alfa antagonist while they continue to show a response to therapy.

A patient who received PBS-subsidised TNF-alfa antagonist treatment prior to 1 March 2007 is considered to be in their first cycle as of 1 March 2007.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised TNF-alfa antagonist more than once. A patient who, prior to 1 March 2007, was authorised to receive PBS-subsidised initial treatment for ankylosing spondylitis with the same agent twice, is exempt from this condition in respect of applications approved prior to 1 March 2007.

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

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

A patient who has failed fewer than 3 TNF-alfa antagonists in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

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

(1) How to prescribe PBS-subsidised TNF-alfa antagonist therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised TNF-alfa antagonist treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or

(ii) a patient has received prior PBS-subsidised (initial or continuing) TNF-alfa antagonist therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to re-commence treatment with a specific TNF-alfa antagonist following a break in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept and golimumab and 18 weeks of treatment for infliximab.

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

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.

For second and subsequent courses of PBS-subsidised TNF-alfa antagonist treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

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

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

Assessments of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised TNF-alfa antagonist is approved, a patient may swap to an alternate TNF-alfa antagonist 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 TNF-alfa antagonist at any time, regardless of whether they are receiving therapy (initial or continuing) with a TNF-alfa antagonist at the time of the application. However, they cannot swap to a particular TNF-alfa antagonist if they have failed to respond to prior treatment with that drug within the same treatment cycle.

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

To avoid confusion, an application for a patient who wishes to swap to an alternate TNF-alfa antagonist should be accompanied by the approved

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| | authority prescription or remaining repeats for the TNF-alfa antagonist the patient is ceasing.<br>(3) Baseline measurements to determine response.<br>Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a TNF-alfa antagonist. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and Medicare Australia will assess response according to these revised baseline measurements.<br>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.<br>To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response.<br>(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.<br>A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised TNF-alfa antagonist therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have received treatment with 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.<br>(5) Patients 'grandfathered' onto PBS-subsidised treatment with golimumab.<br>A patient who commenced treatment with golimumab for active ankylosing spondylitis prior to 1 March 2010 and who continues to receive treatment at the time of application, may qualify for treatment under the initial 'grandfather' treatment restriction.<br>A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment with golimumab will be authorised under this criterion.<br>Following completion of the initial PBS-subsidised course, further applications for treatment with golimumab will be assessed under the continuing treatment restriction.<br>'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must requalify for initial treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' above for further details.<br>**Note**<br>No applications for increased maximum quantities and/or repeats will be authorised.<br>Applications for treatment with adalimumab where the dosing frequency exceeds 40 mg per fortnight will not be approved. | | | | | | | |
| 9103D | adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL cartridges | 1 | 3 | .. | 1774.57 | 36.10 | Humira | VE |
| 9077R | adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes | 1 | 3 | .. | 1774.57 | 36.10 | Humira | VE |
| | **ADALIMUMAB**<br>**Authority required**<br>Continuing treatment for all patients<br>Continuing PBS-subsidised treatment, by a rheumatologist, of an adult with a documented history of active ankylosing spondylitis who:<br>(a) has demonstrated an adequate response to treatment with adalimumab; and<br>(b) whose most recent course of PBS-subsidised therapy in this treatment cycle was with adalimumab.<br>An adequate response is defined as an improvement from baseline of at least 2 of the BASDAI and 1 of the following:<br>(a) an ESR measurement no greater than 25 mm per hour; or<br>(b) a CRP measurement no greater than 10 mg per L; or<br>(c) an ESR or CRP measurement reduced by at least 20% from baseline.<br>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.<br>Authority applications must be made in writing and must include:<br>(a) a completed authority prescription form; and<br>(b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form [www.medicareaustralia.gov.au].<br>All measurements provided must be no more than 1 month old at the time of application.<br>A maximum of 24 weeks of treatment with adalimumab will be authorised under this criterion.<br>Where fewer than 5 repeats are initially requested with the authority prescription, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone.<br>All applications for continuing treatment with adalimumab must include a measurement of response to the prior course of therapy. This assessment must be provided to Medicare Australia no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment following an initial treatment course it must be made following a minimum of 12 weeks of treatment with adalimumab. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment. | | | | | | | |

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

**Note**

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

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe adalimumab should be forwarded to:

Medicare Australia

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GPO Box 9826

HOBART TAS 7001

**Note**

TREATMENT OF ADULT PATIENTS WITH ACTIVE ANKYLOSING SPONDYLITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept, golimumab and infliximab for adult patients with active ankylosing spondylitis. Where the term 'tumour necrosis factor (TNF) alfa antagonist' appears in the following NOTES and restrictions, it refers to adalimumab, etanercept, golimumab and infliximab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 4 TNF-alfa antagonists at any 1 time.

From 1 March 2007, under the PBS, all patients will be able to commence a treatment cycle where they may trial PBS-subsidised TNF-alfa antagonists without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a TNF-alfa antagonist while they continue to show a response to therapy.

A patient who received PBS-subsidised TNF-alfa antagonist treatment prior to 1 March 2007 is considered to be in their first cycle as of 1 March 2007.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised TNF-alfa antagonist more than once. A patient who, prior to 1 March 2007, was authorised to receive PBS-subsidised initial treatment for ankylosing spondylitis with the same agent twice, is exempt from this condition in respect of applications approved prior to 1 March 2007.

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

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

A patient who has failed fewer than 3 TNF-alfa antagonists in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

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

(1) How to prescribe PBS-subsidised TNF-alfa antagonist therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised TNF-alfa antagonist treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or

(ii) a patient has received prior PBS-subsidised (initial or continuing) TNF-alfa antagonist therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to re-commence treatment with a specific TNF-alfa antagonist following a break in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept and golimumab and 18 weeks of treatment for infliximab.

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

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.

For second and subsequent courses of PBS-subsidised TNF-alfa antagonist treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific TNF-alfa antagonist, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive

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continuing TNF-alfa antagonist treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

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

Assessments of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised TNF-alfa antagonist is approved, a patient may swap to an alternate TNF-alfa antagonist 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 TNF-alfa antagonist at any time, regardless of whether they are receiving therapy (initial or continuing) with a TNF-alfa antagonist at the time of the application. However, they cannot swap to a particular TNF-alfa antagonist if they have failed to respond to prior treatment with that drug within the same treatment cycle.

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

To avoid confusion, an application for a patient who wishes to swap to an alternate TNF-alfa antagonist should be accompanied by the approved authority prescription or remaining repeats for the TNF-alfa antagonist the patient is ceasing.

(3) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a TNF-alfa antagonist. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and Medicare Australia will assess response according to these revised baseline measurements.

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

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response.

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

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised TNF-alfa antagonist therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have received treatment with 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.

(5) Patients 'grandfathered' onto PBS-subsidised treatment with golimumab.

A patient who commenced treatment with golimumab for active ankylosing spondylitis prior to 1 March 2010 and who continues to receive treatment at the time of application, may qualify for treatment under the initial 'grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment with golimumab will be authorised under this criterion.

Following completion of the initial PBS-subsidised course, further applications for treatment with golimumab will be assessed under the continuing treatment restriction.

'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must requalify for initial treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' above for further details.

**Note**

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

Applications for treatment with adalimumab where the dosing frequency exceeds 40 mg per fortnight will not be approved.

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 9104E | adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL cartridges | 1 | 5 | .. | 1774.57 | 36.10 | Humira | VE |
| 9078T | adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes | 1 | 5 | .. | 1774.57 | 36.10 | Humira | VE |

**ADALIMUMAB**

**Authority required**

Initial 1 (new patients)

Initial treatment of Crohn disease in a patient assessed by CDAI.

Initial PBS-subsidised treatment with adalimumab by a gastroenterologist or a consultant physician as specified in the NOTE below, of a patient with severe refractory Crohn disease who satisfies the following criteria:

(a) has confirmed Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician as specified in the NOTE below; and

(b) has signed a patient acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not

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meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and

(c) has failed to achieve an adequate response to prior systemic therapy including:

(i) a tapered course of steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period; and

(ii) immunosuppressive therapy including:

— azathioprine at a dose of at least 2 mg per kg daily for 3 or more months; or

— 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months; or

— methotrexate at a dose of at least 15 mg weekly for 3 or more months.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of the accepted toxicities including severity can be found on the Medicare Australia website (www.medicareaustralia.gov.au).

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

(a) have a severity of disease activity which results in a Crohn Disease Activity Index (CDAI) Score greater than or equal to 300 as assessed.

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.

The most recent CDAI assessment must be no more than 1 month old at the time of application.

Applications for authorisation must be made in writing and must include:

(a) two completed authority prescription forms; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) the completed current Crohn Disease Activity Index (CDAI) calculation sheet including the date of assessment of the patient's condition; and

(ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and

(iii) the signed patient acknowledgement.

A maximum of 16 weeks treatment will be authorised under this criterion.

Two completed authority prescriptions must be submitted with every initial application for adalimumab. One prescription must be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats. The second prescription must be written for 2 doses of 40 mg and 2 repeats. Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment with adalimumab may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

A CDAI assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks therapy so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with adalimumab.

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised adalimumab treatment

**Authority required**

Initial 2

Change or re-commencement of treatment of Crohn disease in a patient assessed by CDAI.

Initial PBS-subsidised treatment with adalimumab by a gastroenterologist or a consultant physician as specified in the NOTE below of a patient who:

(a) has a documented history of severe refractory Crohn disease; and

(b) in this treatment cycle, has received prior PBS-subsidised treatment with infliximab or adalimumab for this condition; and

(c) has not failed PBS-subsidised therapy with adalimumab for this condition more than once in the current treatment cycle.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

To demonstrate a response to treatment the application must be accompanied by the results of the most recent course of TNF-alfa antagonist therapy within the timeframes specified in the relevant restriction.

Where the most recent course of PBS-subsidised TNF-alfa antagonist treatment was approved under an initial treatment restriction, the patient must have been assessed for response to that course following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

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If the response assessment to the previous course of TNF-alfa antagonist treatment is not submitted as detailed above, the patient will be deemed to have failed therapy with that particular course of TNF-alfa antagonist.

Authority applications must be made in writing and must include:

(a) two completed authority prescription forms; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) the completed current Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient's condition; and

(ii) details of prior TNF alfa antagonist treatment including details of date and duration of treatment.

Two completed authority prescriptions must be submitted with every initial application for adalimumab. One prescription must be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats. The second prescription must be written for 2 doses of 40 mg and 2 repeats. Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment with adalimumab may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

A CDAI assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks therapy so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with adalimumab.

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised adalimumab treatment

**Authority required**

Initial 1

Initial treatment of Crohn disease in a patient with short gut syndrome or an ostomy patient.

Initial PBS-subsidised treatment with adalimumab by a gastroenterologist, or consultant physician as specified in the NOTE below of a patient who satisfies the following criteria:

(a) has confirmed Crohn disease defined by standard clinical, endoscopic and/or imaging features, including histological evidence with the diagnosis confirmed by a gastroenterologist or consultant physician as specified in the NOTE below; and

(b) has diagnostic imaging or surgical evidence of short gut syndrome or has an ileostomy or colostomy; and

(c) has evidence of intestinal inflammation; and

(d) has signed a patient acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and

(e) has failed to achieve an adequate response to prior systemic drug therapy including:

(i) a tapered course of steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period; and

(ii) immunosuppressive therapy including:

— azathioprine at a dose of at least 2 mg per kg daily for 3 or more months; or

— 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months; or

— methotrexate at a dose of at least 15 mg weekly for 3 or more months.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of the accepted toxicities including severity can be found on the Medicare Australia website (www.medicareaustralia.gov.au).

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

(a) have evidence of intestinal inflammation, including:

(i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; AND/OR

(ii) faeces: higher than normal lactoferrin or calprotectin level; AND/OR

(iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery;

AND/OR

(b) be assessed clinically as being in a high faecal output state;

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AND/OR

(c) be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of adalimumab.

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.

Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the continuing treatment restriction. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy.

Applications for authorisation must be made in writing and must include:

(a) two completed authority prescription forms; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and

(ii) reports and dates of the pathology or diagnostic imaging test(s) nominated as the response criterion, if relevant; and

(iii) date of the most recent clinical assessment; and

(iv) the signed patient acknowledgement.

All assessments, pathology tests and diagnostic imaging studies must be made within 1 month of the date of application.

A maximum of 16 weeks treatment will be authorised under this criterion.

Two completed authority prescriptions must be submitted with every initial application for adalimumab. One prescription must be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats. The second prescription must be written for 2 doses of 40 mg and 2 repeats. Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment with adalimumab may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

The assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks therapy so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with adalimumab.

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised adalimumab treatment

**Authority required**

Initial 2

Change or re-commencement of treatment of Crohn disease in a patient with short gut syndrome, an ostomy patient or a patient with extensive small intestine disease.

Initial PBS-subsidised treatment with adalimumab by a gastroenterologist or a consultant physician as specified in the NOTE below of a patient who:

(a) has a documented history of severe refractory Crohn disease; and

(b) in this treatment cycle, has received prior PBS-subsidised treatment with infliximab or adalimumab for this condition; and

(c) has not failed PBS-subsidised therapy with adalimumab for this condition more than once in the current treatment cycle.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

To demonstrate a response to treatment the application must be accompanied by the results of the most recent course of TNF-alfa antagonist therapy within the timeframes specified in the relevant restriction.

Where the most recent course of PBS-subsidised TNF-alfa antagonist treatment was approved under an initial treatment restriction, the patient must have been assessed for response to that course following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

If the response assessment to the previous course of TNF-alfa antagonist treatment is not submitted as detailed above, the patient will be deemed to have failed therapy with that particular course of TNF-alfa antagonist.

Authority applications must be made in writing and must include:

(a) two completed authority prescription forms; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) reports and dates of the pathology or diagnostic imaging test(s) nominated as the response criteria, if relevant; and

(ii) details of prior TNF alfa antagonist treatment including details of date and duration of treatment.

A maximum of 16 weeks of treatment will be approved under this criterion.

Two completed authority prescriptions must be submitted with every initial application for adalimumab. One prescription must be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats. The second prescription must be written for 2 doses of 40 mg and 2

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repeats. Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment with adalimumab may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

The assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of therapy so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with adalimumab.

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised adalimumab treatment

**Authority required**

Initial 1

Initial treatment of Crohn disease in a patient with extensive small intestine disease.

Initial PBS-subsidised treatment with adalimumab by a gastroenterologist or a consultant physician as specified in the NOTE below, of a patient with severe refractory Crohn disease who satisfies the following criteria:

(a) has confirmed Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or consultant physician as specified in the NOTE below; and

(b) has extensive small intestinal disease with radiological evidence of intestinal inflammation affecting more than 50 cm of the small intestine; and

(c) has signed a patient acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and

(d) has failed to achieve an adequate response to prior systemic therapy including:

(i) a tapered course of steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period; and

(ii) immunosuppressive therapy including:

— azathioprine at a dose of at least 2 mg per kg daily for 3 or more months; or

— 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months; or

— methotrexate at a dose of at least 15 mg weekly for 3 or more months.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of the accepted toxicities including severity can be found on the Medicare Australia website (www.medicareaustralia.gov.au).

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

(a) have severity of disease activity which results in a Crohn Disease Activity Index (CDAI) Score greater than or equal to 220;

AND/OR

(b) have evidence of active intestinal inflammation, including:

(i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; AND/OR

(ii) faeces: higher than normal lactoferrin or calprotectin level; AND/OR

(iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery;

AND/OR

(c) be assessed clinically as being in a high faecal output state;

AND/OR

(d) be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of adalimumab.

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.

Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the continuing treatment restriction. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy.

Applications for authorisation must be made in writing and must include:

(a) two completed authority prescription forms; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website

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(www.medicareaustralia.gov.au)] which includes the following:

(i) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and

(ii) (1) reports and dates of the pathology or diagnostic imaging test(s) nominated as the response criterion, if relevant; or

(2) the completed current Crohn Disease Activity Index (CDAI) calculation sheet including the dates of assessment of the patient's condition, if relevant; and

(iii) date of the most recent clinical assessment; and

(iv) the signed patient acknowledgement.

All assessments, pathology tests and diagnostic imaging studies must be made within 1 month of the date of application.

A maximum of 16 weeks treatment of adalimumab will be authorised under this criterion.

Two completed authority prescriptions must be submitted with every initial application for adalimumab. One prescription must be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats. The second prescription must be written for 2 doses of 40 mg and 2 repeats. Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment with adalimumab may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

The assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of therapy after the first dose so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with adalimumab.

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised adalimumab treatment

**Note**

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

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe adalimumab should be forwarded to:

Medicare Australia

Prior Written Approval of Specialised Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

**Note**

TREATMENT OF ADULT PATIENTS WITH SEVERE REFRACTORY CROHN DISEASE

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab and infliximab for adult patients with severe refractory Crohn disease. Where the term 'tumour necrosis factor (TNF) alfa antagonist' appears in the following NOTES and restrictions, it refers to adalimumab and infliximab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 2 TNF-alfa antagonists at any 1 time.

From 1 August 2008, under the PBS, all patients will be able to commence a treatment cycle where they may trial each PBS-subsidised TNF-alfa antagonist without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a TNF-alfa antagonist while they continue to show a response to therapy.

A patient who received PBS-subsidised TNF-alfa antagonist treatment prior to 1 August 2008 is considered to be in their first cycle as of 1 August 2008.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised TNF-alfa antagonist more than twice.

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

A patient who has failed fewer than 3 trials of TNF-alfa antagonists in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of TNF-alfa antagonists in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

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

(1) How to prescribe PBS-subsidised TNF-alfa antagonist therapy after 1 August 2008.

(a) Initial treatment.

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Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised TNF-alfa antagonist treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or

(ii) a patient has received prior PBS-subsidised (initial or continuing) TNF-alfa antagonist therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to re-commence treatment with a specific TNF-alfa antagonist following a break in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and 14 weeks of therapy for infliximab.

From 1 August 2008, a patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.

For second and subsequent courses of PBS-subsidised TNF-alfa antagonist treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

Adalimumab only: Two completed authority prescriptions must be submitted with every initial application for adalimumab. One prescription must be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats. The second prescription must be written for 2 doses of 40 mg and 2 repeats.

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

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

Assessments of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised TNF-alfa antagonist is approved, a patient may swap if eligible to the alternate TNF-alfa antagonist within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Crohn Disease Activity Index (CDAI) Score, evidence of intestinal inflammation), or the prior corticosteroid therapy and immunosuppressive therapy.

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

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

To avoid confusion, an application for a patient who wishes to swap to the alternate TNF-alfa antagonist should be accompanied by the approved authority prescription or remaining repeats for the TNF-alfa antagonist the patient is ceasing.

(3) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements of the CDAI or evidence of intestinal inflammation submitted with the first authority application for a TNF-alfa antagonist. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and Medicare Australia will assess response according to these revised baseline measurements.

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

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

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised TNF-alfa antagonist therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have received treatment with a corticosteroid and at least 1 immunosuppressive agent, at an adequate dose, for a minimum of 3 consecutive months immediately prior to the time the CDAI score or the indices of intestinal inflammation are measured.

(5) Patients 'grandfathered' onto PBS-subsidised treatment with adalimumab or infliximab.

A patient who commenced treatment with adalimumab for severe refractory Crohn disease prior to 9 November 2007 or infliximab prior to 7 March 2007 and who continues to receive treatment at the time of application, may qualify for treatment under the initial 'grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment with adalimumab or infliximab will be authorised under this criterion.

Following completion of the initial PBS-subsidised course, further applications for treatment with adalimumab or infliximab will be assessed under

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| | the continuing treatment restriction. | | | | | | | |
| | 'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must requalify for initial treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' above for further details. | | | | | | | |
| | **Note** | | | | | | | |
| | No applications for increased maximum quantities and/or repeats will be authorised. | | | | | | | |
| 9190Q | adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL cartridges | 1 | 2 | .. | 1774.57 | 36.10 | Humira | VE |
| 9188N | adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes | 1 | 2 | .. | 1774.57 | 36.10 | Humira | VE |
| 9187M | adalimumab 40 mg/0.8 mL injection, 6 x 0.8 mL cartridges | 1 | .. | .. | 5036.57 | 36.10 | Humira | VE |
| 9186L | adalimumab 40 mg/0.8 mL injection, 6 x 0.8 mL syringes | 1 | .. | .. | 5036.57 | 36.10 | Humira | VE |
| | **ADALIMUMAB** | | | | | | | |
| | **Authority required** | | | | | | | |
| | Initial 3 (grandfather) | | | | | | | |
| | Initial PBS-subsidised treatment of Crohn disease in a patient assessed by CDAI who has previously received non-PBS-subsidised therapy with adalimumab. | | | | | | | |
| | Initial PBS-subsidised supply for continuing treatment with adalimumab by a gastroenterologist, a consultant physician as specified in the NOTE below, or other consultant physician in consultation with a gastroenterologist of a patient who: | | | | | | | |
| | (a) has a documented history of severe refractory Crohn disease and was receiving treatment with adalimumab prior to 9 November 2007; and | | | | | | | |
| | (b) had a Crohn Disease Activity Index (CDAI) Score of greater than or equal to 300 prior to commencing treatment with adalimumab. Where a baseline CDAI assessment is not available, please call Medicare Australia on 1800 700 270 to discuss; and | | | | | | | |
| | (c) has signed a patient acknowledgement indicating that they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and | | | | | | | |
| | (d) has demonstrated or sustained an adequate response to treatment with adalimumab. For advice please contact Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). | | | | | | | |
| | NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)]. | | | | | | | |
| | An adequate response to adalimumab treatment is defined as a reduction in Crohn Disease Activity Index (CDAI) Score to no greater than 150. | | | | | | | |
| | Applications for authorisation must be made in writing and must include: | | | | | | | |
| | (a) a completed authority prescription form; and | | | | | | | |
| | (b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following: | | | | | | | |
| | (i) the completed current and baseline Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient's condition; and | | | | | | | |
| | (ii) the signed patient acknowledgement. | | | | | | | |
| | The current CDAI assessment must be no more than 1 month old at the time of application. The baseline CDAI assessment must be from immediately prior to commencing treatment with adalimumab. | | | | | | | |
| | The assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion. | | | | | | | |
| | Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with adalimumab. | | | | | | | |
| | A maximum of 24 weeks treatment will be approved under this criterion. | | | | | | | |
| | Where fewer than 5 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). | | | | | | | |
| | Patients may qualify for PBS-subsidised treatment under this restriction once only | | | | | | | |
| | **Authority required** | | | | | | | |
| | Continuing treatment of Crohn disease in a patient assessed by CDAI. | | | | | | | |
| | Continuing PBS-subsidised treatment with adalimumab by a gastroenterologist, a consultant physician as specified in the NOTE below or other consultant physician in consultation with a gastroenterologist, of a patient who: | | | | | | | |
| | (a) has a documented history of severe refractory Crohn disease; and | | | | | | | |
| | (b) has demonstrated or sustained an adequate response to treatment with adalimumab. | | | | | | | |
| | NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)]. | | | | | | | |

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An adequate response to adalimumab treatment is defined as a reduction in Crohn Disease Activity Index (CDAI) Score to a level no greater than 150.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) the completed Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient's condition.

The CDAI assessment must be no more than 1 month old at the time of application.

If the application is the first application for continuing treatment with adalimumab, a CDAI assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of therapy so that there is adequate time for a response to be demonstrated.

The assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion.

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with adalimumab.

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

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

Where fewer than 5 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday)

**Authority required**

Continuing treatment of Crohn disease in a patient with short gut syndrome or an ostomy patient.

Continuing PBS-subsidised treatment with adalimumab by a gastroenterologist, a consultant physician as specified in the NOTE below or other consultant physician in consultation with a gastroenterologist, of a patient who:

(a) has a documented history of severe refractory Crohn disease with intestinal inflammation and with short gut syndrome or with an ileostomy or colostomy; and

(b) has demonstrated or sustained an adequate response to treatment with adalimumab.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

An adequate response to adalimumab treatment is defined as:

(a) improvement of intestinal inflammation as demonstrated by:

(i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; AND/OR

(ii) faeces: normalisation of lactoferrin or calprotectin level; AND/OR

(iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or

(b) reversal of high faecal output state; or

(c) avoidance of the need for surgery or total parenteral nutrition (TPN).

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) the reports and dates of the pathology or diagnostic imaging test(s) used to assess response to therapy or the date of clinical assessment.

The patient's assessment must be no more than 1 month old at the time of application.

If the application is the first application for continuing treatment with adalimumab, an assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of therapy after the first dose so that there is adequate time for a response to be demonstrated.

The assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion.

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with adalimumab.

Patients are eligible to receive continuing adalimumab treatment in courses of up to 24 weeks providing they continue to sustain the response.

A maximum of 24 weeks of treatment will be authorised under this criterion.

Where fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday)

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**Authority required**

Continuing treatment of Crohn disease in a patient with extensive small intestine disease.

Continuing PBS-subsidised treatment with adalimumab by a gastroenterologist, or consultant physician as specified in the NOTE below or other consultant physician in consultation with a gastroenterologist, of a patient who:

(a) has a documented history of severe refractory Crohn disease with extensive intestinal inflammation affecting more than 50 cm of the small intestine; and

(b) has demonstrated or sustained an adequate response to treatment with adalimumab.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

An adequate response to adalimumab treatment is defined as:

(a) a reduction in Crohn Disease Activity Index (CDAI) Score to no greater than 150; or

(b) improvement of intestinal inflammation as demonstrated by:

(i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; AND/OR

(ii) faeces: normalisation of lactoferrin or calprotectin level; AND/OR

(iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or

(c) reversal of high faecal output state; or

(d) avoidance of the need for surgery or total parenteral nutrition (TPN).

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) the completed Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient's condition; or

(ii) the reports and dates of the pathology test or diagnostic imaging test(s) used to assess response to therapy; or

(iii) the date of clinical assessment.

All assessments must be no more than 1 month old at the time of application.

If the application is the first application for continuing treatment with adalimumab, an assessment of the patient's response must be made following a minimum of 12 weeks of therapy so that there is adequate time for a response to be demonstrated.

The assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion.

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with adalimumab.

Patients are eligible to receive continuing adalimumab treatment in courses of up to 24 weeks providing they continue to sustain the response.

A maximum of 24 weeks treatment will be authorised under this criterion.

Where fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday)

**Authority required**

Initial 3

Initial PBS-subsidised treatment of Crohn disease in a patient with short gut syndrome, an ostomy patient, or a patient with extensive small intestine disease, who has previously received non-PBS-subsidised therapy with adalimumab.

Initial PBS-subsidised supply for continuing treatment with adalimumab by a gastroenterologist, a consultant physician as specified in the NOTE below, or other consultant physician in consultation with a gastroenterologist, of a patient who:

(a) has a documented history of severe refractory Crohn disease and was receiving treatment with adalimumab prior to 9 November 2007; and

(b) (1) has a history of extensive small intestinal disease with radiological evidence of intestinal inflammation affecting more than 50 cm of the small intestine; or

(2) has diagnostic imaging or surgical evidence of short gut syndrome or has an ileostomy or colostomy with a documented history of intestinal inflammation; and

(c) has signed a patient acknowledgement indicating that they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and

(d) has demonstrated or sustained an adequate response to treatment with adalimumab according to the criteria included in the relevant continuation restriction. For advice please contact Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

The same criteria used to determine an inadequate response to prior treatment at baseline must be used to determine response to treatment and

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eligibility for continuing therapy, according to the criteria included in the continuing treatment restriction.

An adequate response to adalimumab treatment is defined as:

(a) a reduction in Crohn Disease Activity Index (CDAI) Score to no greater than 150; or

(b) improvement of intestinal inflammation as demonstrated by:

(i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; AND/OR

(ii) faeces: normalisation of lactoferrin or calprotectin level; AND/OR

(iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or

(c) reversal of high faecal output state; or

(d) avoidance of the need for surgery or total parenteral nutrition (TPN).

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au) ] which includes the following:

(i) (1) the completed current and baseline Crohn Disease Activity Index (CDAI) Score calculation sheet, where relevant, including the date of the assessment of the patient's condition; or

(2) the reports and dates of the current and baseline pathology or diagnostic imaging test(s) in order to assess response to therapy; or

(3) the date of clinical assessment(s); and

(ii) the signed patient acknowledgement.

The patient's assessment must be no more than 1 month old at the time of application. The baseline CDAI assessments must be from immediately prior to commencing treatment with adalimumab. Where a baseline assessment is not available, please call Medicare Australia on 1800 700 270 to discuss.

The assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion.

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with adalimumab.

Patients are eligible to receive continuing adalimumab treatment in courses of up to 24 weeks providing they continue to sustain the response.

Patients who fail to demonstrate or sustain a response to treatment with adalimumab for Crohn disease as specified in the criteria for continuing treatment with adalimumab, will not be eligible to recommence PBS-subsidised treatment with this drug within 12 months of the date on which treatment was ceased.

A maximum of 24 weeks treatment will be authorised under this criterion.

Where fewer than 5 repeats are requested at the time of this application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Patients may qualify for PBS-subsidised treatment under this restriction once only

**Note**

Any queries concerning the arrangements to prescribe adalimumab may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe adalimumab should be forwarded to:

Medicare Australia

Prior Written Approval of Specialised Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

**Note**

TREATMENT OF ADULT PATIENTS WITH SEVERE REFRACTORY CROHN DISEASE

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab and infliximab for adult patients with severe refractory Crohn disease. Where the term 'tumour necrosis factor (TNF) alfa antagonist' appears in the following NOTES and restrictions, it refers to adalimumab and infliximab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 2 TNF-alfa antagonists at any 1 time.

From 1 August 2008, under the PBS, all patients will be able to commence a treatment cycle where they may trial each PBS-subsidised TNF-alfa antagonist without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a TNF-alfa antagonist while they continue to show a response

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to therapy.

A patient who received PBS-subsidised TNF-alfa antagonist treatment prior to 1 August 2008 is considered to be in their first cycle as of 1 August 2008.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised TNF-alfa antagonist more than twice.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised TNF-alfa antagonist therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised TNF-alfa antagonist treatment in the most recent cycle to the date of the first application for initial treatment with a TNF-alfa antagonist under the new treatment cycle.

A patient who has failed fewer than 3 trials of TNF-alfa antagonists in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of TNF-alfa antagonists in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised TNF-alfa antagonist therapy after 1 August 2008.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised TNF-alfa antagonist treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or

(ii) a patient has received prior PBS-subsidised (initial or continuing) TNF-alfa antagonist therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to re-commence treatment with a specific TNF-alfa antagonist following a break in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and 14 weeks of therapy for infliximab.

From 1 August 2008, a patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.

For second and subsequent courses of PBS-subsidised TNF-alfa antagonist treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

Adalimumab only: Two completed authority prescriptions must be submitted with every initial application for adalimumab. One prescription must be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats. The second prescription must be written for 2 doses of 40 mg and 2 repeats.

(b) Continuing treatment. Following the completion of an initial treatment course with a specific TNF-alfa antagonist, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing TNF-alfa antagonist treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted TNF-alfa antagonist supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised TNF-alfa antagonist is approved, a patient may swap if eligible to the alternate TNF-alfa antagonist within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Crohn Disease Activity Index (CDAI) Score, evidence of intestinal inflammation), or the prior corticosteroid therapy and immunosuppressive therapy.

A patient may trial the alternate TNF-alfa antagonist at any time, regardless of whether they are receiving therapy (initial or continuing) with a TNF-alfa antagonist at the time of the application. However, they cannot swap to a particular TNF-alfa antagonist if they have failed to respond to prior treatment with that drug two times within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to the alternate TNF-alfa antagonist should be accompanied by the approved authority prescription or remaining repeats for the TNF-alfa antagonist the patient is ceasing.

(3) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements of the CDAI or

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evidence of intestinal inflammation submitted with the first authority application for a TNF-alfa antagonist. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and Medicare Australia will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications.

(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised TNF-alfa antagonist therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have received treatment with a corticosteroid and at least 1 immunosuppressive agent, at an adequate dose, for a minimum of 3 consecutive months immediately prior to the time the CDAI score or the indices of intestinal inflammation are measured.

(5) Patients 'grandfathered' onto PBS-subsidised treatment with adalimumab or infliximab.

A patient who commenced treatment with adalimumab for severe refractory Crohn disease prior to 9 November 2007 or infliximab prior to 7 March 2007 and who continues to receive treatment at the time of application, may qualify for treatment under the initial 'grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment with adalimumab or infliximab will be authorised under this criterion.

Following completion of the initial PBS-subsidised course, further applications for treatment with adalimumab or infliximab will be assessed under the continuing treatment restriction.

'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must requalify for initial treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' above for further details.

**Note**

No applications for increased maximum quantities and/or repeats will be authorised.

| | | | | | | | | |
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| 9191R | adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL cartridges | 1 | 5 | .. | 1774.57 | 36.10 | Humira | VE |
| 9189P | adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes | 1 | 5 | .. | 1774.57 | 36.10 | Humira | VE |

**ADALIMUMAB**

**Authority required**

Initial treatment [Initial 1, Whole body (New patients — No prior biological agent)]

Initial treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over who:

(a) have severe chronic plaque psoriasis where lesions have been present for at least 6 months from the time of initial diagnosis; and

(b) have not received any prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle; and

(c) have signed a patient and prescriber acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment (whole body); and

(d) have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 3 of the following 4 treatments:

(i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; and/or

(ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; and/or

(iii) cyclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; and/or

(iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks.

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity to necessitate permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of acceptable toxicities including severity, associated with phototherapy, methotrexate, cyclosporin and acitretin, can be found on the Medicare Australia website (www.medicareaustralia.gov.au).

The following initiation criterion indicates failure to achieve an adequate response and must be demonstrated in all patients at the time of the application:

(a) A current Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.

(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 1 month following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than 1 month old at the time of application.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare

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Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy]; and

(iii) the signed patient and prescriber acknowledgements.

A maximum of 16 weeks of treatment with adalimumab will be authorised under this restriction.

Where fewer than 4 repeats are requested at the time of the authority application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period beyond 16 weeks.

A PASI assessment of the patient's response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with adalimumab. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

It is recommended that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised adalimumab treatment

**Authority required**

Initial or re-Treatment [Initial 2, Whole body (Received prior biological agent under PBS)]

Treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over who:

(a) have a documented history of severe chronic plaque psoriasis; and

(b) have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle; and

(c) have not failed PBS-subsidised therapy with adalimumab for the treatment of this condition in the current Treatment Cycle.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and

(ii) details of prior biological treatment, including dosage, date and duration of treatment.

Applications for patients who have demonstrated a response to PBS-subsidised adalimumab treatment within this Treatment Cycle and who wish to re-commence adalimumab treatment within the same Cycle following a break in therapy, will only be approved where evidence of the patient's response to their most recent course of PBS-subsidised adalimumab treatment has been submitted to Medicare Australia within 1 month of cessation of treatment.

A maximum of 16 weeks of treatment with adalimumab will be authorised under this restriction.

Where fewer than 4 repeats are requested at the time of the authority application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period beyond 16 weeks.

A PASI assessment of the patient's response to this course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with adalimumab. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

It is recommended that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised adalimumab treatment.

Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may re-commence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle

**Authority required**

Initial treatment [Initial 1, Face, hand, foot (New patients — No prior biological agent)]

Initial treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over who:

(a) have severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis; and

(b) have not received any prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle; and

(c) have signed a patient and prescriber acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if

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they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment (face, hand, foot); and

(d) have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 3 of the following 4 treatments:

(i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; and/or

(ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; and/or

(iii) cyclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; and/or

(iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks.

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity to necessitate permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of acceptable toxicities including severity, associated with phototherapy, methotrexate, cyclosporin and acitretin, can be found on the Medicare Australia website (www.medicareaustralia.gov.au).

The following initiation criterion indicates failure to achieve an adequate response and must be demonstrated in all patients at the time of the application:

(a) Chronic plaque psoriasis classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where:

(i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment; or

(ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.

(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 1 month following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than 1 month old at the time of application.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy]; and

(iii) the signed patient and prescriber acknowledgements.

A maximum of 16 weeks of treatment with adalimumab will be authorised under this restriction.

Where fewer than 4 repeats are requested at the time of the authority application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period beyond 16 weeks.

A PASI assessment of the patient's response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with adalimumab. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

It is recommended that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised adalimumab treatment.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline

**Authority required**

Initial or re-Treatment [Initial 2, Face, hand, foot (Received prior biological agent under PBS)]

Treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over who:

(a) have a documented history of severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot; and

(b) have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle; and

(c) have not failed PBS-subsidised therapy with adalimumab for the treatment of this condition in the current Treatment Cycle.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of

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assessment of the patient's condition [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and

(ii) details of prior biological treatment, including dosage, date and duration of treatment.

Applications for patients who have demonstrated a response to PBS-subsidised adalimumab treatment within this Treatment Cycle and who wish to re-commence adalimumab treatment within the same Cycle following a break in therapy, will only be approved where evidence of the patient's response to their most recent course of PBS-subsidised adalimumab treatment has been submitted to Medicare Australia within 1 month of cessation of treatment.

A maximum of 16 weeks of treatment with adalimumab will be authorised under this restriction.

Where fewer than 4 repeats are requested at the time of the authority application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period beyond 16 weeks.

A PASI assessment of the patient's response to this course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with adalimumab. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

It is recommended that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised adalimumab treatment.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may re-commence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle

**Note**

Any queries concerning the arrangements to prescribe adalimumab may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe adalimumab should be forwarded to:

Medicare Australia

Prior Written Approval of Specialised Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

**Note**

TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, etanercept, infliximab and ustekinumab, for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological agents' appears in the following NOTES and restrictions, it only refers to adalimumab, etanercept, infliximab and ustekinumab.

From 1 March 2010, all patients will be able to commence a 'Biological Treatment Cycle' (Cycle), where they may trial adalimumab, etanercept, infliximab or ustekinumab without having to meet the initial treatment criteria, that is they will not need to experience a disease flare when swapping to an alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

A patient who received PBS-subsidised biological agent treatment for chronic plaque psoriasis prior to 1 March 2010 is considered to be in their first Cycle as of 1 March 2010.

Patients are eligible for PBS-subsidised treatment with only 1 biological agent at any 1 time.

Within the same Treatment Cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for a PBS-subsidised biological agent, they must change to an alternate agent if they wish to continue PBS-subsidised biological treatment. A patient who, prior to 1 March 2010, was authorised to receive PBS-subsidised initial treatment for chronic plaque psoriasis with the same agent twice, is exempt from this condition in respect of applications approved prior to 1 March 2010.

Patients must be assessed for response to each course of continuing treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a Treatment Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological agent therapy before they are eligible to commence the next Cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological agent treatment in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Treatment Cycle.

Patients for whom a break in PBS-subsidised therapy of less than 5 years duration has occurred, and, who have failed therapy fewer than 3 times within a particular Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.

Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a

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particular Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle.

There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.

How to prescribe biological agents for the treatment of severe chronic plaque psoriasis after 1 March 2010.

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Application for approval for initial treatment.

Applications for a course of initial treatment should be made in the following situations:

(i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); or

(ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under '(4) Swapping therapy' below]; or

(iii) patients who wish to re-commence treatment following a break in PBS-subsidised therapy with that agent (Initial 2).

All applications for initial treatment will be limited to provide for a maximum of 16 weeks of treatment in the case of adalimumab and etanercept, 22 weeks of treatment in the case of infliximab and 28 weeks of treatment in the case of ustekinumab.

(2) Assessment of response to initial treatment.

When prescribing initial treatment with a biological agent, a PASI assessment must be conducted after at least 12 weeks of treatment. This assessment must be submitted to Medicare Australia within 1 month of the completion of this initial treatment course. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

(3) Application for continuing treatment.

Following the completion of an initial treatment course of a biological agent to which an adequate response has been demonstrated, patients may qualify to receive up to 24 weeks of continuing treatment with that biological agent. Patients are eligible to continue to receive continuous treatment with 24 week courses providing they continue to sustain a response.

For second and subsequent courses of PBS-subsidised treatment with adalimumab, etanercept, infliximab or ustekinumab it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

Where a response assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to sustain a response to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

(4) Swapping therapy.

Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate agent within the same Treatment Cycle without having to requalify with respect to disease severity (i.e. a PASI score of greater than 15), or prior treatment requirements.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

Patients may trial an alternate biological agent at any time, regardless of whether they are receiving therapy with a biological agent at the time of the application or not. However, they cannot swap to a particular agent if they have failed to respond to treatment with that particular agent within the same Cycle.

Patients who commenced treatment with adalimumab prior to 1 June 2009 or ustekinumab prior to 1 March 2010 access these interchangeability arrangements in the same way as patients who have not.

To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the agent being ceased.

(5) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated, based on the baseline PASI assessment submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment authority is submitted within a Treatment Cycle and subsequent response will be assessed according to this revised PASI score.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatment applications.

(6) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

Patients who wish to trial a second or subsequent Biological Treatment Cycle, following a break in PBS-subsidised biological therapy of at least 5 years, must requalify for initial treatment according to the criteria of the relevant restriction and index of disease severity. Patients must have had at least 1 prior treatment, as listed in the criteria, for a minimum of 6 weeks, and must have a PASI assessment conducted preferably whilst still on treatment, but no later than 1 month following cessation of treatment. The PASI assessment must be no older than 1 month at the time of application.

**Note**

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| | No applications for increased maximum quantities and/or repeats will be authorised. | | | | | | | |
| | **Note** Special Pricing Arrangements apply. | | | | | | | |
| 9426D | adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL cartridges | 1 | 4 | .. | 1774.57 | 36.10 | Humira | VE |
| 9425C | adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes | 1 | 4 | .. | 1774.57 | 36.10 | Humira | VE |

**ADALIMUMAB**

**Authority required**

Continuing treatment (Whole body)

Continuing PBS-subsidised treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over:

(a) who have a documented history of severe chronic plaque psoriasis; and

(b) whose most recent course of PBS-subsidised biological treatment for this condition in this Treatment Cycle was with adalimumab; and

(c) who have demonstrated an adequate response to their most recent course of treatment with adalimumab.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the pre-biological treatment baseline value for this Treatment Cycle.

This assessment must be provided to Medicare Australia no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with adalimumab, the assessment of response must be after a minimum of 12 weeks of treatment with an initial course.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) the completed Psoriasis Area and Severity Index (PASI) calculation sheet along with the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 1 month old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with adalimumab.

A maximum of 24 weeks of treatment with adalimumab will be authorised under this restriction.

Where fewer than 5 repeats are requested at the time of the authority application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for continuing authority applications, or for treatment that would otherwise extend the treatment period beyond 24 weeks.

A PASI assessment of the patient's response must be conducted within 4 weeks prior to completion of this course of treatment. This assessment, which will be used to determine eligibility for further continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with adalimumab. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

It is recommended that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised adalimumab treatment.

Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may re-commence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle

**Authority required**

Continuing treatment (Face, hand, foot)

Continuing PBS-subsidised treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over:

(a) who have a documented history of severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot; and

(b) whose most recent course of PBS-subsidised biological treatment for this condition in this Treatment Cycle was with adalimumab; and

(c) who have demonstrated an adequate response to treatment with adalimumab.

An adequate response to adalimumab treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the pre-biological treatment baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the pre-biological treatment baseline value.

This assessment must be provided to Medicare Australia no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with adalimumab, the assessment of response must be after a minimum of 12 weeks of treatment with an initial course.

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Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) the completed Psoriasis Area and Severity Index (PASI) calculation sheet and face, hand, foot area diagrams along with the date of the assessment of the patient's condition [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].

The most recent PASI assessment must be no more than 1 month old at the time of application.

A maximum of 24 weeks of treatment with adalimumab will be authorised under this restriction.

Where fewer than 5 repeats are requested at the time of the authority application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for continuing authority applications, or for treatment that would otherwise extend the treatment period beyond 24 weeks.

A PASI assessment of the patient's response must be conducted within 4 weeks prior to completion of this course of treatment. This assessment, which will be used to determine eligibility for further continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with adalimumab. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

It is recommended that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised adalimumab treatment.

The PASI assessment for continuing treatment must be performed on the same affected area assessed at baseline.

Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may re-commence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle

**Note**

Any queries concerning the arrangements to prescribe adalimumab may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe adalimumab should be forwarded to:

Medicare Australia

Prior Written Approval of Specialised Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

**Note**

TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, etanercept, infliximab and ustekinumab, for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological agents' appears in the following NOTES and restrictions, it only refers to adalimumab, etanercept, infliximab and ustekinumab.

From 1 March 2010, all patients will be able to commence a 'Biological Treatment Cycle' (Cycle), where they may trial adalimumab, etanercept, infliximab or ustekinumab without having to meet the initial treatment criteria, that is they will not need to experience a disease flare when swapping to an alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

A patient who received PBS-subsidised biological agent treatment for chronic plaque psoriasis prior to 1 March 2010 is considered to be in their first Cycle as of 1 March 2010.

Patients are eligible for PBS-subsidised treatment with only 1 biological agent at any 1 time.

Within the same Treatment Cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for a PBS-subsidised biological agent, they must change to an alternate agent if they wish to continue PBS-subsidised biological treatment. A patient who, prior to 1 March 2010, was authorised to receive PBS-subsidised initial treatment for chronic plaque psoriasis with the same agent twice, is exempt from this condition in respect of applications approved prior to 1 March 2010.

Patients must be assessed for response to each course of continuing treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a Treatment Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological agent therapy before they are eligible to commence the next Cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological agent treatment in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Treatment Cycle.

Patients for whom a break in PBS-subsidised therapy of less than 5 years duration has occurred, and, who have failed therapy fewer than 3 times within a particular Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | Brand Name and Manufacturer |
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Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle.

There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.

How to prescribe biological agents for the treatment of severe chronic plaque psoriasis after 1 March 2010.

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Application for approval for initial treatment.

Applications for a course of initial treatment should be made in the following situations:

(i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); or

(ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under '(4) Swapping therapy' below]; or

(iii) patients who wish to re-commence treatment following a break in PBS-subsidised therapy with that agent (Initial 2).

All applications for initial treatment will be limited to provide for a maximum of 16 weeks of treatment in the case of adalimumab and etanercept, 22 weeks of treatment in the case of infliximab and 28 weeks of treatment in the case of ustekinumab.

(2) Assessment of response to initial treatment.

When prescribing initial treatment with a biological agent, a PASI assessment must be conducted after at least 12 weeks of treatment. This assessment must be submitted to Medicare Australia within 1 month of the completion of this initial treatment course. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

(3) Application for continuing treatment.

Following the completion of an initial treatment course of a biological agent to which an adequate response has been demonstrated, patients may qualify to receive up to 24 weeks of continuing treatment with that biological agent. Patients are eligible to continue to receive continuous treatment with 24 week courses providing they continue to sustain a response.

For second and subsequent courses of PBS-subsidised treatment with adalimumab, etanercept, infliximab or ustekinumab it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

Where a response assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to sustain a response to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

(4) Swapping therapy.

Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate agent within the same Treatment Cycle without having to requalify with respect to disease severity (i.e. a PASI score of greater than 15), or prior treatment requirements.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

Patients may trial an alternate biological agent at any time, regardless of whether they are receiving therapy with a biological agent at the time of the application or not. However, they cannot swap to a particular agent if they have failed to respond to treatment with that particular agent within the same Cycle.

Patients who commenced treatment with adalimumab prior to 1 June 2009 or ustekinumab prior to 1 March 2010 access these interchangeability arrangements in the same way as patients who have not.

To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the agent being ceased.

(5) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated, based on the baseline PASI assessment submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment authority is submitted within a Treatment Cycle and subsequent response will be assessed according to this revised PASI score.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatment applications.

(6) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

Patients who wish to trial a second or subsequent Biological Treatment Cycle, following a break in PBS-subsidised biological therapy of at least 5 years, must requalify for initial treatment according to the criteria of the relevant restriction and index of disease severity. Patients must have had at least 1 prior treatment, as listed in the criteria, for a minimum of 6 weeks, and must have a PASI assessment conducted preferably whilst still on treatment, but no later than 1 month following cessation of treatment. The PASI assessment must be no older than 1 month at the time of application.

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | Brand Name and Manufacturer | |
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| | **Note**<br>No applications for increased maximum quantities and/or repeats will be authorised. | | | | | | | |
| | **Note**<br>Special Pricing Arrangements apply. | | | | | | | |
| 9428F | adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL cartridges | 1 | 5 | .. | 1774.57 | 36.10 | Humira | VE |
| 9427E | adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes | 1 | 5 | .. | 1774.57 | 36.10 | Humira | VE |

**CERTOLIZUMAB PEGOL**

**Authority required**

Initial 1 (new patient or patient re-commencing after a break of more than 24 months)

Initial PBS-subsidised treatment with certolizumab pegol, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of adults who:

(a) have severe active rheumatoid arthritis; and

(b) have received no PBS-subsidised treatment with a bDMARD for this condition in the previous 24 months; and

(c) have failed, in the 24 months immediately prior to the date of application, to achieve an adequate response to at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs), which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be:

— hydroxychloroquine at a dose of at least 200 mg daily; or

— leflunomide at a dose of at least 10 mg daily; or

— sulfasalazine at a dose of at least 2 g daily.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, then the 6 months of intensive DMARD treatment must include at least 3 months continuous treatment with each of at least 2 of the DMARDs:

— hydroxychloroquine at a dose of at least 200 mg daily; and/or

— leflunomide at a dose of at least 10 mg daily; and/or

— sulfasalazine at a dose of at least 2 g daily.

The application must include details of the contraindication or intolerance to methotrexate. Details of the toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose can be found on the Medicare Australia website [www.medicareaustralia.gov.au]. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

If 3 or more of methotrexate, hydroxychloroquine, leflunomide and sulfasalazine are contraindicated according to the relevant TGA-approved product information or cannot be tolerated at the doses specified above, then one or more of the following DMARDs may be used in place of these agents in order to satisfy the requirement for a trial of 6 months of intensive DMARD therapy with at least 2 DMARDs taken continuously for at least 3 months each:

— azathioprine at a dose of at least 1 mg/kg per day; and/or

— cyclosporin at a dose of at least 2 mg/kg/day; and/or

— sodium aurothiomalate at a dose of 50 mg weekly.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances. Details of the toxicities, including severity, which will be accepted as a reason for substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial can be found on the Medicare Australia website [www.medicareaustralia.gov.au].

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance and dose for each DMARD must be provided in the authority application. Details of the toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy can be found on the Medicare Australia website [www.medicareaustralia.gov.au].

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L;

AND either

(i) a total active joint count of at least 20 active (swollen and tender) joints; or

(ii) at least 4 active joints from the following list of major joints:

— elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

— shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

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The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reason this criterion cannot be satisfied.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and

(3) a signed patient acknowledgement.

A maximum of 18 to 20 weeks of treatment depending on the dosage regimen will be authorised under this restriction.

Where fewer than 5 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 18 or 20 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Assessment of a patient's response to an initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with certolizumab pegol.

Patients who fail to demonstrate a response to treatment with certolizumab pegol under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition

**Authority required**

Initial 2 (change or re-commencement after break of less than 24 months)

Initial course of PBS-subsidised treatment with certolizumab pegol, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of adults who:

(a) have a documented history of severe active rheumatoid arthritis; and

(b) have received prior PBS-subsidised bDMARD treatment for this condition and are eligible to receive further bDMARD therapy.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].

Applications for patients who have received PBS-subsidised treatment with certolizumab pegol and who wish to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised certolizumab pegol treatment, within the timeframes specified below.

A maximum of 18 to 20 weeks of treatment depending on the dosage regimen will be authorised under this restriction.

Where fewer than 5 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 18 or 20 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Where the most recent course of PBS-subsidised certolizumab pegol treatment was approved under either of the initial 1 or 2 treatment restrictions, patients must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be provided to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised certolizumab pegol treatment was approved under the continuing treatment criteria, patients must have been assessed for response, and the assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Patients who fail to demonstrate a response to treatment with certolizumab pegol under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition

**Authority required**

Continuing treatment

Continuing PBS-subsidised treatment with certolizumab pegol, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of adults:

(a) who have a documented history of severe active rheumatoid arthritis; and

(b) who have demonstrated an adequate response to treatment with certolizumab pegol; and

(c) whose most recent course of PBS-subsidised bDMARD treatment was with certolizumab pegol.

An adequate response to treatment is defined as:

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an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(i) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(ii) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

— elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

— shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].

A maximum of 24 weeks of treatment will be approved under this restriction.

Where fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

All applications for continuing treatment with certolizumab pegol must include a measurement of response to the prior course of therapy. This assessment must be provided to Medicare Australia no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with certolizumab pegol, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.

Patients who fail to demonstrate a response to treatment with certolizumab pegol under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition

**Note**

Any queries concerning the arrangements to prescribe certolizumab pegol may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Further prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe certolizumab pegol should be forwarded to:

Medicare Australia

Prior Written Approval of Specialised Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

**Note**

TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying anti-rheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab) and the T-cell co-stimulation modulator (abatacept).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

PBS-subsidised abatacept, golimumab, infliximab and rituximab must be used in combination with methotrexate at a dose of at least 7.5 mg weekly. Where a patient cannot tolerate 7.5 mg of methotrexate weekly, they are eligible to receive PBS-subsidised adalimumab, certolizumab pegol, etanercept and tocilizumab.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:

— a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,

— a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and

— once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact Medicare Australia on 1800 700 270.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | Brand Name and Manufacturer |
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The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or

(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or

(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or

(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab and tocilizumab, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to Medicare Australia within 4 weeks.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

Abatacept patients:

Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients:

A further application may be submitted to Medicare Australia 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Rituximab patients:

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.

Abatacept patients:

Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the

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subcutaneous formulation.

In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

**Note**

(3) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and Medicare Australia will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

**Note**

Special Pricing Arrangements apply.

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 3425G | certolizumab pegol 200 mg/mL injection, 2 x 1 mL syringes | 1 | 5 | .. | 1708.85 | 36.10 | Cimzia | UC |

**ETANERCEPT**

**Authority required**

TREATMENT OF PATIENTS UNDER 18 YEARS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing of etanercept under the Pharmaceutical Benefits Scheme (PBS) for patients under 18 years with severe chronic plaque psoriasis.

Applications for treatment of this condition will be limited to provide patients with a maximum of 24 weeks of therapy per course of treatment. A maximum of 16 weeks treatment with etanercept will be authorised for the primary application. The balance, a further 8 weeks treatment, will be authorised if the submitted Psoriasis Area and Severity Index (PASI) assessment demonstrates an adequate response to treatment. Where fewer than 3 repeats are requested at the time of the authority application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone.

Once a patient has failed to respond to treatment 2 times, they must have, at a minimum, a 12 month break. The length of a treatment break is measured from the date the most recent treatment was stopped to the date of the first application for initial treatment.

There are separate restrictions for treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Application for approval for initial treatment.

Applications for a course of initial treatment should be made for patients who have received no prior PBS-subsidised biological treatment and wish to commence such therapy.

(2) Applications for approval for re-treatment.

Applications for re-treatment with etanercept should be made in the following situations:

(i) a patient who has received prior PBS-subsidised etanercept and experiences a disease flare, and wishes to start a second or subsequent treatment course with etanercept following a break of less than 12 months in PBS-subsidised therapy; or

(ii) a patient who has received and failed to respond to prior PBS-subsidised etanercept and wishes to start a second or subsequent treatment course following a break of less than 12 months in PBS-subsidised therapy.

For psoriasis affecting the whole body:

Patients are eligible for re-treatment due to disease flare if there is a 50% or greater change in the patients PASI score or the patient has a current PASI score of greater than 15, compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept.

For psoriasis affecting the face, hand or foot:

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | Brand Name and Manufacturer |
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Patients are eligible for re-treatment due to disease flare if:

(i) all subscores are rated moderate to severe or 2 of the three subscores are rated severe to very severe; OR

(ii) the skin area affected is a 50% or greater change or the area affected is 30% or more of the face, palm of a hand or sole of a foot, compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept.

(3) Applications for approval for completion of a course

Applications for a further 8 weeks of treatment to allow for completion of 24 weeks of therapy should be submitted with a PASI assessment.

The PASI assessment must be conducted after at least 12 weeks of treatment.

This assessment must be submitted to Department of Human Services (the Department) within 1 month of the completion of 12 weeks of treatment. Where a response assessment is not undertaken and submitted to the Department within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department on 1800 700 270 to discuss.

(4) Baseline measurements to determine response.

The Department will determine whether a response to treatment has been demonstrated, based on the baseline PASI assessment submitted with the first authority application for etanercept. However, prescribers may provide new baseline measurements any time that an initial or re-treatment authority is submitted and subsequent response will be assessed according to this revised PASI score.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of gaining approval for the remainder of 24 weeks treatment.

(5) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment course with etanercept following a break in PBS-subsidised etanercept therapy of at least 12 months , must requalify for treatment under the initial treatment restriction. The most recent PASI assessment must be no more than 1 month old at the time of application.

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment (whole body)

**The Treatment criteria is:**

Must be treated by a dermatologist,

**AND the Population criteria is:**

Patient must be under 18 years of age and a parent or authorised guardian must have signed a patient acknowledgement,

**AND the Clinical criteria is:**

The treatment must be as systemic monotherapy; OR

The treatment must be in combination with methotrexate,

**AND the Clinical criteria is:**

Patient must have lesions present for at least 6 months from the time of initial diagnosis,

**AND the Clinical criteria is:**

Patient must not have received any PBS-subsidised treatment with etanercept for this condition for at least 12 months; OR

Patient must not have received any prior PBS-subsidised treatment with etanercept for this condition,

**AND the Clinical criteria is:**

Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 3 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; and/or (ii) methotrexate at a dose of at least 10 mg or 10 mg per square metre weekly (whichever is lowest) for at least 6 weeks; and/or (iii) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks,

**AND the Clinical criteria is:**

Patient must not receive more than 16 weeks of treatment with etanercept under this restriction.

Where treatment with any of the above-mentioned drugs was contraindicated according to the relevant TGA-approved Product Information, or where phototherapy was contraindicated, details must be provided at the time of application.

Where intolerance to phototherapy, methotrexate and/or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in a patient at the time of the application:

(a) A current Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.

(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 1 month following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than 1 month old at the time of application.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

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(b) a completed Severe Chronic Plaque Psoriasis in Patients Less Than 18 Years PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition and

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy]; and

(iii) the parent or authorised guardian signed patient and prescriber acknowledgements.

Where a patient has had a 12 month treatment break, the length of the break is measured from the date the most recent treatment was stopped to the date of the application to re-commence treatment.

**Note**
Details of acceptable toxicities including severity, associated with phototherapy, methotrexate and acitretin, can be found on the Department of Human Services website at www.humanservices.gov.au

**Note**
Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

**Note**
No increase in the maximum quantity or number of units may be authorised.

**Note**
No increase in the maximum number of repeats may be authorised.

**Note**
Special Pricing Arrangements apply.

**Authority required**
TREATMENT OF PATIENTS UNDER 18 YEARS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing of etanercept under the Pharmaceutical Benefits Scheme (PBS) for patients under 18 years with severe chronic plaque psoriasis.

Applications for treatment of this condition will be limited to provide patients with a maximum of 24 weeks of therapy per course of treatment. A maximum of 16 weeks treatment with etanercept will be authorised for the primary application. The balance, a further 8 weeks treatment, will be authorised if the submitted Psoriasis Area and Severity Index (PASI) assessment demonstrates an adequate response to treatment. Where fewer than 3 repeats are requested at the time of the authority application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone.

Once a patient has failed to respond to treatment 2 times, they must have, at a minimum, a 12 month break. The length of a treatment break is measured from the date the most recent treatment was stopped to the date of the first application for initial treatment.

There are separate restrictions for treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Application for approval for initial treatment.

Applications for a course of initial treatment should be made for patients who have received no prior PBS-subsidised biological treatment and wish to commence such therapy.

(2) Applications for approval for re-treatment.

Applications for re-treatment with etanercept should be made in the following situations:

(i) a patient who has received prior PBS-subsidised etanercept and experiences a disease flare, and wishes to start a second or subsequent treatment course with etanercept following a break of less than 12 months in PBS-subsidised therapy; or

(ii) a patient who has received and failed to respond to prior PBS-subsidised etanercept and wishes to start a second or subsequent treatment course following a break of less than 12 months in PBS-subsidised therapy.

For psoriasis affecting the whole body:

Patients are eligible for re-treatment due to disease flare if there is a 50% or greater change in the patients PASI score or the patient has a current PASI score of greater than 15, compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept.

For psoriasis affecting the face, hand or foot:

Patients are eligible for re-treatment due to disease flare if:

(i) all subscores are rated moderate to severe or 2 of the three subscores are rated severe to very severe; OR

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|---|---|---|---|---|---|---|---|

(ii) the skin area affected is a 50% or greater change or the area affected is 30% or more of the face, palm of a hand or sole of a foot, compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept.

(3) Applications for approval for completion of a course

Applications for a further 8 weeks of treatment to allow for completion of 24 weeks of therapy should be submitted with a PASI assessment.

The PASI assessment must be conducted after at least 12 weeks of treatment.

This assessment must be submitted to Department of Human Services (the Department) within 1 month of the completion of 12 weeks of treatment. Where a response assessment is not undertaken and submitted to the Department within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department on 1800 700 270 to discuss.

(4) Baseline measurements to determine response.

The Department will determine whether a response to treatment has been demonstrated, based on the baseline PASI assessment submitted with the first authority application for etanercept. However, prescribers may provide new baseline measurements any time that an initial or re-treatment authority is submitted and subsequent response will be assessed according to this revised PASI score.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of gaining approval for the remainder of 24 weeks treatment.

(5) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment course with etanercept following a break in PBS-subsidised etanercept therapy of at least 12 months , must requalify for treatment under the initial treatment restriction. The most recent PASI assessment must be no more than 1 month old at the time of application.

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment or Re-treatment (Whole body) - balance of first supply

**The Treatment criteria is:**

Must be treated by a dermatologist,

**AND the Clinical criteria is:**

The treatment must be as systemic monotherapy; OR

The treatment must be in combination with methotrexate,

**AND the Clinical criteria is:**

Patient must have received insufficient therapy under the Initial treatment (whole body) restriction for severe chronic plaque psoriasis to complete 16 weeks treatment; OR

Patient must have received insufficient therapy under the Re-treatment (whole body) restriction for severe chronic plaque psoriasis to complete 16 weeks treatment,

**AND the Clinical criteria is:**

The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Note**

Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

**Note**

No increase in the maximum quantity or number of units may be authorised.

**Note**

No increase in the maximum number of repeats may be authorised.

**Note**

Special Pricing Arrangements apply.

**Authority required**

TREATMENT OF PATIENTS UNDER 18 YEARS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing of etanercept under the Pharmaceutical Benefits Scheme (PBS) for patients under 18 years with severe chronic plaque psoriasis.

Applications for treatment of this condition will be limited to provide patients with a maximum of 24 weeks of therapy per course of treatment. A maximum of 16 weeks treatment with etanercept will be authorised for the primary application. The balance, a further 8 weeks treatment, will be authorised if the submitted Psoriasis Area and Severity Index (PASI) assessment demonstrates an adequate response to treatment. Where fewer than 3 repeats are requested at the time of the authority application, authority approvals for sufficient repeats to complete a maximum of 16 weeks

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of treatment may be requested by telephone.

Once a patient has failed to respond to treatment 2 times, they must have, at a minimum, a 12 month break. The length of a treatment break is measured from the date the most recent treatment was stopped to the date of the first application for initial treatment.

There are separate restrictions for treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Application for approval for initial treatment.

Applications for a course of initial treatment should be made for patients who have received no prior PBS-subsidised biological treatment and wish to commence such therapy.

(2) Applications for approval for re-treatment.

Applications for re-treatment with etanercept should be made in the following situations:

(i) a patient who has received prior PBS-subsidised etanercept and experiences a disease flare, and wishes to start a second or subsequent treatment course with etanercept following a break of less than 12 months in PBS-subsidised therapy; or

(ii) a patient who has received and failed to respond to prior PBS-subsidised etanercept and wishes to start a second or subsequent treatment course following a break of less than 12 months in PBS-subsidised therapy.

For psoriasis affecting the whole body:

Patients are eligible for re-treatment due to disease flare if there is a 50% or greater change in the patients PASI score or the patient has a current PASI score of greater than 15, compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept.

For psoriasis affecting the face, hand or foot:

Patients are eligible for re-treatment due to disease flare if:

(i) all subscores are rated moderate to severe or 2 of the three subscores are rated severe to very severe; OR

(ii) the skin area affected is a 50% or greater change or the area affected is 30% or more of the face, palm of a hand or sole of a foot, compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept.

(3) Applications for approval for completion of a course

Applications for a further 8 weeks of treatment to allow for completion of 24 weeks of therapy should be submitted with a PASI assessment.

The PASI assessment must be conducted after at least 12 weeks of treatment.

This assessment must be submitted to Department of Human Services (the Department) within 1 month of the completion of 12 weeks of treatment. Where a response assessment is not undertaken and submitted to the Department within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department on 1800 700 270 to discuss.

(4) Baseline measurements to determine response.

The Department will determine whether a response to treatment has been demonstrated, based on the baseline PASI assessment submitted with the first authority application for etanercept. However, prescribers may provide new baseline measurements any time that an initial or re-treatment authority is submitted and subsequent response will be assessed according to this revised PASI score.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of gaining approval for the remainder of 24 weeks treatment.

(5) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment course with etanercept following a break in PBS-subsidised etanercept therapy of at least 12 months , must requalify for treatment under the initial treatment restriction. The most recent PASI assessment must be no more than 1 month old at the time of application.

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment or Re-treatment (Whole body) - completion of course

**The Treatment criteria is:**

Must be treated by a dermatologist,

**AND the Clinical criteria is:**

The treatment must be as systemic monotherapy; OR

The treatment must be in combination with methotrexate,

**AND the Clinical criteria is:**

Patient must have received 16 weeks treatment under the Initial treatment (whole body) restriction for severe chronic plaque psoriasis; OR

Patient must have received 16 weeks treatment under the Re-treatment (whole body) restriction for severe chronic plaque psoriasis,

**AND the Clinical criteria is:**

Patient must have demonstrated an adequate response to treatment,

**AND the Clinical criteria is:**

Patient must not receive more than 8 weeks of treatment with etanercept under this restriction.

An adequate response to treatment is defined as:

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A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, when compared with the pre-etanercept treatment baseline value.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) the completed current Psoriasis Area and Severity Index (PASI) calculation sheet including the date of assessment of the patient's condition.

The same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of gaining approval for the remainder of 24 weeks treatment.

A PASI assessment of the patient's response to the initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for a further 8 weeks of treatment, must be submitted no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with etanercept.

**Note**
It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their initial 16 week treatment course to ensure continuity of treatment for those patients who meet the eligibility criterion for a further 8 weeks of PBS-subsidised etanercept treatment.

**Note**
In circumstances where it is not possible to submit a response assessment after 12 weeks of treatment, please call the Department of Human Services on 1800 700 270 to discuss.

**Note**
The Department of Human Services will determine whether a response to treatment has been demonstrated, based on the baseline PASI assessment submitted with the first authority application for etanercept.

**Note**
Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

**Note**
No increase in the maximum quantity or number of units may be authorised.

**Note**
No increase in the maximum number of repeats may be authorised.

**Note**
Special Pricing Arrangements apply.

**Authority required**
TREATMENT OF PATIENTS UNDER 18 YEARS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing of etanercept under the Pharmaceutical Benefits Scheme (PBS) for patients under 18 years with severe chronic plaque psoriasis.

Applications for treatment of this condition will be limited to provide patients with a maximum of 24 weeks of therapy per course of treatment. A maximum of 16 weeks treatment with etanercept will be authorised for the primary application. The balance, a further 8 weeks treatment, will be authorised if the submitted Psoriasis Area and Severity Index (PASI) assessment demonstrates an adequate response to treatment. Where fewer than 3 repeats are requested at the time of the authority application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone.

Once a patient has failed to respond to treatment 2 times, they must have, at a minimum, a 12 month break. The length of a treatment break is measured from the date the most recent treatment was stopped to the date of the first application for initial treatment.

There are separate restrictions for treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Application for approval for initial treatment.

Applications for a course of initial treatment should be made for patients who have received no prior PBS-subsidised biological treatment and wish to commence such therapy.

(2) Applications for approval for re-treatment.

Applications for re-treatment with etanercept should be made in the following situations:

(i) a patient who has received prior PBS-subsidised etanercept and experiences a disease flare, and wishes to start a second or subsequent treatment course with etanercept following a break of less than 12 months in PBS-subsidised therapy; or

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(ii) a patient who has received and failed to respond to prior PBS-subsidised etanercept and wishes to start a second or subsequent treatment course following a break of less than 12 months in PBS-subsidised therapy.

For psoriasis affecting the whole body:

Patients are eligible for re-treatment due to disease flare if there is a 50% or greater change in the patients PASI score or the patient has a current PASI score of greater than 15, compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept.

For psoriasis affecting the face, hand or foot:

Patients are eligible for re-treatment due to disease flare if:

(i) all subscores are rated moderate to severe or 2 of the three subscores are rated severe to very severe; OR

(ii) the skin area affected is a 50% or greater change or the area affected is 30% or more of the face, palm of a hand or sole of a foot, compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept.

(3) Applications for approval for completion of a course

Applications for a further 8 weeks of treatment to allow for completion of 24 weeks of therapy should be submitted with a PASI assessment.

The PASI assessment must be conducted after at least 12 weeks of treatment.

This assessment must be submitted to Department of Human Services (the Department) within 1 month of the completion of 12 weeks of treatment. Where a response assessment is not undertaken and submitted to the Department within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department on 1800 700 270 to discuss.

(4) Baseline measurements to determine response.

The Department will determine whether a response to treatment has been demonstrated, based on the baseline PASI assessment submitted with the first authority application for etanercept. However, prescribers may provide new baseline measurements any time that an initial or re-treatment authority is submitted and subsequent response will be assessed according to this revised PASI score.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of gaining approval for the remainder of 24 weeks treatment.

(5) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment course with etanercept following a break in PBS-subsidised etanercept therapy of at least 12 months , must requalify for treatment under the initial treatment restriction. The most recent PASI assessment must be no more than 1 month old at the time of application.

Severe chronic plaque psoriasis

Treatment Phase: Re-treatment (Whole body)

**The Treatment criteria is:**

Must be treated by a dermatologist,

**AND the Population criteria is:**

Patient must be under 18 years of age,

**AND the Clinical criteria is:**

The treatment must be as systemic monotherapy; OR

The treatment must be in combination with methotrexate,

**AND the Clinical criteria is:**

Patient must have a documented history of severe chronic plaque psoriasis of the whole body,

**AND the Clinical criteria is:**

Patient must have received prior PBS-subsidised treatment with etanercept for this condition in the past 12 months,

**AND the Clinical criteria is:**

Patient must have demonstrated a response to etanercept and experienced a disease flare; OR

Patient must not have failed more than once to achieve an adequate response with etanercept,

**AND the Clinical criteria is:**

Patient must not receive more than 16 weeks of treatment with etanercept under this restriction.

A patient is eligible for re-treatment due to disease flare if there is a 50% or greater change in the patients PASI score or the patient has a current PASI score of greater than 15, compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis in Patients Less Than 18 Years PBS Authority Application - Supporting Information which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's

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condition; and

(ii) details of prior etanercept treatment, including date ceased.

Where a patient has had a treatment break the length of the break is measured from the date the most recent treatment was stopped to the date of the application for further treatment.

**Note**

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

**Note**

No increase in the maximum quantity or number of units may be authorised.

**Note**

No increase in the maximum number of repeats may be authorised.

**Note**

Special Pricing Arrangements apply.

**Authority required**

TREATMENT OF PATIENTS UNDER 18 YEARS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing of etanercept under the Pharmaceutical Benefits Scheme (PBS) for patients under 18 years with severe chronic plaque psoriasis.

Applications for treatment of this condition will be limited to provide patients with a maximum of 24 weeks of therapy per course of treatment. A maximum of 16 weeks treatment with etanercept will be authorised for the primary application. The balance, a further 8 weeks treatment, will be authorised if the submitted Psoriasis Area and Severity Index (PASI) assessment demonstrates an adequate response to treatment. Where fewer than 3 repeats are requested at the time of the authority application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone.

Once a patient has failed to respond to treatment 2 times, they must have, at a minimum, a 12 month break. The length of a treatment break is measured from the date the most recent treatment was stopped to the date of the first application for initial treatment.

There are separate restrictions for treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Application for approval for initial treatment.

Applications for a course of initial treatment should be made for patients who have received no prior PBS-subsidised biological treatment and wish to commence such therapy.

(2) Applications for approval for re-treatment.

Applications for re-treatment with etanercept should be made in the following situations:

(i) a patient who has received prior PBS-subsidised etanercept and experiences a disease flare, and wishes to start a second or subsequent treatment course with etanercept following a break of less than 12 months in PBS-subsidised therapy; or

(ii) a patient who has received and failed to respond to prior PBS-subsidised etanercept and wishes to start a second or subsequent treatment course following a break of less than 12 months in PBS-subsidised therapy.

For psoriasis affecting the whole body:

Patients are eligible for re-treatment due to disease flare if there is a 50% or greater change in the patients PASI score or the patient has a current PASI score of greater than 15, compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept.

For psoriasis affecting the face, hand or foot:

Patients are eligible for re-treatment due to disease flare if:

(i) all subscores are rated moderate to severe or 2 of the three subscores are rated severe to very severe; OR

(ii) the skin area affected is a 50% or greater change or the area affected is 30% or more of the face, palm of a hand or sole of a foot, compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept.

(3) Applications for approval for completion of a course

Applications for a further 8 weeks of treatment to allow for completion of 24 weeks of therapy should be submitted with a PASI assessment.

The PASI assessment must be conducted after at least 12 weeks of treatment.

This assessment must be submitted to Department of Human Services (the Department) within 1 month of the completion of 12 weeks of treatment. Where a response assessment is not undertaken and submitted to the Department within these timeframes, the patient will be deemed

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to have failed to respond to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department on 1800 700 270 to discuss.

(4) Baseline measurements to determine response.

The Department will determine whether a response to treatment has been demonstrated, based on the baseline PASI assessment submitted with the first authority application for etanercept. However, prescribers may provide new baseline measurements any time that an initial or re-treatment authority is submitted and subsequent response will be assessed according to this revised PASI score.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of gaining approval for the remainder of 24 weeks treatment.

(5) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment course with etanercept following a break in PBS-subsidised etanercept therapy of at least 12 months , must requalify for treatment under the initial treatment restriction. The most recent PASI assessment must be no more than 1 month old at the time of application.

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment (Face, hand, foot)

**The Treatment criteria is:**

Must be treated by a dermatologist,

**AND the Population criteria is:**

Patient must be under 18 years of age and a parent or authorised guardian must have signed a patient acknowledgement,

**AND the Clinical criteria is:**

The treatment must be as systemic monotherapy; OR

The treatment must be in combination with methotrexate,

**AND the Clinical criteria is:**

Patient must have the plaque or plaques of the face, or palm of hand or sole of foot present for at least 6 months from the time of initial diagnosis,

**AND the Clinical criteria is:**

Patient must not have received any PBS-subsidised treatment with etanercept for this condition for at least 12 months; OR

Patient must not have received any prior PBS-subsidised treatment with etanercept for this condition,

**AND the Clinical criteria is:**

Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 3 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; and/or (ii) methotrexate at a dose of at least 10 mg or 10 mg per square metre weekly (whichever is lowest) for at least 6 weeks; and/or (iii)acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks ,

**AND the Clinical criteria is:**

Patient must not receive more than 16 weeks of treatment with etanercept under this restriction.

Where treatment with any of the above-mentioned drugs was contraindicated according to the relevant TGA-approved Product Information, or where phototherapy was contraindicated, details must be provided at the time of application.

Where intolerance to phototherapy, methotrexate and/or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in a patient at the time of the application:

(a) Chronic plaque psoriasis classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where:

(i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment; or

(ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment;

(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 1 month following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than 1 month old at the time of application.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis in Patients Less Than 18 Years PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets, and face, hand, foot area diagrams including the dates of assessment of the patient's condition

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy]; and

(iii) the parent or authorised guardian signed patient and prescriber acknowledgements.

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | Brand Name and Manufacturer |
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Where a patient has had a 12 month treatment break, the length of the break is measured from the date the most recent treatment was stopped to the date of the application to re-commence treatment.

**Note**

Details of acceptable toxicities including severity, associated with phototherapy, methotrexate and acitretin, can be found on the Department of Human Services website at www.humanservices.gov.au

**Note**

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

**Note**

No increase in the maximum quantity or number of units may be authorised.

**Note**

No increase in the maximum number of repeats may be authorised.

**Note**

Special Pricing Arrangements apply.

**Authority required**

TREATMENT OF PATIENTS UNDER 18 YEARS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing of etanercept under the Pharmaceutical Benefits Scheme (PBS) for patients under 18 years with severe chronic plaque psoriasis.

Applications for treatment of this condition will be limited to provide patients with a maximum of 24 weeks of therapy per course of treatment. A maximum of 16 weeks treatment with etanercept will be authorised for the primary application. The balance, a further 8 weeks treatment, will be authorised if the submitted Psoriasis Area and Severity Index (PASI) assessment demonstrates an adequate response to treatment. Where fewer than 3 repeats are requested at the time of the authority application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone.

Once a patient has failed to respond to treatment 2 times, they must have, at a minimum, a 12 month break. The length of a treatment break is measured from the date the most recent treatment was stopped to the date of the first application for initial treatment.

There are separate restrictions for treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Application for approval for initial treatment.

Applications for a course of initial treatment should be made for patients who have received no prior PBS-subsidised biological treatment and wish to commence such therapy.

(2) Applications for approval for re-treatment.

Applications for re-treatment with etanercept should be made in the following situations:

(i) a patient who has received prior PBS-subsidised etanercept and experiences a disease flare, and wishes to start a second or subsequent treatment course with etanercept following a break of less than 12 months in PBS-subsidised therapy; or

(ii) a patient who has received and failed to respond to prior PBS-subsidised etanercept and wishes to start a second or subsequent treatment course following a break of less than 12 months in PBS-subsidised therapy.

For psoriasis affecting the whole body:

Patients are eligible for re-treatment due to disease flare if there is a 50% or greater change in the patients PASI score or the patient has a current PASI score of greater than 15, compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept.

For psoriasis affecting the face, hand or foot:

Patients are eligible for re-treatment due to disease flare if:

(i) all subscores are rated moderate to severe or 2 of the three subscores are rated severe to very severe; OR

(ii) the skin area affected is a 50% or greater change or the area affected is 30% or more of the face, palm of a hand or sole of a foot, compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept.

(3) Applications for approval for completion of a course

Applications for a further 8 weeks of treatment to allow for completion of 24 weeks of therapy should be submitted with a PASI assessment.

The PASI assessment must be conducted after at least 12 weeks of treatment.

This assessment must be submitted to Department of Human Services (the Department) within 1 month of the completion of 12 weeks of

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treatment. Where a response assessment is not undertaken and submitted to the Department within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department on 1800 700 270 to discuss.

(4) Baseline measurements to determine response.

The Department will determine whether a response to treatment has been demonstrated, based on the baseline PASI assessment submitted with the first authority application for etanercept. However, prescribers may provide new baseline measurements any time that an initial or re-treatment authority is submitted and subsequent response will be assessed according to this revised PASI score.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of gaining approval for the remainder of 24 weeks treatment.

(5) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment course with etanercept following a break in PBS-subsidised etanercept therapy of at least 12 months , must requalify for treatment under the initial treatment restriction. The most recent PASI assessment must be no more than 1 month old at the time of application.

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment of Re-treatment (Face, hand, foot) - balance of first supply

**The Treatment criteria is:**

Must be treated by a dermatologist,

**AND the Clinical criteria is:**

The treatment must be as systemic monotherapy; OR

The treatment must be in combination with methotrexate,

**AND the Clinical criteria is:**

Patient must have received insufficient therapy under the Initial treatment (Face, hand, foot) restriction for severe chronic plaque psoriasis to complete 16 weeks treatment; OR

Patient must have received insufficient therapy under the Re-treatment (Face, hand, foot) restriction for severe chronic plaque psoriasis to complete 16 weeks treatment,

**AND the Clinical criteria is:**

The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Note**

Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

**Note**

No increase in the maximum quantity or number of units may be authorised.

**Note**

No increase in the maximum number of repeats may be authorised.

**Note**

Special Pricing Arrangements apply.

**Authority required**

TREATMENT OF PATIENTS UNDER 18 YEARS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing of etanercept under the Pharmaceutical Benefits Scheme (PBS) for patients under 18 years with severe chronic plaque psoriasis.

Applications for treatment of this condition will be limited to provide patients with a maximum of 24 weeks of therapy per course of treatment. A maximum of 16 weeks treatment with etanercept will be authorised for the primary application. The balance, a further 8 weeks treatment, will be authorised if the submitted Psoriasis Area and Severity Index (PASI) assessment demonstrates an adequate response to treatment. Where fewer than 3 repeats are requested at the time of the authority application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone.

Once a patient has failed to respond to treatment 2 times, they must have, at a minimum, a 12 month break. The length of a treatment break is measured from the date the most recent treatment was stopped to the date of the first application for initial treatment.

There are separate restrictions for treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Application for approval for initial treatment.

Applications for a course of initial treatment should be made for patients who have received no prior PBS-subsidised biological treatment and wish

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to commence such therapy.

(2) Applications for approval for re-treatment.

Applications for re-treatment with etanercept should be made in the following situations:

(i) a patient who has received prior PBS-subsidised etanercept and experiences a disease flare, and wishes to start a second or subsequent treatment course with etanercept following a break of less than 12 months in PBS-subsidised therapy; or

(ii) a patient who has received and failed to respond to prior PBS-subsidised etanercept and wishes to start a second or subsequent treatment course following a break of less than 12 months in PBS-subsidised therapy.

For psoriasis affecting the whole body:

Patients are eligible for re-treatment due to disease flare if there is a 50% or greater change in the patients PASI score or the patient has a current PASI score of greater than 15, compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept.

For psoriasis affecting the face, hand or foot:

Patients are eligible for re-treatment due to disease flare if:

(i) all subscores are rated moderate to severe or 2 of the three subscores are rated severe to very severe; OR

(ii) the skin area affected is a 50% or greater change or the area affected is 30% or more of the face, palm of a hand or sole of a foot, compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept.

(3) Applications for approval for completion of a course

Applications for a further 8 weeks of treatment to allow for completion of 24 weeks of therapy should be submitted with a PASI assessment.

The PASI assessment must be conducted after at least 12 weeks of treatment.

This assessment must be submitted to Department of Human Services (the Department) within 1 month of the completion of 12 weeks of treatment. Where a response assessment is not undertaken and submitted to the Department within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department on 1800 700 270 to discuss.

(4) Baseline measurements to determine response.

The Department will determine whether a response to treatment has been demonstrated, based on the baseline PASI assessment submitted with the first authority application for etanercept. However, prescribers may provide new baseline measurements any time that an initial or re-treatment authority is submitted and subsequent response will be assessed according to this revised PASI score.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of gaining approval for the remainder of 24 weeks treatment.

(5) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment course with etanercept following a break in PBS-subsidised etanercept therapy of at least 12 months , must requalify for treatment under the initial treatment restriction. The most recent PASI assessment must be no more than 1 month old at the time of application.

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment or Re-treatment (Face, hand, foot) - completion of course

**The Treatment criteria is:**

Must be treated by a dermatologist,

**AND the Clinical criteria is:**

The treatment must be as systemic monotherapy; OR

The treatment must be in combination with methotrexate,

**AND the Clinical criteria is:**

Patient must have received 16 weeks treatment under the Initial treatment (Face, hand, foot) restriction for severe chronic plaque psoriasis; OR

Patient must have received 16 weeks treatment under the Re-treatment (Face, hand, foot) restriction for severe chronic plaque psoriasis,

**AND the Clinical criteria is:**

Patient must have demonstrated an adequate response to treatment,

**AND the Clinical criteria is:**

Patient must not receive more than 8 weeks of treatment with etanercept under this restriction.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the PASI symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the pre-biological treatment baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the pre-biological treatment baseline value.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) the completed current Psoriasis Area and Severity Index (PASI) calculation sheet including the date of assessment of the patient's condition.

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The same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of gaining approval for the remainder of 24 weeks treatment.

A PASI assessment of the patient's response to the initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for a further 8 weeks of treatment, must be submitted no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with etanercept.

**Note**

It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their initial 16 week treatment course to ensure continuity of treatment for those patients who meet the eligibility criterion for a further 8 weeks of PBS-subsidised etanercept treatment.

**Note**

In circumstances where it is not possible to submit a response assessment after 12 weeks of treatment, please call the Department of Human Services on 1800 700 270 to discuss.

**Note**

The Department of Human Services will determine whether a response to treatment has been demonstrated, based on the baseline PASI assessment submitted with the first authority application for etanercept.

**Note**

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

**Note**

No increase in the maximum quantity or number of units may be authorised.

**Note**

No increase in the maximum number of repeats may be authorised.

**Note**

Special Pricing Arrangements apply.

**Authority required**

TREATMENT OF PATIENTS UNDER 18 YEARS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing of etanercept under the Pharmaceutical Benefits Scheme (PBS) for patients under 18 years with severe chronic plaque psoriasis.

Applications for treatment of this condition will be limited to provide patients with a maximum of 24 weeks of therapy per course of treatment. A maximum of 16 weeks treatment with etanercept will be authorised for the primary application. The balance, a further 8 weeks treatment, will be authorised if the submitted Psoriasis Area and Severity Index (PASI) assessment demonstrates an adequate response to treatment. Where fewer than 3 repeats are requested at the time of the authority application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone.

Once a patient has failed to respond to treatment 2 times, they must have, at a minimum, a 12 month break. The length of a treatment break is measured from the date the most recent treatment was stopped to the date of the first application for initial treatment.

There are separate restrictions for treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Application for approval for initial treatment.

Applications for a course of initial treatment should be made for patients who have received no prior PBS-subsidised biological treatment and wish to commence such therapy.

(2) Applications for approval for re-treatment.

Applications for re-treatment with etanercept should be made in the following situations:

(i) a patient who has received prior PBS-subsidised etanercept and experiences a disease flare, and wishes to start a second or subsequent treatment course with etanercept following a break of less than 12 months in PBS-subsidised therapy; or

(ii) a patient who has received and failed to respond to prior PBS-subsidised etanercept and wishes to start a second or subsequent treatment course following a break of less than 12 months in PBS-subsidised therapy.

For psoriasis affecting the whole body:

Patients are eligible for re-treatment due to disease flare if there is a 50% or greater change in the patients PASI score or the patient has a current PASI score of greater than 15, compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept.

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For psoriasis affecting the face, hand or foot:

Patients are eligible for re-treatment due to disease flare if:

(i) all subscores are rated moderate to severe or 2 of the three subscores are rated severe to very severe; OR

(ii) the skin area affected is a 50% or greater change or the area affected is 30% or more of the face, palm of a hand or sole of a foot, compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept.

(3) Applications for approval for completion of a course

Applications for a further 8 weeks of treatment to allow for completion of 24 weeks of therapy should be submitted with a PASI assessment.

The PASI assessment must be conducted after at least 12 weeks of treatment.

This assessment must be submitted to Department of Human Services (the Department) within 1 month of the completion of 12 weeks of treatment. Where a response assessment is not undertaken and submitted to the Department within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department on 1800 700 270 to discuss.

(4) Baseline measurements to determine response.

The Department will determine whether a response to treatment has been demonstrated, based on the baseline PASI assessment submitted with the first authority application for etanercept. However, prescribers may provide new baseline measurements any time that an initial or re-treatment authority is submitted and subsequent response will be assessed according to this revised PASI score.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of gaining approval for the remainder of 24 weeks treatment.

(5) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment course with etanercept following a break in PBS-subsidised etanercept therapy of at least 12 months , must requalify for treatment under the initial treatment restriction. The most recent PASI assessment must be no more than 1 month old at the time of application.

Severe chronic plaque psoriasis

Treatment Phase: Re-treatment (Face, hand, foot)

**The Treatment criteria is:**

Must be treated by a dermatologist,

**AND the Population criteria is:**

Patient must be under 18 years of age,

**AND the Clinical criteria is:**

The treatment must be as systemic monotherapy; OR

The treatment must be in combination with methotrexate,

**AND the Clinical criteria is:**

Patient must have a documented history of severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot,

**AND the Clinical criteria is:**

Patient must have received prior PBS-subsidised treatment with etanercept for this condition in the past 12 months,

**AND the Clinical criteria is:**

Patient must have demonstrated a response to etanercept and experienced a disease flare; OR

Patient must not have failed more than once to achieve an adequate response with etanercept,

**AND the Clinical criteria is:**

Patient must not receive more than 16 weeks of treatment with etanercept under this restriction.

A patient is eligible for re-treatment due to disease flare if:

(i) all subscores are rated moderate to severe or 2 of the 3 subscores are rated severe to very severe; or

(ii) the skin area affected is a 50% or greater change or the area affected is 30% or more of the face, palm of a hand or sole of a foot, compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept.

The authority application must be made in writing and must include :

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis in Patients Less Than 18 Years PBS Authority Application - Supporting Information which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area digrams including the dates of assessment of the patient's condition; and

(ii) details of prior etanercept treatment, including date ceased.

Where a patient has had a treatment break the length of the break is measured from the date the most recent treatment was stopped to the date of the application for further treatment.

**Note**

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|---|---|---|---|---|---|---|---|---|
| | Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). | | | | | | | |
| | Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au | | | | | | | |
| | Applications for authority to prescribe should be forwarded to: | | | | | | | |
| | Department of Human Services | | | | | | | |
| | Prior Written Approval of Complex Drugs | | | | | | | |
| | Reply Paid 9826 | | | | | | | |
| | GPO Box 9826 | | | | | | | |
| | HOBART TAS 7001 | | | | | | | |
| | **Note** | | | | | | | |
| | No increase in the maximum quantity or number of units may be authorised. | | | | | | | |
| | **Note** | | | | | | | |
| | No increase in the maximum number of repeats may be authorised. | | | | | | | |
| | **Note** | | | | | | | |
| | Special Pricing Arrangements apply. | | | | | | | |
| 1964J | ETANERCEPT Injection 50 mg in 1 mL single use auto-injector, 4, 1 | 1 | 3 | .. | 1774.58 | 36.10 | Enbrel | PF |
| 1963H | ETANERCEPT Injections 50 mg in 1 mL single use pre-filled syringes, 4, 1 | 1 | 3 | .. | 1774.58 | 36.10 | Enbrel | PF |
| 1954W | etanercept 25 mg injection [4 x 25 mg vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack | 2 | 3 | .. | *1774.57 | 36.10 | Enbrel | PF |
| | **ETANERCEPT** | | | | | | | |
| | **Authority required** | | | | | | | |
| | Initial 1 (new patient or patient recommencing after a break of more than 12 months). | | | | | | | |
| | Initial treatment, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of a patient aged 18 years or older who: | | | | | | | |
| | (a) has a documented history of juvenile idiopathic arthritis with onset prior to the age of 18 years; AND | | | | | | | |
| | (b) has received no PBS-subsidised treatment with a bDMARD for this condition in the previous 12 months; and | | | | | | | |
| | (c) has failed to achieve an adequate response to at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs), which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: | | | | | | | |
| | — hydroxychloroquine at a dose of at least 200 mg daily; or | | | | | | | |
| | — leflunomide at a dose of at least 10 mg daily; or | | | | | | | |
| | — sulfasalazine at a dose of at least 2 g daily. | | | | | | | |
| | If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, then the 6 months of intensive DMARD treatment must include at least 3 months continuous treatment with each of at least 2 of the DMARDs: | | | | | | | |
| | — hydroxychloroquine at a dose of at least 200 mg daily; and/or | | | | | | | |
| | — leflunomide at a dose of at least 10 mg daily; and/or | | | | | | | |
| | — sulfasalazine at a dose of at least 2 g daily. | | | | | | | |
| | The application must include details of the contraindication or intolerance to methotrexate. Details of the toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose can be found on the Medicare Australia website [www.medicareaustralia.gov.au]. The maximum tolerated dose of methotrexate must be documented in the application, if applicable. | | | | | | | |
| | If 3 or more of methotrexate, hydroxychloroquine, leflunomide and sulfasalazine are contraindicated according to the relevant TGA-approved product information or cannot be tolerated at the doses specified above, then one or more of the following DMARDs may be used in place of these agents in order to satisfy the requirement for a trial of 6 months of intensive DMARD therapy with at least 2 DMARDs taken continuously for at least 3 months each: | | | | | | | |
| | — azathioprine at a dose of at least 1 mg/kg per day; and/or | | | | | | | |
| | — cyclosporin at a dose of at least 2 mg/kg per day; and/or | | | | | | | |
| | — sodium aurothiomalate at a dose of 50 mg weekly. | | | | | | | |
| | The application must include details of the DMARDs trialed, their doses and duration of treatment, and all relevant contraindications and/or intolerances. Details of the toxicities, including severity, which will be accepted as a reason for substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial can be found on the Medicare Australia website [www.medicareaustralia.gov.au]. | | | | | | | |
| | The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or | | | | | | | |

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more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance and dose for each DMARD must be provided in the authority application. Details of the toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy can be found on the Medicare Australia website [www.medicareaustralia.gov.au].

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either

(i) an active joint count of at least 20 active (swollen and tender) joints; or

(ii) at least 4 active joints from the following list:

— elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

— shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and

(3) a signed patient acknowledgement.

A maximum of 16 weeks of treatment will be authorised under this restriction.

Where fewer than 3 repeats are requested at the time of the initial authority application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Assessment of a patient's response to an initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with etanercept.

If a patient fails to respond to treatment 3 times (twice with one agent and once with the other) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle. A patient may re-trial etanercept after a minimum of 5 years have elapsed between the date of the last approval for PBS-subsidised bDMARD therapy in the last treatment cycle and the date of the first application under a new treatment cycle

**Authority required**

Initial 2 (change or re-commencement after break of less than 12 months).

Initial PBS-subsidised treatment with etanercept by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of a patient aged 18 years or older who:

(a) has a documented history of juvenile idiopathic arthritis with onset prior to the age of 18 years; AND

(b) in this treatment cycle, has received prior PBS-subsidised treatment with adalimumab or etanercept for this condition; and

(c) has not failed PBS-subsidised therapy with etanercept for this condition more than once in the current treatment cycle.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].

Applications for a patient who has received PBS-subsidised treatment with etanercept in this treatment cycle and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised etanercept treatment, within the timeframes specified below.

A maximum of 16 weeks of treatment will be authorised under this restriction.

Where fewer than 3 repeats are requested at the time of the initial authority application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment with etanercept may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|

Where the most recent course of PBS-subsidised etanercept treatment was approved under either of the initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be provided to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised etanercept treatment was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to that particular course of bDMARD.

If a patient fails to respond to treatment 3 times (twice with one agent and once with the other) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle. A patient may re-trial etanercept after a minimum of 5 years have elapsed between the date of the last approval for PBS-subsidised bDMARD therapy in the last treatment cycle and the date of the first application under a new treatment cycle

**Note**

Any queries concerning the arrangements to prescribe etanercept may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe etanercept should be forwarded to:

Medicare Australia

Prior Written Approval of Specialised Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

**Note**

TREATMENT OF ADULT PATIENTS WITH A HISTORY OF JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab and etanercept for a patient over 18 years who has a history of juvenile idiopathic arthritis with onset prior to the age of 18 years. Where the term bDMARD appears in the following NOTES and restrictions, it refers to adalimumab and etanercept only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 2 bDMARDs at any one time.

From 1 November 2010, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to the alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

— continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy, and

— fail to respond, or to sustain a response to one PBS-subsidised bDMARD twice and the other PBS-subsidised bDMARD once only.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 5 year break in PBS-subsidised bDMARD therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date of the last approval for PBS-subsidised bDMARD therapy in the last treatment cycle and the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 November 2010 is considered to be in their first cycle as of 1 November 2010. A patient who has had a break in bDMARD treatment of at least 12 months immediately prior to making a new application, on or after 1 November 2010, will commence a new treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 12 months may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 12 months must commence a new treatment cycle. The length of the break in therapy is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 November 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or

(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 12 months (Initial 1); or

(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or

(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 12 months in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

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Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

A patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to the alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count and ESR/CRP) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 12 months.

A patient may trial the 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 twice within the current treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to the alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and Medicare Australia will assess response according to the revised baseline measurement.

(4) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 12 months, must requalify for treatment under the Initial 1 treatment restriction.

(5) Patients 'grandfathered' onto PBS-subsidised treatment with adalimumab.

A patient who commenced treatment with adalimumab for severe active juvenile idiopathic arthritis prior to 1 March 2010 and who continues to receive treatment at the time of application, may qualify for treatment under the initial 'grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment with adalimumab will be authorised under this criterion.

Following completion of the initial PBS-subsidised course, further applications for treatment with adalimumab will be assessed under the continuing treatment restriction.

'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must qualify for initial treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 12 month break in PBS-subsidised therapy' above for further details.

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 3447K | ETANERCEPT Injection 50 mg in 1 mL single use auto-injector, 4, 1 | 1 | 3 | .. | 1774.58 | 36.10 | Enbrel | PF |
| 3446J | ETANERCEPT Injections 50 mg in 1 mL single use pre-filled syringes, 4, 1 | 1 | 3 | .. | 1774.58 | 36.10 | Enbrel | PF |
| 3445H | etanercept 25 mg injection [4 x 25 mg vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack | 2 | 3 | .. | *1774.57 | 36.10 | Enbrel | PF |

**ETANERCEPT**

**Authority required**

Continuing treatment.

Continuing PBS-subsidised treatment, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of a patient aged 18 years or older:

(a) who has a documented history of severe active juvenile idiopathic arthritis with onset prior to the age of 18 years; and

(b) who has demonstrated an adequate response to treatment with etanercept; and

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(c) whose most recent course of PBS-subsidised bDMARD treatment was with etanercept.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(i) an active joint count of fewer than 10 active (swollen and tender) joints; or

(ii) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or

(iii) a reduction in the number of the following active joints, from at least 4, by at least 50%:

— elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

— shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].

A maximum of 24 weeks of treatment will be approved under this restriction.

Where fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

All applications for continuing treatment with etanercept must include a measurement of response to the prior course of therapy. This assessment must be provided to Medicare Australia no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with etanercept, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.

If a patient fails to respond to treatment 3 times (twice with one agent and once with the other) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle. A patient may re-trial etanercept after a minimum of 5 years have elapsed between the date of the last approval for PBS-subsidised bDMARD therapy in the last treatment cycle and the date of the first application under a new treatment cycle

**Note**

Any queries concerning the arrangements to prescribe etanercept may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe etanercept should be forwarded to:

Medicare Australia

Prior Written Approval of Specialised Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

**Note**

TREATMENT OF ADULT PATIENTS WITH A HISTORY OF JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab and etanercept for a patient over 18 years who has a history of juvenile idiopathic arthritis with onset prior to the age of 18 years. Where the term bDMARD appears in the following NOTES and restrictions, it refers to adalimumab and etanercept only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 2 bDMARDs at any one time.

From 1 November 2010, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to the alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

— continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy, and

— fail to respond, or to sustain a response to one PBS-subsidised bDMARD twice and the other PBS-subsidised bDMARD once only.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 5 year break in PBS-subsidised bDMARD therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date of the last approval for PBS-subsidised bDMARD therapy in the last treatment cycle and the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 November 2010 is considered to be in their first cycle as of 1 November 2010. A patient who has had a break in bDMARD treatment of at least 12 months immediately prior to making a new application, on or after 1 November 2010, will commence a new treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 12 months may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 12 months must commence a new treatment cycle. The length of the break in therapy is measured from the date the most recent treatment with PBS-subsidised

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bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 November 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or

(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 12 months (Initial 1); or

(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or

(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 12 months in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

A patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to the alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count and ESR/CRP) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 12 months.

A patient may trial the 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 twice within the current treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to the alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and Medicare Australia will assess response according to the revised baseline measurement.

(4) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 12 months, must requalify for treatment under the Initial 1 treatment restriction.

(5) Patients 'grandfathered' onto PBS-subsidised treatment with adalimumab.

A patient who commenced treatment with adalimumab for severe active juvenile idiopathic arthritis prior to 1 March 2010 and who continues to receive treatment at the time of application, may qualify for treatment under the initial 'grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment with adalimumab will be authorised under this criterion.

Following completion of the initial PBS-subsidised course, further applications for treatment with adalimumab will be assessed under the continuing treatment restriction.

'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must qualify

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| | for initial treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 12 month break in PBS-subsidised therapy' above for further details. | | | | | | | |
| 3450N | ETANERCEPT Injection 50 mg in 1 mL single use auto-injector, 4, 1 | 1 | 5 | .. | 1774.58 | 36.10 | Enbrel | PF |
| 3449M | ETANERCEPT Injections 50 mg in 1 mL single use pre-filled syringes, 4, 1 | 1 | 5 | .. | 1774.58 | 36.10 | Enbrel | PF |
| 3448L | etanercept 25 mg injection [4 x 25 mg vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack | 2 | 5 | .. | *1774.57 | 36.10 | Enbrel | PF |

**ETANERCEPT**

**Authority required**

Initial 1 (new patients)

Initial PBS-subsidised treatment with etanercept, by a rheumatologist, of an adult with active ankylosing spondylitis who has radiographically (plain X-ray) confirmed Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis and who has not received any PBS-subsidised treatment with either adalimumab, etanercept, golimumab or infliximab in this treatment cycle; AND

(a) who has 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) [for further information on the BASMI please refer to the Medicare Australia website at www.medicareaustralia.gov.au]; or

(iii) limitation of chest expansion relative to normal values for age and gender [for chest expansion normal values please refer to the Medicare Australia website at www.medicareaustralia.gov.au]; AND

(b) who has 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.

The application must include details of the NSAIDs trialled, their doses and duration of treatment. If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used.

If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication.

If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance. Details of the toxicities, including severity, which will be accepted for the purposes of administering this restriction can be found on the Medicare Australia website [www.medicareaustralia.gov.au].

For details on the appropriate minimum exercise program that will be accepted for the purposes of administering this restriction, please refer to the Medicare Australia website at www.medicareaustralia.gov.au.

The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of the initial application:

(a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale; AND

(b) an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 10 mg per L.

The BASDAI must be determined at the completion of the 3 month NSAID and exercise trial, but prior to ceasing NSAID treatment. The BASDAI must be no more than 1 month old at the time of initial application.

Both ESR and CRP measures should be provided with the initial treatment application and both must be no more than 1 month old. If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reason this criterion cannot be satisfied.

Authority applications 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 [www.medicareaustralia.gov.au] which must include the following:

(i) a copy of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and

(ii) a completed BASDAI Assessment Form [www.medicareaustralia.gov.au]; and

(iii) a completed Exercise Program Self Certification Form included in the supporting information form; and

(iv) a signed patient acknowledgment form.

The assessment of the patient's response to the initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted to Medicare Australia no later than 4 weeks from the cessation of that treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

A maximum of 16 weeks of treatment with etanercept will be approved under this criterion.

Where fewer than 3 repeats are initially requested with the authority prescription, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone.

Patients who fail to demonstrate a response to treatment with etanercept under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. Patients may re-trial etanercept after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised TNF-alfa antagonist was approved in this cycle and the date of the first application under a new cycle

**Authority required**

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | Brand Name and Manufacturer |
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Initial 2 (change or re-commencement for all patients)

Initial PBS-subsidised treatment with etanercept, by a rheumatologist, of an adult with a documented history of active ankylosing spondylitis who, in this treatment cycle, has received prior PBS-subsidised TNF-alfa antagonist treatment for this condition and is eligible to receive further TNF-alfa antagonist therapy, and has not failed PBS-subsidised therapy with etanercept in the current treatment cycle.

Where the most recent course of PBS-subsidised TNF-alfa antagonist treatment was approved under either of the initial treatment restrictions (i.e. for patients with no prior PBS-subsidised TNF-alfa antagonist therapy or, under this restriction, for patients who have received previous PBS-subsidised TNF-alfa antagonist 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 Medicare Australia 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 etanercept treatment was approved under the continuing treatment criteria, patients must have been assessed for response, and the assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Authority applications 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 [www.medicareaustralia.gov.au].

A maximum of 16 weeks of treatment with etanercept will be approved under this criterion.

Where fewer than 3 repeats are initially requested with the authority prescription, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone.

Patients who fail to demonstrate a response to treatment with etanercept under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. Patients may re-trial etanercept after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised TNF-alfa antagonist was approved in this cycle and the date of the first application under a new cycle

**Note**

Any queries concerning the arrangements to prescribe etanercept may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe etanercept should be forwarded to:

Medicare Australia

Prior Written Approval of Specialised Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

**Note**

TREATMENT OF ADULT PATIENTS WITH ACTIVE ANKYLOSING SPONDYLITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept, golimumab and infliximab for adult patients with active ankylosing spondylitis. Where the term 'tumour necrosis factor (TNF) alfa antagonist' appears in the following NOTES and restrictions, it refers to adalimumab, etanercept, golimumab and infliximab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 4 TNF-alfa antagonists at any 1 time.

From 1 March 2007, under the PBS, all patients will be able to commence a treatment cycle where they may trial PBS-subsidised TNF-alfa antagonists without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a TNF-alfa antagonist while they continue to show a response to therapy.

A patient who received PBS-subsidised TNF-alfa antagonist treatment prior to 1 March 2007 is considered to be in their first cycle as of 1 March 2007.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised TNF-alfa antagonist more than once. A patient who, prior to 1 March 2007, was authorised to receive PBS-subsidised initial treatment for ankylosing spondylitis with the same agent twice, is exempt from this condition in respect of applications approved prior to 1 March 2007.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised TNF-alfa antagonist therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised TNF-alfa antagonist treatment in the most recent cycle to the date of the first application for initial treatment with a TNF-alfa antagonist under the new treatment cycle.

A patient who has failed fewer than 3 TNF-alfa antagonists in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 TNF-alfa antagonists in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised TNF-alfa antagonist therapy after 1 August 2010.

(a) Initial treatment.

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised TNF-alfa antagonist treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or

(ii) a patient has received prior PBS-subsidised (initial or continuing) TNF-alfa antagonist therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to re-commence treatment with a specific TNF-alfa antagonist following a break in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept and golimumab and 18 weeks of treatment for infliximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.

For second and subsequent courses of PBS-subsidised TNF-alfa antagonist treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific TNF-alfa antagonist, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing TNF-alfa antagonist treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted TNF-alfa antagonist supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised TNF-alfa antagonist is approved, a patient may swap to an alternate TNF-alfa antagonist 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 TNF-alfa antagonist at any time, regardless of whether they are receiving therapy (initial or continuing) with a TNF-alfa antagonist at the time of the application. However, they cannot swap to a particular TNF-alfa antagonist if they have failed to respond to prior treatment with that drug within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate TNF-alfa antagonist should be accompanied by the approved authority prescription or remaining repeats for the TNF-alfa antagonist the patient is ceasing.

(3) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a TNF-alfa antagonist. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and Medicare Australia will assess response according to these revised baseline measurements.

For a new patient, the BASDAI used to determine the baseline must be measured while the patient is receiving NSAID therapy and completing their exercise program.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response.

(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised TNF-alfa antagonist therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have received treatment with 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.

(5) Patients 'grandfathered' onto PBS-subsidised treatment with golimumab.

A patient who commenced treatment with golimumab for active ankylosing spondylitis prior to 1 March 2010 and who continues to receive treatment at the time of application, may qualify for treatment under the initial 'grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment with golimumab will be authorised under this criterion.

Following completion of the initial PBS-subsidised course, further applications for treatment with golimumab will be assessed under the continuing treatment restriction.

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|
| | 'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must requalify for initial treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' above for further details. | | | | | | | |
| | **Note**<br>No applications for increased maximum quantities and/or repeats will be authorised. | | | | | | | |
| 9455P | ETANERCEPT Injection 50 mg in 1 mL single use auto-injector, 4, 1 | 1 | 3 | .. | 1774.58 | 36.10 | Enbrel | PF |
| 9085E | ETANERCEPT Injections 50 mg in 1 mL single use pre-filled syringes, 4, 1 | 1 | 3 | .. | 1774.58 | 36.10 | Enbrel | PF |
| 8778B | etanercept 25 mg injection [4 x 25 mg vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack | 2 | 3 | .. | *1774.57 | 36.10 | Enbrel | PF |

**ETANERCEPT**

**Authority required**

Continuing treatment for all patients

Continuing PBS-subsidised treatment, by a rheumatologist, of an adult with a documented history of active ankylosing spondylitis who:

(a) has demonstrated an adequate response to treatment with etanercept; and

(b) whose most recent course of PBS-subsidised therapy in this treatment cycle was with etanercept.

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.

Authority applications 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 [www.medicareaustralia.gov.au].

All measurements provided must be no more than 1 month old at the time of application.

A maximum of 24 weeks of treatment with etanercept will be authorised under this criterion.

Where fewer than 5 repeats are initially requested with the authority prescription, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone.

All applications for continuing treatment with etanercept must include a measurement of response to the prior course of therapy. This assessment must be provided to Medicare Australia no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment following an initial treatment course it must be made following a minimum of 12 weeks of treatment with etanercept. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

Patients who fail to demonstrate a response to treatment with etanercept under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. Patients may re-trial etanercept after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised TNF-alfa antagonist was approved in this cycle and the date of the first application under a new cycle

**Note**

Any queries concerning the arrangements to prescribe etanercept may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe etanercept should be forwarded to:

Medicare Australia

Prior Written Approval of Specialised Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

**Note**

TREATMENT OF ADULT PATIENTS WITH ACTIVE ANKYLOSING SPONDYLITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept, golimumab and infliximab for adult patients with active ankylosing spondylitis. Where the term 'tumour necrosis factor (TNF) alfa antagonist' appears in the following NOTES and restrictions, it refers to adalimumab, etanercept, golimumab and infliximab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 4 TNF-alfa antagonists at any 1 time.

From 1 March 2007, under the PBS, all patients will be able to commence a treatment cycle where they may trial PBS-subsidised TNF-alfa antagonists without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a TNF-alfa antagonist while they continue to show a

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|---|---|---|---|---|---|---|---|

response to therapy.

A patient who received PBS-subsidised TNF-alfa antagonist treatment prior to 1 March 2007 is considered to be in their first cycle as of 1 March 2007.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised TNF-alfa antagonist more than once. A patient who, prior to 1 March 2007, was authorised to receive PBS-subsidised initial treatment for ankylosing spondylitis with the same agent twice, is exempt from this condition in respect of applications approved prior to 1 March 2007.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised TNF-alfa antagonist therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised TNF-alfa antagonist treatment in the most recent cycle to the date of the first application for initial treatment with a TNF-alfa antagonist under the new treatment cycle.

A patient who has failed fewer than 3 TNF-alfa antagonists in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 TNF-alfa antagonists in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised TNF-alfa antagonist therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised TNF-alfa antagonist treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or

(ii) a patient has received prior PBS-subsidised (initial or continuing) TNF-alfa antagonist therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to re-commence treatment with a specific TNF-alfa antagonist following a break in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept and golimumab and 18 weeks of treatment for infliximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.

For second and subsequent courses of PBS-subsidised TNF-alfa antagonist treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific TNF-alfa antagonist, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing TNF-alfa antagonist treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted TNF-alfa antagonist supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised TNF-alfa antagonist is approved, a patient may swap to an alternate TNF-alfa antagonist 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 TNF-alfa antagonist at any time, regardless of whether they are receiving therapy (initial or continuing) with a TNF-alfa antagonist at the time of the application. However, they cannot swap to a particular TNF-alfa antagonist if they have failed to respond to prior treatment with that drug within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate TNF-alfa antagonist should be accompanied by the approved authority prescription or remaining repeats for the TNF-alfa antagonist the patient is ceasing.

(3) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a TNF-alfa antagonist. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and Medicare Australia will assess response according to these revised baseline measurements.

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|

For a new patient, the BASDAI used to determine the baseline must be measured while the patient is receiving NSAID therapy and completing their exercise program.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response.

(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised TNF-alfa antagonist therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have received treatment with 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.

(5) Patients 'grandfathered' onto PBS-subsidised treatment with golimumab.

A patient who commenced treatment with golimumab for active ankylosing spondylitis prior to 1 March 2010 and who continues to receive treatment at the time of application, may qualify for treatment under the initial 'grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment with golimumab will be authorised under this criterion.

Following completion of the initial PBS-subsidised course, further applications for treatment with golimumab will be assessed under the continuing treatment restriction.

'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must requalify for initial treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' above for further details.

**Note**

No applications for increased maximum quantities and/or repeats will be authorised.

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 9456Q | ETANERCEPT Injection 50 mg in 1 mL single use auto-injector, 4, 1 | 1 | 5 | .. | 1774.58 | 36.10 | Enbrel | PF |
| 9086F | ETANERCEPT Injections 50 mg in 1 mL single use pre-filled syringes, 4, 1 | 1 | 5 | .. | 1774.58 | 36.10 | Enbrel | PF |
| 8779C | etanercept 25 mg injection [4 x 25 mg vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack | 2 | 5 | .. | *1774.57 | 36.10 | Enbrel | PF |

**ETANERCEPT**

**Authority required**

Initial 1

Initial PBS-subsidised treatment with etanercept, by a rheumatologist or clinical immunologist with expertise in the management of psoriatic arthritis, of adults who:

(1) have severe active psoriatic arthritis; and

(2) have received no prior PBS-subsidised biological treatment for this condition in this Treatment Cycle; and

(3) have failed to achieve an adequate response to:

(a) methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months; and

(b) sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months; or

(c) leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months.

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity to necessitate permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of acceptable toxicities, including severity, can be found on the Medicare Australia website (www.medicareaustralia.gov.au).

The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either

(i) an active joint count of at least 20 active (swollen and tender) joints; or

(ii) at least 4 active joints from the following list of major joints:

— elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

— shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

The authority application must be made in writing and must include:

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|

(1) a completed authority prescription form; and

(2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and

(3) a signed patient acknowledgement.

A maximum of 16 weeks treatment will be authorised under this restriction.

Where fewer than 3 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

The assessment of the patient's response to the initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted to Medicare Australia no later than 4 weeks from the cessation of that treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

Patients who fail to demonstrate a response to treatment with etanercept under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug, in this Treatment Cycle. Patients may re-trial etanercept after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle

**Authority required**

Initial 2

Initial PBS-subsidised treatment with etanercept, by a rheumatologist or clinical immunologist with expertise in the management of psoriatic arthritis, of adults who:

(1) have a documented history of severe active psoriatic arthritis; and

(2) have received prior PBS-subsidised biological treatment for this condition in this Treatment Cycle and are eligible to receive further biological therapy; and

(3) have not failed treatment with etanercept during the current Treatment Cycle.

Applications for patients who have received PBS-subsidised treatment with etanercept within this Treatment Cycle and who wish to re-commence therapy with this drug within this same Cycle, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised etanercept treatment, within the timeframes specified below.

A maximum of 16 weeks treatment will be authorised under this restriction.

Where fewer than 3 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Where the most recent course of PBS-subsidised etanercept treatment was approved under either of the initial treatment restrictions (i.e. for patients with no prior PBS-subsidised biological therapy or, under this restriction, for patients who have received previous PBS-subsidised biological therapy), patients must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be provided to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised etanercept treatment was approved under the continuing treatment criteria, patients must have been assessed for response, and the assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].

Patients who fail to demonstrate a response to treatment with etanercept under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug, in this Treatment Cycle. Patients may re-trial etanercept after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle

**Note**

Any queries concerning the arrangements to prescribe etanercept may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe etanercept should be forwarded to:

Medicare Australia

Prior Written Approval of Specialised Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

**Note**

TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents (adalimumab, etanercept, golimumab and infliximab) for adult patients with severe active psoriatic arthritis.

# ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological agents at any 1 time. Where the term 'biological agents' appears in the following NOTES and restrictions, it only refers to adalimumab, etanercept, golimumab and infliximab.

From 1 August 2006, all patients will be able to commence a 'Biological Treatment Cycle' (Cycle), where they may trial biological agents without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

Following demonstration of response to initial treatment, these biological agents are available under the PBS for continuing treatment as set out in the continuing treatment restriction for each agent.

Once patients have either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological therapy before they are eligible to commence another Cycle [further details are under '(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' below].

The 5-year break in therapy will be measured from the date the last approval for PBS-subsidised treatment was granted in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Cycle.

Within the same Cycle, patients are not allowed to fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for any biological agent, they must change to an alternate agent which they have not previously failed, if they wish to continue PBS-subsidised biological treatment.

Patients for whom a break in PBS-subsidised therapy of less than 5 years has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.

Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle.

There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.

How to prescribe biological agents for the treatment of severe active psoriatic arthritis after 1 August 2010.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); and

(ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; and

(iii) patients wish to re-commence treatment with a specific biological agent following a break in PBS-subsidised therapy with that specific agent (Initial 2).

All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 16 weeks of therapy for all agents except for infliximab, for which a maximum of 22 weeks will be authorised. It is recommended that patients be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological agent supply.

Patients must be assessed for response to any course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.

Grandfather patients — golimumab only.

Applications for patients who commenced treatment with golimumab prior to 1 March 2010 may apply for initial PBS-subsidised treatment as continuing therapy under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with any biological agent prior to PBS listing of that agent.

Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment for all agents. Approval will be based on the criteria included in the relevant restriction.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological agent, patients may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. Patients are eligible to receive continuing biological treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

Patients must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.

(3) Swapping therapy.

Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate biological agent without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements.

Patients may swap to an alternate biological agent at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological agent at the time of the application or not.

Patients may alternate between therapy with any biological agent of their choice (1 at a time) providing:

(i) they have not received PBS-subsidised treatment with that particular biological agent previously; or

(ii) they have demonstrated an adequate response to that particular biological agent if they have previously trialled it on the PBS; or

(iii) they have not previously failed to respond to treatment 3 times in this Treatment Cycle.

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | Brand Name and Manufacturer | |
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To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the biological agent the patient is ceasing.

(4) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements of the indices of disease severity submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment authority is submitted within a treatment Cycle and Medicare Australia will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.

(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

Patients who wish to trial a second or subsequent treatment Cycle following a break in PBS-subsidised biological therapy of at least 5 years, must re-qualify for initial treatment with respect to both the indices of disease severity. Patients must have received treatment with methotrexate and sulfasalazine or leflunomide, at an adequate dose, for a minimum of 3 months at the time the ESR or CRP levels and the active joint counts are measured.

**Note**

No applications for increased maximum quantities and/or repeats will be authorised.

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 9457R | ETANERCEPT Injection 50 mg in 1 mL single use auto-injector, 4, 1 | 1 | 3 | .. | 1774.58 | 36.10 | Enbrel | PF |
| 9087G | ETANERCEPT Injections 50 mg in 1 mL single use pre-filled syringes, 4, 1 | 1 | 3 | .. | 1774.58 | 36.10 | Enbrel | PF |
| 9035M | etanercept 25 mg injection [4 x 25 mg vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack | 2 | 3 | .. | *1774.57 | 36.10 | Enbrel | PF |

**ETANERCEPT**

**Authority required**

Continuing treatment

Continuing PBS-subsidised treatment with etanercept, by a rheumatologist or clinical immunologist with expertise in the management of psoriatic arthritis, of adults:

(1) who have a documented history of severe active psoriatic arthritis; and

(2) whose most recent course of PBS-subsidised biological agent for this condition in the current Treatment Cycle was with etanercept; and

(3) who, at the time of application, demonstrate an adequate response to treatment with etanercept.

An adequate response to treatment with etanercept is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following:

(i) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(ii) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

— elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

— shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].

A maximum of 24 weeks of treatment will be approved under this restriction.

Where fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

All applications for continuing treatment with etanercept must include a measurement of response to the prior course of therapy. This assessment must be provided to Medicare Australia no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with etanercept, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with the initial treatment course.

Patients who fail to demonstrate a response to treatment with etanercept under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug, in this Treatment Cycle. Patients may re-trial etanercept after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | Brand Name and Manufacturer |
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**Note**

Any queries concerning the arrangements to prescribe etanercept may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe etanercept should be forwarded to:

Medicare Australia

Prior Written Approval of Specialised Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

**Note**

TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents (adalimumab, etanercept, golimumab and infliximab) for adult patients with severe active psoriatic arthritis.

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological agents at any 1 time. Where the term 'biological agents' appears in the following NOTES and restrictions, it only refers to adalimumab, etanercept, golimumab and infliximab.

From 1 August 2006, all patients will be able to commence a 'Biological Treatment Cycle' (Cycle), where they may trial biological agents without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

Following demonstration of response to initial treatment, these biological agents are available under the PBS for continuing treatment as set out in the continuing treatment restriction for each agent.

Once patients have either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological therapy before they are eligible to commence another Cycle [further details are under '(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' below].

The 5-year break in therapy will be measured from the date the last approval for PBS-subsidised treatment was granted in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Cycle.

Within the same Cycle, patients are not allowed to fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for any biological agent, they must change to an alternate agent which they have not previously failed, if they wish to continue PBS-subsidised biological treatment.

Patients for whom a break in PBS-subsidised therapy of less than 5 years has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.

Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle.

There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.

How to prescribe biological agents for the treatment of severe active psoriatic arthritis after 1 August 2010.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); and

(ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; and

(iii) patients wish to re-commence treatment with a specific biological agent following a break in PBS-subsidised therapy with that specific agent (Initial 2).

All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 16 weeks of therapy for all agents except for infliximab, for which a maximum of 22 weeks will be authorised. It is recommended that patients be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological agent supply.

Patients must be assessed for response to any course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.

Grandfather patients — golimumab only.

Applications for patients who commenced treatment with golimumab prior to 1 March 2010 may apply for initial PBS-subsidised treatment as continuing therapy under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with any biological agent prior to PBS listing of that agent.

Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment for all agents. Approval will be based on the criteria included in the relevant restriction.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological agent, patients may qualify to receive up to 24 weeks of continuing

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| | 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.<br>Patients must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.<br>(3) Swapping therapy.<br>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.<br>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.<br>Patients may alternate between therapy with any biological agent of their choice (1 at a time) providing:<br>(i) they have not received PBS-subsidised treatment with that particular biological agent previously; or<br>(ii) they have demonstrated an adequate response to that particular biological agent if they have previously trialled it on the PBS; or<br>(iii) they have not previously failed to respond to treatment 3 times in this Treatment Cycle.<br>To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.<br>To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the biological agent the patient is ceasing.<br>(4) Baseline measurements to determine response.<br>Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements of the indices of disease severity submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment authority is submitted within a treatment Cycle and Medicare Australia will assess response according to these revised baseline measurements.<br>To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.<br>(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.<br>Patients who wish to trial a second or subsequent treatment Cycle following a break in PBS-subsidised biological therapy of at least 5 years, must re-qualify for initial treatment with respect to both the indices of disease severity. Patients must have received treatment with methotrexate and sulfasalazine or leflunomide, at an adequate dose, for a minimum of 3 months at the time the ESR or CRP levels and the active joint counts are measured.<br>**Note**<br>No applications for increased maximum quantities and/or repeats will be authorised. | | | | | | | |
| 9458T | ETANERCEPT Injection 50 mg in 1 mL single use auto-injector, 4, 1 | 1 | 5 | .. | 1774.58 | 36.10 | Enbrel | PF |
| 9088H | ETANERCEPT Injections 50 mg in 1 mL single use pre-filled syringes, 4, 1 | 1 | 5 | .. | 1774.58 | 36.10 | Enbrel | PF |
| 9036N | etanercept 25 mg injection [4 x 25 mg vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack | 2 | 5 | .. | *1774.57 | 36.10 | Enbrel | PF |
| | **ETANERCEPT**<br>**Authority required**<br>Initial 1 (new patient or patient re-commencing after a break of more than 24 months)<br>Initial PBS-subsidised treatment with etanercept, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of adults who:<br>(a) have severe active rheumatoid arthritis; and<br>(b) have received no PBS-subsidised treatment with a bDMARD for this condition in the previous 24 months; and<br>(c) have failed, in the 24 months immediately prior to the date of application, to achieve an adequate response to at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs), which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be:<br>— hydroxychloroquine at a dose of at least 200 mg daily; or<br>— leflunomide at a dose of at least 10 mg daily; or<br>— sulfasalazine at a dose of at least 2 g daily.<br>If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, then the 6 months of intensive DMARD treatment must include at least 3 months continuous treatment with each of at least 2 of the DMARDs: | | | | | | | |

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | Brand Name and Manufacturer |
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— hydroxychloroquine at a dose of at least 200 mg daily; and/or

— leflunomide at a dose of at least 10 mg daily; and/or

— sulfasalazine at a dose of at least 2 g daily.

The application must include details of the contraindication or intolerance to methotrexate. Details of the toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose can be found on the Medicare Australia website [www.medicareaustralia.gov.au]. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

If 3 or more of methotrexate, hydroxychloroquine, leflunomide and sulfasalazine are contraindicated according to the relevant TGA-approved product information or cannot be tolerated at the doses specified above, then one or more of the following DMARDs may be used in place of these agents in order to satisfy the requirement for a trial of 6 months of intensive DMARD therapy with at least 2 DMARDs taken continuously for at least 3 months each:

— azathioprine at a dose of at least 1 mg/kg per day; and/or

— cyclosporin at a dose of at least 2 mg/kg/day; and/or

— sodium aurothiomalate at a dose of 50 mg weekly.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances. Details of the toxicities, including severity, which will be accepted as a reason for substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial can be found on the Medicare Australia website [www.medicareaustralia.gov.au].

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance and dose for each DMARD must be provided in the authority application. Details of the toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy can be found on the Medicare Australia website [www.medicareaustralia.gov.au].

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L;

AND either

(i) a total active joint count of at least 20 active (swollen and tender) joints; or

(ii) at least 4 active joints from the following list of major joints:

— elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

— shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reason this criterion cannot be satisfied.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and

(3) a signed patient acknowledgement.

A maximum of 16 weeks of treatment will be authorised under this restriction.

Where fewer than 3 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Assessment of a patient's response to an initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with etanercept.

Patients who fail to demonstrate a response to treatment with etanercept under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition

# ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | Brand Name and Manufacturer |
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**Authority required**

Initial 2 (change or re-commencement after break of less than 24 months)

Initial course of PBS-subsidised treatment with etanercept, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of adults who:

(a) have a documented history of severe active rheumatoid arthritis; and

(b) have received prior PBS-subsidised bDMARD treatment for this condition and are eligible to receive further bDMARD therapy.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].

Applications for patients who have received PBS-subsidised treatment with etanercept and who wish to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised etanercept treatment, within the timeframes specified below.

A maximum of 16 weeks of treatment will be authorised under this restriction.

Where fewer than 3 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Where the most recent course of PBS-subsidised etanercept treatment was approved under either of the initial 1 or 2 treatment restrictions, patients must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be provided to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised etanercept treatment was approved under the continuing treatment criteria, patients must have been assessed for response, and the assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Patients who fail to demonstrate a response to treatment with etanercept under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition

**Note**

(3) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and Medicare Australia will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

**Note**

Any queries concerning the arrangements to prescribe etanercept may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe etanercept should be forwarded to:

Medicare Australia

Prior Written Approval of Specialised Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

**Note**

TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying anti-rheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab) and the T-cell co-stimulation modulator (abatacept).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | Brand Name and Manufacturer |
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PBS-subsidised abatacept, golimumab, infliximab and rituximab must be used in combination with methotrexate at a dose of at least 7.5 mg weekly. Where a patient cannot tolerate 7.5 mg of methotrexate weekly, they are eligible to receive PBS-subsidised adalimumab, certolizumab pegol, etanercept and tocilizumab.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:

— a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,

— a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and

— once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact Medicare Australia on 1800 700 270.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or

(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or

(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or

(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab and tocilizumab, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to Medicare Australia within 4 weeks.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

Abatacept patients:

Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients:

A further application may be submitted to Medicare Australia 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia no later than 4 weeks from the date that

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| | course was ceased.<br>Rituximab patients:<br>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.<br>Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.<br>(2) Swapping therapy.<br>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.<br>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.<br>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.<br>Abatacept patients:<br>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.<br>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.<br>To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.<br>PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.<br>To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.<br>**Note**<br>No applications for increased maximum quantities and/or repeats will be authorised.<br>**Note**<br>Special Pricing Arrangements apply. | | | | | | | |
| 9459W | ETANERCEPT Injection 50 mg in 1 mL single use auto-injector, 4, 1 | 1 | 3 | .. | 1774.58 | 36.10 | Enbrel | PF |
| 9089J | ETANERCEPT Injections 50 mg in 1 mL single use pre-filled syringes, 4, 1 | 1 | 3 | .. | 1774.58 | 36.10 | Enbrel | PF |
| 8637N | etanercept 25 mg injection [4 x 25 mg vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack | 2 | 3 | .. | *1774.57 | 36.10 | Enbrel | PF |
| | **ETANERCEPT**<br>**Authority required**<br>Continuing treatment<br>Continuing PBS-subsidised treatment with etanercept, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of adults:<br>(a) who have a documented history of severe active rheumatoid arthritis; and<br>(b) who have demonstrated an adequate response to treatment with etanercept; and<br>(c) whose most recent course of PBS-subsidised bDMARD treatment was with etanercept.<br>An adequate response to treatment is defined as:<br>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;<br>AND either of the following:<br>(i) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or<br>(ii) a reduction in the number of the following major active joints, from at least 4, by at least 50%:<br>— elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or<br>— 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). | | | | | | | |

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The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].

A maximum of 24 weeks of treatment will be approved under this restriction.

Where fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

All applications for continuing treatment with etanercept must include a measurement of response to the prior course of therapy. This assessment must be provided to Medicare Australia no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with etanercept, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.

Patients who fail to demonstrate a response to treatment with etanercept under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition

**Note**

(3) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and Medicare Australia will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

**Note**

Any queries concerning the arrangements to prescribe etanercept may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe etanercept should be forwarded to:

Medicare Australia

Prior Written Approval of Specialised Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

**Note**

TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying anti-rheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab) and the T-cell co-stimulation modulator (abatacept).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

PBS-subsidised abatacept, golimumab, infliximab and rituximab must be used in combination with methotrexate at a dose of at least 7.5 mg weekly. Where a patient cannot tolerate 7.5 mg of methotrexate weekly, they are eligible to receive PBS-subsidised adalimumab, certolizumab pegol, etanercept and tocilizumab.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:

— a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,

— a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and

— once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact Medicare Australia on

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1800 700 270.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or

(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or

(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or

(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab and tocilizumab, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to Medicare Australia within 4 weeks.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

Abatacept patients:

Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients:

A further application may be submitted to Medicare Australia 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Rituximab patients:

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that

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| | agent. | | | | | | | |
| | A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug. | | | | | | | |
| | Abatacept patients: | | | | | | | |
| | Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation. | | | | | | | |
| | In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment. | | | | | | | |
| | To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction. | | | | | | | |
| | PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period. | | | | | | | |
| | To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing. | | | | | | | |
| | **Note**<br>No applications for increased maximum quantities and/or repeats will be authorised. | | | | | | | |
| | **Note**<br>Special Pricing Arrangements apply. | | | | | | | |
| 9460X | ETANERCEPT Injection 50 mg in 1 mL single use auto-injector, 4, 1 | 1 | 5 | .. | 1774.58 | 36.10 | Enbrel | PF |
| 9090K | ETANERCEPT Injections 50 mg in 1 mL single use pre-filled syringes, 4, 1 | 1 | 5 | .. | 1774.58 | 36.10 | Enbrel | PF |
| 8638P | etanercept 25 mg injection [4 x 25 mg vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack | 2 | 5 | .. | *1774.57 | 36.10 | Enbrel | PF |
| | **ETANERCEPT**<br>**Authority required**<br>Initial treatment [Initial 1, Whole body (New patients — No prior biological agent)] | | | | | | | |
| | Initial treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over who: | | | | | | | |
| | (a) have severe chronic plaque psoriasis where lesions have been present for at least 6 months from the time of initial diagnosis; and | | | | | | | |
| | (b) have not received any prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle; and | | | | | | | |
| | (c) have signed a patient and prescriber acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment (whole body); and | | | | | | | |
| | (d) have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 3 of the following 4 treatments: | | | | | | | |
| | (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; and/or | | | | | | | |
| | (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; and/or | | | | | | | |
| | (iii) cyclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; and/or | | | | | | | |
| | (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks. | | | | | | | |
| | If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, please provide details at the time of application. | | | | | | | |
| | If intolerance to treatment develops during the relevant period of use, which is of a severity to necessitate permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of acceptable toxicities including severity, associated with phototherapy, methotrexate, cyclosporin and acitretin, can be found on the Medicare Australia website (www.medicareaustralia.gov.au). | | | | | | | |
| | The following initiation criterion indicates failure to achieve an adequate response and must be demonstrated in all patients at the time of the application: | | | | | | | |
| | (a) A current Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment. | | | | | | | |
| | (b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 1 month following cessation of each course of treatment. | | | | | | | |
| | (c) The most recent PASI assessment must be no more than 1 month old at the time of application. | | | | | | | |
| | Applications for authorisation must be made in writing and must include: | | | | | | | |
| | (a) a completed authority prescription form; and | | | | | | | |
| | (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare | | | | | | | |

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Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy]; and

(iii) the signed patient and prescriber acknowledgements.

A maximum of 16 weeks of treatment with etanercept will be authorised under this restriction.

Where fewer than 3 repeats are requested at the time of the authority application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period beyond 16 weeks.

A PASI assessment of the patient's response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with etanercept. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

It is recommended that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised etanercept treatment

**Authority required**

Initial or re-Treatment [Initial 2, Whole body (Received prior biological agent under PBS)]

Treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over who:

(a) have a documented history of severe chronic plaque psoriasis; and

(b) have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle; and

(c) have not failed PBS-subsidised therapy with etanercept for the treatment of this condition in the current Treatment Cycle.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and

(ii) details of prior biological treatment, including dosage, date and duration of treatment.

Applications for patients who have demonstrated a response to PBS-subsidised etanercept treatment within this Treatment Cycle and who wish to re-commence etanercept treatment within the same Cycle following a break in therapy, will only be approved where evidence of the patient's response to their most recent course of PBS-subsidised etanercept treatment has been submitted to Medicare Australia within 1 month of cessation of treatment.

A maximum of 16 weeks of treatment with etanercept will be authorised under this restriction.

Where fewer than 3 repeats are requested at the time of the authority application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period beyond 16 weeks.

A PASI assessment of the patient's response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with etanercept. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

It is recommended that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised etanercept treatment.

Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may re-commence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle

**Authority required**

Initial treatment [Initial 1, Face, hand, foot (New patients — No prior biological agent)]

Initial treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over who:

(a) have severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis; and

(b) have not received any prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle; and

(c) have signed a patient and prescriber acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if

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they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment (face, hand, foot); and

(d) have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 3 of the following 4 treatments:

(i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; and/or

(ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; and/or

(iii) cyclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; and/or

(iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks.

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity to necessitate permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of acceptable toxicities including severity, associated with phototherapy, methotrexate, cyclosporin and acitretin, can be found on the Medicare Australia website (www.medicareaustralia.gov.au).

The following initiation criterion indicates failure to achieve an adequate response and must be demonstrated in all patients at the time of the application:

(a) Chronic plaque psoriasis classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where:

(i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment; or

(ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.

(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 1 month following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than 1 month old at the time of application.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy]; and

(iii) the signed patient and prescriber acknowledgements.

A maximum of 16 weeks of treatment with etanercept will be authorised under this restriction.

Where fewer than 3 repeats are requested at the time of the authority application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period beyond 16 weeks.

A PASI assessment of the patient's response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with etanercept. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

It is recommended that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised etanercept treatment.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline

**Authority required**

Initial or re-Treatment [Initial 2, Face, hand, foot (Received prior biological agent under PBS)]

Treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over who:

(a) have a documented history of severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot; and

(b) have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle; and

(c) have not failed PBS-subsidised therapy with etanercept for the treatment of this condition in the current Treatment Cycle.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of

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assessment of the patient's condition [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and

(ii) details of prior biological treatment, including dosage, date and duration of treatment.

Applications for patients who have demonstrated a response to PBS-subsidised etanercept treatment within this Treatment Cycle and who wish to re-commence etanercept treatment within the same Cycle following a break in therapy, will only be approved where evidence of the patient's response to their most recent course of PBS-subsidised etanercept treatment has been submitted to Medicare Australia within 1 month of cessation of treatment.

A maximum of 16 weeks of treatment with etanercept will be authorised under this restriction.

Where fewer than 3 repeats are requested at the time of the authority application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period beyond 16 weeks.

A PASI assessment of the patient's response to this course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with etanercept. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

It is recommended that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised etanercept treatment.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may re-commence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle

**Note**

Any queries concerning the arrangements to prescribe etanercept may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe etanercept should be forwarded to:

Medicare Australia

Prior Written Approval of Specialised Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

**Note**

TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, etanercept, infliximab and ustekinumab, for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological agents' appears in the following NOTES and restrictions, it only refers to adalimumab, etanercept, infliximab and ustekinumab.

From 1 March 2010, all patients will be able to commence a 'Biological Treatment Cycle' (Cycle), where they may trial adalimumab, etanercept, infliximab or ustekinumab without having to meet the initial treatment criteria, that is they will not need to experience a disease flare when swapping to an alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

A patient who received PBS-subsidised biological agent treatment for chronic plaque psoriasis prior to 1 March 2010 is considered to be in their first Cycle as of 1 March 2010.

Patients are eligible for PBS-subsidised treatment with only 1 biological agent at any 1 time.

Within the same Treatment Cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for a PBS-subsidised biological agent, they must change to an alternate agent if they wish to continue PBS-subsidised biological treatment. A patient who, prior to 1 March 2010, was authorised to receive PBS-subsidised initial treatment for chronic plaque psoriasis with the same agent twice, is exempt from this condition in respect of applications approved prior to 1 March 2010.

Patients must be assessed for response to each course of continuing treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a Treatment Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological agent therapy before they are eligible to commence the next Cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological agent treatment in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Treatment Cycle.

Patients for whom a break in PBS-subsidised therapy of less than 5 years duration has occurred, and, who have failed therapy fewer than 3 times within a particular Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.

Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a

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particular Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle.

There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.

How to prescribe biological agents for the treatment of severe chronic plaque psoriasis after 1 March 2010.

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Application for approval for initial treatment.

Applications for a course of initial treatment should be made in the following situations:

(i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); or

(ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under '(4) Swapping therapy' below]; or

(iii) patients who wish to re-commence treatment following a break in PBS-subsidised therapy with that agent (Initial 2).

All applications for initial treatment will be limited to provide for a maximum of 16 weeks of treatment in the case of adalimumab and etanercept, 22 weeks of treatment in the case of infliximab and 28 weeks of treatment in the case of ustekinumab.

(2) Assessment of response to initial treatment.

When prescribing initial treatment with a biological agent, a PASI assessment must be conducted after at least 12 weeks of treatment. This assessment must be submitted to Medicare Australia within 1 month of the completion of this initial treatment course. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

(3) Application for continuing treatment.

Following the completion of an initial treatment course of a biological agent to which an adequate response has been demonstrated, patients may qualify to receive up to 24 weeks of continuing treatment with that biological agent. Patients are eligible to continue to receive continuous treatment with 24 week courses providing they continue to sustain a response.

For second and subsequent courses of PBS-subsidised treatment with adalimumab, etanercept, infliximab or ustekinumab it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

Where a response assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to sustain a response to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

(4) Swapping therapy.

Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate agent within the same Treatment Cycle without having to requalify with respect to disease severity (i.e. a PASI score of greater than 15), or prior treatment requirements.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

Patients may trial an alternate biological agent at any time, regardless of whether they are receiving therapy with a biological agent at the time of the application or not. However, they cannot swap to a particular agent if they have failed to respond to treatment with that particular agent within the same Cycle.

Patients who commenced treatment with adalimumab prior to 1 June 2009 or ustekinumab prior to 1 March 2010 access these interchangeability arrangements in the same way as patients who have not.

To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the agent being ceased.

(5) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated, based on the baseline PASI assessment submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment authority is submitted within a Treatment Cycle and subsequent response will be assessed according to this revised PASI score.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatment applications.

(6) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

Patients who wish to trial a second or subsequent Biological Treatment Cycle, following a break in PBS-subsidised biological therapy of at least 5 years, must requalify for initial treatment according to the criteria of the relevant restriction and index of disease severity. Patients must have had at least 1 prior treatment, as listed in the criteria, for a minimum of 6 weeks, and must have a PASI assessment conducted preferably whilst still on treatment, but no later than 1 month following cessation of treatment. The PASI assessment must be no older than 1 month at the time of application.

**Note**

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| | No applications for increased maximum quantities and/or repeats will be authorised. | | | | | | | |
| | **Note** Special Pricing Arrangements apply. | | | | | | | |
| 9461Y | ETANERCEPT Injection 50 mg in 1 mL single use auto-injector, 4, 1 | 1 | 3 | .. | 1774.58 | 36.10 | Enbrel | PF |
| 9091L | ETANERCEPT Injections 50 mg in 1 mL single use pre-filled syringes, 4, 1 | 1 | 3 | .. | 1774.58 | 36.10 | Enbrel | PF |
| 9037P | etanercept 25 mg injection [4 x 25 mg vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack | 2 | 3 | .. | *1774.57 | 36.10 | Enbrel | PF |

**ETANERCEPT**

**Authority required**

Continuing treatment (Whole body)

Continuing PBS-subsidised treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over:

(a) who have a documented history of severe chronic plaque psoriasis; and

(b) whose most recent course of PBS-subsidised biological treatment for this condition in this Treatment Cycle was with etanercept; and

(c) who have demonstrated an adequate response to their most recent course of treatment with etanercept.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the pre-biological treatment baseline value for this Treatment Cycle.

This assessment must be provided to Medicare Australia no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with etanercept, the assessment of response must be after a minimum of 12 weeks of treatment with an initial course.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) the completed Psoriasis Area and Severity Index (PASI) calculation sheet along with the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 1 month old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with etanercept.

A maximum of 24 weeks of treatment with etanercept will be authorised under this restriction.

Where fewer than 5 repeats are requested at the time of the authority application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for continuing authority applications, or for treatment that would otherwise extend the treatment period beyond 24 weeks.

A PASI assessment of the patient's response must be conducted within 4 weeks prior to completion of this course of treatment. This assessment must be submitted to Medicare Australia no later than 1 month from the date of completion of this course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with etanercept. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

It is recommended that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised etanercept treatment.

Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may re-commence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle

**Authority required**

Continuing treatment (Face, hand, foot)

Continuing PBS-subsidised treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over:

(a) who have a documented history of severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot; and

(b) whose most recent course of PBS-subsidised biological treatment for this condition in this Treatment Cycle was with etanercept; and

(c) who have demonstrated an adequate response to treatment with etanercept.

An adequate response to etanercept treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the pre-biological treatment baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the pre-biological treatment baseline value.

This assessment must be provided to Medicare Australia no later than 4 weeks from the cessation of that treatment course. If the application is the

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first application for continuing treatment with etanercept, the assessment of response must be after a minimum of 12 weeks of treatment with an initial course.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) the completed Psoriasis Area and Severity Index (PASI) calculation sheet and face, hand, foot area diagrams along with the date of the assessment of the patient's condition [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].

The most recent PASI assessment must be no more than 1 month old at the time of application.

A maximum of 24 weeks of treatment with etanercept will be authorised under this restriction.

Where fewer than 5 repeats are requested at the time of the authority application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for continuing authority applications, or for treatment that would otherwise extend the treatment period beyond 24 weeks.

A PASI assessment of the patient's response must be conducted within 4 weeks prior to completion of this course of treatment. This assessment must be submitted to Medicare Australia no later than 1 month from the date of completion of this course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with etanercept. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

It is recommended that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised etanercept treatment.

The PASI assessment for continuing treatment must be performed on the same affected area assessed at baseline.

Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may re-commence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle

**Note**

Any queries concerning the arrangements to prescribe etanercept may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe etanercept should be forwarded to:

Medicare Australia

Prior Written Approval of Specialised Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

**Note**

TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, etanercept, infliximab and ustekinumab, for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological agents' appears in the following NOTES and restrictions, it only refers to adalimumab, etanercept, infliximab and ustekinumab.

From 1 March 2010, all patients will be able to commence a 'Biological Treatment Cycle' (Cycle), where they may trial adalimumab, etanercept, infliximab or ustekinumab without having to meet the initial treatment criteria, that is they will not need to experience a disease flare when swapping to an alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

A patient who received PBS-subsidised biological agent treatment for chronic plaque psoriasis prior to 1 March 2010 is considered to be in their first Cycle as of 1 March 2010.

Patients are eligible for PBS-subsidised treatment with only 1 biological agent at any 1 time.

Within the same Treatment Cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for a PBS-subsidised biological agent, they must change to an alternate agent if they wish to continue PBS-subsidised biological treatment. A patient who, prior to 1 March 2010, was authorised to receive PBS-subsidised initial treatment for chronic plaque psoriasis with the same agent twice, is exempt from this condition in respect of applications approved prior to 1 March 2010.

Patients must be assessed for response to each course of continuing treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a Treatment Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological agent therapy before they are eligible to commence the next Cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological agent treatment in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Treatment Cycle.

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Patients for whom a break in PBS-subsidised therapy of less than 5 years duration has occurred, and, who have failed therapy fewer than 3 times within a particular Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.

Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle.

There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.

How to prescribe biological agents for the treatment of severe chronic plaque psoriasis after 1 March 2010.

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Application for approval for initial treatment.

Applications for a course of initial treatment should be made in the following situations:

(i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); or

(ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under '(4) Swapping therapy' below]; or

(iii) patients who wish to re-commence treatment following a break in PBS-subsidised therapy with that agent (Initial 2).

All applications for initial treatment will be limited to provide for a maximum of 16 weeks of treatment in the case of adalimumab and etanercept, 22 weeks of treatment in the case of infliximab and 28 weeks of treatment in the case of ustekinumab.

(2) Assessment of response to initial treatment.

When prescribing initial treatment with a biological agent, a PASI assessment must be conducted after at least 12 weeks of treatment. This assessment must be submitted to Medicare Australia within 1 month of the completion of this initial treatment course. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

(3) Application for continuing treatment.

Following the completion of an initial treatment course of a biological agent to which an adequate response has been demonstrated, patients may qualify to receive up to 24 weeks of continuing treatment with that biological agent. Patients are eligible to continue to receive continuous treatment with 24 week courses providing they continue to sustain a response.

For second and subsequent courses of PBS-subsidised treatment with adalimumab, etanercept, infliximab or ustekinumab it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

Where a response assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to sustain a response to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

(4) Swapping therapy.

Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate agent within the same Treatment Cycle without having to requalify with respect to disease severity (i.e. a PASI score of greater than 15), or prior treatment requirements.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

Patients may trial an alternate biological agent at any time, regardless of whether they are receiving therapy with a biological agent at the time of the application or not. However, they cannot swap to a particular agent if they have failed to respond to treatment with that particular agent within the same Cycle.

Patients who commenced treatment with adalimumab prior to 1 June 2009 or ustekinumab prior to 1 March 2010 access these interchangeability arrangements in the same way as patients who have not.

To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the agent being ceased.

(5) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated, based on the baseline PASI assessment submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment authority is submitted within a Treatment Cycle and subsequent response will be assessed according to this revised PASI score.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatment applications.

(6) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

Patients who wish to trial a second or subsequent Biological Treatment Cycle, following a break in PBS-subsidised biological therapy of at least 5 years, must requalify for initial treatment according to the criteria of the relevant restriction and index of disease severity. Patients must have had at least 1 prior treatment, as listed in the criteria, for a minimum of 6 weeks, and must have a PASI assessment conducted preferably whilst still on treatment, but no later than 1 month following cessation of treatment. The PASI assessment must be no older than 1 month at the time of

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| | application. | | | | | | | |
| | **Note**<br>No applications for increased maximum quantities and/or repeats will be authorised. | | | | | | | |
| | **Note**<br>Special Pricing Arrangements apply. | | | | | | | |
| 9462B | ETANERCEPT Injection 50 mg in 1 mL single use auto-injector, 4, 1 | 1 | 5 | .. | 1774.58 | 36.10 | Enbrel | PF |
| 9431J | ETANERCEPT Injections 50 mg in 1 mL single use pre-filled syringes, 4, 1 | 1 | 5 | .. | 1774.58 | 36.10 | Enbrel | PF |
| 9429G | etanercept 25 mg injection [4 x 25 mg vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack | 2 | 5 | .. | *1774.57 | 36.10 | Enbrel | PF |

**GOLIMUMAB**

**Authority required**

Initial 1 (new patient or patient re-commencing after a break of more than 24 months)

Initial PBS-subsidised treatment with golimumab, in combination with methotrexate at a dose of at least 7.5 mg weekly, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of adults who:

(a) have severe active rheumatoid arthritis; and

(b) have received no PBS-subsidised treatment with a bDMARD for this condition in the previous 24 months; and

(c) have failed, in the 24 months immediately prior to the date of application, to achieve an adequate response to at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs), which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be:

— hydroxychloroquine at a dose of at least 200 mg daily; or

— leflunomide at a dose of at least 10 mg daily; or

— sulfasalazine at a dose of at least 2 g daily.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, then the 6 months of intensive DMARD treatment must include at least 3 months continuous treatment with each of at least 2 of the DMARDs:

— hydroxychloroquine at a dose of at least 200 mg daily; and/or

— leflunomide at a dose of at least 10 mg daily; and/or

— sulfasalazine at a dose of at least 2 g daily.

The application must include details of the contraindication or intolerance to methotrexate. Details of the toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose can be found on the Medicare Australia website [www.medicareaustralia.gov.au]. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

If 3 or more of methotrexate, hydroxychloroquine, leflunomide and sulfasalazine are contraindicated according to the relevant TGA-approved product information or cannot be tolerated at the doses specified above, then one or more of the following DMARDs may be used in place of these agents in order to satisfy the requirement for a trial of 6 months of intensive DMARD therapy with at least 2 DMARDs taken continuously for at least 3 months each:

— azathioprine at a dose of at least 1 mg/kg per day; and/or

— cyclosporin at a dose of at least 2 mg/kg/day; and/or

— sodium aurothiomalate at a dose of 50 mg weekly.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances. Details of the toxicities, including severity, which will be accepted as a reason for substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial can be found on the Medicare Australia website [www.medicareaustralia.gov.au].

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance and dose for each DMARD must be provided in the authority application. Details of the toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy can be found on the Medicare Australia website [www.medicareaustralia.gov.au].

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L;

AND either

(i) a total active joint count of at least 20 active (swollen and tender) joints; or

(ii) at least 4 active joints from the following list of major joints:

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | Brand Name and Manufacturer |
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— elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

— shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reason this criterion cannot be satisfied.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and

(3) a signed patient acknowledgement.

A maximum of 16 weeks of treatment will be authorised under this restriction.

Where fewer than 3 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Assessment of a patient's response to an initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with golimumab.

Patients who fail to demonstrate a response to treatment with golimumab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition

**Authority required**

Initial 2 (change or re-commencement after break of less than 24 months)

Initial course of PBS-subsidised treatment with golimumab, in combination with methotrexate at a dose of at least 7.5 mg weekly, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of adults who:

(a) have a documented history of severe active rheumatoid arthritis; and

(b) have received prior PBS-subsidised bDMARD treatment for this condition and are eligible to receive further bDMARD therapy.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].

Applications for patients who have received PBS-subsidised treatment with golimumab and who wish to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised golimumab treatment, within the timeframes specified below.

A maximum of 16 weeks of treatment will be authorised under this restriction.

Where fewer than 3 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Where the most recent course of PBS-subsidised golimumab treatment was approved under either of the initial 1 or 2 treatment restrictions, patients must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be provided to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised golimumab treatment was approved under the continuing treatment criteria, patients must have been assessed for response, and the assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Patients who fail to demonstrate a response to treatment with golimumab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition

**Note**

(3) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and Medicare Australia will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment

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with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

**Note**

Any queries concerning the arrangements to prescribe golimumab may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe golimumab should be forwarded to:

Medicare Australia

Prior Written Approval of Specialised Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

**Note**

TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying anti-rheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab) and the T-cell co-stimulation modulator (abatacept).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

PBS-subsidised abatacept, golimumab, infliximab and rituximab must be used in combination with methotrexate at a dose of at least 7.5 mg weekly. Where a patient cannot tolerate 7.5 mg of methotrexate weekly, they are eligible to receive PBS-subsidised adalimumab, certolizumab pegol, etanercept and tocilizumab.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:

— a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,

— a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and

— once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact Medicare Australia on 1800 700 270.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or

(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or

(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or

(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab

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| | and tocilizumab, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.<br><br>A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.<br><br>Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to Medicare Australia within 4 weeks.<br><br>Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.<br><br>For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.<br><br>Abatacept patients:<br><br>Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.<br><br>Rituximab patients:<br><br>A further application may be submitted to Medicare Australia 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.<br><br>(b) Continuing treatment.<br><br>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.<br><br>It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.<br><br>Assessments of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.<br><br>Rituximab patients:<br><br>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.<br><br>Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.<br><br>(2) Swapping therapy.<br><br>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.<br><br>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.<br><br>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.<br><br>Abatacept patients:<br><br>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.<br><br>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.<br><br>To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.<br><br>PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.<br><br>To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.<br><br>**Note**<br>Special Pricing Arrangements apply. | | | | | | | |
| 3426H | golimumab 50 mg/0.5 mL injection, 1 x | 1 | 3 | .. | 1777.50 | 36.10 | Simponi | JC |

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | Brand Name and Manufacturer | |
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| 3427J | 0.5 mL syringe golimumab 50 mg/0.5 mL injection, 1 x 0.5 mL syringe | 1 | 3 | .. | 1777.50 | 36.10 | Simponi | JC |

**GOLIMUMAB**

**Authority required**

Continuing treatment

Continuing PBS-subsidised treatment with golimumab, in combination with methotrexate at a dose of at least 7.5 mg weekly, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of adults:

(a) who have a documented history of severe active rheumatoid arthritis; and

(b) who have demonstrated an adequate response to treatment with golimumab; and

(c) whose most recent course of PBS-subsidised bDMARD treatment was with golimumab.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(i) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(ii) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

— elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

— shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].

A maximum of 24 weeks of treatment will be approved under this restriction.

Where fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

All applications for continuing treatment with golimumab must include a measurement of response to the prior course of therapy. This assessment must be provided to Medicare Australia no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with golimumab, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.

Patients who fail to demonstrate a response to treatment with golimumab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition

**Note**

(3) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and Medicare Australia will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

**Note**

Any queries concerning the arrangements to prescribe golimumab may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe golimumab should be forwarded to:

Medicare Australia

Prior Written Approval of Specialised Drugs

Reply Paid 9826

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | Brand Name and Manufacturer |
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GPO Box 9826

HOBART TAS 7001

**Note**

TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying anti-rheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab) and the T-cell co-stimulation modulator (abatacept).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

PBS-subsidised abatacept, golimumab, infliximab and rituximab must be used in combination with methotrexate at a dose of at least 7.5 mg weekly. Where a patient cannot tolerate 7.5 mg of methotrexate weekly, they are eligible to receive PBS-subsidised adalimumab, certolizumab pegol, etanercept and tocilizumab.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:

— a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,

— a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and

— once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact Medicare Australia on 1800 700 270.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or

(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or

(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or

(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab and tocilizumab, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to Medicare Australia within 4 weeks.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

Abatacept patients:

Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients:

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | Brand Name and Manufacturer | |
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A further application may be submitted to Medicare Australia 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Rituximab patients:

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.

Abatacept patients:

Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

**Note**

Special Pricing Arrangements apply.

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|---|---|---|---|---|---|---|---|---|
| 3428K | golimumab 50 mg/0.5 mL injection, 1 x 0.5 mL syringe | 1 | 5 | .. | 1777.50 | 36.10 | Simponi | JC |
| 3429L | golimumab 50 mg/0.5 mL injection, 1 x 0.5 mL syringe | 1 | 5 | .. | 1777.50 | 36.10 | Simponi | JC |

**GOLIMUMAB**

**Authority required**

Initial 1

Initial PBS-subsidised treatment with golimumab, by a rheumatologist or clinical immunologist with expertise in the management of psoriatic arthritis, of adults who:

(1) have severe active psoriatic arthritis; and

(2) have received no prior PBS-subsidised biological treatment for this condition in this Treatment Cycle; and

(3) have failed to achieve an adequate response to:

(a) methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months; and

(b) sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months; or

(c) leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months.

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application.

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | Brand Name and Manufacturer |
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If intolerance to treatment develops during the relevant period of use, which is of a severity to necessitate permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of acceptable toxicities, including severity, can be found on the Medicare Australia website (www.medicareaustralia.gov.au).

The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either

(i) an active joint count of at least 20 active (swollen and tender) joints; or

(ii) at least 4 active joints from the following list of major joints:

— elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

— shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and

(3) a signed patient acknowledgement.

A maximum of 16 weeks treatment will be authorised under this restriction.

Where fewer than 3 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

The assessment of the patient's response to the initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted to Medicare Australia no later than 4 weeks from the cessation of that treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

Patients who fail to demonstrate a response to treatment with golimumab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug, in this Treatment Cycle. Patients may re-trial golimumab after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle

**Authority required**

Initial 2

Initial PBS-subsidised treatment with golimumab, by a rheumatologist or clinical immunologist with expertise in the management of psoriatic arthritis, of adults who:

(1) have a documented history of severe active psoriatic arthritis; and

(2) have received prior PBS-subsidised biological treatment for this condition in this Treatment Cycle and are eligible to receive further biological therapy; and

(3) have not failed treatment with golimumab during the current Treatment Cycle.

Applications for patients who have received PBS-subsidised treatment with golimumab within this Treatment Cycle and who wish to re-commence therapy with this drug within this same Cycle, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised golimumab treatment, within the timeframes specified below.

A maximum of 16 weeks treatment will be authorised under this restriction.

Where fewer than 3 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Where the most recent course of PBS-subsidised golimumab treatment was approved under either of the initial treatment restrictions (i.e. for patients with no prior PBS-subsidised biological therapy or, under this restriction, for patients who have received previous PBS-subsidised biological therapy), patients must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be provided to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised golimumab treatment was approved under the continuing treatment criteria, patients must have been assessed for response, and the assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].

Patients who fail to demonstrate a response to treatment with golimumab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug, in this Treatment Cycle. Patients may re-trial golimumab after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | Brand Name and Manufacturer |
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**Note**

Any queries concerning the arrangements to prescribe golimumab may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe golimumab should be forwarded to:

Medicare Australia

Prior Written Approval of Specialised Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

**Note**

TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents (adalimumab, etanercept, golimumab and infliximab) for adult patients with severe active psoriatic arthritis.

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological agents at any 1 time. Where the term 'biological agents' appears in the following NOTES and restrictions, it only refers to adalimumab, etanercept, golimumab and infliximab.

From 1 August 2006, all patients will be able to commence a 'Biological Treatment Cycle' (Cycle), where they may trial biological agents without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

Following demonstration of response to initial treatment, these biological agents are available under the PBS for continuing treatment as set out in the continuing treatment restriction for each agent.

Once patients have either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological therapy before they are eligible to commence another Cycle [further details are under '(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' below].

The 5-year break in therapy will be measured from the date the last approval for PBS-subsidised treatment was granted in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Cycle.

Within the same Cycle, patients are not allowed to fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for any biological agent, they must change to an alternate agent which they have not previously failed, if they wish to continue PBS-subsidised biological treatment.

Patients for whom a break in PBS-subsidised therapy of less than 5 years has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.

Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle.

There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.

How to prescribe biological agents for the treatment of severe active psoriatic arthritis after 1 August 2010.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); and

(ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; and

(iii) patients wish to re-commence treatment with a specific biological agent following a break in PBS-subsidised therapy with that specific agent (Initial 2).

All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 16 weeks of therapy for all agents except for infliximab, for which a maximum of 22 weeks will be authorised. It is recommended that patients be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological agent supply.

Patients must be assessed for response to any course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.

Grandfather patients — golimumab only.

Applications for patients who commenced treatment with golimumab prior to 1 March 2010 may apply for initial PBS-subsidised treatment as continuing therapy under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with any biological agent prior to PBS listing of that agent.

Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment for all agents. Approval will be based on the criteria included in the relevant restriction.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological agent, patients may qualify to receive up to 24 weeks of continuing

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| | 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.<br>Patients must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.<br>(3) Swapping therapy.<br>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.<br>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.<br>Patients may alternate between therapy with any biological agent of their choice (1 at a time) providing:<br>(i) they have not received PBS-subsidised treatment with that particular biological agent previously; or<br>(ii) they have demonstrated an adequate response to that particular biological agent if they have previously trialled it on the PBS; or<br>(iii) they have not previously failed to respond to treatment 3 times in this Treatment Cycle.<br>To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.<br>To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the biological agent the patient is ceasing.<br>(4) Baseline measurements to determine response.<br>Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements of the indices of disease severity submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment authority is submitted within a treatment Cycle and Medicare Australia will assess response according to these revised baseline measurements.<br>To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.<br>(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.<br>Patients who wish to trial a second or subsequent treatment Cycle following a break in PBS-subsidised biological therapy of at least 5 years, must re-qualify for initial treatment with respect to both the indices of disease severity. Patients must have received treatment with methotrexate and sulfasalazine or leflunomide, at an adequate dose, for a minimum of 3 months at the time the ESR or CRP levels and the active joint counts are measured.<br>**Note**<br>No applications for increased maximum quantities and/or repeats will be authorised. Applications for treatment with golimumab where the dosing frequency exceeds 50 mg every 4 weeks will not be approved. | | | | | | | |
| 3430M | golimumab 50 mg/0.5 mL injection, 1 x 0.5 mL syringe | 1 | 3 | .. | 1777.50 | 36.10 | Simponi | JC |
| 3431N | golimumab 50 mg/0.5 mL injection, 1 x 0.5 mL syringe | 1 | 3 | .. | 1777.50 | 36.10 | Simponi | JC |

**GOLIMUMAB**

**Authority required**

Initial 3 — grandfather golimumab patients

Initial PBS-subsidised supply for continuing treatment with golimumab, by a rheumatologist or clinical immunologist with expertise in the management of psoriatic arthritis, of adults who:

(1) have a documented history of severe active psoriatic arthritis; and

(2) were receiving treatment with golimumab prior to 1 March 2010; and

(3) have demonstrated a response as specified in the criteria for continuing PBS-subsidised treatment with golimumab; and

(4) are receiving treatment with golimumab at the time of application.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and

(3) a signed patient acknowledgement.

A maximum of 24 weeks of treatment with golimumab will be authorised under this restriction.

Where fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | Brand Name and Manufacturer |
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Monday to Friday).

Patients who fail to demonstrate a response to treatment with golimumab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug, in this Treatment Cycle. Patients may re-trial golimumab after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

Patients may qualify for PBS-subsidised treatment under this restriction once only

**Authority required**

Continuing treatment

Continuing PBS-subsidised treatment with golimumab, by a rheumatologist or clinical immunologist with expertise in the management of psoriatic arthritis, of adults:

(1) who have a documented history of severe active psoriatic arthritis; and

(2) whose most recent course of PBS-subsidised biological agent for this condition in the current Treatment Cycle was with golimumab; and

(3) who, at the time of application, demonstrate an adequate response to treatment with golimumab.

An adequate response to treatment with golimumab is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following:

(i) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(ii) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

— elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

— shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].

A maximum of 24 weeks of treatment will be approved under this restriction.

Where fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

All applications for continuing treatment with golimumab must include a measurement of response to the prior course of therapy. This assessment must be provided to Medicare Australia no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with golimumab, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with the initial treatment course.

Patients who fail to demonstrate a response to treatment with golimumab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug, in this Treatment Cycle. Patients may re-trial golimumab after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle

**Note**

Any queries concerning the arrangements to prescribe golimumab may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe golimumab should be forwarded to:

Medicare Australia

Prior Written Approval of Specialised Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

**Note**

TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents (adalimumab, etanercept, golimumab and infliximab) for adult patients with severe active psoriatic arthritis.

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological agents at any 1 time. Where the term 'biological agents' appears in the following NOTES and restrictions, it only refers to adalimumab, etanercept, golimumab and infliximab.

From 1 August 2006, all patients will be able to commence a 'Biological Treatment Cycle' (Cycle), where they may trial biological agents without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

Following demonstration of response to initial treatment, these biological agents are available under the PBS for continuing treatment as set out in the continuing treatment restriction for each agent.

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Once patients have either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological therapy before they are eligible to commence another Cycle [further details are under '(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' below].

The 5-year break in therapy will be measured from the date the last approval for PBS-subsidised treatment was granted in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Cycle.

Within the same Cycle, patients are not allowed to fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for any biological agent, they must change to an alternate agent which they have not previously failed, if they wish to continue PBS-subsidised biological treatment.

Patients for whom a break in PBS-subsidised therapy of less than 5 years has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.

Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle.

There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.

How to prescribe biological agents for the treatment of severe active psoriatic arthritis after 1 August 2010.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); and

(ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; and

(iii) patients wish to re-commence treatment with a specific biological agent following a break in PBS-subsidised therapy with that specific agent (Initial 2).

All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 16 weeks of therapy for all agents except for infliximab, for which a maximum of 22 weeks will be authorised. It is recommended that patients be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological agent supply.

Patients must be assessed for response to any course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.

Grandfather patients — golimumab only.

Applications for patients who commenced treatment with golimumab prior to 1 March 2010 may apply for initial PBS-subsidised treatment as continuing therapy under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with any biological agent prior to PBS listing of that agent.

Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment for all agents. Approval will be based on the criteria included in the relevant restriction.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological agent, patients may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. Patients are eligible to receive continuing biological treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

Patients must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.

(3) Swapping therapy.

Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate biological agent without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements.

Patients may swap to an alternate biological agent at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological agent at the time of the application or not.

Patients may alternate between therapy with any biological agent of their choice (1 at a time) providing:

(i) they have not received PBS-subsidised treatment with that particular biological agent previously; or

(ii) they have demonstrated an adequate response to that particular biological agent if they have previously trialled it on the PBS; or

(iii) they have not previously failed to respond to treatment 3 times in this Treatment Cycle.

To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the biological agent the patient is ceasing.

(4) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements of the indices of disease severity submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements

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any time that an initial treatment authority is submitted within a treatment Cycle and Medicare Australia will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.

(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

Patients who wish to trial a second or subsequent treatment Cycle following a break in PBS-subsidised biological therapy of at least 5 years, must re-qualify for initial treatment with respect to both the indices of disease severity. Patients must have received treatment with methotrexate and sulfasalazine or leflunomide, at an adequate dose, for a minimum of 3 months at the time the ESR or CRP levels and the active joint counts are measured.

**Note**

No applications for increased maximum quantities and/or repeats will be authorised. Applications for treatment with golimumab where the dosing frequency exceeds 50 mg every 4 weeks will not be approved.

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 3432P | golimumab 50 mg/0.5 mL injection, 1 x 0.5 mL syringe | 1 | 5 | .. | 1777.50 | 36.10 | Simponi | JC |
| 3433Q | golimumab 50 mg/0.5 mL injection, 1 x 0.5 mL syringe | 1 | 5 | .. | 1777.50 | 36.10 | Simponi | JC |

**GOLIMUMAB**

**Authority required**

Initial 1 (new patients)

Initial PBS-subsidised treatment with golimumab, by a rheumatologist, of an adult with active ankylosing spondylitis who has radiographically (plain X-ray) confirmed Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis and who has not received any PBS-subsidised treatment with either adalimumab, etanercept, golimumab or infliximab in this treatment cycle; AND

(a) who has 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) [for further information on the BASMI please refer to the Medicare Australia website at www.medicareaustralia.gov.au]; or

(iii) limitation of chest expansion relative to normal values for age and gender [for chest expansion normal values please refer to the Medicare Australia website at www.medicareaustralia.gov.au]; AND

(b) who has 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.

The application must include details of the NSAIDs trialled, their doses and duration of treatment. If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used.

If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication.

If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance. Details of the toxicities, including severity, which will be accepted for the purposes of administering this restriction can be found on the Medicare Australia website [www.medicareaustralia.gov.au].

For details on the appropriate minimum exercise program that will be accepted for the purposes of administering this restriction, please refer to the Medicare Australia website at www.medicareaustralia.gov.au.

The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of the initial application:

(a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale; AND

(b) an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 10 mg per L.

The BASDAI must be determined at the completion of the 3 month NSAID and exercise trial, but prior to ceasing NSAID treatment. The BASDAI must be no more than 1 month old at the time of initial application.

Both ESR and CRP measures should be provided with the initial treatment application and both must be no more than 1 month old. If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reason this criterion cannot be satisfied.

Authority applications 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 [www.medicareaustralia.gov.au] which must include the following:

(i) a copy of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and

(ii) a completed BASDAI Assessment Form [www.medicareaustralia.gov.au]; and

(iii) a completed Exercise Program Self Certification Form included in the supporting information form; and

(iv) a signed patient acknowledgment form.

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | Brand Name and Manufacturer |
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The assessment of the patient's response to the initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted to Medicare Australia no later than 4 weeks from the cessation of that treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

A maximum of 16 weeks of treatment with golimumab will be approved under this criterion.

Where fewer than 3 repeats are initially requested with the authority prescription, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone.

Patients who fail to demonstrate a response to treatment with golimumab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. Patients may re-trial golimumab after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised TNF-alfa antagonist was approved in this cycle and the date of the first application under a new cycle

**Authority required**

Initial 2 (change or re-commencement for all patients)

Initial PBS-subsidised treatment with golimumab, by a rheumatologist, of an adult with a documented history of active ankylosing spondylitis who, in this treatment cycle, has received prior PBS-subsidised TNF-alfa antagonist treatment for this condition and is eligible to receive further TNF-alfa antagonist therapy, and has not failed PBS-subsidised therapy with golimumab in the current treatment cycle.

Where the most recent course of PBS-subsidised TNF-alfa antagonist treatment was approved under either of the initial treatment restrictions (i.e. for patients with no prior PBS-subsidised TNF-alfa antagonist therapy or, under this restriction, for patients who have received previous PBS-subsidised TNF-alfa antagonist 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 Medicare Australia 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 golimumab treatment was approved under the continuing treatment criteria, patients must have been assessed for response, and the assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Authority applications 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 [www.medicareaustralia.gov.au].

A maximum of 16 weeks of treatment with golimumab will be approved under this criterion.

Where fewer than 3 repeats are initially requested with the authority prescription, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone.

Patients who fail to demonstrate a response to treatment with golimumab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. Patients may re-trial golimumab after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised TNF-alfa antagonist was approved in this cycle and the date of the first application under a new cycle

**Note**

Any queries concerning the arrangements to prescribe golimumab may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe golimumab should be forwarded to:

Medicare Australia

Prior Written Approval of Specialised Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

**Note**

TREATMENT OF ADULT PATIENTS WITH ACTIVE ANKYLOSING SPONDYLITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept, golimumab and infliximab for adult patients with active ankylosing spondylitis. Where the term 'tumour necrosis factor (TNF) alfa antagonist' appears in the following NOTES and restrictions, it refers to adalimumab, etanercept, golimumab and infliximab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 4 TNF-alfa antagonists at any 1 time.

From 1 March 2007, under the PBS, all patients will be able to commence a treatment cycle where they may trial PBS-subsidised TNF-alfa antagonists without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a TNF-alfa antagonist while they continue to show a response to therapy.

A patient who received PBS-subsidised TNF-alfa antagonist treatment prior to 1 March 2007 is considered to be in their first cycle as of 1 March 2007.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised TNF-alfa antagonist more than once. A patient who, prior to 1 March 2007, was authorised to receive PBS-subsidised initial treatment for ankylosing spondylitis with the same agent twice, is exempt from this condition in respect of applications approved prior to 1 March 2007.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised TNF-alfa antagonist therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised TNF-alfa antagonist treatment in the most recent cycle to the date of the

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first application for initial treatment with a TNF-alfa antagonist under the new treatment cycle.

A patient who has failed fewer than 3 TNF-alfa antagonists in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 TNF-alfa antagonists in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised TNF-alfa antagonist therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised TNF-alfa antagonist treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or

(ii) a patient has received prior PBS-subsidised (initial or continuing) TNF-alfa antagonist therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to re-commence treatment with a specific TNF-alfa antagonist following a break in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept and golimumab and 18 weeks of treatment for infliximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.

For second and subsequent courses of PBS-subsidised TNF-alfa antagonist treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific TNF-alfa antagonist, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing TNF-alfa antagonist treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted TNF-alfa antagonist supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised TNF-alfa antagonist is approved, a patient may swap to an alternate TNF-alfa antagonist 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 TNF-alfa antagonist at any time, regardless of whether they are receiving therapy (initial or continuing) with a TNF-alfa antagonist at the time of the application. However, they cannot swap to a particular TNF-alfa antagonist if they have failed to respond to prior treatment with that drug within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate TNF-alfa antagonist should be accompanied by the approved authority prescription or remaining repeats for the TNF-alfa antagonist the patient is ceasing.

(3) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a TNF-alfa antagonist. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and Medicare Australia will assess response according to these revised baseline measurements.

For a new patient, the BASDAI used to determine the baseline must be measured while the patient is receiving NSAID therapy and completing their exercise program.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response.

(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised TNF-alfa antagonist therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have received treatment with 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

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| | measured. | | | | | | | |
| | (5) Patients 'grandfathered' onto PBS-subsidised treatment with golimumab. | | | | | | | |
| | A patient who commenced treatment with golimumab for active ankylosing spondylitis prior to 1 March 2010 and who continues to receive treatment at the time of application, may qualify for treatment under the initial 'grandfather' treatment restriction. | | | | | | | |
| | A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment with golimumab will be authorised under this criterion. | | | | | | | |
| | Following completion of the initial PBS-subsidised course, further applications for treatment with golimumab will be assessed under the continuing treatment restriction. | | | | | | | |
| | 'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must requalify for initial treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' above for further details. | | | | | | | |
| | **Note** | | | | | | | |
| | No applications for increased maximum quantities and/or repeats will be authorised. Applications for treatment with golimumab where the dosing frequency exceeds 50 mg every 4 weeks will not be approved. | | | | | | | |
| 3434R | golimumab 50 mg/0.5 mL injection, 1 x 0.5 mL syringe | 1 | 3 | .. | 1777.50 | 36.10 | Simponi | JC |
| 3435T | golimumab 50 mg/0.5 mL injection, 1 x 0.5 mL syringe | 1 | 3 | .. | 1777.50 | 36.10 | Simponi | JC |
| | **GOLIMUMAB** | | | | | | | |
| | **Authority required** | | | | | | | |
| | Initial ('grandfather' patients) | | | | | | | |
| | Initial PBS-subsidised supply for continuing treatment with golimumab, by a rheumatologist, of an adult with a documented history of active ankylosing spondylitis who has radiographically (plain X-ray) confirmed Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis and who was receiving treatment with golimumab prior to 1 March 2010; and | | | | | | | |
| | (a) has demonstrated a response as specified in the criteria for continuing PBS-subsidised treatment with golimumab; and | | | | | | | |
| | (b) is receiving treatment with golimumab at the time of application. | | | | | | | |
| | The BASDAI assessment and ESR and/or CRP measurements provided must be no more than 1 month old at the time of application. 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. | | | | | | | |
| | Authority applications 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 [www.medicareaustralia.gov.au] which includes the following: | | | | | | | |
| | (i) a copy of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and | | | | | | | |
| | (ii) a completed BASDAI Assessment Form [www.medicareaustralia.gov.au]; and | | | | | | | |
| | (iii) a signed patient acknowledgment form. | | | | | | | |
| | The assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of the course and posted to Medicare Australia 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. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment. | | | | | | | |
| | A patient ceasing treatment or swapping to an alternate agent and wishing to demonstrate a response to treatment, must be assessed no earlier than 12 weeks from the commencement of PBS-subsidised treatment. This assessment must be provided to Medicare Australia no later than 4 weeks from the date that 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. | | | | | | | |
| | A maximum of 24 weeks of treatment with golimumab will be authorised under this criterion. | | | | | | | |
| | Where fewer than 5 repeats are initially requested with the authority prescription, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone. | | | | | | | |
| | Patients who fail to demonstrate a response to treatment with golimumab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. Patients may re-trial golimumab after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised TNF-alfa antagonist was approved in this cycle and the date of the first application under a new cycle. | | | | | | | |
| | Patients may only qualify for PBS-subsidised treatment under this criterion once | | | | | | | |
| | **Authority required** | | | | | | | |
| | Continuing treatment for all patients | | | | | | | |
| | Continuing PBS-subsidised treatment, by a rheumatologist, of an adult with a documented history of active ankylosing spondylitis who: | | | | | | | |
| | (a) has demonstrated an adequate response to treatment with golimumab; and | | | | | | | |
| | (b) whose most recent course of PBS-subsidised therapy in this treatment cycle was with golimumab. | | | | | | | |
| | An adequate response is defined as an improvement from baseline of at least 2 of the BASDAI and 1 of the following: | | | | | | | |

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(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.

Authority applications 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 [www.medicareaustralia.gov.au].

All measurements provided must be no more than 1 month old at the time of application.

A maximum of 24 weeks of treatment with golimumab will be authorised under this criterion.

Where fewer than 5 repeats are initially requested with the authority prescription, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone.

All applications for continuing treatment with golimumab must include a measurement of response to the prior course of therapy. This assessment must be provided to Medicare Australia no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment following an initial treatment course it must be made following a minimum of 12 weeks of treatment with golimumab. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

Patients who fail to demonstrate a response to treatment with golimumab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. Patients may re-trial golimumab after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised TNF-alfa antagonist was approved in this cycle and the date of the first application under a new cycle

**Note**

Any queries concerning the arrangements to prescribe golimumab may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe golimumab should be forwarded to:

Medicare Australia

Prior Written Approval of Specialised Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

**Note**

TREATMENT OF ADULT PATIENTS WITH ACTIVE ANKYLOSING SPONDYLITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept, golimumab and infliximab for adult patients with active ankylosing spondylitis. Where the term 'tumour necrosis factor (TNF) alfa antagonist' appears in the following NOTES and restrictions, it refers to adalimumab, etanercept, golimumab and infliximab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 4 TNF-alfa antagonists at any 1 time.

From 1 March 2007, under the PBS, all patients will be able to commence a treatment cycle where they may trial PBS-subsidised TNF-alfa antagonists without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a TNF-alfa antagonist while they continue to show a response to therapy.

A patient who received PBS-subsidised TNF-alfa antagonist treatment prior to 1 March 2007 is considered to be in their first cycle as of 1 March 2007.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised TNF-alfa antagonist more than once. A patient who, prior to 1 March 2007, was authorised to receive PBS-subsidised initial treatment for ankylosing spondylitis with the same agent twice, is exempt from this condition in respect of applications approved prior to 1 March 2007.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised TNF-alfa antagonist therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised TNF-alfa antagonist treatment in the most recent cycle to the date of the first application for initial treatment with a TNF-alfa antagonist under the new treatment cycle.

A patient who has failed fewer than 3 TNF-alfa antagonists in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 TNF-alfa antagonists in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised TNF-alfa antagonist therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised TNF-alfa antagonist treatment in this treatment cycle and wishes to commence such therapy

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(Initial 1); or

(ii) a patient has received prior PBS-subsidised (initial or continuing) TNF-alfa antagonist therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to re-commence treatment with a specific TNF-alfa antagonist following a break in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept and golimumab and 18 weeks of treatment for infliximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.

For second and subsequent courses of PBS-subsidised TNF-alfa antagonist treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific TNF-alfa antagonist, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing TNF-alfa antagonist treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted TNF-alfa antagonist supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised TNF-alfa antagonist is approved, a patient may swap to an alternate TNF-alfa antagonist 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 TNF-alfa antagonist at any time, regardless of whether they are receiving therapy (initial or continuing) with a TNF-alfa antagonist at the time of the application. However, they cannot swap to a particular TNF-alfa antagonist if they have failed to respond to prior treatment with that drug within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate TNF-alfa antagonist should be accompanied by the approved authority prescription or remaining repeats for the TNF-alfa antagonist the patient is ceasing.

(3) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a TNF-alfa antagonist. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and Medicare Australia will assess response according to these revised baseline measurements.

For a new patient, the BASDAI used to determine the baseline must be measured while the patient is receiving NSAID therapy and completing their exercise program.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response.

(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised TNF-alfa antagonist therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have received treatment with 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.

(5) Patients 'grandfathered' onto PBS-subsidised treatment with golimumab.

A patient who commenced treatment with golimumab for active ankylosing spondylitis prior to 1 March 2010 and who continues to receive treatment at the time of application, may qualify for treatment under the initial 'grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment with golimumab will be authorised under this criterion.

Following completion of the initial PBS-subsidised course, further applications for treatment with golimumab will be assessed under the continuing treatment restriction.

'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must requalify for initial treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 5-year break in PBS-

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| | subsidised therapy' above for further details. | | | | | | | |
| | **Note**<br>No applications for increased maximum quantities and/or repeats will be authorised. Applications for treatment with golimumab where the dosing frequency exceeds 50 mg every 4 weeks will not be approved. | | | | | | | |
| 3436W | golimumab 50 mg/0.5 mL injection, 1 x 0.5 mL syringe | 1 | 5 | .. | 1777.50 | 36.10 | Simponi | JC |
| 3437X | golimumab 50 mg/0.5 mL injection, 1 x 0.5 mL syringe | 1 | 5 | .. | 1777.50 | 36.10 | Simponi | JC |

## *Interleukin inhibitors*

**USTEKINUMAB**

**Authority required**

Initial treatment [Initial 1, Whole body (New patients — No prior biological agent)]

Initial treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over who:

(a) have severe chronic plaque psoriasis where lesions have been present for at least 6 months from the time of initial diagnosis; and

(b) have not received any prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle; and

(c) have signed a patient and prescriber acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment (whole body); and

(d) have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 3 of the following 4 treatments:

(i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; and/or

(ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; and/or

(iii) cyclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; and/or

(iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks.

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity to necessitate permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of acceptable toxicities including severity, associated with phototherapy, methotrexate, cyclosporin and acitretin, can be found on the Medicare Australia website (www.medicareaustralia.gov.au).

The following initiation criterion indicates failure to achieve an adequate response and must be demonstrated in all patients at the time of the application:

(a) A current Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.

(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 1 month following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than 1 month old at the time of application.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy]; and

(iii) the signed patient and prescriber acknowledgements.

A maximum of 28 weeks of treatment with ustekinumab will be authorised under this restriction.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single injection. Up to a maximum of 2 repeats will be authorised.

Where fewer than 2 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 28 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period beyond 28 weeks.

A PASI assessment of the patient's response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with ustekinumab. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

It is recommended that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment

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course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised ustekinumab treatment

**Authority required**

Initial or re-Treatment [Initial 2, Whole body (Received prior biological agent under PBS)]

Treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over who:

(a) have a documented history of severe chronic plaque psoriasis; and

(b) have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle; and

(c) have not failed PBS-subsidised therapy with ustekinumab for the treatment of this condition in the current Treatment Cycle.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and

(ii) details of prior biological treatment, including dosage, date and duration of treatment.

Applications for patients who have demonstrated a response to PBS-subsidised ustekinumab treatment within this Treatment Cycle and who wish to re-commence ustekinumab treatment within the same Cycle following a break in therapy, will only be approved where evidence of the patient's response to their most recent course of PBS-subsidised ustekinumab treatment has been submitted to Medicare Australia within 1 month of cessation of treatment.

A maximum of 28 weeks of treatment with ustekinumab will be authorised under this restriction.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single injection. Up to a maximum of 2 repeats will be authorised.

Where fewer than 2 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 28 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period beyond 28 weeks.

A PASI assessment of the patient's response to this course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with ustekinumab. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

It is recommended that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised ustekinumab treatment.

Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may re-commence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle

**Authority required**

Initial treatment [Initial 1, Face, hand, foot (New patients — No prior biological agent)]

Initial treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over who:

(a) have severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis; and

(b) have not received any prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle; and

(c) have signed a patient and prescriber acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment (face, hand, foot); and

(d) have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 3 of the following 4 treatments:

(i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; and/or

(ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; and/or

(iii) cyclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; and/or

(iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks.

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity to necessitate permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of acceptable toxicities including severity, associated with phototherapy, methotrexate, cyclosporin and acitretin, can be found on the Medicare Australia website (www.medicareaustralia.gov.au).

The following initiation criterion indicates failure to achieve an adequate response and must be demonstrated in all patients at the time of the

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application:

(a) Chronic plaque psoriasis classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where:

(i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment; or

(ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.

(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 1 month following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than 1 month old at the time of application.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy]; and

(iii) the signed patient and prescriber acknowledgements.

A maximum of 28 weeks of treatment with ustekinumab will be authorised under this restriction.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single injection. Up to a maximum of 2 repeats will be authorised.

Where fewer than 2 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 28 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period beyond 28 weeks.

A PASI assessment of the patient's response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with ustekinumab. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

It is recommended that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised ustekinumab treatment.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline

**Authority required**

Initial or re-Treatment [Initial 2, Face, hand, foot (Received prior biological agent under PBS)]

Treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over who:

(a) have a documented history of severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot; and

(b) have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle; and

(c) have not failed PBS-subsidised therapy with ustekinumab for the treatment of this condition in the current Treatment Cycle.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and

(ii) details of prior biological treatment, including dosage, date and duration of treatment.

Applications for patients who have demonstrated a response to PBS-subsidised ustekinumab treatment within this Treatment Cycle and who wish to re-commence ustekinumab treatment within the same Cycle following a break in therapy, will only be approved where evidence of the patient's response to their most recent course of PBS-subsidised ustekinumab treatment has been submitted to Medicare Australia within 1 month of cessation of treatment.

A maximum of 28 weeks of treatment with ustekinumab will be authorised under this restriction.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single injection. Up to a maximum of 2 repeats will be authorised.

Where fewer than 2 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 28 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period beyond 28 weeks.

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A PASI assessment of the patient's response to this course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with ustekinumab. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

It is recommended that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised ustekinumab treatment.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may re-commence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle

**Note**

Any queries concerning the arrangements to prescribe ustekinumab may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe ustekinumab should be forwarded to:

Medicare Australia

Prior Written Approval of Specialised Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

**Note**

TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, etanercept, infliximab and ustekinumab, for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological agents' appears in the following NOTES and restrictions, it only refers to adalimumab, etanercept, infliximab and ustekinumab.

From 1 March 2010, all patients will be able to commence a 'Biological Treatment Cycle' (Cycle), where they may trial adalimumab, etanercept, infliximab or ustekinumab without having to meet the initial treatment criteria, that is they will not need to experience a disease flare when swapping to an alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

A patient who received PBS-subsidised biological agent treatment for chronic plaque psoriasis prior to 1 March 2010 is considered to be in their first Cycle as of 1 March 2010.

Patients are eligible for PBS-subsidised treatment with only 1 biological agent at any 1 time.

Within the same Treatment Cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for a PBS-subsidised biological agent, they must change to an alternate agent if they wish to continue PBS-subsidised biological treatment. A patient who, prior to 1 March 2010, was authorised to receive PBS-subsidised initial treatment for chronic plaque psoriasis with the same agent twice, is exempt from this condition in respect of applications approved prior to 1 March 2010.

Patients must be assessed for response to each course of continuing treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a Treatment Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological agent therapy before they are eligible to commence the next Cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological agent treatment in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Treatment Cycle.

Patients for whom a break in PBS-subsidised therapy of less than 5 years duration has occurred, and, who have failed therapy fewer than 3 times within a particular Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.

Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle.

There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.

How to prescribe biological agents for the treatment of severe chronic plaque psoriasis after 1 March 2010.

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Application for approval for initial treatment.

Applications for a course of initial treatment should be made in the following situations:

(i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); or

(ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under '(4)

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Swapping therapy' below]; or

(iii) patients who wish to re-commence treatment following a break in PBS-subsidised therapy with that agent (Initial 2).

All applications for initial treatment will be limited to provide for a maximum of 16 weeks of treatment in the case of adalimumab and etanercept, 22 weeks of treatment in the case of infliximab and 28 weeks of treatment in the case of ustekinumab.

(2) Assessment of response to initial treatment.

When prescribing initial treatment with a biological agent, a PASI assessment must be conducted after at least 12 weeks of treatment. This assessment must be submitted to Medicare Australia within 1 month of the completion of this initial treatment course. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

(3) Application for continuing treatment.

Following the completion of an initial treatment course of a biological agent to which an adequate response has been demonstrated, patients may qualify to receive up to 24 weeks of continuing treatment with that biological agent. Patients are eligible to continue to receive continuous treatment with 24 week courses providing they continue to sustain a response.

For second and subsequent courses of PBS-subsidised treatment with adalimumab, etanercept, infliximab or ustekinumab it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

Where a response assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to sustain a response to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

(4) Swapping therapy.

Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate agent within the same Treatment Cycle without having to requalify with respect to disease severity (i.e. a PASI score of greater than 15), or prior treatment requirements.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

Patients may trial an alternate biological agent at any time, regardless of whether they are receiving therapy with a biological agent at the time of the application or not. However, they cannot swap to a particular agent if they have failed to respond to treatment with that particular agent within the same Cycle.

Patients who commenced treatment with adalimumab prior to 1 June 2009 or ustekinumab prior to 1 March 2010 access these interchangeability arrangements in the same way as patients who have not.

To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the agent being ceased.

(5) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated, based on the baseline PASI assessment submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment authority is submitted within a Treatment Cycle and subsequent response will be assessed according to this revised PASI score.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatment applications.

(6) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

Patients who wish to trial a second or subsequent Biological Treatment Cycle, following a break in PBS-subsidised biological therapy of at least 5 years, must requalify for initial treatment according to the criteria of the relevant restriction and index of disease severity. Patients must have had at least 1 prior treatment, as listed in the criteria, for a minimum of 6 weeks, and must have a PASI assessment conducted preferably whilst still on treatment, but no later than 1 month following cessation of treatment. The PASI assessment must be no older than 1 month at the time of application.

**Note**

No applications for increased repeats will be authorised.

**Note**

Special Pricing Arrangements apply.

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| 9304Q | ustekinumab 45 mg/0.5 mL injection, 1 x 0.5 mL vial | 1 | 2 | .. | 4601.63 | 36.10 | Stelara | JC |

**USTEKINUMAB**

**Authority required**

Continuing treatment (Whole body)

Continuing PBS-subsidised treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over:

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(a) who have a documented history of severe chronic plaque psoriasis; and

(b) whose most recent course of PBS-subsidised biological treatment for this condition in this Treatment Cycle was with ustekinumab; and

(c) who have demonstrated an adequate response to their most recent course of treatment with ustekinumab.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the pre-biological treatment baseline value for this Treatment Cycle.

This assessment must be provided to Medicare Australia no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with ustekinumab, the assessment of response must be after a minimum of 12 weeks of treatment with an initial course.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) the completed Psoriasis Area and Severity Index (PASI) calculation sheet along with the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 1 month old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with ustekinumab.

A maximum of 24 weeks of treatment with ustekinumab will be authorised under this restriction.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single injection. Up to a maximum of 1 repeat will be authorised.

Where fewer than 1 repeat is requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for continuing authority applications, or for treatment that would otherwise extend the treatment period beyond 24 weeks.

A PASI assessment of the patient's response must be conducted within 4 weeks prior to completion of this course of treatment. This assessment, which will be used to determine eligibility for further continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with ustekinumab. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

It is recommended that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised ustekinumab treatment.

Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may re-commence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle

**Authority required**

Continuing treatment (Face, hand, foot)

Continuing PBS-subsidised treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over:

(a) who have a documented history of severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot; and

(b) whose most recent course of PBS-subsidised biological treatment for this condition in this Treatment Cycle was with ustekinumab; and

(c) who have demonstrated an adequate response to treatment with ustekinumab.

An adequate response to ustekinumab treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the pre-biological treatment baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the pre-biological treatment baseline value.

This assessment must be provided to Medicare Australia no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with ustekinumab, the assessment of response must be after a minimum of 12 weeks of treatment with an initial course.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) the completed Psoriasis Area and Severity Index (PASI) calculation sheet and face, hand, foot area diagrams along with the date of the assessment of the patient's condition [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].

The most recent PASI assessment must be no more than 1 month old at the time of application.

A maximum of 24 weeks of treatment with ustekinumab will be authorised under this restriction.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient,

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to provide sufficient for a single injection. Up to a maximum of 1 repeat will be authorised.

Where fewer than 1 repeat is requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for continuing authority applications, or for treatment that would otherwise extend the treatment period beyond 24 weeks.

A PASI assessment of the patient's response must be conducted within 4 weeks prior to completion of this course of treatment. This assessment, which will be used to determine eligibility for further continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with ustekinumab. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

It is recommended that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised ustekinumab treatment.

The PASI assessment for continuing treatment must be performed on the same affected area assessed at baseline.

Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may re-commence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle

**Note**

Any queries concerning the arrangements to prescribe ustekinumab may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe ustekinumab should be forwarded to:

Medicare Australia

Prior Written Approval of Specialised Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

**Note**

TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, etanercept, infliximab and ustekinumab, for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological agents' appears in the following NOTES and restrictions, it only refers to adalimumab, etanercept, infliximab and ustekinumab.

From 1 March 2010, all patients will be able to commence a 'Biological Treatment Cycle' (Cycle), where they may trial adalimumab, etanercept, infliximab or ustekinumab without having to meet the initial treatment criteria, that is they will not need to experience a disease flare when swapping to an alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

A patient who received PBS-subsidised biological agent treatment for chronic plaque psoriasis prior to 1 March 2010 is considered to be in their first Cycle as of 1 March 2010.

Patients are eligible for PBS-subsidised treatment with only 1 biological agent at any 1 time.

Within the same Treatment Cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for a PBS-subsidised biological agent, they must change to an alternate agent if they wish to continue PBS-subsidised biological treatment. A patient who, prior to 1 March 2010, was authorised to receive PBS-subsidised initial treatment for chronic plaque psoriasis with the same agent twice, is exempt from this condition in respect of applications approved prior to 1 March 2010.

Patients must be assessed for response to each course of continuing treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a Treatment Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological agent therapy before they are eligible to commence the next Cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological agent treatment in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Treatment Cycle.

Patients for whom a break in PBS-subsidised therapy of less than 5 years duration has occurred, and, who have failed therapy fewer than 3 times within a particular Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.

Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle.

There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.

How to prescribe biological agents for the treatment of severe chronic plaque psoriasis after 1 March 2010.

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Application for approval for initial treatment.

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|
| | Applications for a course of initial treatment should be made in the following situations:<br>(i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); or<br>(ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under '(4) Swapping therapy' below]; or<br>(iii) patients who wish to re-commence treatment following a break in PBS-subsidised therapy with that agent (Initial 2).<br>All applications for initial treatment will be limited to provide for a maximum of 16 weeks of treatment in the case of adalimumab and etanercept, 22 weeks of treatment in the case of infliximab and 28 weeks of treatment in the case of ustekinumab.<br>(2) Assessment of response to initial treatment.<br>When prescribing initial treatment with a biological agent, a PASI assessment must be conducted after at least 12 weeks of treatment. This assessment must be submitted to Medicare Australia within 1 month of the completion of this initial treatment course. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.<br>The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.<br>(3) Application for continuing treatment.<br>Following the completion of an initial treatment course of a biological agent to which an adequate response has been demonstrated, patients may qualify to receive up to 24 weeks of continuing treatment with that biological agent. Patients are eligible to continue to receive continuous treatment with 24 week courses providing they continue to sustain a response.<br>For second and subsequent courses of PBS-subsidised treatment with adalimumab, etanercept, infliximab or ustekinumab it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.<br>Where a response assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to sustain a response to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.<br>(4) Swapping therapy.<br>Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate agent within the same Treatment Cycle without having to requalify with respect to disease severity (i.e. a PASI score of greater than 15), or prior treatment requirements.<br>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.<br>Patients may trial an alternate biological agent at any time, regardless of whether they are receiving therapy with a biological agent at the time of the application or not. However, they cannot swap to a particular agent if they have failed to respond to treatment with that particular agent within the same Cycle.<br>Patients who commenced treatment with adalimumab prior to 1 June 2009 or ustekinumab prior to 1 March 2010 access these interchangeability arrangements in the same way as patients who have not.<br>To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.<br>To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the agent being ceased.<br>(5) Baseline measurements to determine response.<br>Medicare Australia will determine whether a response to treatment has been demonstrated, based on the baseline PASI assessment submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment authority is submitted within a Treatment Cycle and subsequent response will be assessed according to this revised PASI score.<br>To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatment applications.<br>(6) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.<br>Patients who wish to trial a second or subsequent Biological Treatment Cycle, following a break in PBS-subsidised biological therapy of at least 5 years, must requalify for initial treatment according to the criteria of the relevant restriction and index of disease severity. Patients must have had at least 1 prior treatment, as listed in the criteria, for a minimum of 6 weeks, and must have a PASI assessment conducted preferably whilst still on treatment, but no later than 1 month following cessation of treatment. The PASI assessment must be no older than 1 month at the time of application.<br>**Note**<br>No applications for increased repeats will be authorised.<br>**Note**<br>Special Pricing Arrangements apply. | | | | | | | | |
| 9305R | ustekinumab 45 mg/0.5 mL injection, 1 x 0.5 mL vial | 1 | 1 | .. | 4601.63 | 36.10 | Stelara | JC |

## *Calcineurin inhibitors*

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|---|
| | **CYCLOSPORIN** | | | | | | | | |
| | **Authority required**<br>Maintenance therapy, following initiation and stabilisation of treatment with cyclosporin, of patients with organ or tissue transplants. Therapy must remain under the supervision and direction of the transplant unit reviewing the patient. The name of the specialised transplant unit reviewing treatment and the date of the latest review at the specialised transplant unit must be included in the authority application | | | | | | | | |
| | **Authority required**<br>Maintenance therapy, following initiation and stabilisation of treatment with cyclosporin, of patients with severe atopic dermatitis for whom other systemic therapies are ineffective or inappropriate. Therapy must remain under the supervision and direction of a dermatologist, clinical immunologist or specialised unit reviewing the patient. The name of the dermatologist, clinical immunologist or specialised unit reviewing treatment and the date of the latest review must be included in the authority application | | | | | | | | |
| | **Authority required**<br>Maintenance therapy, following initiation and stabilisation of treatment with cyclosporin, of patients with severe psoriasis for whom other systemic therapies are ineffective or inappropriate and in whom the disease has caused significant interference with quality of life. Therapy must remain under the supervision and direction of a dermatologist or specialised unit reviewing the patient. The name of the dermatologist or specialised unit reviewing treatment and the date of the latest review must be included in the authority application | | | | | | | | |
| | **Authority required**<br>Maintenance therapy, following initiation and stabilisation of treatment with cyclosporin, of patients with nephrotic syndrome in whom steroids and cytostatic drugs have failed or are not tolerated or are considered inappropriate and in whom renal function is unimpaired. Therapy must remain under the supervision and direction of a nephrologist or specialised unit reviewing the patient. The name of the nephrologist or specialised unit reviewing treatment and the date of the latest review must be included in the authority application | | | | | | | | |
| | **Authority required**<br>Maintenance therapy, following initiation and stabilisation of treatment with cyclosporin, of patients with severe active rheumatoid arthritis for whom classical slow-acting anti-rheumatic agents (including methotrexate) are ineffective or inappropriate. Therapy must remain under the supervision and direction of a rheumatologist, clinical immunologist or specialised unit reviewing the patient. The name of the rheumatologist, clinical immunologist or specialised unit reviewing treatment and the date of the latest review must be included in the authority application | | | | | | | | |
| | **Authority required**<br>Management (which includes initiation, stabilisation and review of therapy) by dermatologists or clinical immunologists of patients with severe atopic dermatitis for whom other systemic therapies are ineffective or inappropriate | | | | | | | | |
| | **Authority required**<br>Management (which includes initiation, stabilisation and review of therapy) by dermatologists of patients with severe psoriasis for whom other systemic therapies are ineffective or inappropriate and in whom the disease has caused significant interference with quality of life | | | | | | | | |
| | **Authority required**<br>Management (which includes initiation, stabilisation and review of therapy) by rheumatologists or clinical immunologists of patients with severe active rheumatoid arthritis for whom classical slow-acting anti-rheumatic agents (including methotrexate) are ineffective or inappropriate | | | | | | | | |
| | **Caution**<br>Careful monitoring of patients is mandatory. | | | | | | | | |
| 8657P | cyclosporin 10 mg capsule, 60 | 2 | 3 | .. | *94.63 | 36.10 | | Neoral 10 | NV |
| 8660T | cyclosporin 100 mg capsule, 30 | 2 | 3 | .. | *374.65 | 36.10 | [a] | Cyclosporin Sandoz | SZ |
| | | | | | | | [a] | Neoral 100 | NV |
| 8661W | cyclosporin 100 mg/mL oral liquid, 50 mL | 2 | 3 | .. | *712.87 | 36.10 | | Neoral | NV |
| 8658Q | cyclosporin 25 mg capsule, 30 | 2 | 3 | .. | *97.45 | 36.10 | [a] | Cyclosporin Sandoz | SZ |
| | | | | | | | [a] | Neoral 25 | NV |
| 8659R | cyclosporin 50 mg capsule, 30 | 2 | 3 | .. | *195.59 | 36.10 | [a] | Cyclosporin Sandoz | SZ |
| | | | | | | | [a] | Neoral 50 | NV |
| | **TACROLIMUS** | | | | | | | | |
| | **Authority required**<br>Maintenance therapy, following initiation and stabilisation of treatment with tacrolimus, of patients with organ or tissue transplants. Therapy must remain under the supervision and direction of the transplant unit reviewing the patient. The name of the specialised transplant unit reviewing treatment and the date of the latest review at the specialised transplant unit must be included in the authority application | | | | | | | | |
| | **Caution**<br>Careful monitoring of patients is mandatory. | | | | | | | | |
| 8647D | tacrolimus 1 mg capsule, 100 | 1 | 3 | .. | 377.12 | 36.10 | [a] | Prograf | JC |
| | | | | | | | [a] | Tacrolimus Sandoz | SZ |
| 5300Y | tacrolimus 1 mg capsule: modified release, 60 capsules | 1 | 3 | .. | 236.12 | 36.10 | | Prograf XL | JC |
| 8648E | tacrolimus 5 mg capsule, 50 | 1 | 3 | .. | 922.65 | 36.10 | [a] | Prograf | JC |
| | | | | | | | [a] | Tacrolimus Sandoz | SZ |
| 5451X | tacrolimus 5 mg capsule: modified release, 30 capsules | 1 | 3 | .. | 556.53 | 36.10 | | Prograf XL | JC |
| 8646C | tacrolimus 500 microgram capsule, 100 | 1 | 3 | .. | 200.51 | 36.10 | [a] | Prograf | JC |
| | | | | | | | [a] | Tacrolimus Sandoz | SZ |

# ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|---|
| 5299X | tacrolimus 500 microgram capsule: modified release, 30 capsules | 1 | 3 | .. | 64.80 | 36.10 | | Prograf XL | JC |

## *Other immunosuppressants*

**AZATHIOPRINE**

**Note**

Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 2688L *NP* | azathioprine 25 mg tablet, 100 | 1 | 5 | .. | 29.00 | 30.13 | [a] | Azathioprine Sandoz | SZ |
| | | | | | | | [a] | Imuran | AS |
| 2687K *NP* | azathioprine 50 mg tablet, 100 | 1 | 5 | .. | 44.25 | 36.10 | [a] | Azamun | GM |
| | | | | | | | [a] | Azapin | QA |
| | | | | | | | [a] | Azathioprine Sandoz | SZ |
| | | | | | | | [a] | GenRx Azathioprine | GX |
| | | | | | | | [a] | Imuran | AS |
| | | | | | | | [a] | Thioprine | AF |

**METHOTREXATE**

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 2272N | methotrexate 10 mg tablet, 15 | 1 | 3 | .. | 20.55 | 21.68 | | Methoblastin | PF |
| 1622J | methotrexate 2.5 mg tablet, 30 | 1 | 5 | .. | 13.33 | 14.46 | [a] | Hospira Pty Limited | HH |
| | | | | | | | [a] | Methoblastin | PF |

**METHOTREXATE**

**Restricted benefit**

For patients requiring doses greater than 20 mg per week

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 1623K | methotrexate 10 mg tablet, 50 | 1 | 2 | .. | 51.45 | 36.10 | | Methoblastin | PF |

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|---|

# MUSCULO-SKELETAL SYSTEM

## ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS

### ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS

#### *Acetic acid derivatives and related substances*

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | **DICLOFENAC** | | | | | | | | |
| 1302M<br>*NP,MW* | diclofenac sodium 100 mg suppository, 20 | 2 | 3 | .. | *25.13 | 26.26 | | Voltaren 100 | NV |
| 5079H<br>*DP* | diclofenac sodium 100 mg suppository, 20 | 2 | .. | .. | *25.13 | 26.26 | | Voltaren 100 | NV |
| | **DICLOFENAC**<br>**Restricted benefit**<br>Chronic arthropathies (including osteoarthritis) with an inflammatory component<br>**Restricted benefit**<br>Bone pain due to malignant disease | | | | | | | | |
| 1299J<br>*NP* | diclofenac sodium 25 mg tablet: enteric, 50 tablets | 2 | 3 | .. | *11.65 | 12.78 | [a] | APO-Diclofenac | TX |
| | | | | | | | [a] | Chem mart Diclofenac | CH |
| | | | | | | | [a] | Clonac 25 | QA |
| | | | | | | | [a] | Diclofenac-GA | GM |
| | | | | | | | [a] | Diclofenac Sandoz | SZ |
| | | | | | | | [a] | Fenac 25 | AF |
| | | | | | | | [a] | Terry White Chemists Diclofenac | TW |
| | | | | [B]1.86 | *13.51 | 12.78 | [a] | Voltaren 25 | NV |
| 5076E<br>*DP* | diclofenac sodium 25 mg tablet: enteric, 50 tablets | 2 | .. | .. | *11.65 | 12.78 | [a] | APO-Diclofenac | TX |
| | | | | | | | [a] | Chem mart Diclofenac | CH |
| | | | | | | | [a] | Clonac 25 | QA |
| | | | | | | | [a] | Diclofenac-GA | GM |
| | | | | | | | [a] | Diclofenac Sandoz | SZ |
| | | | | | | | [a] | Fenac 25 | AF |
| | | | | | | | [a] | Terry White Chemists Diclofenac | TW |
| | | | | [B]1.86 | *13.51 | 12.78 | [a] | Voltaren 25 | NV |
| 1300K<br>*NP* | diclofenac sodium 50 mg tablet: enteric, 50 tablets | 1 | 3 | .. | 10.13 | 11.26 | [a] | APO-Diclofenac | TX |
| | | | | | | | [a] | Chem mart Diclofenac | CH |
| | | | | | | | [a] | Clonac 50 | QA |
| | | | | | | | [a] | Diclofenac-GA | GM |
| | | | | | | | [a] | Diclofenac Sandoz | SZ |
| | | | | | | | [a] | Fenac | AF |
| | | | | | | | [a] | Terry White Chemists Diclofenac | TW |
| | | | | [B]1.86 | 11.99 | 11.26 | [a] | Voltaren 50 | NV |
| 5077F<br>*DP* | diclofenac sodium 50 mg tablet: enteric, 50 tablets | 1 | .. | .. | 10.13 | 11.26 | [a] | APO-Diclofenac | TX |
| | | | | | | | [a] | Chem mart Diclofenac | CH |
| | | | | | | | [a] | Clonac 50 | QA |
| | | | | | | | [a] | Diclofenac-GA | GM |
| | | | | | | | [a] | Diclofenac Sandoz | SZ |
| | | | | | | | [a] | Fenac | AF |
| | | | | | | | [a] | Terry White Chemists Diclofenac | TW |
| | | | | [B]1.86 | 11.99 | 11.26 | [a] | Voltaren 50 | NV |
| | **INDOMETHACIN** | | | | | | | | |
| 2757D<br>*NP* | indomethacin 100 mg suppository, 20 | 2 | 3 | .. | *22.71 | 23.84 | | Indocid | AS |
| 5128X<br>*DP* | indomethacin 100 mg suppository, 20 | 2 | .. | .. | *22.71 | 23.84 | | Indocid | AS |

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|---|
| | **INDOMETHACIN** | | | | | | | | |
| | **Restricted benefit** | | | | | | | | |
| | Chronic arthropathies (including osteoarthritis) with an inflammatory component | | | | | | | | |
| | **Restricted benefit** | | | | | | | | |
| | Bone pain due to malignant disease | | | | | | | | |
| 2454E *NP* | indomethacin 25 mg capsule, 50 | 2 | 3 | .. | *12.63 | 13.76 | a | Arthrexin | AF |
| | | | | B2.48 | *15.11 | 13.76 | a | Indocid | AS |
| 5126T *DP* | indomethacin 25 mg capsule, 50 | 2 | .. | .. | *12.63 | 13.76 | a | Arthrexin | AF |
| | | | | B2.48 | *15.11 | 13.76 | a | Indocid | AS |

## *Oxicams*

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | **MELOXICAM** | | | | | | | | |
| | **Restricted benefit** | | | | | | | | |
| | Symptomatic treatment of osteoarthritis | | | | | | | | |
| | **Restricted benefit** | | | | | | | | |
| | Symptomatic treatment of rheumatoid arthritis | | | | | | | | |
| | **Note** | | | | | | | | |
| | The use of meloxicam for the treatment of the following conditions is not subsidised through the PBS: | | | | | | | | |
| | (a) acute pain; | | | | | | | | |
| | (b) soft tissue injury; | | | | | | | | |
| | (c) arthrosis without an inflammatory component. | | | | | | | | |
| | **Note** | | | | | | | | |
| | Pharmaceutical benefits that have the form meloxicam tablet 15 mg and pharmaceutical benefits that have the form meloxicam capsule 15 mg are equivalent for the purposes of substitution. | | | | | | | | |
| 8888T *NP* | meloxicam 15 mg capsule, 30 | 1 | 3 | .. | 18.94 | 20.07 | a | APO-Meloxicam | TX |
| | | | | | | | a | Chem mart Meloxicam | CH |
| | | | | | | | a | Melox 15 | GM |
| | | | | | | | a | Movalis 15 | QA |
| | | | | | | | a | Terry White Chemists Meloxicam | TW |
| | | | | B1.75 | 20.69 | 20.07 | a | Mobic | BY |
| 8562P *NP* | meloxicam 15 mg tablet, 30 | 1 | 3 | .. | 18.94 | 20.07 | a | APO-Meloxicam | TX |
| | | | | | | | a | Chem mart Meloxicam 15 mg | CH |
| | | | | | | | a | GenRx Meloxicam | GX |
| | | | | | | | a | Meloxiauro 15 | DO |
| | | | | | | | a | Meloxibell | GQ |
| | | | | | | | a | Meloxicam-GA | GM |
| | | | | | | | a | Meloxicam Ranbaxy | RA |
| | | | | | | | a | Meloxicam Sandoz | SZ |
| | | | | | | | a | Movalis 15 | QA |
| | | | | | | | a | Moxicam 15 | AF |
| | | | | | | | a | Pharmacor Meloxicam 15 | CR |
| | | | | | | | a | Terry White Chemists Meloxicam 15 mg | TW |
| | | | | B1.75 | 20.69 | 20.07 | a | Mobic | BY |
| | **MELOXICAM** | | | | | | | | |
| | **Restricted benefit** | | | | | | | | |
| | Symptomatic treatment of osteoarthritis | | | | | | | | |
| | **Restricted benefit** | | | | | | | | |
| | Symptomatic treatment of rheumatoid arthritis | | | | | | | | |
| | **Note** | | | | | | | | |
| | The use of meloxicam for the treatment of the following conditions is not subsidised through the PBS: | | | | | | | | |
| | (a) acute pain; | | | | | | | | |
| | (b) soft tissue injury; | | | | | | | | |

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|---|
| | (c) arthrosis without an inflammatory component. | | | | | | | | |
| | **Note** | | | | | | | | |
| | Pharmaceutical benefits that have the form meloxicam tablet 7.5 mg and pharmaceutical benefits that have the form meloxicam capsule 7.5 mg are equivalent for the purposes of substitution. | | | | | | | | |
| 8887R<br>*NP* | meloxicam 7.5 mg capsule, 30 | 1 | 3 | .. | 15.06 | 16.19 | [a] | APO-Meloxicam | TX |
| | | | | | | | [a] | Chem mart Meloxicam | CH |
| | | | | | | | [a] | Melox 7.5 | GM |
| | | | | | | | [a] | Movalis 7.5 | QA |
| | | | | | | | [a] | Terry White Chemists Meloxicam | TW |
| | | | | [B]1.76 | 16.82 | 16.19 | [a] | Mobic | BY |
| 8561N<br>*NP* | meloxicam 7.5 mg tablet, 30 | 1 | 3 | .. | 15.06 | 16.19 | [a] | APO-Meloxicam | TX |
| | | | | | | | [a] | Chem mart Meloxicam 7.5 mg | CH |
| | | | | | | | [a] | GenRx Meloxicam | GX |
| | | | | | | | [a] | Meloxiauro 7.5 | DO |
| | | | | | | | [a] | Meloxibell | GQ |
| | | | | | | | [a] | Meloxicam-GA | GM |
| | | | | | | | [a] | Meloxicam Ranbaxy | RA |
| | | | | | | | [a] | Meloxicam Sandoz | SZ |
| | | | | | | | [a] | Movalis 7.5 | QA |
| | | | | | | | [a] | Moxicam 7.5 | AF |
| | | | | | | | [a] | Pharmacor Meloxicam 7.5 | CR |
| | | | | | | | [a] | Terry White Chemists Meloxicam 7.5 mg | TW |
| | | | | [B]1.76 | 16.82 | 16.19 | [a] | Mobic | BY |
| | **PIROXICAM** | | | | | | | | |
| | **Restricted benefit** | | | | | | | | |
| | Chronic arthropathies (including osteoarthritis) with an inflammatory component | | | | | | | | |
| 1897W<br>*NP* | piroxicam 10 mg capsule, 50 | 1 | 3 | .. | 12.41 | 13.54 | [a] | Chem mart Piroxicam | CH |
| | | | | | | | [a] | GenRx Piroxicam | GX |
| | | | | | | | [a] | Mobilis 10 | AF |
| | | | | | | | [a] | Terry White Chemists Piroxicam | TW |
| | | | | [B]2.53 | 14.94 | 13.54 | [a] | Feldene | PF |
| 5203W<br>*DP* | piroxicam 10 mg capsule, 50 | 1 | .. | .. | 12.41 | 13.54 | [a] | Chem mart Piroxicam | CH |
| | | | | | | | [a] | GenRx Piroxicam | GX |
| | | | | | | | [a] | Mobilis 10 | AF |
| | | | | | | | [a] | Terry White Chemists Piroxicam | TW |
| | | | | [B]2.53 | 14.94 | 13.54 | [a] | Feldene | PF |
| 1895R<br>*NP* | piroxicam 10 mg tablet: dispersible, 50 | 1 | 3 | .. | 12.41 | 13.54 | | Mobilis D-10 | AF |
| 5201R<br>*DP* | piroxicam 10 mg tablet: dispersible, 50 | 1 | .. | .. | 12.41 | 13.54 | | Mobilis D-10 | AF |
| 1898X<br>*NP* | piroxicam 20 mg capsule, 25 | 1 | 3 | .. | 12.13 | 13.26 | [a] | Chem mart Piroxicam | CH |
| | | | | | | | [a] | GenRx Piroxicam | GX |
| | | | | | | | [a] | Mobilis 20 | AF |
| | | | | | | | [a] | Terry White Chemists Piroxicam | TW |
| | | | | [B]2.49 | 14.62 | 13.26 | [a] | Feldene | PF |
| 5204X<br>*DP* | piroxicam 20 mg capsule, 25 | 1 | .. | .. | 12.13 | 13.26 | [a] | Chem mart Piroxicam | CH |
| | | | | | | | [a] | GenRx Piroxicam | GX |
| | | | | | | | [a] | Mobilis 20 | AF |
| | | | | | | | [a] | Terry White Chemists Piroxicam | TW |
| | | | | [B]2.49 | 14.62 | 13.26 | [a] | Feldene | PF |
| 1896T | piroxicam 20 mg tablet: dispersible, 25 | 1 | 3 | .. | 12.13 | 13.26 | [a] | Mobilis D-20 | AF |

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|---|
| *NP* | | | | | | | | | |
| | | | | [B]2.95 | 15.08 | 13.26 | [a] | Feldene-D | PF |
| 5202T | piroxicam 20 mg tablet: dispersible, 25 | 1 | .. | .. | 12.13 | 13.26 | [a] | Mobilis D-20 | AF |
| *DP* | | | | | | | | | |
| | | | | [B]2.95 | 15.08 | 13.26 | [a] | Feldene-D | PF |

## *Propionic acid derivatives*

**IBUPROFEN**

**Restricted benefit**

Chronic arthropathies (including osteoarthritis) with an inflammatory component

**Restricted benefit**

Bone pain due to malignant disease

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 3190X | ibuprofen 400 mg tablet, 30 | 3 | 3 | .. | *14.94 | 16.07 | | Brufen | AB |
| *NP* | | | | | | | | | |
| 5123P | ibuprofen 400 mg tablet, 30 | 3 | .. | .. | *14.94 | 16.07 | | Brufen | AB |
| *DP* | | | | | | | | | |

**IBUPROFEN**

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 3192B | ibuprofen 400 mg tablet, 30 | 1 | .. | .. | 9.40 | 10.53 | | Brufen | AB |
| *NP,MW* | | | | | | | | | |
| 5124Q | ibuprofen 400 mg tablet, 30 | 1 | .. | .. | 9.40 | 10.53 | | Brufen | AB |
| *DP* | | | | | | | | | |

**KETOPROFEN**

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 1588N | ketoprofen 100 mg suppository, 20 | 2 | 3 | .. | *25.51 | 26.64 | | Orudis | SW |
| *NP* | | | | | | | | | |
| 5139L | ketoprofen 100 mg suppository, 20 | 2 | .. | .. | *25.51 | 26.64 | | Orudis | SW |
| *DP* | | | | | | | | | |

**KETOPROFEN**

**Restricted benefit**

Chronic arthropathies (including osteoarthritis) with an inflammatory component

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 1590Q | ketoprofen 200 mg capsule: modified release, 28 capsules | 1 | 3 | .. | 19.31 | 20.44 | [a] | Oruvail SR | AV |
| *NP* | | | | [B]2.21 | 21.52 | 20.44 | [a] | Orudis SR 200 | SW |
| 5136H | ketoprofen 200 mg capsule: modified release, 28 capsules | 1 | .. | .. | 19.31 | 20.44 | [a] | Oruvail SR | AV |
| *DP* | | | | [B]2.21 | 21.52 | 20.44 | [a] | Orudis SR 200 | SW |

**NAPROXEN**

**Restricted benefit**

Chronic arthropathies (including osteoarthritis) with an inflammatory component

**Restricted benefit**

Bone pain due to malignant disease

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 1615B | naproxen 1 g tablet: modified release, 28 tablets | 1 | 3 | .. | 14.17 | 15.30 | [a] | Proxen SR 1000 | MD |
| *NP* | | | | [B]1.29 | 15.46 | 15.30 | [a] | Naprosyn SR1000 | RO |
| 5179N | naproxen 1 g tablet: modified release, 28 tablets | 1 | .. | .. | 14.17 | 15.30 | [a] | Proxen SR 1000 | MD |
| *DP* | | | | [B]1.29 | 15.46 | 15.30 | [a] | Naprosyn SR1000 | RO |
| 1674D | naproxen 250 mg tablet, 50 | 2 | 3 | .. | *13.55 | 14.68 | [a] | Inza 250 | AF |
| *NP* | | | | [B]2.24 | *15.79 | 14.68 | [a] | Naprosyn | RO |
| 5176K | naproxen 250 mg tablet, 50 | 2 | .. | .. | *13.55 | 14.68 | [a] | Inza 250 | AF |
| *DP* | | | | [B]2.24 | *15.79 | 14.68 | [a] | Naprosyn | RO |
| 1659H | naproxen 500 mg tablet, 50 | 1 | 3 | .. | 12.81 | 13.94 | [a] | Inza 500 | AF |
| *NP* | | | | [B]1.28 | 14.09 | 13.94 | [a] | Naprosyn | RO |
| 5177L | naproxen 500 mg tablet, 50 | 1 | .. | .. | 12.81 | 13.94 | [a] | Inza 500 | AF |
| *DP* | | | | [B]1.28 | 14.09 | 13.94 | [a] | Naprosyn | RO |
| 1614Y | naproxen 750 mg tablet: modified release, 28 tablets | 1 | 3 | .. | 12.29 | 13.42 | [a] | Proxen SR 750 | MD |
| *NP* | | | | [B]1.22 | 13.51 | 13.42 | [a] | Naprosyn SR750 | RO |
| 5178M | naproxen 750 mg tablet: modified release, 28 tablets | 1 | .. | .. | 12.29 | 13.42 | [a] | Proxen SR 750 | MD |
| *DP* | | | | | | | | | |

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|---|
| | | | | [B]1.22 | 13.51 | 13.42 | [a] | Naprosyn SR750 | RO |
| | **NAPROXEN**<br>**Authority required (STREAMLINED)**<br>***4159***<br>Chronic arthropathies (including osteoarthritis)<br>**The Clinical criteria is:**<br>The condition must have an inflammatory component,<br>**AND the Clinical criteria is:**<br>Patient must be unable to take a solid dose form of a non-steroidal anti-inflammatory agent.<br>**Authority required (STREAMLINED)**<br>***4124***<br>Bone pain<br>**The Clinical criteria is:**<br>The condition must be due to malignant disease,<br>**AND the Clinical criteria is:**<br>Patient must be unable to take a solid dose form of a non-steroidal anti-inflammatory agent. | | | | | | | | |
| 1658G<br>*NP* | naproxen 125 mg/5 mL oral liquid, 474 mL | ‡1 | 3 | .. | 78.38 | 36.10 | | Phebra Naproxen Suspension | PL |
| | **NAPROXEN**<br>**Restricted benefit**<br>Chronic arthropathies (including osteoarthritis) with an inflammatory component<br>**Restricted benefit**<br>Bone pain due to malignant disease<br>**Note**<br>Naproxen sodium 550 mg is approximately equivalent to 500 mg of naproxen acid. | | | | | | | | |
| 1795L<br>*NP* | naproxen sodium 550 mg tablet, 50 | 1 | 3 | .. | 12.98 | 14.11 | [a] | Crysanal | MD |
| | | | | [B]2.17 | 15.15 | 14.11 | [a] | Anaprox 550 | RO |
| 5186Y<br>*DP* | naproxen sodium 550 mg tablet, 50 | 1 | .. | .. | 12.98 | 14.11 | [a] | Crysanal | MD |
| | | | | [B]2.17 | 15.15 | 14.11 | [a] | Anaprox 550 | RO |
| | **TIAPROFENIC ACID**<br>**Restricted benefit**<br>Chronic arthropathies (including osteoarthritis) with an inflammatory component<br>**Caution**<br>Cystitis and other urinary disorders have been reported with this drug.<br>**Note**<br>The recommended maximum dose is 600 mg per day. | | | | | | | | |
| 2103Q<br>*NP* | tiaprofenic acid 300 mg tablet, 60 | 1 | 3 | .. | 17.79 | 18.92 | | Surgam | SW |

## *Fenamates*

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | **MEFENAMIC ACID**<br>**Restricted benefit**<br>Dysmenorrhoea<br>**Restricted benefit**<br>Menorrhagia | | | | | | | | |
| 1824B<br>*NP* | mefenamic acid 250 mg capsule, 50 | 1 | 2 | .. | 18.37 | 19.50 | | Ponstan | PF |

## *Coxibs*

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | **CELECOXIB**<br>**Restricted benefit**<br>Symptomatic treatment of osteoarthritis<br>**Restricted benefit**<br>Symptomatic treatment of rheumatoid arthritis<br>**Note** | | | | | | | | |

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|---|
| | The use of celecoxib for the treatment of the following conditions is not subsidised through the PBS:<br>(a) acute pain;<br>(b) soft tissue injury;<br>(c) arthrosis without an inflammatory component. | | | | | | | | |
| 8439E<br>*NP* | celecoxib 100 mg capsule, 60 | 1 | 3 | .. | 32.52 | 33.65 | | Celebrex | PF |
| 8440F<br>*NP* | celecoxib 200 mg capsule, 30 | 1 | 3 | .. | 32.52 | 33.65 | | Celebrex | PF |

## SPECIFIC ANTIRHEUMATIC AGENTS

### *Quinolines*

**HYDROXYCHLOROQUINE**

**Note**

Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 1512N<br>*NP* | hydroxychloroquine sulfate 200 mg tablet, 100 | 1 | 1 | .. | 32.80 | 33.93 | [a] | APO-Hydroxychloroquine | TX |
| | | | | | | | [a] | Chem mart Hydroxychloroquine | CH |
| | | | | | | | [a] | Plaquenil | SW |
| | | | | | | | [a] | Terry White Chemists Hydroxychloroquine | TW |

### *Gold preparations*

**AURANOFIN**

**Caution**

Regular blood and urine checks are essential.

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 2022K<br>*NP* | AURANOFIN Capsule 3 mg, 60 | 1 | 5 | .. | 779.20 | 36.10 | | Ridaura | GH |

**AURANOFIN**

**Caution**

Regular blood and urine checks are essential.

**Note**

Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 1095P<br>*NP* | auranofin 3 mg tablet, 60 | 1 | 5 | .. | 63.76 | 36.10 | | Ridaura | GH |

**AUROTHIOMALATE SODIUM**

**Caution**

Regular blood and urine checks are essential.

**Note**

Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 2016D<br>*NP* | aurothiomalate sodium 10 mg/0.5 mL injection, 10 x 0.5 mL ampoules | 1 | .. | .. | 67.24 | 36.10 | | Myocrisin | SW |
| 2017E<br>*NP* | aurothiomalate sodium 20 mg/0.5 mL injection, 10 x 0.5 mL ampoules | 1 | 1 | .. | 102.88 | 36.10 | | Myocrisin | SW |
| 2018F<br>*NP* | aurothiomalate sodium 50 mg/0.5 mL injection, 10 x 0.5 mL ampoules | 1 | 1 | .. | 152.68 | 36.10 | | Myocrisin | SW |

### *Penicillamine and similar agents*

**PENICILLAMINE**

**Caution**

Regular blood and urine checks are essential.

**Note**

Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|---|
| | arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners. | | | | | | | | |
| 2721F *NP* | penicillamine 125 mg tablet, 100 | 1 | 1 | .. | 31.84 | 32.97 | | D-Penamine | AL |
| 2838J *NP* | penicillamine 250 mg tablet, 100 | 1 | 1 | .. | 53.50 | 36.10 | | D-Penamine | AL |

## MUSCLE RELAXANTS

### MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS

#### *Other centrally acting agents*

**BACLOFEN**

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 2729P *NP* | baclofen 10 mg tablet, 100 | 1 | 5 | .. | 21.65 | 22.78 | a | Chem mart Baclofen | CH |
| | | | | | | | a | Clofen 10 | AF |
| | | | | | | | a | GenRx Baclofen | GX |
| | | | | | | | a | Stelax 10 | QA |
| | | | | | | | a | Terry White Chemists Baclofen | TW |
| | | | | B1.33 | 22.98 | 22.78 | a | Lioresal 10 | NV |
| 2730Q *NP* | baclofen 25 mg tablet, 100 | 1 | 5 | .. | 39.47 | 36.10 | a | Chem mart Baclofen | CH |
| | | | | | | | a | Clofen 25 | AF |
| | | | | | | | a | GenRx Baclofen | GX |
| | | | | | | | a | Stelax 25 | QA |
| | | | | | | | a | Terry White Chemists Baclofen | TW |
| | | | | B1.33 | 40.80 | 36.10 | a | Lioresal 25 | NV |

### MUSCLE RELAXANTS, DIRECTLY ACTING AGENTS

#### *Dantrolene and derivatives*

**DANTROLENE**

**Restricted benefit**

Treatment of chronic spasticity

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 1779P *NP* | dantrolene sodium 25 mg capsule, 100 | 1 | 2 | .. | 81.40 | 36.10 | | Dantrium | PF |
| 1780Q *NP* | dantrolene sodium 50 mg capsule, 100 | 1 | 2 | .. | 82.02 | 36.10 | | Dantrium | PF |

## ANTIGOUT PREPARATIONS

### ANTIGOUT PREPARATIONS

#### *Preparations inhibiting uric acid production*

**ALLOPURINOL**

**Note**

The dose should be adjusted in accordance with renal function.

**Note**

For item codes 2600W and 1557Y, pharmaceutical benefits that have the form tablet 100 mg are equivalent for the purposes of substitution.

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 1557Y *NP* | allopurinol 100 mg tablet, 100 | 2 | 2 | .. | *11.93 | 13.06 | a | Progout 100 | AF |
| 2600W *NP* | allopurinol 100 mg tablet, 200 | 1 | 2 | .. | 11.92 | 13.05 | a | Allopurinol Sandoz | SZ |
| | | | | | | | a | Allosig | FM |
| | | | | | | | a | Chem mart Allopurinol | CH |
| | | | | | | | a | GenRx Allopurinol | GX |
| | | | | | | | a | Terry White Chemists Allopurinol | TW |
| | | | | B2.54 | 14.46 | 13.05 | a | Zyloprim | QA |

**ALLOPURINOL**

**Note**

The dose should be adjusted in accordance with renal function.

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 2604C *NP* | allopurinol 300 mg tablet, 60 | 1 | 2 | .. | 9.75 | 10.88 | a | Allopurinol Sandoz | SZ |

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | [a] | Allosig | FM |
| | | | | | | | [a] | Chem mart Allopurinol | CH |
| | | | | | | | [a] | GenRx Allopurinol | GX |
| | | | | | | | [a] | Progout 300 | AF |
| | | | | | | | [a] | Terry White Chemists Allopurinol | TW |
| | | | | [B]2.33 | 12.08 | 10.88 | [a] | Zyloprim | QA |
| | ***Preparations increasing uric acid excretion*** | | | | | | | | |
| | **PROBENECID** | | | | | | | | |
| 1940D *NP* | probenecid 500 mg tablet, 100 | 1 | 5 | .. | 75.90 | 36.10 | | Pro-Cid | PL |
| | ***Preparations with no effect on uric acid metabolism*** | | | | | | | | |
| | **COLCHICINE** | | | | | | | | |
| 3410L *NP* | colchicine 500 microgram tablet, 30 | 1 | 5 | .. | 11.21 | 12.34 | [a] | Lengout | LN |
| | | | | [B]0.85 | 12.06 | 12.34 | [a] | Colgout | AS |

## DRUGS FOR TREATMENT OF BONE DISEASES

### DRUGS AFFECTING BONE STRUCTURE AND MINERALIZATION

#### *Bisphosphonates*

**ALENDRONATE**

**Authority required (STREAMLINED)**

***3256***

Symptomatic Paget disease of bone

**Note**

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 8090T *NP* | alendronate 40 mg tablet, 30 | 1 | 5 | .. | 52.43 | 36.10 | | Fosamax 40 mg | MK |

**ALENDRONATE**

**Authority required (STREAMLINED)**

***4122***

Corticosteroid-induced osteoporosis

**The Clinical criteria is:**

Patient must currently be on long-term (at least 3 months), high-dose (at least 7.5 mg per day prednisolone or equivalent) corticosteroid therapy,

**AND the Clinical criteria is:**

Patient must have a Bone Mineral Density (BMD) T-score of -1.5 or less,

**AND the Clinical criteria is:**

Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

The duration and dose of corticosteroid therapy together with the date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

**Authority required (STREAMLINED)**

***4133***

Osteoporosis

**The Population criteria is:**

Patient must be aged 70 years or older,

**AND the Clinical criteria is:**

Patient must have a Bone Mineral Density (BMD) T-score of -2.5 or less,

**AND the Clinical criteria is:**

Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

The date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

**Authority required (STREAMLINED)**

***4123***

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|---|
| | Established osteoporosis | | | | | | | | |
| | **The Clinical criteria is:** | | | | | | | | |
| | Patient must have fracture due to minimal trauma, | | | | | | | | |
| | **AND the Clinical criteria is:** | | | | | | | | |
| | Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition. | | | | | | | | |
| | The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient's medical records when treatment is initiated. | | | | | | | | |
| | A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body. | | | | | | | | |
| | **Note** | | | | | | | | |
| | Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride, strontium ranelate and zoledronic acid. | | | | | | | | |
| 8511Y<br>*NP* | alendronate 70 mg tablet, 4 | 1 | 5 | .. | 21.01 | 22.14 | [a] | Adronat | AF |
| | | | | | | | [a] | Alendrobell 70mg | GQ |
| | | | | | | | [a] | Alendronate-GA | GM |
| | | | | | | | [a] | Alendronate Sandoz | SZ |
| | | | | | | | [a] | Alendro Once Weekly | QA |
| | | | | | | | [a] | APO-Alendronate | TX |
| | | | | | | | [a] | Chem mart Alendronate 70mg | CH |
| | | | | | | | [a] | Densate 70 | DO |
| | | | | | | | [a] | Fonat | AL |
| | | | | | | | [a] | Ossmax 70mg | RA |
| | | | | | | | [a] | Terry White Chemists Alendronate 70mg | TW |
| | **CLODRONATE** | | | | | | | | |
| | **Restricted benefit** | | | | | | | | |
| | Maintenance treatment of hypercalcaemia of malignancy refractory to anti-neoplastic therapy | | | | | | | | |
| | **Restricted benefit** | | | | | | | | |
| | Multiple myeloma | | | | | | | | |
| | **Restricted benefit** | | | | | | | | |
| | Bone metastases from breast cancer | | | | | | | | |
| | **Note** | | | | | | | | |
| | Continuing Therapy Only: | | | | | | | | |
| | For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners. | | | | | | | | |
| 8132B<br>*NP* | clodronate sodium 400 mg capsule, 100 | 1 | 2 | .. | 334.29 | 36.10 | | Bonefos | BN |
| 8265B<br>*NP* | clodronate sodium 800 mg tablet, 60 | 1 | 2 | .. | 391.65 | 36.10 | | Bonefos 800 mg | BN |
| | **IBANDRONIC ACID** | | | | | | | | |
| | **Restricted benefit** | | | | | | | | |
| | Bone metastases from breast cancer | | | | | | | | |
| | **Note** | | | | | | | | |
| | Continuing Therapy Only: | | | | | | | | |
| | For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners. | | | | | | | | |
| 9357L<br>*NP* | ibandronic acid 50 mg tablet, 28 | 1 | 2 | .. | 342.55 | 36.10 | | Bondronat | RO |
| | **PAMIDRONATE DISODIUM** | | | | | | | | |
| | **Authority required (STREAMLINED)** | | | | | | | | |
| | ***3256*** | | | | | | | | |
| | Symptomatic Paget disease of bone | | | | | | | | |
| | **Note** | | | | | | | | |

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|---|
| | Pharmaceutical benefits that have the form disodium pamidronate powder for I.V. infusion 15 mg (after reconstitution) and pharmaceutical benefits that have the form disodium pamidronate concentrated injection 15 mg are equivalent for the purposes of substitution. | | | | | | | | |
| | **Note**<br>Continuing Therapy Only:<br>For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners. | | | | | | | | |
| 8208B<br>*NP* | pamidronate disodium 15 mg injection [4 x 15 mg vials] (&) inert substance diluent [4 x 5 mL ampoules], 1 pack | 1 | .. | .. | 130.77 | 36.10 | a | Aredia 15 mg | NV |
| 8461H<br>*NP* | pamidronate disodium 15 mg/5 mL injection, 1 x 5 mL vial | 4 | .. | .. | *130.75 | 36.10 | a | Pamisol | HH |
| | **PAMIDRONATE DISODIUM**<br>**Authority required (STREAMLINED)**<br>***3256***<br>Symptomatic Paget disease of bone | | | | | | | | |
| | **Note**<br>Pharmaceutical benefits that have the form disodium pamidronate powder for I.V. infusion 30 mg (after reconstitution) and pharmaceutical benefits that have the form disodium pamidronate concentrated injection 30 mg are equivalent for the purposes of substitution. | | | | | | | | |
| | **Note**<br>Continuing Therapy Only:<br>For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners. | | | | | | | | |
| 8209C<br>*NP* | pamidronate disodium 30 mg injection [2 x 30 mg vials] (&) inert substance diluent [2 x 10 mL ampoules], 1 pack | 1 | .. | .. | 130.77 | 36.10 | a | Aredia 30 mg | NV |
| 8462J<br>*NP* | pamidronate disodium 30 mg/10 mL injection, 1 x 10 mL vial | 2 | .. | .. | *130.77 | 36.10 | a | Pamidronate Strides | YA |
| | | | | | | | a | Pamisol | HH |
| | **PAMIDRONATE DISODIUM**<br>**Authority required (STREAMLINED)**<br>***3256***<br>Symptomatic Paget disease of bone | | | | | | | | |
| | **Note**<br>Continuing Therapy Only:<br>For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners. | | | | | | | | |
| 8463K<br>*NP* | pamidronate disodium 60 mg/10 mL injection, 1 x 10 mL vial | 1 | .. | .. | 130.75 | 36.10 | | Pamisol | HH |
| | **RISEDRONATE**<br>**Authority required (STREAMLINED)**<br>***4122***<br>Corticosteroid-induced osteoporosis<br>**The Clinical criteria is:**<br>Patient must currently be on long-term (at least 3 months), high-dose (at least 7.5 mg per day prednisolone or equivalent) corticosteroid therapy,<br>**AND the Clinical criteria is:**<br>Patient must have a Bone Mineral Density (BMD) T-score of -1.5 or less,<br>**AND the Clinical criteria is:**<br>Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.<br>The duration and dose of corticosteroid therapy together with the date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated. | | | | | | | | |
| | **Authority required (STREAMLINED)**<br>***4133***<br>Osteoporosis<br>**The Population criteria is:**<br>Patient must be aged 70 years or older,<br>**AND the Clinical criteria is:**<br>Patient must have a Bone Mineral Density (BMD) T-score of -2.5 or less, | | | | | | | | |

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|---|
| | **AND the Clinical criteria is:** | | | | | | | | |
| | Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition. | | | | | | | | |
| | The date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated. | | | | | | | | |
| | **Authority required (STREAMLINED)** | | | | | | | | |
| | ***4123*** | | | | | | | | |
| | Established osteoporosis | | | | | | | | |
| | **The Clinical criteria is:** | | | | | | | | |
| | Patient must have fracture due to minimal trauma, | | | | | | | | |
| | **AND the Clinical criteria is:** | | | | | | | | |
| | Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition. | | | | | | | | |
| | The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient's medical records when treatment is initiated. | | | | | | | | |
| | A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body. | | | | | | | | |
| | **Note** | | | | | | | | |
| | Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride, strontium ranelate and zoledronic acid. | | | | | | | | |
| 8972F *NP* | RISEDRONATE SODIUM Tablet 35 mg (enteric coated), 4 | 1 | 5 | .. | 45.60 | 36.10 | | Actonel EC | SW |
| 9391G *NP* | risedronate sodium 150 mg tablet, 1 | 1 | 5 | .. | 48.48 | 36.10 | [a] | Acris Once-a-Month | AF |
| | | | | | | | [a] | Actonel Once-a-Month | SW |
| | | | | | | | [a] | APO-Risedronate | TX |
| | | | | | | | [a] | Chem mart Risedronate | CH |
| | | | | | | | [a] | Terry White Chemists Risedronate | TW |
| 8621R *NP* | risedronate sodium 35 mg tablet, 4 | 1 | 5 | .. | 45.60 | 36.10 | [a] | Acris Once-a-Week | AF |
| | | | | | | | [a] | APO-Risedronate | TX |
| | | | | | | | [a] | Chem mart Risedronate | CH |
| | | | | | | | [a] | Risedronate-GA | GM |
| | | | | | | | [a] | Risedronate Sandoz | SZ |
| | | | | | | | [a] | Risedro once a week | QA |
| | | | | | | | [a] | Terry White Chemists Risedronate | TW |
| 8481J *NP* | risedronate sodium 5 mg tablet, 28 | 1 | 5 | .. | 45.60 | 36.10 | | Actonel | SW |
| | **RISEDRONATE** | | | | | | | | |
| | **Authority required (STREAMLINED)** | | | | | | | | |
| | ***3256*** | | | | | | | | |
| | Symptomatic Paget disease of bone | | | | | | | | |
| | **Note** | | | | | | | | |
| | Continuing Therapy Only: | | | | | | | | |
| | For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners. | | | | | | | | |
| 8482K *NP* | risedronate sodium 30 mg tablet, 28 | 1 | 1 | .. | 260.00 | 36.10 | | Actonel | SW |
| | **TILUDRONATE** | | | | | | | | |
| | **Authority required (STREAMLINED)** | | | | | | | | |
| | ***3256*** | | | | | | | | |
| | Symptomatic Paget disease of bone | | | | | | | | |
| | **Note** | | | | | | | | |
| | Continuing Therapy Only: | | | | | | | | |
| | For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners. | | | | | | | | |

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|
| 8267D *NP* | tiludronate 200 mg tablet, 56 | 1 | 2 | .. | 304.83 | 36.10 | Skelid | SW |

**ZOLEDRONIC ACID**

**Authority required (STREAMLINED)**

***4100***

Corticosteroid-induced osteoporosis

**The Clinical criteria is:**

Patient must currently be on long-term (at least 3 months), high-dose (at least 7.5 mg per day prednisolone or equivalent) corticosteroid therapy,

**AND the Clinical criteria is:**

Patient must have a Bone Mineral Density (BMD) T-score of -1.5 or less,

**AND the Clinical criteria is:**

Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition,

**AND the Clinical criteria is:**

Patient must not receive more than one PBS-subsidised treatment per year.

The duration and dose of corticosteroid therapy together with the date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

**Authority required (STREAMLINED)**

***4149***

Osteoporosis

**The Population criteria is:**

Patient must be aged 70 years or older,

**AND the Clinical criteria is:**

Patient must have a Bone Mineral Density (BMD) T-score of -3.0 or less,

**AND the Clinical criteria is:**

Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition,

**AND the Clinical criteria is:**

Patient must not receive more than one PBS-subsidised treatment per year.

The date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

**Authority required (STREAMLINED)**

***4157***

Established osteoporosis

**The Clinical criteria is:**

Patient must have fracture due to minimal trauma,

**AND the Clinical criteria is:**

Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition,

**AND the Clinical criteria is:**

Patient must not receive more than one PBS-subsidised treatment per year.

The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient's medical records when treatment is initiated.

A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

**Note**

Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride, strontium ranelate and zoledronic acid.

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 9288W | zoledronic acid 5 mg/100 mL injection, 1 x 100 mL vial | 1 | .. | .. | 589.38 | 36.10 | Aclasta | NV |

**ZOLEDRONIC ACID**

**Authority required**

Symptomatic Paget disease of bone.

Only 1 treatment each year per patient will be PBS-subsidised

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|---|
| 9350D | zoledronic acid 5 mg/100 mL injection, 1 x 100 mL vial | 1 | .. | .. | 589.38 | 36.10 | | Aclasta | NV |

## *Bisphosphonates, combinations*

**ALENDRONATE + COLECALCIFEROL**

**Authority required (STREAMLINED)**

***4122***

Corticosteroid-induced osteoporosis

**The Clinical criteria is:**

Patient must currently be on long-term (at least 3 months), high-dose (at least 7.5 mg per day prednisolone or equivalent) corticosteroid therapy,

**AND the Clinical criteria is:**

Patient must have a Bone Mineral Density (BMD) T-score of -1.5 or less,

**AND the Clinical criteria is:**

Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

The duration and dose of corticosteroid therapy together with the date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

**Authority required (STREAMLINED)**

***4133***

Osteoporosis

**The Population criteria is:**

Patient must be aged 70 years or older,

**AND the Clinical criteria is:**

Patient must have a Bone Mineral Density (BMD) T-score of -2.5 or less,

**AND the Clinical criteria is:**

Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

The date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

**Authority required (STREAMLINED)**

***4123***

Established osteoporosis

**The Clinical criteria is:**

Patient must have fracture due to minimal trauma,

**AND the Clinical criteria is:**

Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient's medical records when treatment is initiated.

A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

**Note**

Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride, strontium ranelate and zoledronic acid.

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 9183H *NP* | alendronate 70 mg + colecalciferol 140 microgram tablet, 4 | 1 | 5 | .. | 45.38 | 36.10 | [a] | Dronalen Plus | GM |
| | | | | [B]2.49 | 47.87 | 36.10 | [a] | Fosamax Plus 70 mg/140 mcg | MK |

**ALENDRONATE + COLECALCIFEROL**

**Authority required (STREAMLINED)**

***4070***

Corticosteroid-induced osteoporosis

**The Clinical criteria is:**

Patient must currently be on long-term (at least 3 months), high-dose (at least 7.5 mg per day prednisolone or equivalent) corticosteroid therapy,

**AND the Clinical criteria is:**

Patient must have a Bone Mineral Density (BMD) T-score of -1.5 or less,

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|

**AND the Clinical criteria is:**

Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

The duration and dose of corticosteroid therapy together with the date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

**Authority required (STREAMLINED)**

***4110***

Osteoporosis

**The Population criteria is:**

Patient must be aged 70 years or older,

**AND the Clinical criteria is:**

Patient must have a Bone Mineral Density (BMD) T-score of -2.5 or less,

**AND the Clinical criteria is:**

Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

The date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

**Authority required (STREAMLINED)**

***4087***

Established osteoporosis

**The Clinical criteria is:**

Patient must have fracture due to minimal trauma,

**AND the Clinical criteria is:**

Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient's medical records when treatment is initiated.

A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

**Note**

Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride, strontium ranelate and zoledronic acid.

**Note**

Fosamax Plus provides a supplemental intake of vitamin D. The amount of colecalciferol present in Fosamax Plus is not sufficient to use as the sole treatment for correction of vitamin D deficiency.

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 9012H *NP* | alendronate 70 mg + colecalciferol 70 microgram tablet, 4 | 1 | 5 | .. | 45.38 | 36.10 | Fosamax Plus | MK |

**ALENDRONATE + COLECALCIFEROL (&) CALCIUM CARBONATE**

**Authority required (STREAMLINED)**

***4122***

Corticosteroid-induced osteoporosis

**The Clinical criteria is:**

Patient must currently be on long-term (at least 3 months), high-dose (at least 7.5 mg per day prednisolone or equivalent) corticosteroid therapy,

**AND the Clinical criteria is:**

Patient must have a Bone Mineral Density (BMD) T-score of -1.5 or less,

**AND the Clinical criteria is:**

Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

The duration and dose of corticosteroid therapy together with the date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

**Authority required (STREAMLINED)**

***4133***

Osteoporosis

**The Population criteria is:**

Patient must be aged 70 years or older,

**AND the Clinical criteria is:**

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|---|

Patient must have a Bone Mineral Density (BMD) T-score of -2.5 or less,

**AND the Clinical criteria is:**

Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

The date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

**Authority required (STREAMLINED)**

***4123***

Established osteoporosis

**The Clinical criteria is:**

Patient must have fracture due to minimal trauma,

**AND the Clinical criteria is:**

Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient's medical records when treatment is initiated.

A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

**Note**

Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride, strontium ranelate and zoledronic acid.

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 9351E *NP* | alendronate 70 mg + colecalciferol 140 microgram tablet [4 tablets] (&) calcium (as carbonate) 500 mg tablet [48 tablets], 1 pack | ‡1 | 5 | .. | 45.38 | 36.10 | a | Dronalen Plus D-Cal | FR |
| | | | | | | | a | Fosamax Plus D-Cal | MK |

**RISEDRONATE (&) CALCIUM CARBONATE**

**Authority required (STREAMLINED)**

***4122***

Corticosteroid-induced osteoporosis

**The Clinical criteria is:**

Patient must currently be on long-term (at least 3 months), high-dose (at least 7.5 mg per day prednisolone or equivalent) corticosteroid therapy,

**AND the Clinical criteria is:**

Patient must have a Bone Mineral Density (BMD) T-score of -1.5 or less,

**AND the Clinical criteria is:**

Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

The duration and dose of corticosteroid therapy together with the date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

**Authority required (STREAMLINED)**

***4133***

Osteoporosis

**The Population criteria is:**

Patient must be aged 70 years or older,

**AND the Clinical criteria is:**

Patient must have a Bone Mineral Density (BMD) T-score of -2.5 or less,

**AND the Clinical criteria is:**

Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

The date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

**Authority required (STREAMLINED)**

***4123***

Established osteoporosis

**The Clinical criteria is:**

Patient must have fracture due to minimal trauma,

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|---|
| | **AND the Clinical criteria is:** | | | | | | | | |
| | Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition. | | | | | | | | |
| | The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient's medical records when treatment is initiated. | | | | | | | | |
| | A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body. | | | | | | | | |
| | **Note**<br>Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride, strontium ranelate and zoledronic acid. | | | | | | | | |
| 8973G<br>*NP* | RISEDRONATE SODIUM and CALCIUM CARBONATE Pack containing 4 enteric coated tablets risedronate sodium 35 mg and 24 tablets calcium carbonate 1.25 g (equivalent to 500 mg calcium), 1 | ‡1 | 5 | .. | 45.60 | 36.10 | [a] | Actonel EC Combi | SW |
| | | | | | | | [a] | Risedronate Winthrop EC Combi | WA |
| 8899J<br>*NP* | risedronate sodium 35 mg tablet [4 tablets] (&) calcium (as carbonate) 500 mg tablet [24 tablets], 28 | ‡1 | 5 | .. | 45.60 | 36.10 | [a] | Acris Combi | AF |
| | | | | | | | [a] | Actonel Combi | SW |
| | **RISEDRONATE (&) CALCIUM CARBONATE + COLECALCIFEROL** | | | | | | | | |
| | **Authority required (STREAMLINED)** | | | | | | | | |
| | ***4122***<br>Corticosteroid-induced osteoporosis | | | | | | | | |
| | **The Clinical criteria is:** | | | | | | | | |
| | Patient must currently be on long-term (at least 3 months), high-dose (at least 7.5 mg per day prednisolone or equivalent) corticosteroid therapy, | | | | | | | | |
| | **AND the Clinical criteria is:** | | | | | | | | |
| | Patient must have a Bone Mineral Density (BMD) T-score of -1.5 or less, | | | | | | | | |
| | **AND the Clinical criteria is:** | | | | | | | | |
| | Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition. | | | | | | | | |
| | The duration and dose of corticosteroid therapy together with the date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated. | | | | | | | | |
| | **Authority required (STREAMLINED)** | | | | | | | | |
| | ***4133***<br>Osteoporosis | | | | | | | | |
| | **The Population criteria is:** | | | | | | | | |
| | Patient must be aged 70 years or older, | | | | | | | | |
| | **AND the Clinical criteria is:** | | | | | | | | |
| | Patient must have a Bone Mineral Density (BMD) T-score of -2.5 or less, | | | | | | | | |
| | **AND the Clinical criteria is:** | | | | | | | | |
| | Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition. | | | | | | | | |
| | The date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated. | | | | | | | | |
| | **Authority required (STREAMLINED)** | | | | | | | | |
| | ***4123***<br>Established osteoporosis | | | | | | | | |
| | **The Clinical criteria is:** | | | | | | | | |
| | Patient must have fracture due to minimal trauma, | | | | | | | | |
| | **AND the Clinical criteria is:** | | | | | | | | |
| | Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition. | | | | | | | | |
| | The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient's medical records when treatment is initiated. | | | | | | | | |

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|---|
| | A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body. | | | | | | | | |
| | **Note**<br>Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride, strontium ranelate and zoledronic acid. | | | | | | | | |
| 8974H<br>*NP* | 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 | 5 | .. | 45.60 | 36.10 | [a] | Actonel EC Combi D | SW |
| | | | | | | | [a] | Risedronate Winthrop EC Combi D | WA |

## *Other drugs affecting bone structure and mineralization*

**CALCITRIOL**

**Authority required (STREAMLINED)**
***1165***
Hypocalcaemia due to renal disease

**Authority required (STREAMLINED)**
***1166***
Hypoparathyroidism

**Authority required (STREAMLINED)**
***1167***
Hypophosphataemic rickets

**Authority required (STREAMLINED)**
***1467***
Vitamin D-resistant rickets

**Authority required (STREAMLINED)**
***2636***
Treatment for established osteoporosis in patients with fracture due to minimal trauma. The fracture must have been demonstrated radiologically and the year of plain x-ray or CT-scan or MRI scan must be documented in the patient's medical records when treatment is initiated.

A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 2502Q<br>*NP* | calcitriol 0.25 microgram capsule, 100 | 1 | 3 | .. | 34.16 | 35.29 | [a] | Calciprox | GN |
| | | | | | | | [a] | Calcitriol-GA | GM |
| | | | | | | | [a] | Calcitriol Sandoz | SZ |
| | | | | | | | [a] | GenRx Calcitriol | GX |
| | | | | | | | [a] | Kosteo | QA |
| | | | | | | | [a] | Rocaltrol | RO |
| | | | | | | | [a] | Sical | AF |

**DENOSUMAB**

**Authority required (STREAMLINED)**
***4158***
Bone metastases

**The Clinical criteria is:**

The condition must be due to breast cancer.

**Authority required (STREAMLINED)**
***4150***
Bone metastases

**The Clinical criteria is:**

The condition must be due to castration-resistant prostate cancer.

**Note**
**Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|
| | initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners. | | | | | | | |
| 5110Y<br>*NP* | denosumab 120 mg/1.7 mL injection, 1 x 1.7 mL vial | 1 | 5 | .. | 532.18 | 36.10 | Xgeva | AN |

**DENOSUMAB**

**Authority required (STREAMLINED)**

***4094***

Osteoporosis

**The Population criteria is:**

Patient must be female,

**AND the Population criteria is:**

Patient must be aged 70 years or older,

**AND the Clinical criteria is:**

Patient must have a Bone Mineral Density (BMD) T-score of -2.5 or less,

**AND the Clinical criteria is:**

Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

The date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

**Authority required (STREAMLINED)**

***4145***

Established post-menopausal osteoporosis

**The Clinical criteria is:**

Patient must have fracture due to minimal trauma,

**AND the Clinical criteria is:**

Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient's medical records when treatment is initiated.

A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

**Note**

Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride, strontium ranelate and zoledronic acid.

**Note**

**Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 5457F<br>*NP* | denosumab 60 mg/mL injection, 1 x 1 mL syringe | 1 | .. | .. | 298.90 | 36.10 | Prolia | AN |

**RALOXIFENE**

**Authority required (STREAMLINED)**

***4071***

Established post-menopausal osteoporosis

**The Clinical criteria is:**

Patient must have fracture due to minimal trauma,

**AND the Clinical criteria is:**

Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient's medical records when treatment is initiated.

A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

**Note**

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|
| | Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride, strontium ranelate and zoledronic acid. | | | | | | | |
| 8363E *NP* | raloxifene hydrochloride 60 mg tablet, 28 | 1 | 5 | .. | 58.08 | 36.10 | Evista | LY |

**STRONTIUM**

**Authority required (STREAMLINED)**

***4123***

Established osteoporosis

**The Clinical criteria is:**

Patient must have fracture due to minimal trauma,

**AND the Clinical criteria is:**

Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient's medical records when treatment is initiated.

A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

**Note**

Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride, strontium ranelate and zoledronic acid.

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 3036T *NP* | strontium ranelate 2 g granules, 28 x 2 g sachets | 1 | 5 | .. | 51.87 | 36.10 | Protos 2 g | SE |

**TERIPARATIDE**

**Authority required**

Severe established osteoporosis

Treatment Phase: Initial treatment

**The Treatment criteria is:**

Must be treated by a specialist; OR

Must be treated by a consultant physician,

**AND the Clinical criteria is:**

Patient must be at very high risk of fracture,

**AND the Clinical criteria is:**

Patient must have a bone mineral density (BMD) T-score of -3.0 or less,

**AND the Clinical criteria is:**

Patient must have had 2 or more fractures due to minimal trauma,

**AND the Clinical criteria is:**

Patient must have experienced at least 1 symptomatic new fracture after at least 12 months continuous therapy with an anti-resorptive agent at adequate doses,

**AND the Clinical criteria is:**

The treatment must be the sole PBS-subsidised agent,

**AND the Clinical criteria is:**

The treatment must not exceed a lifetime maximum of 18 months therapy.

A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

If treatment with anti-resorptive therapy is contraindicated according to the relevant TGA-approved Product Information, details of the contraindication must be provided at the time of application.

If an intolerance of a severity necessitating permanent treatment withdrawal develops during the relevant period of use of one anti-resorptive agent, alternate anti-resorptive agents must be trialled so that the patient achieves the minimum requirement of 12 months continuous therapy. Details must be provided at the time of application.

Anti-resorptive therapies for osteoporosis and their adequate doses which will be accepted for the purposes of administering this restriction are alendronate sodium 10 mg per day or 70 mg once weekly, risedronate sodium 5 mg per day or 35 mg once weekly or 150 mg once monthly, raloxifene hydrochloride 60 mg per day (women only), denosumab 60 mg once every 6 months, strontium ranelate 2 g per day and zoledronic acid 5 mg per annum.

# MUSCULO-SKELETAL SYSTEM

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|
| | Details of prior anti-resorptive therapy, fracture history including the date(s), site(s), the symptoms associated with the fracture(s) which developed after at least 12 months continuous anti-resorptive therapy and the score of the qualifying BMD measurement must be provided at the time of application.<br>**Note**<br>Details of accepted toxicities including severity can be found on the Department of Human Services website at www.humanservices.gov.au.<br>**Note**<br>No increase in the maximum quantity or number of units may be authorised.<br>**Note**<br>No increase in the maximum number of repeats may be authorised.<br>**Note**<br>Special Pricing Arrangements apply.<br>**Authority required**<br>Severe established osteoporosis<br>Treatment Phase: Continuing treatment<br>**The Clinical criteria is:**<br>Patient must have previously been issued with an authority prescription for this drug,<br>**AND the Clinical criteria is:**<br>The treatment must not exceed a lifetime maximum of 18 months therapy.<br>**Note**<br>Up to a maximum of 18 pens will be reimbursed through the PBS.<br>**Note**<br>No increase in the maximum quantity or number of units may be authorised.<br>**Note**<br>No increase in the maximum number of repeats may be authorised.<br>**Note**<br>Special Pricing Arrangements apply. | | | | | | | |
| 9411H | teriparatide 20 microgram/dose injection, 1 x 2.4 mL cartridge | 1 | 5 | .. | 438.58 | 36.10 | Forteo | LY |

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|

# NERVOUS SYSTEM

## ANALGESICS

### OPIOIDS

#### *Natural opium alkaloids*

**CODEINE**

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 1214X *NP* | codeine phosphate 30 mg tablet, 20 | 1 | .. | .. | 17.08 | 18.21 | Fawns and McAllan Proprietary Limited | FM |

**CODEINE**

**Note**

Prescribing of drugs of addiction by dentists is not permitted in some States/Territories.

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 5063L *DP* | codeine phosphate 30 mg tablet, 20 | 1 | .. | .. | 17.08 | 18.21 | Fawns and McAllan Proprietary Limited | FM |

**HYDROMORPHONE**

**Restricted benefit**

Severe disabling pain not responding to non-narcotic analgesics

**Caution**

The risk of drug dependence is high.

**Note**

Prescribing of drugs of addiction by dentists is not permitted in some States/Territories.

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 5132D *DP* | hydromorphone hydrochloride 1 mg/mL oral liquid, 473 mL | 1 | .. | .. | 63.91 | 36.10 | Dilaudid | MF |
| 5115F *DP* | hydromorphone hydrochloride 2 mg tablet, 20 | 1 | .. | .. | 17.32 | 18.45 | Dilaudid | MF |
| 5116G *DP* | hydromorphone hydrochloride 4 mg tablet, 20 | 1 | .. | .. | 20.06 | 21.19 | Dilaudid | MF |
| 5117H *DP* | hydromorphone hydrochloride 8 mg tablet, 20 | 1 | .. | .. | 30.24 | 31.37 | Dilaudid | MF |

**HYDROMORPHONE**

**Restricted benefit**

Severe disabling pain not responding to non-narcotic analgesics

**Caution**

The risk of drug dependence is high.

**Note**

Authorities for increased maximum quantities and/or repeats will be granted only for:

(i) severe disabling pain associated with proven malignant neoplasia; or

(ii) chronic severe disabling pain not responding to non-narcotic analgesics where the total duration of narcotic analgesic treatment is less than 12 months; or

(iii) first application for treatment beyond 12 months of chronic severe disabling pain not responding to non-narcotic analgesics where the patient's pain management has been reviewed through consultation by the patient with another medical practitioner, and the clinical need for continuing narcotic analgesic treatment has been confirmed. The date of the consultation must be no more than 3 months prior to the application for a PBS authority. The full name of the medical practitioner consulted and the date of consultation are to be provided at the time of application; or

(iv) subsequent application for treatment of chronic severe disabling pain not responding to non-narcotic analgesics where a PBS authority prescription for treatment beyond 12 months has previously been issued for this patient.

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 8424J *NP* | hydromorphone hydrochloride 1 mg/mL oral liquid, 473 mL | 1 | .. | .. | 63.91 | 36.10 | Dilaudid | MF |
| 8541M *NP* | hydromorphone hydrochloride 2 mg tablet, 20 | 1 | .. | .. | 17.32 | 18.45 | Dilaudid | MF |
| 8542N *NP* | hydromorphone hydrochloride 4 mg tablet, 20 | 1 | .. | .. | 20.06 | 21.19 | Dilaudid | MF |
| 8543P *NP* | hydromorphone hydrochloride 8 mg tablet, 20 | 1 | .. | .. | 30.24 | 31.37 | Dilaudid | MF |

**HYDROMORPHONE**

**Caution**

The risk of drug dependence is high.

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 8421F | hydromorphone hydrochloride 10 | 1 | .. | .. | 29.18 | 30.31 | Dilaudid-HP | MF |

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|
| *NP* | mg/mL injection, 5 x 1 mL ampoules | | | | | | | |
| 8420E *NP* | hydromorphone hydrochloride 2 mg/mL injection, 5 x 1 mL ampoules | 1 | .. | .. | 23.05 | 24.18 | Dilaudid | MF |
| 8422G *NP* | hydromorphone hydrochloride 50 mg/5 mL injection, 5 x 5 mL ampoules | 1 | .. | .. | 52.21 | 36.10 | Dilaudid-HP | MF |
| 8423H *NP* | hydromorphone hydrochloride 500 mg/50 mL injection, 1 x 50 mL vial | 1 | .. | .. | 75.62 | 36.10 | Dilaudid-HP | MF |

**HYDROMORPHONE**

**Restricted benefit**

Chronic severe disabling pain not responding to non-narcotic analgesics

**Caution**

The risk of drug dependence is high.

**Note**

Authorities for increased maximum quantities and/or repeats will be granted only for:

(i) chronic severe disabling pain associated with proven malignant neoplasia; or

(ii) chronic severe disabling pain not responding to non-narcotic analgesics where the total duration of narcotic analgesic treatment is less than 12 months; or

(iii) first application for treatment beyond 12 months of chronic severe disabling pain not responding to non-narcotic analgesics where the patient's pain management has been reviewed through consultation by the patient with another medical practitioner, and the clinical need for continuing narcotic analgesic treatment has been confirmed. The date of the consultation must be no more than 3 months prior to the application for a PBS authority. The full name of the medical practitioner consulted and the date of consultation are to be provided at the time of application; or

(iv) subsequent application for treatment of chronic severe disabling pain not responding to non-narcotic analgesics where a PBS authority prescription for treatment beyond 12 months has previously been issued for this patient.

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 9407D *NP* | hydromorphone hydrochloride 16 mg tablet: modified release, 14 tablets | 1 | .. | .. | 53.03 | 36.10 | Jurnista | JC |
| 9408E *NP* | hydromorphone hydrochloride 32 mg tablet: modified release, 14 tablets | 1 | .. | .. | 88.91 | 36.10 | Jurnista | JC |
| 9299K *NP* | hydromorphone hydrochloride 4 mg tablet: modified release, 14 tablets | 1 | .. | .. | 31.16 | 32.29 | Jurnista | JC |
| 9409F *NP* | hydromorphone hydrochloride 64 mg tablet: modified release, 14 tablets | 1 | .. | .. | 149.59 | 36.10 | Jurnista | JC |
| 9406C *NP* | hydromorphone hydrochloride 8 mg tablet: modified release, 14 tablets | 1 | .. | .. | 36.62 | 36.10 | Jurnista | JC |

**MORPHINE**

**Restricted benefit**

Chronic severe disabling pain not responding to non-narcotic analgesics

**Caution**

The risk of drug dependence is high.

**Note**

Authorities for increased maximum quantities and/or repeats will be granted only for:

(i) chronic severe disabling pain associated with proven malignant neoplasia; or

(ii) chronic severe disabling pain not responding to non-narcotic analgesics where the total duration of narcotic analgesic treatment is less than 12 months; or

(iii) first application for treatment beyond 12 months of chronic severe disabling pain not responding to non-narcotic analgesics where the patient's pain management has been reviewed through consultation by the patient with another medical practitioner, and the clinical need for continuing narcotic analgesic treatment has been confirmed. The date of the consultation must be no more than 3 months prior to the application for a PBS authority. The full name of the medical practitioner consulted and the date of consultation are to be provided at the time of application; or

(iv) subsequent application for treatment of chronic severe disabling pain not responding to non-narcotic analgesics where a PBS authority prescription for treatment beyond 12 months has previously been issued for this patient.

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 8349K *NP* | morphine Capsule 10 mg (containing sustained release pellets), 28 | 1 | .. | .. | 20.24 | 21.37 | Kapanol | YN |
| 2841M *NP* | morphine Capsule 100 mg (containing sustained release pellets), 28 | 1 | .. | .. | 70.68 | 36.10 | Kapanol | YN |
| 2839K *NP* | morphine Capsule 20 mg (containing sustained release pellets), 28 | 1 | .. | .. | 25.22 | 26.35 | Kapanol | YN |
| 2840L *NP* | morphine Capsule 50 mg (containing sustained release pellets), 28 | 1 | .. | .. | 43.52 | 36.10 | Kapanol | YN |
| 8146R *NP* | morphine Sachet containing controlled release granules for oral suspension, 30 mg per sachet, 28 | 1 | .. | .. | 62.28 | 36.10 | MS Contin Suspension 30 mg | MF |

# NERVOUS SYSTEM

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|---|
| 8305D *NP* | morphine Sachet containing controlled release granules for oral suspension, 60 mg per sachet, 28 | 1 | .. | .. | 70.08 | 36.10 | | MS Contin Suspension 60 mg | MF |
| 1653B *NP* | morphine sulfate 10 mg tablet: modified release, 28 tablets | 1 | .. | .. | 20.25 | 21.38 | [a] | APOTEX-MORPHINE MR | TX |
| | | | | | | | [a] | Momex SR 10 | QA |
| | | | | | | | [a] | MS Contin | MF |
| 8306E *NP* | morphine sulfate 100 mg granules: modified release, 28 x 100 mg sachets | 1 | .. | .. | 86.58 | 36.10 | | MS Contin Suspension 100 mg | MF |
| 1656E *NP* | morphine sulfate 100 mg tablet: modified release, 28 tablets | 1 | .. | .. | 72.72 | 36.10 | [a] | APOTEX-MORPHINE MR | TX |
| | | | | | | | [a] | Momex SR 100 | QA |
| | | | | | | | [a] | MS Contin | MF |
| 8494C *NP* | morphine sulfate 120 mg capsule: modified release, 14 capsules | 1 | .. | .. | 54.68 | 36.10 | | MS Mono | MF |
| 8489T *NP* | morphine sulfate 15 mg tablet: modified release, 28 tablets | 1 | .. | .. | 24.44 | 25.57 | | MS Contin | MF |
| 8490W *NP* | morphine sulfate 20 mg granules: modified release, 28 x 20 mg sachets | 1 | .. | .. | 60.50 | 36.10 | | MS Contin Suspension 20 mg | MF |
| 8491X *NP* | morphine sulfate 30 mg capsule: modified release, 14 capsules | 1 | .. | .. | 24.43 | 25.56 | | MS Mono | MF |
| 1654C *NP* | morphine sulfate 30 mg tablet: modified release, 28 tablets | 1 | .. | .. | 36.10 | 36.10 | [a] | APOTEX-MORPHINE MR | TX |
| | | | | | | | [a] | Momex SR 30 | QA |
| | | | | | | | [a] | MS Contin | MF |
| 8035X *NP* | morphine sulfate 5 mg tablet: modified release, 28 tablets | 1 | .. | .. | 17.82 | 18.95 | | MS Contin | MF |
| 8492Y *NP* | morphine sulfate 60 mg capsule: modified release, 14 capsules | 1 | .. | .. | 36.08 | 36.10 | | MS Mono | MF |
| 1655D *NP* | morphine sulfate 60 mg tablet: modified release, 28 tablets | 1 | .. | .. | 54.69 | 36.10 | [a] | APOTEX-MORPHINE MR | TX |
| | | | | | | | [a] | Momex SR 60 | QA |
| | | | | | | | [a] | MS Contin | MF |
| 8493B *NP* | morphine sulfate 90 mg capsule: modified release, 14 capsules | 1 | .. | .. | 41.63 | 36.10 | | MS Mono | MF |

**MORPHINE**

**Restricted benefit**

Severe disabling pain not responding to non-narcotic analgesics

**Caution**

The risk of drug dependence is high.

**Note**

Authorities for increased maximum quantities and/or repeats will be granted only for:

(i) severe disabling pain associated with proven malignant neoplasia; or

(ii) chronic severe disabling pain not responding to non-narcotic analgesics where the total duration of narcotic analgesic treatment is less than 12 months; or

(iii) first application for treatment beyond 12 months of chronic severe disabling pain not responding to non-narcotic analgesics where the patient's pain management has been reviewed through consultation by the patient with another medical practitioner, and the clinical need for continuing narcotic analgesic treatment has been confirmed. The date of the consultation must be no more than 3 months prior to the application for a PBS authority. The full name of the medical practitioner consulted and the date of consultation are to be provided at the time of application; or

(iv) subsequent application for treatment of chronic severe disabling pain not responding to non-narcotic analgesics where a PBS authority prescription for treatment beyond 12 months has previously been issued for this patient.

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 2124T *NP* | morphine hydrochloride 10 mg/mL oral liquid, 200 mL | 1 | .. | .. | 27.07 | 28.20 | | Ordine 10 | MF |
| 2122Q *NP* | morphine hydrochloride 2 mg/mL oral liquid, 200 mL | 1 | .. | .. | 20.54 | 21.67 | | Ordine 2 | MF |
| 2123R *NP* | morphine hydrochloride 5 mg/mL oral liquid, 200 mL | 1 | .. | .. | 22.94 | 24.07 | | Ordine 5 | MF |
| 1646P *NP* | morphine sulfate 30 mg tablet, 20 | 1 | .. | .. | 14.24 | 15.37 | | Anamorph | FM |

**MORPHINE**

**Restricted benefit**

Severe disabling pain not responding to non-narcotic analgesics

**Caution**

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|
| | The risk of drug dependence is high. | | | | | | | |
| | **Note**<br>Prescribing of drugs of addiction by dentists is not permitted in some States/Territories. | | | | | | | |
| 5239R<br>*DP* | morphine hydrochloride 10 mg/mL oral liquid, 200 mL | 1 | .. | .. | 27.07 | 28.20 | Ordine 10 | MF |
| 5237P<br>*DP* | morphine hydrochloride 2 mg/mL oral liquid, 200 mL | 1 | .. | .. | 20.54 | 21.67 | Ordine 2 | MF |
| 5238Q<br>*DP* | morphine hydrochloride 5 mg/mL oral liquid, 200 mL | 1 | .. | .. | 22.94 | 24.07 | Ordine 5 | MF |
| 5163R<br>*DP* | morphine sulfate 30 mg tablet, 20 | 1 | .. | .. | 14.24 | 15.37 | Anamorph | FM |
| | **MORPHINE**<br>**Restricted benefit**<br>Severe disabling pain due to cancer not responding to non-narcotic analgesics | | | | | | | |
| | **Caution**<br>The risk of drug dependence is high. | | | | | | | |
| 8669G<br>*NP* | morphine sulfate 10 mg tablet, 20 | 1 | .. | .. | 14.53 | 15.66 | Sevredol | MF |
| 8670H<br>*NP* | morphine sulfate 20 mg tablet, 20 | 1 | .. | .. | 15.47 | 16.60 | Sevredol | MF |
| | **MORPHINE**<br>**Caution**<br>The risk of drug dependence is high. | | | | | | | |
| 1644M<br>*NP,MW* | morphine sulfate 10 mg/mL injection, 5 x 1 mL ampoules | 1 | .. | .. | 16.63 | 17.76 | Hospira Pty Limited | HH |
| 1645N<br>*NP,MW* | morphine sulfate 15 mg/mL injection, 5 x 1 mL ampoules | 1 | .. | .. | 17.17 | 18.30 | Hospira Pty Limited | HH |
| 1647Q<br>*NP* | morphine sulfate 30 mg/mL injection, 5 x 1 mL ampoules | 1 | .. | .. | 19.30 | 20.43 | Hospira Pty Limited | HH |
| 1607N<br>*NP* | morphine tartrate 120 mg/1.5 mL injection, 5 x 1.5 mL ampoules | 1 | .. | .. | 39.49 | 36.10 | Hospira Pty Limited | HH |
| | **MORPHINE**<br>**Caution**<br>The risk of drug dependence is high. | | | | | | | |
| | **Note**<br>Prescribing of drugs of addiction by dentists is not permitted in some States/Territories. | | | | | | | |
| 5168B<br>*DP* | morphine sulfate 10 mg/mL injection, 5 x 1 mL ampoules | 1 | .. | .. | 16.63 | 17.76 | Hospira Pty Limited | HH |
| 5169C<br>*DP* | morphine sulfate 15 mg/mL injection, 5 x 1 mL ampoules | 1 | .. | .. | 17.17 | 18.30 | Hospira Pty Limited | HH |
| 5170D<br>*DP* | morphine sulfate 30 mg/mL injection, 5 x 1 mL ampoules | 1 | .. | .. | 19.30 | 20.43 | Hospira Pty Limited | HH |
| | **MORPHINE**<br>**Authority required**<br>Chronic severe disabling pain due to cancer | | | | | | | |
| | **Caution**<br>The risk of drug dependence is high. | | | | | | | |
| 8454Y<br>*NP* | morphine sulfate 200 mg granules: modified release, 28 x 200 mg sachets | 1 | .. | .. | 163.96 | 36.10 | MS Contin Suspension 200 mg | MF |
| 8453X<br>*NP* | morphine sulfate 200 mg tablet: modified release, 28 tablets | 1 | .. | .. | 122.07 | 36.10 | MS Contin | MF |
| | **MORPHINE**<br>**Caution**<br>The risk of drug dependence is high. | | | | | | | |
| | **Caution**<br>This formulation contains preservative and must not be administered via epidural or intrathecal route. | | | | | | | |
| 2332R<br>*NP,MW* | morphine sulphate 10 mg/mL injection (with preservative), 10 x 1 mL ampoules | 1 | .. | .. | 23.93 | 25.06 | Morphine Sulphate Wockhardt | HH |

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|
| | **MORPHINE**<br>**Caution**<br>The risk of drug dependence is high.<br>**Caution**<br>This formulation contains preservative and must not be administered via epidural or intrathecal route.<br>**Note**<br>Prescribing of drugs of addication by dentists is not permitted in some States/Territories. | | | | | | | |
| 2333T<br>*DP* | morphine sulphate 10 mg/mL injection (with preservative), 10 x 1 mL ampoules | 1 | .. | .. | 23.93 | 25.06 | Morphine Sulphate Wockhardt | HH |
| | **OXYCODONE**<br>**Restricted benefit**<br>Severe disabling pain not responding to non-narcotic analgesics<br>**Caution**<br>The risk of drug dependence is high.<br>**Note**<br>Authorities for increased maximum quantities and/or repeats will be granted only for:<br>(i) severe disabling pain associated with proven malignant neoplasia; or<br>(ii) chronic severe disabling pain not responding to non-narcotic analgesics where the total duration of narcotic analgesic treatment is less than 12 months; or<br>(iii) first application for treatment beyond 12 months of chronic severe disabling pain not responding to non-narcotic analgesics where the patient's pain management has been reviewed through consultation by the patient with another medical practitioner, and the clinical need for continuing narcotic analgesic treatment has been confirmed. The date of the consultation must be no more than 3 months prior to the application for a PBS authority. The full name of the medical practitioner consulted and the date of consultation are to be provided at the time of application; or<br>(iv) subsequent application for treatment of chronic severe disabling pain not responding to non-narcotic analgesics where a PBS authority prescription for treatment beyond 12 months has previously been issued for this patient. | | | | | | | |
| 2481N<br>*NP* | oxycodone 30 mg suppository, 12 | 1 | .. | .. | 43.87 | 36.10 | Proladone | PL |
| 8501K<br>*NP* | oxycodone hydrochloride 10 mg capsule, 20 | 1 | .. | .. | 15.63 | 16.76 | OxyNorm | MF |
| 8502L<br>*NP* | oxycodone hydrochloride 20 mg capsule, 20 | 1 | .. | .. | 20.36 | 21.49 | OxyNorm | MF |
| 8464L<br>*NP* | oxycodone hydrochloride 5 mg capsule, 20 | 1 | .. | .. | 12.51 | 13.64 | OxyNorm | MF |
| 2622B<br>*NP* | oxycodone hydrochloride 5 mg tablet, 20 | 1 | .. | .. | 12.51 | 13.64 | Endone | QA |
| 8644Y<br>*NP* | oxycodone hydrochloride 5 mg/5 mL oral liquid, 250 mL | 1 | .. | .. | 20.94 | 22.07 | OxyNorm Liquid 5mg/5mL | MF |
| | **OXYCODONE**<br>**Restricted benefit**<br>Severe disabling pain not responding to non-narcotic analgesics<br>**Caution**<br>The risk of drug dependence is high.<br>**Note**<br>Prescribing of drugs of addiction by dentists is not permitted in some States/Territories. | | | | | | | |
| 5194J<br>*DP* | oxycodone 30 mg suppository, 12 | 1 | .. | .. | 43.87 | 36.10 | Proladone | PL |
| 5197M<br>*DP* | oxycodone hydrochloride 10 mg capsule, 20 | 1 | .. | .. | 15.63 | 16.76 | OxyNorm | MF |
| 5191F<br>*DP* | oxycodone hydrochloride 5 mg capsule, 20 | 1 | .. | .. | 12.51 | 13.64 | OxyNorm | MF |
| 5195K<br>*DP* | oxycodone hydrochloride 5 mg tablet, 20 | 1 | .. | .. | 12.51 | 13.64 | Endone | QA |
| 5190E<br>*DP* | oxycodone hydrochloride 5 mg/5 mL oral liquid, 250 mL | 1 | .. | .. | 20.94 | 22.07 | OxyNorm Liquid 5mg/5mL | MF |
| | **OXYCODONE**<br>**Restricted benefit**<br>Chronic severe disabling pain not responding to non-narcotic analgesics<br>**Caution** | | | | | | | |

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|
| | The risk of drug dependence is high.<br>**Note**<br>Authorities for increased maximum quantities and/or repeats will be granted only for:<br>(i) chronic severe disabling pain associated with proven malignant neoplasia; or<br>(ii) chronic severe disabling pain not responding to non-narcotic analgesics where the total duration of narcotic analgesic treatment is less than 12 months; or<br>(iii) first application for treatment beyond 12 months of chronic severe disabling pain not responding to non-narcotic analgesics where the patient's pain management has been reviewed through consultation by the patient with another medical practitioner, and the clinical need for continuing narcotic analgesic treatment has been confirmed. The date of the consultation must be no more than 3 months prior to the application for a PBS authority. The full name of the medical practitioner consulted and the date of consultation are to be provided at the time of application; or<br>(iv) subsequent application for treatment of chronic severe disabling pain not responding to non-narcotic analgesics where a PBS authority prescription for treatment beyond 12 months has previously been issued for this patient. | | | | | | | |
| 8385H<br>*NP* | oxycodone hydrochloride 10 mg tablet: modified release, 28 tablets | 1 | .. | .. | 27.30 | 28.43 | OxyContin | MF |
| 9399Q<br>*NP* | oxycodone hydrochloride 15 mg tablet: modified release, 28 tablets | 1 | .. | .. | 35.68 | 36.10 | OxyContin | MF |
| 8386J<br>*NP* | oxycodone hydrochloride 20 mg tablet: modified release, 28 tablets | 1 | .. | .. | 41.18 | 36.10 | OxyContin | MF |
| 9400R<br>*NP* | oxycodone hydrochloride 30 mg tablet: modified release, 28 tablets | 1 | .. | .. | 52.90 | 36.10 | OxyContin | MF |
| 8387K<br>*NP* | oxycodone hydrochloride 40 mg tablet: modified release, 28 tablets | 1 | .. | .. | 62.81 | 36.10 | OxyContin | MF |
| 8681X<br>*NP* | oxycodone hydrochloride 5 mg tablet: modified release, 28 tablets | 1 | .. | .. | 26.21 | 27.34 | OxyContin | MF |
| 8388L<br>*NP* | oxycodone hydrochloride 80 mg tablet: modified release, 28 tablets | 1 | .. | .. | 96.93 | 36.10 | OxyContin | MF |
| | **OXYCODONE + NALOXONE**<br>**Restricted benefit**<br>Chronic severe disabling pain not responding to non-narcotic analgesics<br>**Caution**<br>The risk of drug dependence is high.<br>**Note**<br>Authorities for increased maximum quantities and/or repeats will be granted only for:<br>(i) chronic severe disabling pain associated with proven malignant neoplasia; or<br>(ii) chronic severe disabling pain not responding to non-narcotic analgesics where the total duration of narcotic analgesic treatment is less than 12 months; or<br>(iii) first application for treatment beyond 12 months of chronic severe disabling pain not responding to non-narcotic analgesics where the patient's pain management has been reviewed through consultation by the patient with another medical practitioner, and the clinical need for continuing narcotic analgesic treatment has been confirmed. The date of the consultation must be no more than 3 months prior to the application for a PBS authority. The full name of the medical practitioner consulted and the date of consultation are to be provided at the time of application; or<br>(iv) subsequent application for treatment of chronic severe disabling pain not responding to non-narcotic analgesics where a PBS authority prescription for treatment beyond 12 months has previously been issued for this patient.<br>**Note**<br>Shared Care Model:<br>For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners. | | | | | | | |
| 8934F<br>*NP* | oxycodone hydrochloride 10 mg + naloxone hydrochloride 5 mg tablet: modified release, 28 tablets | 1 | .. | .. | 30.88 | 32.01 | Targin 10/5mg | MF |
| 8935G<br>*NP* | oxycodone hydrochloride 20 mg + naloxone hydrochloride 10 mg tablet: modified release, 28 tablets | 1 | .. | .. | 47.06 | 36.10 | Targin 20/10mg | MF |
| 8936H<br>*NP* | oxycodone hydrochloride 40 mg + naloxone hydrochloride 20 mg tablet: modified release, 28 tablets | 1 | .. | .. | 73.49 | 36.10 | Targin 40/20mg | MF |
| 8000C<br>*NP* | oxycodone hydrochloride 5 mg + naloxone hydrochloride 2.5 mg tablet: modified release, 28 tablets | 1 | .. | .. | 29.58 | 30.71 | Targin 5/2.5mg | MF |
| | **PARACETAMOL + CODEINE**<br>**Note** | | | | | | | |

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|---|
| | Authorities for increased maximum quantities and/or repeats will not be granted except as detailed under the 'Authority required' listing of codeine phosphate with paracetamol below. | | | | | | | | |
| 1215Y *NP* | CODEINE PHOSPHATE with PARACETAMOL Tablet 30 mg-500 mg, 20 | 1 | .. | .. | 7.55 | 8.68 | [a] | APO-Paracetamol/Codeine 500/30 | TX |
| | | | | | | | [a] | Codalgin Forte | FM |
| | | | | | | | [a] | Codapane Forte | AL |
| | | | | | | | [a] | Comfarol Forte | SZ |
| | | | | | | | [a] | Prodeine Forte | AV |
| | | | | [B]2.40 | 9.95 | 8.68 | [a] | Panadeine Forte | SW |
| | **PARACETAMOL + CODEINE** | | | | | | | | |
| 3316M *DP* | CODEINE PHOSPHATE with PARACETAMOL Tablet 30 mg-500 mg, 20 | 1 | .. | .. | 7.55 | 8.68 | [a] | APO-Paracetamol/Codeine 500/30 | TX |
| | | | | | | | [a] | Codalgin Forte | FM |
| | | | | | | | [a] | Codapane Forte | AL |
| | | | | | | | [a] | Comfarol Forte | SZ |
| | | | | | | | [a] | Prodeine Forte | AV |
| | | | | [B]2.40 | 9.95 | 8.68 | [a] | Panadeine Forte | SW |
| | **PARACETAMOL + CODEINE**<br>**Authority required**<br>Severe disabling pain not responding to non-narcotic analgesics<br>**Note**<br>Each authority approval will be limited to no more than 240 tablets per month for no more than 6 months. | | | | | | | | |
| 8785J *NP* | CODEINE PHOSPHATE with PARACETAMOL Tablet 30 mg-500 mg, 20 | 3 | .. | .. | *9.39 | 10.52 | [a] | APO-Paracetamol/Codeine 500/30 | TX |
| | | | | | | | [a] | Codalgin Forte | FM |
| | | | | | | | [a] | Codapane Forte | AL |
| | | | | | | | [a] | Comfarol Forte | SZ |
| | | | | | | | [a] | Prodeine Forte | AV |
| | | | | [B]7.20 | *16.59 | 10.52 | [a] | Panadeine Forte | SW |

## *Phenylpiperidine derivatives*

**FENTANYL**

**Restricted benefit**

Chronic severe disabling pain not responding to non-narcotic analgesics

**Caution**

The risk of drug dependence is high.

**Note**

Authorities for increased maximum quantities and/or repeats will be granted only for:

(i) chronic severe disabling pain associated with proven malignant neoplasia; or

(ii) chronic severe disabling pain not responding to non-narcotic analgesics where the total duration of narcotic analgesic treatment is less than 12 months; or

(iii) first application for treatment beyond 12 months of chronic severe disabling pain not responding to non-narcotic analgesics where the patient's pain management has been reviewed through consultation by the patient with another medical practitioner, and the clinical need for continuing narcotic analgesic treatment has been confirmed. The date of the consultation must be no more than 3 months prior to the application for a PBS authority. The full name of the medical practitioner consulted and the date of consultation are to be provided at the time of application; or

(iv) subsequent application for treatment of chronic severe disabling pain not responding to non-narcotic analgesics where a PBS authority prescription for treatment beyond 12 months has previously been issued for this patient.

**Note**

Fentanyl transdermal patches are not recommended in opioid naive patients with non-cancer pain, because of a high incidence of adverse events in these patients. Patients with cancer pain may be initiated on the lowest strength patch (12 micrograms per hour).

Pharmaceutical benefits that have the forms fentanyl transdermal patch 16.5 mg, fentanyl transdermal patch 10.20 mg and fentanyl transdermal patch 16.8 mg (all releasing approximately 100 micrograms per hour) are equivalent for the purposes of substitution.

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 5280X *NP* | fentanyl 100 microgram/hour patch, 5 | 1 | .. | .. | 106.80 | 36.10 | [a] | Denpax | AF |
| 5441J *NP* | fentanyl 100 microgram/hour patch, 5 | 1 | .. | .. | 106.80 | 36.10 | [a] | Dutran 100 | GM |
| | | | | | | | [a] | Fenpatch 100 | ZP |

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|---|
| 8894D | fentanyl 100 microgram/hour patch, 5 | 1 | .. | .. | 106.80 | 36.10 | [a] | Durogesic 100 | JC |
| *NP* | | | | | | | | | |
| | | | | | | | [a] | Fentanyl Sandoz | SZ |

**FENTANYL**

**Restricted benefit**

Chronic severe disabling pain not responding to non-narcotic analgesics

**Caution**

The risk of drug dependence is high.

**Note**

Authorities for increased maximum quantities and/or repeats will be granted only for:

(i) chronic severe disabling pain associated with proven malignant neoplasia; or

(ii) chronic severe disabling pain not responding to non-narcotic analgesics where the total duration of narcotic analgesic treatment is less than 12 months; or

(iii) first application for treatment beyond 12 months of chronic severe disabling pain not responding to non-narcotic analgesics where the patient's pain management has been reviewed through consultation by the patient with another medical practitioner, and the clinical need for continuing narcotic analgesic treatment has been confirmed. The date of the consultation must be no more than 3 months prior to the application for a PBS authority. The full name of the medical practitioner consulted and the date of consultation are to be provided at the time of application; or

(iv) subsequent application for treatment of chronic severe disabling pain not responding to non-narcotic analgesics where a PBS authority prescription for treatment beyond 12 months has previously been issued for this patient.

**Note**

Fentanyl transdermal patches are not recommended in opioid naive patients with non-cancer pain, because of a high incidence of adverse events in these patients. Patients with cancer pain may be initiated on the lowest strength patch (12 micrograms per hour).

Pharmaceutical benefits that have the forms fentanyl transdermal patch 2.063 mg, fentanyl transdermal patch 1.28 mg and fentanyl transdermal patch 2.1 mg (all releasing approximately 12 micrograms per hour) are equivalent for the purposes of substitution.

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 5265D | fentanyl 12 microgram/hour patch, 5 | 1 | .. | .. | 34.97 | 36.10 | [a] | Denpax | AF |
| *NP* | | | | | | | | | |
| 5437E | fentanyl 12 microgram/hour patch, 5 | 1 | .. | .. | 34.97 | 36.10 | [a] | Dutran 12 | GM |
| *NP* | | | | | | | | | |
| | | | | | | | [a] | Fenpatch 12 | ZP |
| 8878G | fentanyl 12 microgram/hour patch, 5 | 1 | .. | .. | 34.97 | 36.10 | [a] | Durogesic 12 | JC |
| *NP* | | | | | | | | | |
| | | | | | | | [a] | Fentanyl Sandoz | SZ |

**FENTANYL**

**Restricted benefit**

Chronic severe disabling pain not responding to non-narcotic analgesics

**Caution**

The risk of drug dependence is high.

**Note**

Authorities for increased maximum quantities and/or repeats will be granted only for:

(i) chronic severe disabling pain associated with proven malignant neoplasia; or

(ii) chronic severe disabling pain not responding to non-narcotic analgesics where the total duration of narcotic analgesic treatment is less than 12 months; or

(iii) first application for treatment beyond 12 months of chronic severe disabling pain not responding to non-narcotic analgesics where the patient's pain management has been reviewed through consultation by the patient with another medical practitioner, and the clinical need for continuing narcotic analgesic treatment has been confirmed. The date of the consultation must be no more than 3 months prior to the application for a PBS authority. The full name of the medical practitioner consulted and the date of consultation are to be provided at the time of application; or

(iv) subsequent application for treatment of chronic severe disabling pain not responding to non-narcotic analgesics where a PBS authority prescription for treatment beyond 12 months has previously been issued for this patient.

**Note**

Fentanyl transdermal patches are not recommended in opioid naive patients with non-cancer pain, because of a high incidence of adverse events in these patients. Patients with cancer pain may be initiated on the lowest strength patch (12 micrograms per hour).

Pharmaceutical benefits that have the forms fentanyl transdermal patch 4.125 mg, fentanyl transdermal patch 2.55 mg and fentanyl transdermal patch 4.2 mg (all releasing approximately 25 micrograms per hour) are equivalent for the purposes of substitution.

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 5277R | fentanyl 25 microgram/hour patch, 5 | 1 | .. | .. | 41.93 | 36.10 | [a] | Denpax | AF |
| *NP* | | | | | | | | | |
| 5438F | fentanyl 25 microgram/hour patch, 5 | 1 | .. | .. | 41.93 | 36.10 | [a] | Dutran 25 | GM |
| *NP* | | | | | | | | | |
| | | | | | | | [a] | Fenpatch 25 | ZP |

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|---|
| 8891Y | fentanyl 25 microgram/hour patch, 5 | 1 | .. | .. | 41.93 | 36.10 | a | Durogesic 25 | JC |
| *NP* | | | | | | | | | |
| | | | | | | | a | Fentanyl Sandoz | SZ |

**FENTANYL**

**Restricted benefit**

Chronic severe disabling pain not responding to non-narcotic analgesics

**Caution**

The risk of drug dependence is high.

**Note**

Authorities for increased maximum quantities and/or repeats will be granted only for:

(i) chronic severe disabling pain associated with proven malignant neoplasia; or

(ii) chronic severe disabling pain not responding to non-narcotic analgesics where the total duration of narcotic analgesic treatment is less than 12 months; or

(iii) first application for treatment beyond 12 months of chronic severe disabling pain not responding to non-narcotic analgesics where the patient's pain management has been reviewed through consultation by the patient with another medical practitioner, and the clinical need for continuing narcotic analgesic treatment has been confirmed. The date of the consultation must be no more than 3 months prior to the application for a PBS authority. The full name of the medical practitioner consulted and the date of consultation are to be provided at the time of application; or

(iv) subsequent application for treatment of chronic severe disabling pain not responding to non-narcotic analgesics where a PBS authority prescription for treatment beyond 12 months has previously been issued for this patient.

**Note**

Fentanyl transdermal patches are not recommended in opioid naive patients with non-cancer pain, because of a high incidence of adverse events in these patients. Patients with cancer pain may be initiated on the lowest strength patch (12 micrograms per hour).

Pharmaceutical benefits that have the forms fentanyl transdermal patch 8.25 mg, fentanyl transdermal patch 5.10 mg and fentanyl transdermal patch 8.4 mg (all releasing approximately 50 micrograms per hour) are equivalent for the purposes of substitution.

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 5278T | fentanyl 50 microgram/hour patch, 5 | 1 | .. | .. | 66.65 | 36.10 | a | Denpax | AF |
| *NP* | | | | | | | | | |
| 5439G | fentanyl 50 microgram/hour patch, 5 | 1 | .. | .. | 66.65 | 36.10 | a | Dutran 50 | GM |
| *NP* | | | | | | | | | |
| | | | | | | | a | Fenpatch 50 | ZP |
| 8892B | fentanyl 50 microgram/hour patch, 5 | 1 | .. | .. | 66.65 | 36.10 | a | Durogesic 50 | JC |
| *NP* | | | | | | | | | |
| | | | | | | | a | Fentanyl Sandoz | SZ |

**FENTANYL**

**Restricted benefit**

Chronic severe disabling pain not responding to non-narcotic analgesics

**Caution**

The risk of drug dependence is high.

**Note**

Authorities for increased maximum quantities and/or repeats will be granted only for:

(i) chronic severe disabling pain associated with proven malignant neoplasia; or

(ii) chronic severe disabling pain not responding to non-narcotic analgesics where the total duration of narcotic analgesic treatment is less than 12 months; or

(iii) first application for treatment beyond 12 months of chronic severe disabling pain not responding to non-narcotic analgesics where the patient's pain management has been reviewed through consultation by the patient with another medical practitioner, and the clinical need for continuing narcotic analgesic treatment has been confirmed. The date of the consultation must be no more than 3 months prior to the application for a PBS authority. The full name of the medical practitioner consulted and the date of consultation are to be provided at the time of application; or

(iv) subsequent application for treatment of chronic severe disabling pain not responding to non-narcotic analgesics where a PBS authority prescription for treatment beyond 12 months has previously been issued for this patient.

**Note**

Fentanyl transdermal patches are not recommended in opioid naive patients with non-cancer pain, because of a high incidence of adverse events in these patients. Patients with cancer pain may be initiated on the lowest strength patch (12 micrograms per hour).

Pharmaceutical benefits that have the forms fentanyl transdermal patch 12.375 mg, fentanyl transdermal patch 7.65 mg and fentanyl transdermal patch 12.6 mg (all releasing approximately 75 micrograms per hour) are equivalent for the purposes of substitution.

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 5279W | fentanyl 75 microgram/hour patch, 5 | 1 | .. | .. | 87.86 | 36.10 | a | Denpax | AF |
| *NP* | | | | | | | | | |
| 5440H | fentanyl 75 microgram/hour patch, 5 | 1 | .. | .. | 87.86 | 36.10 | a | Dutran 75 | GM |
| *NP* | | | | | | | | | |
| | | | | | | | a | Fenpatch 75 | ZP |

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|---|
| 8893C *NP* | fentanyl 75 microgram/hour patch, 5 | 1 | .. | .. | 87.86 | 36.10 | [a] | Durogesic 75 | JC |
| | | | | | | | [a] | Fentanyl Sandoz | SZ |

## *Diphenylpropylamine derivatives*

**METHADONE**

**Restricted benefit**

Severe disabling pain not responding to non-narcotic analgesics

**Caution**

The risk of drug dependence is high.

**Note**

Authorities for increased maximum quantities and/or repeats will be granted only for:

(i) severe disabling pain associated with proven malignant neoplasia; or

(ii) chronic severe disabling pain not responding to non-narcotic analgesics where the total duration of narcotic analgesic treatment is less than 12 months; or

(iii) first application for treatment beyond 12 months of chronic severe disabling pain not responding to non-narcotic analgesics where the patient's pain management has been reviewed through consultation by the patient with another medical practitioner, and the clinical need for continuing narcotic analgesic treatment has been confirmed. The date of the consultation must be no more than 3 months prior to the application for a PBS authority. The full name of the medical practitioner consulted and the date of consultation are to be provided at the time of application; or

(iv) subsequent application for treatment of chronic severe disabling pain not responding to non-narcotic analgesics where a PBS authority prescription for treatment beyond 12 months has previously been issued for this patient.

**Note**

Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 1609Q *NP* | methadone hydrochloride 10 mg tablet, 20 | 1 | .. | .. | 15.44 | 16.57 | | Physeptone | QA |
| 1606M *NP* | methadone hydrochloride 10 mg/mL injection, 5 x 1 mL ampoules | 1 | .. | .. | 49.52 | 36.10 | | Physeptone | QA |

## *Oripavine derivatives*

**BUPRENORPHINE**

**Restricted benefit**

Chronic severe disabling pain not responding to non-narcotic analgesics

**Caution**

The risk of drug dependence is high.

**Note**

Authorities for increased maximum quantities and/or repeats will be granted only for:

(i) chronic severe disabling pain associated with proven malignant neoplasia; or

(ii) chronic severe disabling pain not responding to non-narcotic analgesics where the total duration of narcotic analgesic treatment is less than 12 months; or

(iii) first application for treatment beyond 12 months of chronic severe disabling pain not responding to non-narcotic analgesics where the patient's pain management has been reviewed through consultation by the patient with another medical practitioner, and the clinical need for continuing narcotic analgesic treatment has been confirmed. The date of the consultation must be no more than 3 months prior to the application for a PBS authority. The full name of the medical practitioner consulted and the date of consultation are to be provided at the time of application; or

(iv) subsequent application for treatment of chronic severe disabling pain not responding to non-narcotic analgesics where a PBS authority prescription for treatment beyond 12 months has previously been issued for this patient.

**Note**

Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 8866P *NP* | buprenorphine 10 microgram/hour patch, 2 | 1 | .. | .. | 40.98 | 36.10 | | Norspan | MF |
| 8867Q *NP* | buprenorphine 20 microgram/hour patch, 2 | 1 | .. | .. | 56.29 | 36.10 | | Norspan | MF |
| 8865N *NP* | buprenorphine 5 microgram/hour patch, 2 | 1 | .. | .. | 26.91 | 28.04 | | Norspan | MF |

## *Other opioids*

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|---|
| | **TRAMADOL**<br>**Restricted benefit**<br>For pain where aspirin and/or paracetamol alone are inappropriate or have failed<br>**Note**<br>Authorities for increased maximum quantities and/or repeats will be granted only for severe disabling pain not responding to non-narcotic analgesics. | | | | | | | | |
| 8523N<br>*NP* | tramadol hydrochloride 100 mg tablet: modified release, 20 tablets | 1 | .. | .. | 10.93 | 12.06 | [a] | APO-Tramadol SR | TX |
| | | | | | | | [a] | Chem mart Tramadol SR | CH |
| | | | | | | | [a] | GA Tramadol SR 100mg | GM |
| | | | | | | | [a] | Lodam SR 100 | ZP |
| | | | | | | | [a] | Terry White Chemists Tramadol SR | TW |
| | | | | | | | [a] | Tramadol Sandoz SR | SZ |
| | | | | | | | [a] | Tramadol SR generichealth | GQ |
| | | | | | | | [a] | Tramedo SR 100 | AF |
| | | | | | | | [a] | Zydol SR 100 | QA |
| | | | | [B]4.49 | 15.42 | 12.06 | [a] | Tramal SR 100 | CS |
| 8843K<br>*NP* | tramadol hydrochloride 100 mg/mL oral liquid, 10 mL | ‡1 | .. | .. | 13.92 | 15.05 | | Tramal | CS |
| 8524P<br>*NP* | tramadol hydrochloride 150 mg tablet: modified release, 20 tablets | 1 | .. | .. | 12.43 | 13.56 | [a] | APO-Tramadol SR | TX |
| | | | | | | | [a] | Chem mart Tramadol SR | CH |
| | | | | | | | [a] | GA Tramadol SR 150mg | GM |
| | | | | | | | [a] | Lodam SR 150 | ZP |
| | | | | | | | [a] | Terry White Chemists Tramadol SR | TW |
| | | | | | | | [a] | Tramadol Sandoz SR | SZ |
| | | | | | | | [a] | Tramadol SR generichealth | GQ |
| | | | | | | | [a] | Tramedo SR 150 | AF |
| | | | | | | | [a] | Zydol SR 150 | QA |
| | | | | [B]5.37 | 17.80 | 13.56 | [a] | Tramal SR 150 | CS |
| 8525Q<br>*NP* | tramadol hydrochloride 200 mg tablet: modified release, 20 tablets | 1 | .. | .. | 13.69 | 14.82 | [a] | APO-Tramadol SR | TX |
| | | | | | | | [a] | Chem mart Tramadol SR | CH |
| | | | | | | | [a] | GA Tramadol SR 200mg | GM |
| | | | | | | | [a] | Lodam SR 200 | ZP |
| | | | | | | | [a] | Terry White Chemists Tramadol SR | TW |
| | | | | | | | [a] | Tramadol Sandoz SR | SZ |
| | | | | | | | [a] | Tramadol SR generichealth | GQ |
| | | | | | | | [a] | Tramedo SR 200 | AF |
| | | | | | | | [a] | Zydol SR 200 | QA |
| | | | | [B]6.08 | 19.77 | 14.82 | [a] | Tramal SR 200 | CS |
| 2527B<br>*NP* | tramadol hydrochloride 50 mg tablet: modified release, 20 tablets | 1 | .. | .. | 9.63 | 10.76 | | Tramal SR 50 | CS |
| | **TRAMADOL**<br>**Restricted benefit**<br>Short-term treatment of acute pain | | | | | | | | |
| 5231H<br>*DP* | tramadol hydrochloride 100 mg/2 mL injection, 5 x 2 mL ampoules | 1 | .. | .. | 13.31 | 14.44 | [a] | Tramadol Sandoz | SZ |
| | | | | | | | [a] | Tramal 100 | CS |
| | **TRAMADOL**<br>**Restricted benefit**<br>Short-term treatment of acute pain<br>**Note**<br>No applications for increased maximum quantities and/or repeats will be authorised. | | | | | | | | |

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|---|
| 8582Q<br>*NP* | tramadol hydrochloride 100 mg/2 mL injection, 5 x 2 mL ampoules | 1 | .. | .. | 13.31 | 14.44 | [a] | Tramadol Sandoz | SZ |
| | | | | | | | [a] | Tramal 100 | CS |
| | **TRAMADOL**<br>**Restricted benefit**<br>For pain where aspirin and/or paracetamol alone are inappropriate or have failed | | | | | | | | |
| 5150C<br>*DP* | tramadol hydrochloride 100 mg/mL oral liquid, 10 mL | ‡1 | .. | .. | 13.92 | 15.05 | | Tramal | CS |
| | **TRAMADOL**<br>**Restricted benefit**<br>For acute pain where aspirin and/or paracetamol alone are inappropriate or have failed<br>**Restricted benefit**<br>For dosage titration in chronic pain where aspirin and/or paracetamol alone are inappropriate or have failed | | | | | | | | |
| 5232J<br>*DP* | tramadol hydrochloride 50 mg capsule, 20 | 1 | .. | .. | 8.22 | 9.35 | [a] | APO-Tramadol | TX |
| | | | | | | | [a] | Chem mart Tramadol | CH |
| | | | | | | | [a] | GA Tramadol 50mg | GM |
| | | | | | | | [a] | Lodam 50 | ZP |
| | | | | | | | [a] | Terry White Chemists Tramadol | TW |
| | | | | | | | [a] | Tramadol Sandoz | SZ |
| | | | | | | | [a] | Tramedo | AF |
| | | | | | | | [a] | Zydol | QA |
| | | | | [B]2.41 | 10.63 | 9.35 | [a] | Tramal | CS |
| | **TRAMADOL**<br>**Restricted benefit**<br>For acute pain where aspirin and/or paracetamol alone are inappropriate or have failed<br>**Note**<br>No applications for increased maximum quantities and/or repeats will be authorised. | | | | | | | | |
| 8455B<br>*NP* | tramadol hydrochloride 50 mg capsule, 20 | 1 | .. | .. | 8.22 | 9.35 | [a] | APO-Tramadol | TX |
| | | | | | | | [a] | Chem mart Tramadol | CH |
| | | | | | | | [a] | GA Tramadol 50mg | GM |
| | | | | | | | [a] | Lodam 50 | ZP |
| | | | | | | | [a] | Terry White Chemists Tramadol | TW |
| | | | | | | | [a] | Tramadol Sandoz | SZ |
| | | | | | | | [a] | Tramedo | AF |
| | | | | | | | [a] | Zydol | QA |
| | | | | [B]2.41 | 10.63 | 9.35 | [a] | Tramal | CS |
| | **TRAMADOL**<br>**Restricted benefit**<br>For dosage titration in chronic pain where aspirin and/or paracetamol alone are inappropriate or have failed<br>**Note**<br>No applications for increased maximum quantities and/or repeats will be authorised. | | | | | | | | |
| 8611F<br>*NP* | tramadol hydrochloride 50 mg capsule, 20 | 1 | 2 | .. | 8.22 | 9.35 | [a] | APO-Tramadol | TX |
| | | | | | | | [a] | Chem mart Tramadol | CH |
| | | | | | | | [a] | GA Tramadol 50mg | GM |
| | | | | | | | [a] | Lodam 50 | ZP |
| | | | | | | | [a] | Terry White Chemists Tramadol | TW |
| | | | | | | | [a] | Tramadol Sandoz | SZ |
| | | | | | | | [a] | Tramedo | AF |
| | | | | | | | [a] | Zydol | QA |
| | | | | [B]2.41 | 10.63 | 9.35 | [a] | Tramal | CS |

## OTHER ANALGESICS AND ANTIPYRETICS

### *Salicylic acid and derivatives*

# NERVOUS SYSTEM

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|---|
| | **ASPIRIN** | | | | | | | | |
| 1010E *NP* | aspirin 300 mg tablet: effervescent, 96 | 1 | 1 | .. | 8.38 | 9.51 | | Solprin | RC |
| 5018D *DP* | aspirin 300 mg tablet: effervescent, 96 | 1 | .. | .. | 8.38 | 9.51 | | Solprin | RC |

## *Anilides*

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | **PARACETAMOL** | | | | | | | | |
| 1747Y *NP* | paracetamol 120 mg/5 mL oral liquid, 100 mL | ‡1 | 2 | .. | 9.59 | 10.72 | | Panamax | SW |
| 3348F *DP* | paracetamol 120 mg/5 mL oral liquid, 100 mL | ‡1 | .. | .. | 9.59 | 10.72 | | Panamax | SW |
| 1770E *NP* | paracetamol 240 mg/5 mL oral liquid, 200 mL | ‡1 | 2 | .. | 10.89 | 12.02 | | Panamax 240 Elixir | SW |
| 3349G *DP* | paracetamol 240 mg/5 mL oral liquid, 200 mL | ‡1 | .. | .. | 10.89 | 12.02 | | Panamax 240 Elixir | SW |
| 1746X *NP* | paracetamol 500 mg tablet, 100 | 1 | 1 | .. | 8.53 | 9.66 | [a] | APO-Paracetamol | TX |
| | | | | | | | [a] | Febridol | GM |
| | | | | | | | [a] | Generic Health Pty Ltd | GQ |
| | | | | | | | [a] | Panamax | SW |
| | | | | | | | [a] | Paracetamol Sandoz | SZ |
| | | | | | | | [a] | Paralgin | FM |
| 5196L *DP* | paracetamol 500 mg tablet, 100 | 1 | .. | .. | 8.53 | 9.66 | [a] | APO-Paracetamol | TX |
| | | | | | | | [a] | Febridol | GM |
| | | | | | | | [a] | Generic Health Pty Ltd | GQ |
| | | | | | | | [a] | Panamax | SW |
| | | | | | | | [a] | Paracetamol Sandoz | SZ |
| | | | | | | | [a] | Paralgin | FM |
| | **PARACETAMOL**<br>**Restricted benefit**<br>Chronic arthropathies | | | | | | | | |
| 5224Y *DP* | paracetamol 500 mg tablet, 100 | 3 | .. | .. | *12.33 | 13.46 | [a] | APO-Paracetamol | TX |
| | | | | | | | [a] | Febridol | GM |
| | | | | | | | [a] | Generic Health Pty Ltd | GQ |
| | | | | | | | [a] | Panamax | SW |
| | | | | | | | [a] | Paracetamol Sandoz | SZ |
| | | | | | | | [a] | Paralgin | FM |
| 8784H *NP* | paracetamol 500 mg tablet, 100 | 3 | 4 | .. | *12.33 | 13.46 | [a] | APO-Paracetamol | TX |
| | | | | | | | [a] | Febridol | GM |
| | | | | | | | [a] | Generic Health Pty Ltd | GQ |
| | | | | | | | [a] | Panamax | SW |
| | | | | | | | [a] | Paracetamol Sandoz | SZ |
| | | | | | | | [a] | Paralgin | FM |
| | **PARACETAMOL**<br>**Restricted benefit**<br>Relief of persistent pain associated with osteoarthritis | | | | | | | | |
| 8814X *NP* | paracetamol 665 mg tablet: modified release, 96 tablets | 2 | 5 | .. | *16.85 | 17.98 | | Panadol Osteo | GC |

## *Other analgesics and antipyretics*

**PREGABALIN**
**Authority required (STREAMLINED)**
***4172***
Neuropathic pain

**The Clinical criteria is:**

The condition must be refractory to treatment with other drugs.

**Note**
**Continuing Therapy Only:**

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|
| | For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners. | | | | | | | |
| 2355Y *NP* | pregabalin 150 mg capsule, 56 | 1 | 5 | .. | 70.50 | 36.10 | Lyrica | PF |
| 2348N *NP* | pregabalin 25 mg capsule, 56 | 1 | 5 | .. | 26.31 | 27.44 | Lyrica | PF |
| 2363J *NP* | pregabalin 300 mg capsule, 56 | 1 | 5 | .. | 101.92 | 36.10 | Lyrica | PF |
| 2335X *NP* | pregabalin 75 mg capsule, 56 | 1 | 5 | .. | 48.98 | 36.10 | Lyrica | PF |

## ANTIMIGRAINE PREPARATIONS

### *Ergot alkaloids*

**METHYSERGIDE**

**Note**

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 2826R *NP* | methysergide 1 mg tablet, 50 | 2 | 2 | .. | *45.17 | 36.10 | Deseril | LM |

### *Selective serotonin (5HT1) agonists*

**ELETRIPTAN**

**Authority required (STREAMLINED)**

***3233***

Migraine attack in a patient where attacks in the past have usually failed to respond to analgesics

**Caution**

Eletriptan is contraindicated in patients with known or suspected coronary artery disease. The drug should not be used within 24 hours of ergotamine or dihydroergotamine use.

**Note**

No applications for increased maximum quantities and/or repeats will be authorised.

**Note**

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 5290K *NP* | eletriptan 40 mg tablet, 4 | 1 | 5 | .. | 24.97 | 26.10 | Relpax | PF |
| 5291L *NP* | eletriptan 80 mg tablet, 4 | 1 | 5 | .. | 24.97 | 26.10 | Relpax | PF |

**NARATRIPTAN**

**Authority required**

Migraine attack in a patient where attacks in the past have usually failed to respond to analgesics

**Caution**

Naratriptan is contraindicated in patients with known or suspected coronary artery disease. The drug should not be used within 24 hours of ergotamine or dihydroergotamine use.

**Note**

No applications for increased maximum quantities and/or repeats will be authorised.

**Note**

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 8298R *NP* | naratriptan 2.5 mg tablet, 2 | 2 | 5 | $2.78 | *28.89 | 27.24 | Naramig | AS |

**NARATRIPTAN**

**Authority required**

Migraine attack in a patient where attacks in the past have usually failed to respond to analgesics, and where adverse events have occurred with other suitable PBS-listed drugs

**Authority required**

Migraine attack in a patient where attacks in the past have usually failed to respond to analgesics, and where drug interactions have occurred with other suitable PBS-listed drugs

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|---|
| | **Authority required**<br>Migraine attack in a patient where attacks in the past have usually failed to respond to analgesics, and where drug interactions are expected to occur with other suitable PBS-listed drugs | | | | | | | | |
| | **Authority required**<br>Migraine attack in a patient where attacks in the past have usually failed to respond to analgesics, and where transfer to another suitable PBS-listed drug would cause patient confusion resulting in problems with compliance | | | | | | | | |
| | **Authority required**<br>Migraine attack in a patient where attacks in the past have usually failed to respond to analgesics, and where transfer to another suitable PBS-listed drug is likely to result in adverse clinical consequences | | | | | | | | |
| | **Caution**<br>Naratriptan is contraindicated in patients with known or suspected coronary artery disease. The drug should not be used within 24 hours of ergotamine or dihydroergotamine use. | | | | | | | | |
| | **Note**<br>No applications for increased maximum quantities and/or repeats will be authorised. | | | | | | | | |
| | **Note**<br>Continuing Therapy Only:<br>For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners. | | | | | | | | |
| 9734H<br>*NP* | naratriptan 2.5 mg tablet, 2 | 2 | 5 | .. | *28.89 | 30.02 | | Naramig | AS |
| | **RIZATRIPTAN**<br>**Authority required (STREAMLINED)**<br>***3233***<br>Migraine attack in a patient where attacks in the past have usually failed to respond to analgesics | | | | | | | | |
| | **Caution**<br>Rizatriptan is contraindicated in patients with known or suspected coronary artery disease. The drug should not be used within 24 hours of ergotamine or dihydroergotamine use. | | | | | | | | |
| | **Note**<br>No applications for increased maximum quantities and/or repeats will be authorised. | | | | | | | | |
| | **Note**<br>Continuing Therapy Only:<br>For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners. | | | | | | | | |
| 9313E<br>*NP* | rizatriptan 10 mg wafer, 2 | 2 | 5 | .. | *25.33 | 26.46 | | Maxalt | MK |
| | **SUMATRIPTAN**<br>**Authority required (STREAMLINED)**<br>***3233***<br>Migraine attack in a patient where attacks in the past have usually failed to respond to analgesics | | | | | | | | |
| | **Caution**<br>Sumatriptan is contraindicated in patients with known or suspected coronary artery disease. The drug should not be used within 24 hours of ergotamine or dihydroergotamine use. | | | | | | | | |
| | **Note**<br>No applications for increased maximum quantities and/or repeats will be authorised. | | | | | | | | |
| | **Note**<br>Pharmaceutical benefits that have the form sumatriptan tablet 50 mg (as succinate) and pharmaceutical benefits that have the form sumatriptan tablet (fast disintegrating) 50 mg (as succinate) are equivalent for the purposes of substitution. | | | | | | | | |
| | **Note**<br>Continuing Therapy Only:<br>For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners. | | | | | | | | |
| 8885P<br>*NP* | SUMATRIPTAN Tablet (fast disintegrating) 50 mg (as succinate), 2 | 2 | 5 | .. | *21.69 | 22.82 | [a] | Imigran FDT | AS |
| 8144P<br>*NP* | SUMATRIPTAN Tablet 50 mg (as succinate), 2 | 2 | 5 | .. | *21.69 | 22.82 | [a] | APO-Sumatriptan | TX |
| | | | | | | | [a] | Chem mart Sumatriptan | CH |
| | | | | | | | [a] | Sumagran 50 | QA |
| | | | | | | | [a] | Sumagran Aspen 50 | AS |
| | | | | | | | [a] | Sumatab | AF |

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | [a] | Terry White Chemists Sumatriptan | TW |
| | | | | [B]1.56 | *23.25 | 22.82 | [a] | Imigran | LN |
| 1849H *NP* | sumatriptan 50 mg tablet, 4 | 1 | 5 | .. | 21.70 | 22.83 | [a] | APO-Sumatriptan | TX |
| | | | | | | | [a] | Chem mart Sumatriptan | CH |
| | | | | | | | [a] | Pharmacor Sumatriptan 50 | CR |
| | | | | | | | [a] | Sumatriptan-GA | GM |
| | | | | | | | [a] | Sumatriptan generichealth | GQ |
| | | | | | | | [a] | Sumatriptan RBX | RA |
| | | | | | | | [a] | Terry White Chemists Sumatriptan | TW |

**SUMATRIPTAN**

**Authority required (STREAMLINED)**

***3233***

Migraine attack in a patient where attacks in the past have usually failed to respond to analgesics

**Caution**

Sumatriptan is contraindicated in patients with known or suspected coronary artery disease. The drug should not be used within 24 hours of ergotamine or dihydroergotamine use.

**Note**

No applications for increased maximum quantities and/or repeats will be authorised.

**Note**

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 8341B *NP* | sumatriptan 20 mg/actuation nasal spray, 2 actuations | 1 | 5 | .. | 19.46 | 20.59 | | Imigran | AS |

**ZOLMITRIPTAN**

**Authority required**

Migraine attack in a patient where attacks in the past have usually failed to respond to analgesics

**Caution**

Zolmitriptan is contraindicated in patients with known or suspected coronary artery disease. The drug should not be used within 24 hours of ergotamine or dihydroergotamine use.

**Note**

No applications for increased maximum quantities and/or repeats will be authorised.

**Note**

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 8266C *NP* | zolmitriptan 2.5 mg tablet, 2 | 2 | 5 | [$]2.76 | *28.81 | 27.18 | | Zomig | AP |

**ZOLMITRIPTAN**

**Authority required**

Migraine attack in a patient where attacks in the past have usually failed to respond to analgesics, and where adverse events have occurred with other suitable PBS-listed drugs

**Authority required**

Migraine attack in a patient where attacks in the past have usually failed to respond to analgesics, and where drug interactions have occurred with other suitable PBS-listed drugs

**Authority required**

Migraine attack in a patient where attacks in the past have usually failed to respond to analgesics, and where drug interactions are expected to occur with other suitable PBS-listed drugs

**Authority required**

Migraine attack in a patient where attacks in the past have usually failed to respond to analgesics, and where transfer to another suitable PBS-listed drug would cause patient confusion resulting in problems with compliance

**Authority required**

Migraine attack in a patient where attacks in the past have usually failed to respond to analgesics, and where transfer to another suitable PBS-listed drug is likely to result in adverse clinical consequences

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|
| | **Caution**<br>Zolmitriptan is contraindicated in patients with known or suspected coronary artery disease. The drug should not be used within 24 hours of ergotamine or dihydroergotamine use. | | | | | | | |
| | **Note**<br>No applications for increased maximum quantities and/or repeats will be authorised. | | | | | | | |
| | **Note**<br>Continuing Therapy Only:<br>For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners. | | | | | | | |
| 9736K<br>*NP* | zolmitriptan 2.5 mg tablet, 2 | 2 | 5 | .. | *28.81 | 29.94 | Zomig | AP |

### *Other antimigraine preparations*

**CYPROHEPTADINE**
**Restricted benefit**
Prevention of migraine

**Note**
Cyproheptadine hydrochloride is not PBS-subsidised for use in hay fever or atopy.

**Note**
Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 1798P<br>*NP* | cyproheptadine hydrochloride 4 mg tablet, 100 | 1 | 2 | .. | 14.40 | 15.53 | Periactin | AS |

**PIZOTIFEN**
**Note**
Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 3074T<br>*NP* | pizotifen 500 microgram tablet, 100 | 1 | 2 | .. | 21.96 | 23.09 | Sandomigran 0.5 | NV |

## ANTIEPILEPTICS

## ANTIEPILEPTICS

### *Barbiturates and derivatives*

**PHENOBARBITONE**
**Restricted benefit**
Epilepsy

**Note**
Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 1850J<br>*NP* | phenobarbitone 30 mg tablet, 200 | 1 | 4 | .. | 16.81 | 17.94 | Aspen Pharma Pty Ltd | QA |
| 2138M<br>*NP* | phenobarbitone sodium 219 mg/mL injection, 5 x 1 mL ampoules | 1 | .. | .. | 39.23 | 36.10 | Fawns and McAllan Proprietary Limited | FM |

**PRIMIDONE**
**Note**
Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 1939C<br>*NP* | primidone 250 mg tablet, 200 | 1 | 2 | .. | 83.70 | 36.10 | Mysoline | LM |

### *Hydantoin derivatives*

**PHENYTOIN**
**Note**
Continuing Therapy Only:

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|---|
| | For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners. | | | | | | | | |
| 2692Q *NP* | phenytoin 30 mg/5 mL oral liquid, 500 mL | ‡1 | 3 | .. | 26.62 | 27.75 | | Dilantin | PF |
| 1249R *NP* | phenytoin 50 mg tablet: chewable, 200 | 1 | 2 | .. | 43.77 | 36.10 | | Dilantin Infatabs | PF |
| 1874P *NP* | phenytoin sodium 100 mg capsule, 200 | 1 | 2 | .. | 30.33 | 31.46 | | Dilantin Sodium | PF |
| 1873N *NP* | phenytoin sodium 30 mg capsule, 200 | 1 | 2 | .. | 29.39 | 30.52 | | Dilantin Sodium | PF |

## *Succinimide derivatives*

**ETHOSUXIMIDE**

**Note**

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 1413J *NP* | ethosuximide 250 mg capsule, 200 | 1 | 2 | .. | 54.31 | 36.10 | | Zarontin | PF |
| 1414K *NP* | ethosuximide 250 mg/5 mL oral liquid, 200 mL | ‡1 | 5 | .. | 25.50 | 26.63 | | Zarontin | PF |

## *Benzodiazepine derivatives*

**CLONAZEPAM**

**Restricted benefit**

Epilepsy

**Note**

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 1807D *NP* | clonazepam 1 mg/mL injection [5 x 1 mL ampoules] (&) inert substance diluent [5 x 1 mL ampoules], 1 pack | 1 | .. | .. | 18.79 | 19.92 | | Rivotril | RO |

**CLONAZEPAM**

**Authority required**

Neurologically proven epilepsy

**Caution**

Abuse of clonazepam has been reported. Refer to the current product information.

**Note**

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 1806C *NP* | clonazepam 2 mg tablet, 100 | 2 | 2 | .. | *31.27 | 32.40 | a | Paxam 2 | AF |
| | | | | [B]3.86 | *35.13 | 32.40 | a | Rivotril | RO |
| 1808E *NP* | clonazepam 2.5 mg/mL oral liquid, 10 mL | 2 | .. | .. | *15.25 | 16.38 | | Rivotril | RO |
| 1805B *NP* | clonazepam 500 microgram tablet, 100 | 2 | 2 | .. | *19.71 | 20.84 | a | Paxam 0.5 | AF |
| | | | | [B]3.42 | *23.13 | 20.84 | a | Rivotril | RO |

**NITRAZEPAM**

**Authority required**

Myoclonic epilepsy

**Authority required**

Malignant neoplasia (late stage)

**Authority required**

For use by patients who are receiving long-term nursing care on account of age, infirmity or other condition in hospitals, nursing homes or residential facilities and who have been demonstrated, within the past 6 months, to be benzodiazepine dependent by an unsuccessful attempt at gradual withdrawal

**Authority required**

For use by a patient who is receiving long-term nursing care and in respect of whom a Carer Allowance is payable as a disabled adult and who has

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|---|
| | been demonstrated, within the past 6 months, to be benzodiazepine dependent by an unsuccessful attempt at gradual withdrawal | | | | | | | | |
| | **Note** | | | | | | | | |
| | Continuing Therapy Only: | | | | | | | | |
| | For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners. | | | | | | | | |
| 2732T *NP* | nitrazepam 5 mg tablet, 25 | 2 | 5 | .. | *9.41 | 10.54 | a | Alodorm | AF |
| | | | | B2.92 | *12.33 | 10.54 | a | Mogadon | VT |

## *Carboxamide derivatives*

**CARBAMAZEPINE**

**Note**

For item codes 2422L and 1708X, pharmaceutical benefits that have the form tablet 100 mg are equivalent for the purposes of substitution.

**Note**

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 2422L *NP* | CARBAMAZEPINE Tablet 100 mg, 100 | 2 | 2 | B2.96 | *21.67 | 19.84 | a | Tegretol 100 | NV |
| 1708X *NP* | carbamazepine 100 mg tablet, 200 | 1 | 2 | .. | 18.69 | 19.82 | a | Carbamazepine Sandoz | SZ |

**CARBAMAZEPINE**

**Note**

For item codes 5039F and 1755J, pharmaceutical benefits that have the form tablet 100 mg are equivalent for the purposes of substitution.

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 5039F *DP* | CARBAMAZEPINE Tablet 100 mg, 100 | 2 | .. | B2.96 | *21.67 | 19.84 | a | Tegretol 100 | NV |
| 1755J *DP* | carbamazepine 100 mg tablet, 200 | 1 | .. | .. | 18.69 | 19.82 | a | Carbamazepine Sandoz | SZ |

**CARBAMAZEPINE**

**Note**

For item codes 2419H and 1706T, pharmaceutical benefits that have the form tablet 200 mg are equivalent for the purposes of substitution.

**Note**

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 1706T *NP* | CARBAMAZEPINE Tablet 200 mg, 100 | 2 | 2 | B2.96 | *32.17 | 30.34 | a | Tegretol 200 | NV |
| 2419H *NP* | carbamazepine 200 mg tablet, 200 | 1 | 2 | .. | 29.20 | 30.33 | a | Carbamazepine Sandoz | SZ |
| | | | | | | | a | Teril | AF |

**CARBAMAZEPINE**

**Note**

For item codes 5040G and 1724R, pharmaceutical benefits that have the form tablet 200 mg are equivalent for the purposes of substitution.

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 1724R *DP* | CARBAMAZEPINE Tablet 200 mg, 100 | 2 | .. | B2.96 | *32.17 | 30.34 | a | Tegretol 200 | NV |
| 5040G *DP* | carbamazepine 200 mg tablet, 200 | 1 | .. | .. | 29.20 | 30.33 | a | Carbamazepine Sandoz | SZ |
| | | | | | | | a | Teril | AF |

**CARBAMAZEPINE**

**Note**

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 2427R *NP* | carbamazepine 100 mg/5 mL oral liquid, 300 mL | ‡1 | 5 | .. | 21.56 | 22.69 | | Tegretol Liquid | NV |
| 2426Q *NP* | carbamazepine 200 mg tablet: modified release, 200 tablets | 1 | 2 | .. | 29.69 | 30.82 | | Tegretol CR 200 | NV |
| 2431Y *NP* | carbamazepine 400 mg tablet: modified release, 200 tablets | 1 | 2 | .. | 49.24 | 36.10 | | Tegretol CR 400 | NV |

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|---|
| | **CARBAMAZEPINE** | | | | | | | | |
| 5041H *DP* | carbamazepine 100 mg/5 mL oral liquid, 300 mL | ‡1 | .. | .. | 21.56 | 22.69 | | Tegretol Liquid | NV |
| 5038E *DP* | carbamazepine 200 mg tablet: modified release, 200 tablets | 1 | .. | .. | 29.69 | 30.82 | | Tegretol CR 200 | NV |
| 5037D *DP* | carbamazepine 400 mg tablet: modified release, 200 tablets | 1 | .. | .. | 49.24 | 36.10 | | Tegretol CR 400 | NV |
| | **OXCARBAZEPINE**<br>**Authority required (STREAMLINED)**<br>***1587***<br>Treatment of partial epileptic seizures and primary generalised tonic-clonic seizures, which are not controlled satisfactorily by other anti-epileptic drugs<br>**Note**<br>Continuing Therapy Only:<br>For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners. | | | | | | | | |
| 8584T *NP* | oxcarbazepine 150 mg tablet, 100 | 1 | 5 | .. | 72.48 | 36.10 | | Trileptal | NV |
| 8585W *NP* | oxcarbazepine 300 mg tablet, 100 | 1 | 5 | .. | 115.29 | 36.10 | | Trileptal | NV |
| 8588B *NP* | oxcarbazepine 60 mg/mL oral liquid, 250 mL | 2 | 5 | .. | *138.33 | 36.10 | | Trileptal | NV |
| 8586X *NP* | oxcarbazepine 600 mg tablet, 100 | 1 | 5 | .. | 188.19 | 36.10 | | Trileptal | NV |

## *Fatty acid derivatives*

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | **TIAGABINE**<br>**Authority required (STREAMLINED)**<br>***2664***<br>Treatment of partial epileptic seizures which are not controlled satisfactorily by other anti-epileptic drugs<br>**Note**<br>Continuing Therapy Only:<br>For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners. | | | | | | | | |
| 8222R *NP* | tiagabine 10 mg tablet, 50 | 2 | 5 | .. | *139.05 | 36.10 | | Gabitril | OA |
| 8223T *NP* | tiagabine 15 mg tablet, 50 | 2 | 5 | .. | *197.11 | 36.10 | | Gabitril | OA |
| 8221Q *NP* | tiagabine 5 mg tablet, 50 | 2 | 5 | .. | *72.83 | 36.10 | | Gabitril | OA |
| | **VALPROATE**<br>**Caution**<br>There are reports of fatal hepatotoxicity, particularly in children.<br>There is increasing evidence of dose-related teratogenesis from this drug.<br>**Note**<br>Continuing Therapy Only:<br>For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners. | | | | | | | | |
| 2294R *NP* | valproate sodium 100 mg tablet, 100 | 2 | 2 | .. | *32.21 | 33.34 | | Epilim | SW |
| 2289L *NP* | valproate sodium 200 mg tablet: enteric, 100 | 2 | 2 | .. | *30.15 | 31.28 | [a] | Sodium Valproate Sandoz | SZ |
| | | | | | | | [a] | Valprease 200 | QA |
| | | | | | | | [a] | Valpro 200 | AF |
| | | | | | | | [a] | Valproate Winthrop EC 200 | WA |
| | | | | [B]1.98 | *32.13 | 31.28 | [a] | Epilim EC | SW |
| 2293Q *NP* | valproate sodium 200 mg/5 mL oral liquid, 300 mL | 2 | 2 | .. | *35.13 | 36.10 | | Epilim Liquid | SW |
| 2295T *NP* | valproate sodium 200 mg/5 mL oral liquid, 300 mL | 2 | 2 | .. | *35.13 | 36.10 | | Epilim Syrup | SW |
| 2290M | valproate sodium 500 mg tablet: enteric, | 2 | 2 | .. | *51.61 | 36.10 | [a] | Sodium Valproate | SZ |

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|---|
| *NP* | 100 | | | | | | | Sandoz | |
| | | | | | | | [a] | Valprease 500 | QA |
| | | | | | | | [a] | Valpro 500 | AF |
| | | | | | | | [a] | Valproate Winthrop EC 500 | WA |
| | | | | [B]2.00 | *53.61 | 36.10 | [a] | Epilim EC | SW |

**VIGABATRIN**

**Authority required (STREAMLINED)**

***1426***

Treatment of epileptic seizures which are not controlled satisfactorily by other anti-epileptic drugs

**Caution**

Visual field defects have been reported with this drug.

**Note**

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 2668K *NP* | vigabatrin 500 mg oral liquid: powder for, 60 x 500 mg sachets | 1 | 5 | .. | 67.91 | 36.10 | | Sabril | SW |
| 2667J *NP* | vigabatrin 500 mg tablet, 100 | 1 | 5 | .. | 101.14 | 36.10 | | Sabril | SW |

## *Other antiepileptics*

**GABAPENTIN**

**Authority required (STREAMLINED)**

***2664***

Treatment of partial epileptic seizures which are not controlled satisfactorily by other anti-epileptic drugs

**Note**

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 8505P *NP* | gabapentin 100 mg capsule, 100 | 1 | 5 | .. | 15.98 | 17.11 | [a] | APO-Gabapentin | TX |
| | | | | | | | [a] | DBL Gabapentin | HH |
| | | | | | | | [a] | Gabapentin Pfizer | FZ |
| | | | | | | | [a] | Gabatine 100 | QA |
| | | | | | | | [a] | Neurontin | PF |
| | | | | | | | [a] | Nupentin 100 | AF |
| 1834M *NP* | gabapentin 300 mg capsule, 100 | 1 | 5 | .. | 37.88 | 36.10 | [a] | DBL Gabapentin | HH |
| | | | | | | | [a] | Gabapentin 300 | CR |
| | | | | | | | [a] | Gabapentin-GA | GM |
| | | | | | | | [a] | Gabapentin Pfizer | FZ |
| | | | | | | | [a] | Gabapentin Sandoz | SZ |
| | | | | | | | [a] | Gabatine 300 | QA |
| | | | | | | | [a] | Gantin | GN |
| | | | | | | | [a] | GenRx Gabapentin | GX |
| | | | | | | | [a] | Neurontin | PF |
| | | | | | | | [a] | Nupentin 300 | AF |
| 1835N *NP* | gabapentin 400 mg capsule, 100 | 1 | 5 | .. | 48.18 | 36.10 | [a] | DBL Gabapentin | HH |
| | | | | | | | [a] | Gabapentin 400 | CR |
| | | | | | | | [a] | Gabapentin Pfizer | FZ |
| | | | | | | | [a] | Gabapentin Sandoz | SZ |
| | | | | | | | [a] | Gabatine 400 | QA |
| | | | | | | | [a] | Gantin | GN |
| | | | | | | | [a] | GenRx Gabapentin | GX |
| | | | | | | | [a] | Neurontin | PF |
| | | | | | | | [a] | Nupentin 400 | AF |
| 8559L *NP* | gabapentin 600 mg tablet, 100 | 1 | 5 | .. | 71.32 | 36.10 | [a] | Gabapentin Aspen 600 | FM |
| | | | | | | | [a] | Gabaran | RA |
| | | | | | | | [a] | Gabatine 600 | QA |

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | [a] | GenRx Gabapentin | GX |
| | | | | | | | [a] | Neurontin | PF |
| | | | | | | | [a] | Nupentin Tabs | AF |
| | | | | | | | [a] | Pharmacor Gabapentin 600 | CR |
| 8389M *NP* | gabapentin 800 mg tablet, 100 | 1 | 5 | .. | 92.87 | 36.10 | [a] | Gabapentin Aspen 800 | FM |
| | | | | | | | [a] | Gabapentin Pfizer | FZ |
| | | | | | | | [a] | Gabaran | RA |
| | | | | | | | [a] | Gabatine 800 | QA |
| | | | | | | | [a] | Gantin | GN |
| | | | | | | | [a] | GenRx Gabapentin | GX |
| | | | | | | | [a] | Neurontin | PF |
| | | | | | | | [a] | Nupentin Tabs | AF |
| | | | | | | | [a] | Pharmacor Gabapentin 800 | CR |

**LACOSAMIDE**

**Authority required (STREAMLINED)**

***4271***

Intractable partial epileptic seizures

Treatment Phase: Initial

**The Treatment criteria is:**

Must be treated by a neurologist,

**AND the Clinical criteria is:**

The treatment must be in combination with two or more anti-epileptic drugs which includes one second-line adjunctive agent,

**AND the Clinical criteria is:**

The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs, which includes at least one first-line anti-epileptic agent and at least two second-line adjunctive anti-epileptic agents,

**AND the Clinical criteria is:**

The treatment must be for dose titration purposes,

**AND the Population criteria is:**

Patient must be aged 16 years or older.

**Note**

**Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 9334G *NP* | lacosamide 100 mg tablet, 14 | 1 | 1 | .. | 52.50 | 36.10 | Vimpat | UC |
| 9336J *NP* | lacosamide 150 mg tablet, 14 | 1 | 1 | .. | 74.90 | 36.10 | Vimpat | UC |
| 9333F *NP* | lacosamide 50 mg tablet, 14 | 1 | 1 | .. | 30.42 | 31.55 | Vimpat | UC |

**LACOSAMIDE**

**Authority required (STREAMLINED)**

***4264***

Intractable partial epileptic seizures

Treatment Phase: Initial

**The Treatment criteria is:**

Must be treated by a neurologist,

**AND the Clinical criteria is:**

The treatment must be in combination with two or more anti-epileptic drugs which includes one second-line adjunctive agent,

**AND the Clinical criteria is:**

The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs, which includes at least one first-line anti-epileptic agent and at least two second-line adjunctive anti-epileptic agents,

**AND the Population criteria is:**

Patient must be aged 16 years or older.

**Authority required (STREAMLINED)**

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|
| | ***4249*** | | | | | | | |
| | Intractable partial epileptic seizures | | | | | | | |
| | Treatment Phase: Continuing | | | | | | | |
| | **The Clinical criteria is:** | | | | | | | |
| | Patient must have previously been treated with PBS-subsidised lacosamide, | | | | | | | |
| | **AND the Population criteria is:** | | | | | | | |
| | Patient must be aged 16 years or older. | | | | | | | |
| | **Note** | | | | | | | |
| | **Continuing Therapy Only:** | | | | | | | |
| | For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners. | | | | | | | |
| 9335H<br>*NP* | lacosamide 100 mg tablet, 56 | 1 | 5 | .. | 188.67 | 36.10 | Vimpat | UC |
| | **LACOSAMIDE** | | | | | | | |
| | **Authority required (STREAMLINED)** | | | | | | | |
| | ***4240*** | | | | | | | |
| | Intractable partial epileptic seizures | | | | | | | |
| | Treatment Phase: Initial | | | | | | | |
| | **The Treatment criteria is:** | | | | | | | |
| | Must be treated by a neurologist, | | | | | | | |
| | **AND the Clinical criteria is:** | | | | | | | |
| | The treatment must be in combination with two or more anti-epileptic drugs which includes one second-line adjunctive agent, | | | | | | | |
| | **AND the Clinical criteria is:** | | | | | | | |
| | The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs, which includes at least one first-line anti-epileptic agent and at least two second-line adjunctive anti-epileptic agents, | | | | | | | |
| | **AND the Population criteria is:** | | | | | | | |
| | Patient must be aged 16 years or older. | | | | | | | |
| | **Authority required (STREAMLINED)** | | | | | | | |
| | ***4257*** | | | | | | | |
| | Intractable partial epileptic seizures | | | | | | | |
| | Treatment Phase: Continuing | | | | | | | |
| | **The Clinical criteria is:** | | | | | | | |
| | Patient must have previously been treated with PBS-subsidised lacosamide, | | | | | | | |
| | **AND the Population criteria is:** | | | | | | | |
| | Patient must be aged 16 years or older. | | | | | | | |
| | **Note** | | | | | | | |
| | No applications for increased maximum quantities will be authorised for the 56 tablet packs of the 150 mg and 200 mg strengths. | | | | | | | |
| | **Note** | | | | | | | |
| | **Continuing Therapy Only:** | | | | | | | |
| | For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners. | | | | | | | |
| 9337K<br>*NP* | lacosamide 150 mg tablet, 56 | 1 | 5 | .. | 272.87 | 36.10 | Vimpat | UC |
| 9338L<br>*NP* | lacosamide 200 mg tablet, 56 | 1 | 5 | .. | 355.59 | 36.10 | Vimpat | UC |
| | **LAMOTRIGINE** | | | | | | | |
| | **Authority required (STREAMLINED)** | | | | | | | |
| | ***1426*** | | | | | | | |
| | Treatment of epileptic seizures which are not controlled satisfactorily by other anti-epileptic drugs | | | | | | | |
| | **Note** | | | | | | | |
| | Continuing Therapy Only: | | | | | | | |
| | For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners. | | | | | | | |
| 2850B<br>*NP* | lamotrigine 100 mg tablet, 56 | 1 | 5 | .. | 43.90 | 36.10 [a] | APO-Lamotrigine | TX |

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | [a] | GenRx Lamotrigine | GX |
| | | | | | | | [a] | Lamidus | RA |
| | | | | | | | [a] | Lamogine | AF |
| | | | | | | | [a] | Lamotrigine Aspen 100 | FM |
| | | | | | | | [a] | Lamotrigine-GA | GN |
| | | | | | | | [a] | Lamotrigine generichealth | GQ |
| | | | | | | | [a] | Lamotrigine Sandoz | SZ |
| | | | | | | | [a] | Lamotrust 100 | CR |
| | | | | | | | [a] | Reedos 100 | DO |
| | | | | | | | [a] | Seaze 100 | QA |
| | | | | | | | [a] | Torlemo DT 100 | TA |
| | | | | [B]1.34 | 45.24 | 36.10 | [a] | Lamictal | AS |
| 2851C *NP* | lamotrigine 200 mg tablet, 56 | 1 | 5 | .. | 67.20 | 36.10 | [a] | APO-Lamotrigine | TX |
| | | | | | | | [a] | GenRx Lamotrigine | GX |
| | | | | | | | [a] | Lamidus | RA |
| | | | | | | | [a] | Lamogine | AF |
| | | | | | | | [a] | Lamotrigine Aspen 200 | FM |
| | | | | | | | [a] | Lamotrigine-GA | GN |
| | | | | | | | [a] | Lamotrigine generichealth | GQ |
| | | | | | | | [a] | Lamotrigine Sandoz | SZ |
| | | | | | | | [a] | Lamotrust 200 | CR |
| | | | | | | | [a] | Reedos 200 | DO |
| | | | | | | | [a] | Seaze 200 | QA |
| | | | | | | | [a] | Torlemo DT 200 | TA |
| | | | | [B]1.45 | 68.65 | 36.10 | [a] | Lamictal | AS |
| 2848X *NP* | lamotrigine 25 mg tablet, 56 | 1 | 5 | .. | 20.19 | 21.32 | [a] | APO-Lamotrigine | TX |
| | | | | | | | [a] | GenRx Lamotrigine | GX |
| | | | | | | | [a] | Lamidus | RA |
| | | | | | | | [a] | Lamogine | AF |
| | | | | | | | [a] | Lamotrigine Aspen 25 | FM |
| | | | | | | | [a] | Lamotrigine-GA | GN |
| | | | | | | | [a] | Lamotrigine generichealth | GQ |
| | | | | | | | [a] | Lamotrigine Sandoz | SZ |
| | | | | | | | [a] | Lamotrust 25 | CR |
| | | | | | | | [a] | Reedos 25 | DO |
| | | | | | | | [a] | Seaze 25 | QA |
| | | | | | | | [a] | Torlemo DT 25 | TA |
| | | | | [B]1.47 | 21.66 | 21.32 | [a] | Lamictal | AS |
| 8063J *NP* | lamotrigine 5 mg tablet, 56 | 1 | 5 | .. | 12.73 | 13.86 | [a] | Lamogine | AF |
| | | | | | | | [a] | Seaze 5 | QA |
| | | | | [B]1.46 | 14.19 | 13.86 | [a] | Lamictal | AS |
| 2849Y *NP* | lamotrigine 50 mg tablet, 56 | 1 | 5 | .. | 29.26 | 30.39 | [a] | APO-Lamotrigine | TX |
| | | | | | | | [a] | GenRx Lamotrigine | GX |
| | | | | | | | [a] | Lamidus | RA |
| | | | | | | | [a] | Lamogine | AF |
| | | | | | | | [a] | Lamotrigine-GA | GN |
| | | | | | | | [a] | Lamotrigine generichealth | GQ |
| | | | | | | | [a] | Lamotrigine Sandoz | SZ |
| | | | | | | | [a] | Lamotrust 50 | CR |
| | | | | | | | [a] | Reedos 50 | DO |
| | | | | | | | [a] | Seaze 50 | QA |
| | | | | | | | [a] | Torlemo DT 50 | TA |
| | | | | [B]1.68 | 30.94 | 30.39 | [a] | Lamictal | AS |

**LEVETIRACETAM**

**Authority required (STREAMLINED)**

***2664***

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|---|
| | Treatment of partial epileptic seizures which are not controlled satisfactorily by other anti-epileptic drugs | | | | | | | | |
| | **Note** | | | | | | | | |
| | Continuing Therapy Only: | | | | | | | | |
| | For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners. | | | | | | | | |
| 8656N *NP* | levetiracetam 1 g tablet, 60 | 1 | 5 | .. | 121.16 | 36.10 | [a] | APO-Levetiracetam | TX |
| | | | | | | | [a] | Chem mart Levetiracetam | CH |
| | | | | | | | [a] | Kepcet | GM |
| | | | | | | | [a] | Keppra | UC |
| | | | | | | | [a] | Kerron 1000 | DO |
| | | | | | | | [a] | Kevtam | AF |
| | | | | | | | [a] | Levecetam 1000 | RZ |
| | | | | | | | [a] | Levetiracetam generichealth | GQ |
| | | | | | | | [a] | Levetiracetam SZ | SZ |
| | | | | | | | [a] | Levitaccord | RA |
| | | | | | | | [a] | Levitam 1000 | QA |
| | | | | | | | [a] | Terry White Chemists Levetiracetam | TW |
| 8654L *NP* | levetiracetam 250 mg tablet, 60 | 1 | 5 | .. | 48.61 | 36.10 | [a] | APO-Levetiracetam | TX |
| | | | | | | | [a] | Chem mart Levetiracetam | CH |
| | | | | | | | [a] | Kepcet | GM |
| | | | | | | | [a] | Keppra | UC |
| | | | | | | | [a] | Kerron 250 | DO |
| | | | | | | | [a] | Kevtam | AF |
| | | | | | | | [a] | Levecetam 250 | RZ |
| | | | | | | | [a] | Levetiracetam generichealth | GQ |
| | | | | | | | [a] | Levetiracetam SZ | SZ |
| | | | | | | | [a] | Levitaccord | RA |
| | | | | | | | [a] | Levitam 250 | QA |
| | | | | | | | [a] | Terry White Chemists Levetiracetam | TW |
| 8655M *NP* | levetiracetam 500 mg tablet, 60 | 1 | 5 | .. | 75.37 | 36.10 | [a] | APO-Levetiracetam | TX |
| | | | | | | | [a] | Chem mart Levetiracetam | CH |
| | | | | | | | [a] | Kepcet | GM |
| | | | | | | | [a] | Keppra | UC |
| | | | | | | | [a] | Kerron 500 | DO |
| | | | | | | | [a] | Kevtam | AF |
| | | | | | | | [a] | Levecetam 500 | RZ |
| | | | | | | | [a] | Levetiracetam generichealth | GQ |
| | | | | | | | [a] | Levetiracetam SZ | SZ |
| | | | | | | | [a] | Levitaccord | RA |
| | | | | | | | [a] | Levitam 500 | QA |
| | | | | | | | [a] | Terry White Chemists Levetiracetam | TW |
| | **LEVETIRACETAM** | | | | | | | | |
| | **Authority required (STREAMLINED)** | | | | | | | | |
| | ***3291*** | | | | | | | | |
| | Treatment of partial epileptic seizures, which are not controlled satisfactorily by other anti-epileptic drugs in a patient unable to take a solid dose form of levetiracetam | | | | | | | | |
| | **Note** | | | | | | | | |
| | Continuing Therapy Only: | | | | | | | | |
| | For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners. | | | | | | | | |
| 9169N *NP* | levetiracetam 100 mg/mL oral liquid, 300 mL | ‡1 | 5 | .. | 111.63 | 36.10 | | Keppra | UC |

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|---|
| | **SULTHIAME**<br>**Note**<br>Continuing Therapy Only:<br>For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners. | | | | | | | | |
| 2100M<br>*NP* | sulthiame 200 mg tablet, 200 | 1 | 2 | .. | 206.20 | 36.10 | | Ospolot | PL |
| 2099L<br>*NP* | sulthiame 50 mg tablet, 200 | 1 | 2 | .. | 82.68 | 36.10 | | Ospolot | PL |
| | **TOPIRAMATE**<br>**Authority required (STREAMLINED)**<br>***2797***<br>Treatment of partial epileptic seizures, primary generalised tonic-clonic epileptic seizures and seizures of the Lennox-Gastaut syndrome, which are not controlled satisfactorily by other anti-epileptic drugs<br>**Note**<br>Continuing Therapy Only:<br>For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners. | | | | | | | | |
| 8165R<br>*NP* | topiramate 100 mg tablet, 60 | 1 | 5 | .. | 66.59 | 36.10 | [a] | APO-Topiramate | TX |
| | | | | | | | [a] | Epiramax 100 | QA |
| | | | | | | | [a] | RBX Topiramate | RA |
| | | | | | | | [a] | Tamate | AF |
| | | | | | | | [a] | Topamax | JC |
| | | | | | | | [a] | Topiramate-GA | GM |
| | | | | | | | [a] | Topiramate Sandoz | SZ |
| 8166T<br>*NP* | topiramate 200 mg tablet, 60 | 1 | 5 | .. | 107.36 | 36.10 | [a] | APO-Topiramate | TX |
| | | | | | | | [a] | Epiramax 200 | QA |
| | | | | | | | [a] | RBX Topiramate | RA |
| | | | | | | | [a] | Tamate | AF |
| | | | | | | | [a] | Topamax | JC |
| | | | | | | | [a] | Topiramate-GA | GM |
| | | | | | | | [a] | Topiramate Sandoz | SZ |
| | **TOPIRAMATE**<br>**Authority required (STREAMLINED)**<br>***2798***<br>Treatment of partial epileptic seizures, primary generalised tonic-clonic epileptic seizures and seizures of the Lennox-Gastaut syndrome, which are not controlled satisfactorily by other anti-epileptic drugs in patients unable to take a solid dose form of topiramate<br>**Note**<br>Continuing Therapy Only:<br>For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners. | | | | | | | | |
| 8371N<br>*NP* | topiramate 15 mg capsule, 60 | 1 | 5 | .. | 24.29 | 25.42 | | Topamax Sprinkle | JC |
| 8372P<br>*NP* | topiramate 25 mg capsule, 60 | 1 | 5 | .. | 30.50 | 31.63 | | Topamax Sprinkle | JC |
| 8520K<br>*NP* | topiramate 50 mg capsule, 60 | 1 | 5 | .. | 45.74 | 36.10 | | Topamax Sprinkle | JC |
| | **TOPIRAMATE**<br>**Authority required (STREAMLINED)**<br>***2797***<br>Treatment of partial epileptic seizures, primary generalised tonic-clonic epileptic seizures and seizures of the Lennox-Gastaut syndrome, which are not controlled satisfactorily by other anti-epileptic drugs<br>**Authority required (STREAMLINED)**<br>***2799***<br>Prophylaxis of migraine in a patient who has experienced an average of 3 or more migraines per month over a period of at least 6 months, and who:<br>(a) has a contraindication to beta-blockers, as described in the relevant TGA-approved Product Information; OR<br>(b) has experienced intolerance of a severity necessitating permanent withdrawal during treatment with a beta-blocker; | | | | | | | | |

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|---|
| | AND | | | | | | | | |
| | (c) has a contraindication to pizotifen because the weight gain associated with this drug poses an unacceptable risk; OR | | | | | | | | |
| | (d) has experienced intolerance of a severity necessitating permanent withdrawal during treatment with pizotifen. | | | | | | | | |
| | Details of the contraindication and/or intolerance(s) must be documented in the patient's medical records when treatment is initiated | | | | | | | | |
| | **Note** | | | | | | | | |
| | Continuing Therapy Only: | | | | | | | | |
| | For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners. | | | | | | | | |
| 8163P *NP* | topiramate 25 mg tablet, 60 | 1 | 5 | .. | 30.91 | 32.04 | a | APO-Topiramate | TX |
| | | | | | | | a | Epiramax 25 | QA |
| | | | | | | | a | RBX Topiramate | RA |
| | | | | | | | a | Tamate | AF |
| | | | | | | | a | Topamax | JC |
| | | | | | | | a | Topiramate-GA | GM |
| | | | | | | | a | Topiramate Sandoz | SZ |
| 8164Q *NP* | topiramate 50 mg tablet, 60 | 1 | 5 | .. | 45.78 | 36.10 | a | APO-Topiramate | TX |
| | | | | | | | a | Epiramax 50 | QA |
| | | | | | | | a | RBX Topiramate | RA |
| | | | | | | | a | Tamate | AF |
| | | | | | | | a | Topamax | JC |
| | | | | | | | a | Topiramate-GA | GM |
| | | | | | | | a | Topiramate Sandoz | SZ |
| | **ZONISAMIDE** | | | | | | | | |
| | **Authority required (STREAMLINED)** | | | | | | | | |
| | ***2664*** | | | | | | | | |
| | Treatment of partial epileptic seizures which are not controlled satisfactorily by other anti-epileptic drugs | | | | | | | | |
| | **Note** | | | | | | | | |
| | Continuing Therapy Only: | | | | | | | | |
| | For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners. | | | | | | | | |
| 9390F *NP* | zonisamide 100 mg capsule, 56 | 2 | 5 | .. | *93.67 | 36.10 | | Zonegran | SA |
| 9388D *NP* | zonisamide 25 mg capsule, 56 | 1 | 5 | .. | 23.01 | 24.14 | | Zonegran | SA |
| 9389E *NP* | zonisamide 50 mg capsule, 56 | 1 | 5 | .. | 33.93 | 35.06 | | Zonegran | SA |

## ANTI-PARKINSON DRUGS

### ANTICHOLINERGIC AGENTS

#### *Tertiary amines*

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | **BENZHEXOL** | | | | | | | | |
| 1109J *NP* | benzhexol hydrochloride 2 mg tablet, 200 | 1 | 2 | .. | 15.53 | 16.66 | | Artane | QA |
| 1110K *NP* | benzhexol hydrochloride 5 mg tablet, 200 | 1 | 1 | .. | 22.22 | 23.35 | | Artane | QA |
| | **BIPERIDEN** | | | | | | | | |
| | **Note** | | | | | | | | |
| | Continuing Therapy Only: | | | | | | | | |
| | For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners. | | | | | | | | |
| 2544X *NP* | biperiden hydrochloride 2 mg tablet, 100 | 2 | 2 | .. | *21.09 | 22.22 | | Akineton | LM |

#### *Ethers of tropine or tropine derivatives*

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | **BENZTROPINE** | | | | | | | | |
| 2362H *NP* | benztropine mesylate 2 mg tablet, 60 | 1 | 2 | .. | 12.97 | 14.10 | | Benztrop | PL |

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|---|
| 3038X *NP* | benztropine mesylate 2 mg/2 mL injection, 5 x 2 mL ampoules | 1 | .. | .. | 103.80 | 36.10 | | Cogentin | FK |
| 5031T *DP* | benztropine mesylate 2 mg/2 mL injection, 5 x 2 mL ampoules | 1 | .. | .. | 103.80 | 36.10 | | Cogentin | FK |

## DOPAMINERGIC AGENTS

### *Dopa and dopa derivatives*

**LEVODOPA + BENSERAZIDE**

**Note**

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 8219N *NP* | LEVODOPA with BENSERAZIDE Dispersible tablet 100 mg-25 mg, 100 | 1 | 5 | .. | 39.13 | 36.10 | | Madopar Rapid 125 | RO |
| 8218M *NP* | LEVODOPA with BENSERAZIDE Dispersible tablet 50 mg-12.5 mg, 100 | 1 | 5 | .. | 23.21 | 24.34 | | Madopar Rapid 62.5 | RO |
| 2225D *NP* | levodopa 100 mg + benserazide 25 mg capsule, 100 | 1 | 5 | .. | 39.13 | 36.10 | | Madopar 125 | RO |
| 2231K *NP* | levodopa 100 mg + benserazide 25 mg capsule: modified release, 100 capsules | 1 | 5 | .. | 42.21 | 36.10 | | Madopar HBS | RO |
| 2229H *NP* | levodopa 100 mg + benserazide 25 mg tablet, 100 | 1 | 5 | .. | 39.13 | 36.10 | | Madopar 125 | RO |
| 2226E *NP* | levodopa 200 mg + benserazide 50 mg capsule, 100 | 1 | 5 | .. | 50.22 | 36.10 | | Madopar | RO |
| 2228G *NP* | levodopa 200 mg + benserazide 50 mg tablet, 100 | 1 | 5 | .. | 50.22 | 36.10 | | Madopar | RO |
| 2227F *NP* | levodopa 50 mg + benserazide 12.5 mg capsule, 100 | 1 | 5 | .. | 23.21 | 24.34 | | Madopar 62.5 | RO |

**LEVODOPA + CARBIDOPA ANHYDROUS**

**Note**

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 1242J *NP* | levodopa 100 mg + carbidopa anhydrous 25 mg tablet, 100 | 1 | 5 | .. | 38.50 | 36.10 | a | Kinson | AF |
| | | | | [B]5.19 | 43.69 | 36.10 | a | Sinemet 100/25 | MK |
| 1245M *NP* | levodopa 250 mg + carbidopa anhydrous 25 mg tablet, 100 | 1 | 5 | .. | 45.30 | 36.10 | a | Levo/Carbidopa Sandoz | SZ |
| | | | | [B]2.92 | 48.22 | 36.10 | a | Sinemet | MK |

**LEVODOPA + CARBIDOPA ANHYDROUS**

**Authority required**

Maintenance therapy following treatment which was commenced in a hospital-based movement disorder clinic, of a patient with advanced Parkinson disease with severe disabling motor fluctuations not adequately controlled by oral therapy

**Note**

Patients should have adequate cognitive function to manage administration with a portable continuous infusion pump.

**Note**

Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 8970D *NP* | levodopa 20 mg/mL + carbidopa monohydrate 5 mg/mL gel: intestinal, 7 x 100 mL bags | 8 | 5 | .. | *11682.55 | 36.10 | | Duodopa | VE |

**LEVODOPA + CARBIDOPA ANHYDROUS**

**Authority required (STREAMLINED)**

***1257***

Parkinson's disease where fluctuations in motor function are not adequately controlled by frequent dosing with conventional formulations of levodopa with decarboxylase inhibitor

**Note**

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

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|---|---|---|---|---|---|---|---|---|
| 1255C<br>*NP* | levodopa 200 mg + carbidopa anhydrous 50 mg tablet: modified release, 100 tablets | 1 | 5 | .. | 68.08 | 36.10 | Sinemet CR | MK |

**LEVODOPA + CARBIDOPA ANHYDROUS + ENTACAPONE**

**Authority required (STREAMLINED)**

***3305***

Parkinson disease in patients being treated with levodopa—decarboxylase inhibitor combinations who are experiencing fluctuations in motor function due to end-of-dose effect

**Authority required (STREAMLINED)**

***3306***

Parkinson disease in patients stabilised on concomitant treatment with levodopa—decarboxylase inhibitor combinations and entacapone

**Note**

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 8798C<br>*NP* | levodopa 100 mg + carbidopa anhydrous 25 mg + entacapone 200 mg tablet, 100 | 2 | 4 | .. | *342.13 | 36.10 | Stalevo 100/25/200mg | NV |
| 9345W<br>*NP* | levodopa 125 mg + carbidopa anhydrous 31.25 mg + entacapone 200 mg tablet, 100 | 2 | 4 | .. | *354.17 | 36.10 | Stalevo 125/31.25/200mg | NV |
| 8799D<br>*NP* | levodopa 150 mg + carbidopa anhydrous 37.5 mg + entacapone 200 mg tablet, 100 | 2 | 4 | .. | *372.17 | 36.10 | Stalevo 150/37.5/200mg | NV |
| 9292C<br>*NP* | levodopa 200 mg + carbidopa anhydrous 50 mg + entacapone 200 mg tablet, 100 | 2 | 4 | .. | *399.83 | 36.10 | Stalevo 200/50/200mg | NV |
| 8797B<br>*NP* | levodopa 50 mg + carbidopa anhydrous 12.5 mg + entacapone 200 mg tablet, 100 | 2 | 4 | .. | *312.09 | 36.10 | Stalevo 50/12.5/200mg | NV |
| 9344T<br>*NP* | levodopa 75 mg + carbidopa anhydrous 18.75 mg + entacapone 200 mg tablet, 100 | 2 | 4 | .. | *325.33 | 36.10 | Stalevo 75/18.75/200mg | NV |

## *Adamantane derivatives*

**AMANTADINE**

**Restricted benefit**

Parkinson's disease which is not drug induced

**Note**

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 3016R<br>*NP* | amantadine hydrochloride 100 mg capsule, 100 | 1 | 5 | .. | 44.51 | 36.10 | Symmetrel 100 | NV |

## *Dopamine agonists*

**BROMOCRIPTINE**

**Restricted benefit**

Acromegaly

**Restricted benefit**

Parkinson's disease

**Restricted benefit**

Pathological hyperprolactinaemia where surgery is not indicated

**Restricted benefit**

Pathological hyperprolactinaemia where surgery has already been used with incomplete resolution

**Restricted benefit**

Pathological hyperprolactinaemia where radiotherapy is not indicated

**Restricted benefit**

Pathological hyperprolactinaemia where radiotherapy has already been used with incomplete resolution

**Note**

Care should be taken when treating patients with advanced age and significant cognitive impairment with dopamine agonists.

**Note**

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|---|
| | For item codes 1443Y and 1559C, pharmaceutical benefits that have the form tablet 2.5 mg (base) are equivalent for the purposes of substitution. | | | | | | | | |
| 1443Y | bromocriptine 2.5 mg tablet, 30 | 2 | 5 | .. | *31.63 | 32.76 | a | Parlodel | NV |
| 1559C | bromocriptine 2.5 mg tablet, 60 | 1 | 5 | .. | 31.63 | 32.76 | a | Kripton 2.5 | AF |
| | **BROMOCRIPTINE**<br>**Restricted benefit**<br>Acromegaly | | | | | | | | |
| | **Restricted benefit**<br>Parkinson's disease | | | | | | | | |
| | **Restricted benefit**<br>Pathological hyperprolactinaemia where surgery is not indicated | | | | | | | | |
| | **Restricted benefit**<br>Pathological hyperprolactinaemia where surgery has already been used with incomplete resolution | | | | | | | | |
| | **Restricted benefit**<br>Pathological hyperprolactinaemia where radiotherapy is not indicated | | | | | | | | |
| | **Restricted benefit**<br>Pathological hyperprolactinaemia where radiotherapy has already been used with incomplete resolution | | | | | | | | |
| | **Note**<br>Care should be taken when treating patients with advanced age and significant cognitive impairment with dopamine agonists. | | | | | | | | |
| 1446D | bromocriptine 5 mg capsule, 60 | 1 | 5 | .. | 48.49 | 36.10 | | Kripton 5 | AF |
| | **CABERGOLINE**<br>**Restricted benefit**<br>Parkinson's disease | | | | | | | | |
| | **Note**<br>Care should be taken when treating patients with advanced age and significant cognitive impairment with dopamine agonists. | | | | | | | | |
| | **Note**<br>Continuing Therapy Only:<br>For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners. | | | | | | | | |
| 8393R<br>*NP* | cabergoline 1 mg tablet, 30 | 1 | 5 | .. | 59.99 | 36.10 | a | Bergoline 1 | QA |
| | | | | | | | a | Cabaser | PF |
| | | | | | | | a | Cobasol | GM |
| 8394T<br>*NP* | cabergoline 2 mg tablet, 30 | 1 | 5 | .. | 78.15 | 36.10 | a | Bergoline 2 | QA |
| | | | | | | | a | Cabaser | PF |
| | | | | | | | a | Cobasol | GM |
| | **PERGOLIDE**<br>**Restricted benefit**<br>Parkinson's disease as adjunctive therapy in patients being treated with levodopa—decarboxylase inhibitor combinations | | | | | | | | |
| | **Note**<br>Care should be taken when treating patients with advanced age and significant cognitive impairment with dopamine agonists. | | | | | | | | |
| | **Note**<br>Continuing Therapy Only:<br>For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners. | | | | | | | | |
| 2810X<br>*NP* | pergolide 1 mg tablet, 100 | 1 | 5 | .. | 241.90 | 36.10 | | Permax | AS |
| 2809W<br>*NP* | pergolide 250 microgram tablet, 100 | 1 | 5 | .. | 66.39 | 36.10 | | Permax | AS |
| 2808T<br>*NP* | pergolide 50 microgram tablet, 100 | 1 | .. | .. | 53.14 | 36.10 | | Permax | AS |
| | **PRAMIPEXOLE**<br>**Restricted benefit**<br>Parkinson disease | | | | | | | | |
| | **Caution**<br>Episodes of sudden onset of sleep without warning, during activity, have been reported with this drug. | | | | | | | | |

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|---|
| | **Note**<br>Care should be taken when treating patients with advanced age and significant cognitive impairment with dopamine agonists. | | | | | | | | |
| | **Note**<br>Continuing Therapy Only:<br>For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners. | | | | | | | | |
| 9153R<br>*NP* | pramipexole hydrochloride monohydrate 1 mg tablet, 100 | 1 | 5 | .. | 129.03 | 36.10 | [a] | Sifrol | BY |
| | | | | | | | [a] | Simipex 1 | QA |
| 9151P<br>*NP* | pramipexole hydrochloride monohydrate 125 microgram tablet, 30 | 1 | .. | .. | 11.10 | 12.23 | [a] | Sifrol | BY |
| | | | | | | | [a] | Simipex 0.125 | QA |
| 9152Q<br>*NP* | pramipexole hydrochloride monohydrate 250 microgram tablet, 100 | 1 | 5 | .. | 35.94 | 36.10 | [a] | Sifrol | BY |
| | | | | | | | [a] | Simipex 0.25 | QA |
| | **PRAMIPEXOLE**<br>**Restricted benefit**<br>Parkinson disease<br>**Caution**<br>Episodes of sudden onset of sleep without warning, during activity, have been reported with this drug.<br>**Note**<br>Care should be taken when treating patients with advanced age and significant cognitive impairment with dopamine agonists.<br>**Note**<br>No applications for increased maximum quantities and/or repeats will be approved for extended release pramipexole formulations.<br>**Note**<br>Continuing Therapy Only:<br>For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners. | | | | | | | | |
| 3420B<br>*NP* | pramipexole hydrochloride monohydrate 1.5 mg tablet: modified release, 30 tablets | 1 | 5 | .. | 57.11 | 36.10 | | Sifrol ER | BY |
| 5143Q<br>*NP* | pramipexole hydrochloride monohydrate 2.25 mg tablet: modified release, 30 tablets | 1 | 5 | .. | 82.37 | 36.10 | | Sifrol ER | BY |
| 3421C<br>*NP* | pramipexole hydrochloride monohydrate 3 mg tablet: modified release, 30 tablets | 1 | 5 | .. | 116.78 | 36.10 | | Sifrol ER | BY |
| 5145T<br>*NP* | pramipexole hydrochloride monohydrate 3.75 mg tablet: modified release, 30 tablets | 1 | 5 | .. | 142.03 | 36.10 | | Sifrol ER | BY |
| 3418X<br>*NP* | pramipexole hydrochloride monohydrate 375 microgram tablet: modified release, 30 tablets | 1 | 5 | .. | 20.05 | 21.18 | | Sifrol ER | BY |
| 3422D<br>*NP* | pramipexole hydrochloride monohydrate 4.5 mg tablet: modified release, 30 tablets | 1 | 5 | .. | 171.87 | 36.10 | | Sifrol ER | BY |
| 3419Y<br>*NP* | pramipexole hydrochloride monohydrate 750 microgram tablet: modified release, 30 tablets | 1 | 5 | .. | 33.01 | 34.14 | | Sifrol ER | BY |
| | **PRAMIPEXOLE**<br>**Restricted benefit**<br>Treatment of severe primary Restless Legs Syndrome in a patient who manifests all 4 diagnostic criteria below and whose baseline International Restless Legs Syndrome Rating Scale (IRLSRS) score is greater than or equal to 21 points prior to initiation of pramipexole.<br>The date and IRLSRS score must be documented in the patient's medical records at the time pramipexole treatment is initiated.<br>The diagnostic criteria for Restless Legs Syndrome are:<br>(a) An urge to move the legs usually accompanied or caused by unpleasant sensations in the legs; and<br>(b) The urge to move or unpleasant sensations begin or worsen during periods of rest or inactivity such as lying or sitting; and<br>(c) The urge to move or unpleasant sensations are partially or totally relieved by movement, such as walking or stretching, at least as long as the activity continues; and<br>(d) The urge to move or unpleasant sensations are worse in the evening or night than during the day or only occur during the evening or night. | | | | | | | | |

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|---|
| | Pramipexole is not PBS-subsidised for Restless Legs Syndrome secondary to other causes | | | | | | | | |
| | **Caution** | | | | | | | | |
| | Episodes of sudden onset of sleep without warning, during activity, have been reported with this drug. | | | | | | | | |
| | **Note** | | | | | | | | |
| | Care should be taken when treating patients with advanced age and significant cognitive impairment with dopamine agonists. | | | | | | | | |
| | **Note** | | | | | | | | |
| | No applications for increased maximum quantities and/or repeats will be authorised. | | | | | | | | |
| | **Note** | | | | | | | | |
| | Continuing Therapy Only: | | | | | | | | |
| | For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners. | | | | | | | | |
| 9393J *NP* | pramipexole hydrochloride monohydrate 125 microgram tablet, 30 | 1 | 2 | .. | 11.10 | 12.23 | a | Sifrol | BY |
| 9394K *NP* | pramipexole hydrochloride monohydrate 250 microgram tablet, 100 | 1 | 2 | .. | 35.94 | 36.10 | a | Sifrol | BY |
| | **ROTIGOTINE** | | | | | | | | |
| | **Restricted benefit** | | | | | | | | |
| | Parkinson disease | | | | | | | | |
| | **The Clinical criteria is:** | | | | | | | | |
| | The treatment must be as adjunctive therapy to a levodopa-decarboxylase inhibitor combination. | | | | | | | | |
| 2385M | rotigotine 2 mg/24 hours patch, 28 | 1 | 5 | .. | 77.46 | 36.10 | | Neupro | UC |
| | **ROTIGOTINE** | | | | | | | | |
| | **Restricted benefit** | | | | | | | | |
| | Parkinson disease | | | | | | | | |
| | **The Clinical criteria is:** | | | | | | | | |
| | The treatment must be as adjunctive therapy to a levodopa-decarboxylase inhibitor combination. | | | | | | | | |
| 2384L | rotigotine 4 mg/24 hours patch, 28 | 1 | 5 | .. | 101.07 | 36.10 | | Neupro | UC |
| 2410W | rotigotine 6 mg/24 hours patch, 28 | 1 | 5 | .. | 113.79 | 36.10 | | Neupro | UC |

## *Monoamine oxidase B inhibitors*

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | **RASAGILINE** | | | | | | | | |
| | **Authority required (STREAMLINED)** | | | | | | | | |
| | ***4053*** | | | | | | | | |
| | Parkinson disease | | | | | | | | |
| | **Note** | | | | | | | | |
| | No applications for increased maximum quantities and/or repeats will be authorised. | | | | | | | | |
| 1952R *NP* | RASAGILINE Tablet 1 mg (as mesilate), 30 | 1 | 5 | .. | 121.80 | 36.10 | | Azilect | LU |
| | **SELEGILINE** | | | | | | | | |
| | **Restricted benefit** | | | | | | | | |
| | Late stage Parkinson's disease as adjunctive therapy in patients being treated with levodopa—decarboxylase inhibitor combinations | | | | | | | | |
| | **Note** | | | | | | | | |
| | Continuing Therapy Only: | | | | | | | | |
| | For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners. | | | | | | | | |
| 1973W *NP* | selegiline hydrochloride 5 mg tablet, 100 | 1 | 5 | .. | 53.17 | 36.10 | a | Eldepryl | AS |
| | | | | | | | a | Selgene | AF |

## *Other dopaminergic agents*

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | **ENTACAPONE** | | | | | | | | |
| | **Authority required (STREAMLINED)** | | | | | | | | |
| | ***2067*** | | | | | | | | |
| | Parkinson's disease as adjunctive therapy in patients being treated with levodopa—decarboxylase inhibitor combinations who are experiencing fluctuations in motor function due to end-of-dose effect | | | | | | | | |
| | **Note** | | | | | | | | |
| | Continuing Therapy Only: | | | | | | | | |

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|
| | For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners. | | | | | | | |
| 8367J *NP* | entacapone 200 mg tablet, 100 | 2 | 4 | .. | *282.03 | 36.10 | Comtan | NV |

## PSYCHOLEPTICS

### ANTIPSYCHOTICS

#### *Phenothiazines with aliphatic side-chain*

**CHLORPROMAZINE**

**Note**

Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 1196Y *NP* | chlorpromazine hydrochloride 10 mg tablet, 100 | 1 | 5 | .. | 10.70 | 11.83 | Largactil | SW |
| 1199D *NP* | chlorpromazine hydrochloride 100 mg tablet, 100 | 1 | 5 | .. | 17.65 | 18.78 | Largactil | SW |
| 1197B *NP* | chlorpromazine hydrochloride 25 mg tablet, 100 | 1 | 5 | .. | 11.30 | 12.43 | Largactil | SW |
| 1201F *NP* | chlorpromazine hydrochloride 5 mg/mL oral liquid, 100 mL | ‡1 | 5 | .. | 12.78 | 13.91 | Largactil | SW |
| 1195X *NP* | chlorpromazine hydrochloride 50 mg/2 mL injection, 10 x 2 mL ampoules | 1 | .. | .. | 20.69 | 21.82 | Largactil | SW |

#### *Phenothiazines with piperazine structure*

**FLUPHENAZINE DECANOATE**

**Note**

Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 1046C *NP* | fluphenazine decanoate 12.5 mg/0.5 mL injection, 5 x 0.5 mL ampoules | 1 | .. | .. | 19.43 | 20.56 | Modecate | BQ |
| 3098C *NP* | fluphenazine decanoate 25 mg/mL injection, 5 x 1 mL ampoules | 1 | .. | .. | 26.59 | 27.72 | Modecate | BQ |
| 1001Q *NP* | fluphenazine decanoate 50 mg/2 mL injection, 5 x 2 mL ampoules | 1 | .. | .. | 37.86 | 36.10 | Modecate | BQ |

**TRIFLUOPERAZINE**

**Note**

Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 2185B *NP* | trifluoperazine 1 mg tablet, 100 | 1 | 5 | .. | 13.52 | 14.65 | Stelazine | GH |
| 2386N *NP* | trifluoperazine 2 mg tablet, 100 | 1 | 5 | .. | 13.69 | 14.82 | Stelazine | GH |
| 2186C *NP* | trifluoperazine 5 mg tablet, 100 | 1 | 5 | .. | 14.07 | 15.20 | Stelazine | GH |

#### *Phenothiazines with piperidine structure*

**PERICYAZINE**

**Note**

Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 3053Q *NP* | pericyazine 10 mg tablet, 100 | 1 | 5 | .. | 14.67 | 15.80 | Neulactil | SW |
| 3052P *NP* | pericyazine 2.5 mg tablet, 100 | 1 | 5 | .. | 10.62 | 11.75 | Neulactil | SW |

#### *Butyrophenone derivatives*

**HALOPERIDOL**

**Note**

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|
| | Shared Care Model: | | | | | | | |
| | For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners. | | | | | | | |
| 2767P *NP* | haloperidol 1.5 mg tablet, 100 | 1 | 5 | .. | 11.12 | 12.25 | Serenace | QA |
| 2763K *NP* | haloperidol 2 mg/mL oral liquid, 100 mL | ‡1 | 5 | .. | 20.66 | 21.79 | Serenace | QA |
| 2770T *NP* | haloperidol 5 mg tablet, 50 | 1 | 5 | .. | 10.89 | 12.02 | Serenace | QA |
| 2768Q *NP* | haloperidol 5 mg/mL injection, 10 x 1 mL ampoules | 1 | .. | .. | 22.49 | 23.62 | Serenace | QA |
| 2761H *NP* | haloperidol 500 microgram tablet, 100 | 1 | 5 | .. | 10.77 | 11.90 | Serenace | QA |
| | **HALOPERIDOL DECANOATE** | | | | | | | |
| | **Note** | | | | | | | |
| | Shared Care Model: | | | | | | | |
| | For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners. | | | | | | | |
| 2766N *NP* | haloperidol (as decanoate) 150 mg/3 mL injection, 5 x 3 mL ampoules | 1 | .. | .. | 46.44 | 36.10 | Haldol decanoate | JC |
| 2765M *NP* | haloperidol (as decanoate) 50 mg/mL injection, 5 x 1 mL vials | 1 | .. | .. | 26.88 | 28.01 | Haldol decanoate | JC |

## *Indole derivatives*

**ZIPRASIDONE**

**Authority required (STREAMLINED)**

***1589***

Schizophrenia

**Authority required (STREAMLINED)**

***3084***

Monotherapy, for up to 6 months, of an episode of acute mania or mixed episodes associated with bipolar I disorder

**Note**

Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 9070J *NP* | ziprasidone 20 mg capsule, 60 | 1 | 5 | .. | 90.82 | 36.10 | Zeldox | PF |
| 9071K *NP* | ziprasidone 40 mg capsule, 60 | 1 | 5 | .. | 175.32 | 36.10 | Zeldox | PF |
| 9072L *NP* | ziprasidone 60 mg capsule, 60 | 1 | 5 | .. | 253.84 | 36.10 | Zeldox | PF |
| 9073M *NP* | ziprasidone 80 mg capsule, 60 | 1 | 5 | .. | 330.64 | 36.10 | Zeldox | PF |

## *Thioxanthene derivatives*

**FLUPENTHIXOL DECANOATE**

**Note**

Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 2257T *NP* | flupenthixol decanoate 100 mg/mL injection, 5 x 1 mL ampoules | 1 | .. | .. | 48.48 | 36.10 | Fluanxol Concentrated Depot | LU |
| 2255Q *NP* | flupenthixol decanoate 20 mg/mL injection, 5 x 1 mL ampoules | 1 | .. | .. | 20.72 | 21.85 | Fluanxol Depot | LU |

**ZUCLOPENTHIXOL DECANOATE**

**Note**

Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 8097E *NP* | zuclopenthixol decanoate 200 mg/mL injection, 5 x 1 mL ampoules | 1 | .. | .. | 27.45 | 28.58 | Clopixol Depot | LU |

## *Diazepines, oxazepines, thiazepines and oxepines*

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|---|
| | **ASENAPINE**<br>**Authority required (STREAMLINED)**<br>***1589***<br>Schizophrenia<br>**Authority required (STREAMLINED)**<br>***3935***<br>Treatment, for up to 6 months, of an episode of acute mania or mixed episodes associated with bipolar I disorder<br>**Authority required (STREAMLINED)**<br>***3936***<br>Maintenance treatment, as monotherapy, of bipolar I disorder<br>**Note**<br>Shared Care Model:<br>For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners. | | | | | | | | |
| 5141N<br>*NP* | asenapine 10 mg wafer: sublingual, 60 wafers | 1 | 5 | .. | 252.93 | 36.10 | | Saphris | LU |
| 5140M<br>*NP* | asenapine 5 mg wafer: sublingual, 60 wafers | 1 | 5 | .. | 157.28 | 36.10 | | Saphris | LU |
| | **OLANZAPINE**<br>**Authority required (STREAMLINED)**<br>***1589***<br>Schizophrenia<br>**Authority required (STREAMLINED)**<br>***2044***<br>Maintenance treatment of bipolar I disorder<br>**Note**<br>Pharmaceutical benefits that have the form olanzapine tablet 10 mg (orally disintegrating) and pharmaceutical benefits that have the form olanzapine wafer 10 mg are equivalent for the purposes of substitution. | | | | | | | | |
| 3382B<br>*NP* | OLANZAPINE Tablet 10 mg (orally disintegrating), 28 | 1 | 5 | .. | 164.21 | 36.10 | [a] | APO-Olanzapine ODT | TX |
| | | | | | | | [a] | Chem mart Olanzapine ODT | CH |
| | | | | | | | [a] | Olanzapine-GA ODT | GM |
| | | | | | | | [a] | Olanzapine ODT-DRLA | RZ |
| | | | | | | | [a] | Olanzapine ODT generichealth 10 | GQ |
| | | | | | | | [a] | Olanzapine RBX ODT | RA |
| | | | | | | | [a] | Olanzapine Sandoz ODT 10 | SZ |
| | | | | | | | [a] | Pharmacy Choice Olanzapine ODT | RI |
| | | | | | | | [a] | STADA Olanzapine ODT | TD |
| | | | | | | | [a] | Terry White Chemists Olanzapine ODT | TW |
| | | | | | | | [a] | Zylap ODT 10 | QA |
| | **OLANZAPINE**<br>**Authority required (STREAMLINED)**<br>***1589***<br>Schizophrenia<br>**Authority required (STREAMLINED)**<br>***2044***<br>Maintenance treatment of bipolar I disorder<br>**Note**<br>Pharmaceutical benefits that have the form olanzapine tablet 5 mg (orally disintegrating) and pharmaceutical benefits that have the form olanzapine wafer 5 mg are equivalent for the purposes of substitution. | | | | | | | | |
| 3381Y<br>*NP* | OLANZAPINE Tablet 5 mg (orally disintegrating), 28 | 1 | 5 | .. | 84.62 | 36.10 | [a] | APO-Olanzapine ODT | TX |
| | | | | | | | [a] | Chem mart Olanzapine ODT | CH |
| | | | | | | | [a] | Olanzapine-GA ODT | GM |
| | | | | | | | [a] | Olanzapine ODT-DRLA | RZ |

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | [a] | Olanzapine ODT generichealth 5 | GQ |
| | | | | | | | [a] | Olanzapine RBX ODT | RA |
| | | | | | | | [a] | Olanzapine Sandoz ODT 5 | SZ |
| | | | | | | | [a] | Pharmacy Choice Olanzapine ODT | RI |
| | | | | | | | [a] | STADA Olanzapine ODT | TD |
| | | | | | | | [a] | Terry White Chemists Olanzapine ODT | TW |
| | | | | | | | [a] | Zylap ODT 5 | QA |
| | **OLANZAPINE**<br>**Authority required (STREAMLINED)**<br>***1589***<br>Schizophrenia<br>**Authority required (STREAMLINED)**<br>***2044***<br>Maintenance treatment of bipolar I disorder<br>**Note**<br>Pharmaceutical benefits that have the form olanzapine tablet 10 mg and pharmaceutical benefits that have the form olanzapine tablet 10 mg (as benzoate) are equivalent for the purposes of substitution. | | | | | | | | |
| 1042W<br>*NP* | olanzapine 10 mg tablet, 28 | 1 | 5 | .. | 164.21 | 36.10 | [a] | Olanzapine generichealth 10 | GQ |
| | | | | | | | [a] | STADA Olanzapine | TD |
| | **OLANZAPINE**<br>**Authority required (STREAMLINED)**<br>***1589***<br>Schizophrenia<br>**Authority required (STREAMLINED)**<br>***2044***<br>Maintenance treatment of bipolar I disorder<br>**Note**<br>Pharmaceutical benefits that have the form olanzapine tablet 10 mg and pharmaceutical benefits that have the form olanzapine tablet 10 mg (as benzoate) are equivalent for the purposes of substitution.<br>**Note**<br>Shared Care Model:<br>For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners. | | | | | | | | |
| 8187X<br>*NP* | olanzapine 10 mg tablet, 28 | 1 | 5 | .. | 164.21 | 36.10 | [a] | APO-Olanzapine | TX |
| | | | | | | | [a] | Chem mart Olanzapine | CH |
| | | | | | | | [a] | Lanzek | EL |
| | | | | | | | [a] | Olanzapine-DRLA | RZ |
| | | | | | | | [a] | Olanzapine-GA | GM |
| | | | | | | | [a] | Olanzapine RBX | RA |
| | | | | | | | [a] | Olanzapine Sandoz | SZ |
| | | | | | | | [a] | Ozin 10 | DO |
| | | | | | | | [a] | Pharmacor Olanzapine 10 | CR |
| | | | | | | | [a] | Pharmacy Choice Olanzapine | RI |
| | | | | | | | [a] | Terry White Chemists Olanzapine | TW |
| | | | | | | | [a] | Zylap 10 | QA |
| | | | | | | | [a] | Zypine | AF |
| | | | | | | | [a] | Zyprexa | LY |
| | **OLANZAPINE**<br>**Authority required (STREAMLINED)**<br>***1589***<br>Schizophrenia<br>**Authority required (STREAMLINED)** | | | | | | | | |

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|---|
| | ***2044***<br>Maintenance treatment of bipolar I disorder<br>**Note**<br>Pharmaceutical benefits that have the form olanzapine tablet 10 mg (orally disintegrating) and pharmaceutical benefits that have the form olanzapine wafer 10 mg are equivalent for the purposes of substitution.<br>**Note**<br>Shared Care Model:<br>For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners. | | | | | | | | |
| 8434X<br>*NP* | olanzapine 10 mg wafer, 28 | 1 | 5 | .. | 164.21 | 36.10 | [a] | Lanzek Zydis | EL |
| | | | | | | | [a] | Zypine ODT | AF |
| | | | | | | | [a] | Zyprexa Zydis | LY |
| | **OLANZAPINE**<br>**Authority required (STREAMLINED)**<br>***1589***<br>Schizophrenia<br>**Authority required (STREAMLINED)**<br>***2044***<br>Maintenance treatment of bipolar I disorder<br>**Note**<br>Pharmaceutical benefits that have the form olanzapine tablet 15 mg (orally disintegrating) and pharmaceutical benefits that have the form olanzapine wafer 15 mg are equivalent for the purposes of substitution. | | | | | | | | |
| 3384D<br>*NP* | olanzapine 15 mg tablet, 28 | 1 | 5 | .. | 239.50 | 36.10 | [a] | APO-Olanzapine ODT | TX |
| | | | | | | | [a] | Chem mart Olanzapine ODT | CH |
| | | | | | | | [a] | Terry White Chemists Olanzapine ODT | TW |
| | **OLANZAPINE**<br>**Authority required (STREAMLINED)**<br>***1589***<br>Schizophrenia<br>**Authority required (STREAMLINED)**<br>***2044***<br>Maintenance treatment of bipolar I disorder<br>**Note**<br>Pharmaceutical benefits that have the form olanzapine tablet 15 mg (orally disintegrating) and pharmaceutical benefits that have the form olanzapine wafer 15 mg are equivalent for the purposes of substitution.<br>**Note**<br>Shared Care Model:<br>For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners. | | | | | | | | |
| 8952E<br>*NP* | olanzapine 15 mg wafer, 28 | 1 | 5 | .. | 239.50 | 36.10 | [a] | Zypine ODT | AF |
| | | | | | | | [a] | Zyprexa Zydis | LY |
| | **OLANZAPINE**<br>**Authority required (STREAMLINED)**<br>***1589***<br>Schizophrenia<br>**Authority required (STREAMLINED)**<br>***2044***<br>Maintenance treatment of bipolar I disorder<br>**Note**<br>Pharmaceutical benefits that have the form olanzapine tablet 2.5 mg and pharmaceutical benefits that have the form olanzapine tablet 2.5 mg (as benzoate) are equivalent for the purposes of substitution. | | | | | | | | |
| 1024X<br>*NP* | olanzapine 2.5 mg tablet, 28 | 1 | 5 | .. | 46.94 | 36.10 | [a] | Olanzapine generichealth 2.5 | GQ |
| | | | | | | | [a] | STADA Olanzapine | TD |

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|---|---|---|---|---|---|---|---|---|---|
| | **OLANZAPINE**<br>**Authority required (STREAMLINED)**<br>***1589***<br>Schizophrenia<br>**Authority required (STREAMLINED)**<br>***2044***<br>Maintenance treatment of bipolar I disorder<br>**Note**<br>Pharmaceutical benefits that have the form olanzapine tablet 2.5 mg and pharmaceutical benefits that have the form olanzapine tablet 2.5 mg (as benzoate) are equivalent for the purposes of substitution.<br>**Note**<br>Shared Care Model:<br>For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners. | | | | | | | | |
| 8170B<br>*NP* | olanzapine 2.5 mg tablet, 28 | 1 | 5 | .. | 46.94 | 36.10 | [a] | APO-Olanzapine | TX |
| | | | | | | | [a] | Chem mart Olanzapine | CH |
| | | | | | | | [a] | Lanzek | EL |
| | | | | | | | [a] | Olanzapine-DRLA | RZ |
| | | | | | | | [a] | Olanzapine-GA | GM |
| | | | | | | | [a] | Olanzapine RBX | RA |
| | | | | | | | [a] | Olanzapine Sandoz | SZ |
| | | | | | | | [a] | Ozin 2.5 | DO |
| | | | | | | | [a] | Pharmacor Olanzapine 2.5 | CR |
| | | | | | | | [a] | Pharmacy Choice Olanzapine | RI |
| | | | | | | | [a] | Terry White Chemists Olanzapine | TW |
| | | | | | | | [a] | Zylap 2.5 | QA |
| | | | | | | | [a] | Zypine | AF |
| | | | | | | | [a] | Zyprexa | LY |
| | **OLANZAPINE**<br>**Authority required (STREAMLINED)**<br>***1589***<br>Schizophrenia<br>**Authority required (STREAMLINED)**<br>***2044***<br>Maintenance treatment of bipolar I disorder<br>**Note**<br>Pharmaceutical benefits that have the form olanzapine tablet 20 mg (orally disintegrating) and pharmaceutical benefits that have the form olanzapine wafer 20 mg are equivalent for the purposes of substitution. | | | | | | | | |
| 3385E<br>*NP* | olanzapine 20 mg tablet, 28 | 1 | 5 | .. | 311.11 | 36.10 | [a] | APO-Olanzapine ODT | TX |
| | | | | | | | [a] | Chem mart Olanzapine ODT | CH |
| | | | | | | | [a] | Terry White Chemists Olanzapine ODT | TW |
| | **OLANZAPINE**<br>**Authority required (STREAMLINED)**<br>***1589***<br>Schizophrenia<br>**Authority required (STREAMLINED)**<br>***2044***<br>Maintenance treatment of bipolar I disorder<br>**Note**<br>Pharmaceutical benefits that have the form olanzapine tablet 20 mg (orally disintegrating) and pharmaceutical benefits that have the form olanzapine wafer 20 mg are equivalent for the purposes of substitution.<br>**Note**<br>Shared Care Model: | | | | | | | | |

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|---|
| | For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners. | | | | | | | | |
| 8953F *NP* | olanzapine 20 mg wafer, 28 | 1 | 5 | .. | 311.11 | 36.10 | a | Zypine ODT | AF |
| | | | | | | | a | Zyprexa Zydis | LY |

**OLANZAPINE**
**Authority required (STREAMLINED)**
***1589***
Schizophrenia

**Caution**
Monitor for post-injection syndrome for at least three hours after each injection.

**Note**
Special Pricing Arrangements apply.

**Note**
Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 9294E *NP* | olanzapine 210 mg injection: modified release [1 x 210 mg vial] (&) inert substance diluent [1 x 3 mL vial], 1 pack | 2 | 5 | .. | *499.99 | 36.10 | | Zyprexa Relprevv | LY |
| 9295F *NP* | olanzapine 300 mg injection: modified release [1 x 300 mg vial] (&) inert substance diluent [1 x 3 mL vial], 1 pack | 2 | 5 | .. | *809.47 | 36.10 | | Zyprexa Relprevv | LY |
| 9303P *NP* | olanzapine 405 mg injection: modified release [1 x 405 mg vial] (&) inert substance diluent [1 x 3 mL vial], 1 pack | 1 | 5 | .. | 499.99 | 36.10 | | Zyprexa Relprevv | LY |

**OLANZAPINE**
**Authority required (STREAMLINED)**
***1589***
Schizophrenia

**Authority required (STREAMLINED)**
***2044***
Maintenance treatment of bipolar I disorder

**Note**
Pharmaceutical benefits that have the form olanzapine tablet 5 mg and pharmaceutical benefits that have the form olanzapine tablet 5 mg (as benzoate) are equivalent for the purposes of substitution.

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 1037N *NP* | olanzapine 5 mg tablet, 28 | 1 | 5 | .. | 84.62 | 36.10 | a | Olanzapine generichealth 5 | GQ |
| | | | | | | | a | STADA Olanzapine | TD |

**OLANZAPINE**
**Authority required (STREAMLINED)**
***1589***
Schizophrenia

**Authority required (STREAMLINED)**
***2044***
Maintenance treatment of bipolar I disorder

**Note**
Pharmaceutical benefits that have the form olanzapine tablet 5 mg and pharmaceutical benefits that have the form olanzapine tablet 5 mg (as benzoate) are equivalent for the purposes of substitution.

**Note**
Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 8185T *NP* | olanzapine 5 mg tablet, 28 | 1 | 5 | .. | 84.62 | 36.10 | a | APO-Olanzapine | TX |
| | | | | | | | a | Chem mart Olanzapine | CH |
| | | | | | | | a | Lanzek | EL |
| | | | | | | | a | Olanzapine-DRLA | RZ |
| | | | | | | | a | Olanzapine-GA | GM |
| | | | | | | | a | Olanzapine RBX | RA |

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | [a] | Olanzapine Sandoz | SZ |
| | | | | | | | [a] | Ozin 5 | DO |
| | | | | | | | [a] | Pharmacor Olanzapine 5 | CR |
| | | | | | | | [a] | Pharmacy Choice Olanzapine | RI |
| | | | | | | | [a] | Terry White Chemists Olanzapine | TW |
| | | | | | | | [a] | Zylap 5 | QA |
| | | | | | | | [a] | Zypine | AF |
| | | | | | | | [a] | Zyprexa | LY |
| | **OLANZAPINE**<br>**Authority required (STREAMLINED)**<br>***1589***<br>Schizophrenia<br>**Authority required (STREAMLINED)**<br>***2044***<br>Maintenance treatment of bipolar I disorder<br>**Note**<br>Pharmaceutical benefits that have the form olanzapine tablet 5 mg (orally disintegrating) and pharmaceutical benefits that have the form olanzapine wafer 5 mg are equivalent for the purposes of substitution.<br>**Note**<br>Shared Care Model:<br>For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners. | | | | | | | | |
| 8433W<br>*NP* | olanzapine 5 mg wafer, 28 | 1 | 5 | .. | 84.62 | 36.10 | [a] | Lanzek Zydis | EL |
| | | | | | | | [a] | Zypine ODT | AF |
| | | | | | | | [a] | Zyprexa Zydis | LY |
| | **OLANZAPINE**<br>**Authority required (STREAMLINED)**<br>***1589***<br>Schizophrenia<br>**Authority required (STREAMLINED)**<br>***2044***<br>Maintenance treatment of bipolar I disorder<br>**Note**<br>Pharmaceutical benefits that have the form olanzapine tablet 7.5 mg and pharmaceutical benefits that have the form olanzapine tablet 7.5 mg (as benzoate) are equivalent for the purposes of substitution. | | | | | | | | |
| 1041T<br>*NP* | olanzapine 7.5 mg tablet, 28 | 1 | 5 | .. | 124.81 | 36.10 | [a] | Olanzapine generichealth 7.5 | GQ |
| | | | | | | | [a] | STADA Olanzapine | TD |
| | **OLANZAPINE**<br>**Authority required (STREAMLINED)**<br>***1589***<br>Schizophrenia<br>**Authority required (STREAMLINED)**<br>***2044***<br>Maintenance treatment of bipolar I disorder<br>**Note**<br>Pharmaceutical benefits that have the form olanzapine tablet 7.5 mg and pharmaceutical benefits that have the form olanzapine tablet 7.5 mg (as benzoate) are equivalent for the purposes of substitution.<br>**Note**<br>Shared Care Model:<br>For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners. | | | | | | | | |
| 8186W<br>*NP* | olanzapine 7.5 mg tablet, 28 | 1 | 5 | .. | 124.81 | 36.10 | [a] | APO-Olanzapine | TX |
| | | | | | | | [a] | Chem mart Olanzapine | CH |
| | | | | | | | [a] | Lanzek | EL |

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | [a] | Olanzapine-DRLA | RZ |
| | | | | | | | [a] | Olanzapine-GA | GM |
| | | | | | | | [a] | Olanzapine RBX | RA |
| | | | | | | | [a] | Olanzapine Sandoz | SZ |
| | | | | | | | [a] | Ozin 7.5 | DO |
| | | | | | | | [a] | Pharmacor Olanzapine 7.5 | CR |
| | | | | | | | [a] | Pharmacy Choice Olanzapine | RI |
| | | | | | | | [a] | Terry White Chemists Olanzapine | TW |
| | | | | | | | [a] | Zylap 7.5 | QA |
| | | | | | | | [a] | Zypine | AF |
| | | | | | | | [a] | Zyprexa | LY |
| | **QUETIAPINE**<br>**Authority required (STREAMLINED)**<br>***1589***<br>Schizophrenia | | | | | | | | |
| | **Authority required (STREAMLINED)**<br>***2765***<br>Monotherapy, for up to 6 months, of an episode of acute mania associated with bipolar I disorder | | | | | | | | |
| | **Authority required (STREAMLINED)**<br>***2044***<br>Maintenance treatment of bipolar I disorder | | | | | | | | |
| | **Note**<br>Shared Care Model:<br>For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners. | | | | | | | | |
| 8457D<br>*NP* | quetiapine 100 mg tablet, 90 | 1 | 5 | .. | 118.39 | 36.10 | [a] | APO-Quetiapine | TX |
| | | | | | | | [a] | Chem mart Quetiapine | CH |
| | | | | | | | [a] | Delucon 100 | DO |
| | | | | | | | [a] | Pharmacy Choice Quetiapine | RI |
| | | | | | | | [a] | Quetiaccord | WQ |
| | | | | | | | [a] | Quetiapine Actavis 100 | TA |
| | | | | | | | [a] | Quetiapine-DRLA | RZ |
| | | | | | | | [a] | Quetiapine-GA | GN |
| | | | | | | | [a] | Quetiapine GH 100 | GQ |
| | | | | | | | [a] | Quetiapine RBX | RA |
| | | | | | | | [a] | Quetiapine Sandoz | SZ |
| | | | | | | | [a] | Quipine | GM |
| | | | | | | | [a] | Sequase | PM |
| | | | | | | | [a] | Seronia 100 | QA |
| | | | | | | | [a] | Seroquel | AP |
| | | | | | | | [a] | STADA Quetiapine | TD |
| | | | | | | | [a] | Syquet | AF |
| | | | | | | | [a] | Terry White Chemists Quetiapine | TW |
| 5458G<br>*NP* | quetiapine 150 mg tablet: modified release, 60 tablets | 1 | 5 | .. | 118.39 | 36.10 | | Seroquel XR | AP |
| 8458E<br>*NP* | quetiapine 200 mg tablet, 60 | 1 | 5 | .. | 158.90 | 36.10 | [a] | APO-Quetiapine | TX |
| | | | | | | | [a] | Chem mart Quetiapine | CH |
| | | | | | | | [a] | Delucon 200 | DO |
| | | | | | | | [a] | Pharmacy Choice Quetiapine | RI |
| | | | | | | | [a] | Quetiaccord | WQ |
| | | | | | | | [a] | Quetiapine Actavis 200 | TA |
| | | | | | | | [a] | Quetiapine-DRLA | RZ |
| | | | | | | | [a] | Quetiapine-GA | GN |
| | | | | | | | [a] | Quetiapine GH 200 | GQ |
| | | | | | | | [a] | Quetiapine RBX | RA |

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | [a] | Quetiapine Sandoz | SZ |
| | | | | | | | [a] | Quipine | GM |
| | | | | | | | [a] | Sequase | PM |
| | | | | | | | [a] | Seronia 200 | QA |
| | | | | | | | [a] | Seroquel | AP |
| | | | | | | | [a] | STADA Quetiapine | TD |
| | | | | | | | [a] | Syquet | AF |
| | | | | | | | [a] | Terry White Chemists Quetiapine | TW |
| 9203J *NP* | quetiapine 200 mg tablet: modified release, 60 tablets | 1 | 5 | .. | 158.90 | 36.10 | | Seroquel XR | AP |
| 8456C *NP* | quetiapine 25 mg tablet, 60 | 1 | 5 | .. | 47.03 | 36.10 | [a] | APO-Quetiapine | TX |
| | | | | | | | [a] | Chem mart Quetiapine | CH |
| | | | | | | | [a] | Delucon 25 | DO |
| | | | | | | | [a] | Pharmacy Choice Quetiapine | RI |
| | | | | | | | [a] | Quetiaccord | WQ |
| | | | | | | | [a] | Quetiapine Actavis 25 | TA |
| | | | | | | | [a] | Quetiapine-DRLA | RZ |
| | | | | | | | [a] | Quetiapine-GA | GN |
| | | | | | | | [a] | Quetiapine GH 25 | GQ |
| | | | | | | | [a] | Quetiapine RBX | RA |
| | | | | | | | [a] | Quetiapine Sandoz | SZ |
| | | | | | | | [a] | Quipine | GM |
| | | | | | | | [a] | Sequase | PM |
| | | | | | | | [a] | Seronia 25 | QA |
| | | | | | | | [a] | Seroquel | AP |
| | | | | | | | [a] | STADA Quetiapine | TD |
| | | | | | | | [a] | Syquet | AF |
| | | | | | | | [a] | Terry White Chemists Quetiapine | TW |
| 8580N *NP* | quetiapine 300 mg tablet, 60 | 1 | 5 | .. | 227.75 | 36.10 | [a] | APO-Quetiapine | TX |
| | | | | | | | [a] | Chem mart Quetiapine | CH |
| | | | | | | | [a] | Delucon 300 | DO |
| | | | | | | | [a] | Pharmacy Choice Quetiapine | RI |
| | | | | | | | [a] | Quetiaccord | WQ |
| | | | | | | | [a] | Quetiapine Actavis 300 | TA |
| | | | | | | | [a] | Quetiapine-DRLA | RZ |
| | | | | | | | [a] | Quetiapine-GA | GN |
| | | | | | | | [a] | Quetiapine GH 300 | GQ |
| | | | | | | | [a] | Quetiapine RBX | RA |
| | | | | | | | [a] | Quetiapine Sandoz | SZ |
| | | | | | | | [a] | Quipine | GM |
| | | | | | | | [a] | Sequase | PM |
| | | | | | | | [a] | Seronia 300 | QA |
| | | | | | | | [a] | Seroquel | AP |
| | | | | | | | [a] | STADA Quetiapine | TD |
| | | | | | | | [a] | Syquet | AF |
| | | | | | | | [a] | Terry White Chemists Quetiapine | TW |
| 9204K *NP* | quetiapine 300 mg tablet: modified release, 60 tablets | 1 | 5 | .. | 227.75 | 36.10 | | Seroquel XR | AP |
| 9205L *NP* | quetiapine 400 mg tablet: modified release, 60 tablets | 1 | 5 | .. | 301.49 | 36.10 | | Seroquel XR | AP |
| 9202H *NP* | quetiapine 50 mg tablet: modified release, 60 tablets | 1 | 5 | .. | 85.61 | 36.10 | | Seroquel XR | AP |

## *Benzamides*

**AMISULPRIDE**

**Authority required (STREAMLINED)**

***1589***

Schizophrenia

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|---|
| | **Note** | | | | | | | | |
| | Shared Care Model: | | | | | | | | |
| | For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners. | | | | | | | | |
| 8594H *NP* | amisulpride 100 mg tablet, 30 | 1 | 5 | .. | 28.05 | 29.18 | [a] | Amisulpride 100 Winthrop | WA |
| | | | | | | | [a] | Amisulpride Sandoz | SZ |
| | | | | | | | [a] | APO-Amisulpride | TX |
| | | | | | | | [a] | Solian 100 | SW |
| | | | | | | | [a] | Sulprix | AF |
| 8736T *NP* | amisulpride 100 mg/mL oral liquid, 60 mL | 2 | 5 | .. | *148.95 | 36.10 | | Solian Solution | SW |
| 8595J *NP* | amisulpride 200 mg tablet, 60 | 1 | 5 | .. | 94.91 | 36.10 | [a] | Amisulpride 200 Winthrop | WA |
| | | | | | | | [a] | Amisulpride Sandoz | SZ |
| | | | | | | | [a] | APO-Amisulpride | TX |
| | | | | | | | [a] | Solian 200 | SW |
| | | | | | | | [a] | Sulprix | AF |
| 8596K *NP* | amisulpride 400 mg tablet, 60 | 1 | 5 | .. | 166.71 | 36.10 | [a] | Amipride 400 | QA |
| | | | | | | | [a] | Amisulpride 400 Winthrop | WA |
| | | | | | | | [a] | Amisulpride Sandoz | SZ |
| | | | | | | | [a] | APO-Amisulpride | TX |
| | | | | | | | [a] | Solian 400 | SW |
| | | | | | | | [a] | Sulprix | AF |

## *Other antipsychotics*

**ARIPIPRAZOLE**
**Authority required (STREAMLINED)**
***1589***
Schizophrenia

**Note**
Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 8717T *NP* | aripiprazole 10 mg tablet, 30 | 1 | 5 | .. | 152.46 | 36.10 | Abilify | BQ |
| 8718W *NP* | aripiprazole 15 mg tablet, 30 | 1 | 5 | .. | 212.77 | 36.10 | Abilify | BQ |
| 8719X *NP* | aripiprazole 20 mg tablet, 30 | 1 | 5 | .. | 253.64 | 36.10 | Abilify | BQ |
| 8720Y *NP* | aripiprazole 30 mg tablet, 30 | 1 | 5 | .. | 303.70 | 36.10 | Abilify | BQ |

**PALIPERIDONE**
**Authority required (STREAMLINED)**
***4246***
Schizophrenia

**Note**
**Shared Care Model**:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 5107T *NP* | paliperidone 100 mg injection: modified release, 1 syringe | 1 | 5 | .. | 440.90 | 36.10 | Invega Sustenna | JC |
| 5109X *NP* | paliperidone 150 mg injection: modified release, 1 syringe | 1 | 5 | .. | 440.90 | 36.10 | Invega Sustenna | JC |
| 5100K *NP* | paliperidone 25 mg injection: modified release, 1 syringe | 1 | 5 | .. | 149.84 | 36.10 | Invega Sustenna | JC |
| 9140C *NP* | paliperidone 3 mg tablet: modified release, 28 tablets | 1 | 5 | .. | 79.80 | 36.10 | Invega | JC |
| 5102M *NP* | paliperidone 50 mg injection: modified release, 1 syringe | 1 | 5 | .. | 285.01 | 36.10 | Invega Sustenna | JC |
| 9141D *NP* | paliperidone 6 mg tablet: modified release, 28 tablets | 1 | 5 | .. | 154.47 | 36.10 | Invega | JC |

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|---|---|---|---|---|---|---|---|---|---|
| 5103N<br>*NP* | paliperidone 75 mg injection: modified release, 1 syringe | 1 | 5 | .. | 363.35 | 36.10 | | Invega Sustenna | JC |
| 9142E<br>*NP* | paliperidone 9 mg tablet: modified release, 28 tablets | 1 | 5 | .. | 226.22 | 36.10 | | Invega | JC |
| | **RISPERIDONE**<br>**Authority required (STREAMLINED)**<br>***1589***<br>Schizophrenia | | | | | | | | |
| | **Authority required (STREAMLINED)**<br>***2272***<br>Adjunctive therapy to mood stabilisers for up to 6 months, of an episode of acute mania associated with bipolar I disorder | | | | | | | | |
| | **Note**<br>Shared Care Model:<br>For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners. | | | | | | | | |
| 3169T<br>*NP* | risperidone 1 mg tablet, 60 | 1 | 5 | .. | 30.10 | 31.23 | [a] | APO-Risperidone | TX |
| | | | | | | | [a] | Ozidal | RA |
| | | | | | | | [a] | Rispa | QA |
| | | | | | | | [a] | Risperdal | JC |
| | | | | | | | [a] | Rispericor 1 | CR |
| | | | | | | | [a] | Risperidone-DRLA | RZ |
| | | | | | | | [a] | Risperidone-GA | GM |
| | | | | | | | [a] | Risperidone generichealth | GQ |
| | | | | | | | [a] | Risperidone Sandoz | SZ |
| | | | | | | | [a] | Rixadone | AF |
| 8792R<br>*NP* | risperidone 1 mg tablet: orally disintegrating, 28 | 2 | 5 | .. | *33.89 | 35.02 | | Risperdal Quicklet | JC |
| 8100H<br>*NP* | risperidone 1 mg/mL oral liquid, 100 mL | ‡1 | 5 | .. | 118.24 | 36.10 | | Risperdal | JC |
| 3170W<br>*NP* | risperidone 2 mg tablet, 60 | 1 | 5 | .. | 57.99 | 36.10 | [a] | APO-Risperidone | TX |
| | | | | | | | [a] | Ozidal | RA |
| | | | | | | | [a] | Rispa | QA |
| | | | | | | | [a] | Risperdal | JC |
| | | | | | | | [a] | Rispericor 2 | CR |
| | | | | | | | [a] | Risperidone-DRLA | RZ |
| | | | | | | | [a] | Risperidone-GA | GM |
| | | | | | | | [a] | Risperidone generichealth | GQ |
| | | | | | | | [a] | Risperidone Sandoz | SZ |
| | | | | | | | [a] | Rixadone | AF |
| 8794W<br>*NP* | risperidone 2 mg tablet: orally disintegrating, 28 | 2 | 5 | .. | *58.97 | 36.10 | | Risperdal Quicklet | JC |
| 3171X<br>*NP* | risperidone 3 mg tablet, 60 | 1 | 5 | .. | 85.81 | 36.10 | [a] | APO-Risperidone | TX |
| | | | | | | | [a] | Ozidal | RA |
| | | | | | | | [a] | Rispa | QA |
| | | | | | | | [a] | Risperdal | JC |
| | | | | | | | [a] | Rispericor 3 | CR |
| | | | | | | | [a] | Risperidone-DRLA | RZ |
| | | | | | | | [a] | Risperidone-GA | GM |
| | | | | | | | [a] | Risperidone generichealth | GQ |
| | | | | | | | [a] | Risperidone Sandoz | SZ |
| | | | | | | | [a] | Rixadone | AF |
| 9075P<br>*NP* | risperidone 3 mg tablet: orally disintegrating, 28 | 2 | 5 | .. | *84.43 | 36.10 | | Risperdal Quicklet | JC |
| 3172Y<br>*NP* | risperidone 4 mg tablet, 60 | 1 | 5 | .. | 113.53 | 36.10 | [a] | APO-Risperidone | TX |
| | | | | | | | [a] | Ozidal | RA |
| | | | | | | | [a] | Rispa | QA |
| | | | | | | | [a] | Risperdal | JC |

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|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | [a] | Rispericor 4 | CR |
| | | | | | | | [a] | Risperidone-DRLA | RZ |
| | | | | | | | [a] | Risperidone-GA | GM |
| | | | | | | | [a] | Risperidone generichealth | GQ |
| | | | | | | | [a] | Risperidone Sandoz | SZ |
| | | | | | | | [a] | Rixadone | AF |
| 9076Q *NP* | risperidone 4 mg tablet: orally disintegrating, 28 | 2 | 5 | .. | *110.29 | 36.10 | | Risperdal Quicklet | JC |

**RISPERIDONE**

**Authority required (STREAMLINED)**

***2061***

Behavioural disturbances characterised by psychotic symptoms and aggression in patients with dementia where non-pharmacological methods have been unsuccessful

**Authority required (STREAMLINED)**

***3083***

Treatment under the supervision of a paediatrician or psychiatrist, in combination with non-pharmacological measures, of severe behavioural disturbances in a patient aged less than 18 years with autism.

Continuing PBS-subsidised treatment under the supervision of a paediatrician or psychiatrist, in combination with non-pharmacological measures, of severe behavioural disturbances in a patient 18 years of age or older with autism who was commenced on PBS-subsidised treatment with risperidone prior to turning 18 years of age.

Behaviour disturbances are defined as severe aggression and injuries to self or others where non-pharmacological methods alone have been unsuccessful.

The diagnosis of autism must be made based on the Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV) or ICD-10 international classification of mental and behavioural disorders

**Caution**

In placebo controlled trials in elderly patients with dementia there was a significantly higher incidence of cerebrovascular adverse events, such as stroke (including fatalities) and transient ischaemic attacks, in patients treated with risperidone compared with patients treated with placebo.

**Note**

Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 8789N *NP* | risperidone 1 mg tablet, 60 | 1 | 2 | .. | 30.10 | 31.23 | [a] | APO-Risperidone | TX |
| | | | | | | | [a] | Ozidal | RA |
| | | | | | | | [a] | Rispa | QA |
| | | | | | | | [a] | Risperdal | JC |
| | | | | | | | [a] | Rispericor 1 | CR |
| | | | | | | | [a] | Risperidone-DRLA | RZ |
| | | | | | | | [a] | Risperidone-GA | GM |
| | | | | | | | [a] | Risperidone generichealth | GQ |
| | | | | | | | [a] | Risperidone Sandoz | SZ |
| | | | | | | | [a] | Rixadone | AF |
| 8790P *NP* | risperidone 1 mg tablet: orally disintegrating, 28 | 2 | 2 | .. | *33.89 | 35.02 | | Risperdal Quicklet | JC |
| 9293D *NP* | risperidone 1 mg/mL oral liquid, 100 mL | ‡1 | 2 | .. | 118.24 | 36.10 | | Risperdal | JC |
| 8788M *NP* | risperidone 500 microgram tablet: orally disintegrating, 28 | 2 | 2 | .. | *20.25 | 21.38 | | Risperdal Quicklet | JC |

**RISPERIDONE**

**Authority required (STREAMLINED)**

***3083***

Treatment under the supervision of a paediatrician or psychiatrist, in combination with non-pharmacological measures, of severe behavioural disturbances in a patient aged less than 18 years with autism.

Continuing PBS-subsidised treatment under the supervision of a paediatrician or psychiatrist, in combination with non-pharmacological measures, of severe behavioural disturbances in a patient 18 years of age or older with autism who was commenced on PBS-subsidised treatment with risperidone prior to turning 18 years of age.

Behaviour disturbances are defined as severe aggression and injuries to self or others where non-pharmacological methods alone have been unsuccessful.

The diagnosis of autism must be made based on the Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV) or ICD-10

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|---|
| | international classification of mental and behavioural disorders | | | | | | | | |
| | **Note**<br>Shared Care Model:<br>For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners. | | | | | | | | |
| 9079W<br>*NP* | risperidone 2 mg tablet, 60 | 1 | 2 | .. | 57.99 | 36.10 | [a] | APO-Risperidone | TX |
| | | | | | | | [a] | Ozidal | RA |
| | | | | | | | [a] | Rispa | QA |
| | | | | | | | [a] | Risperdal | JC |
| | | | | | | | [a] | Rispericor 2 | CR |
| | | | | | | | [a] | Risperidone-DRLA | RZ |
| | | | | | | | [a] | Risperidone-GA | GM |
| | | | | | | | [a] | Risperidone generichealth | GQ |
| | | | | | | | [a] | Risperidone Sandoz | SZ |
| | | | | | | | [a] | Rixadone | AF |
| 9080X<br>*NP* | risperidone 2 mg tablet: orally disintegrating, 28 | 2 | 2 | .. | *58.97 | 36.10 | | Risperdal Quicklet | JC |
| | **RISPERIDONE**<br>**Authority required (STREAMLINED)**<br>***1589***<br>Schizophrenia | | | | | | | | |
| | **Authority required (STREAMLINED)**<br>***3841***<br>Maintenance treatment, in combination with lithium or sodium valproate, of treatment refractory bipolar I disorder | | | | | | | | |
| | **Note**<br>Shared Care Model:<br>For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners. | | | | | | | | |
| 8780D<br>*NP* | risperidone 25 mg injection: modified release [1 x 25 mg vial] (&) inert substance diluent [1 x 2 mL syringe], 1 pack | 2 | 5 | .. | *277.31 | 36.10 | | Risperdal Consta | JC |
| 8781E<br>*NP* | risperidone 37.5 mg injection: modified release [1 x 37.5 mg vial] (&) inert substance diluent [1 x 2 mL syringe], 1 pack | 2 | 5 | .. | *353.65 | 36.10 | | Risperdal Consta | JC |
| 8782F<br>*NP* | risperidone 50 mg injection: modified release [1 x 50 mg vial] (&) inert substance diluent [1 x 2 mL syringe], 1 pack | 2 | 5 | .. | *429.19 | 36.10 | | Risperdal Consta | JC |
| | **RISPERIDONE**<br>**Authority required (STREAMLINED)**<br>***2061***<br>Behavioural disturbances characterised by psychotic symptoms and aggression in patients with dementia where non-pharmacological methods have been unsuccessful | | | | | | | | |
| | **Authority required (STREAMLINED)**<br>***3083***<br>Treatment under the supervision of a paediatrician or psychiatrist, in combination with non-pharmacological measures, of severe behavioural disturbances in a patient aged less than 18 years with autism.<br>Continuing PBS-subsidised treatment under the supervision of a paediatrician or psychiatrist, in combination with non-pharmacological measures, of severe behavioural disturbances in a patient 18 years of age or older with autism who was commenced on PBS-subsidised treatment with risperidone prior to turning 18 years of age.<br>Behaviour disturbances are defined as severe aggression and injuries to self or others where non-pharmacological methods alone have been unsuccessful.<br>The diagnosis of autism must be made based on the Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV) or ICD-10 international classification of mental and behavioural disorders | | | | | | | | |
| | **Caution**<br>In placebo controlled trials in elderly patients with dementia there was a significantly higher incidence of cerebrovascular adverse events, such as stroke (including fatalities) and transient ischaemic attacks, in patients treated with risperidone compared with patients treated with placebo. | | | | | | | | |

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|---|
| | **Note**<br>For item codes 8787L and 1842Y, pharmaceutical benefits that have the form tablet 0.5 mg are equivalent for the purposes of substitution. | | | | | | | | |
| | **Note**<br>Shared Care Model:<br>For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners. | | | | | | | | |
| 1842Y<br>*NP* | risperidone 500 microgram tablet, 20 | 3 | 2 | .. | *18.81 | 19.94 | [a] | APO-Risperidone | TX |
| | | | | | | | [a] | Risperdal | JC |
| 8787L<br>*NP* | risperidone 500 microgram tablet, 60 | 1 | 2 | .. | 18.80 | 19.93 | [a] | Ozidal | RA |
| | | | | | | | [a] | Rispa | QA |
| | | | | | | | [a] | Rispericor 0.5 | CR |
| | | | | | | | [a] | Risperidone-DRLA | RZ |
| | | | | | | | [a] | Risperidone-GA | GM |
| | | | | | | | [a] | Risperidone GH | GQ |
| | | | | | | | [a] | Risperidone Sandoz | SZ |
| | | | | | | | [a] | Rixadone | AF |
| | **RISPERIDONE**<br>**Authority required (STREAMLINED)**<br>***1589***<br>Schizophrenia | | | | | | | | |
| | **Note**<br>For item codes 8869T and 1846E, pharmaceutical benefits that have the form tablet 0.5 mg are equivalent for the purposes of substitution. | | | | | | | | |
| | **Note**<br>Shared Care Model:<br>For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners. | | | | | | | | |
| 1846E<br>*NP* | risperidone 500 microgram tablet, 20 | 3 | 5 | .. | *18.81 | 19.94 | [a] | APO-Risperidone | TX |
| | | | | | | | [a] | Risperdal | JC |
| 8869T<br>*NP* | risperidone 500 microgram tablet, 60 | 1 | 5 | .. | 18.80 | 19.93 | [a] | Ozidal | RA |
| | | | | | | | [a] | Rispa | QA |
| | | | | | | | [a] | Rispericor 0.5 | CR |
| | | | | | | | [a] | Risperidone-DRLA | RZ |
| | | | | | | | [a] | Risperidone-GA | GM |
| | | | | | | | [a] | Risperidone GH | GQ |
| | | | | | | | [a] | Risperidone Sandoz | SZ |
| | | | | | | | [a] | Rixadone | AF |
| | **RISPERIDONE**<br>**Authority required (STREAMLINED)**<br>***1589***<br>Schizophrenia | | | | | | | | |
| | **Note**<br>Shared Care Model:<br>For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners. | | | | | | | | |
| 8870W<br>*NP* | risperidone 500 microgram tablet: orally disintegrating, 28 | 2 | 5 | .. | *20.25 | 21.38 | | Risperdal Quicklet | JC |

## ANXIOLYTICS

### *Benzodiazepine derivatives*

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | **ALPRAZOLAM**<br>**Authority required**<br>Panic disorder where other treatments have failed or are inappropriate | | | | | | | | |
| 2132F<br>*NP* | alprazolam 1 mg tablet, 50 | 1 | 2 | .. | 12.68 | 13.81 | [a] | Alprax 1 | QA |
| | | | | | | | [a] | Alprazolam Sandoz | SZ |
| | | | | | | | [a] | Chem mart Alprazolam | CH |

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | [a] | GenRx Alprazolam | GX |
| | | | | | | | [a] | Kalma 1 | AF |
| | | | | | | | [a] | Ralozam | GM |
| | | | | | | | [a] | Terry White Chemists Alprazolam | TW |
| | | | | [B]1.95 | 14.63 | 13.81 | [a] | Xanax | PF |
| 8118G *NP* | alprazolam 2 mg tablet, 50 | 1 | 2 | .. | 16.00 | 17.13 | [a] | Alprax 2 | QA |
| | | | | | | | [a] | Alprazolam Sandoz | SZ |
| | | | | | | | [a] | Chem mart Alprazolam | CH |
| | | | | | | | [a] | GenRx Alprazolam | GX |
| | | | | | | | [a] | Kalma 2 | AF |
| | | | | | | | [a] | Ralozam | GM |
| | | | | | | | [a] | Terry White Chemists Alprazolam | TW |
| | | | | [B]1.96 | 17.96 | 17.13 | [a] | Xanax Tri-Score | PF |
| 2130D *NP* | alprazolam 250 microgram tablet, 50 | 1 | .. | .. | 8.78 | 9.91 | [a] | Alprax 0.25 | QA |
| | | | | | | | [a] | Alprazolam Sandoz | SZ |
| | | | | | | | [a] | Kalma 0.25 | AF |
| | | | | [B]1.96 | 10.74 | 9.91 | [a] | Xanax | PF |
| 2131E *NP* | alprazolam 500 microgram tablet, 50 | 1 | .. | .. | 10.10 | 11.23 | [a] | Alprax 0.5 | QA |
| | | | | | | | [a] | Alprazolam Sandoz | SZ |
| | | | | | | | [a] | Kalma 0.5 | AF |
| | | | | [B]1.95 | 12.05 | 11.23 | [a] | Xanax | PF |

**DIAZEPAM**

**Authority required**

Chronic spasticity

**The Population criteria is:**

Patient must be under 18 years of age.

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 2669L *NP* | diazepam 1 mg/mL oral liquid, 100 mL | ‡1 | .. | .. | 42.99 | 36.10 | | Diazepam Elixir | ON |

**DIAZEPAM**

**Note**

Authorities for increased maximum quantities and/or repeats for the oral forms of diazepam will be granted only for

(i) the treatment of disabling spasticity; or

(ii) malignant neoplasia (late stage); or

(iii) use by patients who are receiving long-term nursing care on account of age, infirmity or other condition in hospitals, nursing homes or residential facilities and who have been demonstrated, within the past six months, to be benzodiazepine dependent by an unsuccessful attempt at gradual withdrawal; or

(iv) use by a patient who is receiving long-term nursing care and in respect of whom a Carer Allowance is payable as a disabled adult and who has been demonstrated, within the past six months, to be benzodiazepine dependent by an unsuccessful attempt at gradual withdrawal.

Up to six months' treatment (i.e. one month's treatment with five repeats) may be requested.

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 2558P *NP* | diazepam 10 mg/2 mL injection, 5 x 2 mL ampoules | 1 | .. | .. | 12.50 | 13.63 | | Hospira Pty Limited | HH |
| 3161J *NP* | diazepam 2 mg tablet, 50 | 1 | .. | .. | 7.93 | 9.06 | [a] | Antenex 2 | AF |
| | | | | | | | [a] | APO-Diazepam | TX |
| | | | | | | | [a] | Ranzepam | RA |
| | | | | | | | [a] | Valpam 2 | QA |
| | | | | [B]0.82 | 8.75 | 9.06 | [a] | Valium | RO |
| 3162K *NP* | diazepam 5 mg tablet, 50 | 1 | .. | .. | 8.06 | 9.19 | [a] | Antenex 5 | AF |
| | | | | | | | [a] | APO-Diazepam | TX |
| | | | | | | | [a] | Diazepam-GA | GM |
| | | | | | | | [a] | Ranzepam | RA |
| | | | | | | | [a] | Valpam 5 | QA |
| | | | | [B]0.85 | 8.91 | 9.19 | [a] | Valium | RO |

**DIAZEPAM**

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|---|
| 5073B *DP* | diazepam 10 mg/2 mL injection, 5 x 2 mL ampoules | 1 | .. | .. | 12.50 | 13.63 | | Hospira Pty Limited | HH |
| 5071X *DP* | diazepam 2 mg tablet, 50 | 1 | .. | .. | 7.93 | 9.06 | a | Antenex 2 | AF |
| | | | | | | | a | APO-Diazepam | TX |
| | | | | | | | a | Ranzepam | RA |
| | | | | | | | a | Valpam 2 | QA |
| | | | | | [B]0.82 | 8.75 | 9.06 | a | Valium | RO |
| 5072Y *DP* | diazepam 5 mg tablet, 50 | 1 | .. | .. | 8.06 | 9.19 | a | Antenex 5 | AF |
| | | | | | | | a | APO-Diazepam | TX |
| | | | | | | | a | Diazepam-GA | GM |
| | | | | | | | a | Ranzepam | RA |
| | | | | | | | a | Valpam 5 | QA |
| | | | | | [B]0.85 | 8.91 | 9.19 | a | Valium | RO |

**OXAZEPAM**

**Note**

Authorities for increased maximum quantities and/or repeats will not be granted except as detailed under the 'Authority required' listing of oxazepam below.

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 3132W *NP* | oxazepam 15 mg tablet, 25 | 1 | .. | .. | 7.87 | 9.00 | a | Alepam 15 | AF |
| | | | | [B]2.68 | 10.55 | 9.00 | a | Serepax | QA |
| 3133X *NP* | oxazepam 30 mg tablet, 25 | 1 | .. | .. | 7.87 | 9.00 | a | Alepam 30 | AF |
| | | | | | | | a | APO-Oxazepam | TX |
| | | | | | | | a | Murelax | FM |
| | | | | [B]2.68 | 10.55 | 9.00 | a | Serepax | QA |

**OXAZEPAM**

**Authority required**

Malignant neoplasia (late stage)

**Authority required**

For use by patients who are receiving long-term nursing care on account of age, infirmity or other condition in hospitals, nursing homes or residential facilities and who have been demonstrated, within the past 6 months, to be benzodiazepine dependent by an unsuccessful attempt at gradual withdrawal

**Authority required**

For use by a patient who is receiving long-term nursing care and in respect of whom a Carer Allowance is payable as a disabled adult and who has been demonstrated, within the past 6 months, to be benzodiazepine dependent by an unsuccessful attempt at gradual withdrawal

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 3134Y *NP* | oxazepam 15 mg tablet, 25 | 2 | 5 | .. | *9.11 | 10.24 | a | Alepam 15 | AF |
| | | | | [B]5.36 | *14.47 | 10.24 | a | Serepax | QA |
| 3135B *NP* | oxazepam 30 mg tablet, 25 | 2 | 5 | .. | *9.11 | 10.24 | a | Alepam 30 | AF |
| | | | | | | | a | APO-Oxazepam | TX |
| | | | | | | | a | Murelax | FM |
| | | | | [B]5.36 | *14.47 | 10.24 | a | Serepax | QA |

**OXAZEPAM**

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 5192G *DP* | oxazepam 15 mg tablet, 25 | 1 | .. | .. | 7.87 | 9.00 | a | Alepam 15 | AF |
| | | | | [B]2.68 | 10.55 | 9.00 | a | Serepax | QA |
| 5193H *DP* | oxazepam 30 mg tablet, 25 | 1 | .. | .. | 7.87 | 9.00 | a | Alepam 30 | AF |
| | | | | | | | a | APO-Oxazepam | TX |
| | | | | | | | a | Murelax | FM |
| | | | | [B]2.68 | 10.55 | 9.00 | a | Serepax | QA |

## HYPNOTICS AND SEDATIVES

### *Benzodiazepine derivatives*

**NITRAZEPAM**

**Note**

Authorities for increased maximum quantities and/or repeats will not be granted except as detailed under the 'Authority required' listing of nitrazepam below.

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|---|
| 2723H | nitrazepam 5 mg tablet, 25 | 1 | .. | .. | 8.02 | 9.15 | a | Alodorm | AF |
| *NP* | | | | | | | | | |
| | | | | [B]1.46 | 9.48 | 9.15 | a | Mogadon | VT |

**NITRAZEPAM**

**Authority required**

Myoclonic epilepsy

**Authority required**

Malignant neoplasia (late stage)

**Authority required**

For use by patients who are receiving long-term nursing care on account of age, infirmity or other condition in hospitals, nursing homes or residential facilities and who have been demonstrated, within the past 6 months, to be benzodiazepine dependent by an unsuccessful attempt at gradual withdrawal

**Authority required**

For use by a patient who is receiving long-term nursing care and in respect of whom a Carer Allowance is payable as a disabled adult and who has been demonstrated, within the past 6 months, to be benzodiazepine dependent by an unsuccessful attempt at gradual withdrawal

**Note**

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 2732T | nitrazepam 5 mg tablet, 25 | 2 | 5 | .. | *9.41 | 10.54 | a | Alodorm | AF |
| *NP* | | | | | | | | | |
| | | | | [B]2.92 | *12.33 | 10.54 | a | Mogadon | VT |

**NITRAZEPAM**

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 5189D | nitrazepam 5 mg tablet, 25 | 1 | .. | .. | 8.02 | 9.15 | a | Alodorm | AF |
| *DP* | | | | | | | | | |
| | | | | [B]1.46 | 9.48 | 9.15 | a | Mogadon | VT |

**TEMAZEPAM**

**Authority required**

Malignant neoplasia (late stage)

**Authority required**

For use by patients who are receiving long-term nursing care on account of age, infirmity or other condition in hospitals, nursing homes or residential facilities and who have been demonstrated, within the past 6 months, to be benzodiazepine dependent by an unsuccessful attempt at gradual withdrawal

**Authority required**

For use by a patient who is receiving long-term nursing care and in respect of whom a Carer Allowance is payable as a disabled adult and who has been demonstrated, within the past 6 months, to be benzodiazepine dependent by an unsuccessful attempt at gradual withdrawal

**Note**

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 2088X | temazepam 10 mg tablet, 25 | 2 | 5 | .. | *8.71 | 9.84 | a | APO-Temazepam | TX |
| *NP* | | | | | | | a | Temaze | AF |
| | | | | | | | a | Temtabs | FM |
| | | | | [B]4.10 | *12.81 | 9.84 | a | Normison | QA |

**TEMAZEPAM**

**Note**

Authorities for increased maximum quantities and/or repeats will not be granted except as detailed under the 'Authority required' listing of temazepam below.

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 2089Y | temazepam 10 mg tablet, 25 | 1 | .. | .. | 7.67 | 8.80 | a | APO-Temazepam | TX |
| *NP* | | | | | | | a | Temaze | AF |
| | | | | | | | a | Temtabs | FM |
| | | | | [B]2.05 | 9.72 | 8.80 | a | Normison | QA |

**TEMAZEPAM**

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 5221T | temazepam 10 mg tablet, 25 | 1 | .. | .. | 7.67 | 8.80 | a | APO-Temazepam | TX |
| *DP* | | | | | | | a | Temaze | AF |

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | [a] | Temtabs | FM |
| | | | | [B]2.05 | 9.72 | 8.80 | [a] | Normison | QA |

## PSYCHOANALEPTICS

### ANTIDEPRESSANTS

#### *Non-selective monoamine reuptake inhibitors*

**AMITRIPTYLINE**

**Note**

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 2417F *NP* | amitriptyline hydrochloride 10 mg tablet, 50 | 1 | 2 | .. | 9.52 | 10.65 | | Endep 10 | AF |
| 2418G *NP* | amitriptyline hydrochloride 25 mg tablet, 50 | 1 | 2 | .. | 9.74 | 10.87 | | Endep 25 | AF |
| 2429W *NP* | amitriptyline hydrochloride 50 mg tablet, 50 | 1 | 2 | .. | 10.20 | 11.33 | | Endep 50 | AF |

**CLOMIPRAMINE**

**Restricted benefit**

Cataplexy associated with narcolepsy

**Restricted benefit**

Obsessive-compulsive disorder

**Restricted benefit**

Phobic disorders in adults

**Note**

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 1561E *NP* | clomipramine hydrochloride 25 mg tablet, 50 | 1 | 2 | .. | 15.30 | 16.43 | [a] | Chem mart Clomipramine | CH |
| | | | | | | | [a] | GenRx Clomipramine | GX |
| | | | | | | | [a] | Placil | AF |
| | | | | | | | [a] | Terry White Chemists Clomipramine | TW |
| | | | | [B]3.06 | 18.36 | 16.43 | [a] | Anafranil 25 | NV |

**DOTHIEPIN**

**Note**

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 1357K *NP* | dothiepin hydrochloride 25 mg capsule, 50 | 1 | 2 | .. | 11.29 | 12.42 | | Dothep 25 | AF |
| 1358L *NP* | dothiepin hydrochloride 75 mg tablet, 30 | 1 | 2 | .. | 11.29 | 12.42 | | Dothep 75 | AF |

**DOXEPIN**

**Note**

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 1011F *NP* | doxepin 10 mg capsule, 50 | 1 | 2 | .. | 10.13 | 11.26 | | Deptran 10 | AF |
| | | | | [B]1.95 | 12.08 | 11.26 | | Sinequan | PF |
| 1013H *NP* | doxepin 25 mg capsule, 50 | 1 | 2 | .. | 10.26 | 11.39 | | Deptran 25 | AF |
| | | | | [B]1.95 | 12.21 | 11.39 | | Sinequan | PF |
| 1012G *NP* | doxepin 50 mg tablet, 50 | 1 | 2 | .. | 11.23 | 12.36 | | Deptran 50 | AF |

**IMIPRAMINE**

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|---|
| | **Note** | | | | | | | | |
| | Continuing Therapy Only: | | | | | | | | |
| | For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners. | | | | | | | | |
| 2420J *NP* | imipramine hydrochloride 10 mg tablet, 50 | 1 | 2 | .. | 8.75 | 9.88 | a | Tolerade 10 | PQ |
| | | | | B2.79 | 11.54 | 9.88 | a | Tofranil 10 | LM |
| 2421K *NP* | imipramine hydrochloride 25 mg tablet, 50 | 1 | 2 | .. | 12.64 | 13.77 | a | Tolerade 25 | PQ |
| | | | | B2.78 | 15.42 | 13.77 | a | Tofranil 25 | LM |
| | **NORTRIPTYLINE** | | | | | | | | |
| | **Restricted benefit** | | | | | | | | |
| | Major depression where other antidepressant therapy has failed | | | | | | | | |
| | **Restricted benefit** | | | | | | | | |
| | Major depression where other antidepressant therapy is contraindicated | | | | | | | | |
| | **Note** | | | | | | | | |
| | Continuing Therapy Only: | | | | | | | | |
| | For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners. | | | | | | | | |
| 2522R *NP* | nortriptyline 10 mg tablet, 50 | 1 | 2 | .. | 13.53 | 14.66 | | Allegron | AS |
| 2523T *NP* | nortriptyline 25 mg tablet, 50 | 1 | 2 | .. | 15.31 | 16.44 | | Allegron | AS |
| | ***Selective serotonin reuptake inhibitors*** | | | | | | | | |
| | **CITALOPRAM** | | | | | | | | |
| | **Restricted benefit** | | | | | | | | |
| | Major depressive disorders | | | | | | | | |
| 8702B *NP* | citalopram 10 mg tablet, 28 | 1 | 5 | .. | 9.54 | 10.67 | a | Celapram | AF |
| | | | | | | | a | Citalopram-GA | GN |
| 8220P *NP* | citalopram 20 mg tablet, 28 | 1 | 5 | .. | 11.03 | 12.16 | a | APO-Citalopram | TX |
| | | | | | | | a | Auro-Citalopram 20 | DO |
| | | | | | | | a | Celapram | AF |
| | | | | | | | a | Celica | RA |
| | | | | | | | a | Chem mart Citalopram | CH |
| | | | | | | | a | Ciazil | GM |
| | | | | | | | a | Citalopram-GA | GN |
| | | | | | | | a | Citalopram generichealth | GQ |
| | | | | | | | a | Citalopram Sandoz | SZ |
| | | | | | | | a | Pharmacor Citalo 20 | CR |
| | | | | | | | a | Talam | QA |
| | | | | | | | a | Terry White Chemists Citalopram | TW |
| | | | | B2.79 | 13.82 | 12.16 | a | Cipramil | LU |
| 8703C *NP* | citalopram 40 mg tablet, 28 | 1 | 5 | .. | 14.08 | 15.21 | a | APO-Citalopram | TX |
| | | | | | | | a | Auro-Citalopram 40 | DO |
| | | | | | | | a | Celapram | AF |
| | | | | | | | a | Citalopram-GA | GN |
| | | | | | | | a | Citalopram Sandoz | SZ |
| | **ESCITALOPRAM** | | | | | | | | |
| | **Restricted benefit** | | | | | | | | |
| | Major depressive disorders | | | | | | | | |
| 8700X *NP* | escitalopram 10 mg tablet, 28 | 1 | 5 | .. | 15.86 | 16.99 | a | APO-Escitalopram | TX |
| | | | | | | | a | Chem mart Escitalopram | CH |
| | | | | | | | a | Escicor 10 | RA |
| | | | | | | | a | Escitalopram-DRLA | RZ |

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|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | [a] | Escitalopram GA | GN |
| | | | | | | | [a] | Escitalopram generichealth | GQ |
| | | | | | | | [a] | Esipram | GM |
| | | | | | | | [a] | Esitalo | SZ |
| | | | | | | | [a] | Lexam 10 | QA |
| | | | | | | | [a] | LoxaLate | AF |
| | | | | | | | [a] | Pharmacor Escitalopram 10 | CR |
| | | | | | | | [a] | Terry White Chemists Escitalopram | TW |
| | | | | [B]4.70 | 20.56 | 16.99 | [a] | Lexapro | LU |
| 8701Y *NP* | escitalopram 20 mg tablet, 28 | 1 | 5 | .. | 15.95 | 17.08 | [a] | APO-Escitalopram | TX |
| | | | | | | | [a] | Chem mart Escitalopram | CH |
| | | | | | | | [a] | Escicor 20 | RA |
| | | | | | | | [a] | Escitalopram-DRLA | RZ |
| | | | | | | | [a] | Escitalopram GA | GN |
| | | | | | | | [a] | Escitalopram generichealth | GQ |
| | | | | | | | [a] | Esipram | GM |
| | | | | | | | [a] | Esitalo | SZ |
| | | | | | | | [a] | Lexam 20 | QA |
| | | | | | | | [a] | LoxaLate | AF |
| | | | | | | | [a] | Pharmacor Escitalopram 20 | CR |
| | | | | | | | [a] | Terry White Chemists Escitalopram | TW |
| | | | | [B]6.85 | 22.80 | 17.08 | [a] | Lexapro | LU |

**ESCITALOPRAM**

**Restricted benefit**

Moderate to severe generalised anxiety disorder (GAD), as defined by Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV) criteria, in a patient who has not responded to non-pharmacological therapy and for whom a GP Mental Health Care Plan, as described under item 2710 of the Medicare Benefits Schedule, has been prepared

**Restricted benefit**

Moderate to severe generalised anxiety disorder (GAD), as defined by Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV) criteria, in a patient who has not responded to non-pharmacological therapy and who has been assessed by a psychiatrist

**Restricted benefit**

Continuing PBS-subsidised treatment, for moderate to severe generalised anxiety disorder (GAD), of a patient commenced on escitalopram prior to 1 March 2008

**Restricted benefit**

Moderate to severe social anxiety disorder (social phobia, SAD), as described by Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV) criteria, in a patient who has not responded to non-pharmacological therapy and for whom a GP Mental Health Care Plan, as described under item 2710 of the Medicare Benefits Schedule, has been prepared

**Restricted benefit**

Moderate to severe social anxiety disorder (social phobia, SAD), as described by Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV) criteria, in a patient who has not responded to non-pharmacological therapy and who has been assessed by a psychiatrist

**Restricted benefit**

Continuing PBS-subsidised treatment, for moderate to severe social anxiety disorder (social phobia, SAD), of a patient commenced on escitalopram prior to 1 March 2008

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 9432K *NP* | escitalopram 10 mg tablet, 28 | 1 | 5 | .. | 15.86 | 16.99 | [a] | Esipram | GM |
| | | | | [B]4.70 | 20.56 | 16.99 | [a] | Lexapro | LU |
| 9433L *NP* | escitalopram 20 mg tablet, 28 | 1 | 5 | .. | 15.95 | 17.08 | [a] | Esipram | GM |
| | | | | [B]6.85 | 22.80 | 17.08 | [a] | Lexapro | LU |

**ESCITALOPRAM**

**Restricted benefit**

Major depressive disorders

**Restricted benefit**

Moderate to severe generalised anxiety disorder (GAD), as defined by Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV) criteria, in a patient who has not responded to non-pharmacological therapy and for whom a GP Mental Health Care Plan, as described under

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|---|---|---|---|---|---|---|---|---|---|
| | item 2710 of the Medicare Benefits Schedule, has been prepared | | | | | | | | |
| | **Restricted benefit**<br>Moderate to severe generalised anxiety disorder (GAD), as defined by Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV) criteria, in a patient who has not responded to non-pharmacological therapy and who has been assessed by a psychiatrist | | | | | | | | |
| | **Restricted benefit**<br>Continuing PBS-subsidised treatment, for moderate to severe generalised anxiety disorder (GAD), of a patient commenced on escitalopram prior to 1 November 2008 | | | | | | | | |
| | **Restricted benefit**<br>Moderate to severe social anxiety disorder (social phobia, SAD), as described by Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV) criteria, in a patient who has not responded to non-pharmacological therapy and for whom a GP Mental Health Care Plan, as described under item 2710 of the Medicare Benefits Schedule, has been prepared | | | | | | | | |
| | **Restricted benefit**<br>Moderate to severe social anxiety disorder (social phobia, SAD), as described by Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV) criteria, in a patient who has not responded to non-pharmacological therapy and who has been assessed by a psychiatrist | | | | | | | | |
| | **Restricted benefit**<br>Continuing PBS-subsidised treatment, for moderate to severe social anxiety disorder (social phobia, SAD), of a patient commenced on escitalopram prior to 1 November 2008 | | | | | | | | |
| 8849R<br>*NP* | escitalopram 10 mg/mL oral liquid, 28 mL | ‡1 | 5 | .. | 34.51 | 35.64 | | Lexapro | LU |
| | **FLUOXETINE**<br>**Restricted benefit**<br>Major depressive disorders | | | | | | | | |
| | **Restricted benefit**<br>Obsessive-compulsive disorder | | | | | | | | |
| 1434L<br>*NP* | fluoxetine 20 mg capsule, 28 | 1 | 5 | .. | 15.70 | 16.83 | [a] | Auscap Aspen | QA |
| | | | | | | | [a] | Chem mart Fluoxetine | CH |
| | | | | | | | [a] | Fluoxetine 20 | CR |
| | | | | | | | [a] | Fluoxetine-GA | GM |
| | | | | | | | [a] | Fluoxetine generichealth | GQ |
| | | | | | | | [a] | Fluoxetine RBX | RA |
| | | | | | | | [a] | Fluoxetine Sandoz | SZ |
| | | | | | | | [a] | GenRx Fluoxetine | GX |
| | | | | | | | [a] | Lovan | AL |
| | | | | | | | [a] | Terry White Chemists Fluoxetine | TW |
| | | | | | | | [a] | Zactin | AF |
| | | | | [B]2.90 | 18.60 | 16.83 | [a] | Prozac 20 | LY |
| 8270G<br>*NP* | fluoxetine 20 mg tablet: dispersible, 28 | 1 | 5 | .. | 15.70 | 16.83 | [a] | Lovan 20 Tab | AL |
| | | | | | | | [a] | Zactin Tablet | AF |
| | | | | [B]2.90 | 18.60 | 16.83 | [a] | Prozac Tab | LY |
| | **FLUVOXAMINE**<br>**Restricted benefit**<br>Major depressive disorders | | | | | | | | |
| | **Restricted benefit**<br>Obsessive-compulsive disorder | | | | | | | | |
| 8174F<br>*NP* | fluvoxamine maleate 100 mg tablet, 30 | 1 | 5 | .. | 20.84 | 21.97 | [a] | APO-Fluvoxamine | TX |
| | | | | | | | [a] | Faverin 100 | QA |
| | | | | | | | [a] | Fluvoxamine GA | GM |
| | | | | | | | [a] | Movox 100 | AF |
| | | | | | | | [a] | Voxam | SZ |
| | | | | [B]2.01 | 22.85 | 21.97 | [a] | Luvox | AB |
| 8512B<br>*NP* | fluvoxamine maleate 50 mg tablet, 30 | 1 | 5 | .. | 16.01 | 17.14 | [a] | APO-Fluvoxamine | TX |
| | | | | | | | [a] | Faverin 50 | QA |
| | | | | | | | [a] | Fluvoxamine GA | GM |
| | | | | | | | [a] | Movox 50 | AL |
| | | | | | | | [a] | Voxam | SZ |

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|---|---|---|---|---|---|---|---|---|---|
| | | | | [B]1.99 | 18.00 | 17.14 | [a] | Luvox | AB |
| | **PAROXETINE**<br>**Restricted benefit**<br>Major depressive disorders<br>**Restricted benefit**<br>Obsessive-compulsive disorder<br>**Restricted benefit**<br>Panic disorder<br>**Note**<br>Pharmaceutical benefits that have the form paroxetine tablet 20 mg (as hydrochloride) and pharmaceutical benefits that have the form paroxetine tablet 20 mg (as mesilate) are equivalent for the purposes of substitution. | | | | | | | | |
| 2242B<br>*NP* | paroxetine 20 mg tablet, 30 | 1 | 5 | .. | 14.43 | 15.56 | [a] | Chem mart Paroxetine | CH |
| | | | | | | | [a] | Extine 20 | QA |
| | | | | | | | [a] | GenRx Paroxetine | GX |
| | | | | | | | [a] | Paroxetine-GA | GN |
| | | | | | | | [a] | Paroxetine Sandoz | SZ |
| | | | | | | | [a] | Paxtine | AF |
| | | | | | | | [a] | Roxet 20 | DO |
| | | | | | | | [a] | Terry White Chemists Paroxetine | TW |
| | | | | [B]0.58 | 15.01 | 15.56 | [a] | Aropax | AS |
| 9197C<br>*NP* | paroxetine 20 mg tablet, 30 | 1 | 5 | .. | 14.43 | 15.56 | [a] | Paroxetine generichealth | GQ |
| | **SERTRALINE**<br>**Restricted benefit**<br>Major depressive disorders | | | | | | | | |
| 2237R<br>*NP* | sertraline 100 mg tablet, 30 | 1 | 5 | .. | 12.48 | 13.61 | [a] | Auro-Sertraline 100 | DO |
| | | | | | | | [a] | Chem mart Sertraline | CH |
| | | | | | | | [a] | Eleva 100 | AF |
| | | | | | | | [a] | GenRx Sertraline | GX |
| | | | | | | | [a] | Sertra 100 | QA |
| | | | | | | | [a] | Sertracor 100 | CR |
| | | | | | | | [a] | Sertraline-DRLA | RZ |
| | | | | | | | [a] | Sertraline-GA | GM |
| | | | | | | | [a] | Sertraline generichealth | GQ |
| | | | | | | | [a] | Sertraline Pfizer | FZ |
| | | | | | | | [a] | Sertraline Sandoz | SZ |
| | | | | | | | [a] | Setrona | RA |
| | | | | | | | [a] | Terry White Chemists Sertraline | TW |
| | | | | | | | [a] | Xydep 100 | GN |
| | | | | [B]1.20 | 13.68 | 13.61 | [a] | Zoloft | PF |
| 2236Q<br>*NP* | sertraline 50 mg tablet, 30 | 1 | 5 | .. | 12.48 | 13.61 | [a] | Auro-Sertraline 50 | DO |
| | | | | | | | [a] | Chem mart Sertraline | CH |
| | | | | | | | [a] | Eleva 50 | AF |
| | | | | | | | [a] | GenRx Sertraline | GX |
| | | | | | | | [a] | Sertra 50 | QA |
| | | | | | | | [a] | Sertracor 50 | CR |
| | | | | | | | [a] | Sertraline-DRLA | RZ |
| | | | | | | | [a] | Sertraline-GA | GM |
| | | | | | | | [a] | Sertraline generichealth | GQ |
| | | | | | | | [a] | Sertraline Pfizer | FZ |
| | | | | | | | [a] | Sertraline Sandoz | SZ |
| | | | | | | | [a] | Setrona | RA |
| | | | | | | | [a] | Terry White Chemists Sertraline | TW |
| | | | | | | | [a] | Xydep 50 | GN |
| | | | | [B]1.20 | 13.68 | 13.61 | [a] | Zoloft | PF |

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|---|---|---|---|---|---|---|---|---|---|
| | **SERTRALINE**<br>**Restricted benefit**<br>Obsessive-compulsive disorder<br>**Restricted benefit**<br>Panic disorder where other treatments have failed or are inappropriate | | | | | | | | |
| 8837D<br>*NP* | sertraline 100 mg tablet, 30 | 1 | 5 | .. | 12.48 | 13.61 | [a] | Auro-Sertraline 100 | DO |
| | | | | | | | [a] | Eleva 100 | AF |
| | | | | | | | [a] | Sertraline Pfizer | FZ |
| | | | | | | | [a] | Xydep 100 | GN |
| | | | | [B]1.20 | 13.68 | 13.61 | [a] | Zoloft | PF |
| 8836C<br>*NP* | sertraline 50 mg tablet, 30 | 1 | 5 | .. | 12.48 | 13.61 | [a] | Auro-Sertraline 50 | DO |
| | | | | | | | [a] | Eleva 50 | AF |
| | | | | | | | [a] | Sertraline Pfizer | FZ |
| | | | | | | | [a] | Xydep 50 | GN |
| | | | | [B]1.20 | 13.68 | 13.61 | [a] | Zoloft | PF |
| | ***Monoamine oxidase inhibitors, non-selective*** | | | | | | | | |
| | **PHENELZINE**<br>**Restricted benefit**<br>Depression where all other anti-depressant therapy has failed or is inappropriate<br>**Caution**<br>This drug is an irreversible monoamine oxidase inhibitor. | | | | | | | | |
| 2856H | phenelzine 15 mg tablet, 100 | 1 | 1 | .. | 100.31 | 36.10 | | Nardil | LM |
| | **TRANYLCYPROMINE**<br>**Caution**<br>This drug is an irreversible monoamine oxidase inhibitor. | | | | | | | | |
| 2444P | tranylcypromine 10 mg tablet, 50 | 1 | 2 | .. | 33.76 | 34.89 | | Parnate | GH |
| | ***Monoamine oxidase A inhibitors*** | | | | | | | | |
| | **MOCLOBEMIDE**<br>**Restricted benefit**<br>Major depressive disorders<br>**Note**<br>Continuing Therapy Only:<br>For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners. | | | | | | | | |
| 1900B<br>*NP* | moclobemide 150 mg tablet, 60 | 1 | 5 | .. | 14.83 | 15.96 | [a] | Amira 150 | AF |
| | | | | | | | [a] | Chem mart Moclobemide | CH |
| | | | | | | | [a] | Clobemix | GM |
| | | | | | | | [a] | GenRx Moclobemide | GX |
| | | | | | | | [a] | Moclobemide Sandoz | SZ |
| | | | | | | | [a] | Mohexal | HX |
| | | | | | | | [a] | Terry White Chemists Moclobemide | TW |
| | | | | [B]0.48 | 15.31 | 15.96 | [a] | Aurorix | VP |
| 8003F<br>*NP* | moclobemide 300 mg tablet, 60 | 1 | 5 | .. | 22.42 | 23.55 | [a] | Amira 300 | AF |
| | | | | | | | [a] | Chem mart Moclobemide | CH |
| | | | | | | | [a] | Clobemix | GM |
| | | | | | | | [a] | GenRx Moclobemide | GX |
| | | | | | | | [a] | Moclobemide Sandoz | SZ |
| | | | | | | | [a] | Terry White Chemists Moclobemide | TW |
| | | | | [B]0.95 | 23.37 | 23.55 | [a] | Aurorix 300 mg | VP |
| | ***Other antidepressants*** | | | | | | | | |

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|---|---|---|---|---|---|---|---|---|---|
| | **DESVENLAFAXINE** | | | | | | | | |
| | **Restricted benefit** | | | | | | | | |
| | Major depressive disorders | | | | | | | | |
| | **Note** | | | | | | | | |
| | Continuing Therapy Only: | | | | | | | | |
| | For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners. | | | | | | | | |
| 9367B *NP* | desvenlafaxine 100 mg tablet: modified release, 28 tablets | 1 | 5 | .. | 48.62 | 36.10 | | Pristiq | PF |
| 9366Y *NP* | desvenlafaxine 50 mg tablet: modified release, 28 tablets | 1 | 5 | .. | 41.65 | 36.10 | | Pristiq | PF |
| | **DULOXETINE** | | | | | | | | |
| | **Restricted benefit** | | | | | | | | |
| | Major depressive disorders | | | | | | | | |
| | **Note** | | | | | | | | |
| | Continuing Therapy Only: | | | | | | | | |
| | For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners. | | | | | | | | |
| 9155W *NP* | duloxetine 30 mg capsule: enteric, 28 | 1 | .. | .. | 33.33 | 34.46 | [a] | Andepra | EL |
| | | | | | | | [a] | APO-Duloxetine | TX |
| | | | | | | | [a] | Chem mart Duloxetine | CH |
| | | | | | | | [a] | Coperin | AF |
| | | | | | | | [a] | Cymbalta | LY |
| | | | | | | | [a] | Drulox | GM |
| | | | | | | | [a] | Duloxetine DR GH | GQ |
| | | | | | | | [a] | Duloxetine-DRLA | RZ |
| | | | | | | | [a] | Terry White Chemists Duloxetine | TW |
| 9156X *NP* | duloxetine 60 mg capsule: enteric, 28 | 1 | 5 | .. | 44.31 | 36.10 | [a] | Andepra | EL |
| | | | | | | | [a] | APO-Duloxetine | TX |
| | | | | | | | [a] | Chem mart Duloxetine | CH |
| | | | | | | | [a] | Coperin | AF |
| | | | | | | | [a] | Cymbalta | LY |
| | | | | | | | [a] | Drulox | GM |
| | | | | | | | [a] | Duloxetine DR GH | GQ |
| | | | | | | | [a] | Duloxetine-DRLA | RZ |
| | | | | | | | [a] | Terry White Chemists Duloxetine | TW |
| | **LITHIUM CARBONATE** | | | | | | | | |
| | **Note** | | | | | | | | |
| | Continuing Therapy Only: | | | | | | | | |
| | For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners. | | | | | | | | |
| 3059B *NP* | lithium carbonate 250 mg tablet, 200 | 1 | 2 | .. | 17.10 | 18.23 | | Lithicarb | AS |
| 8290H *NP* | lithium carbonate 450 mg tablet: modified release, 100 tablets | 2 | 2 | .. | *34.51 | 35.64 | | Quilonum SR | AS |
| | **MIANSERIN** | | | | | | | | |
| | **Restricted benefit** | | | | | | | | |
| | Severe depression | | | | | | | | |
| | **Caution** | | | | | | | | |
| | Neutropenia and agranulocytosis are more frequent in the elderly, especially in the early months of therapy. | | | | | | | | |
| | **Note** | | | | | | | | |
| | Continuing Therapy Only: | | | | | | | | |
| | For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners. | | | | | | | | |
| 1627P | mianserin hydrochloride 10 mg tablet, 50 | 1 | 5 | .. | 15.60 | 16.73 | [a] | Lumin 10 | AF |

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|---|
| *NP* | | | | | | | | | |
| | | | | [B]3.29 | 18.89 | 16.73 | [a] | Tolvon | MK |
| 1628Q | mianserin hydrochloride 20 mg tablet, 50 | 1 | 5 | .. | 25.55 | 26.68 | [a] | Lumin 20 | AF |
| *NP* | | | | | | | | | |
| | | | | [B]3.30 | 28.85 | 26.68 | [a] | Tolvon | MK |
| | **MIRTAZAPINE** | | | | | | | | |
| | **Restricted benefit** | | | | | | | | |
| | Major depressive disorders | | | | | | | | |
| | **Note** | | | | | | | | |
| | Continuing Therapy Only: | | | | | | | | |
| | For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners. | | | | | | | | |
| 8855C | MIRTAZAPINE Tablet 15 mg (orally disintegrating), 30 | 1 | 5 | .. | 19.35 | 20.48 | [a] | Milivin OD 15 | DO |
| *NP* | | | | | | | | | |
| | | | | | | | [a] | Remeron SolTab | FR |
| | | | | [B]1.20 | 20.55 | 20.48 | [a] | Avanza SolTab | MK |
| 8856D | MIRTAZAPINE Tablet 30 mg (orally disintegrating), 30 | 1 | 5 | .. | 23.59 | 24.72 | [a] | Milivin OD 30 | DO |
| *NP* | | | | | | | | | |
| | | | | | | | [a] | Remeron SolTab | FR |
| | | | | [B]1.20 | 24.79 | 24.72 | [a] | Avanza SolTab | MK |
| 8857E | MIRTAZAPINE Tablet 45 mg (orally disintegrating), 30 | 1 | 5 | .. | 32.21 | 33.34 | [a] | Milivin OD 45 | DO |
| *NP* | | | | | | | | | |
| | | | | | | | [a] | Remeron SolTab | FR |
| | | | | [B]1.20 | 33.41 | 33.34 | [a] | Avanza SolTab | MK |
| 9365X | mirtazapine 15 mg tablet, 30 | 1 | 5 | .. | 14.00 | 15.13 | [a] | APO-Mirtazapine | TX |
| *NP* | | | | | | | | | |
| | | | | | | | [a] | Axit 15 | AF |
| 8513C | mirtazapine 30 mg tablet, 30 | 1 | 5 | .. | 17.69 | 18.82 | [a] | Aurozapine 30 | DO |
| *NP* | | | | | | | | | |
| | | | | | | | [a] | Axit 30 | AF |
| | | | | | | | [a] | Chem mart Mirtazapine | CH |
| | | | | | | | [a] | GenRx Mirtazapine | GX |
| | | | | | | | [a] | Mirtazapine-DP | GM |
| | | | | | | | [a] | Mirtazapine-GA | GN |
| | | | | | | | [a] | Mirtazapine GH | GQ |
| | | | | | | | [a] | Mirtazapine Sandoz | SZ |
| | | | | | | | [a] | Mirtazon | QA |
| | | | | | | | [a] | Terry White Chemists Mirtazapine | TW |
| | | | | [B]3.50 | 21.19 | 18.82 | [a] | Avanza | MK |
| 8883M | mirtazapine 45 mg tablet, 30 | 1 | 5 | .. | 25.09 | 26.22 | [a] | APO-Mirtazapine | TX |
| *NP* | | | | | | | | | |
| | | | | | | | [a] | Aurozapine 45 | DO |
| | | | | | | | [a] | Axit 45 | AF |
| | | | | | | | [a] | Chem mart Mirtazapine | CH |
| | | | | | | | [a] | Mirtazapine-GA | GM |
| | | | | | | | [a] | Mirtazapine GH | GQ |
| | | | | | | | [a] | Mirtazapine Sandoz | SZ |
| | | | | | | | [a] | Mirtazon | QA |
| | | | | | | | [a] | Terry White Chemists Mirtazapine | TW |
| | | | | [B]3.51 | 28.60 | 26.22 | [a] | Avanza | MK |
| | **REBOXETINE** | | | | | | | | |
| | **Restricted benefit** | | | | | | | | |
| | Major depressive disorders | | | | | | | | |
| | **Note** | | | | | | | | |
| | Continuing Therapy Only: | | | | | | | | |
| | For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners. | | | | | | | | |
| 8583R | reboxetine 4 mg tablet, 60 | 1 | 5 | .. | 38.97 | 36.10 | | Edronax | PF |
| *NP* | | | | | | | | | |
| | **VENLAFAXINE** | | | | | | | | |

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|---|
| | **Restricted benefit**<br>Major depressive disorders<br>**Note**<br>Continuing Therapy Only:<br>For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners. | | | | | | | | |
| 8302Y<br>*NP* | venlafaxine 150 mg capsule: modified release, 28 capsules | 1 | 5 | .. | 44.31 | 36.10 | [a] | Altven | FZ |
| | | | | | | | [a] | APO-Venlafaxine XR | TX |
| | | | | | | | [a] | Chem mart Venlafaxine XR | CH |
| | | | | | | | [a] | Efexor-XR | PF |
| | | | | | | | [a] | Elaxine SR 150 | ZP |
| | | | | | | | [a] | Enlafax-XR | AF |
| | | | | | | | [a] | STADA Venlafaxine-SR | TD |
| | | | | | | | [a] | Terry White Chemists Venlafaxine XR | TW |
| | | | | | | | [a] | Venlafaxine generichealth XR | GQ |
| | | | | | | | [a] | Venlafaxine Sandoz XR | SZ |
| | | | | | | | [a] | Venla RBX | RA |
| | | | | | | | [a] | Venlexor XR | GM |
| 8868R<br>*NP* | venlafaxine 37.5 mg capsule: modified release, 28 capsules | 1 | .. | .. | 24.36 | 25.49 | [a] | Altven | FZ |
| | | | | | | | [a] | Efexor-XR | PF |
| | | | | | | | [a] | Elaxine SR 37.5 | ZP |
| 8301X<br>*NP* | venlafaxine 75 mg capsule: modified release, 28 capsules | 1 | 5 | .. | 37.92 | 36.10 | [a] | Altven | FZ |
| | | | | | | | [a] | APO-Venlafaxine XR | TX |
| | | | | | | | [a] | Chem mart Venlafaxine XR | CH |
| | | | | | | | [a] | Efexor-XR | PF |
| | | | | | | | [a] | Elaxine SR 75 | ZP |
| | | | | | | | [a] | Enlafax-XR | AF |
| | | | | | | | [a] | STADA Venlafaxine-SR | TD |
| | | | | | | | [a] | Terry White Chemists Venlafaxine XR | TW |
| | | | | | | | [a] | Venlafaxine generichealth XR | GQ |
| | | | | | | | [a] | Venlafaxine Sandoz XR | SZ |
| | | | | | | | [a] | Venla RBX | RA |
| | | | | | | | [a] | Venlexor XR | GM |

## PSYCHOSTIMULANTS, AGENTS USED FOR ADHD AND NOOTROPICS

### *Centrally acting sympathomimetics*

**ATOMOXETINE**

**Authority required**

Initial sole PBS-subsidised treatment of attention-deficit hyperactivity disorder (ADHD) diagnosed between the ages of 6 and 18 years inclusive, by a paediatrician or psychiatrist according to the DSM-IV criteria, where treatment with dexamphetamine sulfate or methylphenidate hydrochloride poses an unacceptable medical risk due to the following contraindications as specified in the TGA-approved product information:

(1) The patient has a history of substance abuse or misuse (other than alcohol); and/or

(2) The patient has comorbid motor tics or Tourette's Syndrome; and/or

(3) The patient has comorbid severe anxiety diagnosed according to the DSM-IV

**Authority required**

Initial sole PBS-subsidised treatment of attention-deficit hyperactivity disorder (ADHD) diagnosed between the ages of 6 and 18 years inclusive, by a paediatrician or psychiatrist according to the DSM-IV criteria, where treatment with dexamphetamine sulfate or methylphenidate hydrochloride has resulted in the development or worsening of a comorbid mood disorder (diagnosed according to the DSM-IV criteria i.e. anxiety disorder, obsessive compulsive disorder, depressive disorder) of a severity necessitating permanent stimulant treatment withdrawal; or where the combination of stimulant treatment with another agent would pose an unacceptable medical risk of a severity necessitating permanent stimulant treatment withdrawal

**Authority required**

Initial sole PBS-subsidised treatment of attention-deficit hyperactivity disorder (ADHD) diagnosed between the ages of 6 and 18 years inclusive, by a paediatrician or psychiatrist according to the DSM-IV criteria, where treatment with dexamphetamine sulfate AND methylphenidate hydrochloride

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|
| | has resulted in the development of adverse reactions of a severity necessitating permanent treatment withdrawal:<br>(1) Adverse effects on growth and weight; and/or<br>(2) Adverse effects on sleep including insomnia; and/or<br>(3) Adverse effects on appetite including anorexia<br>**Authority required**<br>Continuing sole PBS-subsidised treatment where the patient has previously been issued with an authority prescription for this drug<br>**Note**<br>No applications for increased maximum quantities and/or repeats will be authorised. | | | | | | | |
| 9092M | atomoxetine 10 mg capsule, 28 | 2 | 5 | .. | *221.39 | 36.10 | Strattera | LY |
| 9290Y | atomoxetine 100 mg capsule, 28 | 1 | 5 | .. | 147.32 | 36.10 | Strattera | LY |
| 9093N | atomoxetine 18 mg capsule, 28 | 2 | 5 | .. | *221.39 | 36.10 | Strattera | LY |
| 9094P | atomoxetine 25 mg capsule, 28 | 2 | 5 | .. | *221.39 | 36.10 | Strattera | LY |
| 9095Q | atomoxetine 40 mg capsule, 28 | 2 | 5 | .. | *221.39 | 36.10 | Strattera | LY |
| 9096R | atomoxetine 60 mg capsule, 28 | 2 | 5 | .. | *221.39 | 36.10 | Strattera | LY |
| 9289X | atomoxetine 80 mg capsule, 28 | 1 | 5 | .. | 147.32 | 36.10 | Strattera | LY |
| | **DEXAMPHETAMINE**<br>**Authority required**<br>Use in attention deficit hyperactivity disorder, in accordance with State/Territory law<br>**Authority required**<br>Narcolepsy<br>**Note**<br>Care must be taken to comply with the provisions of State/Territory law when prescribing dexamphetamine.<br>**Note**<br>Continuing Therapy Only:<br>For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners. | | | | | | | |
| 1165H<br>*NP* | dexamphetamine sulfate 5 mg tablet, 100 | 1 | 5 | .. | 18.40 | 19.53 | Aspen Pharma Pty Ltd | QA |
| | **METHYLPHENIDATE**<br>**Authority required**<br>Treatment of attention deficit hyperactivity disorder (ADHD) in a patient diagnosed between the ages of 6 and 18 years inclusive, who has demonstrated a response to immediate release methylphenidate hydrochloride with no emergence of serious adverse events, and who requires continuous coverage over 8 hours<br>**Note**<br>Care must be taken to comply with the provisions of State/Territory law when prescribing methylphenidate hydrochloride.<br>**Note**<br>Continuing Therapy Only:<br>For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners. | | | | | | | |
| 3440C<br>*NP* | methylphenidate hydrochloride 10 mg capsule: modified release, 30 capsules | 1 | 5 | .. | 34.26 | 35.39 | Ritalin LA | NV |
| 2276T<br>*NP* | methylphenidate hydrochloride 20 mg capsule: modified release, 30 capsules | 1 | 5 | .. | 44.78 | 36.10 | Ritalin LA | NV |
| 2280B<br>*NP* | methylphenidate hydrochloride 30 mg capsule: modified release, 30 capsules | 1 | 5 | .. | 52.24 | 36.10 | Ritalin LA | NV |
| 2283E<br>*NP* | methylphenidate hydrochloride 40 mg capsule: modified release, 30 capsules | 1 | 5 | .. | 54.77 | 36.10 | Ritalin LA | NV |
| | **METHYLPHENIDATE**<br>**Authority required**<br>Use in attention deficit hyperactivity disorder, in accordance with State/Territory law<br>**Note**<br>Care must be taken to comply with the provisions of State/Territory law when prescribing methylphenidate hydrochloride.<br>**Note**<br>Continuing Therapy Only:<br>For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners. | | | | | | | |
| 8839F | methylphenidate hydrochloride 10 mg | 1 | 5 | .. | 17.10 | 18.23 | Ritalin 10 | NV |

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|
| *NP* | tablet, 100 | | | | | | | |

**METHYLPHENIDATE**

**Authority required**

Treatment of attention deficit hyperactivity disorder (ADHD) in a patient diagnosed between the ages of 6 and 18 years inclusive, who has demonstrated a response to immediate release methylphenidate hydrochloride with no emergence of serious adverse events, and who requires continuous coverage over 12 hours

**Note**

Care must be taken to comply with the provisions of State/Territory law when prescribing methylphenidate hydrochloride.

**Note**

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 2387P *NP* | methylphenidate hydrochloride 18 mg tablet: modified release, 30 tablets | 1 | 5 | .. | 51.53 | 36.10 | Concerta | JC |
| 2172H *NP* | methylphenidate hydrochloride 27 mg tablet: modified release, 30 tablets | 1 | 5 | .. | 55.67 | 36.10 | Concerta | JC |
| 2388Q *NP* | methylphenidate hydrochloride 36 mg tablet: modified release, 30 tablets | 1 | 5 | .. | 59.90 | 36.10 | Concerta | JC |
| 2432B *NP* | methylphenidate hydrochloride 54 mg tablet: modified release, 30 tablets | 1 | 5 | .. | 69.96 | 36.10 | Concerta | JC |

**MODAFINIL**

**Authority required**

Initial treatment, by a qualified sleep medicine practitioner or neurologist, of patients with narcolepsy where:

(i) therapy with dexamphetamine sulfate poses an unacceptable medical risk; or

(ii) intolerance to dexamphetamine sulfate of a severity necessitating treatment withdrawal develops.

The presence of any 1 of the following indicates treatment with dexamphetamine sulfate poses an unacceptable medical risk:

(a) a psychiatric disorder;

(b) a cardiovascular disorder;

(c) a history of substance abuse;

(d) glaucoma;

(e) any other absolute contraindication to dexamphetamine sulfate as specified in the TGA-approved Product Information.

Patients must meet the following definition of narcolepsy:

Excessive daytime sleepiness, recurrent naps or lapses into sleep occurring almost daily for at least 3 months and:

(i) a definite history of cataplexy;

or

a mean sleep latency less than or equal to 10 minutes on a Multiple Sleep Latency Test (MSLT). The MSLT must be preceded by nocturnal polysomnography. Sleep prior to the MSLT must be at least 6 hours in duration;

or

an electroencephalographic (EEG) recording showing the pathologically rapid development of REM sleep; and

(ii) absence of any medical or psychiatric disorder that could otherwise account for the hypersomnia.

The authority application must be made in writing and must include the following:

(a) a completed authority prescription form; and

(b) a completed Modafinil (Modavigil) PBS Authority Application for Use in the Treatment of Narcolepsy - Supporting Information Form [www.medicareaustralia.gov.au]; and

(c) details of the contraindication or intolerance to dexamphetamine sulfate; and

(d) either:

(i) the result and date of the polysomnography test and MSLT conducted by, or under the supervision of, a qualified sleep medicine practitioner; or

(ii) the result and date of the EEG, conducted by, or under the supervision of, a neurologist.

The polysomnography, MSLT or EEG test reports must be provided with the authority application

**Authority required**

Continuing treatment of narcolepsy, where the patient has previously been issued with an authority prescription for this drug

**Note**

Any queries concerning the arrangements to prescribe modafinil may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written applications for authority to prescribe modafinil should be forwarded to:

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|---|
| | Medicare Australia | | | | | | | | |
| | Prior Written Approval of Specialised Drugs | | | | | | | | |
| | Reply Paid 9826 | | | | | | | | |
| | GPO Box 9826 | | | | | | | | |
| | HOBART TAS 7001 | | | | | | | | |
| | Further prescribing information is on the Medicare Australia website at www.medicareaustralia.gov.au. | | | | | | | | |
| | **Note** | | | | | | | | |
| | Modafinil is not PBS-subsidised when used in combination with PBS-subsidised dexamphetamine sulfate. | | | | | | | | |
| 8816B | modafinil 100 mg tablet, 60 | 2 | 5 | .. | *347.19 | 36.10 | | Modavigil | CS |

## ANTI-DEMENTIA DRUGS
### *Anticholinesterases*

**DONEPEZIL**

**Authority required (STREAMLINED)**

***4219***

Mild to moderately severe Alzheimer disease

Treatment Phase: Continuing

**The Clinical criteria is:**

Patient must have received six months of sole PBS-subsidised initial therapy with this drug,

**AND the Clinical criteria is:**

Patient must demonstrate a clinically meaningful response to the initial treatment,

**AND the Clinical criteria is:**

The treatment must be the sole PBS-subsidised therapy for this condition.

Prior to continuing treatment, a comprehensive assessment must be undertaken and documented, involving the patient, the patient's family or carer and the treating physician to establish agreement that treatment is continuing to produce worthwhile benefit.

Treatment should cease if there is no agreement of benefit as there is always the possibility of harm from unnecessary use.

Re-assessments for a clinically meaningful response are to be undertaken and documented every six months.

Clinically meaningful response to treatment is demonstrated in the following areas:

Patient's quality of life including but not limited to level of independence and happiness;

Patient's cognitive function including but not limited to memory, recognition and interest in environment;

Patient's behavioural symptoms, including but not limited to hallucination, delusions, anxiety, marked agitation or associated aggressive behaviour.

**Note**

**Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 2479L<br>*NP* | donepezil hydrochloride 10 mg tablet, 28 | 1 | 5 | .. | 81.74 | 36.10 | [a] | APO-Donepezil | TX |
| | | | | | | | [a] | Arazil | AF |
| | | | | | | | [a] | Aricept | PF |
| | | | | | | | [a] | Aridon 10 | QA |
| | | | | | | | [a] | Chem mart Donepezil | CH |
| | | | | | | | [a] | Donepezil-DRLA | RZ |
| | | | | | | | [a] | Donepezil-GA | GM |
| | | | | | | | [a] | Donepezil generichealth | GQ |
| | | | | | | | [a] | Donepezil RBX | RA |
| | | | | | | | [a] | Donepezil Sandoz | SZ |
| | | | | | | | [a] | Pharmacor Donepezil 10 | CR |
| | | | | | | | [a] | STADA Donepezil | TD |
| | | | | | | | [a] | Terry White Chemists Donepezil | TW |
| 2532G<br>*NP* | donepezil hydrochloride 5 mg tablet, 28 | 1 | 5 | .. | 81.74 | 36.10 | [a] | APO-Donepezil | TX |
| | | | | | | | [a] | Arazil | AF |
| | | | | | | | [a] | Aricept | PF |
| | | | | | | | [a] | Aridon 5 | QA |
| | | | | | | | [a] | Chem mart Donepezil | CH |

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|
| | | | | | | | [a] Donepezil-DRLA | RZ |
| | | | | | | | [a] Donepezil-GA | GM |
| | | | | | | | [a] Donepezil generichealth | GQ |
| | | | | | | | [a] Donepezil RBX | RA |
| | | | | | | | [a] Donepezil Sandoz | SZ |
| | | | | | | | [a] Pharmacor Donepezil 5 | CR |
| | | | | | | | [a] STADA Donepezil | TD |
| | | | | | | | [a] Terry White Chemists Donepezil | TW |

**DONEPEZIL**

**Authority required**

Mild to moderately severe Alzheimer disease

Treatment Phase: Initial

**The Clinical criteria is:**

Patient must have a baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE) score of 10 or more,

**AND the Clinical criteria is:**

The condition must be confirmed by, or in consultation with, a specialist/consultant physician (including a psychiatrist),

**AND the Clinical criteria is:**

The treatment must be the sole PBS-subsidised therapy for this condition.

The authority application must include the result of the baseline MMSE or SMMSE. If this score is 25 - 30 points, the result of a baseline Alzheimer Disease Assessment Scale, cognitive sub-scale (ADAS-Cog) may also be specified.

The application must be made in writing, but initial supply may be sought by telephone.

For telephone applications, up to a maximum of 2 months' initial therapy will be authorised. This telephone application must be followed by a written authority application for no more than 1 month's therapy and sufficient repeats to complete a maximum of up to 6 months' initial treatment.

For written applications where no prior telephone approval has been issued, up to a maximum of 1 month's therapy plus 5 repeats will be authorised.

**Authority required**

Mild to moderately severe Alzheimer disease

Treatment Phase: Initial

**The Clinical criteria is:**

Patient must have a baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE) score of 9 or less,

**AND the Clinical criteria is:**

The condition must be confirmed by, or in consultation with, a specialist/consultant physician (including a psychiatrist),

**AND the Clinical criteria is:**

The treatment must be the sole PBS-subsidised therapy for this condition.

A patient who is unable to register a score of 10 or more for reasons other than their Alzheimer disease, as specified below.

Such patients will need to be assessed using the Clinicians Interview Based Impression of Severity (CIBIS) scale. The authority application must include the result of the baseline (S)MMSE and specify to which group(s) (see below) the patient belongs.

Patients who qualify under this criterion are from 1 or more of the following groups:

(1) Unable to communicate adequately because of lack of competence in English, in people of non-English speaking background;

(2) Limited education, as defined by less than 6 years of education, or who are illiterate or innumerate;

(3) Aboriginal or Torres Strait Islanders who, by virtue of cultural factors, are unable to complete an (S)MMSE test;

(4) Intellectual (developmental or acquired) disability, eg Down's syndrome;

(5) Significant sensory impairment despite best correction, which precludes completion of an (S)MMSE test;

(6) Prominent dysphasia, out of proportion to other cognitive and functional impairment.

The application must be made in writing, but initial supply may be sought by telephone.

For telephone applications, up to a maximum of 2 months' initial therapy will be authorised. This telephone application must be followed by a written authority application for no more than 1 month's therapy and sufficient repeats to complete a maximum of up to 6 months' initial treatment.

For written applications where no prior telephone approval has been issued, up to a maximum of 1 month's therapy plus 5 repeats will be authorised.

**Note**

**Continuing Therapy Only:**

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|---|
| | For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners. | | | | | | | | |
| 8496E<br>*NP* | donepezil hydrochloride 10 mg tablet, 28 | 1 | 5 | .. | 81.74 | 36.10 | [a] | APO-Donepezil | TX |
| | | | | | | | [a] | Arazil | AF |
| | | | | | | | [a] | Aricept | PF |
| | | | | | | | [a] | Aridon 10 | QA |
| | | | | | | | [a] | Chem mart Donepezil | CH |
| | | | | | | | [a] | Donepezil-DRLA | RZ |
| | | | | | | | [a] | Donepezil-GA | GM |
| | | | | | | | [a] | Donepezil generichealth | GQ |
| | | | | | | | [a] | Donepezil RBX | RA |
| | | | | | | | [a] | Donepezil Sandoz | SZ |
| | | | | | | | [a] | Pharmacor Donepezil 10 | CR |
| | | | | | | | [a] | STADA Donepezil | TD |
| | | | | | | | [a] | Terry White Chemists Donepezil | TW |
| 8495D<br>*NP* | donepezil hydrochloride 5 mg tablet, 28 | 1 | 5 | .. | 81.74 | 36.10 | [a] | APO-Donepezil | TX |
| | | | | | | | [a] | Arazil | AF |
| | | | | | | | [a] | Aricept | PF |
| | | | | | | | [a] | Aridon 5 | QA |
| | | | | | | | [a] | Chem mart Donepezil | CH |
| | | | | | | | [a] | Donepezil-DRLA | RZ |
| | | | | | | | [a] | Donepezil-GA | GM |
| | | | | | | | [a] | Donepezil generichealth | GQ |
| | | | | | | | [a] | Donepezil RBX | RA |
| | | | | | | | [a] | Donepezil Sandoz | SZ |
| | | | | | | | [a] | Pharmacor Donepezil 5 | CR |
| | | | | | | | [a] | STADA Donepezil | TD |
| | | | | | | | [a] | Terry White Chemists Donepezil | TW |

**GALANTAMINE**

**Authority required (STREAMLINED)**

***4219***

Mild to moderately severe Alzheimer disease

Treatment Phase: Continuing

**The Clinical criteria is:**

Patient must have received six months of sole PBS-subsidised initial therapy with this drug,

**AND the Clinical criteria is:**

Patient must demonstrate a clinically meaningful response to the initial treatment,

**AND the Clinical criteria is:**

The treatment must be the sole PBS-subsidised therapy for this condition.

Prior to continuing treatment, a comprehensive assessment must be undertaken and documented, involving the patient, the patient's family or carer and the treating physician to establish agreement that treatment is continuing to produce worthwhile benefit.

Treatment should cease if there is no agreement of benefit as there is always the possibility of harm from unnecessary use.

Re-assessments for a clinically meaningful response are to be undertaken and documented every six months.

Clinically meaningful response to treatment is demonstrated in the following areas:

Patient's quality of life including but not limited to level of independence and happiness;

Patient's cognitive function including but not limited to memory, recognition and interest in environment;

Patient's behavioural symptoms, including but not limited to hallucination, delusions, anxiety, marked agitation or associated aggressive behaviour.

**Note**

**Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 2537M | galantamine 16 mg capsule: modified | 1 | 5 | .. | 64.66 | 36.10 | [a] | APO-Galantamine MR | TX |

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|---|
| *NP* | release, 28 capsules | | | | | | | | |
| | | | | | | | [a] | Galantyl | AF |
| | | | | | | | [a] | Gamine XR | QA |
| | | | | | | | [a] | Reminyl | JC |
| 2531F | galantamine 24 mg capsule: modified | 1 | 5 | .. | 75.78 | 36.10 | [a] | APO-Galantamine MR | TX |
| *NP* | release, 28 capsules | | | | | | | | |
| | | | | | | | [a] | Galantyl | AF |
| | | | | | | | [a] | Gamine XR | QA |
| | | | | | | | [a] | Reminyl | JC |
| 2463P | galantamine 8 mg capsule: modified | 1 | 5 | .. | 54.25 | 36.10 | [a] | APO-Galantamine MR | TX |
| *NP* | release, 28 capsules | | | | | | | | |
| | | | | | | | [a] | Galantyl | AF |
| | | | | | | | [a] | Gamine XR | QA |
| | | | | | | | [a] | Reminyl | JC |

**GALANTAMINE**

**Authority required**

Mild to moderately severe Alzheimer disease

Treatment Phase: Initial

**The Clinical criteria is:**

Patient must have a baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE) score of 10 or more,

**AND the Clinical criteria is:**

The condition must be confirmed by, or in consultation with, a specialist/consultant physician (including a psychiatrist),

**AND the Clinical criteria is:**

The treatment must be the sole PBS-subsidised therapy for this condition.

The authority application must include the result of the baseline MMSE or SMMSE. If this score is 25 - 30 points, the result of a baseline Alzheimer Disease Assessment Scale, cognitive sub-scale (ADAS-Cog) may also be specified.

The application must be made in writing, but initial supply may be sought by telephone.

For telephone applications, up to a maximum of 2 months' initial therapy will be authorised. This telephone application must be followed by a written authority application for no more than 1 month's therapy and sufficient repeats to complete a maximum of up to 6 months' initial treatment.

For written applications where no prior telephone approval has been issued, up to a maximum of 1 month's therapy plus 5 repeats will be authorised.

**Authority required**

Mild to moderately severe Alzheimer disease

Treatment Phase: Initial

**The Clinical criteria is:**

Patient must have a baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE) score of 9 or less,

**AND the Clinical criteria is:**

The condition must be confirmed by, or in consultation with, a specialist/consultant physician (including a psychiatrist),

**AND the Clinical criteria is:**

The treatment must be the sole PBS-subsidised therapy for this condition.

A patient who is unable to register a score of 10 or more for reasons other than their Alzheimer disease, as specified below.

Such patients will need to be assessed using the Clinicians Interview Based Impression of Severity (CIBIS) scale. The authority application must include the result of the baseline (S)MMSE and specify to which group(s) (see below) the patient belongs.

Patients who qualify under this criterion are from 1 or more of the following groups:

(1) Unable to communicate adequately because of lack of competence in English, in people of non-English speaking background;

(2) Limited education, as defined by less than 6 years of education, or who are illiterate or innumerate;

(3) Aboriginal or Torres Strait Islanders who, by virtue of cultural factors, are unable to complete an (S)MMSE test;

(4) Intellectual (developmental or acquired) disability, eg Down's syndrome;

(5) Significant sensory impairment despite best correction, which precludes completion of an (S)MMSE test;

(6) Prominent dysphasia, out of proportion to other cognitive and functional impairment.

The application must be made in writing, but initial supply may be sought by telephone.

For telephone applications, up to a maximum of 2 months' initial therapy will be authorised. This telephone application must be followed by a written authority application for no more than 1 month's therapy and sufficient repeats to complete a maximum of up to 6 months' initial treatment.

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|---|
| | For written applications where no prior telephone approval has been issued, up to a maximum of 1 month's therapy plus 5 repeats will be authorised. | | | | | | | | |
| | **Note**<br>**Continuing Therapy Only:**<br>For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners. | | | | | | | | |
| 8771P<br>*NP* | galantamine 16 mg capsule: modified release, 28 capsules | 1 | 5 | .. | 64.66 | 36.10 | [a] | APO-Galantamine MR | TX |
| | | | | | | | [a] | Galantyl | AF |
| | | | | | | | [a] | Gamine XR | QA |
| | | | | | | | [a] | Reminyl | JC |
| 8772Q<br>*NP* | galantamine 24 mg capsule: modified release, 28 capsules | 1 | 5 | .. | 75.78 | 36.10 | [a] | APO-Galantamine MR | TX |
| | | | | | | | [a] | Galantyl | AF |
| | | | | | | | [a] | Gamine XR | QA |
| | | | | | | | [a] | Reminyl | JC |
| 8770N<br>*NP* | galantamine 8 mg capsule: modified release, 28 capsules | 1 | 5 | .. | 54.25 | 36.10 | [a] | APO-Galantamine MR | TX |
| | | | | | | | [a] | Galantyl | AF |
| | | | | | | | [a] | Gamine XR | QA |
| | | | | | | | [a] | Reminyl | JC |
| | **RIVASTIGMINE**<br>**Authority required (STREAMLINED)**<br>***4219***<br>Mild to moderately severe Alzheimer disease<br>Treatment Phase: Continuing<br>**The Clinical criteria is:**<br>Patient must have received six months of sole PBS-subsidised initial therapy with this drug,<br>**AND the Clinical criteria is:**<br>Patient must demonstrate a clinically meaningful response to the initial treatment,<br>**AND the Clinical criteria is:**<br>The treatment must be the sole PBS-subsidised therapy for this condition.<br>Prior to continuing treatment, a comprehensive assessment must be undertaken and documented, involving the patient, the patient's family or carer and the treating physician to establish agreement that treatment is continuing to produce worthwhile benefit.<br>Treatment should cease if there is no agreement of benefit as there is always the possibility of harm from unnecessary use.<br>Re-assessments for a clinically meaningful response are to be undertaken and documented every six months.<br>Clinically meaningful response to treatment is demonstrated in the following areas:<br>Patient's quality of life including but not limited to level of independence and happiness;<br>Patient's cognitive function including but not limited to memory, recognition and interest in environment;<br>Patient's behavioural symptoms, including but not limited to hallucination, delusions, anxiety, marked agitation or associated aggressive behaviour. | | | | | | | | |
| | **Note**<br>**Continuing Therapy Only:**<br>For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners. | | | | | | | | |
| 2475G<br>*NP* | rivastigmine 1.5 mg capsule, 56 | 1 | 5 | .. | 96.05 | 36.10 | | Exelon | NV |
| 2476H<br>*NP* | rivastigmine 2 mg/mL oral liquid, 120 mL | ‡1 | 5 | .. | 96.05 | 36.10 | | Exelon | NV |
| 2493F<br>*NP* | rivastigmine 3 mg capsule, 56 | 1 | 5 | .. | 96.05 | 36.10 | | Exelon | NV |
| 2494G<br>*NP* | rivastigmine 4.5 mg capsule, 56 | 1 | 5 | .. | 96.05 | 36.10 | | Exelon | NV |
| 2477J<br>*NP* | rivastigmine 4.6 mg/24 hours patch, 30 | 1 | 5 | .. | 102.43 | 36.10 | | Exelon Patch 5 | NV |
| 2526Y<br>*NP* | rivastigmine 6 mg capsule, 56 | 1 | 5 | .. | 96.05 | 36.10 | | Exelon | NV |
| 2551G<br>*NP* | rivastigmine 9.5 mg/24 hours patch, 30 | 1 | 5 | .. | 102.43 | 36.10 | | Exelon Patch 10 | NV |
| | **RIVASTIGMINE** | | | | | | | | |

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|
| | **Authority required**<br>Mild to moderately severe Alzheimer disease<br>Treatment Phase: Initial<br>**The Clinical criteria is:**<br>Patient must have a baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE) score of 10 or more,<br>**AND the Clinical criteria is:**<br>The condition must be confirmed by, or in consultation with, a specialist/consultant physician (including a psychiatrist),<br>**AND the Clinical criteria is:**<br>The treatment must be the sole PBS-subsidised therapy for this condition.<br>The authority application must include the result of the baseline MMSE or SMMSE. If this score is 25 - 30 points, the result of a baseline Alzheimer Disease Assessment Scale, cognitive sub-scale (ADAS-Cog) may also be specified.<br>The application must be made in writing, but initial supply may be sought by telephone.<br>For telephone applications, up to a maximum of 2 months' initial therapy will be authorised. This telephone application must be followed by a written authority application for no more than 1 month's therapy and sufficient repeats to complete a maximum of up to 6 months' initial treatment.<br>For written applications where no prior telephone approval has been issued, up to a maximum of 1 month's therapy plus 5 repeats will be authorised.<br>**Authority required**<br>Mild to moderately severe Alzheimer disease<br>Treatment Phase: Initial<br>**The Clinical criteria is:**<br>Patient must have a baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE) score of 9 or less,<br>**AND the Clinical criteria is:**<br>The condition must be confirmed by, or in consultation with, a specialist/consultant physician (including a psychiatrist),<br>**AND the Clinical criteria is:**<br>The treatment must be the sole PBS-subsidised therapy for this condition.<br>A patient who is unable to register a score of 10 or more for reasons other than their Alzheimer disease, as specified below.<br>Such patients will need to be assessed using the Clinicians Interview Based Impression of Severity (CIBIS) scale. The authority application must include the result of the baseline (S)MMSE and specify to which group(s) (see below) the patient belongs.<br>Patients who qualify under this criterion are from 1 or more of the following groups:<br>(1) Unable to communicate adequately because of lack of competence in English, in people of non-English speaking background;<br>(2) Limited education, as defined by less than 6 years of education, or who are illiterate or innumerate;<br>(3) Aboriginal or Torres Strait Islanders who, by virtue of cultural factors, are unable to complete an (S)MMSE test;<br>(4) Intellectual (developmental or acquired) disability, eg Down's syndrome;<br>(5) Significant sensory impairment despite best correction, which precludes completion of an (S)MMSE test;<br>(6) Prominent dysphasia, out of proportion to other cognitive and functional impairment.<br>The application must be made in writing, but initial supply may be sought by telephone.<br>For telephone applications, up to a maximum of 2 months' initial therapy will be authorised. This telephone application must be followed by a written authority application for no more than 1 month's therapy and sufficient repeats to complete a maximum of up to 6 months' initial treatment.<br>For written applications where no prior telephone approval has been issued, up to a maximum of 1 month's therapy plus 5 repeats will be authorised.<br>**Note**<br>**Continuing Therapy Only:**<br>For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners. | | | | | | | | |
| 8497F<br>*NP* | rivastigmine 1.5 mg capsule, 56 | 1 | 5 | .. | 96.05 | 36.10 | Exelon | NV |
| 8563Q<br>*NP* | rivastigmine 2 mg/mL oral liquid, 120 mL | ‡1 | 5 | .. | 96.05 | 36.10 | Exelon | NV |
| 8498G<br>*NP* | rivastigmine 3 mg capsule, 56 | 1 | 5 | .. | 96.05 | 36.10 | Exelon | NV |
| 8499H<br>*NP* | rivastigmine 4.5 mg capsule, 56 | 1 | 5 | .. | 96.05 | 36.10 | Exelon | NV |
| 9161E<br>*NP* | rivastigmine 4.6 mg/24 hours patch, 30 | 1 | 5 | .. | 102.43 | 36.10 | Exelon Patch 5 | NV |

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|---|
| 8500J *NP* | rivastigmine 6 mg capsule, 56 | 1 | 5 | .. | 96.05 | 36.10 | | Exelon | NV |
| 9162F *NP* | rivastigmine 9.5 mg/24 hours patch, 30 | 1 | 5 | .. | 102.43 | 36.10 | | Exelon Patch 10 | NV |

## *Other anti-dementia drugs*

**MEMANTINE**

**Authority required**

Moderately severe Alzheimer disease

Treatment Phase: Initial

**The Clinical criteria is:**

Patient must have a baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE) score of 10 to 14,

**AND the Clinical criteria is:**

The condition must be confirmed by, or in consultation with, a specialist/consultant physician (including a psychiatrist),

**AND the Clinical criteria is:**

The treatment must be the sole PBS-subsidised therapy for this condition.

The authority application must include the result of the baseline MMSE or SMMSE of 10 to 14.

The application must be made in writing, but initial supply may be sought by telephone.

For telephone applications, up to a maximum of 2 months' initial therapy will be authorised. This telephone application must be followed by a written authority application for no more than 1 month's therapy and sufficient repeats to complete a maximum of up to 6 months' initial treatment.

For written applications where no prior telephone approval has been issued, up to a maximum of 1 month's therapy plus 5 repeats will be authorised.

**Authority required**

Moderately severe Alzheimer disease

Treatment Phase: Initial

**The Clinical criteria is:**

Patient must have a baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE) score of 9 or less,

**AND the Clinical criteria is:**

The condition must be confirmed by, or in consultation with, a specialist/consultant physician (including a psychiatrist),

**AND the Clinical criteria is:**

The treatment must be the sole PBS-subsidised therapy for this condition.

A patient who is unable to register a score of 10 to 14 for reasons other than their Alzheimer disease, as specified below.

Such patients will need to be assessed using the Clinicians Interview Based Impression of Severity (CIBIS) scale. The authority application must include the result of the baseline (S)MMSE and specify to which group(s) (see below) the patient belongs.

Patients who qualify under this criterion are from 1 or more of the following groups:

(1) Unable to communicate adequately because of lack of competence in English, in people of non-English speaking background;

(2) Limited education, as defined by less than 6 years of education, or who are illiterate or innumerate;

(3) Aboriginal or Torres Strait Islanders who, by virtue of cultural factors, are unable to complete an (S)MMSE test;

(4) Intellectual (developmental or acquired) disability, eg Down's syndrome;

(5) Significant sensory impairment despite best correction, which precludes completion of an (S)MMSE test;

(6) Prominent dysphasia, out of proportion to other cognitive and functional impairment.

The application must be made in writing, but initial supply may be sought by telephone.

For telephone applications, up to a maximum of 2 months' initial therapy will be authorised. This telephone application must be followed by a written authority application for no more than 1 month's therapy and sufficient repeats to complete a maximum of up to 6 months' initial treatment.

For written applications where no prior telephone approval has been issued, up to a maximum of 1 month's therapy plus 5 repeats will be authorised.

**Note**

**Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 1956Y *NP* | memantine hydrochloride 10 mg tablet, 56 | 1 | 5 | .. | 66.95 | 36.10 | [a] | APO-Memantine | TX |
| | | | | | | | [a] | Ebixa | LU |
| | | | | | | | [a] | Memanxa | QA |

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|---|
| 9306T *NP* | memantine hydrochloride 20 mg tablet, 28 | 1 | 5 | .. | 66.95 | 36.10 | | Ebixa | LU |

**MEMANTINE**

**Authority required (STREAMLINED)**

***4214***

Moderately severe Alzheimer disease

Treatment Phase: Continuing

**The Clinical criteria is:**

Patient must have received six months of sole PBS-subsidised initial therapy with this drug,

**AND the Clinical criteria is:**

Patient must demonstrate a clinically meaningful response to the initial treatment,

**AND the Clinical criteria is:**

The treatment must be the sole PBS-subsidised therapy for this condition.

Prior to continuing treatment, a comprehensive assessment must be undertaken and documented, involving the patient, the patient's family or carer and the treating physician to establish agreement that treatment is continuing to produce worthwhile benefit.

Treatment should cease if there is no agreement of benefit as there is always the possibility of harm from unnecessary use.

Re-assessments for a clinically meaningful response are to be undertaken and documented every six months.

Clinically meaningful response to treatment is demonstrated in the following areas:

Patient's quality of life including but not limited to level of independence and happiness;

Patient's cognitive function including but not limited to memory, recognition and interest in environment;

Patient's behavioural symptoms, including but not limited to hallucination, delusions, anxiety, marked agitation or associated aggressive behaviour.

**Note**

**Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 2492E *NP* | memantine hydrochloride 10 mg tablet, 56 | 1 | 5 | .. | 66.95 | 36.10 | [a] | APO-Memantine | TX |
| | | | | | | | [a] | Ebixa | LU |
| | | | | | | | [a] | Memanxa | QA |
| 2513G *NP* | memantine hydrochloride 20 mg tablet, 28 | 1 | 5 | .. | 66.95 | 36.10 | | Ebixa | LU |

## OTHER NERVOUS SYSTEM DRUGS

### PARASYMPATHOMIMETICS

#### *Anticholinesterases*

**PYRIDOSTIGMINE**

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 2724J | PYRIDOSTIGMINE BROMIDE Tablet 10 mg, 50 | 2 | 5 | .. | *23.21 | 24.34 | Mestinon | VT |
| 2608G | pyridostigmine bromide 180 mg tablet: modified release, 50 tablets | 2 | 5 | .. | *149.43 | 36.10 | Mestinon Timespan | VT |
| 1959D | pyridostigmine bromide 60 mg tablet, 150 | 1 | 5 | .. | 71.53 | 36.10 | Mestinon | VT |

#### *Choline esters*

**BETHANECHOL**

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 1062X *NP* | bethanechol chloride 10 mg tablet, 100 | 1 | 2 | .. | 33.74 | 34.87 | Uro-Carb | YN |

### DRUGS USED IN ADDICTIVE DISORDERS

#### *Drugs used in nicotine dependence*

**BUPROPION**

**Authority required**

Commencement of short-term, sole PBS-subsidised, therapy as an aid to achieving abstinence in a patient who has indicated they are ready to cease smoking and who has entered a comprehensive support and counselling program. Details of the program must be specified in the authority application

**Authority required**

Commencement of short-term, sole PBS-subsidised, therapy as an aid to achieving abstinence in a patient who has indicated they are ready to cease smoking and who is entering a comprehensive support and counselling program during the consultation at which this authority is requested. Details

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|---|
| | of the program must be specified in the authority application | | | | | | | | |
| | **Note** | | | | | | | | |
| | Only one course of PBS-subsidised bupropion hydrochloride will be authorised per 12 months. The period between commencing a course of bupropion hydrochloride and varenicline tartrate must be at least 6 months. A course of treatment with bupropion hydrochloride is 9 weeks. No increased maximum quantities or repeats will be authorised. Clinical review is recommended within 2 to 3 weeks of the original prescription being requested. | | | | | | | | |
| 8465M<br>*NP* | bupropion hydrochloride 150 mg tablet: modified release, 30 tablets | 1 | .. | .. | 63.21 | 36.10 | a | Prexaton | GM |
| | | | | B0.80 | 64.01 | 36.10 | a | Zyban | AS |
| | **BUPROPION** | | | | | | | | |
| | **Authority required** | | | | | | | | |
| | Completion of short-term, sole PBS-subsidised, therapy as an aid to achieving abstinence in a patient who has previously been issued with an authority prescription for this drug and who is enrolled in a comprehensive support and counselling program | | | | | | | | |
| | **Note** | | | | | | | | |
| | Only one course of PBS-subsidised bupropion hydrochloride will be authorised per 12 months. The period between commencing a course of bupropion hydrochloride and varenicline tartrate must be at least 6 months. A course of treatment with bupropion hydrochloride is 9 weeks. No increased maximum quantities or repeats will be authorised. Clinical review is recommended within 2 to 3 weeks of the original prescription being requested. | | | | | | | | |
| 8710K<br>*NP* | bupropion hydrochloride 150 mg tablet: modified release, 90 tablets | 1 | .. | .. | 176.37 | 36.10 | a | Prexaton | GM |
| | | | | B0.96 | 177.33 | 36.10 | a | Zyban | AS |
| | **NICOTINE** | | | | | | | | |
| | **Authority required** | | | | | | | | |
| | Nicotine dependence | | | | | | | | |
| | **The Population criteria is:** | | | | | | | | |
| | Patient must be an Aboriginal or a Torres Strait Islander person, | | | | | | | | |
| | **AND the Clinical criteria is:** | | | | | | | | |
| | The treatment must be the sole PBS-subsidised therapy for this condition. | | | | | | | | |
| | **Note** | | | | | | | | |
| | Only 2 courses of PBS-subsidised nicotine replacement therapy will be authorised per year. | | | | | | | | |
| | Benefit is improved if used in conjunction with a comprehensive support and counselling program. | | | | | | | | |
| | **Note** | | | | | | | | |
| | No increase in the maximum quantity or number of units may be authorised. | | | | | | | | |
| | **Note** | | | | | | | | |
| | No increase in the maximum number of repeats may be authorised. | | | | | | | | |
| | **Authority required** | | | | | | | | |
| | Nicotine dependence | | | | | | | | |
| | **The Clinical criteria is:** | | | | | | | | |
| | The treatment must be the sole PBS-subsidised therapy for this condition, | | | | | | | | |
| | **AND the Clinical criteria is:** | | | | | | | | |
| | Patient must have indicated they are ready to cease smoking, | | | | | | | | |
| | **AND the Clinical criteria is:** | | | | | | | | |
| | Patient must have entered a comprehensive support and counselling program, | | | | | | | | |
| | **AND the Clinical criteria is:** | | | | | | | | |
| | Patient must not receive more than 12 weeks of PBS-subsidised nicotine replacement therapy per year. | | | | | | | | |
| | Details of the support and counselling program must be specified in the initial authority application. | | | | | | | | |
| | **Note** | | | | | | | | |
| | No increase in the maximum quantity or number of units may be authorised. | | | | | | | | |
| | **Note** | | | | | | | | |
| | No increase in the maximum number of repeats may be authorised. | | | | | | | | |
| | **Authority required** | | | | | | | | |
| | Nicotine dependence | | | | | | | | |
| | **The Clinical criteria is:** | | | | | | | | |

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|
| | The treatment must be the sole PBS-subsidised therapy for this condition,<br>**AND the Clinical criteria is:**<br>Patient must have indicated they are ready to cease smoking,<br>**AND the Clinical criteria is:**<br>Patient must be entering a comprehensive support and counselling program during the consultation at which this authority is requested,<br>**AND the Clinical criteria is:**<br>Patient must not receive more than 12 weeks of PBS-subsidised nicotine replacement therapy per year.<br><br>Details of the support and counselling program must be specified in the initial authority application.<br><br>**Note**<br>No increase in the maximum quantity or number of units may be authorised.<br>**Note**<br>No increase in the maximum number of repeats may be authorised. | | | | | | | |
| 9198D<br>*NP* | NICOTINE Transdermal patch releasing approximately 15 mg per 16 hours, 28 | 1 | 2 | .. | 55.43 | 36.10 | Nicorette Patch | JT |
| 5465P<br>*NP* | nicotine 21 mg/24 hours patch, 28 | 1 | 2 | .. | 55.43 | 36.10 | Nicabate P | GC |
| | **NICOTINE**<br>**Authority required**<br>Short-term sole PBS-subsidised therapy as an aid to achieving abstinence in a patient who has indicated they are ready to cease smoking and who has entered a comprehensive support and counselling program.<br>Details of the program must be specified in the initial authority application<br>**Authority required**<br>Short-term sole PBS-subsidised therapy as an aid to achieving abstinence in a patient who has indicated they are ready to cease smoking and who is entering a comprehensive support and counselling program during the consultation at which this authority is requested.<br>Details of the program must be specified in the initial authority application<br>**Note**<br>No applications for increased maximum quantities will be authorised.<br>Applications for increased repeats, up to a maximum of 2, may be authorised.<br>A maximum of 12 weeks of PBS-subsidised nicotine replacement therapy will be authorised per year. | | | | | | | |
| 5572G<br>*NP* | nicotine 14 mg/24 hours patch, 28 | 1 | .. | .. | 55.43 | 36.10 | Nicotinell Step 2 | NC |
| 3414Q<br>*NP* | nicotine 21 mg/24 hours patch, 28 | 1 | .. | .. | 55.43 | 36.10 | Nicotinell Step 1 | NC |
| 5573H<br>*NP* | nicotine 7 mg/24 hours patch, 28 | 1 | .. | .. | 55.43 | 36.10 | Nicotinell Step 3 | NC |
| | **NICOTINE**<br>**Authority required**<br>Nicotine dependence in an Aboriginal or a Torres Strait Islander person as the sole PBS-subsidised therapy<br>**Note**<br>Only 2 courses of PBS-subsidised nicotine replacement therapy will be authorised per year.<br>No applications for increased maximum quantities and/or repeats will be authorised.<br>Benefit is improved if used in conjunction with a comprehensive support and counselling program. | | | | | | | |
| 5571F<br>*NP* | nicotine 21 mg/24 hours patch, 28 | 1 | 2 | .. | 55.43 | 36.10 | Nicotinell Step 1 | NC |
| | **VARENICLINE**<br>**Authority required**<br>Completion of short-term sole PBS-subsidised therapy as an aid to achieving long-term abstinence after completion of an initial 12-week PBS-subsidised course in a patient who has ceased smoking, and who is enrolled in a comprehensive support and counselling program<br>**Note**<br>A course of treatment with varenicline tartrate is 12 weeks or up to 24 weeks, if initial treatment of 12 weeks has been successful. Only one course of 12 or up to 24 weeks of PBS-subsidised varenicline tartrate will be authorised per year. The period between commencing varenicline tartrate and bupropion hydrochloride must be at least 6 months. No increased maximum quantities or repeats will be authorised. Clinical review is recommended within 2 to 3 weeks of the initial prescription being requested. | | | | | | | |
| 5469W<br>*NP* | varenicline 1 mg tablet, 56 | 1 | 2 | .. | 120.63 | 36.10 | Champix | PF |

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|---|
| | **VARENICLINE**<br>**Authority required**<br>Continuation of short-term sole PBS-subsidised therapy as an aid to achieving abstinence in a patient who has previously been issued with an authority prescription for this drug and who is enrolled in a comprehensive support and counselling program<br>**Note**<br>A course of treatment with varenicline tartrate is 12 weeks or up to 24 weeks, if initial treatment of 12 weeks has been successful. Only one course of 12 or up to 24 weeks of PBS-subsidised varenicline tartrate will be authorised per year. The period between commencing varenicline tartrate and bupropion hydrochloride must be at least 6 months. No increased maximum quantities or repeats will be authorised. Clinical review is recommended within 2 to 3 weeks of the initial prescription being requested. | | | | | | | | |
| 9129L<br>*NP* | varenicline 1 mg tablet, 56 | 2 | .. | .. | *231.91 | 36.10 | | Champix | PF |
| | **VARENICLINE**<br>**Authority required**<br>Commencement of short-term, sole PBS-subsidised, therapy as an aid to achieving abstinence in a patient who has indicated they are ready to cease smoking and who has entered a comprehensive support and counselling program. Details of the program must be specified in the authority application<br>**Authority required**<br>Commencement of short-term, sole PBS-subsidised, therapy as an aid to achieving abstinence in a patient who has indicated they are ready to cease smoking and who is entering a comprehensive support and counselling program during the consultation at which this authority is requested. Details of the program must be specified in the authority application<br>**Note**<br>A course of treatment with varenicline tartrate is 12 weeks or up to 24 weeks, if initial treatment of 12 weeks has been successful. Only one course of 12 or up to 24 weeks of PBS-subsidised varenicline tartrate will be authorised per year. The period between commencing varenicline tartrate and bupropion hydrochloride must be at least 6 months. No increased maximum quantities or repeats will be authorised. Clinical review is recommended within 2 to 3 weeks of the initial prescription being requested. | | | | | | | | |
| 9128K<br>*NP* | varenicline 500 microgram tablet [11 tablets] (&) varenicline 1 mg tablet [42 tablets], 53 | ‡1 | .. | .. | 103.33 | 36.10 | | Champix | PF |

## *Drugs used in alcohol dependence*

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | **ACAMPROSATE**<br>**Authority required (STREAMLINED)**<br>***2665***<br>For use within a comprehensive treatment program for alcohol dependence with the goal of maintaining abstinence<br>**Note**<br>No applications for increased maximum quantities and/or repeats will be authorised. | | | | | | | | |
| 8357W<br>*NP* | acamprosate calcium 333 mg tablet: enteric, 180 tablets | 1 | 1 | .. | 166.79 | 36.10 | | Campral | AF |
| | **NALTREXONE**<br>**Authority required**<br>For use within a comprehensive treatment program for alcohol dependence with the goal of maintaining abstinence<br>**Caution**<br>Naltrexone hydrochloride is contraindicated in patients receiving opioid drugs.<br>**Note**<br>No applications for increased maximum quantities and/or repeats will be authorised. | | | | | | | | |
| 8370M<br>*NP* | naltrexone hydrochloride 50 mg tablet, 30 | 1 | 1 | .. | 135.88 | 36.10 | [a] | Naltrexone GH | GQ |
| | | | | | | | [a] | ReVia | BQ |

# OTHER NERVOUS SYSTEM DRUGS

## *Other nervous system drugs*

**RILUZOLE**

**Authority required**

Initial treatment of amyotrophic lateral sclerosis, as diagnosed by a neurologist, in patients with disease duration of 5 years or less and who have at least 60 percent of predicted forced vital capacity within 2 months prior to commencing riluzole therapy and who:

(1) are ambulatory, and

(a) have not undergone tracheostomy, and

(b) have not experienced respiratory failure; OR

(2) are not ambulatory, and

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|---|
| | (a) have not undergone tracheostomy, and | | | | | | | | |
| | (b) have not experienced respiratory failure, and | | | | | | | | |
| | (c) are either able to use upper limbs or able to swallow. | | | | | | | | |
| | The date of diagnosis and the date and results of spirometry (in terms of percent of predicted forced vital capacity) must be supplied with the initial authority application | | | | | | | | |
| | **Authority required** | | | | | | | | |
| | Continuing treatment of amyotrophic lateral sclerosis in patients who have previously been issued with an authority prescription for this drug and who: | | | | | | | | |
| | (1) are ambulatory, and | | | | | | | | |
| | (a) have not undergone tracheostomy, and | | | | | | | | |
| | (b) have not experienced respiratory failure; OR | | | | | | | | |
| | (2) are not ambulatory, and | | | | | | | | |
| | (a) have not undergone tracheostomy, and | | | | | | | | |
| | (b) have not experienced respiratory failure, and | | | | | | | | |
| | (c) are either able to use upper limbs or able to swallow | | | | | | | | |
| | **Note** | | | | | | | | |
| | Continuing Therapy Only: | | | | | | | | |
| | For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners. | | | | | | | | |
| 8664B *NP* | riluzole 50 mg tablet, 56 | 1 | 5 | .. | 557.32 | 36.10 | [a] | APO-Riluzole | TX |
| | | | | | | | [a] | Rilutek | SW |
| | | | | | | | [a] | Riluzole Sandoz | SZ |
| | **TETRABENAZINE** | | | | | | | | |
| | **Authority required (STREAMLINED)** | | | | | | | | |
| | ***1161*** | | | | | | | | |
| | Hyperkinetic extrapyramidal disorders | | | | | | | | |
| | **Note** | | | | | | | | |
| | Continuing Therapy Only: | | | | | | | | |
| | For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners. | | | | | | | | |
| 1330B *NP* | tetrabenazine 25 mg tablet, 112 | 1 | 5 | .. | 337.76 | 36.10 | | iNova Pharmaceuticals (Australia) Pty Ltd | IA |

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|

# ANTIPARASITIC PRODUCTS, INSECTICIDES AND REPELLENTS

## ANTIPROTOZOALS

### AGENTS AGAINST AMOEBIASIS AND OTHER PROTOZOAL DISEASES

#### *Other agents against amoebiasis and other protozoal diseases*

**ATOVAQUONE**

**Authority required (STREAMLINED)**

***1433***

Treatment of mild to moderate Pneumocystis carinii pneumonia in adult patients who are intolerant of trimethoprim/sulfamethoxazole therapy

**Note**

Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 8300W *NP* | atovaquone 750 mg/5 mL oral liquid, 210 mL | ‡1 | .. | .. | 1034.78 | 36.10 | Wellvone | AS |

**PYRIMETHAMINE**

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 1966L *NP* | pyrimethamine 25 mg tablet, 50 | 1 | .. | .. | 16.59 | 17.72 | Daraprim | AS |

### ANTIMALARIALS

#### *Biguanides*

**ATOVAQUONE + PROGUANIL**

**Authority required**

Treatment of suspected or confirmed Plasmodium falciparum malaria in a patient aged 3 years or older where quinine containing regimens are inappropriate

**Note**

Atovaquone with proguanil hydrochloride is not PBS-subsidised for the prophylaxis of malaria.

**Note**

Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 9439T *NP* | atovaquone 250 mg + proguanil hydrochloride 100 mg tablet, 12 | 1 | .. | .. | 67.21 | 36.10 | Malarone | GK |

#### *Methanolquinolines*

**QUININE**

**Authority required (STREAMLINED)**

***2142***

Malaria

**Caution**

Severe thrombocytopenia has been reported with this drug.

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 1975Y *NP* | quinine sulfate 300 mg tablet, 50 | 1 | 2 | .. | 14.35 | 15.48 | Quinate | AS |

#### *Artemisinin and derivatives, combinations*

**ARTEMETHER + LUMEFANTRINE**

**Authority required**

Treatment of suspected or confirmed malaria due to Plasmodium falciparum

**Note**

Artemether with lumefantrine is not PBS-subsidised for prophylaxis of malaria.

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 9498X | artemether 20 mg + lumefantrine 120 mg tablet, 24 | 1 | .. | .. | 97.11 | 36.10 | Riamet | NV |

**ARTEMETHER + LUMEFANTRINE**

**Authority required**

Treatment of suspected or confirmed malaria due to Plasmodium falciparum in a patient unable to swallow a solid dosage form of artemether with

# ANTIPARASITIC PRODUCTS, INSECTICIDES AND REPELLENTS

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|
| | lumefantrine | | | | | | | |
| | **Note**<br>Artemether with lumefantrine is not PBS-subsidised for prophylaxis of malaria. | | | | | | | |
| 5296R | artemether 20 mg + lumefantrine 120 mg tablet: dispersible, 18 | 1 | .. | .. | 97.11 | 36.10 | Riamet 20mg/120mg Dispersible | NV |

## ANTHELMINTICS

### ANTITREMATODALS

#### *Quinoline derivatives and related substances*

**PRAZIQUANTEL**
**Authority required (STREAMLINED)**
***3147***
Schistosomiasis

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 9447F<br>*NP* | praziquantel 600 mg tablet, 8 | 1 | .. | .. | 41.06 | 36.10 | Biltricide | BN |

### ANTINEMATODAL AGENTS

#### *Benzimidazole derivatives*

**ALBENDAZOLE**
**Authority required (STREAMLINED)**
***1525***
Treatment of tapeworm infestation

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 8503M<br>*NP* | albendazole 200 mg tablet: chewable, 6 | 1 | 1 | .. | 33.31 | 34.44 | Zentel | AS |

**ALBENDAZOLE**
**Authority required (STREAMLINED)**
***2446***
Treatment of whipworm infestation in an Aboriginal or a Torres Strait Islander person

**Authority required (STREAMLINED)**
***1388***
Strongyloidiasis

**Authority required (STREAMLINED)**
***3241***
Treatment of hookworm infestation

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 9047E<br>*NP* | albendazole 200 mg tablet: chewable, 6 | 1 | .. | .. | 33.31 | 34.44 | Zentel | AS |

**ALBENDAZOLE**
**Authority required (STREAMLINED)**
***1496***
For the treatment of hydatid disease in conjunction with surgery or when a surgical cure cannot be achieved or where surgery cannot be used

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 8459F | albendazole 400 mg tablet: chewable, 60 | 1 | 2 | .. | 185.46 | 36.10 | Eskazole | AS |

#### *Tetrahydropyrimidine derivatives*

**PYRANTEL**

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 3047J<br>*NP* | pyrantel 125 mg tablet, 6 | 1 | .. | .. | 14.81 | 15.94 | Anthel 125 | AF |
| 3048K<br>*NP* | pyrantel 250 mg tablet, 6 | 1 | .. | .. | 22.98 | 24.11 | Anthel 250 | AF |

#### *Avermectines*

**IVERMECTIN**
**Authority required (STREAMLINED)**
***1242***
Onchocerciasis

**Authority required (STREAMLINED)**
***1388***
Strongyloidiasis

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 8359Y<br>*NP* | ivermectin 3 mg tablet, 4 | 1 | .. | .. | 31.52 | 32.65 | Stromectol | MK |

# ANTIPARASITIC PRODUCTS, INSECTICIDES AND REPELLENTS

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|
| **ECTOPARASITICIDES, INCL. SCABICIDES, INSECTICIDES AND REPELLENTS** | | | | | | | | |
| **ECTOPARASITICIDES, INCL. SCABICIDES** | | | | | | | | |
| ***Pyrethrines, incl. synthetic compounds*** | | | | | | | | |
| | **PERMETHRIN** | | | | | | | |
| 3054R<br>*NP* | permethrin 5% (50 mg/g) cream, 30 g | ‡1 | 1 | .. | 16.98 | 18.11 | Lyclear | JT |

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|---|

# RESPIRATORY SYSTEM

## NASAL PREPARATIONS

### DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE

#### *Other nasal preparations*

**MUPIROCIN**

**Authority required (STREAMLINED)**

***3136***

Nasal colonisation with Staphylococcus aureus in an Aboriginal or a Torres Strait Islander person

**Note**

No applications for increased maximum quantities and/or repeats will be authorised.

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 9440W *NP* | mupirocin 2% (20 mg/g) ointment, 3 g | ‡1 | .. | .. | 20.84 | 21.97 | | Bactroban | GK |

## DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES

### ADRENERGICS, INHALANTS

#### *Selective beta-2-adrenoreceptor agonists*

**EFORMOTEROL**

**Restricted benefit**

Patients with frequent episodes of asthma who are currently receiving treatment with oral corticosteroids

**Restricted benefit**

Patients with frequent episodes of asthma who are currently receiving treatment with optimal doses of inhaled corticosteroids

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 8240Q *NP* | eformoterol fumarate dihydrate 12 microgram/actuation inhalation: powder for, 60 actuations | ‡1 | 5 | .. | 36.65 | 36.10 | | Oxis Turbuhaler | AP |
| 8136F *NP* | eformoterol fumarate dihydrate 12 microgram/actuation inhalation: powder for, 60 capsules | 1 | 5 | .. | 37.54 | 36.10 | | Foradile | NV |
| 8239P *NP* | eformoterol fumarate dihydrate 6 microgram/actuation inhalation: powder for, 60 actuations | ‡1 | 5 | .. | 26.59 | 27.72 | | Oxis Turbuhaler | AP |

**INDACATEROL**

**Restricted benefit**

Chronic obstructive pulmonary disease

**Note**

Indacaterol is not PBS-subsidised for the treatment of asthma.

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 5134F *NP* | indacaterol 150 microgram inhalation: powder for, 30 capsules | 1 | 5 | .. | 73.65 | 36.10 | | Onbrez | NV |
| 5137J *NP* | indacaterol 300 microgram inhalation: powder for, 30 capsules | 1 | 5 | .. | 73.65 | 36.10 | | Onbrez | NV |

**SALBUTAMOL**

**Restricted benefit**

Asthma in patients unable to use this drug delivered from an oral pressurised inhalation device via a spacer

**Restricted benefit**

Chronic obstructive pulmonary disease in patients unable to use this drug delivered from an oral pressurised inhalation device via a spacer

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 2003K *NP* | salbutamol 0.5% (5 mg/mL) inhalation: solution, 1 x 30 mL bottle | 2 | 2 | .. | *17.47 | 18.60 | | Pfizer Australia Pty Ltd | PF |
| 2000G *NP* | salbutamol 2.5 mg/2.5 mL inhalation: solution, 30 x 2.5 mL ampoules | 2 | 5 | .. | *16.89 | 18.02 | [a] | Asmol 2.5 uni-dose | AF |
| | | | | | | | [a] | Butamol 2.5 | QA |
| | | | | | | | [a] | GenRx Salbutamol | GX |
| | | | | | | | [a] | Pharmacor Salbutamol 2.5 | CR |
| | | | | | | | [a] | Salbutamol-GA | GM |
| | | | | | | | [a] | Salbutamol Sandoz | SZ |
| | | | | [B]1.18 | *18.07 | 18.02 | [a] | Ventolin Nebules | GK |
| 2001H | salbutamol 5 mg/2.5 mL inhalation: | 2 | 5 | .. | *17.47 | 18.60 | [a] | Asmol 5 uni-dose | AF |

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|---|---|---|---|---|---|---|---|---|---|
| *NP* | solution, 30 x 2.5 mL ampoules | | | | | | | | |
| | | | | | | | [a] | Butamol 5 | QA |
| | | | | | | | [a] | GenRx Salbutamol | GX |
| | | | | | | | [a] | Pharmacor Salbutamol 5 | CR |
| | | | | | | | [a] | Salbutamol-GA | GM |
| | | | | | | | [a] | Salbutamol Sandoz | SZ |
| | | | | [B]1.14 | *18.61 | 18.60 | [a] | Ventolin Nebules | GK |
| | **SALBUTAMOL** | | | | | | | | |
| 8288F *NP* | salbutamol 100 microgram/actuation inhalation: pressurised, 200 actuations | 2 | 5 | .. | *14.01 | 15.14 | [a] | Airomir | IA |
| | | | | | | | [a] | APO-Salbutamol Inhaler | TX |
| | | | | | | | [a] | Asmol CFC-free | AL |
| | | | | [B]2.34 | *16.35 | 15.14 | [a] | Ventolin CFC-free | GK |
| 1099W *NP* | salbutamol 200 microgram inhalation: powder for, 100 capsules | 2 | 5 | .. | *16.27 | 17.40 | | Ventolin Rotacaps | GK |
| | **SALBUTAMOL**<br>**Restricted benefit**<br>Patients unable to achieve co-ordinated use of other metered dose inhalers containing this drug | | | | | | | | |
| 8354Q *NP* | salbutamol Oral pressurised inhalation in breath actuated device 100 micrograms (base) per dose (200 doses), CFC-free formulation, 1 | 2 | 5 | .. | *38.81 | 36.10 | | Airomir Autohaler | IA |
| | **SALMETEROL**<br>**Restricted benefit**<br>Patients with frequent episodes of asthma who are currently receiving treatment with oral corticosteroids | | | | | | | | |
| | **Restricted benefit**<br>Patients with frequent episodes of asthma who are currently receiving treatment with optimal doses of inhaled corticosteroids | | | | | | | | |
| 8141L *NP* | salmeterol 50 microgram/actuation inhalation: powder for, 60 actuations | ‡1 | 5 | .. | 37.54 | 36.10 | | Serevent Accuhaler | GK |
| | **TERBUTALINE** | | | | | | | | |
| 1252X *NP* | terbutaline sulfate 500 microgram/actuation inhalation: powder for, 200 actuations | ‡1 | 5 | .. | 18.04 | 19.17 | | Bricanyl Turbuhaler | AP |

## *Adrenergics and other drugs for obstructive airway diseases*

**BUDESONIDE + EFORMOTEROL**

**Restricted benefit**

Patients who previously had frequent episodes of asthma while receiving treatment with oral corticosteroids and who have been stabilised on concomitant inhaled eformoterol fumarate dihydrate and budesonide

**Restricted benefit**

Patients who previously had frequent episodes of asthma while receiving treatment with optimal doses of inhaled corticosteroids and who have been stabilised on concomitant inhaled eformoterol fumarate dihydrate and budesonide

**Restricted benefit**

For single maintenance and reliever therapy in a patient who experiences frequent asthma symptoms while receiving treatment with oral corticosteroids

**Restricted benefit**

For single maintenance and reliever therapy in a patient who experiences frequent asthma symptoms while receiving treatment with inhaled corticosteroids

**Restricted benefit**

For maintenance and reliever therapy in a patient who experiences frequent asthma symptoms while receiving treatment with a combination of an inhaled corticosteroid and a long-acting beta-2 agonist

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 8796Y *NP* | budesonide 100 microgram/actuation + eformoterol fumarate dihydrate 6 microgram/actuation inhalation: powder for, 120 actuations | ‡1 | 5 | .. | 54.68 | 36.10 | | Symbicort Turbuhaler 100/6 | AP |
| 8625Y *NP* | budesonide 200 microgram / 1 actuation + eformoterol 4.92 microgram / 1 actuation \| eformoterol fumarate dihydrate 6 microgram / 1 actuation inhalation: powder for, 120 actuations | ‡1 | 5 | .. | 58.98 | 36.10 | | Symbicort Turbuhaler 200/6 | AP |

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|
| | **BUDESONIDE + EFORMOTEROL** | | | | | | | |
| | **Restricted benefit**<br>Patients who previously had frequent episodes of asthma while receiving treatment with oral corticosteroids and who have been stabilised on concomitant inhaled eformoterol fumarate dihydrate and budesonide | | | | | | | |
| | **Restricted benefit**<br>Patients who previously had frequent episodes of asthma while receiving treatment with optimal doses of inhaled corticosteroids and who have been stabilised on concomitant inhaled eformoterol fumarate dihydrate and budesonide | | | | | | | |
| | **Restricted benefit**<br>Symptomatic treatment of chronic obstructive pulmonary disease (COPD), where the FEV1 is less than 50% predicted normal and there is a history of repeated exacerbations with significant symptoms despite regular beta-2 agonist bronchodilator therapy | | | | | | | |
| | **Note**<br>Symbicort 400/12 is not recommended nor PBS-subsidised for use as 'maintenance and reliever' therapy. | | | | | | | |
| | **Note**<br>Budesonide with eformoterol fumarate dihydrate is not indicated for the initiation of bronchodilator therapy in COPD. | | | | | | | |
| 8750M<br>*NP* | budesonide 400 microgram/actuation + eformoterol fumarate dihydrate 12 microgram/actuation inhalation: powder for, 120 actuations | 1 | 5 | .. | 90.76 | 36.10 | Symbicort Turbuhaler 400/12 | AP |
| | **FLUTICASONE + SALMETEROL** | | | | | | | |
| | **Restricted benefit**<br>Patients who previously had frequent episodes of asthma while receiving treatment with oral corticosteroids and who have been stabilised on concomitant inhaled salmeterol xinafoate and fluticasone propionate | | | | | | | |
| | **Restricted benefit**<br>Patients who previously had frequent episodes of asthma while receiving treatment with optimal doses of inhaled corticosteroids and who have been stabilised on concomitant inhaled salmeterol xinafoate and fluticasone propionate | | | | | | | |
| 8430Q<br>*NP* | fluticasone propionate 100 microgram/actuation + salmeterol 50 microgram/actuation inhalation: powder for, 60 actuations | ‡1 | 5 | .. | 47.41 | 36.10 | Seretide Accuhaler 100/50 | GK |
| 8518H<br>*NP* | fluticasone propionate 125 microgram/actuation + salmeterol 25 microgram/actuation inhalation: pressurised, 120 actuations | ‡1 | 5 | .. | 59.52 | 36.10 | Seretide MDI 125/25 | GK |
| 8431R<br>*NP* | fluticasone propionate 250 microgram/actuation + salmeterol 50 microgram/actuation inhalation: powder for, 60 actuations | ‡1 | 5 | .. | 59.52 | 36.10 | Seretide Accuhaler 250/50 | GK |
| 8517G<br>*NP* | fluticasone propionate 50 microgram/actuation + salmeterol 25 microgram/actuation inhalation: pressurised, 120 actuations | ‡1 | 5 | .. | 47.41 | 36.10 | Seretide MDI 50/25 | GK |
| | **FLUTICASONE + SALMETEROL** | | | | | | | |
| | **Restricted benefit**<br>Patients who previously had frequent episodes of asthma while receiving treatment with oral corticosteroids and who have been stabilised on concomitant inhaled salmeterol xinafoate and fluticasone propionate | | | | | | | |
| | **Restricted benefit**<br>Patients who previously had frequent episodes of asthma while receiving treatment with optimal doses of inhaled corticosteroids and who have been stabilised on concomitant inhaled salmeterol xinafoate and fluticasone propionate | | | | | | | |
| | **Restricted benefit**<br>Symptomatic treatment of chronic obstructive pulmonary disease (COPD), where the FEV1 is less than 50% predicted normal and there is a history of repeated exacerbations with significant symptoms despite regular beta-2 agonist bronchodilator therapy | | | | | | | |
| | **Note**<br>Seretide is not indicated for the initiation of bronchodilator therapy in COPD. | | | | | | | |
| 8519J<br>*NP* | fluticasone propionate 250 microgram/actuation + salmeterol 25 microgram/actuation inhalation: pressurised, 120 actuations | ‡1 | 5 | .. | 78.65 | 36.10 | Seretide MDI 250/25 | GK |
| 8432T<br>*NP* | fluticasone propionate 500 microgram/actuation + salmeterol 50 microgram/actuation inhalation: powder for, 60 actuations | ‡1 | 5 | .. | 78.65 | 36.10 | Seretide Accuhaler 500/50 | GK |

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|
| | **OTHER DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, INHALANTS** | | | | | | | |
| | ***Glucocorticoids*** | | | | | | | |
| | **BECLOMETHASONE** | | | | | | | |
| | **Restricted benefit** | | | | | | | |
| | Patients unable to achieve co-ordinated use of other metered dose inhalers containing this drug | | | | | | | |
| 8409N *NP* | BECLOMETHASONE DIPROPIONATE Oral pressurised inhalation in breath actuated device 100 micrograms per dose (200 doses), CFC-free formulation, 1 | ‡1 | 5 | .. | 39.34 | 36.10 | Qvar 100 Autohaler | IA |
| 8408M *NP* | BECLOMETHASONE DIPROPIONATE Oral pressurised inhalation in breath actuated device 50 micrograms per dose (200 doses), CFC-free formulation, 1 | ‡1 | 5 | .. | 28.08 | 29.21 | Qvar 50 Autohaler | IA |
| | **BECLOMETHASONE** | | | | | | | |
| 8407L *NP* | beclomethasone dipropionate 100 microgram/actuation inhalation: pressurised, 200 actuations | ‡1 | 5 | .. | 33.67 | 34.80 | Qvar 100 | IA |
| 8406K *NP* | beclomethasone dipropionate 50 microgram/actuation inhalation: pressurised, 200 actuations | ‡1 | 5 | .. | 19.50 | 20.63 | Qvar 50 | IA |
| | **BUDESONIDE** | | | | | | | |
| | **Authority required (STREAMLINED)** | | | | | | | |
| | ***1351*** | | | | | | | |
| | Severe chronic asthma in patients who require long-term steroid therapy and who are unable to use other forms of inhaled steroid therapy | | | | | | | |
| 2066R *NP* | budesonide 1 mg/2 mL inhalation: solution, 30 x 2 mL ampoules | ‡1 | 5 | .. | 49.21 | 36.10 | Pulmicort Respules | AP |
| 2065Q *NP* | budesonide 500 microgram/2 mL inhalation: solution, 30 x 2 mL ampoules | ‡1 | 5 | .. | 38.07 | 36.10 | Pulmicort Respules | AP |
| | **BUDESONIDE** | | | | | | | |
| 2070Y *NP* | budesonide 100 microgram/actuation inhalation: powder for, 200 actuations | ‡1 | 5 | .. | 23.55 | 24.68 | Pulmicort Turbuhaler | AP |
| 2071B *NP* | budesonide 200 microgram/actuation inhalation: powder for, 200 actuations | ‡1 | 5 | .. | 31.29 | 32.42 | Pulmicort Turbuhaler | AP |
| 2072C *NP* | budesonide 400 microgram/actuation inhalation: powder for, 200 actuations | ‡1 | 5 | .. | 46.05 | 36.10 | Pulmicort Turbuhaler | AP |
| | **CICLESONIDE** | | | | | | | |
| 8854B *NP* | ciclesonide 160 microgram/actuation inhalation: pressurised, 120 actuations | ‡1 | 5 | .. | 42.46 | 36.10 | Alvesco 160 | NQ |
| 8853Y *NP* | ciclesonide 80 microgram/actuation inhalation: pressurised, 120 actuations | ‡1 | 5 | .. | 26.36 | 27.49 | Alvesco 80 | NQ |
| | **FLUTICASONE** | | | | | | | |
| 8147T *NP* | fluticasone propionate 100 microgram/actuation inhalation: powder for, 60 actuations | ‡1 | 5 | .. | 17.30 | 18.43 | Flixotide Junior Accuhaler | GK |
| 8345F *NP* | fluticasone propionate 125 microgram/actuation inhalation: pressurised, 120 actuations | ‡1 | 5 | .. | 30.87 | 32.00 | Flixotide | GK |
| 8148W *NP* | fluticasone propionate 250 microgram/actuation inhalation: powder for, 60 actuations | ‡1 | 5 | .. | 30.87 | 32.00 | Flixotide Accuhaler | GK |
| 8346G *NP* | fluticasone propionate 250 microgram/actuation inhalation: pressurised, 120 actuations | ‡1 | 1 | .. | 49.93 | 36.10 | Flixotide | GK |
| 8516F *NP* | fluticasone propionate 50 microgram/actuation inhalation: pressurised, 120 actuations | ‡1 | 5 | .. | 17.30 | 18.43 | Flixotide Junior | GK |
| 8149X *NP* | fluticasone propionate 500 microgram/actuation inhalation: powder for, 60 actuations | ‡1 | 1 | .. | 49.93 | 36.10 | Flixotide Accuhaler | GK |
| | ***Anticholinergics*** | | | | | | | |

# RESPIRATORY SYSTEM

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|---|
| | **IPRATROPIUM** | | | | | | | | |
| 8671J *NP* | ipratropium bromide 20 microgram/actuation inhalation: pressurised, 200 actuations | 2 | 5 | .. | *34.05 | 35.18 | | Atrovent | BY |
| | **IPRATROPIUM** | | | | | | | | |
| | **Restricted benefit** | | | | | | | | |
| | Asthma in patients unable to use this drug delivered from an oral pressurised inhalation device via a spacer | | | | | | | | |
| | **Restricted benefit** | | | | | | | | |
| | Chronic obstructive pulmonary disease in patients unable to use this drug delivered from an oral pressurised inhalation device via a spacer | | | | | | | | |
| 1542E *NP* | ipratropium bromide 250 microgram/mL inhalation: solution, 30 x 1 mL ampoules | 2 | 5 | .. | *30.97 | 32.10 | [a] | Aeron 250 | QA |
| | | | | | | | [a] | APO-Ipratropium | TX |
| | | | | | | | [a] | Ipratrin | AF |
| | | | | | | | [a] | Ipravent | PF |
| | | | | [B]0.54 | *31.51 | 32.10 | [a] | Atrovent | BY |
| 8238N *NP* | ipratropium bromide 500 microgram/mL inhalation: solution, 30 x 1 mL ampoules | 2 | 5 | .. | *35.39 | 36.10 | [a] | Aeron 500 | QA |
| | | | | | | | [a] | APO-Ipratropium | TX |
| | | | | | | | [a] | Ipratrin Adult | AF |
| | | | | | | | [a] | Ipravent | PF |
| | | | | [B]0.54 | *35.93 | 36.10 | [a] | Atrovent Adult | BY |
| | **TIOTROPIUM** | | | | | | | | |
| | **Restricted benefit** | | | | | | | | |
| | Chronic obstructive pulmonary disease | | | | | | | | |
| 8626B *NP* | tiotropium 18 microgram inhalation: powder for, 30 capsules | 1 | 5 | .. | 73.65 | 36.10 | | Spiriva | BY |

## *Antiallergic agents, excl. corticosteroids*

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | **CROMOGLYCATE** | | | | | | | | |
| 8767K *NP* | cromoglycate sodium 1 mg/actuation inhalation: pressurised, 200 actuations | ‡1 | 5 | .. | 30.50 | 31.63 | | Intal CFC-Free | SW |
| 2878L *NP* | cromoglycate sodium 20 mg inhalation: powder for, 100 capsules | 1 | 5 | .. | 31.62 | 32.75 | | Intal Spincaps | GM |
| 8334P *NP* | cromoglycate sodium 5 mg/actuation inhalation: pressurised, 112 actuations | ‡1 | 5 | .. | 36.05 | 36.10 | | Intal Forte CFC-Free | SW |
| | **NEDOCROMIL** | | | | | | | | |
| 8365G *NP* | nedocromil sodium 2 mg/actuation inhalation: pressurised, 112 actuations | ‡1 | 5 | .. | 37.90 | 36.10 | | Tilade CFC-Free | SW |

# ADRENERGICS FOR SYSTEMIC USE

## *Alpha- and beta-adrenoreceptor agonists*

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | **ADRENALINE** | | | | | | | | |
| 1016L *NP* | adrenaline 1 in 1000 (1 mg/mL) injection, 5 x 1 mL ampoules | 1 | 1 | .. | 20.55 | 21.68 | | Link Medical Products Pty Ltd | LM |
| 5004J *DP* | adrenaline 1 in 1000 (1 mg/mL) injection, 5 x 1 mL ampoules | 1 | .. | .. | 20.55 | 21.68 | | Link Medical Products Pty Ltd | LM |
| | **ADRENALINE** | | | | | | | | |
| | **Authority required** | | | | | | | | |
| | Initial sole PBS-subsidised supply for anticipated emergency treatment of acute allergic reactions with anaphylaxis in a patient who has been assessed to be at significant risk of anaphylaxis by, or in consultation with, a clinical immunologist, allergist, paediatrician or respiratory physician. The name of the specialist consulted must be provided at the time of application for initial supply | | | | | | | | |
| | **Authority required** | | | | | | | | |
| | Initial sole PBS-subsidised supply for anticipated emergency treatment of acute allergic reactions with anaphylaxis in a patient who has been discharged from hospital or an emergency department after treatment with adrenaline for acute allergic reaction with anaphylaxis | | | | | | | | |
| | **Authority required** | | | | | | | | |
| | Continuing sole PBS-subsidised supply for anticipated emergency treatment of acute allergic reactions with anaphylaxis, where the patient has previously been issued with an authority prescription for this drug | | | | | | | | |
| | **Caution** | | | | | | | | |
| | EpiPen and Anapen products have different administration techniques and should not be prescribed to the same patient without training in their | | | | | | | | |

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|
| | use. | | | | | | | |
| | **Note**<br>The auto-injector should be provided in the framework of a comprehensive anaphylaxis prevention program and an emergency action plan including training in recognition of the symptoms of anaphylaxis and the use of the auto-injector device. (For further information see the Australasian Society of Clinical Immunology and Allergy website at www.allergy.org.au.) | | | | | | | |
| | **Note**<br>Authority approvals will be limited to a maximum quantity of 2 auto-injectors (Anapen or EpiPen) at any one time.<br>No repeats will be issued. | | | | | | | |
| 3408J<br>*NP* | adrenaline 150 microgram/0.3 mL injection, 1 x 0.3 mL syringe | 1 | .. | .. | 106.21 | 36.10 | Anapen Junior | LM |
| 8697R<br>*NP* | adrenaline 150 microgram/0.3 mL injection, 1 x 0.3 mL syringe | 1 | .. | .. | 106.21 | 36.10 | EpiPen Jr. | AL |
| 3409K<br>*NP* | adrenaline 300 microgram/0.3 mL injection, 1 x 0.3 mL syringe | 1 | .. | .. | 106.21 | 36.10 | Anapen | LM |
| 8698T<br>*NP* | adrenaline 300 microgram/0.3 mL injection, 1 x 0.3 mL syringe | 1 | .. | .. | 106.21 | 36.10 | EpiPen | AL |
| | ***Selective beta-2-adrenoreceptor agonists*** | | | | | | | |
| | **SALBUTAMOL** | | | | | | | |
| 1103C<br>*NP* | salbutamol 2 mg/5 mL oral liquid, 150 mL | 2 | 5 | .. | *22.41 | 23.54 | Ventolin | GK |
| | **TERBUTALINE** | | | | | | | |
| 1034K<br>*NP* | terbutaline sulfate 500 microgram/mL injection, 5 x 1 mL ampoules | 1 | .. | .. | 30.80 | 31.93 | Bricanyl | AP |
| | **OTHER SYSTEMIC DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES** | | | | | | | |
| | ***Xanthines*** | | | | | | | |
| | **THEOPHYLLINE** | | | | | | | |
| | **Caution**<br>Because of variable effects of food on absorption of sustained release theophylline preparations, patients stabilised on one brand should not be changed to another without appropriate monitoring. | | | | | | | |
| | **Note**<br>Continuing Therapy Only:<br>For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners. | | | | | | | |
| 2614N<br>*NP* | theophylline 133.3 mg/25 mL oral liquid, 500 mL | ‡1 | 5 | .. | 12.52 | 13.65 | Nuelin | IA |
| 8230E<br>*NP* | theophylline 200 mg tablet: modified release, 100 tablets | 1 | 5 | .. | 12.37 | 13.50 | Nuelin-SR 200 | IA |
| 2634P<br>*NP* | theophylline 250 mg tablet: modified release, 100 tablets | 1 | 5 | .. | 13.53 | 14.66 | Nuelin-SR 250 | IA |
| 8231F<br>*NP* | theophylline 300 mg tablet: modified release, 100 tablets | 1 | 5 | .. | 14.91 | 16.04 | Nuelin-SR 300 | IA |
| | ***Leukotriene receptor antagonists*** | | | | | | | |
| | **MONTELUKAST**<br>**Authority required (STREAMLINED)**<br>***2617***<br>First-line preventer medication, as the single preventer agent for children aged 2 to 5 years with frequent intermittent or mild persistent asthma, as an alternative to sodium cromoglycate or nedocromil sodium | | | | | | | |
| | **Note**<br>Montelukast sodium is not PBS-subsidised for use in a child aged 2 to 5 years with moderate to severe asthma. It is not intended as an alternative for a child aged 2 to 5 years who requires a corticosteroid as a preventer medication.<br>Montelukast sodium is not subsidised in a child aged 2 to 5 years for use in combination with other preventer medications. PBS subsidy for montelukast sodium will therefore cease for a child aged 2 to 5 years who requires a preventer medication in addition to montelukast sodium. | | | | | | | |
| | **Note**<br>No applications for increased maximum quantities and/or repeats will be authorised. | | | | | | | |
| 8627C<br>*NP* | montelukast 4 mg tablet: chewable, 28 | 1 | 5 | .. | 42.21 | 36.10 | [a] APO-Montelukast | TX |
| | | | | | | | [a] Chemmart Montelukast | CH |
| | | | | | | | [a] Lukair | FR |
| | | | | | | | [a] Montair 4 | GM |
| | | | | | | | [a] Montelukast GH | GQ |

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | [a] | Montelukast RBX | RA |
| | | | | | | | [a] | Montelukast Sandoz 4 | SZ |
| | | | | | | | [a] | Respikast 4 | QA |
| | | | | | | | [a] | Singulair | MK |
| | | | | | | | [a] | Terry White Chemists Montelukast | TW |
| | **MONTELUKAST**<br>**Authority required (STREAMLINED)**<br>***2618***<br>First-line preventer medication, as the single preventer agent for children aged 6 to 14 years with frequent intermittent or mild persistent asthma, as an alternative to sodium cromoglycate or nedocromil sodium<br>**Authority required (STREAMLINED)**<br>***3217***<br>Prevention of exercise-induced asthma, as an alternative to adding salmeterol xinafoate or eformoterol fumarate, in a child aged 6 to 14 years whose asthma is otherwise well controlled while receiving optimal dose inhaled corticosteroid, but who requires short-acting beta-2 agonist 3 or more times per week for prevention or relief of residual exercise-related symptoms<br>**Note**<br>Montelukast sodium is not PBS-subsidised for use in a patient aged 15 years or older, or for use in addition to a long-acting beta-agonist in any age group, or for use as a single second line preventer, as an alternative to corticosteroids, in a child aged 6 to 14 years with moderate to severe asthma.<br>**Note**<br>No applications for increased maximum quantities and/or repeats will be authorised. | | | | | | | | | |
| 8628D<br>*NP* | montelukast 5 mg tablet: chewable, 28 | 1 | 5 | .. | 40.23 | 36.10 | [a] | APO-Montelukast | TX |
| | | | | | | | [a] | Chemmart Montelukast | CH |
| | | | | | | | [a] | Lukair | FR |
| | | | | | | | [a] | Montair 5 | GM |
| | | | | | | | [a] | Montelukast GH | GQ |
| | | | | | | | [a] | Montelukast RBX | RA |
| | | | | | | | [a] | Montelukast Sandoz 5 | SZ |
| | | | | | | | [a] | Respikast 5 | QA |
| | | | | | | | [a] | Singulair | MK |
| | | | | | | | [a] | Terry White Chemists Montelukast | TW |

## COUGH AND COLD PREPARATIONS

### COUGH SUPPRESSANTS, EXCL. COMBINATIONS WITH EXPECTORANTS

#### *Opium alkaloids and derivatives*

**CODEINE**

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 1214X<br>*NP* | codeine phosphate 30 mg tablet, 20 | 1 | .. | .. | 17.08 | 18.21 | Fawns and McAllan Proprietary Limited | FM |

## ANTIHISTAMINES FOR SYSTEMIC USE

### ANTIHISTAMINES FOR SYSTEMIC USE

#### *Phenothiazine derivatives*

**PROMETHAZINE**

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 1948M<br>*NP* | promethazine hydrochloride 50 mg/2 mL injection, 5 x 2 mL ampoules | 2 | .. | .. | *30.45 | 31.58 | Hospira Pty Limited | HH |

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|---|

# SENSORY ORGANS

## OPHTHALMOLOGICALS

### ANTIINFECTIVES

#### *Antibiotics*

**AZITHROMYCIN**

**Restricted benefit**

Trachoma

**Note**

No applications for increased maximum quantities and/or repeats will be authorised.

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 8201P *NP* | azithromycin 200 mg/5 mL oral liquid: powder for, 15 mL | ǂ1 | .. | .. | #21.39 | 22.87 | | Zithromax | PF |
| 8336R *NP* | azithromycin 500 mg tablet, 2 | 1 | 2 | .. | 21.30 | 22.43 | [a] | APO-Azithromycin | TX |
| | | | | | | | [a] | Azithromycin Sandoz | SZ |
| | | | | | | | [a] | Chem mart Azithromycin | CH |
| | | | | | | | [a] | Terry White Chemists Azithromycin | TW |
| | | | | | | | [a] | Zithromax | PF |
| | | | | | | | [a] | Zitrocin | GM |

**CHLORAMPHENICOL**

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 2360F *NP,MW* | chloramphenicol 0.5% eye drops, 10 mL | ǂ1 | 2 | .. | 11.21 | 12.34 | | Chloromycetin | PF |
| | | | | | | | | Chlorsig | QA |
| 5055C *DP* | chloramphenicol 0.5% eye drops, 10 mL | ǂ1 | .. | .. | 11.21 | 12.34 | | Chloromycetin | PF |
| | | | | | | | | Chlorsig | QA |
| 5512D *OP* | chloramphenicol 0.5% eye drops, 10 mL | ǂ1 | 2 | .. | 11.21 | 12.34 | | Chloromycetin | PF |
| | | | | | | | | Chlorsig | QA |
| 1171P *NP,MW* | chloramphenicol 1% (10 mg/g) eye ointment, 4 g | ǂ1 | .. | .. | 9.97 | 11.10 | | Chloromycetin | PF |
| | | | | | | | | Chlorsig | QA |
| 5511C *OP* | chloramphenicol 1% (10 mg/g) eye ointment, 4 g | ǂ1 | .. | .. | 9.97 | 11.10 | | Chloromycetin | PF |
| | | | | | | | | Chlorsig | QA |

**GENTAMICIN**

**Restricted benefit**

Invasive ocular infection

**Restricted benefit**

Perioperative use in ophthalmic surgery

**Restricted benefit**

Suspected pseudomonal eye infection

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 1441W | gentamicin 0.3% eye drops, 5 mL | ǂ1 | 2 | .. | 18.50 | 19.63 | | Genoptic | AG |

**GENTAMICIN**

**Restricted benefit**

Perioperative use in ophthalmic surgery

**Restricted benefit**

Suspected pseudomonal eye infection

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 5566Y *OP* | gentamicin 0.3% eye drops, 5 mL | ǂ1 | 2 | .. | 18.50 | 19.63 | | Genoptic | AG |

**TOBRAMYCIN**

**Restricted benefit**

Invasive ocular infection

**Restricted benefit**

Perioperative use in ophthalmic surgery

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|---|
| | **Restricted benefit**<br>Suspected pseudomonal eye infection | | | | | | | | |
| 2329N | tobramycin 0.3% (3 mg/g) eye ointment, 3.5 g | ‡1 | .. | .. | 22.59 | 23.72 | | Tobrex | AQ |
| 2328M | tobramycin 0.3% (3 mg/mL) eye drops, 5 mL | ‡1 | 2 | .. | 19.49 | 20.62 | | Tobrex | AQ |
| | **TOBRAMYCIN**<br>**Restricted benefit**<br>Perioperative use in ophthalmic surgery | | | | | | | | |
| | **Restricted benefit**<br>Suspected pseudomonal eye infection | | | | | | | | |
| 5570E<br>*OP* | tobramycin 0.3% (3 mg/g) eye ointment, 3.5 g | ‡1 | .. | .. | 22.59 | 23.72 | | Tobrex | AQ |
| 5569D<br>*OP* | tobramycin 0.3% (3 mg/mL) eye drops, 5 mL | ‡1 | 2 | .. | 19.49 | 20.62 | | Tobrex | AQ |

## *Antivirals*

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | **ACICLOVIR**<br>**Restricted benefit**<br>Herpes simplex keratitis<br>**Note**<br>Shared Care Model:<br>For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners. | | | | | | | | |
| 1002R<br>*NP* | aciclovir 3% (30 mg/g) eye ointment, 4.5 g | ‡1 | .. | .. | 37.67 | 36.10 | | Zovirax | GK |
| | **ACICLOVIR**<br>**Restricted benefit**<br>Herpes simplex keratitis | | | | | | | | |
| 5501M<br>*OP* | aciclovir 3% (30 mg/g) eye ointment, 4.5 g | ‡1 | .. | .. | 37.67 | 36.10 | | Zovirax | GK |

## *Other antiinfectives*

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | **CIPROFLOXACIN**<br>**Authority required**<br>Bacterial keratitis<br>**The Treatment criteria is:**<br>Must be treated by an ophthalmologist or in consultation with an ophthalmologist. | | | | | | | | |
| 1217C | ciprofloxacin 0.3% eye drops, 5 mL | 2 | .. | .. | *28.69 | 29.82 | [a] | CiloQuin | IQ |
| | | | | [B]2.06 | *30.75 | 29.82 | [a] | Ciloxan | AQ |
| | **CIPROFLOXACIN**<br>**Authority required**<br>Bacterial keratitis<br>**The Treatment criteria is:**<br>Must be treated by an ophthalmologist or in consultation with an ophthalmologist. | | | | | | | | |
| 5564W<br>*OP* | ciprofloxacin 0.3% eye drops, 5 mL | 2 | .. | .. | *28.69 | 29.82 | [a] | CiloQuin | IQ |
| | | | | [B]2.06 | *30.75 | 29.82 | [a] | Ciloxan | AQ |
| | **OFLOXACIN**<br>**Authority required**<br>Bacterial keratitis<br>**The Treatment criteria is:**<br>Must be treated by an ophthalmologist or in consultation with an ophthalmologist. | | | | | | | | |
| 5567B<br>*OP* | ofloxacin 0.3% (3 mg/mL) eye drops, 5 mL | 2 | .. | .. | *32.35 | 33.48 | | Ocuflox | AG |
| | **OFLOXACIN**<br>**Authority required** | | | | | | | | |

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|
| | Bacterial keratitis | | | | | | | |
| | **The Treatment criteria is:** | | | | | | | |
| | Must be treated by an ophthalmologist or in consultation with an ophthalmologist. | | | | | | | |
| 8383F | ofloxacin 0.3% (3 mg/mL) eye drops, 5 mL | 2 | .. | .. | *32.35 | 33.48 | Ocuflox | AG |

## ANTIINFLAMMATORY AGENTS

### *Corticosteroids, plain*

**DEXAMETHASONE**

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 1288T *NP* | DEXAMETHASONE Eye drops 1 mg per mL (0.1%), 5 mL, 1 | ‡1 | 2 | .. | 10.82 | 11.95 | Maxidex | AQ |

**DEXAMETHASONE**

**Note**

No applications for increased maximum quantities and/or repeats will be authorised.

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 5565X *OP* | DEXAMETHASONE Eye drops 1 mg per mL (0.1%), 5 mL, 1 | ‡1 | .. | .. | 10.82 | 11.95 | Maxidex | AQ |

**FLUOROMETHOLONE**

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 1204J *NP* | fluorometholone 0.1% eye drops, 5 mL | ‡1 | 5 | .. | 10.82 | 11.95 | Flucon | AQ |
| | | | | | | | FML Liquifilm | AG |

**FLUOROMETHOLONE**

**Note**

No applications for increased maximum quantities and/or repeats will be authorised.

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 5513E *OP* | fluorometholone 0.1% eye drops, 5 mL | ‡1 | .. | .. | 10.82 | 11.95 | Flucon | AQ |
| | | | | | | | FML Liquifilm | AG |

**FLUOROMETHOLONE ACETATE**

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 1438Q *NP* | fluorometholone acetate 0.1% eye drops, 5 mL | ‡1 | 2 | .. | 10.82 | 11.95 | Flarex | AQ |

**FLUOROMETHOLONE ACETATE**

**Note**

No applications for increased maximum quantities and/or repeats will be authorised.

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 5533F *OP* | fluorometholone acetate 0.1% eye drops, 5 mL | ‡1 | .. | .. | 10.82 | 11.95 | Flarex | AQ |

**HYDROCORTISONE ACETATE**

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 2441L *NP* | hydrocortisone acetate 1% (10 mg/g) eye ointment, 5 g | ‡1 | .. | .. | 12.90 | 14.03 | Hycor | QA |

**HYDROCORTISONE ACETATE**

**Note**

No applications for increased maximum quantities and/or repeats will be authorised.

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 5516H *OP* | hydrocortisone acetate 1% (10 mg/g) eye ointment, 5 g | ‡1 | .. | .. | 12.90 | 14.03 | Hycor | QA |

### *Corticosteroids and mydriatics in combination*

**PHENYLEPHRINE + PREDNISOLONE ACETATE**

**Restricted benefit**

Corneal grafts

**Restricted benefit**

Uveitis

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 3112T *NP* | phenylephrine hydrochloride 0.12% + prednisolone acetate 1% eye drops, 10 mL | ‡1 | 2 | .. | 23.94 | 25.07 | Prednefrin Forte | AG |

**PHENYLEPHRINE + PREDNISOLONE ACETATE**

**Restricted benefit**

Uveitis

**Note**

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|---|
| | No applications for increased maximum quantities and/or repeats will be authorised. | | | | | | | | |
| 5568C *OP* | phenylephrine hydrochloride 0.12% + prednisolone acetate 1% eye drops, 10 mL | ‡1 | .. | .. | 23.94 | 25.07 | | Prednefrin Forte | AG |

## *Antiinflammatory agents, non-steroids*

**FLURBIPROFEN**

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 5514F *OP* | flurbiprofen sodium 0.03% (120 microgram/0.4 mL) eye drops, 5 x 0.4 mL ampoules | 1 | .. | .. | 17.03 | 18.16 | | Ocufen | AG |
| 8699W *NP* | flurbiprofen sodium 0.03% (120 microgram/0.4 mL) eye drops, 5 x 0.4 mL ampoules | 1 | .. | .. | 17.03 | 18.16 | | Ocufen | AG |

# ANTIGLAUCOMA PREPARATIONS AND MIOTICS

## *Sympathomimetics in glaucoma therapy1)*

**APRACLONIDINE**

**Restricted benefit**

Short-term reduction of intra-ocular pressure in patients already on maximally tolerated anti-glaucoma therapy

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 8083K | apraclonidine 0.5% eye drops, 10 mL | ‡1 | 2 | .. | 41.98 | 36.10 | | Iopidine 0.5% | AQ |

**BRIMONIDINE**

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 5298W | brimonidine tartrate 0.15% eye drops, 5 mL | ‡1 | 5 | .. | 20.35 | 21.48 | | Alphagan P 1.5 | AG |
| 5563T *OP* | brimonidine tartrate 0.15% eye drops, 5 mL | ‡1 | 5 | .. | 20.35 | 21.48 | | Alphagan P 1.5 | AG |
| 5534G *OP* | brimonidine tartrate 0.2% eye drops, 5 mL | ‡1 | 5 | .. | 20.35 | 21.48 | [a] | Enidin | PE |
| | | | | [B]1.63 | 21.98 | 21.48 | [a] | Alphagan | AG |
| 8351M | brimonidine tartrate 0.2% eye drops, 5 mL | ‡1 | 5 | .. | 20.35 | 21.48 | [a] | Enidin | PE |
| | | | | [B]1.63 | 21.98 | 21.48 | [a] | Alphagan | AG |

**BRIMONIDINE + TIMOLOL**

**Restricted benefit**

Reduction of elevated intra-ocular pressure in a patient with open-angle glaucoma that is not adequately controlled with monotherapy

**Restricted benefit**

Reduction of elevated intra-ocular pressure in a patient with ocular hypertension that is not adequately controlled with monotherapy

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 5535H *OP* | brimonidine tartrate 0.2% + timolol 0.5% eye drops, 5 mL | ‡1 | 5 | .. | 26.24 | 27.37 | | Combigan | AG |
| 8826M | brimonidine tartrate 0.2% + timolol 0.5% eye drops, 5 mL | ‡1 | 5 | .. | 26.24 | 27.37 | | Combigan | AG |

## *Parasympathomimetics*

**PILOCARPINE**

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 2595N | pilocarpine hydrochloride 1% eye drops, 15 mL | ‡1 | 5 | .. | 12.74 | 13.87 | | Isopto Carpine | AQ |
| 5536J *OP* | pilocarpine hydrochloride 1% eye drops, 15 mL | ‡1 | 5 | .. | 12.74 | 13.87 | | Isopto Carpine | AQ |
| 2596P | pilocarpine hydrochloride 2% eye drops, 15 mL | ‡1 | 5 | .. | 13.99 | 15.12 | | Isopto Carpine | AQ |
| 5537K *OP* | pilocarpine hydrochloride 2% eye drops, 15 mL | ‡1 | 5 | .. | 13.99 | 15.12 | | Isopto Carpine | AQ |
| 2598R | pilocarpine hydrochloride 4% eye drops, 15 mL | ‡1 | 5 | .. | 16.84 | 17.97 | | Isopto Carpine | AQ |
| 5538L *OP* | pilocarpine hydrochloride 4% eye drops, 15 mL | ‡1 | 5 | .. | 16.84 | 17.97 | | Isopto Carpine | AQ |

## *Carbonic anhydrase inhibitors*

**ACETAZOLAMIDE**

**Note**

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 1004W *NP* | acetazolamide 250 mg tablet, 100 | 1 | 3 | .. | 24.00 | 25.13 | | Diamox | QA |

# SENSORY ORGANS

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|---|
| | **BRINZOLAMIDE** | | | | | | | | |
| 5540N *OP* | brinzolamide 1% (10 mg/mL) eye drops, 5 mL | ‡1 | 5 | .. | 22.98 | 24.11 | a | BrinzoQuin | IQ |
| | | | | B1.18 | 24.16 | 24.11 | a | Azopt | AQ |
| 8483L | brinzolamide 1% (10 mg/mL) eye drops, 5 mL | ‡1 | 5 | .. | 22.98 | 24.11 | a | BrinzoQuin | IQ |
| | | | | B1.18 | 24.16 | 24.11 | a | Azopt | AQ |
| | **BRINZOLAMIDE + TIMOLOL** | | | | | | | | |
| | **Restricted benefit** | | | | | | | | |
| | Reduction of elevated intra-ocular pressure in a patient with open-angle glaucoma that is not adequately controlled with monotherapy | | | | | | | | |
| | **Restricted benefit** | | | | | | | | |
| | Reduction of elevated intra-ocular pressure in a patient with ocular hypertension that is not adequately controlled with monotherapy | | | | | | | | |
| 3438Y | brinzolamide 1% (10 mg/mL) + timolol 0.5% (5 mg/mL) eye drops, 5 mL | ‡1 | 5 | .. | 27.09 | 28.22 | | Azarga | AQ |
| 5562R *OP* | brinzolamide 1% (10 mg/mL) + timolol 0.5% (5 mg/mL) eye drops, 5 mL | ‡1 | 5 | .. | 27.09 | 28.22 | | Azarga | AQ |
| | **DORZOLAMIDE** | | | | | | | | |
| 5541P *OP* | dorzolamide 2% (20 mg/mL) eye drops, 5 mL | ‡1 | 5 | .. | 21.50 | 22.63 | | Trusopt | MK |
| 8488R | dorzolamide 2% (20 mg/mL) eye drops, 5 mL | ‡1 | 5 | .. | 21.50 | 22.63 | | Trusopt | MK |
| | **DORZOLAMIDE + TIMOLOL** | | | | | | | | |
| | **Restricted benefit** | | | | | | | | |
| | Reduction of elevated intra-ocular pressure in a patient with open-angle glaucoma that is not adequately controlled with monotherapy | | | | | | | | |
| | **Restricted benefit** | | | | | | | | |
| | Reduction of elevated intra-ocular pressure in a patient with ocular hypertension that is not adequately controlled with monotherapy | | | | | | | | |
| 5542Q *OP* | dorzolamide 2% + timolol 0.5% eye drops, 5 mL | ‡1 | 5 | .. | 27.39 | 28.52 | | Cosopt | MK |
| 8567X | dorzolamide 2% + timolol 0.5% eye drops, 5 mL | ‡1 | 5 | .. | 27.39 | 28.52 | | Cosopt | MK |

## *Beta blocking agents1)*

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | **BETAXOLOL** | | | | | | | | |
| 2811Y | betaxolol 0.25% eye drops, 5 mL | ‡1 | 5 | .. | 14.98 | 16.11 | | Betoptic S | AQ |
| 5543R *OP* | betaxolol 0.25% eye drops, 5 mL | ‡1 | 5 | .. | 14.98 | 16.11 | | Betoptic S | AQ |
| 2825Q | betaxolol 0.5% eye drops, 5 mL | ‡1 | 5 | .. | 14.98 | 16.11 | a | BetoQuin | IQ |
| | | | | B2.08 | 17.06 | 16.11 | a | Betoptic | AQ |
| 5544T *OP* | betaxolol 0.5% eye drops, 5 mL | ‡1 | 5 | .. | 14.98 | 16.11 | a | BetoQuin | IQ |
| | | | | B2.08 | 17.06 | 16.11 | a | Betoptic | AQ |
| | **TIMOLOL** | | | | | | | | |
| 5546X *OP* | timolol 0.1% (1 mg/g) eye gel, 5 g | ‡1 | 5 | .. | 13.08 | 14.21 | | Nyogel | NV |
| 8803H | timolol 0.1% (1 mg/g) eye gel, 5 g | ‡1 | 5 | .. | 13.08 | 14.21 | | Nyogel | NV |
| 1925H | timolol 0.25% (2.5 mg/mL) eye drops, 2.5 mL | ‡1 | 5 | .. | 11.75 | 12.88 | | Timoptol XE | MK |
| 5549C *OP* | timolol 0.25% (2.5 mg/mL) eye drops, 2.5 mL | ‡1 | 5 | .. | 11.75 | 12.88 | | Timoptol XE | MK |
| 1278G | timolol 0.25% (2.5 mg/mL) eye drops, 5 mL | ‡1 | 5 | .. | 11.75 | 12.88 | | Tenopt | QA |
| 5547Y *OP* | timolol 0.25% (2.5 mg/mL) eye drops, 5 mL | ‡1 | 5 | .. | 11.75 | 12.88 | | Tenopt | QA |
| 1926J | timolol 0.5% (5 mg/mL) eye drops, 2.5 mL | ‡1 | 5 | .. | 12.52 | 13.65 | | Timoptol XE | MK |
| 5550D *OP* | timolol 0.5% (5 mg/mL) eye drops, 2.5 mL | ‡1 | 5 | .. | 12.52 | 13.65 | | Timoptol XE | MK |
| 1279H | timolol 0.5% (5 mg/mL) eye drops, 5 mL | ‡1 | 5 | .. | 12.52 | 13.65 | a | Tenopt | QA |
| | | | | B3.03 | 15.55 | 13.65 | a | Timoptol | FR |
| 5548B *OP* | timolol 0.5% (5 mg/mL) eye drops, 5 mL | ‡1 | 5 | .. | 12.52 | 13.65 | a | Tenopt | QA |
| | | | | B3.03 | 15.55 | 13.65 | a | Timoptol | FR |

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|---|
| | ***Prostaglandin analogues1)*** | | | | | | | | |
| | **BIMATOPROST** | | | | | | | | |
| 5551E<br>*OP* | bimatoprost 0.03% eye drops, 3 mL | ‡1 | 5 | .. | 42.35 | 36.10 | | Lumigan | AG |
| 8620Q | bimatoprost 0.03% eye drops, 3 mL | ‡1 | 5 | .. | 42.35 | 36.10 | | Lumigan | AG |
| | **BIMATOPROST + TIMOLOL**<br>**Restricted benefit**<br>Reduction of elevated intra-ocular pressure in a patient with open-angle glaucoma that is not adequately controlled with monotherapy<br>**Restricted benefit**<br>Reduction of elevated intra-ocular pressure in a patient with ocular hypertension that is not adequately controlled with monotherapy | | | | | | | | |
| 5558M<br>*OP* | bimatoprost 0.03% + timolol 0.5% eye drops, 3 mL | ‡1 | 5 | .. | 46.81 | 36.10 | | Ganfort 0.3/5 | AG |
| 9464D | bimatoprost 0.03% + timolol 0.5% eye drops, 3 mL | ‡1 | 5 | .. | 46.81 | 36.10 | | Ganfort 0.3/5 | AG |
| | **LATANOPROST** | | | | | | | | |
| 5552F<br>*OP* | latanoprost 0.005% eye drops, 2.5 mL | ‡1 | 5 | .. | 36.78 | 36.10 | [a] | APO-Latanoprost | TX |
| | | | | | | | [a] | Chem mart Latanoprost | CH |
| | | | | | | | [a] | Latanoprost Pfizer | FZ |
| | | | | | | | [a] | Latanoprost Sandoz | SZ |
| | | | | | | | [a] | Terry White Chemists Latanoprost | TW |
| | | | | | | | [a] | Xalatan | PF |
| 8243W | latanoprost 0.005% eye drops, 2.5 mL | ‡1 | 5 | .. | 36.78 | 36.10 | [a] | APO-Latanoprost | TX |
| | | | | | | | [a] | Chem mart Latanoprost | CH |
| | | | | | | | [a] | Latanoprost Pfizer | FZ |
| | | | | | | | [a] | Latanoprost Sandoz | SZ |
| | | | | | | | [a] | Terry White Chemists Latanoprost | TW |
| | | | | | | | [a] | Xalatan | PF |
| | **LATANOPROST + TIMOLOL**<br>**Restricted benefit**<br>Reduction of elevated intra-ocular pressure in a patient with open-angle glaucoma that is not adequately controlled with monotherapy<br>**Restricted benefit**<br>Reduction of elevated intra-ocular pressure in a patient with ocular hypertension that is not adequately controlled with monotherapy | | | | | | | | |
| 5553G<br>*OP* | latanoprost 0.005% + timolol 0.5% eye drops, 2.5 mL | ‡1 | 5 | .. | 41.08 | 36.10 | [a] | Latanocom | FZ |
| | | | | | | | [a] | Xalacom | PF |
| 8895E | latanoprost 0.005% + timolol 0.5% eye drops, 2.5 mL | ‡1 | 5 | .. | 41.08 | 36.10 | [a] | Latanocom | FZ |
| | | | | | | | [a] | Xalacom | PF |
| | **TIMOLOL + TRAVOPROST**<br>**Restricted benefit**<br>Reduction of elevated intra-ocular pressure in a patient with open-angle glaucoma that is not adequately controlled with monotherapy<br>**Restricted benefit**<br>Reduction of elevated intra-ocular pressure in a patient with ocular hypertension that is not adequately controlled with monotherapy | | | | | | | | |
| 5555J<br>*OP* | timolol 0.5% + travoprost 0.004% eye drops, 2.5 mL | ‡1 | 5 | .. | 46.81 | 36.10 | | Duotrav | AQ |
| 9057Q | timolol 0.5% + travoprost 0.004% eye drops, 2.5 mL | ‡1 | 5 | .. | 46.81 | 36.10 | | Duotrav | AQ |
| | **TRAVOPROST** | | | | | | | | |
| 5554H<br>*OP* | travoprost 0.004% (40 microgram/mL) eye drops, 2.5 mL | ‡1 | 5 | .. | 42.35 | 36.10 | | Travatan | AQ |
| 8597L | travoprost 0.004% (40 microgram/mL) eye drops, 2.5 mL | ‡1 | 5 | .. | 42.35 | 36.10 | | Travatan | AQ |

## MYDRIATICS AND CYCLOPLEGICS

### *Anticholinergics*

**ATROPINE**

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|---|
| 1093M *NP* | ATROPINE Eye drops containing atropine sulfate 10 mg per mL (1%), 15 mL, 1 | ‡1 | 2 | .. | 21.98 | 23.11 | | Atropt | QA |
| | **HOMATROPINE** | | | | | | | | |
| 2541R *NP* | homatropine hydrobromide 2% eye drops, 15 mL | ‡1 | 2 | .. | 19.02 | 20.15 | | Isopto Homatropine | AQ |

## DECONGESTANTS AND ANTIALLERGICS

### *Other antiallergics*

**CROMOGLYCATE**

**Restricted benefit**

Vernal kerato-conjunctivitis

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 1127H *NP* | cromoglycate sodium 2% (20 mg/mL) eye drops, 10 mL | ‡1 | 5 | .. | 14.42 | 15.55 | [a] | Cromolux | AE |
| | | | | | | | [a] | Opticrom | SW |
| 5529B *OP* | cromoglycate sodium 2% (20 mg/mL) eye drops, 10 mL | ‡1 | 5 | .. | 14.42 | 15.55 | [a] | Cromolux | AE |
| | | | | | | | [a] | Opticrom | SW |

## OCULAR VASCULAR DISORDER AGENTS

### *Antineovascularisation agents*

**AFLIBERCEPT**

**Authority required**

Subfoveal choroidal neovascularisation (CNV)

Treatment Phase: Initial treatment

**The Treatment criteria is:**

Must be treated by a ophthalmologist,

**AND the Clinical criteria is:**

The condition must be due to age-related macular degeneration (AMD),

**AND the Clinical criteria is:**

The condition must be diagnosed by fluorescein angiography,

**AND the Clinical criteria is:**

The treatment must be the sole PBS-subsidised therapy for this condition.

Authority approval for initial treatment of each eye must be sought.

The first authority application for each eye must be made in writing or by telephone.

A written application must include:

a) a completed authority prescription form;

b) a completed Subfoveal Choroidal Neovascularisation (CNV) PBS Supporting Information Form; and

c) a copy of the fluorescein angiogram.

A telephone application must be made following submission by facsimile of a copy of a completed Subfoveal Choroidal Neovascularisation (CNV) - PBS Supporting Information Form and a copy of the fluorescein angiogram. The original documentation must be submitted to the Chief Executive Medicare by post after the application has been authorised.

Where a fluorescein angiogram cannot be performed due to a contraindication as listed in the TGA-approved product information, details of the contraindication must be provided. A copy of the report of an alternative method of diagnosis must be included in the application, for example, optical coherence tomography (OCT) or red free photography.

**Note**

The first authority application may be faxed to the Department of Human Services on 1300 093 177 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). The Department will then contact the prescriber by telephone.

**Note**

Authority approvals will be administered by the Complex Drugs Unit of the Department of Human Services.

**Note**

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|
| | Reply Paid 9826<br>GPO Box 9826<br>HOBART TAS 7001<br>**Note**<br>Special Pricing Arrangements apply.<br>**Authority required**<br>Subfoveal choroidal neovascularisation (CNV)<br>Treatment Phase: Continuing treatment<br>**The Treatment criteria is:**<br>Must be treated by a ophthalmologist,<br>**AND the Clinical criteria is:**<br>The condition must be due to age-related macular degeneration (AMD),<br>**AND the Clinical criteria is:**<br>The treatment must be the sole PBS-subsidised therapy for this condition,<br>**AND the Clinical criteria is:**<br>Patient must have previously been granted an authority prescription for the same eye.<br>**Note**<br>Authority approvals will be administered by the Complex Drugs Unit of the Department of Human Services.<br>**Note**<br>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).<br>**Note**<br>No increase in the maximum number of repeats may be authorised.<br>**Note**<br>Special Pricing Arrangements apply. | | | | | | | |
| 2168D | aflibercept 4 mg/0.1 mL injection, 1 x 0.1 mL vial | 1 | 2 | .. | 1431.37 | 36.10 | Eylea | BN |
| | **RANIBIZUMAB**<br>**Authority required**<br>Initial treatment by an ophthalmologist, as the sole PBS-subsidised therapy, of subfoveal choroidal neovascularisation (CNV) due to age-related macular degeneration (AMD), as diagnosed by fluorescein angiography.<br>Where a fluoroscein angiogram cannot be performed due to a contraindication as listed in the TGA-approved product information, details of the contraindication must be provided. A copy of the report of an alternative method of diagnosis must be included in the application, for example, optical coherence tomography (OCT) or red free photography.<br>Authority approvals will be administered by the PBS and Specialised Drugs Branch of Medicare Australia.<br>The first authority application for each eye must be made in writing, and must include:<br>(a) a completed authority prescription form; and<br>(b) a completed Subfoveal Choroidal Neovascularisation (CNV) - PBS Supporting Information Form [www.medicareaustralia.gov.au]; and<br>(c) a copy of the fluorescein angiogram or alternative method of diagnosis where applicable.<br>Written applications for authority to prescribe ranibizumab should be forwarded to:<br>Medicare Australia<br>Prior Written Approval of Specialised Drugs<br>Reply Paid 9826<br>GPO Box 9826<br>HOBART TAS 7001<br>Alternatively, the first authority application may be faxed to Medicare Australia on 1300 093 177 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Medicare Australia will then contact the prescriber by telephone. The original documentation must be posted to the above address after approval has been gained<br>**Authority required**<br>Continuing treatment by an ophthalmologist, as the sole PBS-subsidised therapy, of subfoveal choroidal neovascularisation (CNV) due to age-related macular degeneration (AMD) where the patient has previously been granted an authority prescription for the same eye.<br>Authority approvals will be administered by the PBS and Specialised Drugs Branch of Medicare Australia. Authority applications for continuing treatment in the same eye may be made by telephone on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday)<br>**Note** | | | | | | | |

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|
| | Special Pricing Arrangements apply. | | | | | | | |
| 1382R | ranibizumab 2.3 mg/0.23 mL injection, 1 x 0.23 mL vial | 1 | 2 | .. | 1431.37 | 36.10 | Lucentis | NV |

**VERTEPORFIN**

**Authority required**

Initial treatment by an ophthalmologist, as the sole PBS-subsidised therapy, of predominantly (greater than or equal to 50%) classic, subfoveal choroidal neovascularisation (CNV) due to age-related macular degeneration (AMD), as diagnosed by fluorescein angiography, in a patient with a baseline visual acuity equal to or better than 6/60 (20/200).

Authority approvals will be administered by the PBS and Specialised Drugs Branch of Medicare Australia.

The first authority application for each eye must be made in writing, and must include:

(a) a completed authority prescription form; and

(b) a completed Subfoveal Choroidal Neovascularisation (CNV) - PBS Supporting Information Form [www.medicareaustralia.gov.au]; and

(c) a copy of the fluorescein angiogram demonstrating that the CNV is predominantly classic (greater than or equal to 50%).

Written applications for authority to prescribe verteporfin should be forwarded to:

Medicare Australia

Prior Written Approval of Specialised Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

Alternatively, the first authority application may be faxed to Medicare Australia on 1300 093 177 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Medicare Australia will then contact the prescriber by telephone. The original documentation must be posted to the above address after approval has been gained.

No more than 15 treatments (1 initial and 14 continuing) per eye will be authorised.

Medicare Australia should be notified if treatment is abandoned prior to completion of the laser activation step but after infusion of verteporfin. Telephone 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). The reason treatment is abandoned must be provided. Where such notification has been made, the treatment so affected will not count towards the maximum

**Authority required**

Initial PBS-subsidised treatment by an ophthalmologist, as the sole PBS-subsidised therapy, of predominantly (greater than or equal to 50%) classic, subfoveal choroidal neovascularisation (CNV) due to macular degeneration where the patient has been authorised by the Angiogram Review Panel to receive treatment with verteporfin in the same eye under the MBS Visudyne Therapy Program.

Authority approvals will be administered by the PBS and Specialised Drugs Branch of Medicare Australia.

The first authority application for each eye must be made in writing, and must include:

(a) a completed authority prescription form; and

(b) a completed Subfoveal Choroidal Neovascularisation (CNV) - PBS Supporting Information Form [www.medicareaustralia.gov.au], which includes the date of review by the Angiogram Review Panel and the number of treatments administered in that eye under the MBS Visudyne Therapy Program; and

(c) a copy of the fluorescein angiogram demonstrating that the CNV is predominantly classic (greater than or equal to 50%).

Written applications for authority to prescribe verteporfin should be forwarded to:

Medicare Australia

Prior Written Approval of Specialised Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

Alternatively, the first authority application may be faxed to Medicare Australia on 1300 093 177 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Medicare Australia will then contact the prescriber by telephone. The original documentation must be posted to the above address after approval has been gained.

A patient is eligible for a total of 15 subsidised treatments per eye. This maximum includes treatments administered under the MBS Visudyne Therapy Program and the PBS.

Medicare Australia should be notified if treatment is abandoned prior to completion of the laser activation step but after infusion of verteporfin. Telephone 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). The reason treatment is abandoned must be provided. Where such notification has been made, the treatment so affected will not count towards the maximum

**Authority required**

Continuing treatment by an ophthalmologist, as the sole PBS-subsidised therapy, of predominantly (greater than or equal to 50%) classic, subfoveal choroidal neovascularisation (CNV) due to macular degeneration where the patient has previously been granted an authority prescription for the same eye.

A patient is eligible for a total of 15 subsidised treatments per eye. This maximum includes treatments administered under the MBS Visudyne

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|
| | Therapy Program and the PBS. | | | | | | | |
| | Medicare Australia should be notified if treatment is abandoned prior to completion of the laser activation step but after infusion of verteporfin. Telephone 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). The reason treatment is abandoned must be provided. Where such notification has been made, the treatment so affected will not count towards the maximum. | | | | | | | |
| | Authority approvals will be administered by the PBS and Specialised Drugs Branch of Medicare Australia. Authority applications for continuing treatment in the same eye may be made by telephone on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) | | | | | | | |
| 1349B | verteporfin 15 mg injection, 1 x 15 mg vial | 1 | .. | .. | 2246.57 | 36.10 | Visudyne | NV |

## OTHER OPHTHALMOLOGICALS

### *Other ophthalmologicals*

**CARBOMER + TRIGLYCERIDE LIPIDS**
**Authority required (STREAMLINED)**
***1359***
Severe dry eye syndrome in patients who are sensitive to preservatives in multi-dose eye drops

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 2058H *NP* | carbomer 0.2% (1.2 mg/600 mg) + triglyceride lipids 1% (6 mg/600 mg) eye gel, 30 x 600 mg unit doses | 3 | 5 | .. | *36.30 | 36.10 | Artelac | BU |

**CARBOMER + TRIGLYCERIDE LIPIDS**
**Authority required**
Severe dry eye syndrome in patients who are sensitive to preservatives in multi-dose eye drops

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 2090B *OP* | carbomer 0.2% (1.2 mg/600 mg) + triglyceride lipids 1% (6 mg/600 mg) eye gel, 30 x 600 mg unit doses | 3 | 5 | .. | *36.30 | 36.10 | Artelac | BU |

**CARBOMER + TRIGLYCERIDE LIPIDS**
**Restricted benefit**
Severe dry eye syndrome, including Sjogren's syndrome

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 2041K *NP* | carbomer 0.2% (2 mg/g) + triglyceride lipids 1% (10 mg/g) eye gel, 10 g | ‡1 | 5 | .. | 10.48 | 11.61 | Artelac | BU |
| 2082N *OP* | carbomer 0.2% (2 mg/g) + triglyceride lipids 1% (10 mg/g) eye gel, 10 g | ‡1 | 5 | .. | 10.48 | 11.61 | Artelac | BU |

**CARBOMER + TRIGLYCERIDE LIPIDS**
**Restricted benefit**
For use in patients who have severe dry eye syndrome, including Sjogren's syndrome, and who are receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements

**Note**
No applications for increased maximum quantities and/or repeats will be authorised.

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 2044N | carbomer 0.2% (2 mg/g) + triglyceride lipids 1% (10 mg/g) eye gel, 10 g | ‡1 | 11 | .. | 10.48 | 11.61 | Artelac | BU |

**CARBOMER-974**
**Authority required**
Severe dry eye syndrome in patients who are sensitive to preservatives in multi-dose eye drops

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 5502N *OP* | carbomer-974 0.3% (1.5 mg/500 mg) eye gel, 30 x 500 mg unit doses | 3 | 5 | .. | *36.27 | 36.10 | Poly Gel | AQ |

**CARBOMER-974**
**Authority required (STREAMLINED)**
***1359***
Severe dry eye syndrome in patients who are sensitive to preservatives in multi-dose eye drops

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 8514D *NP* | carbomer-974 0.3% (1.5 mg/500 mg) eye gel, 30 x 500 mg unit doses | 3 | 5 | .. | *36.27 | 36.10 | Poly Gel | AQ |

**CARBOMER-980**
**Authority required**
Severe dry eye syndrome in patients who are sensitive to preservatives in multi-dose eye drops

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 5504Q *OP* | carbomer-980 0.2% (2 mg/g) eye drops, 30 x 0.6 mL unit doses | 3 | 5 | .. | *36.30 | 36.10 | Viscotears Gel PF | AQ |

**CARBOMER-980**
**Authority required (STREAMLINED)**
***1359***

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|---|
| | Severe dry eye syndrome in patients who are sensitive to preservatives in multi-dose eye drops | | | | | | | | |
| 8578L *NP* | carbomer-980 0.2% (2 mg/g) eye drops, 30 x 0.6 mL unit doses | 3 | 5 | .. | *36.30 | 36.10 | | Viscotears Gel PF | AQ |
| | **CARBOMER-980** | | | | | | | | |
| | **Restricted benefit** | | | | | | | | |
| | Severe dry eye syndrome, including Sjogren's syndrome | | | | | | | | |
| 5503P *OP* | carbomer-980 0.2% (2 mg/g) eye gel, 10 g | ‡1 | 5 | .. | 10.48 | 11.61 | | GelTears | BU |
| | | | | | | | [a] | PAA | IQ |
| | | | | [B]1.49 | 11.97 | 11.61 | [a] | Viscotears | AQ |
| 8384G *NP* | carbomer-980 0.2% (2 mg/g) eye gel, 10 g | ‡1 | 5 | .. | 10.48 | 11.61 | [a] | PAA | IQ |
| | | | | | | | | GelTears | BU |
| | | | | [B]1.49 | 11.97 | 11.61 | [a] | Viscotears | AQ |
| | **CARBOMER-980** | | | | | | | | |
| | **Restricted benefit** | | | | | | | | |
| | For use in patients who have severe dry eye syndrome, including Sjogren's syndrome, and who are receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements | | | | | | | | |
| | **Note** | | | | | | | | |
| | No applications for increased maximum quantities and/or repeats will be authorised. | | | | | | | | |
| 9210R | carbomer-980 0.2% (2 mg/g) eye gel, 10 g | ‡1 | 11 | .. | 10.48 | 11.61 | | GelTears | BU |
| | | | | | | | [a] | PAA | IQ |
| | | | | [B]1.49 | 11.97 | 11.61 | [a] | Viscotears | AQ |
| | **CARBOMER-980 + HYPROMELLOSE** | | | | | | | | |
| | **Restricted benefit** | | | | | | | | |
| | Severe dry eye syndrome, including Sjogren's syndrome | | | | | | | | |
| 5519L *OP* | carbomer-980 0.2% (2 mg/g) + hypromellose 0.3% (3 mg/g) eye gel, 10 g | ‡1 | 5 | .. | 10.48 | 11.61 | [a] | HPMC PAA | IQ |
| | | | | [B]1.95 | 12.43 | 11.61 | [a] | Genteal gel | AQ |
| 8564R *NP* | carbomer-980 0.2% (2 mg/g) + hypromellose 0.3% (3 mg/g) eye gel, 10 g | ‡1 | 5 | .. | 10.48 | 11.61 | [a] | HPMC PAA | IQ |
| | | | | [B]1.95 | 12.43 | 11.61 | [a] | Genteal gel | AQ |
| | **CARBOMER-980 + HYPROMELLOSE** | | | | | | | | |
| | **Restricted benefit** | | | | | | | | |
| | For use in patients who have severe dry eye syndrome, including Sjogren's syndrome, and who are receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements | | | | | | | | |
| | **Note** | | | | | | | | |
| | No applications for increased maximum quantities and/or repeats will be authorised. | | | | | | | | |
| 9215B | carbomer-980 0.2% (2 mg/g) + hypromellose 0.3% (3 mg/g) eye gel, 10 g | ‡1 | 11 | .. | 10.48 | 11.61 | [a] | HPMC PAA | IQ |
| | | | | [B]1.95 | 12.43 | 11.61 | [a] | Genteal gel | AQ |
| | **CARMELLOSE SODIUM** | | | | | | | | |
| | **Restricted benefit** | | | | | | | | |
| | Severe dry eye syndrome, including Sjogren's syndrome | | | | | | | | |
| 5508X *OP* | carmellose sodium 1% (10 mg/mL) eye drops, 15 mL | ‡1 | 5 | .. | 10.80 | 11.93 | | Refresh Liquigel | AG |
| 8593G *NP* | carmellose sodium 1% (10 mg/mL) eye drops, 15 mL | ‡1 | 5 | .. | 10.80 | 11.93 | | Refresh Liquigel | AG |
| 5507W *OP* | carmellose sodium 0.5% (5 mg/mL) eye drops, 15 mL | ‡1 | 5 | .. | 10.80 | 11.93 | | Refresh Tears Plus | AG |
| 8548X *NP* | carmellose sodium 0.5% (5 mg/mL) eye drops, 15 mL | ‡1 | 5 | .. | 10.80 | 11.93 | | Refresh Tears Plus | AG |
| | **CARMELLOSE SODIUM** | | | | | | | | |
| | **Restricted benefit** | | | | | | | | |
| | For use in patients who have severe dry eye syndrome, including Sjogren's syndrome, and who are receiving treatment under a GP Management | | | | | | | | |

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|
| | Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements | | | | | | | |
| | **Note** | | | | | | | |
| | No applications for increased maximum quantities and/or repeats will be authorised. | | | | | | | |
| 9212W | carmellose sodium 1% (10 mg/mL) eye drops, 15 mL | ‡1 | 11 | .. | 10.80 | 11.93 | Refresh Liquigel | AG |
| 9211T | carmellose sodium 0.5% (5 mg/mL) eye drops, 15 mL | ‡1 | 11 | .. | 10.80 | 11.93 | Refresh Tears Plus | AG |
| | **CARMELLOSE SODIUM** | | | | | | | |
| | **Authority required (STREAMLINED)** | | | | | | | |
| | ***1359*** | | | | | | | |
| | Severe dry eye syndrome in patients who are sensitive to preservatives in multi-dose eye drops | | | | | | | |
| 2324H *NP* | carmellose sodium 1% (4 mg/0.4 mL) eye drops, 30 x 0.4 mL unit doses | 3 | 5 | .. | *36.27 | 36.10 | Celluvisc | AG |
| 8823J *NP* | carmellose sodium 0.25% (1.5 mg/0.6 mL) eye drops, 24 x 0.6 mL unit doses | 4 | 5 | .. | *40.63 | 36.10 | TheraTears | CX |
| 2338C *NP* | carmellose sodium 0.5% (2 mg/0.4 mL) eye drops, 30 x 0.4 mL unit doses | 3 | 5 | .. | *36.27 | 36.10 | Cellufresh | AG |
| 8824K *NP* | carmellose sodium 1% (6 mg/0.6 mL) eye gel, 28 x 0.6 mL unit doses | 3 | 5 | .. | *34.29 | 35.42 | TheraTears | CX |
| | **CARMELLOSE SODIUM** | | | | | | | |
| | **Authority required** | | | | | | | |
| | Severe dry eye syndrome in patients who are sensitive to preservatives in multi-dose eye drops | | | | | | | |
| 5505R *OP* | carmellose sodium 1% (4 mg/0.4 mL) eye drops, 30 x 0.4 mL unit doses | 3 | 5 | .. | *36.27 | 36.10 | Celluvisc | AG |
| 5509Y *OP* | carmellose sodium 0.25% (1.5 mg/0.6 mL) eye drops, 24 x 0.6 mL unit doses | 4 | 5 | .. | *40.63 | 36.10 | TheraTears | CX |
| 5506T *OP* | carmellose sodium 0.5% (2 mg/0.4 mL) eye drops, 30 x 0.4 mL unit doses | 3 | 5 | .. | *36.27 | 36.10 | Cellufresh | AG |
| 5510B *OP* | carmellose sodium 1% (6 mg/0.6 mL) eye gel, 28 x 0.6 mL unit doses | 3 | 5 | .. | *34.29 | 35.42 | TheraTears | CX |
| | **CARMELLOSE SODIUM + GLYCEROL** | | | | | | | |
| | **Authority required** | | | | | | | |
| | Severe dry eye syndrome in patients who are sensitive to preservatives in multi-dose eye drops | | | | | | | |
| 5561Q *OP* | carmellose sodium 0.5% (2 mg/0.4 mL) + glycerol 0.9% (3.6 mg/0.4 mL) eye drops, 30 x 0.4 mL unit doses | 3 | 5 | .. | *36.27 | 36.10 | Optive | AG |
| | **CARMELLOSE SODIUM + GLYCEROL** | | | | | | | |
| | **Authority required (STREAMLINED)** | | | | | | | |
| | ***1359*** | | | | | | | |
| | Severe dry eye syndrome in patients who are sensitive to preservatives in multi-dose eye drops | | | | | | | |
| 9307W *NP* | carmellose sodium 0.5% (2 mg/0.4 mL) + glycerol 0.9% (3.6 mg/0.4 mL) eye drops, 30 x 0.4 mL unit doses | 3 | 5 | .. | *36.27 | 36.10 | Optive | AG |
| | **CARMELLOSE SODIUM + GLYCEROL** | | | | | | | |
| | **Restricted benefit** | | | | | | | |
| | Severe dry eye syndrome, including Sjogren's syndrome | | | | | | | |
| | **Note** | | | | | | | |
| | The in-use shelf life of Optive is 6 months from the date of opening. | | | | | | | |
| 5556K *OP* | carmellose sodium 0.5% (5 mg/mL) + glycerol 0.9% (9 mg/mL) eye drops, 15 mL | ‡1 | 3 | .. | 10.80 | 11.93 | Optive | AG |
| 9355J *NP* | carmellose sodium 0.5% (5 mg/mL) + glycerol 0.9% (9 mg/mL) eye drops, 15 mL | ‡1 | 3 | .. | 10.80 | 11.93 | Optive | AG |
| | **CARMELLOSE SODIUM + GLYCEROL** | | | | | | | |
| | **Restricted benefit** | | | | | | | |
| | For use in patients who have severe dry eye syndrome, including Sjogren's syndrome, and who are receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements | | | | | | | |
| | **Note** | | | | | | | |
| | No applications for increased maximum quantities and/or repeats will be authorised. | | | | | | | |

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|---|---|---|---|---|---|---|---|---|---|
| | **Note**<br>The in-use shelf life of Optive is 6 months from the date of opening. | | | | | | | | |
| 9356K | carmellose sodium 0.5% (5 mg/mL) + glycerol 0.9% (9 mg/mL) eye drops, 15 mL | ‡1 | 7 | .. | 10.80 | 11.93 | | Optive | AG |
| | **DEXTRAN-70 + HYPROMELLOSE**<br>**Restricted benefit**<br>Severe dry eye syndrome, including Sjogren's syndrome | | | | | | | | |
| 1509K<br>*NP* | dextran-70 0.1% (1 mg/mL) + hypromellose 0.3% (3 mg/mL) eye drops, 15 mL | ‡1 | 5 | .. | 10.70 | 11.83 | a | Poly-Tears | IQ |
| | | | | B2.04 | 12.74 | 11.83 | a | Tears Naturale | AQ |
| 5520M<br>*OP* | dextran-70 0.1% (1 mg/mL) + hypromellose 0.3% (3 mg/mL) eye drops, 15 mL | ‡1 | 5 | .. | 10.70 | 11.83 | a | Poly-Tears | IQ |
| | | | | B2.04 | 12.74 | 11.83 | a | Tears Naturale | AQ |
| | **DEXTRAN-70 + HYPROMELLOSE**<br>**Restricted benefit**<br>For use in patients who have severe dry eye syndrome, including Sjogren's syndrome, and who are receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements<br>**Note**<br>No applications for increased maximum quantities and/or repeats will be authorised. | | | | | | | | |
| 9216C | dextran-70 0.1% (1 mg/mL) + hypromellose 0.3% (3 mg/mL) eye drops, 15 mL | ‡1 | 11 | .. | 10.70 | 11.83 | a | Poly-Tears | IQ |
| | | | | B2.04 | 12.74 | 11.83 | a | Tears Naturale | AQ |
| | **DEXTRAN-70 + HYPROMELLOSE**<br>**Authority required**<br>Severe dry eye syndrome in patients who are sensitive to preservatives in multi-dose eye drops | | | | | | | | |
| 5521N<br>*OP* | dextran-70 0.1% + hypromellose 0.3% eye drops, 28 x 0.4 mL unit doses | 3 | 5 | .. | *35.28 | 36.10 | | Bion Tears | AQ |
| | **DEXTRAN-70 + HYPROMELLOSE**<br>**Authority required (STREAMLINED)**<br>***1359***<br>Severe dry eye syndrome in patients who are sensitive to preservatives in multi-dose eye drops | | | | | | | | |
| 8299T<br>*NP* | dextran-70 0.1% + hypromellose 0.3% eye drops, 28 x 0.4 mL unit doses | 3 | 5 | .. | *35.28 | 36.10 | | Bion Tears | AQ |
| | **HYPROMELLOSE**<br>**Restricted benefit**<br>Severe dry eye syndrome, including Sjogren's syndrome | | | | | | | | |
| 5518K<br>*OP* | HYPROMELLOSE Eye drops 3 mg per mL (0.3%), 15 mL (contains sodium perborate as preservative), 1 | ‡1 | 5 | .. | 10.48 | 11.61 | a | In a Wink Moisturising | IQ |
| | | | | B1.95 | 12.43 | 11.61 | a | Genteal | AQ |
| 8287E<br>*NP* | HYPROMELLOSE Eye drops 3 mg per mL (0.3%), 15 mL (contains sodium perborate as preservative), 1 | ‡1 | 5 | .. | 10.48 | 11.61 | a | In a Wink Moisturising | IQ |
| | | | | B1.95 | 12.43 | 11.61 | a | Genteal | AQ |
| 2956N<br>*NP* | HYPROMELLOSE Eye drops 5 mg per mL (0.5%), 15 mL, 1 | ‡1 | 5 | .. | 10.48 | 11.61 | | Methopt | QA |
| 5517J<br>*OP* | HYPROMELLOSE Eye drops 5 mg per mL (0.5%), 15 mL, 1 | ‡1 | 5 | .. | 10.48 | 11.61 | | Methopt | QA |
| | **HYPROMELLOSE**<br>**Restricted benefit**<br>For use in patients who have severe dry eye syndrome, including Sjogren's syndrome, and who are receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements<br>**Note**<br>No applications for increased maximum quantities and/or repeats will be authorised. | | | | | | | | |
| 9213X | HYPROMELLOSE Eye drops 3 mg per mL | ‡1 | 11 | .. | 10.48 | 11.61 | a | In a Wink Moisturising | IQ |

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|---|---|---|---|---|---|---|---|---|---|
| | (0.3%), 15 mL (contains sodium perborate as preservative), 1 | | | | | | | | |
| | | | | [B]1.95 | 12.43 | 11.61 | [a] | Genteal | AQ |
| 9214Y | HYPROMELLOSE Eye drops 5 mg per mL (0.5%), 15 mL, 1 | ‡1 | 11 | .. | 10.48 | 11.61 | | Methopt | QA |
| | **PARAFFIN** | | | | | | | | |
| | **Note** | | | | | | | | |
| | The in-use shelf life of VitA-POS is 6 months from the date of opening. | | | | | | | | |
| 2167C *OP* | paraffin + retinyl palmitate 138 microgram/g (equivalent to 250 units/g vitamin A) eye ointment, 5 g | 2 | 5 | .. | *21.45 | 22.58 | | VitA-POS | AE |
| 2222Y *NP* | paraffin + retinyl palmitate 138 microgram/g (equivalent to 250 units/g vitamin A) eye ointment, 5 g | 2 | 5 | .. | *21.45 | 22.58 | | VitA-POS | AE |
| | **PARAFFIN** | | | | | | | | |
| | **Restricted benefit** | | | | | | | | |
| | For use in patients who are receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements. | | | | | | | | |
| | **Note** | | | | | | | | |
| | The in-use shelf life of VitA-POS is 6 months from the date of opening. | | | | | | | | |
| | **Note** | | | | | | | | |
| | No increase in the maximum quantity or number of units may be authorised. | | | | | | | | |
| | **Note** | | | | | | | | |
| | No increase in the maximum number of repeats may be authorised. | | | | | | | | |
| 2202X | paraffin + retinyl palmitate 138 microgram/g (equivalent to 250 units/g vitamin A) eye ointment, 5 g | 2 | 11 | .. | *21.45 | 22.58 | | VitA-POS | AE |
| | **PARAFFIN** | | | | | | | | |
| 1750D *NP* | paraffin 1 g/g eye ointment, 2 x 3.5 g tubes | ‡1 | 5 | .. | 20.81 | 21.94 | [a] | Ircal | PE |
| | | | | | | | | Poly Visc | IQ |
| | | | | [B]2.12 | 22.93 | 21.94 | [a] | Lacri-Lube | AG |
| 5522P *OP* | paraffin 1 g/g eye ointment, 2 x 3.5 g tubes | ‡1 | 5 | .. | 20.81 | 21.94 | | Poly Visc | IQ |
| | | | | | | | [a] | Ircal | PE |
| | | | | [B]2.12 | 22.93 | 21.94 | [a] | Lacri-Lube | AG |
| 1754H *NP* | paraffin 1 g/g eye ointment, 3.5 g | 2 | 5 | .. | *21.45 | 22.58 | [a] | Poly Visc | IQ |
| | | | | [B]2.54 | *23.99 | 22.58 | [a] | Duratears | AQ |
| 5523Q *OP* | paraffin 1 g/g eye ointment, 3.5 g | 2 | 5 | .. | *21.45 | 22.58 | [a] | Poly Visc | IQ |
| | | | | [B]2.54 | *23.99 | 22.58 | [a] | Duratears | AQ |
| | **PARAFFIN** | | | | | | | | |
| | **Restricted benefit** | | | | | | | | |
| | For use in patients who are receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements | | | | | | | | |
| | **Note** | | | | | | | | |
| | No applications for increased maximum quantities and/or repeats will be authorised. | | | | | | | | |
| 9218E | paraffin 1 g/g eye ointment, 2 x 3.5 g tubes | ‡1 | 11 | .. | 20.81 | 21.94 | [a] | Ircal | PE |
| | | | | | | | | Poly Visc | IQ |
| | | | | [B]2.12 | 22.93 | 21.94 | [a] | Lacri-Lube | AG |
| 9217D | paraffin 1 g/g eye ointment, 3.5 g | 2 | 11 | .. | *21.45 | 22.58 | [a] | Poly Visc | IQ |
| | | | | [B]2.54 | *23.99 | 22.58 | [a] | Duratears | AQ |
| | **POLYETHYLENE GLYCOL-400** | | | | | | | | |
| | **Authority required** | | | | | | | | |
| | Severe dry eye syndrome in patients who are sensitive to preservatives in multi-dose eye drops | | | | | | | | |
| 5560P *OP* | polyethylene glycol-400 0.25% (1 mg/0.4 mL) eye drops, 20 x 0.4 mL unit doses | 5 | 5 | .. | *39.58 | 36.10 | | Blink Intensive Tears | AO |

# SENSORY ORGANS

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|
| | **POLYETHYLENE GLYCOL-400**<br>**Authority required (STREAMLINED)**<br>***1359***<br>Severe dry eye syndrome in patients who are sensitive to preservatives in multi-dose eye drops | | | | | | | |
| 9493P<br>*NP* | polyethylene glycol-400 0.25% (1 mg/0.4 mL) eye drops, 20 x 0.4 mL unit doses | 5 | 5 | .. | *39.58 | 36.10 | Blink Intensive Tears | AO |
| | **POLYETHYLENE GLYCOL-400**<br>**Restricted benefit**<br>Severe dry eye syndrome, including Sjogren's syndrome<br>**Note**<br>The in-use shelf life of Blink Intensive Tears multi-dose formulation is 45 days from the date of opening. | | | | | | | |
| 5559N<br>*OP* | polyethylene glycol-400 0.25% (2.5 mg/mL) eye drops, 15 mL | ‡1 | 5 | .. | 10.80 | 11.93 | Blink Intensive Tears | AO |
| 9491M<br>*NP* | polyethylene glycol-400 0.25% (2.5 mg/mL) eye drops, 15 mL | ‡1 | 5 | .. | 10.80 | 11.93 | Blink Intensive Tears | AO |
| | **POLYETHYLENE GLYCOL-400**<br>**Restricted benefit**<br>For use in patients who have severe dry eye syndrome, including Sjogren's syndrome, and who are receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements<br>**Note**<br>No applications for increased maximum quantities and/or repeats will be authorised.<br>**Note**<br>The in-use shelf life of Blink Intensive Tears multi-dose formulation is 45 days from the date of opening. | | | | | | | |
| 9492N | polyethylene glycol-400 0.25% (2.5 mg/mL) eye drops, 15 mL | ‡1 | 11 | .. | 10.80 | 11.93 | Blink Intensive Tears | AO |
| | **POLYETHYLENE GLYCOL-400 + PROPYLENE GLYCOL**<br>**Authority required**<br>Severe dry eye syndrome in patients who are sensitive to preservatives in multi-dose eye drops | | | | | | | |
| 5532E<br>*OP* | polyethylene glycol-400 0.4% (3.2 mg/0.8 mL) + propylene glycol 0.3% (2.4 mg/0.8 mL) eye drops, 28 x 0.8 mL unit doses | 2 | 5 | .. | *34.29 | 35.42 | Systane | AQ |
| | **POLYETHYLENE GLYCOL-400 + PROPYLENE GLYCOL**<br>**Authority required (STREAMLINED)**<br>***1359***<br>Severe dry eye syndrome in patients who are sensitive to preservatives in multi-dose eye drops | | | | | | | |
| 9170P<br>*NP* | polyethylene glycol-400 0.4% (3.2 mg/0.8 mL) + propylene glycol 0.3% (2.4 mg/0.8 mL) eye drops, 28 x 0.8 mL unit doses | 2 | 5 | .. | *34.29 | 35.42 | Systane | AQ |
| | **POLYETHYLENE GLYCOL-400 + PROPYLENE GLYCOL**<br>**Restricted benefit**<br>Severe dry eye syndrome, including Sjogren's syndrome | | | | | | | |
| 5524R<br>*OP* | polyethylene glycol-400 0.4% (4 mg/mL) + propylene glycol 0.3% (3 mg/mL) eye drops, 15 mL | ‡1 | 5 | .. | 10.80 | 11.93 | Systane | AQ |
| 8676P<br>*NP* | polyethylene glycol-400 0.4% (4 mg/mL) + propylene glycol 0.3% (3 mg/mL) eye drops, 15 mL | ‡1 | 5 | .. | 10.80 | 11.93 | Systane | AQ |
| | **POLYETHYLENE GLYCOL-400 + PROPYLENE GLYCOL**<br>**Restricted benefit**<br>For use in patients who have severe dry eye syndrome, including Sjogren's syndrome, and who are receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements<br>**Note**<br>No applications for increased maximum quantities and/or repeats will be authorised. | | | | | | | |
| 9219F | polyethylene glycol-400 0.4% (4 mg/mL) + propylene glycol 0.3% (3 mg/mL) eye drops, 15 mL | ‡1 | 11 | .. | 10.80 | 11.93 | Systane | AQ |

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|---|
| | **POLYVINYL ALCOHOL** | | | | | | | | |
| | **Restricted benefit** | | | | | | | | |
| | Severe dry eye syndrome, including Sjogren's syndrome | | | | | | | | |
| 2682E *NP* | polyvinyl alcohol 1.4% eye drops, 15 mL | ‡1 | 5 | .. | 10.48 | 11.61 | a | PVA Tears | PE |
| | | | | [B]1.60 | 12.08 | 11.61 | a | Liquifilm Tears | AG |
| 5526W *OP* | polyvinyl alcohol 1.4% eye drops, 15 mL | ‡1 | 5 | .. | 10.48 | 11.61 | a | PVA Tears | PE |
| | | | | [B]1.60 | 12.08 | 11.61 | a | Liquifilm Tears | AG |
| 5527X *OP* | polyvinyl alcohol 1.4% eye drops, 15 mL | ‡1 | 5 | .. | 10.48 | 11.61 | | Vistil | AE |
| 8831T *NP* | polyvinyl alcohol 1.4% eye drops, 15 mL | ‡1 | 5 | .. | 10.48 | 11.61 | | Vistil | AE |
| 2681D *NP* | polyvinyl alcohol 3% eye drops, 15 mL | ‡1 | 5 | .. | 10.48 | 11.61 | a | PVA Forte | PE |
| | | | | [B]5.59 | 16.07 | 11.61 | a | Liquifilm Forte | AG |
| 5525T *OP* | polyvinyl alcohol 3% eye drops, 15 mL | ‡1 | 5 | .. | 10.48 | 11.61 | a | PVA Forte | PE |
| | | | | [B]5.59 | 16.07 | 11.61 | a | Liquifilm Forte | AG |
| 5528Y *OP* | polyvinyl alcohol 3% eye drops, 15 mL | ‡1 | 5 | .. | 10.48 | 11.61 | | Vistil Forte | AE |
| 8832W *NP* | polyvinyl alcohol 3% eye drops, 15 mL | ‡1 | 5 | .. | 10.48 | 11.61 | | Vistil Forte | AE |
| | **POLYVINYL ALCOHOL** | | | | | | | | |
| | **Restricted benefit** | | | | | | | | |
| | For use in patients who have severe dry eye syndrome, including Sjogren's syndrome, and who are receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements | | | | | | | | |
| | **Note** | | | | | | | | |
| | No applications for increased maximum quantities and/or repeats will be authorised. | | | | | | | | |
| 9220G | polyvinyl alcohol 1.4% eye drops, 15 mL | ‡1 | 11 | .. | 10.48 | 11.61 | a | PVA Tears | PE |
| | | | | [B]1.60 | 12.08 | 11.61 | a | Liquifilm Tears | AG |
| 9221H | polyvinyl alcohol 1.4% eye drops, 15 mL | ‡1 | 11 | .. | 10.48 | 11.61 | | Vistil | AE |
| 9222J | polyvinyl alcohol 3% eye drops, 15 mL | ‡1 | 11 | .. | 10.48 | 11.61 | a | PVA Forte | PE |
| | | | | [B]5.59 | 16.07 | 11.61 | a | Liquifilm Forte | AG |
| 9223K | polyvinyl alcohol 3% eye drops, 15 mL | ‡1 | 11 | .. | 10.48 | 11.61 | | Vistil Forte | AE |
| | **SODIUM HYALURONATE** | | | | | | | | |
| | **Authority required (STREAMLINED)** | | | | | | | | |
| | ***4105*** | | | | | | | | |
| | Severe dry eye syndrome | | | | | | | | |
| | **The Clinical criteria is:** | | | | | | | | |
| | Patient must be sensitive to preservatives in multi-dose eye drops. | | | | | | | | |
| | **Note** | | | | | | | | |
| | The in-use shelf life of Hylo-Fresh and Hylo-Forte is 6 months from the date of opening. | | | | | | | | |
| 2181T *NP* | sodium hyaluronate 0.1% (1 mg/mL) eye drops, 10 mL | ‡1 | 5 | .. | 33.83 | 34.96 | | Hylo-Fresh | AE |
| 2253N *NP* | sodium hyaluronate 0.2% (2 mg/mL) eye drops, 10 mL | ‡1 | 5 | .. | 33.83 | 34.96 | | Hylo-Forte | AE |
| | **SODIUM HYALURONATE** | | | | | | | | |
| | **Authority required** | | | | | | | | |
| | Severe dry eye syndrome | | | | | | | | |
| | **The Clinical criteria is:** | | | | | | | | |
| | Patient must be sensitive to preservatives in multi-dose eye drops. | | | | | | | | |
| | **Note** | | | | | | | | |
| | The in-use shelf life of Hylo-Fresh and Hylo-Forte is 6 months from the date of opening. | | | | | | | | |
| 2184Y *OP* | sodium hyaluronate 0.1% (1 mg/mL) eye drops, 10 mL | ‡1 | 5 | .. | 33.83 | 34.96 | | Hylo-Fresh | AE |
| 2171G *OP* | sodium hyaluronate 0.2% (2 mg/mL) eye drops, 10 mL | ‡1 | 5 | .. | 33.83 | 34.96 | | Hylo-Forte | AE |
| | **SOY LECITHIN + TOCOPHEROLS + VITAMIN A** | | | | | | | | |

# SENSORY ORGANS

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|---|
| | **Authority required**<br>Severe dry eye syndrome in patients who are sensitive to preservatives in multi-dose eye drops | | | | | | | | |
| 5545W<br>*OP* | soy lecithin 1% (10 mg/mL) + tocopherols 0.002% (20 microgram/mL) + vitamin A palmitate 0.025% (250 microgram/mL) eye spray, 100 actuations | 2 | 5 | .. | *36.27 | 36.10 | | tearsagain | RB |
| | **SOY LECITHIN + TOCOPHEROLS + VITAMIN A**<br>**Authority required (STREAMLINED)**<br>***1359***<br>Severe dry eye syndrome in patients who are sensitive to preservatives in multi-dose eye drops | | | | | | | | |
| 9448G<br>*NP* | soy lecithin 1% (10 mg/mL) + tocopherols 0.002% (20 microgram/mL) + vitamin A palmitate 0.025% (250 microgram/mL) eye spray, 100 actuations | 2 | 5 | .. | *36.27 | 36.10 | | tearsagain | RB |

## OTOLOGICALS

### ANTIINFECTIVES

#### *Antiinfectives*

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | **CHLORAMPHENICOL** | | | | | | | | |
| 1172Q<br>*NP* | chloramphenicol 0.5% (5 mg/mL) ear drops, 5 mL | ‡1 | 2 | .. | 11.26 | 12.39 | | Chloromycetin | PF |
| | **CIPROFLOXACIN**<br>**Authority required**<br>Treatment of chronic suppurative otitis media in an Aboriginal or a Torres Strait Islander person aged 1 month or older | | | | | | | | |
| | **Authority required**<br>Treatment of chronic suppurative otitis media in a patient less than 18 years of age with perforation of the tympanic membrane | | | | | | | | |
| | **Authority required**<br>Treatment of chronic suppurative otitis media in a patient less than 18 years of age with a grommet in situ | | | | | | | | |
| 2480M<br>*NP* | ciprofloxacin 0.3% (3 mg/mL) ear drops, 5 mL | ‡1 | 1 | .. | 19.49 | 20.62 | | Ciloxan | AQ |

### CORTICOSTEROIDS AND ANTIINFECTIVES IN COMBINATION

#### *Corticosteroids and antiinfectives in combination*

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | **DEXAMETHASONE + FRAMYCETIN SULFATE + GRAMICIDIN** | | | | | | | | |
| 2781J<br>*NP* | dexamethasone 0.05% (500 microgram/mL) + framycetin sulfate 0.5% (5 mg/mL) + gramicidin 0.005% (50 microgram/mL) ear drops, 8 mL | ‡1 | 2 | .. | 9.60 | 10.73 | a | Otodex | AV |
| | | | | [B]1.91 | 11.51 | 10.73 | a | Sofradex | SW |
| | **TRIAMCINOLONE + NEOMYCIN SULFATE + GRAMICIDIN + NYSTATIN** | | | | | | | | |
| 2974M<br>*NP* | triamcinolone acetonide 0.1% (1 mg/g) + neomycin sulfate 0.25% (2.5 mg/g) + gramicidin 0.025% (250 microgram/g) + nystatin 100 000 international units/g ointment, 5 g | ‡1 | 2 | .. | 8.39 | 9.52 | a | Otocomb Otic | FM |
| | | | | [B]1.95 | 10.34 | 9.52 | a | Kenacomb Otic | QA |
| 2971J<br>*NP* | triamcinolone acetonide 0.1% (1 mg/mL) + neomycin sulfate 0.25% (2.5 mg/mL) + gramicidin 0.025% (250 microgram/mL) + nystatin 100 000 international units/mL ear drops, 7.5 mL | ‡1 | 2 | .. | 11.30 | 12.43 | a | Otocomb Otic | FM |
| | | | | [B]1.95 | 13.25 | 12.43 | a | Kenacomb Otic | QA |

## OPHTHALMOLOGICAL AND OTOLOGICAL PREPARATIONS

### ANTIINFECTIVES

#### *Antiinfectives*

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | **FRAMYCETIN SULFATE** | | | | | | | | |
| 1440T | framycetin sulfate 0.5% (5 mg/mL) | ‡1 | 2 | .. | 10.32 | 11.45 | | Soframycin | SW |

# SENSORY ORGANS

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|
| *NP,MW* | eye/ear drops, 8 mL | | | | | | | |
| 5557L | framycetin sulfate 0.5% (5 mg/mL) | ‡1 | 2 | .. | 10.32 | 11.45 | Soframycin | SW |
| *OP* | eye/ear drops, 8 mL | | | | | | | |

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|

# VARIOUS

## ALLERGENS

### ALLERGENS

#### *Allergen extracts*

**BEE VENOM**

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 2886X | bee venom 550 microgram injection [1 x 550 microgram vial] (&) inert substance diluent [4 vials], 1 pack | 1 | .. | .. | 238.59 | 36.10 | Albey Bee Venom | HL |

**PAPER WASP VENOM**

**Note**

Paper wasp venom is not European wasp venom.

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 2918N | paper wasp venom 550 microgram injection [1 x 550 microgram vial] (&) inert substance diluent [4 vials], 1 pack | 1 | .. | .. | 238.59 | 36.10 | Albey Paper Wasp Venom | HL |

**VESPULA SPP VENOM**

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 2883R | vespula spp venom 550 microgram injection [1 x 550 microgram vial] (&) inert substance diluent [4 vials], 1 pack | 1 | .. | .. | 238.59 | 36.10 | Albey Yellow Jacket Venom | HL |

## ALL OTHER THERAPEUTIC PRODUCTS

### ALL OTHER THERAPEUTIC PRODUCTS

#### *Antidotes*

**NALOXONE**

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 2192J *NP* | naloxone hydrochloride 400 microgram/mL injection, 1 x 1 mL syringe | 5 | .. | .. | *105.03 | 36.10 | Naloxone minijet | UC |
| 2196N *DP* | naloxone hydrochloride 400 microgram/mL injection, 1 x 1 mL syringe | 5 | .. | .. | *105.03 | 36.10 | Naloxone minijet | UC |

#### *Drugs for treatment of hyperkalemia and hyperphosphatemia*

**LANTHANUM**

**Authority required (STREAMLINED)**

***3546***

Maintenance therapy, following initiation and stabilisation of treatment with lanthanum carbonate, of hyperphosphataemia in a patient with chronic kidney disease on dialysis whose serum phosphate is not controlled on calcium and where serum phosphate is greater than 1.6 mmol per L at the commencement of therapy

**Authority required (STREAMLINED)**

***3547***

Maintenance therapy, following initiation and stabilisation of treatment with lanthanum carbonate, of hyperphosphataemia in a patient with chronic kidney disease on dialysis whose serum phosphate is not controlled on calcium and where the serum calcium times phosphate product is greater than 4.0 at the commencement of therapy

**Note**

Not to be used in combination with sevelamer.

**Note**

Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 9405B *NP* | LANTHANUM Tablet, chewable, 1000 mg (as carbonate hydrate), 90 | 1 | 5 | .. | 504.24 | 36.10 | Fosrenol | ZI |
| 9403X *NP* | LANTHANUM Tablet, chewable, 500 mg (as carbonate hydrate), 90 | 1 | 5 | .. | 306.09 | 36.10 | Fosrenol | ZI |
| 9404Y *NP* | LANTHANUM Tablet, chewable, 750 mg (as carbonate hydrate), 90 | 1 | 5 | .. | 449.64 | 36.10 | Fosrenol | ZI |

**SEVELAMER**

**Authority required (STREAMLINED)**

***3548***

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|---|
| | Maintenance therapy, following initiation and stabilisation of treatment with sevelamer hydrochloride, of hyperphosphataemia in a patient with chronic kidney disease on dialysis whose serum phosphate is not controlled on calcium and where serum phosphate is greater than 1.6 mmol per L at the commencement of therapy | | | | | | | | |
| | **Authority required (STREAMLINED)** | | | | | | | | |
| | ***3549*** | | | | | | | | |
| | Maintenance therapy, following initiation and stabilisation of treatment with sevelamer hydrochloride, of hyperphosphataemia in a patient with chronic kidney disease on dialysis whose serum phosphate is not controlled on calcium and where the serum calcium times phosphate product is greater than 4.0 at the commencement of therapy | | | | | | | | |
| | **Note** | | | | | | | | |
| | Not to be used in combination with lanthanum. | | | | | | | | |
| | **Note** | | | | | | | | |
| | Shared Care Model: | | | | | | | | |
| | For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners. | | | | | | | | |
| 2142R *NP* | sevelamer hydrochloride 800 mg tablet, 180 | 1 | 5 | .. | 357.94 | 36.10 | | Renagel | GZ |

## *Detoxifying agents for antineoplastic treatment*

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | **FOLINIC ACID** | | | | | | | | |
| 8969C | folinic acid 1 g/100 mL injection, 1 x 100 mL vial | 1 | 1 | .. | 105.65 | 36.10 | | Calcium Folinate Ebewe | SZ |
| 9041W | folinic acid 300 mg/30 mL injection, 1 x 30 mL vial | 4 | 1 | .. | *122.47 | 36.10 | [a] | Calcium Folinate Ebewe | SZ |
| | | | | | | | [a] | Leucovorin Calcium (Hospira Pty Limited) | HH |
| | **FOLINIC ACID** | | | | | | | | |
| | **Note** | | | | | | | | |
| | For item codes 8812T and 1704Q, pharmaceutical benefits that have the form injection equivalent to 100 mg folinic acid in 10 mL are equivalent for the purposes of substitution. | | | | | | | | |
| 8812T | folinic acid 100 mg/10 mL injection, 1 x 10 mL vial | 10 | 1 | .. | *105.73 | 36.10 | [a] | Calcium Folinate Ebewe | SZ |
| 1704Q | folinic acid 100 mg/10 mL injection, 10 x 10 mL ampoules | 1 | 1 | .. | 105.74 | 36.10 | [a] | Leucovorin Calcium (Pfizer Australia Pty Ltd) | PF |
| | **FOLINIC ACID** | | | | | | | | |
| | **Restricted benefit** | | | | | | | | |
| | Antidote to folic acid antagonists | | | | | | | | |
| 2308L | folinic acid 15 mg tablet, 10 | 1 | .. | .. | 96.52 | 36.10 | | Leucovorin Calcium (Hospira Pty Limited) | HH |
| | **FOLINIC ACID** | | | | | | | | |
| | **Note** | | | | | | | | |
| | For item codes 8740B, 1575X and 1610R, pharmaceutical benefits that have the form injection equivalent to 50 mg folinic acid in 5 mL are equivalent for the purposes of substitution. | | | | | | | | |
| 8740B | folinic acid 50 mg/5 mL injection, 1 x 5 mL vial | 10 | 2 | .. | *113.93 | 36.10 | [a] | Leucovorin Calcium (Hospira Pty Limited) | HH |
| 1610R | folinic acid 50 mg/5 mL injection, 10 x 5 mL ampoules | 1 | 2 | .. | 113.90 | 36.10 | [a] | Leucovorin Calcium (Pfizer Australia Pty Ltd) | PF |
| 1575X | folinic acid 50 mg/5 mL injection, 5 x 5 mL ampoules | 2 | 2 | .. | *113.91 | 36.10 | [a] | Calcium Folinate Ebewe | SZ |
| | **MESNA** | | | | | | | | |
| | **Restricted benefit** | | | | | | | | |
| | Adjunctive therapy for use with ifosfamide or high dose cyclophosphamide | | | | | | | | |
| 8079F | mesna 1 g/10 mL injection, 15 x 10 mL ampoules | 1 | 5 | .. | 224.02 | 36.10 | | Uromitexan | BX |
| 8078E | mesna 400 mg/4 mL injection, 15 x 4 mL ampoules | 1 | 5 | .. | 103.49 | 36.10 | | Uromitexan | BX |

## *Drugs for treatment of hypercalcemia*

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | **PHOSPHORUS** | | | | | | | | |
| | **Authority required (STREAMLINED)** | | | | | | | | |
| | ***1099*** | | | | | | | | |

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|
| | Familial hypophosphataemia | | | | | | | |
| | **Authority required (STREAMLINED)** | | | | | | | |
| | ***1157*** | | | | | | | |
| | Hypercalcaemia | | | | | | | |
| | **Authority required (STREAMLINED)** | | | | | | | |
| | ***1167*** | | | | | | | |
| | Hypophosphataemic rickets | | | | | | | |
| | **Authority required (STREAMLINED)** | | | | | | | |
| | ***1467*** | | | | | | | |
| | Vitamin D-resistant rickets | | | | | | | |
| 2946C *NP* | phosphorus 500 mg tablet: effervescent, 100 | 1 | 5 | .. | 81.84 | 36.10 | Phosphate Sandoz | NV |

## *Other therapeutic products*

**POLYLACTIC ACID**

**Authority required**

Initial PBS-subsidised treatment, for facial administration only, of severe facial lipoatrophy caused by therapy for HIV infection.

Accreditation following completion of injection administration training with Sanofi-Aventis is required to prescribe poly-l-lactic acid under the PBS. Patients must be referred from the HIV physician to the accredited injector

**Note**

Authority applications to prescribe poly-l-lactic acid may be made by telephone to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**Note**

No applications for increased maximum quantities and/or repeats will be authorised.

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 9475Q | polylactic acid 150 mg injection, 1 x 150 mg vial | 2 | 4 | .. | *446.67 | 36.10 | Sculptra | SW |

**POLYLACTIC ACID**

**Authority required**

Maintenance PBS-subsidised treatment, for facial administration only, of severe facial lipoatrophy caused by therapy for HIV infection.

Accreditation following completion of injection administration training with Sanofi-Aventis is required to prescribe poly-l-lactic acid under the PBS. Patients must be referred from the HIV physician to the accredited injector

**Note**

Authority applications to prescribe poly-l-lactic acid may be made by telephone to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**Note**

No applications for increased maximum quantities and/or repeats will be authorised.

Maintenance treatment is limited to one re-treatment (maximum 2 vials) every 2 years.

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 9476R | polylactic acid 150 mg injection, 1 x 150 mg vial | 2 | .. | .. | *446.67 | 36.10 | Sculptra | SW |

# DIAGNOSTIC AGENTS

## URINE TESTS

**GLUCOSE AND KETONE INDICATOR URINE**

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 3106L *NP* | glucose and ketone indicator urine strip: diagnostic, 50 diagnostic strips | 2 | 2 | .. | *17.51 | 18.64 | Keto-Diabur- Test 5000 | RD |
| 3107M *NP* | glucose and ketone indicator urine strip: diagnostic, 50 diagnostic strips | 2 | 2 | .. | *17.63 | 18.76 | Keto-Diastix | BN |

**GLUCOSE AND KETONE INDICATOR URINE**

**Restricted benefit**

For use in patients who are receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements

**Note**

No applications for increased maximum quantities and/or repeats will be authorised.

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 9254C | glucose and ketone indicator urine strip: diagnostic, 50 diagnostic strips | 2 | 4 | .. | *17.51 | 18.64 | Keto-Diabur- Test 5000 | RD |
| 9255D | glucose and ketone indicator urine strip: diagnostic, 50 diagnostic strips | 2 | 4 | .. | *17.63 | 18.76 | Keto-Diastix | BN |

**GLUCOSE INDICATOR URINE**

# VARIOUS

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|
| 3104J<br>*NP* | glucose indicator urine strip: diagnostic, 50 diagnostic strips | 2 | 2 | .. | *20.03 | 21.16 | Diastix | BN |

**GLUCOSE INDICATOR URINE**

**Restricted benefit**

For use in patients who are receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements

**Note**

No applications for increased maximum quantities and/or repeats will be authorised.

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 9253B | glucose indicator urine strip: diagnostic, 50 diagnostic strips | 2 | 4 | .. | *20.03 | 21.16 | Diastix | BN |

## OTHER DIAGNOSTIC AGENTS

### *Tests for diabetes*

**GLUCOSE INDICATOR BLOOD**

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 1503D<br>*NP* | glucose indicator blood strip: diagnostic, 100 diagnostic strips | ‡1 | 5 | .. | 53.37 | 36.10 | Contour | IK |
| 1519Y<br>*NP* | glucose indicator blood strip: diagnostic, 100 diagnostic strips | ‡1 | 5 | .. | 53.37 | 36.10 | BGStar | SW |
| 2562W<br>*NP* | glucose indicator blood strip: diagnostic, 100 diagnostic strips | ‡1 | 5 | .. | 53.37 | 36.10 | TRUEbalance | NX |
| 2575M<br>*NP* | glucose indicator blood strip: diagnostic, 100 diagnostic strips | ‡1 | 5 | .. | 53.37 | 36.10 | TRUEtrack | NX |
| 2624D<br>*NP* | glucose indicator blood strip: diagnostic, 100 diagnostic strips | ‡1 | 5 | .. | 53.37 | 36.10 | TRUEresult | NX |
| 2979T<br>*NP* | glucose indicator blood strip: diagnostic, 100 diagnostic strips | ‡1 | 5 | .. | 53.37 | 36.10 | Accu-Chek Performa | RD |
| 3411M<br>*NP* | glucose indicator blood strip: diagnostic, 100 diagnostic strips | ‡1 | 5 | .. | 53.37 | 36.10 | Accu-Chek Advantage/Sensor Comfort | RD |
| 8190C<br>*NP* | glucose indicator blood strip: diagnostic, 100 diagnostic strips | ‡1 | 5 | .. | 53.37 | 36.10 | Accu-Chek Active | RD |
| 8522M<br>*NP* | glucose indicator blood strip: diagnostic, 100 diagnostic strips | ‡1 | 5 | .. | 53.37 | 36.10 | FreeStyle Optium | MS |
| 9154T<br>*NP* | glucose indicator blood strip: diagnostic, 100 diagnostic strips | ‡1 | 5 | .. | 53.37 | 36.10 | FreeStyle Lite | MS |
| 2263D<br>*NP* | glucose indicator blood strip: diagnostic, 50 diagnostic strips | 2 | 5 | .. | *53.39 | 36.10 | Optium Omega | MS |
| 2673Q<br>*NP* | glucose indicator blood strip: diagnostic, 50 diagnostic strips | 2 | 5 | .. | *53.39 | 36.10 | OneTouch Select | JJ |
| 2860M<br>*NP* | glucose indicator blood strip: diagnostic, 50 diagnostic strips | 2 | 5 | .. | *53.39 | 36.10 | Betachek G5 | NA |
| 2890D<br>*NP* | glucose indicator blood strip: diagnostic, 50 diagnostic strips | 2 | 5 | .. | *53.39 | 36.10 | Betachek | NA |
| 2914J<br>*NP* | glucose indicator blood strip: diagnostic, 50 diagnostic strips | 2 | 5 | .. | *46.11 | 36.10 | Glucoflex-R | NA |
| 3406G<br>*NP* | glucose indicator blood strip: diagnostic, 50 diagnostic strips | 2 | 5 | .. | *53.39 | 36.10 | CareSens N | LB |
| 3441D<br>*NP* | glucose indicator blood strip: diagnostic, 50 diagnostic strips | 2 | 5 | .. | *53.39 | 36.10 | OneTouch Verio | JJ |
| 5043K<br>*NP* | glucose indicator blood strip: diagnostic, 50 diagnostic strips | 2 | 5 | .. | *53.39 | 36.10 | Accu-Chek Aviva | RD |
| 8723D<br>*NP* | glucose indicator blood strip: diagnostic, 50 diagnostic strips | 2 | 5 | .. | *53.39 | 36.10 | Omnitest EZ | BR |
| 8739Y<br>*NP* | glucose indicator blood strip: diagnostic, 50 diagnostic strips | 2 | 5 | .. | *53.39 | 36.10 | Accu-Chek Go | RD |
| 8749L<br>*NP* | glucose indicator blood strip: diagnostic, 50 diagnostic strips | 2 | 5 | .. | *53.39 | 36.10 | GlucoDr | OZ |
| 8759B<br>*NP* | glucose indicator blood strip: diagnostic, 50 diagnostic strips | 2 | 5 | .. | *53.39 | 36.10 | CareSens | LB |
| 8795X<br>*NP* | glucose indicator blood strip: diagnostic, 50 diagnostic strips | 2 | 5 | .. | *53.39 | 36.10 | SensoCard | PX |
| 9013J<br>*NP* | glucose indicator blood strip: diagnostic, 50 diagnostic strips | 2 | 5 | .. | *53.39 | 36.10 | Glucocard 01 Sensor | OZ |
| 9298J<br>*NP* | glucose indicator blood strip: diagnostic, 50 diagnostic strips | 2 | 5 | .. | *53.39 | 36.10 | Bionime Rightest | QB |
| 9471L<br>*NP* | glucose indicator blood strip: diagnostic, 50 diagnostic strips | 2 | 5 | .. | *53.39 | 36.10 | MyGlucoHealth | EH |
| 9485F | glucose indicator blood strip: diagnostic, | 2 | 5 | .. | *53.39 | 36.10 | Lifeline Attest | OI |

# VARIOUS

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|
| *NP* | 50 diagnostic strips | | | | | | | |
| 8806L | glucose indicator blood strip: diagnostic, | 2 | 5 | .. | *53.39 | 36.10 | Accu-Chek Integra | RD |
| *NP* | 51 diagnostic strips | | | | | | | |

**GLUCOSE INDICATOR BLOOD**

**Restricted benefit**

Blood glucose monitoring

**The Clinical criteria is:**

Patient must be receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements.

**Note**

No increase in the maximum quantity or number of units may be authorised.

**Note**

No increase in the maximum number of repeats may be authorised.

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 1518X | glucose indicator blood strip: diagnostic, 100 diagnostic strips | ǂ1 | 11 | .. | 53.37 | 36.10 | Contour | IK |
| 1520B | glucose indicator blood strip: diagnostic, 100 diagnostic strips | ǂ1 | 11 | .. | 53.37 | 36.10 | BGStar | SW |
| 2568E | glucose indicator blood strip: diagnostic, 100 diagnostic strips | ǂ1 | 11 | .. | 53.37 | 36.10 | TRUEresult | NX |
| 2571H | glucose indicator blood strip: diagnostic, 100 diagnostic strips | ǂ1 | 11 | .. | 53.37 | 36.10 | TRUEbalance | NX |
| 2602Y | glucose indicator blood strip: diagnostic, 100 diagnostic strips | ǂ1 | 11 | .. | 53.37 | 36.10 | TRUEtrack | NX |
| 3412N | glucose indicator blood strip: diagnostic, 100 diagnostic strips | ǂ1 | 11 | .. | 53.37 | 36.10 | Accu-Chek Advantage/Sensor Comfort | RD |
| 9257F | glucose indicator blood strip: diagnostic, 100 diagnostic strips | ǂ1 | 11 | .. | 53.37 | 36.10 | Accu-Chek Performa | RD |
| 9269W | glucose indicator blood strip: diagnostic, 100 diagnostic strips | ǂ1 | 11 | .. | 53.37 | 36.10 | FreeStyle Lite | MS |
| 9270X | glucose indicator blood strip: diagnostic, 100 diagnostic strips | ǂ1 | 11 | .. | 53.37 | 36.10 | FreeStyle Optium | MS |
| 9273C | glucose indicator blood strip: diagnostic, 100 diagnostic strips | ǂ1 | 11 | .. | 53.37 | 36.10 | Accu-Chek Active | RD |
| 2697Y | glucose indicator blood strip: diagnostic, 50 diagnostic strips | 2 | 11 | .. | *53.39 | 36.10 | OneTouch Select | JJ |
| 3407H | glucose indicator blood strip: diagnostic, 50 diagnostic strips | 2 | 11 | .. | *53.39 | 36.10 | CareSens N | LB |
| 3442E | glucose indicator blood strip: diagnostic, 50 diagnostic strips | 2 | 11 | .. | *53.39 | 36.10 | OneTouch Verio | JJ |
| 5053Y | glucose indicator blood strip: diagnostic, 50 diagnostic strips | 2 | 11 | .. | *53.39 | 36.10 | Accu-Chek Aviva | RD |
| 9261K | glucose indicator blood strip: diagnostic, 50 diagnostic strips | 2 | 11 | .. | *53.39 | 36.10 | Glucocard 01 Sensor | OZ |
| 9263M | glucose indicator blood strip: diagnostic, 50 diagnostic strips | 2 | 11 | .. | *53.39 | 36.10 | GlucoDr | OZ |
| 9265P | glucose indicator blood strip: diagnostic, 50 diagnostic strips | 2 | 11 | .. | *53.39 | 36.10 | Omnitest EZ | BR |
| 9267R | glucose indicator blood strip: diagnostic, 50 diagnostic strips | 2 | 11 | .. | *53.39 | 36.10 | Optium Omega | MS |
| 9274D | glucose indicator blood strip: diagnostic, 50 diagnostic strips | 2 | 11 | .. | *53.39 | 36.10 | Accu-Chek Go | RD |
| 9276F | glucose indicator blood strip: diagnostic, 50 diagnostic strips | 2 | 11 | .. | *53.39 | 36.10 | Betachek | NA |
| 9277G | glucose indicator blood strip: diagnostic, 50 diagnostic strips | 2 | 11 | .. | *53.39 | 36.10 | Betachek G5 | NA |
| 9278H | glucose indicator blood strip: diagnostic, 50 diagnostic strips | 2 | 11 | .. | *53.39 | 36.10 | CareSens | LB |
| 9279J | glucose indicator blood strip: diagnostic, 50 diagnostic strips | 2 | 11 | .. | *46.11 | 36.10 | Glucoflex-R | NA |
| 9281L | glucose indicator blood strip: diagnostic, 50 diagnostic strips | 2 | 11 | .. | *53.39 | 36.10 | SensoCard | PX |
| 9297H | glucose indicator blood strip: diagnostic, 50 diagnostic strips | 2 | 11 | .. | *53.39 | 36.10 | Bionime Rightest | QB |
| 9472M | glucose indicator blood strip: diagnostic, 50 diagnostic strips | 2 | 11 | .. | *53.39 | 36.10 | MyGlucoHealth | EH |
| 9486G | glucose indicator blood strip: diagnostic, | 2 | 11 | .. | *53.39 | 36.10 | Lifeline Attest | OI |

# VARIOUS

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|
| | 50 diagnostic strips | | | | | | | |
| 9275E | glucose indicator blood strip: diagnostic, 51 diagnostic strips | 2 | 11 | .. | *53.39 | 36.10 | Accu-Chek Integra | RD |
| | **GLUCOSE INDICATOR BLOOD**<br>**Restricted benefit**<br>For use in patients on insulin therapy | | | | | | | |
| 9300L<br>*NP* | glucose indicator blood strip: diagnostic, 100 diagnostic strips | ‡1 | 5 | .. | 53.37 | 36.10 | Accu-Chek Mobile | RD |
| | **GLUCOSE INDICATOR BLOOD**<br>**Restricted benefit**<br>For use in patients on insulin therapy who are receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements<br>**Note**<br>No applications for increased maximum quantities and/or repeats will be authorised. | | | | | | | |
| 9301M | glucose indicator blood strip: diagnostic, 100 diagnostic strips | ‡1 | 11 | .. | 53.37 | 36.10 | Accu-Chek Mobile | RD |

## GENERAL NUTRIENTS

## OTHER NUTRIENTS

**TRIGLYCERIDES MEDIUM CHAIN**

**Authority required**
Chylous ascites

**Authority required**
Chylothorax

**Authority required**
Fat malabsorption due to liver disease, short gut syndrome, cystic fibrosis and gastrointestinal disorders

**Authority required**
Hyperlipoproteinaemia type 1

**Authority required**
Intractable childhood epilepsy or cerebrospinal fluid glucose transporter defect, requiring a ketogenic diet

**Authority required**
Long chain fatty acid oxidation disorders

**Note**
No applications for increased maximum quantities and/or repeats will be authorised.

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 3128P<br>*NP* | triglycerides medium chain oil: oral, 500 mL | 2 | 5 | .. | *52.59 | 36.10 | MCT Oil | SB |
| 9327X<br>*NP* | triglycerides medium chain oral liquid, 1 x 250 mL bottle | 8 | 5 | .. | *214.63 | 36.10 | Liquigen | SB |

### *Fat/carbohydrates/proteins/minerals/vitamins, combinations*

**AMINO ACID SYNTHETIC FORMULA**

**Authority required**
Initial treatment, in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist, for up to 6 months, for cows' milk protein enteropathy with combined intolerance to both soy protein and protein hydrolysate formulae (not isolated colic or reflux) in a child up to the age of 24 months. Combined intolerance is demonstrated when the child has failed to respond to a strict cows' milk protein free and strict soy protein free diet with a protein hydrolysate (with or without medium chain triglycerides) as the principal formula. The name of the specialist and the date of birth of the patient must be included in the authority application

**Authority required**
Initial treatment, in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist, for up to 6 months, for severe cows' milk protein enteropathy with failure to thrive (not isolated infant colic or reflux) in a child up to the age of 24 months. The name of the specialist and the date of birth of the patient must be included in the authority application

**Authority required**
Initial treatment for combined intolerance (not isolated infant colic or reflux) to cows' milk protein, soy protein and protein hydrolysate formulae in a child aged over 24 months. The child must have been assessed by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist. The name of the specialist and the date of birth of the patient must be included in the authority application

**Note**
No applications for increased maximum quantities and/or repeats will be authorised.

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 1180D<br>*NP* | amino acid synthetic formula oral liquid: powder for, 400 g | 8 | 5 | .. | *361.35 | 36.10 | Neocate Advance Vanilla | SB |

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|
| 8574G<br>*NP* | amino acid synthetic formula oral liquid: powder for, 400 g | 8 | 5 | .. | *361.35 | 36.10 | EleCare | AB |
| 8754R<br>*NP* | amino acid synthetic formula oral liquid: powder for, 400 g | 8 | 5 | .. | *361.35 | 36.10 | Neocate Advance | SB |

**AMINO ACID SYNTHETIC FORMULA**

**Authority required**

Treatment, in consultation with a specialist allergist or clinical immunologist, for a child with cows' milk anaphylaxis, up to the age of 24 months. Anaphylaxis is defined as a severe and/or potentially life threatening allergic reaction. The name of the specialist and the date of birth of the patient must be included in the authority application

**Authority required**

Continuing treatment for cows' milk protein enteropathy with combined intolerance to both soy protein and protein hydrolysate formulae (not isolated infant colic or reflux) in a child up to the age of 24 months. The child must have been assessed or have an appointment to be assessed by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist. The name of the specialist and the date of birth of the patient must be included in the authority application

**Authority required**

Continuing treatment for severe cows' milk protein enteropathy with failure to thrive (not isolated infant colic or reflux) in a child up to the age of 24 months. The child must have been assessed at least once or have an appointment to be assessed by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist. Then name of the specialist and the date of birth of the patient must be included in the authority application

**Authority required**

Continuing treatment for combined intolerance (not isolated infant colic or reflux) to cows' milk protein, soy protein and protein hydrolysate formulae in a child aged over 24 months. The child must have been assessed by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist at intervals not greater than 12 months. The name of the specialist and the date of birth of the patient must be included in the authority application

**Authority required**

Severe intestinal malabsorption including short bowel syndrome where protein hydrolysate formulae have failed

**Authority required**

Severe intestinal malabsorption including short bowel syndrome where the patient has been receiving parenteral nutrition

**Note**

Authorities for increased maximum quantities, up to a maximum of 20, may be authorised.

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 1192R<br>*NP* | amino acid synthetic formula oral liquid: powder for, 400 g | 8 | 5 | .. | *361.35 | 36.10 | Neocate Advance Vanilla | SB |
| 8575H<br>*NP* | amino acid synthetic formula oral liquid: powder for, 400 g | 8 | 5 | .. | *361.35 | 36.10 | EleCare | AB |
| 8755T<br>*NP* | amino acid synthetic formula oral liquid: powder for, 400 g | 8 | 5 | .. | *361.35 | 36.10 | Neocate Advance | SB |

**AMINO ACID SYNTHETIC FORMULA**

**Authority required**

Initial treatment for up to 3 months, by a clinical immunologist, suitably qualified allergist or gastroenterologist in a patient 18 years of age or less with eosinophilic oesophagitis who requires an amino acid based formula as a component of a dietary elimination programme. Treatment with oral steroids should not be commenced during the period of initial treatment.

Eosinophilic oesophagitis is demonstrated by the following criteria:

(i) Chronic symptoms of reflux that persisted despite a 2-month trial of a proton pump inhibitor or chronic dysphagia; and

(ii) A lack of demonstrable anatomic abnormality with the exception of stricture, which can be attributable to eosinophilic oesophagitis; and

(iii) Eosinophilic infiltration of the oesophagus, demonstrated by oesophageal biopsy specimens obtained by endoscopy and where the most densely involved oesophageal biopsy had 20 or more eosinophils in any single 400 x high powered field, along with normal antral and duodenal biopsies.

The date of birth of the patient must be included in the authority

**Authority required**

Continuing treatment by a clinical immunologist, suitably qualified allergist or gastroenterologist in a patient 18 years of age or less with eosinophilic oesophagitis who has responded to an initial course of PBS-subsidised treatment. Response to initial treatment is demonstrated by oesophageal biopsy specimens obtained by endoscopy, where the most densely involved oesophageal biopsy had 5 or less eosinophils in any single 400 x high powered field, along with normal antral and duodenal biopsies. The response criteria will not be deemed to have been met if oral steroids were commenced during initial treatment

**Note**

Authorities for increased maximum quantities, up to a maximum of 52, may be authorised.

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 1521C<br>*NP* | amino acid synthetic formula oral liquid: powder for, 400 g | 12 | 5 | .. | *531.87 | 36.10 | Neocate Advance Vanilla | SB |
| 2250K<br>*NP* | amino acid synthetic formula oral liquid: powder for, 400 g | 12 | 5 | .. | *531.87 | 36.10 | EleCare | AB |

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|
| | **AMINO ACID SYNTHETIC FORMULA SUPPLEMENTED WITH LONG CHAIN POLYUNSATURATED FATTY ACIDS**<br>**Authority required**<br>Initial treatment, in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist, for up to 6 months, for cows' milk protein enteropathy with combined intolerance to both soy protein and protein hydrolysate formulae (not isolated colic or reflux) in a child up to the age of 24 months. Combined intolerance is demonstrated when the child has failed to respond to a strict cows' milk protein free and strict soy protein free diet with a protein hydrolysate (with or without medium chain triglycerides) as the principal formula. The name of the specialist and the date of birth of the patient must be included in the authority application<br>**Authority required**<br>Initial treatment, in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist, for up to 6 months, for severe cows' milk protein enteropathy with failure to thrive (not isolated infant colic or reflux) in a child up to the age of 24 months. The name of the specialist and the date of birth of the patient must be included in the authority application<br>**Authority required**<br>Initial treatment for combined intolerance (not isolated infant colic or reflux) to cows' milk protein, soy protein and protein hydrolysate formulae in a child aged over 24 months. The child must have been assessed by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist. The name of the specialist and the date of birth of the patient must be included in the authority application<br>**Note**<br>No applications for increased maximum quantities and/or repeats will be authorised. | | | | | | | |
| 2246F<br>*NP* | amino acid synthetic formula supplemented with long chain polyunsaturated fatty acids oral liquid: powder for, 400 g | 8 | 5 | .. | *368.07 | 36.10 | Neocate LCP | SB |
| 9339M<br>*NP* | amino acid synthetic formula supplemented with long chain polyunsaturated fatty acids oral liquid: powder for, 400 g | 8 | 5 | .. | *368.07 | 36.10 | EleCare LCP | AB |
| | **AMINO ACID SYNTHETIC FORMULA SUPPLEMENTED WITH LONG CHAIN POLYUNSATURATED FATTY ACIDS**<br>**Authority required**<br>Treatment, in consultation with a specialist allergist or clinical immunologist, for a child with cows' milk anaphylaxis, up to the age of 24 months. Anaphylaxis is defined as a severe and/or potentially life threatening allergic reaction. The name of the specialist and the date of birth of the patient must be included in the authority application<br>**Authority required**<br>Continuing treatment for cows' milk protein enteropathy with combined intolerance to both soy protein and protein hydrolysate formulae (not isolated infant colic or reflux) in a child up to the age of 24 months. The child must have been assessed or have an appointment to be assessed by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist. The name of the specialist and the date of birth of the patient must be included in the authority application<br>**Authority required**<br>Continuing treatment for severe cows' milk protein enteropathy with failure to thrive (not isolated infant colic or reflux) in a child up to the age of 24 months. The child must have been assessed at least once or have an appointment to be assessed by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist. Then name of the specialist and the date of birth of the patient must be included in the authority application<br>**Authority required**<br>Continuing treatment for combined intolerance (not isolated infant colic or reflux) to cows' milk protein, soy protein and protein hydrolysate formulae in a child aged over 24 months. The child must have been assessed by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist at intervals not greater than 12 months. The name of the specialist and the date of birth of the patient must be included in the authority application<br>**Authority required**<br>Severe intestinal malabsorption including short bowel syndrome where protein hydrolysate formulae have failed<br>**Authority required**<br>Severe intestinal malabsorption including short bowel syndrome where the patient has been receiving parenteral nutrition<br>**Note**<br>Authorities for increased maximum quantities, up to a maximum of 20, may be authorised. | | | | | | | |
| 2560R<br>*NP* | amino acid synthetic formula supplemented with long chain polyunsaturated fatty acids oral liquid: powder for, 400 g | 8 | 5 | .. | *368.07 | 36.10 | Neocate LCP | SB |
| 9340N<br>*NP* | amino acid synthetic formula supplemented with long chain polyunsaturated fatty acids oral liquid: powder for, 400 g | 8 | 5 | .. | *368.07 | 36.10 | EleCare LCP | AB |
| | **AMINO ACID SYNTHETIC FORMULA SUPPLEMENTED WITH LONG CHAIN POLYUNSATURATED FATTY ACIDS AND MEDIUM CHAIN TRIGLYCERIDES** | | | | | | | |

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|
| | **Authority required**<br>Initial treatment for up to 3 months, by a clinical immunologist, suitably qualified allergist or gastroenterologist in a patient 18 years of age or less with eosinophilic oesophagitis who requires an amino acid based formula as a component of a dietary elimination programme. Treatment with oral steroids should not be commenced during the period of initial treatment.<br>Eosinophilic oesophagitis is demonstrated by the following criteria:<br>(i) Chronic symptoms of reflux that persisted despite a 2-month trial of a proton pump inhibitor or chronic dysphagia; and<br>(ii) A lack of demonstrable anatomic abnormality with the exception of stricture, which can be attributable to eosinophilic oesophagitis; and<br>(iii) Eosinophilic infiltration of the oesophagus, demonstrated by oesophageal biopsy specimens obtained by endoscopy and where the most densely involved oesophageal biopsy had 20 or more eosinophils in any single 400 x high powered field, along with normal antral and duodenal biopsies.<br>The date of birth of the patient must be included in the authority<br>**Authority required**<br>Continuing treatment by a clinical immunologist, suitably qualified allergist or gastroenterologist in a patient 18 years of age or less with eosinophilic oesophagitis who has responded to an initial course of PBS-subsidised treatment. Response to initial treatment is demonstrated by oesophageal biopsy specimens obtained by endoscopy, where the most densely involved oesophageal biopsy had 5 or less eosinophils in any single 400 x high powered field, along with normal antral and duodenal biopsies. The response criteria will not be deemed to have been met if oral steroids were commenced during initial treatment<br>**Note**<br>Authorities for increased maximum quantities, up to a maximum of 52, may be authorised. | | | | | | | |
| 1545H<br>*NP* | amino acid synthetic formula supplemented with long chain polyunsaturated fatty acids and medium chain triglycerides oral liquid: powder for, 400 g | 12 | 5 | .. | *542.43 | 36.10 | Neocate Gold | SB |
| | **AMINO ACID SYNTHETIC FORMULA SUPPLEMENTED WITH LONG CHAIN POLYUNSATURATED FATTY ACIDS AND MEDIUM CHAIN TRIGLYCERIDES**<br>**Authority required**<br>Initial treatment, in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist, for up to 6 months, for cows' milk protein enteropathy with combined intolerance to both soy protein and protein hydrolysate formulae (not isolated colic or reflux) in a child up to the age of 24 months. Combined intolerance is demonstrated when the child has failed to respond to a strict cows' milk protein free and strict soy protein free diet with a protein hydrolysate (with or without medium chain triglycerides) as the principal formula. The name of the specialist and the date of birth of the patient must be included in the authority application<br>**Authority required**<br>Initial treatment, in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist, for up to 6 months, for severe cows' milk protein enteropathy with failure to thrive (not isolated infant colic or reflux) in a child up to the age of 24 months. The name of the specialist and the date of birth of the patient must be included in the authority application<br>**Authority required**<br>Initial treatment for combined intolerance (not isolated infant colic or reflux) to cows' milk protein, soy protein and protein hydrolysate formulae in a child aged over 24 months. The child must have been assessed by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist. The name of the specialist and the date of birth of the patient must be included in the authority application<br>**Note**<br>No applications for increased maximum quantities and/or repeats will be authorised. | | | | | | | |
| 5466Q<br>*NP* | amino acid synthetic formula supplemented with long chain polyunsaturated fatty acids and medium chain triglycerides oral liquid: powder for, 400 g | 8 | 5 | .. | *368.07 | 36.10 | Neocate Gold | SB |
| | **AMINO ACID SYNTHETIC FORMULA SUPPLEMENTED WITH LONG CHAIN POLYUNSATURATED FATTY ACIDS AND MEDIUM CHAIN TRIGLYCERIDES**<br>**Authority required**<br>Treatment, in consultation with a specialist allergist or clinical immunologist, for a child with cows' milk anaphylaxis, up to the age of 24 months. Anaphylaxis is defined as a severe and/or potentially life threatening allergic reaction. The name of the specialist and the date of birth of the patient must be included in the authority application<br>**Authority required**<br>Continuing treatment for cows' milk protein enteropathy with combined intolerance to both soy protein and protein hydrolysate formulae (not isolated infant colic or reflux) in a child up to the age of 24 months. The child must have been assessed or have an appointment to be assessed by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist. The name of the specialist and the date of birth of the patient must be included in the authority application<br>**Authority required**<br>Continuing treatment for severe cows' milk protein enteropathy with failure to thrive (not isolated infant colic or reflux) in a child up to the age of 24 months. The child must have been assessed at least once or have an appointment to be assessed by a specialist allergist, clinical immunologist or | | | | | | | |

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|
| | specialist paediatric gastroenterologist. Then name of the specialist and the date of birth of the patient must be included in the authority application | | | | | | | |
| | **Authority required**<br>Continuing treatment for combined intolerance (not isolated infant colic or reflux) to cows' milk protein, soy protein and protein hydrolysate formulae in a child aged over 24 months. The child must have been assessed by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist at intervals not greater than 12 months. The name of the specialist and the date of birth of the patient must be included in the authority application | | | | | | | |
| | **Authority required**<br>Severe intestinal malabsorption including short bowel syndrome where protein hydrolysate formulae have failed | | | | | | | |
| | **Authority required**<br>Severe intestinal malabsorption including short bowel syndrome where the patient has been receiving parenteral nutrition | | | | | | | |
| | **Note**<br>Authorities for increased maximum quantities, up to a maximum of 20, may be authorised. | | | | | | | |
| 5467R<br>*NP* | amino acid synthetic formula supplemented with long chain polyunsaturated fatty acids and medium chain triglycerides oral liquid: powder for, 400 g | 8 | 5 | .. | *368.07 | 36.10 | Neocate Gold | SB |
| | **PROTEIN HYDROLYSATE FORMULA WITH MEDIUM CHAIN TRIGLYCERIDES**<br>**Authority required**<br>Initial treatment by, or in consultation with, a specialist allergist, clinical immunologist, paediatrician or specialist paediatric gastroenterologist for both cows' milk protein enteropathy and intolerance to soy protein (not isolated infant colic or reflux) in a child up to the age of 24 months. The child should have failed to respond to a strict soy-based cows' milk protein free diet. The date of birth of the patient must be included in the authority application | | | | | | | |
| | **Authority required**<br>Continuing treatment by, or in consultation with, a specialist allergist, clinical immunologist, paediatrician or specialist paediatric gastroenterologist for both cows' milk protein enteropathy and intolerance to soy protein (not isolated infant colic or reflux) in a child up to the age of 24 months, where clinical improvement has been demonstrated with the protein hydrolysate formula with medium chain triglycerides. The date of birth of the patient must be included in the authority application | | | | | | | |
| | **Authority required**<br>Treatment by a specialist allergist, clinical immunologist, paediatrician or specialist paediatric gastroenterologist for both cows' milk protein enteropathy and intolerance to soy protein (not isolated infant colic or reflux) in a child aged over 24 months. The child must have been assessed by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist. The name of the specialist and the date of birth of the patient must be included in the authority application | | | | | | | |
| | **Authority required**<br>Biliary atresia | | | | | | | |
| | **Authority required**<br>Severe diarrhoea of greater than 2 weeks' duration in an infant aged less than 4 months. The date of birth of the patient must be included in the authority application | | | | | | | |
| | **Authority required**<br>Severe intestinal malabsorption including short bowel syndrome | | | | | | | |
| | **Authority required**<br>Chronic liver failure with fat malabsorption | | | | | | | |
| | **Authority required**<br>Chylous ascites | | | | | | | |
| | **Authority required**<br>Chylothorax | | | | | | | |
| | **Authority required**<br>Cystic fibrosis | | | | | | | |
| | **Authority required**<br>Enterokinase deficiency | | | | | | | |
| | **Authority required**<br>Proven fat malabsorption | | | | | | | |
| | **Note**<br>No applications for increased maximum quantities and/or repeats will be authorised. | | | | | | | |
| 2676W<br>*NP* | protein hydrolysate formula with medium chain triglycerides oral liquid: powder for, 400 g | 8 | 5 | .. | *172.15 | 36.10 | Alfaré | NT |
| | **PROTEIN HYDROLYSATE FORMULA WITH MEDIUM CHAIN TRIGLYCERIDES** | | | | | | | |

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|
| | **Authority required**<br>Initial treatment by, or in consultation with, a specialist allergist, clinical immunologist, paediatrician or specialist paediatric gastroenterologist for both cows' milk protein enteropathy and intolerance to soy protein (not isolated infant colic or reflux) in a child up to the age of 24 months. The child should have failed to respond to a strict soy-based cows' milk protein free diet. The date of birth of the patient must be included in the authority application | | | | | | | |
| | **Authority required**<br>Continuing treatment by, or in consultation with, a specialist allergist, clinical immunologist, paediatrician or specialist paediatric gastroenterologist for both cows' milk protein enteropathy and intolerance to soy protein (not isolated infant colic or reflux) in a child up to the age of 24 months, where clinical improvement has been demonstrated with the protein hydrolysate formula with medium chain triglycerides. The date of birth of the patient must be included in the authority application | | | | | | | |
| | **Authority required**<br>Treatment by a specialist allergist, clinical immunologist, paediatrician or specialist paediatric gastroenterologist for both cows' milk protein enteropathy and intolerance to soy protein (not isolated infant colic or reflux) in a child aged over 24 months. The child must have been assessed by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist. The name of the specialist and the date of birth of the patient must be included in the authority application | | | | | | | |
| | **Authority required**<br>Biliary atresia | | | | | | | |
| | **Authority required**<br>Chronic liver failure with fat malabsorption | | | | | | | |
| | **Authority required**<br>Chylous ascites | | | | | | | |
| | **Authority required**<br>Cystic fibrosis | | | | | | | |
| | **Authority required**<br>Enterokinase deficiency | | | | | | | |
| | **Authority required**<br>Proven fat malabsorption | | | | | | | |
| | **Authority required**<br>Severe diarrhoea of greater than 2 weeks' duration in an infant aged less than 4 months. The date of birth of the patient must be included in the authority application | | | | | | | |
| | **Authority required**<br>Severe intestinal malabsorption including short bowel syndrome | | | | | | | |
| | **Note**<br>No applications for increased maximum quantities and/or repeats will be authorised. | | | | | | | |
| 8259Q<br>*NP* | protein hydrolysate formula with medium chain triglycerides oral liquid: powder for, 450 g | 8 | 5 | .. | *110.07 | 36.10 | Karicare Aptamil Pepti-Junior Gold | NU |
| | **TRIGLYCERIDES MEDIUM CHAIN FORMULA**<br>**Restricted benefit**<br>Fat malabsorption due to liver disease, short gut syndrome, cystic fibrosis and gastrointestinal disorders | | | | | | | |
| | **Restricted benefit**<br>Hyperlipoproteinaemia type 1 | | | | | | | |
| | **Restricted benefit**<br>Long chain fatty acid oxidation disorders | | | | | | | |
| | **Restricted benefit**<br>Chylous ascites | | | | | | | |
| | **Restricted benefit**<br>Chylothorax | | | | | | | |
| | **Note**<br>No applications for increased maximum quantities and/or repeats will be authorised. | | | | | | | |
| | **Note**<br>Not indicated for the treatment of intractable childhood epilepsy or cerebrospinal fluid glucose transporter defect requiring a ketogenic diet. | | | | | | | |
| 1938B<br>*NP* | triglycerides medium chain formula oral liquid: powder for, 400 g | 8 | 5 | .. | *443.03 | 36.10 | Lipistart | VF |
| 8478F<br>*NP* | triglycerides medium chain formula oral liquid: powder for, 400 g | 8 | 5 | .. | *421.51 | 36.10 | Monogen | SB |
| | **TRIGLYCERIDES MEDIUM CHAIN FORMULA**<br>**Restricted benefit** | | | | | | | |

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|
| | Chylous ascites | | | | | | | |
| | **Restricted benefit** | | | | | | | |
| | Chylothorax | | | | | | | |
| | **Restricted benefit** | | | | | | | |
| | Fat malabsorption due to liver disease, short gut syndrome, cystic fibrosis and gastrointestinal disorders | | | | | | | |
| | **Note** | | | | | | | |
| | No applications for increased maximum quantities and/or repeats will be authorised. | | | | | | | |
| | **Note** | | | | | | | |
| | Caprilon is not indicated for the treatment of intractable childhood epilepsy or cerebrospinal fluid glucose transporter defect requiring a ketogenic diet, long chain fatty acid oxidation disorders or hyperlipoproteinaemia type 1. | | | | | | | |
| 8629E *NP* | triglycerides medium chain formula oral liquid: powder for, 420 g | 8 | 5 | .. | *467.67 | 36.10 | Caprilon | SB |

## *Carbohydrates*

**AMYLOPECTIN MODIFIED LONG CHAIN**

**Restricted benefit**

Glycogen storage disease

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 9386B *NP* | amylopectin modified long chain oral liquid: powder for, 30 x 60 g sachets | 4 | 5 | .. | *752.51 | 36.10 | Glycosade | VF |

## *Milk substitutes*

**MILK POWDER LACTOSE FREE FORMULA**

**Authority required**

Acute lactose intolerance in infants up to the age of 12 months. The date of birth of the patient must be included in the authority application

**Note**

No applications for increased maximum quantities and/or repeats will be authorised. No more than 1 application per patient will be authorised.

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 8282X *NP* | milk powder lactose free formula oral liquid: powder for, 900 g | 5 | .. | .. | *113.08 | 36.10 | S-26 LF | PF |

**MILK POWDER LACTOSE FREE FORMULA**

**Authority required**

Proven chronic lactose intolerance in infants up to the age of 12 months. The date of birth of the patient must be included in the authority application. Lactose intolerance must have been proven by either:

(a) relief of symptoms on supervised withdrawal of lactose from the diet for 3 or 4 days and subsequent re-emergence of symptoms on rechallenge with lactose containing formulae or milk or food; or

(b) not less than 0.5% reducing substance in stool exudate tested with copper sulfate diagnostic compound tablet; or

(c) hydrogen breath test

**Note**

No applications for increased maximum quantities and/or repeats will be authorised.

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 8283Y *NP* | milk powder lactose free formula oral liquid: powder for, 900 g | 5 | 5 | .. | *113.08 | 36.10 | S-26 LF | PF |

**MILK POWDER LACTOSE FREE FORMULA PREDIGESTED**

**Authority required**

Proven chronic lactose intolerance in infants up to the age of 12 months. The date of birth of the patient must be included in the authority application. Lactose intolerance must have been proven by either:

(a) relief of symptoms on supervised withdrawal of lactose from the diet for 3 or 4 days and subsequent re-emergence of symptoms on rechallenge with lactose containing formulae or milk or food; or

(b) not less than 0.5% reducing substance in stool exudate tested with copper sulfate diagnostic compound tablet; or

(c) hydrogen breath test

**Note**

No applications for increased maximum quantities and/or repeats will be authorised.

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 2349P *NP* | milk powder lactose free formula predigested oral liquid: powder for, 900 g | 5 | 5 | .. | *89.13 | 36.10 | Karicare Aptamil De-Lact | NU |

**MILK POWDER LACTOSE FREE FORMULA PREDIGESTED**

**Authority required**

Acute lactose intolerance in infants up to the age of 12 months. The date of birth of the patient must be included in the authority application

**Note**

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|
| | No applications for increased maximum quantities and/or repeats will be authorised. No more than 1 application per patient will be authorised. | | | | | | | |
| 2350Q *NP* | milk powder lactose free formula predigested oral liquid: powder for, 900 g | 5 | .. | .. | *89.13 | 36.10 | Karicare Aptamil De-Lact | NU |

**MILK POWDER LACTOSE MODIFIED PREDIGESTED**

**Authority required**

Proven chronic lactose intolerance in children aged 1 year and over who are significantly malnourished. The date of birth of the patient must be included in the authority application. Lactose intolerance must have been proven by either:

(a) relief of symptoms on supervised withdrawal of lactose from the diet for 3 or 4 days and subsequent re-emergence of symptoms on rechallenge with lactose containing formulae or milk or food; or

(b) not less than 0.5% reducing substance in stool exudate tested with copper sulfate diagnostic compound tablet; or

(c) hydrogen breath test

**Note**

No applications for increased maximum quantities and/or repeats will be authorised.

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 2357C *NP* | milk powder lactose modified predigested oral liquid: powder for, 900 g | 3 | 10 | .. | *73.02 | 36.10 | Digestelact | SJ |

**MILK POWDER LACTOSE MODIFIED PREDIGESTED**

**Authority required**

Acute lactose intolerance in children aged 1 year and over. The date of birth of the patient must be included in the authority application

**Note**

No applications for increased maximum quantities and/or repeats will be authorised. No more than 1 application per patient will be authorised.

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 2358D *NP* | milk powder lactose modified predigested oral liquid: powder for, 900 g | 3 | 1 | .. | *73.02 | 36.10 | Digestelact | SJ |

**MILK POWDER SYNTHETIC LOW CALCIUM**

**Authority required**

Hypercalcaemia in children under the age of 4 years

**Note**

No applications for increased maximum quantities and/or repeats will be authorised.

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 3092R *NP* | milk powder synthetic low calcium oral liquid: powder for, 400 g | 8 | 5 | .. | *381.59 | 36.10 | Locasol | SB |

## *Other combinations of nutrients*

**AMINO ACID FORMULA WITH FAT, CARBOHYDRATE, VITAMINS, MINERALS AND TRACE ELEMENTS WITHOUT METHIONINE AND SUPPLEMENTED WITH DOCOSAHEXANOIC ACID**

**Restricted benefit**

Pyridoxine non-responsive homocystinuria

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 3417W *NP* | amino acid formula with fat, carbohydrate, vitamins, minerals and trace elements without methionine and supplemented with docosahexanoic acid oral liquid, 36 x 125 mL cans | 4 | 5 | .. | *2508.19 | 36.10 | HCU Anamix junior LQ | SB |

**AMINO ACID FORMULA WITH FAT, CARBOHYDRATE, VITAMINS, MINERALS AND TRACE ELEMENTS WITHOUT PHENYLALANINE AND TYROSINE, AND SUPPLEMENTED WITH DOCOSAHEXANOIC ACID**

**Restricted benefit**

Tyrosinaemia

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 9330C *NP* | amino acid formula with fat, carbohydrate, vitamins, minerals and trace elements without phenylalanine and tyrosine, and supplemented with docosahexanoic acid oral liquid, 36 x 125 mL cans | 4 | 5 | .. | *2508.19 | 36.10 | TYR Anamix junior LQ | SB |

**AMINO ACID FORMULA WITHOUT PHENYLALANINE**

**Restricted benefit**

Phenylketonuria

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 8678R *NP* | amino acid formula without phenylalanine 1 g tablet, 75 | 24 | 5 | .. | *1427.19 | 36.10 | Phlexy-10 | SB |

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|
| 8554F<br>*NP* | amino acid formula without phenylalanine 500 mg capsule, 200 | 16 | 5 | .. | *1276.55 | 36.10 | Phlexy-10 | SB |
| 2347M<br>*NP* | amino acid formula without phenylalanine oral liquid: powder for, 30 x 20 g sachets | 7 | 5 | .. | *1463.12 | 36.10 | Phlexy-10 Drink Mix | SB |
| | **AMINO ACID FORMULA WITH VITAMINS, MINERALS AND LONG CHAIN POLYUNSATURATED FATTY ACIDS WITHOUT PHENYLALANINE**<br>**Restricted benefit**<br>Phenylketonuria | | | | | | | |
| 8479G<br>*NP* | amino acid formula with vitamins, minerals and long chain polyunsaturated fatty acids without phenylalanine oral liquid: powder for, 400 g | 8 | 5 | .. | *703.83 | 36.10 | PKU Anamix infant | SB |
| | **AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT LYSINE AND LOW IN TRYPTOPHAN**<br>**Restricted benefit**<br>A child aged from 6 months up to 10 years with proven glutaric aciduria type 1 | | | | | | | |
| 9438R<br>*NP* | amino acid formula with vitamins and minerals without lysine and low in tryptophan oral liquid: powder for, 30 x 24 g sachets | 4 | 5 | .. | *2114.59 | 36.10 | GA gel | VF |
| | **AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT LYSINE AND LOW IN TRYPTOPHAN**<br>**Restricted benefit**<br>A patient aged 3 years or older with proven glutaric aciduria type 1 | | | | | | | |
| 5484P<br>*NP* | amino acid formula with vitamins and minerals without lysine and low in tryptophan oral liquid: powder for, 30 x 25 g sachets | 4 | 5 | .. | *3154.63 | 36.10 | GA express 15 | VF |
| | **AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT LYSINE AND LOW IN TRYPTOPHAN**<br>**Restricted benefit**<br>An infant or young child with proven glutaric aciduria type 1 | | | | | | | |
| 2650L<br>*NP* | amino acid formula with vitamins and minerals without lysine and low in tryptophan oral liquid: powder for, 400 g | 8 | 5 | .. | *769.51 | 36.10 | GA1 Anamix infant | SB |
| | **AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT LYSINE AND LOW IN TRYPTOPHAN**<br>**Restricted benefit**<br>A child aged less than 9 years with proven glutaric aciduria type 1 | | | | | | | |
| 2646G<br>*NP* | amino acid formula with vitamins and minerals without lysine and low in tryptophan oral liquid: powder for, 500 g | 8 | 5 | .. | *1784.95 | 36.10 | XLYS, LOW TRY Maxamaid | SB |
| | **AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT METHIONINE**<br>**Restricted benefit**<br>Pyridoxine non-responsive homocystinuria | | | | | | | |
| 1548L<br>*NP* | AMINO ACID FORMULA with VITAMINS and MINERALS without METHIONINE Oral liquid 125 mL, 30, 1 | 3 | 5 | .. | *3098.55 | 36.10 | HCU Lophlex LQ 20 | SB |
| 9133Q<br>*NP* | amino acid formula with vitamins and minerals without methionine oral liquid, 30 x 130 mL cans | 4 | 5 | .. | *3098.59 | 36.10 | HCU cooler 15 | VF |
| 2640Y<br>*NP* | amino acid formula with vitamins and minerals without methionine oral liquid, 30 x 174 mL pouches | 4 | 5 | .. | *4082.59 | 36.10 | HCU cooler 20 | VF |
| 2639X<br>*NP* | amino acid formula with vitamins and minerals without methionine oral liquid, 30 x 87 mL pouches | 4 | 5 | .. | *2114.59 | 36.10 | HCU cooler 10 | VF |
| 8677Q<br>*NP* | amino acid formula with vitamins and minerals without methionine oral liquid: powder for, 30 x 24 g sachets | 4 | 5 | .. | *2114.59 | 36.10 | HCU gel | VF |
| 8744F | amino acid formula with vitamins and | 4 | 5 | .. | *3098.59 | 36.10 | HCU express 15 | VF |

# VARIOUS

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|
| *NP* | minerals without methionine oral liquid: powder for, 30 x 25 g sachets | | | | | | | |
| 8328H *NP* | amino acid formula with vitamins and minerals without methionine oral liquid: powder for, 500 g | 8 | 5 | .. | *1784.95 | 36.10 | XMET Maxamaid | SB |
| 8416Y *NP* | amino acid formula with vitamins and minerals without methionine oral liquid: powder for, 500 g | 8 | 5 | .. | *2704.95 | 36.10 | XMET Maxamum | SB |
| | **AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT METHIONINE** | | | | | | | |
| | **Restricted benefit** | | | | | | | |
| | For infants and very young children with pyridoxine non-responsive homocystinuria | | | | | | | |
| 8417B *NP* | amino acid formula with vitamins and minerals without methionine oral liquid: powder for, 400 g | 8 | 5 | .. | *769.51 | 36.10 | HCU Anamix infant | SB |
| | **AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT METHIONINE, THREONINE AND VALINE AND LOW IN ISOLEUCINE** | | | | | | | |
| | **Restricted benefit** | | | | | | | |
| | Methylmalonic acidaemia | | | | | | | |
| | **Restricted benefit** | | | | | | | |
| | Propionic acidaemia | | | | | | | |
| 1923F *NP* | AMINO ACID FORMULA with VITAMINS and MINERALS without METHIONINE, THREONINE and VALINE and low in ISOLEUCINE Oral liquid 130 mL, 30, 1 | 4 | 5 | .. | *3098.59 | 36.10 | MMA/PA cooler 15 | VF |
| 3444G *NP* | amino acid formula with vitamins and minerals without methionine, threonine and valine and low in isoleucine oral liquid: powder for, 30 x 24 g sachets | 4 | 5 | .. | *2114.59 | 36.10 | MMA/PA gel | VF |
| 3443F *NP* | amino acid formula with vitamins and minerals without methionine, threonine and valine and low in isoleucine oral liquid: powder for, 30 x 25 g sachets | 4 | 5 | .. | *3098.59 | 36.10 | MMA/PA express 15 | VF |
| 8058D *NP* | amino acid formula with vitamins and minerals without methionine, threonine and valine and low in isoleucine oral liquid: powder for, 400 g | 8 | 5 | .. | *769.51 | 36.10 | MMA/PA Anamix infant | SB |
| 8059E *NP* | amino acid formula with vitamins and minerals without methionine, threonine and valine and low in isoleucine oral liquid: powder for, 500 g | 8 | 5 | .. | *1784.95 | 36.10 | XMTVI Maxamaid | SB |
| 8061G *NP* | amino acid formula with vitamins and minerals without methionine, threonine and valine and low in isoleucine oral liquid: powder for, 500 g | 8 | 5 | .. | *2704.95 | 36.10 | XMTVI Maxamum | SB |
| | **AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT PHENYLALANINE** | | | | | | | |
| | **Restricted benefit** | | | | | | | |
| | Phenylketonuria | | | | | | | |
| 1411G *NP* | AMINO ACID FORMULA with VITAMINS and MINERALS without PHENYLALANINE Sachets 18.2 g, 60, 1 | 3 | 5 | .. | *1640.28 | 36.10 | add-ins | SB |
| 1909L *NP* | AMINO ACID FORMULA with VITAMINS and MINERALS without PHENYLALANINE Sachets 34 g, 30, 1 | 4 | 5 | .. | *2054.23 | 36.10 | PKU express 20 | VF |
| 8746H *NP* | amino acid formula with vitamins and minerals without phenylalanine oral liquid, 18 x 250 mL cans | 5 | 5 | .. | *1313.48 | 36.10 | Easiphen | SB |
| 9021T *NP* | amino acid formula with vitamins and minerals without phenylalanine oral liquid, 30 x 125 mL cans | 3 | 5 | .. | *1549.65 | 36.10 | PKU Lophlex LQ 20 | SB |
| 8846N *NP* | amino acid formula with vitamins and minerals without phenylalanine oral liquid, 30 x 130 mL cans | 4 | 5 | .. | *1548.55 | 36.10 | PKU Cooler 15 | VF |
| 2474F | amino acid formula with vitamins and | 4 | 5 | .. | *2054.23 | 36.10 | PKU Cooler 20 | VF |

# VARIOUS

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|
| *NP* | minerals without phenylalanine oral liquid, 30 x 174 mL cans | | | | | | | |
| 5483N *NP* | amino acid formula with vitamins and minerals without phenylalanine oral liquid, 30 x 85 g sachets | 4 | 5 | .. | *1058.83 | 36.10 | PKU squeezie | VF |
| 2382J *NP* | amino acid formula with vitamins and minerals without phenylalanine oral liquid, 30 x 87 mL cans | 4 | 5 | .. | *1034.99 | 36.10 | PKU Cooler 10 | VF |
| 9396M *NP* | amino acid formula with vitamins and minerals without phenylalanine oral liquid, 36 x 125 mL cans | 4 | 5 | .. | *1270.07 | 36.10 | PKU Anamix Junior LQ | SB |
| 9397N *NP* | amino acid formula with vitamins and minerals without phenylalanine oral liquid, 60 x 62.5 mL cans | 2 | 5 | .. | *1059.57 | 36.10 | PKU Lophlex LQ 10 | SB |
| 8555G *NP* | amino acid formula with vitamins and minerals without phenylalanine oral liquid: powder for, 30 x 24 g sachets | 4 | 5 | .. | *1058.83 | 36.10 | PKU gel | VF |
| 8591E *NP* | amino acid formula with vitamins and minerals without phenylalanine oral liquid: powder for, 30 x 25 g sachets | 4 | 5 | .. | *1549.35 | 36.10 | PKU express 15 | VF |
| 8804J *NP* | amino acid formula with vitamins and minerals without phenylalanine oral liquid: powder for, 30 x 27.8 g sachets | 3 | 5 | .. | *1549.65 | 36.10 | Lophlex | SB |
| 8613H *NP* | amino acid formula with vitamins and minerals without phenylalanine oral liquid: powder for, 30 x 29 g sachets | 4 | 5 | .. | *892.31 | 36.10 | PKU Anamix Junior | SB |
| 8727H *NP* | amino acid formula with vitamins and minerals without phenylalanine oral liquid: powder for, 30 x 50 g sachets | 3 | 5 | .. | *1512.27 | 36.10 | XP Maxamum | SB |
| 8545R *NP* | amino acid formula with vitamins and minerals without phenylalanine oral liquid: powder for, 400 g | 8 | 5 | .. | *848.79 | 36.10 | Phenex-2 | AB |
| 2738D *NP* | amino acid formula with vitamins and minerals without phenylalanine oral liquid: powder for, 500 g | 8 | 5 | .. | *884.23 | 36.10 | XP Maxamaid | SB |
| 2739E *NP* | amino acid formula with vitamins and minerals without phenylalanine oral liquid: powder for, 500 g | 8 | 5 | .. | *1352.63 | 36.10 | XP Maxamum | SB |
| | **AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT PHENYLALANINE AND TYROSINE** | | | | | | | |
| | **Restricted benefit** | | | | | | | |
| | Tyrosinaemia | | | | | | | |
| 1547K *NP* | AMINO ACID FORMULA with VITAMINS and MINERALS without PHENYLALANINE and TYROSINE Oral liquid 125 mL, 30, 1 | 3 | 5 | .. | *3098.55 | 36.10 | TYR Lophlex LQ 20 | SB |
| 9132P *NP* | amino acid formula with vitamins and minerals without phenylalanine and tyrosine oral liquid, 30 x 130 mL cans | 4 | 5 | .. | *3098.59 | 36.10 | TYR cooler 15 | VF |
| 2701E *NP* | amino acid formula with vitamins and minerals without phenylalanine and tyrosine oral liquid, 30 x 174 mL pouches | 4 | 5 | .. | *4082.59 | 36.10 | TYR cooler 20 | VF |
| 2674R *NP* | amino acid formula with vitamins and minerals without phenylalanine and tyrosine oral liquid, 30 x 87 mL pouches | 4 | 5 | .. | *2114.59 | 36.10 | TYR cooler 10 | VF |
| 8631G *NP* | amino acid formula with vitamins and minerals without phenylalanine and tyrosine oral liquid: powder for, 30 x 24 g sachets | 4 | 5 | .. | *2114.59 | 36.10 | TYR gel | VF |
| 8667E *NP* | amino acid formula with vitamins and minerals without phenylalanine and tyrosine oral liquid: powder for, 30 x 25 g sachets | 4 | 5 | .. | *3098.59 | 36.10 | TYR express 15 | VF |
| 9395L *NP* | amino acid formula with vitamins and minerals without phenylalanine and tyrosine oral liquid: powder for, 30 x 29 g sachets | 4 | 5 | .. | *1800.67 | 36.10 | TYR Anamix Junior | SB |
| 8445L *NP* | amino acid formula with vitamins and minerals without phenylalanine and | 8 | 5 | .. | *769.51 | 36.10 | TYR Anamix infant | SB |

# VARIOUS

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|---|---|---|---|---|---|---|---|---|
| | tyrosine oral liquid: powder for, 400 g | | | | | | | |
| 3078B *NP* | amino acid formula with vitamins and minerals without phenylalanine and tyrosine oral liquid: powder for, 500 g | 8 | 5 | .. | *2704.95 | 36.10 | XPhen, Tyr Maxamum | SB |
| 8446M *NP* | amino acid formula with vitamins and minerals without phenylalanine and tyrosine oral liquid: powder for, 500 g | 8 | 5 | .. | *1784.95 | 36.10 | XPhen, Tyr Maxamaid | SB |
| | **AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT VALINE, LEUCINE AND ISOLEUCINE** | | | | | | | |
| | **Restricted benefit** | | | | | | | |
| | Maple syrup urine disease | | | | | | | |
| 1546J *NP* | AMINO ACID FORMULA with VITAMINS and MINERALS without VALINE, LEUCINE and ISOLEUCINE Oral liquid 125 mL, 30, 1 | 3 | 5 | .. | *3098.55 | 36.10 | MSUD Lophlex LQ 20 | SB |
| 1914R *NP* | AMINO ACID FORMULA with VITAMINS and MINERALS without VALINE, LEUCINE and ISOLEUCINE Sachets 34 g, 30, 1 | 4 | 5 | .. | *4094.35 | 36.10 | MSUD express 20 | VF |
| 2375B *NP* | amino acid formula with vitamins and minerals without valine, leucine and isoleucine oral liquid, 30 x 130 mL cans | 4 | 5 | .. | *3098.59 | 36.10 | MSUD cooler 15 | VF |
| 2654Q *NP* | amino acid formula with vitamins and minerals without valine, leucine and isoleucine oral liquid, 30 x 174 mL pouches | 4 | 5 | .. | *4082.59 | 36.10 | MSUD cooler 20 | VF |
| 2651M *NP* | amino acid formula with vitamins and minerals without valine, leucine and isoleucine oral liquid, 30 x 87 mL pouches | 4 | 5 | .. | *2114.59 | 36.10 | MSUD cooler 10 | VF |
| 8592F *NP* | amino acid formula with vitamins and minerals without valine, leucine and isoleucine oral liquid: powder for, 30 x 24 g sachets | 4 | 5 | .. | *2114.59 | 36.10 | MSUD gel | VF |
| 8632H *NP* | amino acid formula with vitamins and minerals without valine, leucine and isoleucine oral liquid: powder for, 30 x 25 g sachets | 4 | 5 | .. | *3098.59 | 36.10 | MSUD express 15 | VF |
| 8745G *NP* | amino acid formula with vitamins and minerals without valine, leucine and isoleucine oral liquid: powder for, 30 x 29 g sachets | 4 | 5 | .. | *1800.67 | 36.10 | MSUD Anamix Junior | SB |
| 2380G *NP* | amino acid formula with vitamins and minerals without valine, leucine and isoleucine oral liquid: powder for, 400 g | 8 | 5 | .. | *769.51 | 36.10 | MSUD Anamix infant | SB |
| 8057C *NP* | amino acid formula with vitamins and minerals without valine, leucine and isoleucine oral liquid: powder for, 500 g | 8 | 5 | .. | *2704.95 | 36.10 | MSUD Maxamum | SB |
| 8260R *NP* | amino acid formula with vitamins and minerals without valine, leucine and isoleucine oral liquid: powder for, 500 g | 8 | 5 | .. | *1784.95 | 36.10 | MSUD Maxamaid | SB |
| 8310J *NP* | amino acid formula with vitamins and minerals without valine, leucine and isoleucine oral liquid: powder for, 500 g | 4 | 5 | .. | *2672.19 | 36.10 | MSUD AID III | SB |
| | **AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT VALINE, LEUCINE AND ISOLEUCINE WITH FAT, CARBOHYDRATE AND TRACE ELEMENTS AND SUPPLEMENTED WITH DOCOSAHEXANOIC ACID** | | | | | | | |
| | **Restricted benefit** | | | | | | | |
| | Maple syrup urine disease | | | | | | | |
| 9499Y *NP* | amino acid formula with vitamins and minerals without valine, leucine and isoleucine with fat, carbohydrate and trace elements and supplemented with docosahexanoic acid oral liquid, 36 cans | 4 | 5 | .. | *2508.19 | 36.10 | MSUD Anamix Junior LQ | SB |
| | **ARGININE WITH CARBOHYDRATE** | | | | | | | |
| | **Restricted benefit** | | | | | | | |
| | Urea cycle disorders | | | | | | | |

# VARIOUS

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|---|---|---|---|---|---|---|---|---|
| | **Note**<br>Arginine with carbohydrate is not indicated for the treatment of arginase deficiency and other inborn errors of protein metabolism. | | | | | | | |
| 5482M<br>*NP* | arginine with carbohydrate containing 2 g arginine oral liquid: powder for, 30 x 4 g sachets | 4 | 5 | .. | *771.03 | 36.10 | Arginine 2000 | VF |
| 9437Q<br>*NP* | arginine with carbohydrate containing 500 mg arginine oral liquid: powder for, 30 x 4 g sachets | 4 | 5 | .. | *516.23 | 36.10 | Arginine 500 | VF |
| | **CARBOHYDRATE, FAT, VITAMINS, MINERALS AND TRACE ELEMENTS**<br>**Restricted benefit**<br>Patients with proven inborn errors of protein metabolism who are unable to meet their energy requirements with permitted food and formulae | | | | | | | |
| 8369L<br>*NP* | carbohydrate, fat, vitamins, minerals and trace elements oral liquid: powder for, 400 g | 8 | 5 | .. | *318.39 | 36.10 | Energivit | SB |
| | **CITRULLINE WITH CARBOHYDRATE**<br>**Restricted benefit**<br>Urea cycle disorders in order to prevent low plasma arginine or citrulline levels | | | | | | | |
| | **Note**<br>Citrulline with carbohydrate is not indicated for the treatment of arginase deficiency and other inborn errors of protein metabolism. | | | | | | | |
| 5481L<br>*NP* | citrulline with carbohydrate containing 1 g citrulline oral liquid: powder for, 30 x 4 g sachets | 4 | 5 | .. | *516.23 | 36.10 | Citrulline 1000 | VF |
| | **CYSTINE WITH CARBOHYDRATE**<br>**Restricted benefit**<br>Pyridoxine non-responsive homocystinuria | | | | | | | |
| 9164H<br>*NP* | cystine with carbohydrate containing 500 mg cystine oral liquid: powder for, 30 x 4 g sachets | 4 | 5 | .. | *516.23 | 36.10 | Cystine 500 | VF |
| | **ESSENTIAL AMINO ACIDS FORMULA**<br>**Restricted benefit**<br>Gyrate atrophy of the choroid and retina | | | | | | | |
| | **Restricted benefit**<br>Urea cycle disorders | | | | | | | |
| 9329B<br>*NP* | essential amino acids formula oral liquid: powder for, 2 x 200 g cans | 6 | 5 | .. | *1200.75 | 36.10 | Essential Amino Acid Mix | SB |
| | **ESSENTIAL AMINO ACIDS FORMULA WITH MINERALS AND VITAMIN C**<br>**Restricted benefit**<br>Gyrate atrophy of the choroid and retina | | | | | | | |
| | **Restricted benefit**<br>Urea cycle disorders | | | | | | | |
| 2027Q<br>*NP* | essential amino acids formula with minerals and vitamin C oral liquid: powder for, 400 g | 5 | 5 | .. | *634.38 | 36.10 | Dialamine | SB |
| | **ESSENTIAL AMINO ACIDS FORMULA WITH VITAMINS AND MINERALS**<br>**Restricted benefit**<br>Gyrate atrophy of the choroid and retina | | | | | | | |
| | **Restricted benefit**<br>Urea cycle disorders | | | | | | | |
| 9385Y<br>*NP* | essential amino acids formula with vitamins and minerals oral liquid: powder for, 50 x 12.5 g sachets | 4 | 5 | .. | *1516.71 | 36.10 | EAA Supplement | VF |
| | **GLYCOMACROPEPTIDE AND ESSENTIAL AMINO ACIDS**<br>**Restricted benefit**<br>Phenylketonuria | | | | | | | |
| 2712R<br>*NP* | glycomacropeptide and essential amino acids oral liquid, 12 x 500 mL bottles | 12 | 5 | .. | *1270.35 | 36.10 | Camino Pro Restore | QH |

# VARIOUS

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|---|---|---|---|---|---|---|---|---|
| | **GLYCOMACROPEPTIDE AND ESSENTIAL AMINO ACIDS WITH VITAMINS AND MINERALS**<br>**Restricted benefit**<br>Phenylketonuria | | | | | | | |
| 2696X<br>*NP* | glycomacropeptide and essential amino acids with vitamins and minerals bar, 7 x 54 g | 14 | 5 | .. | *866.65 | 36.10 | Camino Pro Complete | QH |
| 2644E<br>*NP* | glycomacropeptide and essential amino acids with vitamins and minerals bar, 7 x 81 g | 14 | 5 | .. | *1296.73 | 36.10 | Camino Pro Complete | QH |
| 2685H<br>*NP* | glycomacropeptide and essential amino acids with vitamins and minerals oral liquid: powder for, 28 x 49 g sachets | 4 | 5 | .. | *1479.99 | 36.10 | Camino Pro Bettermilk | QH |
| | **HIGH FAT FORMULA WITH VITAMINS, MINERALS AND TRACE ELEMENTS AND LOW IN PROTEIN AND CARBOHYDRATE**<br>**Restricted benefit**<br>Ketogenic diet<br>**The Clinical criteria is:**<br>Patient must have intractable seizures requiring treatment with a ketogenic diet; OR<br>Patient must have a glucose transport protein defect; OR<br>Patient must have pyruvate dehydrogenase deficiency.<br>KetoCal 3:1 should only be used under strict supervision of a dietician, together with a metabolic physician and/or neurologist.<br>**Note**<br>Authorities for increased maximum quantities, up to a maximum of 48, may be authorised. | | | | | | | |
| 2652N<br>*NP* | high fat formula with vitamins, minerals and trace elements and low in protein and carbohydrate (3:1 ratio long chain fat to carbohydrate plus protein) oral liquid: powder for, 300 g | 24 | 5 | .. | *1037.67 | 36.10 | KetoCal 3:1 | SB |
| | **HIGH FAT FORMULA WITH VITAMINS, MINERALS AND TRACE ELEMENTS AND LOW IN PROTEIN AND CARBOHYDRATE**<br>**Restricted benefit**<br>Patients with intractable seizures requiring treatment with a ketogenic diet<br>**Restricted benefit**<br>Glucose transport protein defects<br>**Restricted benefit**<br>Pyruvate dehydrogenase deficiency<br>**Note**<br>KetoCal should only be used under strict supervision of a dietician, together with a metabolic physician and/or neurologist.<br>**Note**<br>Authorities for increased maximum quantities, up to a maximum of 48, may be authorised. | | | | | | | |
| 9446E<br>*NP* | high fat formula with vitamins, minerals and trace elements and low in protein and carbohydrate oral liquid: powder for, 300 g | 24 | 5 | .. | *1037.67 | 36.10 | KetoCal | SB |
| | **ISOLEUCINE WITH CARBOHYDRATE**<br>**Restricted benefit**<br>Maple syrup urine disease | | | | | | | |
| 9436P<br>*NP* | isoleucine with carbohydrate containing 1 g isoleucine oral liquid: powder for, 30 x 4 g sachets | 4 | 5 | .. | *567.19 | 36.10 | Isoleucine 1000 | VF |
| 9134R<br>*NP* | isoleucine with carbohydrate containing 50 mg isoleucine oral liquid: powder for, 30 x 4 g sachets | 4 | 5 | .. | *516.23 | 36.10 | Isoleucine 50 | VF |
| | **MILK PROTEIN AND FAT FORMULA WITH VITAMINS AND MINERALS CARBOHYDRATE FREE**<br>**Restricted benefit**<br>Patients with intractable seizures requiring treatment with a ketogenic diet<br>**Restricted benefit**<br>Glucose transport protein defects<br>**Restricted benefit** | | | | | | | |

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|
| | Pyruvate dehydrogenase deficiency | | | | | | | |
| | **Restricted benefit**<br>Infants and young children with glucose-galactose intolerance and multiple monosaccharide intolerance | | | | | | | |
| 8630F<br>*NP* | milk protein and fat formula with vitamins and minerals carbohydrate free oral liquid: powder for, 225 g | 24 | 5 | .. | *648.63 | 36.10 | Carbohydrate Free Mixture | SB |
| | **PHENYLALANINE WITH CARBOHYDRATE**<br>**Restricted benefit**<br>Tyrosinaemia | | | | | | | |
| 9384X<br>*NP* | phenylalanine with carbohydrate containing 50 mg phenylalanine oral liquid: powder for, 30 x 4 g sachets | 4 | 5 | .. | *516.23 | 36.10 | Phenylalanine 50 | VF |
| | **SOY PROTEIN AND FAT FORMULA WITH VITAMINS AND MINERALS CARBOHYDRATE FREE**<br>**Restricted benefit**<br>Patients with intractable seizures requiring treatment with a ketogenic diet | | | | | | | |
| | **Restricted benefit**<br>Glucose transport protein defects | | | | | | | |
| | **Restricted benefit**<br>Pyruvate dehydrogenase deficiency | | | | | | | |
| | **Restricted benefit**<br>Infants and young children with glucose-galactose intolerance and multiple monosaccharide intolerance | | | | | | | |
| 8577K<br>*NP* | soy protein and fat formula with vitamins and minerals carbohydrate free oral liquid, 1 x 384 mL can | 120 | 5 | .. | *670.23 | 36.10 | RCF | AB |
| | **TRIGLYCERIDES LONG CHAIN WITH GLUCOSE POLYMER**<br>**Restricted benefit**<br>Patients with proven inborn errors of protein metabolism who are unable to meet their energy requirements with permitted food and formulae | | | | | | | |
| 9308X<br>*NP* | triglycerides long chain with glucose polymer oral liquid, 18 x 250 mL cans | 6 | 5 | .. | *339.99 | 36.10 | ProZero | VF |
| 9309Y<br>*NP* | triglycerides long chain with glucose polymer oral liquid, 6 x 1000 mL bottles | 4 | 5 | .. | *304.23 | 36.10 | ProZero | VF |
| | **TRIGLYCERIDES MEDIUM CHAIN AND LONG CHAIN WITH GLUCOSE POLYMER**<br>**Restricted benefit**<br>Patients with proven inborn errors of protein metabolism who are unable to meet their energy requirements with permitted food and formulae | | | | | | | |
| 3136C<br>*NP* | triglycerides medium chain and long chain with glucose polymer oral liquid: powder for, 400 g | 8 | 5 | .. | *295.75 | 36.10 | Duocal | SB |
| | **TRIGLYCERIDES MEDIUM CHAIN FORMULA**<br>**Authority required**<br>Chylous ascites | | | | | | | |
| | **Authority required**<br>Chylothorax | | | | | | | |
| | **Authority required**<br>Fat malabsorption due to liver disease, short gut syndrome, cystic fibrosis and gastrointestinal disorders | | | | | | | |
| | **Authority required**<br>Hyperlipoproteinaemia type 1 | | | | | | | |
| | **Authority required**<br>Long chain fatty acid oxidation disorders | | | | | | | |
| | **Note**<br>No applications for increased maximum quantities and/or repeats will be authorised. | | | | | | | |
| | **Note**<br>MCT Pro-Cal is not indicated for the treatment of intractable childhood epilepsy or cerebrospinal fluid glucose transporter defect requiring a ketogenic diet. | | | | | | | |
| 9383W<br>*NP* | triglycerides medium chain formula oral liquid: powder for, 30 x 16 g sachets | 4 | 5 | .. | *253.83 | 36.10 | MCT Pro-Cal | VF |
| | **TYROSINE WITH CARBOHYDRATE** | | | | | | | |

# VARIOUS

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|---|---|---|---|---|---|---|---|---|
| | **Restricted benefit**<br>Phenylketonuria | | | | | | | |
| 9165J<br>*NP* | tyrosine with carbohydrate containing 1 g tyrosine oral liquid: powder for, 30 x 4 g sachets | 4 | 5 | .. | *516.23 | 36.10 | Tyrosine 1000 | VF |
| | **VALINE WITH CARBOHYDRATE**<br>**Restricted benefit**<br>Maple syrup urine disease | | | | | | | |
| 9434M<br>*NP* | valine with carbohydrate containing 1 g valine oral liquid: powder for, 30 x 4 g sachets | 4 | 5 | .. | *567.19 | 36.10 | Valine 1000 | VF |
| 9135T<br>*NP* | valine with carbohydrate containing 50 mg valine oral liquid: powder for, 30 x 4 g sachets | 4 | 5 | .. | *516.23 | 36.10 | Valine 50 | VF |
| | **VITAMINS, MINERALS AND TRACE ELEMENTS WITH CARBOHYDRATE**<br>**Authority required**<br>Infants and children whose vitamin and mineral intake is insufficient due to a specific diagnosis requiring a highly restrictive therapeutic diet, and whose vitamin, mineral and trace element needs cannot be adequately met with other proprietary vitamin and mineral preparations<br>**Note**<br>Paediatric Seravit should only be used under strict supervision of a dietitian and a paediatrician. | | | | | | | |
| 9328Y<br>*NP* | vitamins, minerals and trace elements with carbohydrate oral liquid: powder for, 200 g | 6 | 5 | .. | *390.63 | 36.10 | Paediatric Seravit | SB |
| | **WHEY PROTEIN FORMULA SUPPLEMENTED WITH AMINO ACIDS, LONG CHAIN POLYUNSATURATED FATTY ACIDS, VITAMINS AND MINERALS, LOW IN PROTEIN, PHOSPHATE, POTASSIUM AND LACTOSE**<br>**Authority required**<br>Infants and young children with chronic renal failure requiring treatment with a low protein and a low phosphorus diet, or a low protein, a low phosphorus and a low potassium diet | | | | | | | |
| 9382T<br>*NP* | whey protein formula supplemented with amino acids, long chain polyunsaturated fatty acids, vitamins and minerals, low in protein, phosphate, potassium and lactose oral liquid: powder for, 10 x 100 g sachets | 9 | 5 | .. | *1485.78 | 36.10 | RenaStart | VF |
| | **WHEY PROTEIN FORMULA SUPPLEMENTED WITH AMINO ACIDS, VITAMINS AND MINERALS, AND LOW IN PROTEIN, PHOSPHATE, POTASSIUM AND LACTOSE**<br>**Authority required**<br>Infants and young children with chronic renal failure requiring treatment with a low protein and a low phosphorus diet, or a low protein, a low phosphorus and a low potassium diet | | | | | | | |
| 8587Y<br>*NP* | whey protein formula supplemented with amino acids, vitamins and minerals, and low in protein, phosphate, potassium and lactose oral liquid: powder for, 400 g | 16 | 5 | .. | *1066.15 | 36.10 | Kindergen | SB |

# Pharmaceutical Benefits for Palliative Care

# PREPARATIONS WHICH MAY BE PRESCRIBED FOR PATIENTS RECEIVING PALLIATIVE CARE

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|

# ALIMENTARY TRACT AND METABOLISM

## STOMATOLOGICAL PREPARATIONS

### STOMATOLOGICAL PREPARATIONS

#### *Other agents for local oral treatment*

**BENZYDAMINE**
**Authority required (STREAMLINED)**
***3634***
Initial supply, for up to 4 months, for a palliative care patient where a painful mouth is a problem

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 5385K *NP* | benzydamine hydrochloride 0.15% mouthwash, 500 mL | ‡1 | 3 | .. | 22.47 | 23.60 | Difflam | IA |

**BENZYDAMINE**
**Authority required (STREAMLINED)**
***3635***
Continuing supply for a palliative care patient where a painful mouth is a problem

**Note**
Written or telephone authority applications for increased repeats may be approved where consultation with a palliative care specialist or service has occurred.

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 5386L *NP* | benzydamine hydrochloride 0.15% mouthwash, 500 mL | ‡1 | .. | .. | 22.47 | 23.60 | Difflam | IA |

**CARMELLOSE SODIUM**
**Authority required (STREAMLINED)**
***3636***
Initial supply, for up to 4 months, for a palliative care patient where dry mouth is a symptom

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 5334R *NP* | carmellose sodium 10 mg/mL oral spray, 100 mL | ‡1 | 3 | .. | 13.36 | 14.49 | Aquae | VT |
| 5333Q *NP* | carmellose sodium 10 mg/mL oral spray, 25 mL | ‡1 | 3 | .. | 11.51 | 12.64 | Aquae | VT |

**CARMELLOSE SODIUM**
**Authority required (STREAMLINED)**
***3637***
Continuing supply for a palliative care patient where dry mouth is a symptom

**Note**
Written or telephone authority applications for increased repeats may be approved where consultation with a palliative care specialist or service has occurred.

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 5336W *NP* | carmellose sodium 10 mg/mL oral spray, 100 mL | ‡1 | .. | .. | 13.36 | 14.49 | Aquae | VT |
| 5335T *NP* | carmellose sodium 10 mg/mL oral spray, 25 mL | ‡1 | .. | .. | 11.51 | 12.64 | Aquae | VT |

**HYPROMELLOSE**
**Authority required (STREAMLINED)**
***3636***
Initial supply, for up to 4 months, for a palliative care patient where dry mouth is a symptom

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 5421H *NP* | HYPROMELLOSE Oral gel 20 mg per g, 100 g, 1 | ‡1 | 3 | .. | 13.58 | 14.71 | Aquae Gel | VT |

**HYPROMELLOSE**
**Authority required (STREAMLINED)**
***3637***
Continuing supply for a palliative care patient where dry mouth is a symptom

**Note**
Written or telephone authority applications for increased repeats may be approved where consultation with a palliative care specialist or service has occurred.

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 5422J *NP* | HYPROMELLOSE Oral gel 20 mg per g, 100 g, 1 | ‡1 | .. | .. | 13.58 | 14.71 | Aquae Gel | VT |

# PREPARATIONS WHICH MAY BE PRESCRIBED FOR PATIENTS RECEIVING PALLIATIVE CARE

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|---|
| **DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS** | | | | | | | | | |
| **BELLADONNA AND DERIVATIVES, PLAIN** | | | | | | | | | |
| ***Belladonna alkaloids, semisynthetic, quaternary ammonium compounds*** | | | | | | | | | |
| | **HYOSCINE BUTYLBROMIDE**<br>**Authority required (STREAMLINED)**<br>***3638***<br>Initial supply, for up to 4 months, for a palliative care patient where colicky pain is a symptom | | | | | | | | |
| 5317W<br>*NP* | hyoscine butylbromide 20 mg/mL injection, 5 x 1 mL ampoules | 6 | 3 | .. | *108.75 | 36.10 | | Buscopan | BY |
| | **HYOSCINE BUTYLBROMIDE**<br>**Authority required (STREAMLINED)**<br>***3639***<br>Continuing supply for a palliative care patient where colicky pain is a symptom<br>**Note**<br>Written or telephone authority applications for increased repeats may be approved where consultation with a palliative care specialist or service has occurred. | | | | | | | | |
| 5318X<br>*NP* | hyoscine butylbromide 20 mg/mL injection, 5 x 1 mL ampoules | 6 | .. | .. | *108.75 | 36.10 | | Buscopan | BY |
| **LAXATIVES** | | | | | | | | | |
| **LAXATIVES** | | | | | | | | | |
| ***Contact laxatives*** | | | | | | | | | |
| | **BISACODYL**<br>**Authority required (STREAMLINED)**<br>***3642***<br>Initial supply, for up to 4 months, for a palliative care patient where constipation is a problem | | | | | | | | |
| 5303D<br>*NP* | bisacodyl 10 mg suppository, 10 | 3 | 3 | .. | *21.15 | 22.28 | a | Petrus Bisacodyl Suppositories | PP |
| | | | | B1.50 | *22.65 | 22.28 | a | Dulcolax | BY |
| 5304E<br>*NP* | bisacodyl 10 mg suppository, 12 | 3 | 3 | .. | *18.54 | 19.67 | | Petrus Bisacodyl Suppositories | PP |
| 5301B<br>*NP* | bisacodyl 5 mg tablet: enteric, 200 tablets | 1 | 3 | .. | 14.32 | 15.45 | | Bisalax | AS |
| | | | | | | | | Lax-Tab | AE |
| | **BISACODYL**<br>**Authority required (STREAMLINED)**<br>***3643***<br>Continuing supply for a palliative care patient where constipation is a problem<br>**Note**<br>Written or telephone authority applications for increased repeats may be approved where consultation with a palliative care specialist or service has occurred. | | | | | | | | |
| 5307H<br>*NP* | bisacodyl 10 mg suppository, 10 | 3 | .. | .. | *21.15 | 22.28 | a | Petrus Bisacodyl Suppositories | PP |
| | | | | B1.50 | *22.65 | 22.28 | a | Dulcolax | BY |
| 5308J<br>*NP* | bisacodyl 10 mg suppository, 12 | 3 | .. | .. | *18.54 | 19.67 | | Petrus Bisacodyl Suppositories | PP |
| 5305F<br>*NP* | bisacodyl 5 mg tablet: enteric, 200 tablets | 1 | .. | .. | 14.32 | 15.45 | | Bisalax | AS |
| | | | | | | | | Lax-Tab | AE |
| ***Bulk producers*** | | | | | | | | | |
| | **RHAMNUS FRANGULA + STERCULIA**<br>**Authority required (STREAMLINED)**<br>***3642***<br>Initial supply, for up to 4 months, for a palliative care patient where constipation is a problem | | | | | | | | |
| 5322D<br>*NP* | rhamnus frangula 80 mg/g + sterculia 620 mg/g granules, 500 g | ‡1 | 3 | .. | 26.58 | 27.71 | | Normacol Plus | NE |

# PREPARATIONS WHICH MAY BE PRESCRIBED FOR PATIENTS RECEIVING PALLIATIVE CARE

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|---|---|---|---|---|---|---|---|---|---|
| | **RHAMNUS FRANGULA + STERCULIA**<br>**Authority required (STREAMLINED)**<br>***3643***<br>Continuing supply for a palliative care patient where constipation is a problem<br>**Note**<br>Written or telephone authority applications for increased repeats may be approved where consultation with a palliative care specialist or service has occurred. | | | | | | | | |
| 5324F<br>*NP* | rhamnus frangula 80 mg/g + sterculia 620 mg/g granules, 500 g | ‡1 | .. | .. | 26.58 | 27.71 | | Normacol Plus | NE |

## *Osmotically acting laxatives*

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | **LACTULOSE**<br>**Authority required (STREAMLINED)**<br>***3642***<br>Initial supply, for up to 4 months, for a palliative care patient where constipation is a problem | | | | | | | | |
| 5387M<br>*NP* | LACTULOSE Mixture 3.34 g per 5 mL, 500 mL, 1 | 3 | 3 | .. | *20.79 | 21.92 | [a] | Actilax | AF |
| | | | | | | | [a] | Genlac | QA |
| | | | | | | | [a] | GenRx Lactulose | GX |
| | | | | | | | [a] | Lac-Dol | GM |
| | | | | | | | [a] | Lactocur | SZ |
| | | | | [B]3.03 | *23.82 | 21.92 | [a] | Duphalac | AB |
| | **LACTULOSE**<br>**Authority required (STREAMLINED)**<br>***3643***<br>Continuing supply for a palliative care patient where constipation is a problem<br>**Note**<br>Written or telephone authority applications for increased repeats may be approved where consultation with a palliative care specialist or service has occurred. | | | | | | | | |
| 5388N<br>*NP* | LACTULOSE Mixture 3.34 g per 5 mL, 500 mL, 1 | 3 | .. | .. | *20.79 | 21.92 | [a] | Actilax | AF |
| | | | | | | | [a] | Genlac | QA |
| | | | | | | | [a] | GenRx Lactulose | GX |
| | | | | | | | [a] | Lac-Dol | GM |
| | | | | | | | [a] | Lactocur | SZ |
| | | | | [B]3.03 | *23.82 | 21.92 | [a] | Duphalac | AB |
| | **MACROGOL-3350**<br>**Authority required (STREAMLINED)**<br>***4176***<br>Constipation<br>Treatment Phase: Initial treatment<br>**The Clinical criteria is:**<br>Patient must be receiving palliative care,<br>**AND the Clinical criteria is:**<br>Patient must not receive more than 4 months treatment under this restriction.<br>**Note**<br>Pharmaceutical benefits that have the form macrogol-3350 1 g/g oral liquid: powder for, 510 g and pharmaceutical benefits that have the form macrogol-3350 1 g/g oral liquid: powder for, 30 x 17 g sachets are equivalent for the purposes of substitution. | | | | | | | | |
| 2351R<br>*NP* | macrogol-3350 1 g/g oral liquid: powder for, 30 x 17 g sachets | 2 | 3 | .. | *34.89 | 36.02 | [a] | MediHealth ClearLax | ON |
| 5426N<br>*NP* | macrogol-3350 1 g/g oral liquid: powder for, 510 g | 2 | 3 | .. | *34.89 | 36.02 | [a] | OsmoLax | KY |
| | **MACROGOL-3350**<br>**Authority required (STREAMLINED)**<br>***4170***<br>Constipation<br>Treatment Phase: Continuing treatment | | | | | | | | |

# PREPARATIONS WHICH MAY BE PRESCRIBED FOR PATIENTS RECEIVING PALLIATIVE CARE

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|---|---|---|---|---|---|---|---|---|---|
| | **The Clinical criteria is:** | | | | | | | | |
| | Patient must be receiving palliative care. | | | | | | | | |
| | **Note** | | | | | | | | |
| | Written or telephone authority applications for increased repeats may be approved where consultation with a palliative care specialist or service has occurred. | | | | | | | | |
| | **Note** | | | | | | | | |
| | Pharmaceutical benefits that have the form macrogol-3350 1 g/g oral liquid: powder for, 510 g and pharmaceutical benefits that have the form macrogol-3350 1 g/g oral liquid: powder for, 30 x 17 g sachets are equivalent for the purposes of substitution. | | | | | | | | |
| 2353W *NP* | macrogol-3350 1 g/g oral liquid: powder for, 30 x 17 g sachets | 2 | .. | .. | *34.89 | 36.02 | a | MediHealth ClearLax | ON |
| 5427P *NP* | macrogol-3350 1 g/g oral liquid: powder for, 510 g | 2 | .. | .. | *34.89 | 36.02 | a | OsmoLax | KY |
| | **MACROGOL-3350 + SODIUM CHLORIDE + POTASSIUM CHLORIDE + BICARBONATE** | | | | | | | | |
| | **Authority required (STREAMLINED)** | | | | | | | | |
| | ***3642*** | | | | | | | | |
| | Initial supply, for up to 4 months, for a palliative care patient where constipation is a problem | | | | | | | | |
| 5389P *NP* | 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 | 2 | 3 | .. | *34.89 | 36.02 | a | LaxaCon | GM |
| | | | | | | | a | Movicol | NE |
| | **MACROGOL-3350 + SODIUM CHLORIDE + POTASSIUM CHLORIDE + BICARBONATE** | | | | | | | | |
| | **Authority required (STREAMLINED)** | | | | | | | | |
| | ***3643*** | | | | | | | | |
| | Continuing supply for a palliative care patient where constipation is a problem | | | | | | | | |
| | **Note** | | | | | | | | |
| | Written or telephone authority applications for increased repeats may be approved where consultation with a palliative care specialist or service has occurred. | | | | | | | | |
| 5390Q *NP* | 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 | 2 | .. | .. | *34.89 | 36.02 | a | LaxaCon | GM |
| | | | | | | | a | Movicol | NE |

## *Enemas*

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | **BISACODYL** | | | | | | | | |
| | **Authority required (STREAMLINED)** | | | | | | | | |
| | ***3642*** | | | | | | | | |
| | Initial supply, for up to 4 months, for a palliative care patient where constipation is a problem | | | | | | | | |
| 5302C *NP* | bisacodyl 10 mg/5 mL enema, 25 x 5 mL | ‡1 | 3 | .. | 38.15 | 36.10 | | Bisalax | AS |
| | **BISACODYL** | | | | | | | | |
| | **Authority required (STREAMLINED)** | | | | | | | | |
| | ***3643*** | | | | | | | | |
| | Continuing supply for a palliative care patient where constipation is a problem | | | | | | | | |
| | **Note** | | | | | | | | |
| | Written or telephone authority applications for increased repeats may be approved where consultation with a palliative care specialist or service has occurred. | | | | | | | | |
| 5306G *NP* | bisacodyl 10 mg/5 mL enema, 25 x 5 mL | ‡1 | .. | .. | 38.15 | 36.10 | | Bisalax | AS |
| | **SORBITOL + CITRATE + LAURYL SULFOACETATE SODIUM** | | | | | | | | |
| | **Authority required (STREAMLINED)** | | | | | | | | |
| | ***3642*** | | | | | | | | |
| | Initial supply, for up to 4 months, for a palliative care patient where constipation is a problem | | | | | | | | |
| 5331N *NP* | sorbitol 3.125 g/5 mL + citrate sodium dihydrate 450 mg/5 mL + lauryl sulfoacetate sodium 45 mg/5 mL | 2 | 3 | .. | *32.49 | 33.62 | a | Micolette | AE |

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|---|---|---|---|---|---|---|---|---|---|
| | enema, 12 x 5 mL | | | | | | [a] | Microlax | JT |
| | **SORBITOL + CITRATE + LAURYL SULFOACETATE SODIUM**<br>**Authority required (STREAMLINED)**<br>***3643***<br>Continuing supply for a palliative care patient where constipation is a problem<br>**Note**<br>Written or telephone authority applications for increased repeats may be approved where consultation with a palliative care specialist or service has occurred. | | | | | | | | |
| 5332P<br>*NP* | sorbitol 3.125 g/5 mL + citrate sodium dihydrate 450 mg/5 mL + lauryl sulfoacetate sodium 45 mg/5 mL enema, 12 x 5 mL | 2 | .. | .. | *32.49 | 33.62 | [a] | Micolette | AE |
| | | | | | | | [a] | Microlax | JT |

## *Peripheral opioid receptor antagonists*

**METHYLNALTREXONE**
**Authority required**
Continuing supply, in combination with oral laxatives, for a palliative care patient with opioid-induced constipation who has demonstrated a response to methylnaltrexone

**Note**
For first continuing supply, applications for increased repeats may be authorised.

Where consultation with a palliative care specialist or service has occurred, applications for increased repeats may be authorised.

**Note**
Special Pricing Arrangements apply.

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 5424L<br>*NP* | METHYLNALTREXONE Solution for injection containing methylnaltrexone bromide 12 mg in 0.6 mL, 7 | 1 | .. | .. | 288.05 | 36.10 | | Relistor | LM |

**METHYLNALTREXONE**
**Authority required**
Initial supply, in combination with oral laxatives, for a palliative care patient with opioid-induced constipation who has failed to respond to laxatives

**Note**
No applications for repeats will be authorised.

**Note**
Special Pricing Arrangements apply.

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 5423K<br>*NP* | methylnaltrexone bromide 12 mg/0.6 mL injection, 1 x 0.6 mL vial | 3 | .. | .. | *130.80 | 36.10 | | Relistor | LM |

## *Other laxatives*

**GLYCEROL**
**Authority required (STREAMLINED)**
***3642***
Initial supply, for up to 4 months, for a palliative care patient where constipation is a problem

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 5312N<br>*NP* | glycerol 1.4 g suppository, 12 | 3 | 3 | .. | *20.10 | 21.23 | | Petrus Pharmaceuticals Pty Ltd | PP |
| 5313P<br>*NP* | glycerol 2.8 g suppository, 12 | 3 | 3 | .. | *20.61 | 21.74 | | Petrus Pharmaceuticals Pty Ltd | PP |
| 5311M<br>*NP* | glycerol 700 mg suppository, 12 | 3 | 3 | .. | *19.68 | 20.81 | | Petrus Pharmaceuticals Pty Ltd | PP |

**GLYCEROL**
**Authority required (STREAMLINED)**
***3643***
Continuing supply for a palliative care patient where constipation is a problem

**Note**
Written or telephone authority applications for increased repeats may be approved where consultation with a palliative care specialist or service has occurred.

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 5315R<br>*NP* | glycerol 1.4 g suppository, 12 | 3 | .. | .. | *20.10 | 21.23 | | Petrus Pharmaceuticals Pty Ltd | PP |
| 5316T | glycerol 2.8 g suppository, 12 | 3 | .. | .. | *20.61 | 21.74 | | Petrus Pharmaceuticals | PP |

# PREPARATIONS WHICH MAY BE PRESCRIBED FOR PATIENTS RECEIVING PALLIATIVE CARE

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|---|---|---|---|---|---|---|---|---|
| *NP* | | | | | | | Pty Ltd | |
| 5314Q | glycerol 700 mg suppository, 12 | 3 | .. | .. | *19.68 | 20.81 | Petrus Pharmaceuticals | PP |
| *NP* | | | | | | | Pty Ltd | |

# PREPARATIONS WHICH MAY BE PRESCRIBED FOR PATIENTS RECEIVING PALLIATIVE CARE

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|---|---|---|---|---|---|---|---|---|---|

# MUSCULO-SKELETAL SYSTEM

## ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS

### ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS

#### *Acetic acid derivatives and related substances*

**DICLOFENAC**
**Authority required**
Initial supply, for up to 4 months, for a palliative care patient where severe pain is a problem

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 5363G *NP* | diclofenac sodium 100 mg suppository, 20 | 2 | 3 | .. | *25.13 | 26.26 | | Voltaren 100 | NV |

**DICLOFENAC**
**Authority required**
Continuing supply for a palliative care patient where severe pain is a problem

**Note**
Written or telephone authority applications for increased repeats may be approved where consultation with a palliative care specialist or service has occurred.

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 5366K *NP* | diclofenac sodium 100 mg suppository, 20 | 2 | .. | .. | *25.13 | 26.26 | | Voltaren 100 | NV |

**DICLOFENAC**
**Authority required (STREAMLINED)**
***3645***
Initial supply, for up to 4 months, for a palliative care patient where severe pain is a problem

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 5361E *NP* | diclofenac sodium 25 mg tablet: enteric, 50 tablets | 2 | 3 | .. | *11.65 | 12.78 | [a] | APO-Diclofenac | TX |
| | | | | | | | [a] | Chem mart Diclofenac | CH |
| | | | | | | | [a] | Clonac 25 | QA |
| | | | | | | | [a] | Diclofenac-GA | GM |
| | | | | | | | [a] | Diclofenac Sandoz | SZ |
| | | | | | | | [a] | Fenac 25 | AF |
| | | | | | | | [a] | Terry White Chemists Diclofenac | TW |
| | | | | [B]1.86 | *13.51 | 12.78 | [a] | Voltaren 25 | NV |
| 5362F *NP* | diclofenac sodium 50 mg tablet: enteric, 50 tablets | 1 | 3 | .. | 10.13 | 11.26 | [a] | APO-Diclofenac | TX |
| | | | | | | | [a] | Chem mart Diclofenac | CH |
| | | | | | | | [a] | Clonac 50 | QA |
| | | | | | | | [a] | Diclofenac-GA | GM |
| | | | | | | | [a] | Diclofenac Sandoz | SZ |
| | | | | | | | [a] | Fenac | AF |
| | | | | | | | [a] | Terry White Chemists Diclofenac | TW |
| | | | | [B]1.86 | 11.99 | 11.26 | [a] | Voltaren 50 | NV |

**DICLOFENAC**
**Authority required (STREAMLINED)**
***3646***
Continuing supply for a palliative care patient where severe pain is a problem

**Note**
Written or telephone authority applications for increased repeats may be approved where consultation with a palliative care specialist or service has occurred.

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 5364H *NP* | diclofenac sodium 25 mg tablet: enteric, 50 tablets | 2 | .. | .. | *11.65 | 12.78 | [a] | APO-Diclofenac | TX |
| | | | | | | | [a] | Chem mart Diclofenac | CH |
| | | | | | | | [a] | Clonac 25 | QA |
| | | | | | | | [a] | Diclofenac-GA | GM |
| | | | | | | | [a] | Diclofenac Sandoz | SZ |
| | | | | | | | [a] | Fenac 25 | AF |

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|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | [a] | Terry White Chemists Diclofenac | TW |
| | | | | [B]1.86 | *13.51 | 12.78 | [a] | Voltaren 25 | NV |
| 5365J *NP* | diclofenac sodium 50 mg tablet: enteric, 50 tablets | 1 | .. | .. | 10.13 | 11.26 | [a] | APO-Diclofenac | TX |
| | | | | | | | [a] | Chem mart Diclofenac | CH |
| | | | | | | | [a] | Clonac 50 | QA |
| | | | | | | | [a] | Diclofenac-GA | GM |
| | | | | | | | [a] | Diclofenac Sandoz | SZ |
| | | | | | | | [a] | Fenac | AF |
| | | | | | | | [a] | Terry White Chemists Diclofenac | TW |
| | | | | [B]1.86 | 11.99 | 11.26 | [a] | Voltaren 50 | NV |
| | **INDOMETHACIN**<br>**Authority required**<br>Initial supply, for up to 4 months, for a palliative care patient where severe pain is a problem | | | | | | | | |
| 5378C *NP* | indomethacin 100 mg suppository, 20 | 2 | 3 | .. | *22.71 | 23.84 | | Indocid | AS |
| | **INDOMETHACIN**<br>**Authority required**<br>Continuing supply for a palliative care patient where severe pain is a problem<br>**Note**<br>Written or telephone authority applications for increased repeats may be approved where consultation with a palliative care specialist or service has occurred. | | | | | | | | |
| 5380E *NP* | indomethacin 100 mg suppository, 20 | 2 | .. | .. | *22.71 | 23.84 | | Indocid | AS |
| | **INDOMETHACIN**<br>**Authority required (STREAMLINED)**<br>***3645***<br>Initial supply, for up to 4 months, for a palliative care patient where severe pain is a problem | | | | | | | | |
| 5377B *NP* | indomethacin 25 mg capsule, 50 | 2 | 3 | .. | *12.63 | 13.76 | [a] | Arthrexin | AF |
| | | | | [B]2.48 | *15.11 | 13.76 | [a] | Indocid | AS |
| | **INDOMETHACIN**<br>**Authority required (STREAMLINED)**<br>***3646***<br>Continuing supply for a palliative care patient where severe pain is a problem<br>**Note**<br>Written or telephone authority applications for increased repeats may be approved where consultation with a palliative care specialist or service has occurred. | | | | | | | | |
| 5379D *NP* | indomethacin 25 mg capsule, 50 | 2 | .. | .. | *12.63 | 13.76 | [a] | Arthrexin | AF |
| | | | | [B]2.48 | *15.11 | 13.76 | [a] | Indocid | AS |
| | ***Propionic acid derivatives*** | | | | | | | | |
| | **IBUPROFEN**<br>**Authority required**<br>Initial supply, for up to 4 months, for a palliative care patient where severe pain is a problem | | | | | | | | |
| 5368M *NP* | ibuprofen 400 mg tablet, 30 | 3 | 3 | .. | *14.94 | 16.07 | | Brufen | AB |
| | **IBUPROFEN**<br>**Authority required**<br>Continuing supply for a palliative care patient where severe pain is a problem<br>**Note**<br>Written or telephone authority applications for increased repeats may be approved where consultation with a palliative care specialist or service has occurred. | | | | | | | | |
| 5370P *NP* | ibuprofen 400 mg tablet, 30 | 3 | .. | .. | *14.94 | 16.07 | | Brufen | AB |

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|---|---|---|---|---|---|---|---|---|---|
| | **NAPROXEN**<br>**Authority required (STREAMLINED)**<br>***3645***<br>Initial supply, for up to 4 months, for a palliative care patient where severe pain is a problem | | | | | | | | |
| 5348L<br>*NP* | naproxen 1 g tablet: modified release, 28 tablets | 1 | 3 | .. | 14.17 | 15.30 | a | Proxen SR 1000 | MD |
| | | | | B1.29 | 15.46 | 15.30 | a | Naprosyn SR1000 | RO |
| 5345H<br>*NP* | naproxen 250 mg tablet, 50 | 2 | 3 | .. | *13.55 | 14.68 | a | Inza 250 | AF |
| | | | | B2.24 | *15.79 | 14.68 | a | Naprosyn | RO |
| 5346J<br>*NP* | naproxen 500 mg tablet, 50 | 1 | 3 | .. | 12.81 | 13.94 | a | Inza 500 | AF |
| | | | | B1.28 | 14.09 | 13.94 | a | Naprosyn | RO |
| 5347K<br>*NP* | naproxen 750 mg tablet: modified release, 28 tablets | 1 | 3 | .. | 12.29 | 13.42 | a | Proxen SR 750 | MD |
| | | | | B1.22 | 13.51 | 13.42 | a | Naprosyn SR750 | RO |
| | **NAPROXEN**<br>**Authority required (STREAMLINED)**<br>***3646***<br>Continuing supply for a palliative care patient where severe pain is a problem<br>**Note**<br>Written or telephone authority applications for increased repeats may be approved where consultation with a palliative care specialist or service has occurred. | | | | | | | | |
| 5352Q<br>*NP* | naproxen 1 g tablet: modified release, 28 tablets | 1 | .. | .. | 14.17 | 15.30 | a | Proxen SR 1000 | MD |
| | | | | B1.29 | 15.46 | 15.30 | a | Naprosyn SR1000 | RO |
| 5349M<br>*NP* | naproxen 250 mg tablet, 50 | 2 | .. | .. | *13.55 | 14.68 | a | Inza 250 | AF |
| | | | | B2.24 | *15.79 | 14.68 | a | Naprosyn | RO |
| 5350N<br>*NP* | naproxen 500 mg tablet, 50 | 1 | .. | .. | 12.81 | 13.94 | a | Inza 500 | AF |
| | | | | B1.28 | 14.09 | 13.94 | a | Naprosyn | RO |
| 5351P<br>*NP* | naproxen 750 mg tablet: modified release, 28 tablets | 1 | .. | .. | 12.29 | 13.42 | a | Proxen SR 750 | MD |
| | | | | B1.22 | 13.51 | 13.42 | a | Naprosyn SR750 | RO |
| | **NAPROXEN**<br>**Authority required (STREAMLINED)**<br>***4128***<br>Severe pain<br>Treatment Phase: Initial treatment<br>**The Treatment criteria is:**<br>Patient must be undergoing palliative care,<br>**AND the Clinical criteria is:**<br>Patient must be unable to take a solid dose form of a non-steroidal anti-inflammatory agent,<br>**AND the Clinical criteria is:**<br>Patient must not receive more than 4 months treatment under this restriction. | | | | | | | | |
| 5397C<br>*NP* | naproxen 125 mg/5 mL oral liquid, 474 mL | ‡1 | 3 | .. | 78.38 | 36.10 | | Phebra Naproxen Suspension | PL |
| | **NAPROXEN**<br>**Authority required (STREAMLINED)**<br>***4129***<br>Severe pain<br>Treatment Phase: Continuing treatment<br>**The Treatment criteria is:**<br>Patient must be undergoing palliative care,<br>**AND the Clinical criteria is:** | | | | | | | | |

# PREPARATIONS WHICH MAY BE PRESCRIBED FOR PATIENTS RECEIVING PALLIATIVE CARE

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|---|
| | Patient must be unable to take a solid dose form of a non-steroidal anti-inflammatory agent. | | | | | | | | |
| | **Note**<br>Written or telephone authority applications for increased repeats may be approved where consultation with a palliative care specialist or service has occurred. | | | | | | | | |
| 5398D<br>*NP* | naproxen 125 mg/5 mL oral liquid, 474 mL | ‡1 | .. | .. | 78.38 | 36.10 | | Phebra Naproxen Suspension | PL |
| | **NAPROXEN**<br>**Authority required (STREAMLINED)**<br>***3645***<br>Initial supply, for up to 4 months, for a palliative care patient where severe pain is a problem | | | | | | | | |
| | **Note**<br>Naproxen sodium 550 mg is approximately equivalent to 500 mg of naproxen acid. | | | | | | | | |
| 5353R<br>*NP* | naproxen sodium 550 mg tablet, 50 | 1 | 3 | .. | 12.98 | 14.11 | a | Crysanal | MD |
| | | | | [B]2.17 | 15.15 | 14.11 | a | Anaprox 550 | RO |
| | **NAPROXEN**<br>**Authority required (STREAMLINED)**<br>***3646***<br>Continuing supply for a palliative care patient where severe pain is a problem | | | | | | | | |
| | **Note**<br>Written or telephone authority applications for increased repeats may be approved where consultation with a palliative care specialist or service has occurred. | | | | | | | | |
| | **Note**<br>Naproxen sodium 550 mg is approximately equivalent to 500 mg of naproxen acid. | | | | | | | | |
| 5354T<br>*NP* | naproxen sodium 550 mg tablet, 50 | 1 | .. | .. | 12.98 | 14.11 | a | Crysanal | MD |
| | | | | [B]2.17 | 15.15 | 14.11 | a | Anaprox 550 | RO |

# PREPARATIONS WHICH MAY BE PRESCRIBED FOR PATIENTS RECEIVING PALLIATIVE CARE

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|

# NERVOUS SYSTEM

## ANALGESICS

### OPIOIDS

#### *Natural opium alkaloids*

**MORPHINE**

**Authority required**

Initial supply, for up to 3 months, for a palliative care patient with severe disabling pain not responding to non-narcotic analgesics

**Caution**

The risk of drug dependence is high.

**Note**

Telephone approvals are limited to 1 month's therapy.

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 5393W *NP* | morphine sulfate 10 mg tablet, 20 | 1 | 2 | .. | 14.53 | 15.66 | Sevredol | MF |
| 5394X *NP* | morphine sulfate 20 mg tablet, 20 | 1 | 2 | .. | 15.47 | 16.60 | Sevredol | MF |

**MORPHINE**

**Authority required**

Continuing supply for a palliative care patient with severe disabling pain not responding to non-narcotic analgesics

**Caution**

The risk of drug dependence is high.

**Note**

Where consultation with a palliative care specialist or service has occurred, applications for increased repeats for up to 3 months' supply may be authorised.

Telephone approvals are limited to 1 month's therapy.

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 5395Y *NP* | morphine sulfate 10 mg tablet, 20 | 1 | .. | .. | 14.53 | 15.66 | Sevredol | MF |
| 5396B *NP* | morphine sulfate 20 mg tablet, 20 | 1 | .. | .. | 15.47 | 16.60 | Sevredol | MF |

**MORPHINE**

**Authority required**

Initial supply, for up to 3 months, for a palliative care patient with chronic severe disabling pain not responding to non-narcotic analgesics

**Caution**

The risk of drug dependence is high.

**Note**

Telephone approvals are limited to 1 month's therapy.

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 5391R *NP* | morphine sulfate 200 mg tablet: modified release, 28 tablets | 1 | 2 | .. | 122.07 | 36.10 | MS Contin | MF |

**MORPHINE**

**Authority required**

Continuing supply for a palliative care patient with chronic severe disabling pain not responding to non-narcotic analgesics

**Caution**

The risk of drug dependence is high.

**Note**

Where consultation with a palliative care specialist or service has occurred, applications for increased repeats for up to 3 months' supply may be authorised.

Telephone approvals are limited to 1 month's therapy.

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 5392T *NP* | morphine sulfate 200 mg tablet: modified release, 28 tablets | 1 | .. | .. | 122.07 | 36.10 | MS Contin | MF |

#### *Phenylpiperidine derivatives*

**FENTANYL**

**Authority required**

Breakthrough pain

# PREPARATIONS WHICH MAY BE PRESCRIBED FOR PATIENTS RECEIVING PALLIATIVE CARE

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|
| | Treatment Phase: Continuing treatment<br>**The Treatment criteria is:**<br>Patient must be undergoing palliative care,<br>**AND the Clinical criteria is:**<br>Patient must have cancer,<br>**AND the Clinical criteria is:**<br>Patient must be receiving opioids for their persistent pain,<br>**AND the Clinical criteria is:**<br>Patient must be unable to tolerate further escalation in the dose of morphine for breakthrough pain due to adverse effects.<br>**Caution**<br>The risk of drug dependence is high.<br>**Note**<br>For first continuing supply, applications for increased repeats for up to 3 months' supply may be authorised.<br>**Note**<br>Where consultation with a palliative care specialist or service has occurred, applications for increased repeats for up to 3 months' supply may be authorised.<br>**Note**<br>Telephone approvals are limited to 1 months' therapy.<br>**Note**<br>**Shared Care Model**:<br>For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners. | | | | | | | |
| 5411T<br>*NP* | FENTANYL Lozenge 1200 micrograms (as citrate), 30 | 2 | .. | .. | *579.64 | 36.10 | Actiq | OA |
| 5412W<br>*NP* | FENTANYL Lozenge 1600 micrograms (as citrate), 30 | 2 | .. | .. | *579.64 | 36.10 | Actiq | OA |
| 5407N<br>*NP* | FENTANYL Lozenge 200 micrograms (as citrate), 30 | 2 | .. | .. | *579.64 | 36.10 | Actiq | OA |
| 5408P<br>*NP* | FENTANYL Lozenge 400 micrograms (as citrate), 30 | 2 | .. | .. | *579.64 | 36.10 | Actiq | OA |
| 5409Q<br>*NP* | FENTANYL Lozenge 600 micrograms (as citrate), 30 | 2 | .. | .. | *579.64 | 36.10 | Actiq | OA |
| 5410R<br>*NP* | FENTANYL Lozenge 800 micrograms (as citrate), 30 | 2 | .. | .. | *579.64 | 36.10 | Actiq | OA |
| | **FENTANYL**<br>**Authority required**<br>Breakthrough pain<br>Treatment Phase: Initial treatment for dose titration<br>**The Treatment criteria is:**<br>Patient must be undergoing palliative care,<br>**AND the Clinical criteria is:**<br>Patient must have cancer,<br>**AND the Clinical criteria is:**<br>Patient must be receiving opioids for their persistent pain,<br>**AND the Clinical criteria is:**<br>Patient must be unable to tolerate further escalation in the dose of morphine for breakthrough pain due to adverse effects.<br>**Caution**<br>The risk of drug dependence is high.<br>**Note**<br>No increase in the maximum number of repeats may be authorised.<br>**Note**<br>**Shared Care Model**:<br>For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners. | | | | | | | |
| 5405L | FENTANYL Lozenge 1200 micrograms (as | 1 | .. | .. | 99.82 | 36.10 | Actiq | OA |

# PREPARATIONS WHICH MAY BE PRESCRIBED FOR PATIENTS RECEIVING PALLIATIVE CARE

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|---|
| *NP* | citrate), 9 | | | | | | | | |
| 5406M *NP* | FENTANYL Lozenge 1600 micrograms (as citrate), 9 | 1 | .. | .. | 99.82 | 36.10 | | Actiq | OA |
| 5401G *NP* | FENTANYL Lozenge 200 micrograms (as citrate), 9 | 1 | .. | .. | 99.82 | 36.10 | | Actiq | OA |
| 5402H *NP* | FENTANYL Lozenge 400 micrograms (as citrate), 9 | 1 | .. | .. | 99.82 | 36.10 | | Actiq | OA |
| 5403J *NP* | FENTANYL Lozenge 600 micrograms (as citrate), 9 | 1 | .. | .. | 99.82 | 36.10 | | Actiq | OA |
| 5404K *NP* | FENTANYL Lozenge 800 micrograms (as citrate), 9 | 1 | .. | .. | 99.82 | 36.10 | | Actiq | OA |

### *Diphenylpropylamine derivatives*

**METHADONE**

**Authority required**

Initial supply, for up to 3 months, for a palliative care patient with chronic severe disabling pain not responding to non-narcotic analgesics

**Caution**

The risk of drug dependence is high.

**Note**

Telephone approvals are limited to 1 month's therapy.

**Note**

Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 5399E *NP* | methadone hydrochloride 5 mg/mL oral liquid, 200 mL | 1 | 2 | .. | 19.12 | 20.25 | [a] | Sigma Methadone Syrup | QA |

**METHADONE**

**Authority required**

Continuing supply for a palliative care patient with chronic severe disabling pain not responding to non-narcotic analgesics

**Caution**

The risk of drug dependence is high.

**Note**

Where consultation with a palliative care specialist or service has occurred, applications for increased repeats for up to 3 months' supply may be authorised.

Telephone approvals are limited to 1 month's therapy.

**Note**

Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 5400F *NP* | methadone hydrochloride 5 mg/mL oral liquid, 200 mL | 1 | .. | .. | 19.12 | 20.25 | [a] | Sigma Methadone Syrup | QA |

## OTHER ANALGESICS AND ANTIPYRETICS

### *Anilides*

**PARACETAMOL**

**Authority required (STREAMLINED)**

***3649***

Initial supply, for up to 4 months, for a palliative care patient for analgesia or fever where alternative therapy cannot be tolerated

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 5319Y *NP* | paracetamol 500 mg suppository, 24 | 4 | 3 | .. | *84.67 | 36.10 | | Panadol | GC |
| 5343F *NP* | paracetamol 665 mg tablet: modified release, 96 tablets | 2 | 3 | .. | *16.85 | 17.98 | | Panadol Osteo | GC |

**PARACETAMOL**

**Authority required (STREAMLINED)**

***3650***

Continuing supply for a palliative care patient for analgesia or fever where alternative therapy cannot be tolerated

**Note**

Written or telephone authority applications for increased repeats may be approved where consultation with a palliative care specialist or service has occurred.

# PREPARATIONS WHICH MAY BE PRESCRIBED FOR PATIENTS RECEIVING PALLIATIVE CARE

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|---|
| 5320B *NP* | paracetamol 500 mg suppository, 24 | 4 | .. | .. | *84.67 | 36.10 | | Panadol | GC |
| 5344G *NP* | paracetamol 665 mg tablet: modified release, 96 tablets | 2 | .. | .. | *16.85 | 17.98 | | Panadol Osteo | GC |

## ANTIEPILEPTICS

### ANTIEPILEPTICS

#### *Benzodiazepine derivatives*

**CLONAZEPAM**

**Authority required**

Initial supply, for up to 4 months, for a palliative care patient for the prevention of epilepsy

**Note**

No applications for increased repeats will be authorised.

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 5338Y *NP* | clonazepam 2 mg tablet, 100 | 1 | 3 | .. | 18.95 | 20.08 | a | Paxam 2 | AF |
| | | | | B1.93 | 20.88 | 20.08 | a | Rivotril | RO |
| 5339B *NP* | clonazepam 2.5 mg/mL oral liquid, 10 mL | 2 | 3 | .. | *15.25 | 16.38 | | Rivotril | RO |
| 5337X *NP* | clonazepam 500 microgram tablet, 100 | 1 | 3 | .. | 13.17 | 14.30 | a | Paxam 0.5 | AF |
| | | | | B1.71 | 14.88 | 14.30 | a | Rivotril | RO |

**CLONAZEPAM**

**Authority required**

Continuing supply for a palliative care patient for the prevention of epilepsy

**Note**

Where consultation with a palliative care specialist or service has occurred, applications for increased repeats may be authorised.

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 5341D *NP* | clonazepam 2 mg tablet, 100 | 1 | .. | .. | 18.95 | 20.08 | a | Paxam 2 | AF |
| | | | | B1.93 | 20.88 | 20.08 | a | Rivotril | RO |
| 5342E *NP* | clonazepam 2.5 mg/mL oral liquid, 10 mL | 2 | .. | .. | *15.25 | 16.38 | | Rivotril | RO |
| 5340C *NP* | clonazepam 500 microgram tablet, 100 | 1 | .. | .. | 13.17 | 14.30 | a | Paxam 0.5 | AF |
| | | | | B1.71 | 14.88 | 14.30 | a | Rivotril | RO |

## PSYCHOLEPTICS

### ANXIOLYTICS

#### *Benzodiazepine derivatives*

**DIAZEPAM**

**Authority required**

Initial supply, for up to 4 months, for a palliative care patient where anxiety is a problem

**Note**

No applications for increased repeats will be authorised.

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 5355W *NP* | diazepam 2 mg tablet, 50 | 1 | 3 | .. | 7.93 | 9.06 | a | Antenex 2 | AF |
| | | | | | | | a | APO-Diazepam | TX |
| | | | | | | | a | Ranzepam | RA |
| | | | | | | | a | Valpam 2 | QA |
| | | | | B0.82 | 8.75 | 9.06 | a | Valium | RO |
| 5356X *NP* | diazepam 5 mg tablet, 50 | 1 | 3 | .. | 8.06 | 9.19 | a | Antenex 5 | AF |
| | | | | | | | a | APO-Diazepam | TX |
| | | | | | | | a | Diazepam-GA | GM |
| | | | | | | | a | Ranzepam | RA |
| | | | | | | | a | Valpam 5 | QA |
| | | | | B0.85 | 8.91 | 9.19 | a | Valium | RO |

**DIAZEPAM**

# PREPARATIONS WHICH MAY BE PRESCRIBED FOR PATIENTS RECEIVING PALLIATIVE CARE

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|---|
| | **Authority required**<br>Continuing supply for a palliative care patient where anxiety is a problem | | | | | | | | |
| | **Note**<br>Where consultation with a palliative care specialist or service has occurred, applications for increased repeats may be authorised. | | | | | | | | |
| 5357Y<br>*NP* | diazepam 2 mg tablet, 50 | 1 | .. | .. | 7.93 | 9.06 | [a] | Antenex 2 | AF |
| | | | | | | | [a] | APO-Diazepam | TX |
| | | | | | | | [a] | Ranzepam | RA |
| | | | | | | | [a] | Valpam 2 | QA |
| | | | | [B]0.82 | 8.75 | 9.06 | [a] | Valium | RO |
| 5358B<br>*NP* | diazepam 5 mg tablet, 50 | 1 | .. | .. | 8.06 | 9.19 | [a] | Antenex 5 | AF |
| | | | | | | | [a] | APO-Diazepam | TX |
| | | | | | | | [a] | Diazepam-GA | GM |
| | | | | | | | [a] | Ranzepam | RA |
| | | | | | | | [a] | Valpam 5 | QA |
| | | | | [B]0.85 | 8.91 | 9.19 | [a] | Valium | RO |
| | **OXAZEPAM**<br>**Authority required**<br>Initial supply, for up to 4 months, for a palliative care patient where anxiety is a problem | | | | | | | | |
| | **Note**<br>No applications for increased repeats will be authorised. | | | | | | | | |
| 5371Q<br>*NP* | oxazepam 15 mg tablet, 25 | 2 | 3 | .. | *9.11 | 10.24 | [a] | Alepam 15 | AF |
| | | | | [B]5.36 | *14.47 | 10.24 | [a] | Serepax | QA |
| 5372R<br>*NP* | oxazepam 30 mg tablet, 25 | 2 | 3 | .. | *9.11 | 10.24 | [a] | Alepam 30 | AF |
| | | | | | | | [a] | APO-Oxazepam | TX |
| | | | | | | | [a] | Murelax | FM |
| | | | | [B]5.36 | *14.47 | 10.24 | [a] | Serepax | QA |
| | **OXAZEPAM**<br>**Authority required**<br>Continuing supply for a palliative care patient where anxiety is a problem | | | | | | | | |
| | **Note**<br>Where consultation with a palliative care specialist or service has occurred, applications for increased repeats may be authorised. | | | | | | | | |
| 5373T<br>*NP* | oxazepam 15 mg tablet, 25 | 2 | .. | .. | *9.11 | 10.24 | [a] | Alepam 15 | AF |
| | | | | [B]5.36 | *14.47 | 10.24 | [a] | Serepax | QA |
| 5374W<br>*NP* | oxazepam 30 mg tablet, 25 | 2 | .. | .. | *9.11 | 10.24 | [a] | Alepam 30 | AF |
| | | | | | | | [a] | APO-Oxazepam | TX |
| | | | | | | | [a] | Murelax | FM |
| | | | | [B]5.36 | *14.47 | 10.24 | [a] | Serepax | QA |

## HYPNOTICS AND SEDATIVES

### *Benzodiazepine derivatives*

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | **NITRAZEPAM**<br>**Authority required**<br>Initial supply, for up to 4 months, for a palliative care patient where insomnia is a problem | | | | | | | | |
| | **Note**<br>No applications for increased repeats will be authorised. | | | | | | | | |
| 5359C<br>*NP* | nitrazepam 5 mg tablet, 25 | 2 | 3 | .. | *9.41 | 10.54 | [a] | Alodorm | AF |
| | | | | [B]2.92 | *12.33 | 10.54 | [a] | Mogadon | VT |
| | **NITRAZEPAM**<br>**Authority required**<br>Continuing supply for a palliative care patient where insomnia is a problem | | | | | | | | |
| | **Note** | | | | | | | | |

# PREPARATIONS WHICH MAY BE PRESCRIBED FOR PATIENTS RECEIVING PALLIATIVE CARE

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|---|
| | Where consultation with a palliative care specialist or service has occurred, applications for increased repeats may be authorised. | | | | | | | | |
| 5360D<br>*NP* | nitrazepam 5 mg tablet, 25 | 2 | .. | .. | *9.41 | 10.54 | a | Alodorm | AF |
| | | | | B2.92 | *12.33 | 10.54 | a | Mogadon | VT |
| | **TEMAZEPAM**<br>**Authority required**<br>Initial supply, for up to 4 months, for a palliative care patient where insomnia is a problem | | | | | | | | |
| | **Note**<br>No applications for increased repeats will be authorised. | | | | | | | | |
| 5375X<br>*NP* | temazepam 10 mg tablet, 25 | 2 | 3 | .. | *8.71 | 9.84 | a | APO-Temazepam | TX |
| | | | | | | | a | Temaze | AF |
| | | | | | | | a | Temtabs | FM |
| | | | | B4.10 | *12.81 | 9.84 | a | Normison | QA |
| | **TEMAZEPAM**<br>**Authority required**<br>Continuing supply for a palliative care patient where insomnia is a problem | | | | | | | | |
| | **Note**<br>Where consultation with a palliative care specialist or service has occurred, applications for increased repeats may be authorised. | | | | | | | | |
| 5376Y<br>*NP* | temazepam 10 mg tablet, 25 | 2 | .. | .. | *8.71 | 9.84 | a | APO-Temazepam | TX |
| | | | | | | | a | Temaze | AF |
| | | | | | | | a | Temtabs | FM |
| | | | | B4.10 | *12.81 | 9.84 | a | Normison | QA |

# Items Available under Special Arrangements(Section 100)

# Section 100 – Items Available under Special Arrangement

In addition to the drugs and medicinal preparations available under normal PBS arrangements listed in this Schedule, a number of drugs are also available as pharmaceutical benefits but are distributed under alternative arrangements where these are considered more appropriate.

These alternative arrangements are provided for under section 100 of the National Health Act 1953. Several programs exist for the provision of drugs as pharmaceutical benefits in this way and this section lists those drugs which are available under the following programs:

- **Highly Specialised Drugs Program**
- **Botulinum Toxin Program**
- **Human Growth Hormone Program**
- **IVF/GIFT Program**
- **Opiate Dependence Treatment Program**

Complete details concerning the availability of drugs as benefits under these programs may be obtained by telephoning the relevant contact number(s) shown in each section, or in certain cases, by referring to the telephone number provided for individual drugs listings.

# Section 100 – Highly Specialised Drugs Program

The Australian Government provides funding for certain specialised medications under the Highly Specialised Drugs Program. Highly Specialised Drugs are medicines for the treatment of chronic conditions which, because of their clinical use or other special features, are restricted to supply through public and private hospitals having access to appropriate specialist facilities. To prescribe these drugs as pharmaceutical benefit items, medical practitioners are required to be affiliated with these specialist hospital units. A general practitioner or non-specialist hospital doctor may only prescribe Highly Specialised Drugs to provide maintenance therapy under the guidance of the treating specialist.

Benefits are available for the listed clinical indications only. There is no facility for individual patient approval for indications outside those listed.

To gain access to a Commonwealth funded drug under this program, a patient must attend a participating hospital and be a day admitted patient, a non-admitted patient or a patient on discharge, be under appropriate specialist medical care, meet the specific medical criteria and be an Australian resident in Australia (or other eligible person).

A patient will be required to pay a contribution for each supply of a highly specialised drug at a similar rate to the Pharmaceutical Benefits Scheme. Commonwealth subsidy is not available for hospital in-patients.

Reciprocal Health Care Agreement – Where a patient is entitled to be treated as an eligible person as a visitor from a country with which Australia has entered into a Reciprocal Health Care Agreement, the supply will be limited to the original prescription only. Repeat prescriptions for these patients are not permitted.

Private Hospitals – **In addition to the above requirements**, for Highly Specialised Drugs prescribed through private hospitals, claiming and approval of authority prescriptions is administered by Medicare Australia. Highly Specialised Drugs are authority required items. Medical practitioners must seek approval to prescribe these items as pharmaceutical benefits prior to their dispensing under the PBS. Approval of authority prescriptions by Medicare Australia may be obtained either by posting an Authority Prescription Form to Medicare Australia, or by using Medicare Australia's Authority Freecall service (1800 888 333). **Prescribers must quote the provider number of the hospital when applying**. Not more than two months' supply (one month's supply in the case of Clozapine), with provision for up to 5 repeats, will be authorised. Prescriptions for Highly Specialised Drugs can be dispensed by an approved private hospital's dispensary or by a community pharmacy.

The remuneration rates for Highly Specialised Drugs prescribed through private hospitals comprise the normal PBS ready- prepared dispensing fee plus a mark-up ascertained as follows:

- 10% for drugs with a price ex-manufacturer of less than $40;
- $4 for drugs with a price ex-manufacturer of between $40 and $100;
- 4% for drugs with a price ex-manufacturer of between $100.01 and $1000;
- $40 for drugs with a price ex-manufacturer of greater than $1000.

Public Hospitals – For Highly Specialised Drugs prescribed through public hospitals, claiming and access to the program is administered by the States/Territories Health Departments. Prescriptions for Highly Specialised Drugs can be dispensed by public hospital pharmacies.

If you would like further information about the Highly Specialised Drugs Program, please contact your pharmacy, Medicare Australia (Ph: 132 290) or the Australian Government adviser, the Highly Specialised Drugs Working Party Secretariat (Ph: (02) 6289 2331).

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|

# BLOOD AND BLOOD FORMING ORGANS

## ANTIHEMORRHAGICS

### VITAMIN K AND OTHER HEMOSTATICS

#### *Other systemic hemostatics*

**ELTROMBOPAG**

**Authority required**

Initial (new patients)

Initial treatment, as the sole PBS-subsidised thrombopoietin receptor agonist (TRA), of severe thrombocytopenia in an adult patient with severe chronic immune (idiopathic) thrombocytopenic purpura (ITP) who is:

(1) Splenectomised and:

(a) has had an inadequate response to, or is intolerant to, corticosteroid therapy post splenectomy; and

(b) has had an inadequate response to, or is intolerant to, immunoglobulin therapy post splenectomy;

OR

(2) Not splenectomised and:

(a) has had an inadequate response, or is intolerant to, corticosteroid therapy at a dose equivalent to 0.5-2 mg/kg/day of prednisone for at least 4-6 weeks; and

(b) has had an inadequate response, or is intolerant to, immunoglobulin therapy; and

(c) in whom splenectomy is contraindicated for medical reasons.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of initial application:

(a) a platelet count of less than or equal to 20,000 million per L;

OR

(b) a platelet count of 20-30,000 million per L, where the patient is experiencing significant bleeding or has a history of significant bleeding in this platelet range.

The authority application must be made in writing and must include:

(1) a completed authority prescription form,

(2) a signed patient acknowledgement,

(3) a completed Idiopathic Thrombocytopenic Purpura Initial PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)],

(4) a copy of a full blood count pathology report supporting the diagnosis of ITP, and

(5) where the application is sought on the basis of a medical contraindication to surgery, a signed and dated letter from the clinician making this assessment which includes the date upon which the patient was assessed for surgery and the clinical grounds upon which surgery is contraindicated.

The full blood count must be no more than 1 month old at the time of application.

A maximum of 24 weeks of treatment with eltrombopag will be authorised under this criterion

**Authority required**

Initial (grandfather patients)

Initial treatment, as the sole PBS-subsidised thrombopoietin receptor agonist (TRA), of severe thrombocytopenia in an adult patient with severe chronic immune (idiopathic) thrombocytopenic purpura (ITP) who was receiving treatment with eltrombopag prior to 1 November 2011 and in whom the criteria for initial treatment can be demonstrated to have been met at the time eltrombopag was commenced.

The authority application must be made in writing and must include:

(1) a completed authority prescription form,

(2) a signed patient acknowledgement,

(3) a completed Idiopathic Thrombocytopenic Purpura Initial PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)], and

(4) where the application is sought on the basis of a medical contraindication to surgery, a signed and dated letter from the clinician making this assessment which includes the date upon which the patient was assessed for surgery and the clinical grounds upon which surgery is contraindicated.

A maximum of 24 weeks of treatment with eltrombopag will be authorised under this criterion

**Authority required**

Continuing therapy or re-initiation after a break in therapy

First period of PBS-subsidised continuing treatment or re-initiation of interrupted PBS-subsidised treatment, as the sole PBS-subsidised thrombopoietin receptor agonist (TRA), of severe thrombocytopenia in an adult patient with chronic immune (idiopathic) thrombocytopenic purpura (ITP) who has displayed a sustained platelet response to treatment with eltrombopag during the initial period of PBS-subsidised treatment.

For the purposes of this restriction, a sustained platelet response is defined as:

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|---|---|---|---|---|---|---|---|
| | (a) use of rescue medication (corticosteroids or immunoglobulins) on no more than one occasion during the initial period of PBS-subsidised eltrombopag, | | | | | | |
| | AND either of the following: | | | | | | |
| | (b) a platelet count greater than or equal to 50,000 million per L on at least four (4) occasions, each at least one week apart; | | | | | | |
| | OR | | | | | | |
| | (c) a platelet count greater than 30,000 million per L and which is double the baseline (pre-treatment) platelet count on at least four (4) occasions, each at least one week apart. | | | | | | |
| | Applications for the first period of continuing PBS-subsidised treatment or re-initiation of interrupted treatment must be made in writing and must include: | | | | | | |
| | (1) a completed authority prescription form, and | | | | | | |
| | (2) a completed Idiopathic Thrombocytopenic Purpura Continuing PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)], and | | | | | | |
| | (3) copies of the platelet count pathology reports (unless previously provided for patients re-initiating therapy). | | | | | | |
| | The most recent platelet count must be no more than one month old at the time of application. | | | | | | |
| | A maximum of 24 weeks of treatment with eltrombopag will be authorised under this criterion. | | | | | | |
| | Where fewer than 5 repeats are initially requested with the authority prescription, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be made by telephone | | | | | | |
| | **Authority required** | | | | | | |
| | Second and subsequent applications for continuing therapy | | | | | | |
| | Continuing treatment, as the sole PBS-subsidised thrombopoietin receptor agonist (TRA), of severe thrombocytopenia in an adult patient with chronic immune (idiopathic) thrombocytopenic purpura (ITP) who has previously received PBS-subsidised therapy with eltrombopag and who continues to display a response to treatment with eltrombopag. | | | | | | |
| | For the purposes of this restriction, a continuing response to treatment with eltrombopag is defined as: | | | | | | |
| | (a) use of rescue medication (corticosteroids or immunoglobulins) on no more than one occasion during the most recent 24 week period of PBS-subsidised treatment with eltrombopag, | | | | | | |
| | AND either of the following: | | | | | | |
| | (b) a platelet count greater than or equal to 50,000 million per L | | | | | | |
| | OR | | | | | | |
| | (c) a platelet count greater than 30,000 million per L and which is double the baseline platelet count. | | | | | | |
| | Platelet counts must be no more than 1 month old at the time of application. | | | | | | |
| | Authority applications for second and subsequent periods of continuing therapy may be made by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) | | | | | | |
| | **Note** | | | | | | |
| | Eltrombopag is not PBS-subsidised as an alternative to splenectomy. | | | | | | |
| | Any queries concerning the arrangements to prescribe eltrombopag may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). | | | | | | |
| | Written applications for authority to prescribe eltrombopag should be forwarded to: | | | | | | |
| | Medicare Australia | | | | | | |
| | Prior Written Approval of Specialised Drugs | | | | | | |
| | Reply Paid 9826 | | | | | | |
| | GPO Box 9826 | | | | | | |
| | HOBART TAS 7001 | | | | | | |
| | Further prescribing information is on the Medicare Australia website at www.medicareaustralia.gov.au. | | | | | | |
| | **Note** | | | | | | |
| | Patients will be able to trial either eltrombopag and/or romiplostim within the initial 24 weeks treatment period. Patients who fail to demonstrate a response to treatment with either eltrombopag and/or romiplostim under the initial restriction will not be eligible to receive further PBS-subsidised treatment with either of these drugs. | | | | | | |
| | No applications for increased repeats will be authorised. | | | | | | |
| | **Note** | | | | | | |
| | No applications for increased repeats will be authorised. | | | | | | |
| 5827Q | eltrombopag 25 mg tablet, 28 | 1 | 5 | .. | 1558.63 | Revolade | GK |
| 5828R | eltrombopag 50 mg tablet, 28 | 1 | 5 | .. | 3070.63 | Revolade | GK |
| | **ROMIPLOSTIM** | | | | | | |
| | **Authority required** | | | | | | |
| | Initial (new patients) | | | | | | |

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|

Initial treatment, as the sole PBS-subsidised thrombopoietin receptor agonist (TRA), of severe thrombocytopenia in an adult patient with severe chronic immune (idiopathic) thrombocytopenic purpura (ITP) who is:

(1) Splenectomised and:

(a) has had an inadequate response to, or is intolerant to, corticosteroid therapy post splenectomy; and

(b) has had an inadequate response to, or is intolerant to, immunoglobulin therapy post splenectomy;

OR

(2) Not splenectomised and:

(a) has had an inadequate response, or is intolerant to, corticosteroid therapy at a dose equivalent to 0.5-2 mg/kg/day of prednisone for at least 4-6 weeks; and

(b) has had an inadequate response, or is intolerant to, immunoglobulin therapy; and

(c) in whom splenectomy is contraindicated for medical reasons.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of initial application:

(a) a platelet count of less than or equal to 20,000 million per L;

OR

(b) a platelet count of 20-30,000 million per L, where the patient is experiencing significant bleeding or has a history of significant bleeding in this platelet range.

The authority application must be made in writing and must include:

(1) a completed authority prescription form,

(2) a signed patient acknowledgement,

(3) a completed Idiopathic Thrombocytopenic Purpura Initial PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)],

(4) a copy of a full blood count pathology report supporting the diagnosis of ITP, and

(5) where the application is sought on the basis of a medical contraindication to surgery, a signed and dated letter from the clinician making this assessment which includes the date upon which the patient was assessed for surgery and the clinical grounds upon which surgery is contraindicated.

The full blood count must be no more than 1 month old at the time of application.

At the time of the written authority application, medical practitioners should request the appropriate quantity of vials of appropriate strength to provide sufficient drug for a single treatment at a dose of 1 microgram/kg. Up to 1 repeat may be requested with the initial written application.

Subsequently during the initial period of dose titration, authority applications for a single dose and up to 1 repeat may be made by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). The dose (microgram/kg/week) must be provided at the time of application.

Once a patient's dose has been stable for a period of 4 weeks, authority approvals for sufficient vials of appropriate strength based on the weight of the patient and dose (microgram/kg/week) for up to 4 weeks of treatment and up to 4 repeats may be granted, as long as the total period of treatment authorised under this restriction does not exceed 24 weeks.

Authority approval will not be given for doses of higher than 10 micrograms/kg/week

**Authority required**

Initial (grandfather patients)

Initial PBS-subsidised treatment, as the sole PBS-subsidised thrombopoietin receptor agonist (TRA), of severe thrombocytopenia in an adult patient with severe chronic immune (idiopathic) thrombocytopenic purpura (ITP) who was receiving treatment with romiplostim prior to 1 April 2011 and in whom the criteria for initial treatment can be demonstrated to have been met at the time romiplostim was commenced.

The authority application must be made in writing and must include:

(1) a completed authority prescription form,

(2) a signed patient acknowledgement,

(3) a completed Idiopathic Thrombocytopenic Purpura Initial PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)], and

(4) where the application is sought on the basis of a medical contraindication to surgery, a signed and dated letter from the clinician making this assessment which includes the date upon which the patient was assessed for surgery and the clinical grounds upon which surgery is contraindicated.

For patients whose dose of romiplostim had been stable for at least 4 weeks at the time of the initial application for PBS-subsidy, the medical practitioner should request sufficient number of vials based on the weight of the patient and dose (microgram/kg/week) to provide up to 4 weeks of treatment. Up to a maximum of 5 repeats may be authorised.

Where the patient is in the titration phase of treatment with romiplostim, medical practitioners should request the appropriate quantity of vials of appropriate strength to provide sufficient drug for a single treatment at a dose of 1 microgram/kg. Up to 1 repeat may be requested with the initial written application.

Subsequently during the initial period of dose titration, authority applications for a single dose and up to 1 repeat may be made by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). The dose (microgram/kg/week) must be provided at the time of application.

Once a patient's dose has been stable for a period of 4 weeks, authority approvals for sufficient vials of appropriate strength based on the weight of the patient and dose (microgram/kg/week) for up to 4 weeks of treatment and up to 4 repeats may be granted, as long as the total period of

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|---|---|---|---|---|---|---|

treatment authorised under this restriction does not exceed 24 weeks.

Authority approval will not be given for doses of higher than 10 micrograms/kg/week

**Authority required**

Continuing therapy or re-initiation after a break in therapy

First period of PBS-subsidised continuing treatment or re-initiation of interrupted PBS-subsidised treatment, as the sole PBS-subsidised thrombopoietin receptor agonist (TRA), of severe thrombocytopenia in an adult patient with chronic immune (idiopathic) thrombocytopenic purpura (ITP) who has displayed a sustained platelet response to treatment with romiplostim during the initial period of PBS-subsidised treatment.

For the purposes of this restriction, a sustained platelet response is defined as:

(a) use of rescue medication (corticosteroids or immunoglobulins) on no more than one occasion during the initial period of PBS-subsidised romiplostim,

AND either of the following:

(b) a platelet count greater than or equal to 50,000 million per L on at least four (4) occasions, each at least one week apart;

OR

(c) a platelet count greater than 30,000 million per L and which is double the baseline (pre-treatment) platelet count on at least four (4) occasions, each at least one week apart.

Applications for the first period of continuing PBS-subsidised treatment or re-initiation of interrupted treatment must be made in writing and must include:

(1) a completed authority prescription form, and

(2) a completed Idiopathic Thrombocytopenic Purpura Continuing PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)], and

(3) copies of the platelet count pathology reports (unless previously provided for patients re-initiating therapy).

The most recent platelet count must be no more than one month old at the time of application.

The medical practitioner should request sufficient number of vials of appropriate strength based on the weight of the patient and dose (microgram/kg/week) to provide 4 weeks of treatment. Up to a maximum of 5 repeats may be authorised.

Where fewer than 5 repeats are initially requested with the authority prescription, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be made by telephone.

Authority approval will not be given for doses of higher than 10 micrograms/kg/week

**Authority required**

Second and subsequent applications for continuing therapy

Continuing treatment, as the sole PBS-subsidised thrombopoietin receptor agonist (TRA), of severe thrombocytopenia in an adult patient with chronic immune (idiopathic) thrombocytopenic purpura (ITP) who has previously received PBS-subsidised therapy with romiplostim and who continues to display a response to treatment with romiplostim.

For the purposes of this restriction, a continuing response to treatment with romiplostim is defined as:

(a) use of rescue medication (corticosteroids or immunoglobulins) on no more than one occasion during the most recent 24 week period of PBS-subsidised treatment with romiplostim,

AND either of the following:

(b) a platelet count greater than or equal to 50,000 million per L

OR

(c) a platelet count greater than 30,000 million per L and which is double the baseline platelet count.

Platelet counts must be no more than 1 month old at the time of application.

Authority applications for second and subsequent periods of continuing therapy may be made by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

The medical practitioner should request sufficient number of vials of appropriate strength based on the weight of the patient and dose (microgram/kg/week) to provide 4 weeks of treatment. Up to a maximum of 5 repeats may be authorised.

Authority approval will not be given for doses of higher than 10 micrograms/kg/week

**Note**

Romiplostim is not PBS-subsidised as an alternative to splenectomy.

Any queries concerning the arrangements to prescribe romiplostim may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written applications for authority to prescribe romiplostim should be forwarded to:

Medicare Australia

Prior Written Approval of Specialised Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|
| | Further prescribing information is on the Medicare Australia website at www.medicareaustralia.gov.au. | | | | | | |
| | **Note**<br>Patients will be able to trial either eltrombopag and/or romiplostim within the initial 24 weeks treatment period. Patients who fail to demonstrate a response to treatment with either eltrombopag and/or romiplostim under the initial restriction will not be eligible to receive further PBS-subsidised treatment with either of these drugs. | | | | | | |
| | **Note**<br>Special Pricing Arrangements apply. | | | | | | |
| 9697J | romiplostim 250 microgram injection, 1 x 250 microgram vial | 1 | .. | .. | 1023.23 | Nplate | AN |
| 9699L | romiplostim 500 microgram injection, 1 x 500 microgram vial | 1 | .. | .. | 2001.63 | Nplate | AN |

## ANTIANEMIC PREPARATIONS

### OTHER ANTIANEMIC PREPARATIONS

#### *Other antianemic preparations*

**DARBEPOETIN ALFA**

**Authority required**

Treatment of anaemia requiring transfusion, defined as a haemoglobin level of less than 100 g per L, where intrinsic renal disease, as assessed by a nephrologist, is the primary cause of the anaemia

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| 6320P | darbepoetin alfa 10 microgram/0.4 mL injection, 4 x 0.4 mL syringes | 2 | 5 | .. | *376.95 | Aranesp | AN |
| 6492Q | darbepoetin alfa 100 microgram/0.5 mL injection, 1 x 0.5 mL syringe | 8 | 5 | .. | *2667.11 | Aranesp SureClick | AN |
| 6326Y | darbepoetin alfa 100 microgram/0.5 mL injection, 4 x 0.5 mL syringes | 2 | 5 | .. | *2667.13 | Aranesp | AN |
| 6493R | darbepoetin alfa 150 microgram/0.3 mL injection, 1 x 0.3 mL syringe | 8 | 5 | .. | *3951.11 | Aranesp SureClick | AN |
| 6365B | darbepoetin alfa 150 microgram/0.3 mL injection, 4 x 0.3 mL syringes | 2 | 5 | .. | *3951.13 | Aranesp | AN |
| 6488L | darbepoetin alfa 20 microgram/0.5 mL injection, 1 x 0.5 mL syringe | 8 | 5 | .. | *704.07 | Aranesp SureClick | AN |
| 6321Q | darbepoetin alfa 20 microgram/0.5 mL injection, 4 x 0.5 mL syringes | 2 | 5 | .. | *704.07 | Aranesp | AN |
| 6322R | darbepoetin alfa 30 microgram/0.3 mL injection, 4 x 0.3 mL syringes | 2 | 5 | .. | *960.79 | Aranesp | AN |
| 6489M | darbepoetin alfa 40 microgram/0.4 mL injection, 1 x 0.4 mL syringe | 8 | 5 | .. | *1160.23 | Aranesp SureClick | AN |
| 6323T | darbepoetin alfa 40 microgram/0.4 mL injection, 4 x 0.4 mL syringes | 2 | 5 | .. | *1160.23 | Aranesp | AN |
| 6324W | darbepoetin alfa 50 microgram/0.5 mL injection, 4 x 0.5 mL syringes | 2 | 5 | .. | *1423.41 | Aranesp | AN |
| 6490N | darbepoetin alfa 60 microgram/0.3 mL injection, 1 x 0.3 mL syringe | 8 | 5 | .. | *1663.27 | Aranesp SureClick | AN |
| 6325X | darbepoetin alfa 60 microgram/0.3 mL injection, 4 x 0.3 mL syringes | 2 | 5 | .. | *1663.29 | Aranesp | AN |
| 6491P | darbepoetin alfa 80 microgram/0.4 mL injection, 1 x 0.4 mL syringe | 8 | 5 | .. | *2174.63 | Aranesp SureClick | AN |
| 6438W | darbepoetin alfa 80 microgram/0.4 mL injection, 4 x 0.4 mL syringes | 2 | 5 | .. | *2174.63 | Aranesp | AN |

**EPOETIN ALFA**

**Authority required**

Treatment of anaemia requiring transfusion, defined as a haemoglobin level of less than 100 g per L, where intrinsic renal disease, as assessed by a nephrologist, is the primary cause of the anaemia

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| 6207Q | epoetin alfa 10 000 international units/mL injection, 6 x 1 mL syringes | 2 | 5 | .. | *2016.93 | Eprex 10000 | JC |
| 6251B | epoetin alfa 1000 international units/0.5 mL injection, 6 x 0.5 mL syringes | 2 | 5 | .. | *297.11 | Eprex 1000 | JC |
| 6434P | epoetin alfa 20 000 international units/0.5 mL injection, 6 x 0.5 mL syringes | 2 | 5 | .. | *3922.63 | Eprex 20,000 | JC |
| 6204M | epoetin alfa 2000 international units/0.5 mL injection, 6 x 0.5 mL syringes | 2 | 5 | .. | *544.11 | Eprex 2000 | JC |
| 6205N | epoetin alfa 3000 international units/0.3 mL injection, 6 x 0.3 mL syringes | 2 | 5 | .. | *700.21 | Eprex 3000 | JC |
| 6339P | epoetin alfa 40 000 international units/mL injection, 1 x 1 mL syringe | 2 | 5 | .. | *1300.63 | Eprex 40,000 | JC |

# HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|
| 6206P | epoetin alfa 4000 international units/0.4 mL injection, 6 x 0.4 mL syringes | 2 | 5 | .. | *889.91 | Eprex 4000 | JC |
| 6302Q | epoetin alfa 5000 international units/0.5 mL injection, 6 x 0.5 mL syringes | 2 | 5 | .. | *1103.97 | Eprex 5000 | JC |
| 6303R | epoetin alfa 6000 international units/0.6 mL injection, 6 x 0.6 mL syringes | 2 | 5 | .. | *1301.77 | Eprex 6000 | JC |
| 6305W | epoetin alfa 8000 international units/0.8 mL injection, 6 x 0.8 mL syringes | 2 | 5 | .. | *1674.55 | Eprex 8000 | JC |
| | **EPOETIN BETA** | | | | | | |
| | **Authority required** | | | | | | |
| | Treatment of anaemia requiring transfusion, defined as a haemoglobin level of less than 100 g per L, where intrinsic renal disease, as assessed by a nephrologist, is the primary cause of the anaemia | | | | | | |
| 6485H | epoetin beta 10 000 international units/0.6 mL injection, 6 x 0.6 mL syringes | 2 | 5 | .. | *2016.93 | NeoRecormon | RO |
| 6480C | epoetin beta 2000 international units/0.3 mL injection, 6 x 0.3 mL syringes | 2 | 5 | .. | *544.11 | NeoRecormon | RO |
| 6481D | epoetin beta 3000 international units/0.3 mL injection, 6 x 0.3 mL syringes | 2 | 5 | .. | *700.21 | NeoRecormon | RO |
| 6482E | epoetin beta 4000 international units/0.3 mL injection, 6 x 0.3 mL syringes | 2 | 5 | .. | *889.91 | NeoRecormon | RO |
| 6483F | epoetin beta 5000 international units/0.3 mL injection, 6 x 0.3 mL syringes | 2 | 5 | .. | *1103.99 | NeoRecormon | RO |
| 6484G | epoetin beta 6000 international units/0.3 mL injection, 6 x 0.3 mL syringes | 2 | 5 | .. | *1301.77 | NeoRecormon | RO |
| | **EPOETIN LAMBDA** | | | | | | |
| | **Authority required** | | | | | | |
| | Treatment of anaemia requiring transfusion, defined as a haemoglobin level of less than 100 g per L, where intrinsic renal disease, as assessed by a nephrologist, is the primary cause of the anaemia | | | | | | |
| | **Note** | | | | | | |
| | Epoetin lambda should only be administered by the intravenous route. | | | | | | |
| 9595B | epoetin lambda 10 000 international units/mL injection, 6 x 1 mL syringes | 2 | 5 | .. | *1913.23 | Novicrit | NV |
| 9685R | epoetin lambda 1000 international units/0.5 mL injection, 6 x 0.5 mL syringes | 2 | 5 | .. | *281.81 | Novicrit | NV |
| 9686T | epoetin lambda 2000 international units/mL injection, 6 x 1 mL syringes | 2 | 5 | .. | *515.81 | Novicrit | NV |
| 9687W | epoetin lambda 3000 international units/0.3 mL injection, 6 x 0.3 mL syringes | 2 | 5 | .. | *663.71 | Novicrit | NV |
| 9688X | epoetin lambda 4000 international units/0.4 mL injection, 6 x 0.4 mL syringes | 2 | 5 | .. | *843.41 | Novicrit | NV |
| 9588P | epoetin lambda 5000 international units/0.5 mL injection, 6 x 0.5 mL syringes | 2 | 5 | .. | *1048.33 | Novicrit | NV |
| 9590R | epoetin lambda 6000 international units/0.6 mL injection, 6 x 0.6 mL syringes | 2 | 5 | .. | *1235.71 | Novicrit | NV |
| 9593X | epoetin lambda 8000 international units/0.8 mL injection, 6 x 0.8 mL syringes | 2 | 5 | .. | *1588.87 | Novicrit | NV |
| | **METHOXY POLYETHYLENE GLYCOL-EPOETIN BETA** | | | | | | |
| | **Authority required** | | | | | | |
| | Treatment of anaemia requiring transfusion, defined as a haemoglobin level of less than 100 g per L, where intrinsic renal disease, as assessed by a nephrologist, is the primary cause of the anaemia | | | | | | |
| 9577C | methoxy polyethylene glycol-epoetin beta 100 microgram/0.3 mL injection, 1 x 0.3 mL syringe | 2 | 5 | .. | *1205.45 | Mircera | RO |
| 9578D | methoxy polyethylene glycol-epoetin beta 120 microgram/0.3 mL injection, 1 x 0.3 mL syringe | 2 | 5 | .. | *1388.27 | Mircera | RO |
| 9579E | methoxy polyethylene glycol-epoetin beta 200 microgram/0.3 mL injection, 1 x 0.3 mL syringe | 2 | 5 | .. | *1970.93 | Mircera | RO |
| 9574X | methoxy polyethylene glycol-epoetin beta 30 microgram/0.3 mL injection, 1 x 0.3 mL syringe | 2 | 5 | .. | *390.57 | Mircera | RO |
| 9580F | methoxy polyethylene glycol-epoetin beta 360 microgram/0.6 mL injection, 1 x 0.6 mL syringe | 2 | 5 | .. | *3373.15 | Mircera | RO |
| 9575Y | methoxy polyethylene glycol-epoetin beta 50 microgram/0.3 mL injection, 1 x 0.3 mL syringe | 2 | 5 | .. | *646.55 | Mircera | RO |
| 9576B | methoxy polyethylene glycol-epoetin beta 75 microgram/0.3 mL injection, 1 x 0.3 mL syringe | 2 | 5 | .. | *938.49 | Mircera | RO |

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Brand Name and Manufacturer |
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# CARDIOVASCULAR SYSTEM

## ANTIHYPERTENSIVES

### OTHER ANTIHYPERTENSIVES

#### *Other antihypertensives*

**AMBRISENTAN**

**Authority required**

Initial (new patients)

Application for initial PBS-subsidised treatment with ambrisentan of patients who have not received prior PBS-subsidised treatment with a PAH agent and who have been assessed by a physician from a designated hospital to have:

(a) WHO Functional Class III primary pulmonary hypertension and a mean right atrial pressure of 8 mmHg or less, as measured by RHC, or, where a RHC cannot be performed on clinical grounds, right ventricular function as assessed by ECHO; OR

(b) WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease and a mean right atrial pressure of 8 mmHg or less, as measured by RHC, or, where a RHC cannot be performed on clinical grounds, right ventricular function as assessed by ECHO.

Patients must have failed to respond [see Note for definition of response] to 6 or more weeks of appropriate vasodilator treatment unless intolerance or a contraindication to such treatment exists.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form [www.medicareaustralia.gov.au] which includes results from the 3 tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6MWT; and

(3) a signed patient acknowledgment form.

Details of prior vasodilator treatment, including the dose and duration of treatment, must be provided at the time of application. Where the patient has an adverse event to a vasodilator or where vasodilator treatment is contraindicated, details on the nature of the adverse event or contraindication according to the TGA-approved Product Information must also be provided with the application.

Where fewer than 3 tests (see requirement 2 above) are able to be performed on clinical grounds, a patient specific reason outlining why the particular test/s could not be conducted must be provided with the authority application [see Note for test requirements].

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. A maximum of 5 repeats may be requested. Where fewer than 5 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 6 months of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday)

**Authority required**

Initial (new patients)

Application for initial PBS-subsidised treatment with ambrisentan of patients who have not received prior PBS-subsidised treatment with a PAH agent and who have been assessed by a physician from a designated hospital to have:

(a) WHO Functional Class III primary pulmonary hypertension and a mean right atrial pressure greater than 8 mmHg, as measured by RHC, or, where a RHC cannot be performed on clinical grounds, right ventricular function as assessed by ECHO; OR

(b) WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease and a mean right atrial pressure greater than 8 mmHg, as measured by RHC, or, where a RHC cannot be performed on clinical grounds, right ventricular function as assessed by ECHO; OR

(c) WHO Functional Class IV primary pulmonary hypertension; OR

(d) WHO Functional Class IV pulmonary arterial hypertension secondary to connective tissue disease.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form [www.medicareaustralia.gov.au] which includes results from the 3 tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6MWT; and

(3) a signed patient acknowledgment form.

Where fewer than 3 tests (see requirement 2 above) are able to be performed on clinical grounds, a patient specific reason outlining why the particular test/s could not be conducted must be provided with the authority application [see Note for test requirements].

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. A maximum of 5 repeats may be requested. Where fewer than 5 repeats are requested at the time of

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application, authority approvals for sufficient repeats to complete a maximum of 6 months of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday)

**Authority required**

Initial (change or re-commencement for all patients)

Application for initial treatment with ambrisentan of patients with one of the following:

(a) primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease who wish to re-commence PBS-subsidised ambrisentan after a break in therapy and who have demonstrated a response to their most recent course of PBS-subsidised treatment with ambrisentan; OR

(b) primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease and whose most recent course of PBS-subsidised treatment was with an alternate PAH agent other than ambrisentan.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form [www.medicareaustralia.gov.au] which includes the results on which approval for the first application for PBS-subsidised PAH agent was granted; and

(3) the date of the first application for PBS-subsidised treatment with a PAH agent; and

(4) the results of the patient's response to treatment with their last course of PBS-subsidised PAH agent.

Where fewer than 3 tests (see requirement 2 above) are able to be performed on clinical grounds, a patient specific reason outlining why the particular test/s could not be conducted must be provided with the authority application [see Note for test requirements].

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. A maximum of 5 repeats may be requested. Where fewer than 5 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 6 months of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday)

**Authority required**

Continuing treatment (all patients)

Continuing PBS-subsidised treatment with ambrisentan of patients who have received approval for initial PBS-subsidised treatment with ambrisentan and who have been assessed by a physician from a designated hospital to have achieved a response to their most recent course of ambrisentan treatment [see Note for definition of response].

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form [www.medicareaustralia.gov.au] which includes results from the 3 tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6MWT.

The results of the same tests as conducted at baseline should be provided with each written continuing treatment application (i.e. every 6 months), except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be provided with the application.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. A maximum of 5 repeats will be authorised. Where fewer than 5 repeats are initially requested under this criterion, authority approvals for sufficient repeats to complete a maximum of 6 months of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday)

**Caution**

Ambrisentan is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 3 months following cessation of treatment with this drug.

**Note**

Any queries concerning the arrangements to prescribe ambrisentan may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written applications for authority to prescribe PAH agents should be forwarded to:

Medicare Australia

Prior Written Approval of Specialised Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

**Note**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of agents for primary pulmonary hypertension and pulmonary arterial hypertension. Where the term PAH agents appears in the following notes and restrictions it refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan and tadalafil.

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Brand Name and Manufacturer |
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Patients are eligible for PBS-subsidised treatment with only 1 of the above PAH agents at any 1 time. Eligible patients may only swap between PAH agents if they have not failed prior PBS-subsidised treatment with that agent.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of that predicted.

The following provides some explanatory notes regarding the availability of PBS-subsidised treatment of patients with:

(a) bosentan monohydrate, of primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, or pulmonary arterial hypertension associated with a congential systemic-to-pulmonary shunt (including Eisenmenger's physiology), in patients with disease of WHO Functional Class III or IV severity; AND

(b) iloprost trometamol, of:

— primary pulmonary hypertension, or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class III severity and who have failed to respond to prior PBS-subsidised treatment with an alternate PAH agent; AND

— primary pulmonary hypertension, or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class IV severity; AND

— drug-induced pulmonary arterial hypertension, in patients with disease of WHO Functional Class III and IV severity; AND

(c) epoprostenol sodium, of:

— primary pulmonary hypertension, or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class III severity and who have failed to respond to prior PBS-subsidised treatment with an alternate PAH agent; AND

— primary pulmonary hypertension, or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class IV severity; AND

(d) sildenafil citrate, of primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class III severity; AND

(e) ambrisentan, of primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class III or IV severity; AND

(f) tadalafil, of primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class III severity.

From 1 April 2012, patients can access PAH agents through the PBS according to the relevant restrictions. Once these patients are approved initial treatment with 1 of these 6 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary. (New baselines may be submitted where the patient has failed to respond to their current treatment.)

1. Definition of primary pulmonary hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease, including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology).

Primary pulmonary hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease, including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary capillary wedge pressure (PCWP) less than 18 mmHg; or

(ii) mPAP greater than 30 mmHg with exercise and PCWP less than 18 mmHg; or

(iii) where a right heart catheter cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

2. Definition of WHO Functional Class III or IV disease severity.

(a) WHO Functional Class III disease severity is defined as follows:

Patients with pulmonary hypertension resulting in marked limitation of physical activity who are comfortable at rest and on ordinary physical activity experience dyspnoea or fatigue, chest pain or near syncope.

(b) WHO Functional Class IV disease severity is defined as follows:

Patients with the inability to carry out any physical activity without symptoms. These patients manifest signs of right heart failure. Dyspnoea and/or fatigue may even be present at rest. Discomfort is increased by any physical activity.

3. Designated hospitals.

Refer to the Medicare Australia website at www.medicareaustralia.gov.au for a list of designated hospitals.

4. Test requirements to establish baseline for initiation of treatment and response to treatment for continuation of treatment.

(a) Initiation of treatment.

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment, plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

(1) RHC plus ECHO composite assessments;

(2) RHC composite assessment plus 6MWT;

# HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

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(3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted to Medicare Australia for consideration based on the results of the following test combinations, which are listed in descending order of preference:

(1) ECHO composite assessment plus 6MWT;

(2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test/s could not be conducted must be provided with the authority application.

(b) Continuation of treatment.

The following list outlines the preferred test combination, in descending order, for the purposes of continuation of PBS-subsidised treatment:

(1) RHC plus ECHO composite assessments plus 6MWT;

(2) RHC plus ECHO composite assessments;

(3) RHC composite assessment plus 6MWT;

(4) ECHO composite assessment plus 6MWT;

(5) RHC composite assessment only;

(6) ECHO composite assessment only.

The results of the same tests as conducted at baseline should be provided with each written continuing treatment application (i.e. every 6 months), except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be provided with the application. The test(s) results provided with the application for continuing treatment must be no more than 2 months old at the time of application.

**Note**

5. Definition of response to a PAH agent or prior vasodilator treatment.

For patients with 2 or more baseline tests, response to treatment is defined as 2 or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least 1 of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

6. Authority approval requirements.

(a) Initiation of PBS-subsidised treatment with a PAH agent, where the patient has not received prior PBS-subsidised treatment with that agent.

All applications for initial treatment must be made in writing, must include a completed authority prescription and must be submitted to Medicare Australia for authorisation. The total duration of initial PBS-subsidised treatment that will be approved with this first written application is up to 6 months, based on the dosage recommendations in the TGA-approved Product Information.

Bosentan only:

Approvals for the first authority prescription will be limited to 1 month of therapy with the 62.5 mg strength tablet, with the quantity approved based on the dosage recommendations in the Therapeutic Goods Administration (TGA)-approved Product Information. No repeats will be authorised for this prescription. The second authority prescription may be written for either the 62.5 mg tablet or the 125 mg tablet strengths. Where the 62.5 mg tablet strength is required, please contact Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) for further advice. Approvals for the second authority prescription will be limited to 1 month of treatment, with the quantity approved based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 4 repeats. The approved second authority prescription will be returned to the prescriber by Medicare Australia 2 weeks after the date of the approval of the first authority prescription, to allow for the uninterrupted completion of the 6 month initial treatment course. Medicare Australia will contact prescribers prior to dispatch of the second authority prescription to confirm the tablet strength required for the patient.

(b) Continuation of treatment.

Written applications for continuing treatment for patients who have demonstrated an adequate response to their current treatment must be submitted to Medicare Australia for authorisation every 6 months. Approvals will be limited to provide sufficient supply for up to a maximum of 6 months of treatment, based on the dosage recommendations in the TGA-approved Product Information.

The assessment of the patient's response to the first and subsequent 6 month courses of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated. Applications for continuing treatment with a PAH agent should be made prior to the completion of the 6 month treatment course to ensure continuity for those patients who respond to treatment, as assessed by the treating physician.

(c) Swapping between PAH agents.

For eligible patients, applications to swap between these 6 drugs must be made under the relevant initial treatment restriction. Patients should be assessed for response to the treatment they are ceasing at the time the application to swap therapy is being made. Patients who fail to demonstrate a response or for whom no assessment results are submitted with the application to swap therapy may not re-commence PBS-subsidised treatment with the drug they are ceasing.

It is important that patients are assessed for response to every course of treatment approved within the timeframes specified in the relevant

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restriction, in order to maximise the choice of treatment.

To avoid confusion, applications for patients who wish to swap to an alternate treatment should be accompanied by the previously approved authority prescription, or remaining repeats, for the treatment the patient is ceasing.

(d) Cessation of treatment — bosentan patients only.

Patients who fail to demonstrate a response to PBS-subsidised bosentan monohydrate treatment at the time where an assessment is required must cease PBS-subsidised bosentan monohydrate therapy.

For patients ceasing treatment, approval will only be granted to provide sufficient supply of the 62.5 mg tablet strength to allow gradual dose reduction over a period of no more than 1 month duration. Prescribers should telephone Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) to receive authorisation for this final supply and to ensure no unintended break in treatment occurs.

7. Re-treatment with a PAH agent.

Patients who do not respond to treatment are not eligible to receive further PBS-subsidised treatment with that agent under any circumstances.

8. Further information.

A tabulated representation of the above information and the restriction can be obtained from the Medicare Australia website at www.medicareaustralia.gov.au.

**Note**

Special Pricing Arrangements apply.

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| 9649W | ambrisentan 10 mg tablet, 30 | 1 | .. | .. | 2923.10 | Volibris | GK |
| 9648T | ambrisentan 5 mg tablet, 30 | 1 | .. | .. | 2923.10 | Volibris | GK |

**BOSENTAN**

**Authority required**

Initial (new patients)

Application for initial PBS-subsidised treatment with bosentan monohydrate of patients who have not received prior PBS-subsidised treatment with a PAH agent and who have been assessed by a physician from a designated hospital to have:

(a) WHO Functional Class III primary pulmonary hypertension and a mean right atrial pressure of 8 mmHg or less, as measured by RHC, or, where a RHC cannot be performed on clinical grounds, right ventricular function as assessed by ECHO; OR

(b) WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease and a mean right atrial pressure of 8 mmHg or less, as measured by RHC, or, where a RHC cannot be performed on clinical grounds, right ventricular function as assessed by ECHO.

Patients must have failed to respond [see Note for definition of response] to 6 or more weeks of appropriate vasodilator treatment unless intolerance or a contraindication to such treatment exists.

Applications for authorisation must be in writing and must include:

(1) two completed authority prescription forms [see Note for authority approval requirements]; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form [www.medicareaustralia.gov.au] which includes results from the 3 tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6MWT; and

(3) a signed patient acknowledgment form.

Details of prior vasodilator treatment, including the dose and duration of treatment, must be provided at the time of application. Where the patient has an adverse event to a vasodilator or where vasodilator treatment is contraindicated, details on the nature of the adverse event or contraindication according to the TGA-approved Product Information must also be provided with the application.

Where fewer than 3 tests (see requirement 2 above) are able to be performed on clinical grounds, a patient specific reason outlining why the particular test/s could not be conducted must be provided with the authority application [see Note for test requirements].

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. No repeats will be authorised for the first authority prescription issued under this criterion [see Note for full details of authority approval requirements]. A maximum of 4 repeats will be authorised for the second authority prescription issued under this criterion. Where fewer than 4 repeats are initially requested with the second authority prescription, authority approvals for sufficient repeats to complete a maximum of 6 months of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday)

**Authority required**

Initial (new patients)

Application for initial PBS-subsidised treatment with bosentan monohydrate of patients who have not received prior PBS-subsidised treatment with a PAH agent and who have been assessed by a physician from a designated hospital to have:

(a) WHO Functional Class III primary pulmonary hypertension and a mean right atrial pressure greater than 8 mmHg, as measured by RHC, or, where a RHC cannot be performed on clinical grounds, right ventricular function as assessed by ECHO; OR

(b) WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease and a mean right atrial pressure greater than 8 mmHg, as measured by RHC, or, where a RHC cannot be performed on clinical grounds, right ventricular function as assessed by ECHO; OR

(c) WHO Functional Class IV primary pulmonary hypertension; OR

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(d) WHO Functional Class IV pulmonary arterial hypertension secondary to connective tissue disease; OR

(e) WHO Functional Class III or IV pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology).

Applications for authorisation must be in writing and must include:

(1) two completed authority prescription forms [see Note for authority approval requirements]; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form [www.medicareaustralia.gov.au] which includes results from the 3 tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6MWT; and

(3) a signed patient acknowledgment form.

Where fewer than 3 tests (see requirement 2 above) are able to be performed on clinical grounds, a patient specific reason outlining why the particular test/s could not be conducted must be provided with the authority application [see Note for test requirements].

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. No repeats will be authorised for the first authority prescription issued under this criterion [see Note for full details of authority approval requirements]. A maximum of 4 repeats will be authorised for the second authority prescription issued under this criterion. Where fewer than 4 repeats are initially requested with the second authority prescription, authority approvals for sufficient repeats to complete a maximum of 6 months of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday)

**Authority required**

Initial (change or re-commencement for all patients)

Application for initial treatment with bosentan monohydrate of patients with one of the following:

(a) primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology), who wish to re-commence PBS-subsidised bosentan monohydrate after a break in therapy and who have demonstrated a response to their most recent course of PBS-subsidised treatment with bosentan monohydrate; OR

(b) primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease and whose most recent course of PBS-subsidised treatment was with an alternate PAH agent other than bosentan monohydrate.

Applications for authorisation must be in writing and must include:

(1) two completed authority prescription forms [see Note for authority approval requirements]; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form [www.medicareaustralia.gov.au] which includes the results on which approval for the first application for PBS-subsidised PAH agent was granted; and

(3) the date of the first application for PBS-subsidised treatment with a PAH agent; and

(4) the results of the patient's response to treatment with their last course of PBS-subsidised PAH agent.

Where fewer than 3 tests (see requirement 2 above) are able to be performed on clinical grounds, a patient specific reason outlining why the particular test/s could not be conducted must be provided with the authority application [see Note for test requirements].

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. No repeats will be authorised for the first authority prescription issued under this criterion [see Note for full details of authority approval requirements]. A maximum of 4 repeats will be authorised for the second authority prescription issued under this criterion. Where fewer than 4 repeats are initially requested with the second authority prescription, authority approvals for sufficient repeats to complete a maximum of 6 months of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday)

**Authority required**

Continuing treatment (all patients)

Continuing PBS-subsidised treatment with bosentan monohydrate of patients who have received approval for initial PBS-subsidised treatment with bosentan monohydrate and who have been assessed by a physician from a designated hospital to have achieved a response to their most recent course of bosentan monohydrate treatment [see Note for definition of response].

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form [www.medicareaustralia.gov.au] which includes results from the 3 tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6MWT.

The results of the same tests as conducted at baseline should be provided with each written continuing treatment application (i.e. every 6 months), except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be provided with the application.

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The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. A maximum of 5 repeats will be authorised.

Where fewer than 5 repeats are initially requested under this criterion, authority approvals for sufficient repeats to complete a maximum of 6 months of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday)

**Authority required**

Cessation of treatment (all patients)

Final PBS-subsidised supply for patients with WHO Functional Class III or IV primary pulmonary hypertension or WHO Functional Class III or IV pulmonary arterial hypertension secondary to connective tissue disease or WHO Functional Class III or IV pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology), who have not responded to bosentan monohydrate therapy [see Note for definition of response], to allow for gradual cessation of treatment.

Applications for authorisation under this criterion should be made on the telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) [see Note on authority approval requirements].

Approval will only be granted for the 62.5 mg tablet strength. The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment.

Under no circumstances will telephone approvals be granted for treatment that would extend the final treatment period beyond 1 month

**Caution**

Bosentan monohydrate is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 3 months following cessation of treatment with this drug.

**Note**

Any queries concerning the arrangements to prescribe bosentan monohydrate may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written applications for authority to prescribe PAH agents should be forwarded to:

Medicare Australia

Prior Written Approval of Specialised Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

**Note**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of agents for primary pulmonary hypertension and pulmonary arterial hypertension. Where the term PAH agents appears in the following notes and restrictions it refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan and tadalafil.

Patients are eligible for PBS-subsidised treatment with only 1 of the above PAH agents at any 1 time. Eligible patients may only swap between PAH agents if they have not failed prior PBS-subsidised treatment with that agent.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of that predicted.

The following provides some explanatory notes regarding the availability of PBS-subsidised treatment of patients with:

(a) bosentan monohydrate, of primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, or pulmonary arterial hypertension associated with a congential systemic-to-pulmonary shunt (including Eisenmenger's physiology), in patients with disease of WHO Functional Class III or IV severity; AND

(b) iloprost trometamol, of:

— primary pulmonary hypertension, or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class III severity and who have failed to respond to prior PBS-subsidised treatment with an alternate PAH agent; AND

— primary pulmonary hypertension, or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class IV severity; AND

— drug-induced pulmonary arterial hypertension, in patients with disease of WHO Functional Class III and IV severity; AND

(c) epoprostenol sodium, of:

— primary pulmonary hypertension, or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class III severity and who have failed to respond to prior PBS-subsidised treatment with an alternate PAH agent; AND

— primary pulmonary hypertension, or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class IV severity; AND

(d) sildenafil citrate, of primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class III severity; AND

(e) ambrisentan, of primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class III or IV severity; AND

(f) tadalafil, of primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class III severity.

From 1 April 2012, patients can access PAH agents through the PBS according to the relevant restrictions. Once these patients are approved initial treatment with 1 of these 6 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate

# HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

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agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary. (New baselines may be submitted where the patient has failed to respond to their current treatment.)

1. Definition of primary pulmonary hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease, including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology).

Primary pulmonary hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease, including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary capillary wedge pressure (PCWP) less than 18 mmHg; or

(ii) mPAP greater than 30 mmHg with exercise and PCWP less than 18 mmHg; or

(iii) where a right heart catheter cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

2. Definition of WHO Functional Class III or IV disease severity.

(a) WHO Functional Class III disease severity is defined as follows:

Patients with pulmonary hypertension resulting in marked limitation of physical activity who are comfortable at rest and on ordinary physical activity experience dyspnoea or fatigue, chest pain or near syncope.

(b) WHO Functional Class IV disease severity is defined as follows:

Patients with the inability to carry out any physical activity without symptoms. These patients manifest signs of right heart failure. Dyspnoea and/or fatigue may even be present at rest. Discomfort is increased by any physical activity.

3. Designated hospitals.

Refer to the Medicare Australia website at www.medicareaustralia.gov.au for a list of designated hospitals.

4. Test requirements to establish baseline for initiation of treatment and response to treatment for continuation of treatment.

(a) Initiation of treatment.

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment, plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

(1) RHC plus ECHO composite assessments;

(2) RHC composite assessment plus 6MWT;

(3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted to Medicare Australia for consideration based on the results of the following test combinations, which are listed in descending order of preference:

(1) ECHO composite assessment plus 6MWT;

(2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test/s could not be conducted must be provided with the authority application.

(b) Continuation of treatment.

The following list outlines the preferred test combination, in descending order, for the purposes of continuation of PBS-subsidised treatment:

(1) RHC plus ECHO composite assessments plus 6MWT;

(2) RHC plus ECHO composite assessments;

(3) RHC composite assessment plus 6MWT;

(4) ECHO composite assessment plus 6MWT;

(5) RHC composite assessment only;

(6) ECHO composite assessment only.

The results of the same tests as conducted at baseline should be provided with each written continuing treatment application (i.e. every 6 months), except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be provided with the application. The test(s) results provided with the application for continuing treatment must be no more than 2 months old at the time of application.

**Note**

5. Definition of response to a PAH agent or prior vasodilator treatment.

For patients with 2 or more baseline tests, response to treatment is defined as 2 or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or

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improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least 1 of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

6. Authority approval requirements.

(a) Initiation of PBS-subsidised treatment with a PAH agent, where the patient has not received prior PBS-subsidised treatment with that agent.

All applications for initial treatment must be made in writing, must include a completed authority prescription and must be submitted to Medicare Australia for authorisation. The total duration of initial PBS-subsidised treatment that will be approved with this first written application is up to 6 months, based on the dosage recommendations in the TGA-approved Product Information.

Bosentan only:

Approvals for the first authority prescription will be limited to 1 month of therapy with the 62.5 mg strength tablet, with the quantity approved based on the dosage recommendations in the Therapeutic Goods Administration (TGA)-approved Product Information. No repeats will be authorised for this prescription. The second authority prescription may be written for either the 62.5 mg tablet or the 125 mg tablet strengths. Where the 62.5 mg tablet strength is required, please contact Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) for further advice. Approvals for the second authority prescription will be limited to 1 month of treatment, with the quantity approved based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 4 repeats. The approved second authority prescription will be returned to the prescriber by Medicare Australia 2 weeks after the date of the approval of the first authority prescription, to allow for the uninterrupted completion of the 6 month initial treatment course. Medicare Australia will contact prescribers prior to dispatch of the second authority prescription to confirm the tablet strength required for the patient.

(b) Continuation of treatment.

Written applications for continuing treatment for patients who have demonstrated an adequate response to their current treatment must be submitted to Medicare Australia for authorisation every 6 months. Approvals will be limited to provide sufficient supply for up to a maximum of 6 months of treatment, based on the dosage recommendations in the TGA-approved Product Information.

The assessment of the patient's response to the first and subsequent 6 month courses of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated. Applications for continuing treatment with a PAH agent should be made prior to the completion of the 6 month treatment course to ensure continuity for those patients who respond to treatment, as assessed by the treating physician.

(c) Swapping between PAH agents.

For eligible patients, applications to swap between these 6 drugs must be made under the relevant initial treatment restriction. Patients should be assessed for response to the treatment they are ceasing at the time the application to swap therapy is being made. Patients who fail to demonstrate a response or for whom no assessment results are submitted with the application to swap therapy may not re-commence PBS-subsidised treatment with the drug they are ceasing.

It is important that patients are assessed for response to every course of treatment approved within the timeframes specified in the relevant restriction, in order to maximise the choice of treatment.

To avoid confusion, applications for patients who wish to swap to an alternate treatment should be accompanied by the previously approved authority prescription, or remaining repeats, for the treatment the patient is ceasing.

(d) Cessation of treatment — bosentan patients only.

Patients who fail to demonstrate a response to PBS-subsidised bosentan monohydrate treatment at the time where an assessment is required must cease PBS-subsidised bosentan monohydrate therapy.

For patients ceasing treatment, approval will only be granted to provide sufficient supply of the 62.5 mg tablet strength to allow gradual dose reduction over a period of no more than 1 month duration. Prescribers should telephone Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) to receive authorisation for this final supply and to ensure no unintended break in treatment occurs.

7. Re-treatment with a PAH agent.

Patients who do not respond to treatment are not eligible to receive further PBS-subsidised treatment with that agent under any circumstances.

8. Further information.

A tabulated representation of the above information and the restriction can be obtained from the Medicare Australia website at www.medicareaustralia.gov.au.

**Note**

Special Pricing Arrangements apply.

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| 6430K | bosentan 125 mg tablet, 60 | 1 | .. | .. | 2923.10 | Tracleer | AT |
| 6429J | bosentan 62.5 mg tablet, 60 | 1 | .. | .. | 2923.10 | Tracleer | AT |

**EPOPROSTENOL**

**Authority required**

Initial (new patients)

Application for initial PBS-subsidised treatment with epoprostenol sodium of patients who have not received prior PBS-subsidised treatment with a PAH agent and who have been assessed by a physician from a designated hospital to have:

(a) WHO Functional Class IV primary pulmonary hypertension; OR

(b) WHO Functional Class IV pulmonary arterial hypertension secondary to connective tissue disease.

# HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

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Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form [www.medicareaustralia.gov.au] which includes results from the 3 tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6MWT; and

(3) a signed patient acknowledgment form.

Where fewer than 3 tests (see requirement 2 above) are able to be performed on clinical grounds, a patient specific reason outlining why the particular test/s could not be conducted must be provided with the authority application [see Note for test requirements].

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. A maximum of 5 repeats may be requested. Where fewer than 5 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 6 months of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday)

**Authority required**

Initial (change or re-commencement for all patients)

Application for initial PBS-subsidised treatment with epoprostenol sodium of patients with one of the following:

(a) primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease who wish to re-commence PBS-subsidised epoprostenol sodium after a break in therapy and who have demonstrated a response to their most recent course of PBS-subsidised treatment with epoprostenol sodium; OR

(b) WHO Functional Class IV primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease and who have received prior treatment with a PBS-subsidised PAH agent other than epoprostenol sodium; OR

(c) WHO Functional Class III primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease and who have failed to respond to a prior PBS-subsidised PAH agent.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form [www.medicareaustralia.gov.au] which includes the results on which approval for the first application for PBS-subsidised PAH agent was granted; and

(3) the date of the first application for PBS-subsidised treatment with a PAH agent; and

(4) the results of the patient's response to treatment with their last course of PBS-subsidised PAH agent; and

(5) for WHO Functional Class III patients, where this is the first application for epoprostenol sodium, assessment details of the PBS-subsidised PAH agent they have failed to respond to.

Where fewer than 3 tests (see requirement 2 above) are able to be performed on clinical grounds, a patient specific reason outlining why the particular test/s could not be conducted must be provided with the authority application [see Note for test requirements].

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. A maximum of 5 repeats may be requested. Where fewer than 5 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 6 months of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday)

**Authority required**

Continuing treatment (all patients)

Continuing PBS-subsidised treatment with epoprostenol sodium of patients who have received approval for initial PBS-subsidised treatment with epoprostenol sodium, and who have been assessed by a physician from a designated hospital to have achieved a response to their most recent course of epoprostenol sodium treatment [see Note for definition of response].

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form [www.medicareaustralia.gov.au] which includes results from the 3 tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6MWT.

The results of the same tests as conducted at baseline should be provided with each written continuing treatment application (i.e. every 6 months), except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be provided with the application.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. A maximum of 5 repeats may be requested. Where fewer than 5 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 6 months of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday)

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**Note**

Any queries concerning the arrangements to prescribe epoprostenol sodium may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written applications for authority to prescribe PAH agents should be forwarded to:

Medicare Australia

Prior Written Approval of Specialised Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

**Note**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of agents for primary pulmonary hypertension and pulmonary arterial hypertension. Where the term PAH agents appears in the following notes and restrictions it refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan and tadalafil.

Patients are eligible for PBS-subsidised treatment with only 1 of the above PAH agents at any 1 time. Eligible patients may only swap between PAH agents if they have not failed prior PBS-subsidised treatment with that agent.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of that predicted.

The following provides some explanatory notes regarding the availability of PBS-subsidised treatment of patients with:

(a) bosentan monohydrate, of primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, or pulmonary arterial hypertension associated with a congential systemic-to-pulmonary shunt (including Eisenmenger's physiology), in patients with disease of WHO Functional Class III or IV severity; AND

(b) iloprost trometamol, of:

— primary pulmonary hypertension, or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class III severity and who have failed to respond to prior PBS-subsidised treatment with an alternate PAH agent; AND

— primary pulmonary hypertension, or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class IV severity; AND

— drug-induced pulmonary arterial hypertension, in patients with disease of WHO Functional Class III and IV severity; AND

(c) epoprostenol sodium, of:

— primary pulmonary hypertension, or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class III severity and who have failed to respond to prior PBS-subsidised treatment with an alternate PAH agent; AND

— primary pulmonary hypertension, or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class IV severity; AND

(d) sildenafil citrate, of primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class III severity; AND

(e) ambrisentan, of primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class III or IV severity; AND

(f) tadalafil, of primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class III severity.

From 1 April 2012, patients can access PAH agents through the PBS according to the relevant restrictions. Once these patients are approved initial treatment with 1 of these 6 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary. (New baselines may be submitted where the patient has failed to respond to their current treatment.)

1. Definition of primary pulmonary hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease, including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology).

Primary pulmonary hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease, including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary capillary wedge pressure (PCWP) less than 18 mmHg; or

(ii) mPAP greater than 30 mmHg with exercise and PCWP less than 18 mmHg; or

(iii) where a right heart catheter cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

2. Definition of WHO Functional Class III or IV disease severity.

(a) WHO Functional Class III disease severity is defined as follows:

Patients with pulmonary hypertension resulting in marked limitation of physical activity who are comfortable at rest and on ordinary physical activity experience dyspnoea or fatigue, chest pain or near syncope.

(b) WHO Functional Class IV disease severity is defined as follows:

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Patients with the inability to carry out any physical activity without symptoms. These patients manifest signs of right heart failure. Dyspnoea and/or fatigue may even be present at rest. Discomfort is increased by any physical activity.

3. Designated hospitals.

Refer to the Medicare Australia website at www.medicareaustralia.gov.au for a list of designated hospitals.

4. Test requirements to establish baseline for initiation of treatment and response to treatment for continuation of treatment.

(a) Initiation of treatment.

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment, plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

(1) RHC plus ECHO composite assessments;

(2) RHC composite assessment plus 6MWT;

(3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted to Medicare Australia for consideration based on the results of the following test combinations, which are listed in descending order of preference:

(1) ECHO composite assessment plus 6MWT;

(2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test/s could not be conducted must be provided with the authority application.

(b) Continuation of treatment.

The following list outlines the preferred test combination, in descending order, for the purposes of continuation of PBS-subsidised treatment:

(1) RHC plus ECHO composite assessments plus 6MWT;

(2) RHC plus ECHO composite assessments;

(3) RHC composite assessment plus 6MWT;

(4) ECHO composite assessment plus 6MWT;

(5) RHC composite assessment only;

(6) ECHO composite assessment only.

The results of the same tests as conducted at baseline should be provided with each written continuing treatment application (i.e. every 6 months), except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be provided with the application. The test(s) results provided with the application for continuing treatment must be no more than 2 months old at the time of application.

**Note**

5. Definition of response to a PAH agent or prior vasodilator treatment.

For patients with 2 or more baseline tests, response to treatment is defined as 2 or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least 1 of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

6. Authority approval requirements.

(a) Initiation of PBS-subsidised treatment with a PAH agent, where the patient has not received prior PBS-subsidised treatment with that agent.

All applications for initial treatment must be made in writing, must include a completed authority prescription and must be submitted to Medicare Australia for authorisation. The total duration of initial PBS-subsidised treatment that will be approved with this first written application is up to 6 months, based on the dosage recommendations in the TGA-approved Product Information.

Bosentan only:

Approvals for the first authority prescription will be limited to 1 month of therapy with the 62.5 mg strength tablet, with the quantity approved based on the dosage recommendations in the Therapeutic Goods Administration (TGA)-approved Product Information. No repeats will be authorised for this prescription. The second authority prescription may be written for either the 62.5 mg tablet or the 125 mg tablet strengths. Where the 62.5 mg tablet strength is required, please contact Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) for further advice. Approvals for the second authority prescription will be limited to 1 month of treatment, with the quantity approved based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 4 repeats. The approved second authority prescription will be returned to the prescriber by Medicare Australia 2 weeks after the date of the approval of the first authority prescription, to allow for the uninterrupted completion of the 6 month initial treatment course. Medicare Australia will contact prescribers prior to dispatch of the second authority prescription to confirm the tablet strength required for the patient.

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| | (b) Continuation of treatment. | | | | | | |
| | Written applications for continuing treatment for patients who have demonstrated an adequate response to their current treatment must be submitted to Medicare Australia for authorisation every 6 months. Approvals will be limited to provide sufficient supply for up to a maximum of 6 months of treatment, based on the dosage recommendations in the TGA-approved Product Information. | | | | | | |
| | The assessment of the patient's response to the first and subsequent 6 month courses of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated. Applications for continuing treatment with a PAH agent should be made prior to the completion of the 6 month treatment course to ensure continuity for those patients who respond to treatment, as assessed by the treating physician. | | | | | | |
| | (c) Swapping between PAH agents. | | | | | | |
| | For eligible patients, applications to swap between these 6 drugs must be made under the relevant initial treatment restriction. Patients should be assessed for response to the treatment they are ceasing at the time the application to swap therapy is being made. Patients who fail to demonstrate a response or for whom no assessment results are submitted with the application to swap therapy may not re-commence PBS-subsidised treatment with the drug they are ceasing. | | | | | | |
| | It is important that patients are assessed for response to every course of treatment approved within the timeframes specified in the relevant restriction, in order to maximise the choice of treatment. | | | | | | |
| | To avoid confusion, applications for patients who wish to swap to an alternate treatment should be accompanied by the previously approved authority prescription, or remaining repeats, for the treatment the patient is ceasing. | | | | | | |
| | (d) Cessation of treatment — bosentan patients only. | | | | | | |
| | Patients who fail to demonstrate a response to PBS-subsidised bosentan monohydrate treatment at the time where an assessment is required must cease PBS-subsidised bosentan monohydrate therapy. | | | | | | |
| | For patients ceasing treatment, approval will only be granted to provide sufficient supply of the 62.5 mg tablet strength to allow gradual dose reduction over a period of no more than 1 month duration. Prescribers should telephone Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) to receive authorisation for this final supply and to ensure no unintended break in treatment occurs. | | | | | | |
| | 7. Re-treatment with a PAH agent. | | | | | | |
| | Patients who do not respond to treatment are not eligible to receive further PBS-subsidised treatment with that agent under any circumstances. | | | | | | |
| | 8. Further information. | | | | | | |
| | A tabulated representation of the above information and the restriction can be obtained from the Medicare Australia website at www.medicareaustralia.gov.au. | | | | | | |
| 5042J | EPOPROSTENOL SODIUM Powder for I.V. infusion 1.5 mg (base) infusion administration set, 1 | 1 | .. | .. | 89.86 | Flolan Kit | GK |
| 5036C | EPOPROSTENOL SODIUM Powder for I.V. infusion 500 micrograms (base) infusion administration set, 1 | 1 | .. | .. | 50.21 | Flolan Kit | GK |
| | **ILOPROST** | | | | | | |
| | **Authority required** | | | | | | |
| | Initial (new patients) | | | | | | |
| | Application for initial PBS-subsidised treatment with iloprost trometamol of patients who have not received prior PBS-subsidised treatment with iloprost and who have been assessed by a physician from a designated hospital to have: | | | | | | |
| | WHO Functional Class III drug-induced pulmonary arterial hypertension and a mean right atrial pressure of 8 mmHg or less, as measured by RHC, or, where a RHC cannot be performed on clinical grounds, right ventricular function as assessed by ECHO. | | | | | | |
| | Patients must have failed to respond [see Note for definition of response] to 6 or more weeks of appropriate vasodilator treatment unless intolerance or a contraindication to such treatment exists. | | | | | | |
| | Applications for authorisation must be in writing and must include: | | | | | | |
| | (1) a completed authority prescription form; and | | | | | | |
| | (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form [www.medicareaustralia.gov.au] which includes results from the 3 tests below, where available: | | | | | | |
| | (i) RHC composite assessment; and | | | | | | |
| | (ii) ECHO composite assessment; and | | | | | | |
| | (iii) 6MWT; and | | | | | | |
| | (3) a signed patient acknowledgment form. | | | | | | |
| | Details of prior vasodilator treatment, including the dose and duration of treatment, must be provided at the time of application. Where the patient has an adverse event to a vasodilator or where vasodilator treatment is contraindicated, details on the nature of the adverse event or contraindication according to the TGA-approved Product Information must also be provided with the application. | | | | | | |
| | Where fewer than 3 tests (see requirement 2 above) are able to be performed on clinical grounds, a patient specific reason outlining why the particular test/s could not be conducted must be provided with the authority application [see Note for test requirements]. | | | | | | |
| | The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. A maximum of 5 repeats may be requested. Where fewer than 5 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 6 months of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) | | | | | | |
| | **Authority required** | | | | | | |

# HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|

Initial (new patients)

Application for initial PBS-subsidised treatment with iloprost trometamol of patients who have not received prior PBS-subsidised treatment with a PAH agent and who have been assessed by a physician from a designated hospital to have:

(a) WHO Functional Class III drug-induced pulmonary arterial hypertension and a mean right atrial pressure greater than 8 mmHg, as measured by RHC, or, where a RHC cannot be performed on clinical grounds, right ventricular function as assessed by ECHO; OR

(b) WHO Functional Class IV primary pulmonary hypertension; OR

(c) WHO Functional Class IV pulmonary arterial hypertension secondary to connective tissue disease; OR

(d) WHO Functional Class IV drug-induced pulmonary arterial hypertension.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form [www.medicareaustralia.gov.au] which includes results from the 3 tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6MWT; and

(3) a signed patient acknowledgment form.

Where fewer than 3 tests (see requirement 2 above) are able to be performed on clinical grounds, a patient specific reason outlining why the particular test/s could not be conducted must be provided with the authority application [see Note for test requirements].

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. A maximum of 5 repeats may be requested. Where fewer than 5 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 6 months of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday)

**Authority required**

Initial (change or re-commencement for all patients)

Application for initial PBS-subsidised treatment with iloprost trometamol of patients with one of the following:

(a) primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease who wish to re-commence PBS-subsidised iloprost trometamol after a break in therapy and who have demonstrated a response to their most recent course of PBS-subsidised treatment with iloprost trometamol; OR

(b) WHO Functional Class IV primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease and who have received prior treatment with a PBS-subsidised PAH agent other than iloprost trometamol; OR

(c) WHO Functional Class III primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease and who have failed to respond to a prior PBS-subsidised PAH agent.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form [www.medicareaustralia.gov.au] which includes the results on which approval for the first application for PBS-subsidised PAH agent was granted; and

(3) the date of the first application for PBS-subsidised treatment with a PAH agent; and

(4) the results of the patient's response to treatment with their last course of PBS-subsidised PAH agent; and

(5) for WHO Functional Class III patients, where this is the first application for iloprost trometamol, assessment details of the PBS-subsidised PAH agent they have failed to respond to.

Where fewer than 3 tests (see requirement 2 above) are able to be performed on clinical grounds, a patient specific reason outlining why the particular test/s could not be conducted must be provided with the authority application [see Note for test requirements].

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. A maximum of 5 repeats may be requested. Where fewer than 5 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 6 months of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday)

**Authority required**

Continuing treatment (all patients)

Continuing PBS-subsidised treatment with iloprost trometamol of patients who have received approval for initial PBS-subsidised treatment with iloprost trometamol, and who have been assessed by a physician from a designated hospital to have achieved a response to their most recent course of iloprost trometamol treatment [see Note for definition of response].

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form [www.medicareaustralia.gov.au] which includes results from the 3 tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

# HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Brand Name and Manufacturer |
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(iii) 6MWT.

The results of the same tests as conducted at baseline should be provided with each written continuing treatment application (i.e. every 6 months), except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be provided with the application.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. A maximum of 5 repeats may be requested. Where fewer than 5 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 6 months of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday)

**Note**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of agents for primary pulmonary hypertension and pulmonary arterial hypertension. Where the term PAH agents appears in the following notes and restrictions it refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan and tadalafil.

Patients are eligible for PBS-subsidised treatment with only 1 of the above PAH agents at any 1 time. Eligible patients may only swap between PAH agents if they have not failed prior PBS-subsidised treatment with that agent.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of that predicted.

The following provides some explanatory notes regarding the availability of PBS-subsidised treatment of patients with:

(a) bosentan monohydrate, of primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, or pulmonary arterial hypertension associated with a congential systemic-to-pulmonary shunt (including Eisenmenger's physiology), in patients with disease of WHO Functional Class III or IV severity; AND

(b) iloprost trometamol, of:

— primary pulmonary hypertension, or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class III severity and who have failed to respond to prior PBS-subsidised treatment with an alternate PAH agent; AND

— primary pulmonary hypertension, or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class IV severity; AND

— drug-induced pulmonary arterial hypertension, in patients with disease of WHO Functional Class III and IV severity; AND

(c) epoprostenol sodium, of:

— primary pulmonary hypertension, or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class III severity and who have failed to respond to prior PBS-subsidised treatment with an alternate PAH agent; AND

— primary pulmonary hypertension, or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class IV severity; AND

(d) sildenafil citrate, of primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class III severity; AND

(e) ambrisentan, of primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class III or IV severity; AND

(f) tadalafil, of primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class III severity.

From 1 April 2012, patients can access PAH agents through the PBS according to the relevant restrictions. Once these patients are approved initial treatment with 1 of these 6 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary. (New baselines may be submitted where the patient has failed to respond to their current treatment.)

1. Definition of primary pulmonary hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease, including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology).

Primary pulmonary hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease, including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary capillary wedge pressure (PCWP) less than 18 mmHg; or

(ii) mPAP greater than 30 mmHg with exercise and PCWP less than 18 mmHg; or

(iii) where a right heart catheter cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

2. Definition of WHO Functional Class III or IV disease severity.

(a) WHO Functional Class III disease severity is defined as follows:

Patients with pulmonary hypertension resulting in marked limitation of physical activity who are comfortable at rest and on ordinary physical activity experience dyspnoea or fatigue, chest pain or near syncope.

(b) WHO Functional Class IV disease severity is defined as follows:

Patients with the inability to carry out any physical activity without symptoms. These patients manifest signs of right heart failure. Dyspnoea

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and/or fatigue may even be present at rest. Discomfort is increased by any physical activity.

3. Designated hospitals.

Refer to the Medicare Australia website at www.medicareaustralia.gov.au for a list of designated hospitals.

4. Test requirements to establish baseline for initiation of treatment and response to treatment for continuation of treatment.

(a) Initiation of treatment.

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment, plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

(1) RHC plus ECHO composite assessments;

(2) RHC composite assessment plus 6MWT;

(3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted to Medicare Australia for consideration based on the results of the following test combinations, which are listed in descending order of preference:

(1) ECHO composite assessment plus 6MWT;

(2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test/s could not be conducted must be provided with the authority application.

(b) Continuation of treatment.

The following list outlines the preferred test combination, in descending order, for the purposes of continuation of PBS-subsidised treatment:

(1) RHC plus ECHO composite assessments plus 6MWT;

(2) RHC plus ECHO composite assessments;

(3) RHC composite assessment plus 6MWT;

(4) ECHO composite assessment plus 6MWT;

(5) RHC composite assessment only;

(6) ECHO composite assessment only.

The results of the same tests as conducted at baseline should be provided with each written continuing treatment application (i.e. every 6 months), except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be provided with the application. The test(s) results provided with the application for continuing treatment must be no more than 2 months old at the time of application.

**Note**

5. Definition of response to a PAH agent or prior vasodilator treatment.

For patients with 2 or more baseline tests, response to treatment is defined as 2 or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least 1 of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

6. Authority approval requirements.

(a) Initiation of PBS-subsidised treatment with a PAH agent, where the patient has not received prior PBS-subsidised treatment with that agent.

All applications for initial treatment must be made in writing, must include a completed authority prescription and must be submitted to Medicare Australia for authorisation. The total duration of initial PBS-subsidised treatment that will be approved with this first written application is up to 6 months, based on the dosage recommendations in the TGA-approved Product Information.

Bosentan only:

Approvals for the first authority prescription will be limited to 1 month of therapy with the 62.5 mg strength tablet, with the quantity approved based on the dosage recommendations in the Therapeutic Goods Administration (TGA)-approved Product Information. No repeats will be authorised for this prescription. The second authority prescription may be written for either the 62.5 mg tablet or the 125 mg tablet strengths. Where the 62.5 mg tablet strength is required, please contact Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) for further advice. Approvals for the second authority prescription will be limited to 1 month of treatment, with the quantity approved based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 4 repeats. The approved second authority prescription will be returned to the prescriber by Medicare Australia 2 weeks after the date of the approval of the first authority prescription, to allow for the uninterrupted completion of the 6 month initial treatment course. Medicare Australia will contact prescribers prior to dispatch of the second authority prescription to confirm the tablet strength required for the patient.

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Brand Name and Manufacturer | |
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(b) Continuation of treatment.

Written applications for continuing treatment for patients who have demonstrated an adequate response to their current treatment must be submitted to Medicare Australia for authorisation every 6 months. Approvals will be limited to provide sufficient supply for up to a maximum of 6 months of treatment, based on the dosage recommendations in the TGA-approved Product Information.

The assessment of the patient's response to the first and subsequent 6 month courses of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated. Applications for continuing treatment with a PAH agent should be made prior to the completion of the 6 month treatment course to ensure continuity for those patients who respond to treatment, as assessed by the treating physician.

(c) Swapping between PAH agents.

For eligible patients, applications to swap between these 6 drugs must be made under the relevant initial treatment restriction. Patients should be assessed for response to the treatment they are ceasing at the time the application to swap therapy is being made. Patients who fail to demonstrate a response or for whom no assessment results are submitted with the application to swap therapy may not re-commence PBS-subsidised treatment with the drug they are ceasing.

It is important that patients are assessed for response to every course of treatment approved within the timeframes specified in the relevant restriction, in order to maximise the choice of treatment.

To avoid confusion, applications for patients who wish to swap to an alternate treatment should be accompanied by the previously approved authority prescription, or remaining repeats, for the treatment the patient is ceasing.

(d) Cessation of treatment — bosentan patients only.

Patients who fail to demonstrate a response to PBS-subsidised bosentan monohydrate treatment at the time where an assessment is required must cease PBS-subsidised bosentan monohydrate therapy.

For patients ceasing treatment, approval will only be granted to provide sufficient supply of the 62.5 mg tablet strength to allow gradual dose reduction over a period of no more than 1 month duration. Prescribers should telephone Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) to receive authorisation for this final supply and to ensure no unintended break in treatment occurs.

7. Re-treatment with a PAH agent.

Patients who do not respond to treatment are not eligible to receive further PBS-subsidised treatment with that agent under any circumstances.

8. Further information.

A tabulated representation of the above information and the restriction can be obtained from the Medicare Australia website at www.medicareaustralia.gov.au.

**Note**

Any queries concerning the arrangements to prescribe iloprost trometamol may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written applications for authority to prescribe PAH agents should be forwarded to:

Medicare Australia

Prior Written Approval of Specialised Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

**Note**

Special Pricing Arrangements apply.

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| 6456T | iloprost 20 microgram/2 mL inhalation: solution, 30 x 2 mL ampoules | 1 | .. | .. | 1122.63 | Ventavis | BN |

**SILDENAFIL**

**Authority required**

Initial (new patients)

Application for initial PBS-subsidised treatment with sildenafil citrate of patients who have not received prior PBS-subsidised treatment with a PAH agent and who have been assessed by a physician from a designated hospital to have:

(a) WHO Functional Class III primary pulmonary hypertension and a mean right atrial pressure of 8 mmHg or less, as measured by RHC, or, where a RHC cannot be performed on clinical grounds, right ventricular function as assessed by ECHO; OR

(b) WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease and a mean right atrial pressure of 8 mmHg or less, as measured by RHC, or, where a RHC cannot be performed on clinical grounds, right ventricular function as assessed by ECHO.

Patients must have failed to respond [see Note for definition of response] to 6 or more weeks of appropriate vasodilator treatment unless intolerance or a contraindication to such treatment exists.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form [www.medicareaustralia.gov.au] which includes results from the 3 tests below, where available:

(i) RHC composite assessment; and

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(ii) ECHO composite assessment; and

(iii) 6MWT; and

(3) a signed patient acknowledgment form.

Details of prior vasodilator treatment, including the dose and duration of treatment, must be provided at the time of application. Where the patient has an adverse event to a vasodilator or where vasodilator treatment is contraindicated, details on the nature of the adverse event or contraindication according to the TGA-approved Product Information must also be provided with the application.

Where fewer than 3 tests (see requirement 2 above) are able to be performed on clinical grounds, a patient specific reason outlining why the particular test/s could not be conducted must be provided with the authority application [see Note for test requirements].

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. A maximum of 5 repeats may be requested. Where fewer than 5 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 6 months of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday)

**Authority required**

Initial (new patients)

Application for initial PBS-subsidised treatment with sildenafil citrate of patients who have not received prior PBS-subsidised treatment with a PAH agent and who have been assessed by a physician from a designated hospital to have:

(a) WHO Functional Class III primary pulmonary hypertension and a mean right atrial pressure greater than 8 mmHg, as measured by RHC, or, where a RHC cannot be performed on clinical grounds, right ventricular function as assessed by ECHO; OR

(b) WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease and a mean right atrial pressure greater than 8 mmHg, as measured by RHC, or, where a RHC cannot be performed on clinical grounds, right ventricular function as assessed by ECHO.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form [www.medicareaustralia.gov.au] which includes results from the 3 tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6MWT; and

(3) a signed patient acknowledgment form.

Where fewer than 3 tests (see requirement 2 above) are able to be performed on clinical grounds, a patient specific reason outlining why the particular test/s could not be conducted must be provided with the authority application [see Note for test requirements].

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. A maximum of 5 repeats may be requested. Where fewer than 5 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 6 months of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday)

**Authority required**

Initial (change or re-commencement for all patients)

Application for initial PBS-subsidised treatment with sildenafil citrate of patients with one of the following:

(a) WHO Functional Class III primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease who wish to re-commence PBS-subsidised sildenafil citrate after a break in therapy and who have demonstrated a response to their most recent course of PBS-subsidised treatment with sildenafil citrate; OR

(b) WHO Functional Class III primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease and whose most recent course of PBS-subsidised treatment was with a PAH agent other than sildenafil citrate.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form [www.medicareaustralia.gov.au] which includes the results on which approval for the first application for PBS-subsidised PAH agent was granted; and

(3) the date of the first application for PBS-subsidised treatment with a PAH agent; and

(4) the results of the patient's response to treatment with their last course of PBS-subsidised PAH agent.

Where fewer than 3 tests (see requirement 2 above) are able to be performed on clinical grounds, a patient specific reason outlining why the particular test/s could not be conducted must be provided with the authority application [see Note for test requirements].

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. A maximum of 5 repeats may be requested. Where fewer than 5 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 6 months of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday)

**Authority required**

Continuing treatment (all patients)

Continuing PBS-subsidised treatment with sildenafil citrate of patients who have received approval for initial PBS-subsidised treatment with sildenafil citrate, and who have been assessed by a physician from a designated hospital to have achieved a response to their most recent course of

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Brand Name and Manufacturer |
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sildenafil citrate treatment [see Note for definition of response].

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form [www.medicareaustralia.gov.au] which includes results from the 3 tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6MWT.

The results of the same tests as conducted at baseline should be provided with each written continuing treatment application (i.e. every 6 months), except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be provided with the application.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. A maximum of 5 repeats may be requested. Where fewer than 5 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 6 months of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday)

**Note**

Any queries concerning the arrangements to prescribe sildenafil citrate may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written applications for authority to prescribe PAH agents should be forwarded to:

Medicare Australia

Prior Written Approval of Specialised Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

**Note**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of agents for primary pulmonary hypertension and pulmonary arterial hypertension. Where the term PAH agents appears in the following notes and restrictions it refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan and tadalafil.

Patients are eligible for PBS-subsidised treatment with only 1 of the above PAH agents at any 1 time. Eligible patients may only swap between PAH agents if they have not failed prior PBS-subsidised treatment with that agent.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of that predicted.

The following provides some explanatory notes regarding the availability of PBS-subsidised treatment of patients with:

(a) bosentan monohydrate, of primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, or pulmonary arterial hypertension associated with a congential systemic-to-pulmonary shunt (including Eisenmenger's physiology), in patients with disease of WHO Functional Class III or IV severity; AND

(b) iloprost trometamol, of:

— primary pulmonary hypertension, or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class III severity and who have failed to respond to prior PBS-subsidised treatment with an alternate PAH agent; AND

— primary pulmonary hypertension, or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class IV severity; AND

— drug-induced pulmonary arterial hypertension, in patients with disease of WHO Functional Class III and IV severity; AND

(c) epoprostenol sodium, of:

— primary pulmonary hypertension, or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class III severity and who have failed to respond to prior PBS-subsidised treatment with an alternate PAH agent; AND

— primary pulmonary hypertension, or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class IV severity; AND

(d) sildenafil citrate, of primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class III severity; AND

(e) ambrisentan, of primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class III or IV severity; AND

(f) tadalafil, of primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class III severity.

From 1 April 2012, patients can access PAH agents through the PBS according to the relevant restrictions. Once these patients are approved initial treatment with 1 of these 6 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary. (New

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|

baselines may be submitted where the patient has failed to respond to their current treatment.)

1. Definition of primary pulmonary hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease, including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology).

Primary pulmonary hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease, including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary capillary wedge pressure (PCWP) less than 18 mmHg; or

(ii) mPAP greater than 30 mmHg with exercise and PCWP less than 18 mmHg; or

(iii) where a right heart catheter cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

2. Definition of WHO Functional Class III or IV disease severity.

(a) WHO Functional Class III disease severity is defined as follows:

Patients with pulmonary hypertension resulting in marked limitation of physical activity who are comfortable at rest and on ordinary physical activity experience dyspnoea or fatigue, chest pain or near syncope.

(b) WHO Functional Class IV disease severity is defined as follows:

Patients with the inability to carry out any physical activity without symptoms. These patients manifest signs of right heart failure. Dyspnoea and/or fatigue may even be present at rest. Discomfort is increased by any physical activity.

3. Designated hospitals.

Refer to the Medicare Australia website at www.medicareaustralia.gov.au for a list of designated hospitals.

4. Test requirements to establish baseline for initiation of treatment and response to treatment for continuation of treatment.

(a) Initiation of treatment.

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment, plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

(1) RHC plus ECHO composite assessments;

(2) RHC composite assessment plus 6MWT;

(3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted to Medicare Australia for consideration based on the results of the following test combinations, which are listed in descending order of preference:

(1) ECHO composite assessment plus 6MWT;

(2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test/s could not be conducted must be provided with the authority application.

(b) Continuation of treatment.

The following list outlines the preferred test combination, in descending order, for the purposes of continuation of PBS-subsidised treatment:

(1) RHC plus ECHO composite assessments plus 6MWT;

(2) RHC plus ECHO composite assessments;

(3) RHC composite assessment plus 6MWT;

(4) ECHO composite assessment plus 6MWT;

(5) RHC composite assessment only;

(6) ECHO composite assessment only.

The results of the same tests as conducted at baseline should be provided with each written continuing treatment application (i.e. every 6 months), except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be provided with the application. The test(s) results provided with the application for continuing treatment must be no more than 2 months old at the time of application.

**Note**

5. Definition of response to a PAH agent or prior vasodilator treatment.

For patients with 2 or more baseline tests, response to treatment is defined as 2 or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Brand Name and Manufacturer | |
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improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least 1 of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

6. Authority approval requirements.

(a) Initiation of PBS-subsidised treatment with a PAH agent, where the patient has not received prior PBS-subsidised treatment with that agent.

All applications for initial treatment must be made in writing, must include a completed authority prescription and must be submitted to Medicare Australia for authorisation. The total duration of initial PBS-subsidised treatment that will be approved with this first written application is up to 6 months, based on the dosage recommendations in the TGA-approved Product Information.

Bosentan only:

Approvals for the first authority prescription will be limited to 1 month of therapy with the 62.5 mg strength tablet, with the quantity approved based on the dosage recommendations in the Therapeutic Goods Administration (TGA)-approved Product Information. No repeats will be authorised for this prescription. The second authority prescription may be written for either the 62.5 mg tablet or the 125 mg tablet strengths. Where the 62.5 mg tablet strength is required, please contact Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) for further advice. Approvals for the second authority prescription will be limited to 1 month of treatment, with the quantity approved based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 4 repeats. The approved second authority prescription will be returned to the prescriber by Medicare Australia 2 weeks after the date of the approval of the first authority prescription, to allow for the uninterrupted completion of the 6 month initial treatment course. Medicare Australia will contact prescribers prior to dispatch of the second authority prescription to confirm the tablet strength required for the patient.

(b) Continuation of treatment.

Written applications for continuing treatment for patients who have demonstrated an adequate response to their current treatment must be submitted to Medicare Australia for authorisation every 6 months. Approvals will be limited to provide sufficient supply for up to a maximum of 6 months of treatment, based on the dosage recommendations in the TGA-approved Product Information.

The assessment of the patient's response to the first and subsequent 6 month courses of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated. Applications for continuing treatment with a PAH agent should be made prior to the completion of the 6 month treatment course to ensure continuity for those patients who respond to treatment, as assessed by the treating physician.

(c) Swapping between PAH agents.

For eligible patients, applications to swap between these 6 drugs must be made under the relevant initial treatment restriction. Patients should be assessed for response to the treatment they are ceasing at the time the application to swap therapy is being made. Patients who fail to demonstrate a response or for whom no assessment results are submitted with the application to swap therapy may not re-commence PBS-subsidised treatment with the drug they are ceasing.

It is important that patients are assessed for response to every course of treatment approved within the timeframes specified in the relevant restriction, in order to maximise the choice of treatment.

To avoid confusion, applications for patients who wish to swap to an alternate treatment should be accompanied by the previously approved authority prescription, or remaining repeats, for the treatment the patient is ceasing.

(d) Cessation of treatment — bosentan patients only.

Patients who fail to demonstrate a response to PBS-subsidised bosentan monohydrate treatment at the time where an assessment is required must cease PBS-subsidised bosentan monohydrate therapy.

For patients ceasing treatment, approval will only be granted to provide sufficient supply of the 62.5 mg tablet strength to allow gradual dose reduction over a period of no more than 1 month duration. Prescribers should telephone Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) to receive authorisation for this final supply and to ensure no unintended break in treatment occurs.

7. Re-treatment with a PAH agent.

Patients who do not respond to treatment are not eligible to receive further PBS-subsidised treatment with that agent under any circumstances.

8. Further information.

A tabulated representation of the above information and the restriction can be obtained from the Medicare Australia website at www.medicareaustralia.gov.au.

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|---|---|---|---|---|---|---|---|
| 9605M | sildenafil 20 mg tablet, 90 | 1 | .. | .. | 941.00 | Revatio | PF |

**TADALAFIL**

**Authority required**

Initial (new patients)

Application for initial PBS-subsidised treatment with tadalafil of patients who have not received prior PBS-subsidised treatment with a PAH agent and who have been assessed by a physician from a designated hospital to have:

(a) WHO Functional Class III primary pulmonary hypertension and a mean right atrial pressure of 8 mmHg or less, as measured by RHC, or, where a RHC cannot be performed on clinical grounds, right ventricular function as assessed by ECHO; OR

(b) WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease and a mean right atrial pressure of 8 mmHg or less, as measured by RHC, or, where a RHC cannot be performed on clinical grounds, right ventricular function as assessed by ECHO.

Patients must have failed to respond [see Note for definition of response] to 6 or more weeks of appropriate vasodilator treatment unless intolerance or a contraindication to such treatment exists.

Applications for authorisation must be in writing and must include:

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Brand Name and Manufacturer |
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(1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form [www.medicareaustralia.gov.au] which includes results from the 3 tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6MWT; and

(3) a signed patient acknowledgment form.

Details of prior vasodilator treatment, including the dose and duration of treatment, must be provided at the time of application. Where the patient has an adverse event to a vasodilator or where vasodilator treatment is contraindicated, details on the nature of the adverse event or contraindication according to the TGA-approved Product Information must also be provided with the application.

Where fewer than 3 tests (see requirement 2 above) are able to be performed on clinical grounds, a patient specific reason outlining why the particular test/s could not be conducted must be provided with the authority application [see Note for test requirements].

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. A maximum of 5 repeats may be requested. Where fewer than 5 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 6 months of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday)

**Authority required**

Initial (new patients)

Application for initial PBS-subsidised treatment with tadalafil of patients who have not received prior PBS-subsidised treatment with a PAH agent and who have been assessed by a physician from a designated hospital to have:

(a) WHO Functional Class III primary pulmonary hypertension and a mean right atrial pressure greater than 8 mmHg, as measured by RHC, or, where a RHC cannot be performed on clinical grounds, right ventricular function as assessed by ECHO; OR

(b) WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease and a mean right atrial pressure greater than 8 mmHg, as measured by RHC, or, where a RHC cannot be performed on clinical grounds, right ventricular function as assessed by ECHO;

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form [www.medicareaustralia.gov.au] which includes results from the 3 tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6MWT; and

(3) a signed patient acknowledgment form.

Where fewer than 3 tests (see requirement 2 above) are able to be performed on clinical grounds, a patient specific reason outlining why the particular test/s could not be conducted must be provided with the authority application [see Note for test requirements].

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. A maximum of 5 repeats may be requested. Where fewer than 5 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 6 months of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday)

**Authority required**

Initial (change or re-commencement for all patients)

Application for initial treatment with tadalafil of patients with one of the following:

(a) WHO Functional Class III primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease who wish to re-commence PBS-subsidised tadalafil after a break in therapy and who have demonstrated a response to their most recent course of PBS-subsidised treatment with tadalafil; OR

(b) WHO Functional Class III primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease and whose most recent course of PBS-subsidised treatment was with a PAH agent other than tadalafil.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form [www.medicareaustralia.gov.au] which includes the results on which approval for the first application for PBS-subsidised PAH agent was granted; and

(3) the date of the first application for PBS-subsidised treatment with a PAH agent; and

(4) the results of the patient's response to treatment with their last course of PBS-subsidised PAH agent.

Where fewer than 3 tests (see requirement 2 above) are able to be performed on clinical grounds, a patient specific reason outlining why the particular test/s could not be conducted must be provided with the authority application [see Note for test requirements].

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. A maximum of 5 repeats may be requested. Where fewer than 5 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 6 months of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday)

# HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Brand Name and Manufacturer |
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**Authority required**

Continuing treatment (all patients)

Continuing PBS-subsidised treatment with tadalafil of patients who have received approval for initial PBS-subsidised treatment with tadalafil, and who have been assessed by a physician from a designated hospital to have achieved a response to their most recent course of tadalafil treatment [see Note for definition of response].

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form [www.medicareaustralia.gov.au] which includes results from the 3 tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6MWT.

The results of the same tests as conducted at baseline should be provided with each written continuing treatment application (i.e. every 6 months), except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be provided with the application.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. A maximum of 5 repeats will be authorised. Where fewer than 5 repeats are initially requested under this criterion, authority approvals for sufficient repeats to complete a maximum of 6 months of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday)

**Note**

Any queries concerning the arrangements to prescribe tadalafil may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written applications for authority to prescribe PAH agents should be forwarded to:

Medicare Australia

Prior Written Approval of Specialised Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

**Note**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of agents for primary pulmonary hypertension and pulmonary arterial hypertension. Where the term PAH agents appears in the following notes and restrictions it refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan and tadalafil.

Patients are eligible for PBS-subsidised treatment with only 1 of the above PAH agents at any 1 time. Eligible patients may only swap between PAH agents if they have not failed prior PBS-subsidised treatment with that agent.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of that predicted.

The following provides some explanatory notes regarding the availability of PBS-subsidised treatment of patients with:

(a) bosentan monohydrate, of primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, or pulmonary arterial hypertension associated with a congential systemic-to-pulmonary shunt (including Eisenmenger's physiology), in patients with disease of WHO Functional Class III or IV severity; AND

(b) iloprost trometamol, of:

— primary pulmonary hypertension, or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class III severity and who have failed to respond to prior PBS-subsidised treatment with an alternate PAH agent; AND

— primary pulmonary hypertension, or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class IV severity; AND

— drug-induced pulmonary arterial hypertension, in patients with disease of WHO Functional Class III and IV severity; AND

(c) epoprostenol sodium, of:

— primary pulmonary hypertension, or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class III severity and who have failed to respond to prior PBS-subsidised treatment with an alternate PAH agent; AND

— primary pulmonary hypertension, or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class IV severity; AND

(d) sildenafil citrate, of primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class III severity; AND

(e) ambrisentan, of primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class III or IV severity; AND

(f) tadalafil, of primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class III severity.

# HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Brand Name and Manufacturer |
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From 1 April 2012, patients can access PAH agents through the PBS according to the relevant restrictions. Once these patients are approved initial treatment with 1 of these 6 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary. (New baselines may be submitted where the patient has failed to respond to their current treatment.)

1. Definition of primary pulmonary hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease, including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology).

Primary pulmonary hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease, including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary capillary wedge pressure (PCWP) less than 18 mmHg; or

(ii) mPAP greater than 30 mmHg with exercise and PCWP less than 18 mmHg; or

(iii) where a right heart catheter cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

2. Definition of WHO Functional Class III or IV disease severity.

(a) WHO Functional Class III disease severity is defined as follows:

Patients with pulmonary hypertension resulting in marked limitation of physical activity who are comfortable at rest and on ordinary physical activity experience dyspnoea or fatigue, chest pain or near syncope.

(b) WHO Functional Class IV disease severity is defined as follows:

Patients with the inability to carry out any physical activity without symptoms. These patients manifest signs of right heart failure. Dyspnoea and/or fatigue may even be present at rest. Discomfort is increased by any physical activity.

3. Designated hospitals.

Refer to the Medicare Australia website at www.medicareaustralia.gov.au for a list of designated hospitals.

4. Test requirements to establish baseline for initiation of treatment and response to treatment for continuation of treatment.

(a) Initiation of treatment.

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment, plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

(1) RHC plus ECHO composite assessments;

(2) RHC composite assessment plus 6MWT;

(3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted to Medicare Australia for consideration based on the results of the following test combinations, which are listed in descending order of preference:

(1) ECHO composite assessment plus 6MWT;

(2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test/s could not be conducted must be provided with the authority application.

(b) Continuation of treatment.

The following list outlines the preferred test combination, in descending order, for the purposes of continuation of PBS-subsidised treatment:

(1) RHC plus ECHO composite assessments plus 6MWT;

(2) RHC plus ECHO composite assessments;

(3) RHC composite assessment plus 6MWT;

(4) ECHO composite assessment plus 6MWT;

(5) RHC composite assessment only;

(6) ECHO composite assessment only.

The results of the same tests as conducted at baseline should be provided with each written continuing treatment application (i.e. every 6 months), except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be provided with the application. The test(s) results provided with the application for continuing treatment must be no more than 2 months old at the time of application.

**Note**

5. Definition of response to a PAH agent or prior vasodilator treatment.

For patients with 2 or more baseline tests, response to treatment is defined as 2 or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Brand Name and Manufacturer | |
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| | For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.<br>For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.<br>For patients aged less than 18 years, response to treatment is defined as at least 1 of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.<br>6. Authority approval requirements.<br>(a) Initiation of PBS-subsidised treatment with a PAH agent, where the patient has not received prior PBS-subsidised treatment with that agent.<br>All applications for initial treatment must be made in writing, must include a completed authority prescription and must be submitted to Medicare Australia for authorisation. The total duration of initial PBS-subsidised treatment that will be approved with this first written application is up to 6 months, based on the dosage recommendations in the TGA-approved Product Information.<br>Bosentan only:<br>Approvals for the first authority prescription will be limited to 1 month of therapy with the 62.5 mg strength tablet, with the quantity approved based on the dosage recommendations in the Therapeutic Goods Administration (TGA)-approved Product Information. No repeats will be authorised for this prescription. The second authority prescription may be written for either the 62.5 mg tablet or the 125 mg tablet strengths. Where the 62.5 mg tablet strength is required, please contact Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) for further advice. Approvals for the second authority prescription will be limited to 1 month of treatment, with the quantity approved based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 4 repeats. The approved second authority prescription will be returned to the prescriber by Medicare Australia 2 weeks after the date of the approval of the first authority prescription, to allow for the uninterrupted completion of the 6 month initial treatment course. Medicare Australia will contact prescribers prior to dispatch of the second authority prescription to confirm the tablet strength required for the patient.<br>(b) Continuation of treatment.<br>Written applications for continuing treatment for patients who have demonstrated an adequate response to their current treatment must be submitted to Medicare Australia for authorisation every 6 months. Approvals will be limited to provide sufficient supply for up to a maximum of 6 months of treatment, based on the dosage recommendations in the TGA-approved Product Information.<br>The assessment of the patient's response to the first and subsequent 6 month courses of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated. Applications for continuing treatment with a PAH agent should be made prior to the completion of the 6 month treatment course to ensure continuity for those patients who respond to treatment, as assessed by the treating physician.<br>(c) Swapping between PAH agents.<br>For eligible patients, applications to swap between these 6 drugs must be made under the relevant initial treatment restriction. Patients should be assessed for response to the treatment they are ceasing at the time the application to swap therapy is being made. Patients who fail to demonstrate a response or for whom no assessment results are submitted with the application to swap therapy may not re-commence PBS-subsidised treatment with the drug they are ceasing.<br>It is important that patients are assessed for response to every course of treatment approved within the timeframes specified in the relevant restriction, in order to maximise the choice of treatment.<br>To avoid confusion, applications for patients who wish to swap to an alternate treatment should be accompanied by the previously approved authority prescription, or remaining repeats, for the treatment the patient is ceasing.<br>(d) Cessation of treatment — bosentan patients only.<br>Patients who fail to demonstrate a response to PBS-subsidised bosentan monohydrate treatment at the time where an assessment is required must cease PBS-subsidised bosentan monohydrate therapy.<br>For patients ceasing treatment, approval will only be granted to provide sufficient supply of the 62.5 mg tablet strength to allow gradual dose reduction over a period of no more than 1 month duration. Prescribers should telephone Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) to receive authorisation for this final supply and to ensure no unintended break in treatment occurs.<br>7. Re-treatment with a PAH agent.<br>Patients who do not respond to treatment are not eligible to receive further PBS-subsidised treatment with that agent under any circumstances.<br>8. Further information.<br>A tabulated representation of the above information and the restriction can be obtained from the Medicare Australia website at www.medicareaustralia.gov.au. | | | | | | |
| 1304P | tadalafil 20 mg tablet, 56 | 1 | .. | .. | 878.70 | Adcirca | LY |

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# SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS

## PITUITARY AND HYPOTHALAMIC HORMONES AND ANALOGUES

### HYPOTHALAMIC HORMONES

#### *Somatostatin and analogues*

**LANREOTIDE**

**Authority required**

Active acromegaly in a patient with persistent elevation of mean growth hormone levels of greater than 2.5 micrograms per litre AND

(a) after failure of other therapy including dopamine agonists; or

(b) as interim treatment while awaiting the effects of radiotherapy and where treatment with dopamine agonists has failed; or

(c) if the patient is unfit for or unwilling to undergo surgery and where radiotherapy is contraindicated.

In a patient treated with radiotherapy, treatment must cease if there is biochemical evidence of remission (normal IGF1) after lanreotide has been withdrawn for at least 4 weeks (8 weeks after the last dose). Lanreotide should be withdrawn every 2 years in the 10 years after radiotherapy for assessment of remission.

Treatment must cease if IGF1 is not lower after 3 months treatment

**Authority required**

Functional carcinoid tumour causing intractable symptoms. The patient must have experienced on average over 1 week, 3 or more episodes per day of diarrhoea and/or flushing, which persisted despite the use of anti-histamines, anti-serotonin agents and anti-diarrhoea agents, and surgery or antineoplastic therapy must have failed or be inappropriate.

Treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 3 months' therapy at a dose of 120 mg every 28 days. Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose

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|---|---|---|---|---|---|---|---|
| 6425E | lanreotide 120 mg/0.5 mL injection, 1 x 0.5 mL syringe | 2 | 11 | .. | *4526.63 | Somatuline Autogel | IS |
| 6423C | lanreotide 60 mg/0.3 mL injection: modified release, 1 x 0.3 mL syringe | 2 | 11 | .. | *2736.63 | Somatuline Autogel | IS |
| 6424D | lanreotide 90 mg/0.3 mL injection: modified release, 1 x 0.3 mL syringe | 2 | 11 | .. | *3626.63 | Somatuline Autogel | IS |

**LANREOTIDE**

**Authority required**

Active acromegaly in a patient with persistent elevation of mean growth hormone levels of greater than 2.5 micrograms per litre AND

(a) after failure of other therapy including dopamine agonists; or

(b) as interim treatment while awaiting the effects of radiotherapy and where treatment with dopamine agonists has failed; or

(c) if the patient is unfit for or unwilling to undergo surgery and where radiotherapy is contraindicated.

In a patient treated with radiotherapy, treatment must cease if there is biochemical evidence of remission (normal IGF1) after lanreotide has been withdrawn for at least 4 weeks (6 weeks after the last dose). Lanreotide should be withdrawn every 2 years in the 10 years after radiotherapy for assessment of remission.

Treatment must cease if IGF1 is not lower after 3 months treatment

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|---|---|---|---|---|---|---|---|
| 6332G | lanreotide 30 mg injection: modified release [1 x 30 mg vial] (&) inert substance diluent [1 x 2 mL ampoule], 1 pack | 2 | 11 | .. | *1546.63 | Somatuline LA | IS |

**OCTREOTIDE**

**Authority required**

Acromegaly in a patient controlled on Sandostatin subcutaneous injections.

In a patient treated with radiotherapy, treatment must cease if there is biochemical evidence of remission (normal IGF1) after octreotide has been withdrawn for at least 4 weeks (8 weeks after the last dose). Octreotide should be withdrawn every 2 years in the 10 years after radiotherapy for assessment of remission.

Treatment must cease if IGF1 is not lower after 3 months of treatment

**Authority required**

Functional carcinoid tumour or vasoactive intestinal peptide secreting tumour (VIPoma) with symptom control on Sandostatin subcutaneous injections.

Treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 3 months' therapy at a dose of 30 mg every 28 days and having allowed adequate rescue therapy with Sandostatin subcutaneous injections. Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| 6426F | octreotide 10 mg injection: modified release [1 x 10 mg | 1 | 11 | .. | 1353.49 | Sandostatin LAR | NV |

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|
| | vial] (&) inert substance diluent [1 x 2.5 mL syringe], 1 pack | | | | | | | |
| 6427G | octreotide 20 mg injection: modified release [1 x 20 mg vial] (&) inert substance diluent [1 x 2.5 mL syringe], 1 pack | 1 | 11 | .. | 1786.44 | | Sandostatin LAR | NV |
| 6428H | octreotide 30 mg injection: modified release [1 x 30 mg vial] (&) inert substance diluent [1 x 2.5 mL syringe], 1 pack | 1 | 11 | .. | 2224.09 | | Sandostatin LAR | NV |

**OCTREOTIDE**

**Authority required**

Active acromegaly in a patient with persistent elevation of mean growth hormone levels of greater than 2.5 micrograms per litre AND

(a) after failure of other therapy including dopamine agonists; or

(b) as interim treatment while awaiting the effects of radiotherapy and where treatment with dopamine agonists has failed; or

(c) if the patient is unfit for or unwilling to undergo surgery and where radiotherapy is contraindicated.

In a patient treated with radiotherapy, treatment must cease if there is biochemical evidence of remission (normal IGF1) after octreotide has been withdrawn for at least 4 weeks. Octreotide should be withdrawn every 2 years in the 10 years after radiotherapy for assessment of remission.

Treatment must cease if IGF1 is not lower after 3 months treatment at a dose of 100 micrograms 3 times daily

**Authority required**

Functional carcinoid tumour or vasoactive intestinal peptide secreting tumour (VIPoma) causing intractable symptoms. The patient must have experienced on average over 1 week, 3 or more episodes per day of diarrhoea and/or flushing, which persisted despite the use of anti-histamines, anti-serotonin agents and anti-diarrhoea agents, and surgery or antineoplastic therapy must have failed or be inappropriate.

Treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 2 months' therapy. Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 6228T | octreotide 100 microgram/mL injection, 5 x 1 mL ampoules | 18 | 11 | .. | *1283.01 | [a] | Hospira Pty Limited | HH |
| | | | | | | [a] | Octreotide (SUN) | ZF |
| | | | | | | [a] | Octreotide MaxRx | GQ |
| | | | | | | [a] | Sandostatin 0.1 | NV |
| 6227R | octreotide 50 microgram/mL injection, 5 x 1 mL ampoules | 18 | 11 | .. | *650.49 | [a] | Hospira Pty Limited | HH |
| | | | | | | [a] | Octreotide (SUN) | ZF |
| | | | | | | [a] | Octreotide MaxRx | GQ |
| | | | | | | [a] | Sandostatin 0.05 | NV |
| 6229W | octreotide 500 microgram/mL injection, 5 x 1 mL ampoules | 18 | 11 | .. | *6241.11 | [a] | Hospira Pty Limited | HH |
| | | | | | | [a] | Octreotide (SUN) | ZF |
| | | | | | | [a] | Octreotide MaxRx | GQ |
| | | | | | | [a] | Sandostatin 0.5 | NV |

## CALCIUM HOMEOSTASIS

### ANTI-PARATHYROID AGENTS

#### *Other anti-parathyroid agents*

**CINACALCET**

**Authority required**

Management, including initiation and stabilisation, by a nephrologist, of a patient with chronic kidney disease on dialysis who has sustained secondary hyperparathyroidism with iPTH of at least 50 pmol per L, not responding to conventional therapy

**Authority required**

Management, including initiation and stabilisation, by a nephrologist, of a patient with chronic kidney disease on dialysis who has sustained secondary hyperparathyroidism with iPTH of at least 15 pmol per L and less than 50 pmol per L AND an (adjusted) serum calcium concentration at least 2.6 mmol per L, not responding to conventional treatment

**Note**

During the titration phase, intact PTH should be monitored 4 weekly (measured at least 12 hours post dose) and dose titrated until an appropriate iPTH concentration is achieved. During the titration phase, approval will be limited to sufficient supply for 4 weeks treatment at a time, with doses between 30 and 180 mg per day according to the patient's response and tolerability.

During the maintenance phase, approval will be limited to provide sufficient quantity for 4 weeks treatment up to a maximum of 6 months supply for doses between 30 and 180 mg per day according to the patient's response and tolerability. Intact PTH should be monitored quarterly (measured at least 12 hours post dose) and dose adjusted as necessary to maintain an appropriate iPTH concentration.

"Sustained" means the abnormality was detected on at least 2 blood samples collected over a period of 2 to 4 months.

**Note**

# HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|
| | Special Pricing Arrangements apply. | | | | | | |
| 9625N | cinacalcet 30 mg tablet, 28 | 2 | 5 | .. | *624.09 | Sensipar | AN |
| 9626P | cinacalcet 60 mg tablet, 28 | 2 | 5 | .. | *1234.07 | Sensipar | AN |
| 9627Q | cinacalcet 90 mg tablet, 28 | 2 | 5 | .. | *1827.79 | Sensipar | AN |

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|

# ANTIINFECTIVES FOR SYSTEMIC USE

## ANTIBACTERIALS FOR SYSTEMIC USE

### MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS

#### *Macrolides*

**AZITHROMYCIN**

**Authority required**

Prophylaxis against Mycobacterium avium complex infections in HIV-positive patients with CD4 cell counts of less than 75 per cubic millimetre

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| 6221K | azithromycin 600 mg tablet, 8 | 2 | 5 | .. | *125.15 | Zithromax | PF |

**CLARITHROMYCIN**

**Authority required**

Treatment of Mycobacterium avium complex infections

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| 6151R | clarithromycin 250 mg tablet, 100 | 1 | 2 | .. | 32.71 | Klacid | AB |
| 6152T | clarithromycin 500 mg tablet, 100 | 1 | 2 | .. | 57.93 | Klacid | AB |

## ANTIMYCOBACTERIALS

### DRUGS FOR TREATMENT OF TUBERCULOSIS

#### *Antibiotics*

**RIFABUTIN**

**Authority required**

Treatment of Mycobacterium avium complex infections in HIV-positive patients

**Authority required**

Prophylaxis against Mycobacterium avium complex infections in HIV-positive patients with CD4 cell counts of less than 75 per cubic millimetre

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| 6195C | rifabutin 150 mg capsule, 30 | 4 | 5 | .. | *618.15 | Mycobutin | PF |

## ANTIVIRALS FOR SYSTEMIC USE

### DIRECT ACTING ANTIVIRALS

#### *Nucleosides and nucleotides excl. reverse transcriptase inhibitors*

**CIDOFOVIR**

**Authority required**

Treatment of cytomegalovirus retinitis in patients with AIDS

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| 6247T | cidofovir 375 mg/5 mL injection, 1 x 5 mL vial | 4 | 3 | .. | *3646.63 | Vistide | GI |

**GANCICLOVIR**

**Authority required**

Cytomegalovirus retinitis in severely immunocompromised patients

**Authority required**

Prophylaxis of cytomegalovirus disease in bone marrow transplant patients at risk of cytomegalovirus disease

**Authority required**

Prophylaxis of cytomegalovirus disease in solid organ transplant patients at risk of cytomegalovirus disease

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| 6136Y | ganciclovir 500 mg injection, 5 x 500 mg vials | 2 | 1 | .. | *589.03 | Cymevene | RO |

**VALACICLOVIR**

**Authority required**

Prophylaxis of cytomegalovirus (CMV) infection and disease following renal transplantation in patients at risk of CMV disease

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 6280M | valaciclovir 500 mg tablet, 100 | 5 | 2 | .. | *2146.63 | [a] | APO-Valaciclovir | TX |
| | | | | | | [a] | Valaciclovir RBX | RA |
| | | | | | | [a] | Valtrex | AS |
| | | | | | | [a] | Zelitrex | GM |

**VALGANCICLOVIR**

**Authority required**

Cytomegalovirus retinitis in patients with acquired immunodeficiency syndrome

**Authority required**

Prophylaxis of cytomegalovirus infection and disease in solid organ transplant patients at risk of cytomegalovirus disease

# HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|
| 6357N | valganciclovir 450 mg tablet, 60 | 2 | 5 | .. | *4538.23 | Valcyte | RO |
| 9675F | valganciclovir 50 mg/mL oral liquid: powder for, 100 mL | 11 | 5 | .. | *#4624.08 | Valcyte | RO |

## *Phosphonic acid derivatives*

**FOSCARNET**

**Authority required**

Treatment of cytomegalovirus retinitis in patients with AIDS

**Authority required**

Treatment of aciclovir-resistant herpes simplex virus infection in immunocompromised patients with HIV infection

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| 6134W | FOSCARNET SODIUM I.V. infusion 24 mg per mL, 250 mL bottle, 6 | 1 | 1 | .. | 1224.13 | Foscavir | IX |

## *Protease inhibitors*

**ATAZANAVIR**

**Authority required**

Initial treatment of HIV infection in combination with other antiretroviral agents in a patient with a CD4 count of less than 500 per cubic millimetre or symptomatic HIV disease

**Authority required**

Continuing treatment of HIV infection in combination with other antiretroviral agents where the patient has previously received PBS-subsidised therapy for HIV infection

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| 9646Q | atazanavir 100 mg capsule, 60 | 2 | 5 | .. | *730.35 | Reyataz | BQ |
| 6451M | atazanavir 150 mg capsule, 60 | 2 | 5 | .. | *1090.45 | Reyataz | BQ |
| 6452N | atazanavir 200 mg capsule, 60 | 2 | 5 | .. | *1438.39 | Reyataz | BQ |
| 9614B | atazanavir 300 mg capsule, 30 | 2 | 5 | .. | *1090.45 | Reyataz | BQ |

**BOCEPREVIR**

**Authority required**

Chronic genotype 1 hepatitis C infection

**The Treatment criteria is:**

Must be treated in an accredited treatment centre,

**AND the Clinical criteria is:**

Patient must have compensated liver disease,

**AND the Clinical criteria is:**

Patient must have received no more than one prior treatment with interferon alfa or peginterferon alfa for hepatitis C,

**AND the Clinical criteria is:**

The treatment must be in combination with peginterferon alfa and ribavirin,

**AND the Clinical criteria is:**

The treatment must be limited to a maximum duration of 32 weeks in patients without hepatic cirrhosis who were partial responders or relapsers to the prior course of interferon based therapy for hepatitis C; OR

The treatment must be limited to a maximum duration of 44 weeks in patients without hepatic cirrhosis who were null responders to the prior course of interferon based therapy for hepatitis C; OR

The treatment must be limited to a maximum duration of 44 weeks for all patients with hepatic cirrhosis,

**AND the Clinical criteria is:**

The treatment must cease after the first 8 weeks of boceprevir treatment if plasma HCV RNA is detectable by an HCV RNA qualitative assay at treatment week 12,

**AND the Clinical criteria is:**

The treatment must cease after the first 20 weeks of boceprevir treatment if plasma HCV RNA is detectable by an HCV RNA qualitative assay at treatment week 24,

**AND the Population criteria is:**

Patient must be 18 years or older,

**AND the Population criteria is:**

Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

Chronic genotype 1 hepatitis C infection (repeated anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records.

Patients who have received prior treatment with an NS3/4A protease inhibitor are not eligible to receive PBS-subsidised boceprevir, except where the patient has developed an intolerance to the other NS3/4A protease inhibitor of a severity necessitating permanent treatment withdrawal. Details of the intolerance must be documented in the patient's medical records.

For patients without hepatic cirrhosis who were partial responders or relapsers to the prior course of interferon based therapy, a maximum of 7

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|---|---|---|---|---|---|---|---|
| | repeats may be prescribed. | | | | | | |
| | For patients without hepatic cirrhosis who were null responders to the prior course of interferon based therapy, a maximum of 10 repeats may be prescribed. | | | | | | |
| | For patients with hepatic cirrhosis, a maximum of 10 repeats may be prescribed. | | | | | | |
| | **Authority required** | | | | | | |
| | Chronic genotype 1 hepatitis C infection | | | | | | |
| | **The Treatment criteria is:** | | | | | | |
| | Must be treated in an accredited treatment centre, | | | | | | |
| | **AND the Clinical criteria is:** | | | | | | |
| | Patient must have compensated liver disease, | | | | | | |
| | **AND the Clinical criteria is:** | | | | | | |
| | Patient must not have received prior interferon alfa or peginterferon alfa treatment for hepatitis C, | | | | | | |
| | **AND the Clinical criteria is:** | | | | | | |
| | The treatment must be in combination with peginterferon alfa and ribavirin, | | | | | | |
| | **AND the Clinical criteria is:** | | | | | | |
| | The treatment must be limited to a maximum duration of 24 weeks in patients without hepatic cirrhosis; OR | | | | | | |
| | The treatment must be limited to a maximum duration of 44 weeks in patients with hepatic cirrhosis, | | | | | | |
| | **AND the Clinical criteria is:** | | | | | | |
| | The treatment must cease after the first 20 weeks of boceprevir treatment if plasma HCV RNA is detectable by an HCV RNA qualitative assay at treatment week 24, | | | | | | |
| | **AND the Population criteria is:** | | | | | | |
| | Patient must be 18 years or older, | | | | | | |
| | **AND the Population criteria is:** | | | | | | |
| | Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age. | | | | | | |
| | Evidence of chronic genotype 1 hepatitis C infection (repeated anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records. | | | | | | |
| | Patients who have received prior treatment with an NS3/4A protease inhibitor are not eligible to receive PBS-subsidised boceprevir, except where the patient has developed an intolerance to the other NS3/4A protease inhibitor of a severity necessitating permanent treatment withdrawal. Details of the intolerance must be documented in the patient's medical records. | | | | | | |
| | For patients without hepatic cirrhosis, a maximum of 5 repeats may be prescribed. | | | | | | |
| | For patients with hepatic cirrhosis, a maximum of 10 repeats may be prescribed. | | | | | | |
| | **Note** | | | | | | |
| | No increase in the maximum quantity or number of units may be authorised. | | | | | | |
| | **Note** | | | | | | |
| | Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C: | | | | | | |
| | (a) a nurse educator/counsellor for patients; and | | | | | | |
| | (b) 24-hour access by patients to medical advice; and | | | | | | |
| | (c) an established liver clinic. | | | | | | |
| 2435E | Boceprevir 200 mg capsule, 336 capsules | 1 | 10 | .. | 3966.63 | Victrelis | MK |
| | **DARUNAVIR** | | | | | | |
| | **Authority required** | | | | | | |
| | Treatment of HIV infection, in addition to optimised background therapy in combination with other antiretroviral agents, and co-administered with 100 mg ritonavir twice daily in an antiretroviral experienced patient who, after at least one antiretroviral regimen, has experienced virological failure or clinical failure or genotypic resistance. | | | | | | |
| | Virological failure is defined as a viral load greater than 400 copies per mL on two consecutive occasions, while clinical failure is linked to emerging signs and symptoms of progressing HIV infection or treatment-limiting toxicity | | | | | | |
| 9581G | darunavir 150 mg tablet, 240 | 1 | 5 | .. | 1095.34 | Prezista | JC |
| 5000E | darunavir 600 mg tablet, 60 | 2 | 5 | .. | *2144.05 | Prezista | JC |
| | **DARUNAVIR** | | | | | | |
| | **Authority required** | | | | | | |
| | Treatment of HIV infection, in addition to optimised background therapy in combination with other antiretroviral agents, and co-administered with 100 mg ritonavir in an antiretroviral experienced patient who, after at least one antiretroviral regimen, has experienced virological failure or clinical failure or genotypic resistance, and who has not demonstrated darunavir resistance associated mutations detected on resistance testing. | | | | | | |

# HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|
| | Virological failure is defined as a viral load greater than 400 copies per mL on two consecutive occasions, while clinical failure is linked to emerging signs and symptoms of progressing HIV infection or treatment-limiting toxicity | | | | | | |
| 5823L | darunavir 400 mg tablet, 60 | 2 | 5 | .. | *1444.91 | Prezista | JC |
| | **FOSAMPRENAVIR** | | | | | | |
| | **Authority required** | | | | | | |
| | Initial treatment of HIV infection in combination with other antiretroviral agents in a patient with a CD4 count of less than 500 per cubic millimetre or symptomatic HIV disease | | | | | | |
| | **Authority required** | | | | | | |
| | Continuing treatment of HIV infection in combination with other antiretroviral agents where the patient has previously received PBS-subsidised therapy for HIV infection | | | | | | |
| 6454Q | fosamprenavir 50 mg/mL oral liquid, 225 mL | 8 | 5 | .. | *851.59 | Telzir | VI |
| 6453P | fosamprenavir 700 mg tablet, 60 | 2 | 5 | .. | *795.29 | Telzir | VI |
| | **INDINAVIR** | | | | | | |
| | **Authority required** | | | | | | |
| | Initial treatment of HIV infection in combination with other antiretroviral agents in a patient with a CD4 count of less than 500 per cubic millimetre or symptomatic HIV disease | | | | | | |
| | **Authority required** | | | | | | |
| | Continuing treatment of HIV infection in combination with other antiretroviral agents where the patient has previously received PBS-subsidised therapy for HIV infection | | | | | | |
| 6202K | indinavir 400 mg capsule, 180 | 2 | 5 | .. | *953.03 | Crixivan 400 mg | MK |
| | **RITONAVIR** | | | | | | |
| | **Authority required** | | | | | | |
| | Initial treatment of HIV infection in combination with other antiretroviral agents in a patient with a CD4 count of less than 500 per cubic millimetre or symptomatic HIV disease | | | | | | |
| | **Authority required** | | | | | | |
| | Continuing treatment of HIV infection in combination with other antiretroviral agents where the patient has previously received PBS-subsidised therapy for HIV infection | | | | | | |
| 9677H | ritonavir 100 mg tablet, 30 | 24 | 5 | .. | *1028.79 | Norvir | VE |
| 6494T | ritonavir 600 mg/7.5 mL oral liquid, 90 mL | 10 | 5 | .. | *953.03 | Norvir | VE |
| | **SAQUINAVIR** | | | | | | |
| | **Authority required** | | | | | | |
| | Initial treatment of HIV infection in combination with other antiretroviral agents in a patient with a CD4 count of less than 500 per cubic millimetre or symptomatic HIV disease | | | | | | |
| | **Authority required** | | | | | | |
| | Continuing treatment of HIV infection in combination with other antiretroviral agents where the patient has previously received PBS-subsidised therapy for HIV infection | | | | | | |
| 6498B | saquinavir 500 mg tablet, 120 | 2 | 5 | .. | *1057.75 | Invirase | RO |
| | **TELAPREVIR** | | | | | | |
| | **Authority required** | | | | | | |
| | Chronic genotype 1 hepatitis C infection | | | | | | |
| | **The Treatment criteria is:** | | | | | | |
| | Must be treated in an accredited treatment centre, | | | | | | |
| | **AND the Clinical criteria is:** | | | | | | |
| | Patient must have compensated liver disease, | | | | | | |
| | **AND the Clinical criteria is:** | | | | | | |
| | Patient must not have received prior treatment with interferon alfa or peginterferon alfa for hepatitis C, | | | | | | |
| | **AND the Clinical criteria is:** | | | | | | |
| | The treatment must be in combination with peginterferon alfa and ribavirin, | | | | | | |
| | **AND the Clinical criteria is:** | | | | | | |
| | The treatment must be limited to a maximum duration of 12 weeks, | | | | | | |
| | **AND the Clinical criteria is:** | | | | | | |
| | The treatment must cease if the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is greater than 1000 IU/mL, | | | | | | |
| | **AND the Population criteria is:** | | | | | | |
| | Patient must be 18 years or older, | | | | | | |

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|

**AND the Population criteria is:**

Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

Evidence of chronic genotype 1 hepatitis C infection (repeatedly anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records.

Patients who have received prior treatment with an NS3/4A protease inhibitor are not eligible to receive PBS-subsidised telaprevir, except where the patient has developed an intolerance to the other NS3/4A protease inhibitor of a severity necessitating permanent treatment withdrawal. Details of the intolerance must be documented in the patient's medical records.

**Authority required**

Chronic genotype 1 hepatitis C infection

**The Treatment criteria is:**

Must be treated in an accredited treatment centre,

**AND the Clinical criteria is:**

Patient must have compensated liver disease,

**AND the Clinical criteria is:**

Patient must have received prior treatment with interferon alfa or peginterferon alfa for hepatitis C,

**AND the Clinical criteria is:**

The treatment must be in combination with peginterferon alfa and ribavirin,

**AND the Clinical criteria is:**

The treatment must be limited to a maximum duration of 12 weeks,

**AND the Clinical criteria is:**

The treatment must cease if the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is greater than 1000 IU/mL,

**AND the Population criteria is:**

Patient must be 18 years or older,

**AND the Population criteria is:**

Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

Evidence of chronic genotype 1 hepatitis C infection (repeatedly anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records.

Patients who have received prior treatment with an NS3/4A protease inhibitor are not eligible to receive PBS-subsidised telaprevir, except where the patient has developed an intolerance to the other NS3/4A protease inhibitor of a severity necessitating permanent treatment withdrawal. Details of the intolerance must be documented in the patient's medical records.

**Note**

No increase in the maximum quantity or number of units may be authorised.

**Note**

No increase in the maximum number of repeats may be authorised.

**Note**

Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C:

(a) a nurse educator/counsellor for patients; and

(b) 24-hour access by patients to medical advice; and

(c) an established liver clinic.

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| 2378E | telaprevir 375 mg tablet, 42 | 6 | .. | .. | *14912.37 | Incivo | JC |

**TIPRANAVIR**

**Authority required**

Treatment of HIV infection, in addition to optimised background therapy in combination with other antiretroviral agents, and co-administered with 200 mg ritonavir twice daily in an antiretroviral experienced patient who, after each of at least three different antiretroviral regimens that have included one drug from at least 3 different antiretroviral classes, has experienced virological failure or clinical failure or genotypic resistance.

Virological failure is defined as a viral load greater than 400 copies per mL on two consecutive occasions, while clinical failure is linked to emerging signs and symptoms of progressing HIV infection or treatment-limiting toxicity

**Note**

Special Pricing Arrangements apply.

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| 9610T | tipranavir 250 mg capsule, 120 | 2 | 5 | .. | *2188.63 | Aptivus | BY |

## *Nucleoside and nucleotide reverse transcriptase inhibitors*

**ABACAVIR**

# HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|
| | **Authority required**<br>Initial treatment of HIV infection in combination with other antiretroviral agents in a patient with a CD4 count of less than 500 per cubic millimetre or symptomatic HIV disease<br>**Authority required**<br>Continuing treatment of HIV infection in combination with other antiretroviral agents where the patient has previously received PBS-subsidised therapy for HIV infection | | | | | | |
| 6265R | abacavir 20 mg/mL oral liquid, 240 mL | 8 | 5 | .. | *690.07 | Ziagen | VI |
| 6264Q | abacavir 300 mg tablet, 60 | 2 | 5 | .. | *593.19 | Ziagen | VI |
| | **ADEFOVIR DIPIVOXIL**<br>**Authority required**<br>Chronic hepatitis B in a patient without cirrhosis who has failed antihepadnaviral therapy and who satisfies all of the following criteria:<br>(a) Repeatedly elevated serum ALT levels while on concurrent antihepadnaviral therapy of greater than or equal to 6 months duration in conjunction with documented chronic hepatitis B infection; or<br>(b) Repeatedly elevated HBV DNA levels one log greater than the nadir value or failure to achieve a 1 log reduction in HBV DNA within 3 months, whilst on previous antihepadnaviral therapy except in patients with evidence of poor compliance<br>**Authority required**<br>Chronic hepatitis B in a patient with cirrhosis who has failed antihepadnaviral therapy and who has detectable HBV DNA.<br>Persons with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy<br>**Note**<br>Patients may receive treatment in combination with lamivudine but not with other PBS-subsidised antihepadnaviral therapy. | | | | | | |
| 6450L | adefovir dipivoxil 10 mg tablet, 30 | 2 | 5 | .. | *1296.63 | Hepsera | GI |
| | **DIDANOSINE**<br>**Authority required**<br>Initial treatment of HIV infection in combination with other antiretroviral agents in a patient with a CD4 count of less than 500 per cubic millimetre or symptomatic HIV disease<br>**Authority required**<br>Continuing treatment of HIV infection in combination with other antiretroviral agents where the patient has previously received PBS-subsidised therapy for HIV infection | | | | | | |
| 6298L | didanosine 125 mg capsule: enteric, 30 | 2 | 5 | .. | *298.73 | Videx EC | BQ |
| 6299M | didanosine 200 mg capsule: enteric, 30 | 2 | 5 | .. | *346.51 | Videx EC | BQ |
| 6300N | didanosine 250 mg capsule: enteric, 30 | 2 | 5 | .. | *431.45 | Videx EC | BQ |
| 6301P | didanosine 400 mg capsule: enteric, 30 | 2 | 5 | .. | *686.35 | Videx EC | BQ |
| | **EMTRICITABINE**<br>**Authority required**<br>Initial treatment of HIV infection in combination with other antiretroviral agents in a patient with a CD4 count of less than 500 per cubic millimetre or symptomatic HIV disease<br>**Authority required**<br>Continuing treatment of HIV infection in combination with other antiretroviral agents where the patient has previously received PBS-subsidised therapy for HIV infection | | | | | | |
| 6137B | emtricitabine 200 mg capsule, 30 | 2 | 5 | .. | *593.19 | Emtriva | GI |
| | **ENTECAVIR**<br>**Authority required**<br>Chronic hepatitis B in a patient without cirrhosis who has failed lamivudine and who satisfies all of the following criteria:<br>(a) Repeatedly elevated serum ALT levels while on concurrent antihepadnaviral therapy of greater than or equal to 6 months duration in conjunction with documented chronic hepatitis B infection; or<br>(b) Repeatedly elevated HBV DNA levels one log greater than the nadir value or failure to achieve a 1 log reduction in HBV DNA within 3 months, whilst on previous antihepadnaviral therapy except in patients with evidence of poor compliance<br>**Authority required**<br>Chronic hepatitis B in a patient with cirrhosis who has failed lamivudine and who has detectable HBV DNA.<br>Persons with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy<br>**Note**<br>PBS-subsidised entecavir monohydrate must be used as monotherapy. | | | | | | |
| 9603K | entecavir monohydrate 1 mg tablet, 30 | 2 | 5 | .. | *1296.63 | Baraclude | BQ |
| | **ENTECAVIR** | | | | | | |

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|
| | **Authority required**<br>Chronic hepatitis B in a patient without cirrhosis who satisfies all of the following criteria:<br>(1) Elevated HBV DNA levels - greater than 20,000 IU/mL (100,000 copies/mL) if HBeAg positive, or greater than 2,000 IU/mL (10,000 copies/mL) if HBeAg negative - in conjunction with documented chronic hepatitis B infection;<br>(2) Evidence of chronic liver injury as determined by:<br>(a) Confirmed elevated serum ALT; or<br>(b) Liver biopsy<br>**Authority required**<br>Chronic hepatitis B in a patient with cirrhosis who has detectable HBV DNA.<br>Persons with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy<br>**Note**<br>PBS-subsidised entecavir monohydrate must be used as monotherapy. | | | | | | | |
| 9602J | entecavir monohydrate 500 microgram tablet, 30 | 2 | 5 | .. | *805.97 | | Baraclude | BQ |
| | **LAMIVUDINE**<br>**Authority required**<br>Initial treatment of HIV infection in combination with other antiretroviral agents in a patient with a CD4 count of less than 500 per cubic millimetre or symptomatic HIV disease<br>**Authority required**<br>Continuing treatment of HIV infection in combination with other antiretroviral agents where the patient has previously received PBS-subsidised therapy for HIV infection | | | | | | | |
| 6194B | lamivudine 10 mg/mL oral liquid, 240 mL | 8 | 5 | .. | *726.15 | | 3TC | VI |
| 6193Y | lamivudine 150 mg tablet, 60 | 2 | 5 | .. | *499.37 | [a] | 3TC | VI |
| | | | | | | [a] | Lamivudine Alphapharm | AF |
| | | | | | | [a] | Lamivudine RBX | RA |
| 6435Q | lamivudine 300 mg tablet, 30 | 2 | 5 | .. | *499.37 | [a] | 3TC | VI |
| | | | | | | [a] | Lamivudine Alphapharm | AF |
| | | | | | | [a] | Lamivudine RBX | RA |
| | **LAMIVUDINE**<br>**Authority required**<br>Chronic hepatitis B in a patient without cirrhosis who satisfies all of the following criteria:<br>(1) Elevated HBV DNA levels - greater than 20,000 IU/mL (100,000 copies/mL) if HBeAg positive, or greater than 2,000 IU/mL (10,000 copies/mL) if HBeAg negative - in conjunction with documented chronic hepatitis B infection;<br>(2) Evidence of chronic liver injury as determined by:<br>(a) Confirmed elevated serum ALT; or<br>(b) Liver biopsy<br>**Authority required**<br>Chronic hepatitis B in a patient with cirrhosis who has detectable HBV DNA.<br>Persons with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy | | | | | | | |
| 6257H | lamivudine 100 mg tablet, 28 | 2 | 5 | .. | *267.61 | [a] | Zeffix | AS |
| | | | | | | [a] | Zetlam | AF |
| 6271C | lamivudine 5 mg/mL oral liquid, 240 mL | 5 | 5 | .. | *370.18 | | Zeffix | AS |
| | **STAVUDINE**<br>**Authority required**<br>Initial treatment of HIV infection in combination with other antiretroviral agents in a patient with a CD4 count of less than 500 per cubic millimetre or symptomatic HIV disease<br>**Authority required**<br>Continuing treatment of HIV infection in combination with other antiretroviral agents where the patient has previously received PBS-subsidised therapy for HIV infection | | | | | | | |
| 6186N | stavudine 20 mg capsule, 60 | 2 | 5 | .. | *589.03 | | Zerit | BQ |
| 6189R | stavudine 30 mg capsule, 60 | 2 | 5 | .. | *700.69 | | Zerit | BQ |
| 6190T | stavudine 40 mg capsule, 60 | 2 | 5 | .. | *932.03 | | Zerit | BQ |
| | **TELBIVUDINE**<br>**Authority required** | | | | | | | |

# HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|
| | Treatment, as sole PBS-subsidised therapy, in a patient with chronic hepatitis B without cirrhosis who is nucleoside analogue naive and satisfies all of the following criteria:<br>(1) Elevated HBV DNA levels - greater than 20,000 IU/mL (100,000 copies/mL) if HBeAg positive, or greater than 2,000 IU/mL (10,000 copies/mL) if HBeAg negative - in conjunction with documented hepatitis B infection;<br>(2) Evidence of chronic liver injury as determined by:<br>(a) Confirmed elevated serum ALT; or<br>(b) Liver biopsy<br>**Authority required**<br>Treatment, as sole PBS-subsidised therapy, in a patient with chronic hepatitis B with cirrhosis who is nucleoside analogue naive and who has detectable HBV DNA.<br>Persons with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy | | | | | | |
| 9630W | telbivudine 600 mg tablet, 28 | 2 | 5 | .. | *528.47 | Sebivo | NV |
| | **TENOFOVIR**<br>**Authority required**<br>Initial treatment of HIV infection in combination with other antiretroviral agents in a patient with a CD4 count of less than 500 per cubic millimetre or symptomatic HIV disease<br>**Authority required**<br>Continuing treatment of HIV infection in combination with other antiretroviral agents where the patient has previously received PBS-subsidised therapy for HIV infection<br>**Authority required**<br>Treatment, as sole PBS-subsidised therapy, in a patient with chronic hepatitis B without cirrhosis who is nucleoside analogue naive and satisfies all of the following criteria:<br>(1) Elevated HBV DNA levels - greater than 20,000 IU/mL (100,000 copies/mL) if HBeAg positive, or greater than 2,000 IU/mL (10,000 copies/mL) if HBeAg negative - in conjunction with documented hepatitis B infection;<br>(2) Evidence of chronic liver injury as determined by:<br>(a) Confirmed elevated serum ALT; or<br>(b) Liver biopsy<br>**Authority required**<br>Treatment, as sole PBS-subsidised therapy, in a patient with chronic hepatitis B with cirrhosis who is nucleoside analogue naive and who has detectable HBV DNA.<br>Persons with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy<br>**Authority required**<br>Chronic hepatitis B in a patient without cirrhosis who has failed antihepadnaviral therapy and who satisfies all of the following criteria:<br>(a) Repeatedly elevated serum ALT levels while on concurrent antihepadnaviral therapy of greater than or equal to 6 months duration in conjunction with documented chronic hepatitis B infection; or<br>(b) Repeatedly elevated HBV DNA levels one log greater than the nadir value or failure to achieve a 1 log reduction in HBV DNA within 3 months, whilst on previous antihepadnaviral therapy except in patients with evidence of poor compliance<br>**Authority required**<br>Chronic hepatitis B in a patient with cirrhosis who has failed antihepadnaviral therapy and who has detectable HBV DNA.<br>Persons with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy<br>**Note**<br>Patients may receive treatment in combination with lamivudine but not with other PBS-subsidised antihepadnaviral therapy. | | | | | | |
| 6358P | tenofovir disoproxil fumarate 300 mg tablet, 30 | 2 | 5 | .. | *1011.47 | Viread | GI |
| | **ZIDOVUDINE**<br>**Authority required**<br>Initial treatment of HIV infection in combination with other antiretroviral agents in a patient with a CD4 count of less than 500 per cubic millimetre or symptomatic HIV disease<br>**Authority required**<br>Continuing treatment of HIV infection in combination with other antiretroviral agents where the patient has previously received PBS-subsidised therapy for HIV infection | | | | | | |
| 6153W | zidovudine 100 mg capsule, 100 | 4 | 5 | .. | *861.35 | Retrovir | VI |
| 6154X | zidovudine 250 mg capsule, 40 | 6 | 5 | .. | *1279.41 | Retrovir | VI |
| 6155Y | zidovudine 50 mg/5 mL oral liquid, 200 mL | 15 | 5 | .. | *706.83 | Retrovir | VI |

## *Non-nucleoside reverse transcriptase inhibitors*

# HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|
| | **EFAVIRENZ** | | | | | | | |
| | **Authority required** | | | | | | | |
| | Initial treatment of HIV infection in combination with other antiretroviral agents in a patient with a CD4 count of less than 500 per cubic millimetre or symptomatic HIV disease | | | | | | | |
| | **Authority required** | | | | | | | |
| | Continuing treatment of HIV infection in combination with other antiretroviral agents where the patient has previously received PBS-subsidised therapy for HIV infection | | | | | | | |
| 9618F | efavirenz 200 mg tablet, 90 | 2 | 5 | .. | *571.51 | | Stocrin | MK |
| 6372J | efavirenz 30 mg/mL oral liquid, 180 mL | 7 | 5 | .. | *599.74 | | Stocrin | MK |
| 6356M | efavirenz 600 mg tablet, 30 | 2 | 5 | .. | *571.51 | | Stocrin | MK |
| | **ETRAVIRINE** | | | | | | | |
| | **Authority required** | | | | | | | |
| | Treatment of HIV infection, in addition to optimised background therapy in combination with other antiretroviral agents in an antiretroviral experienced patient who, after each of at least three different antiretroviral regimens that have included one drug from at least 3 different antiretroviral classes, has experienced virological failure or clinical failure or genotypic resistance. | | | | | | | |
| | Virological failure is defined as a viral load greater than 400 copies per mL on two consecutive occasions, while clinical failure is linked to emerging signs and symptoms of progressing HIV infection or treatment-limiting toxicity | | | | | | | |
| 5062K | etravirine 200 mg tablet, 60 | 2 | 5 | .. | *1279.63 | | Intelence | JC |
| | **NEVIRAPINE** | | | | | | | |
| | **Authority required** | | | | | | | |
| | Initial treatment of HIV infection in combination with other antiretroviral agents in a patient with a CD4 count of less than 500 per cubic millimetre or symptomatic HIV disease | | | | | | | |
| | **Authority required** | | | | | | | |
| | Continuing treatment of HIV infection in combination with other antiretroviral agents where the patient has previously received PBS-subsidised therapy for HIV infection | | | | | | | |
| 9571R | nevirapine 10 mg/mL oral liquid, 240 mL | 10 | 5 | .. | *1396.63 | | Viramune | BY |
| 6215D | nevirapine 200 mg tablet, 60 | 2 | 5 | .. | *481.15 | [a] | Nevirapine Alphapharm | AF |
| | | | | | | [a] | Nevirapine RBX | RA |
| | | | | | | [a] | Viramune | BY |
| | **NEVIRAPINE** | | | | | | | |
| | **Authority required** | | | | | | | |
| | Initial treatment of HIV infection in combination with other antiretroviral agents in a patient who has been stabilised on nevirapine immediate release with a CD4 count of less than 500 per cubic millimetre or symptomatic HIV disease | | | | | | | |
| | **Authority required** | | | | | | | |
| | Continuing treatment of HIV infection in combination with other antiretroviral agents where the patient has previously received PBS-subsidised therapy for HIV infection | | | | | | | |
| 1129K | nevirapine 400 mg tablet: modified release, 30 tablets | 2 | 5 | .. | *481.15 | | Viramune XR | BY |
| | **RILPIVIRINE** | | | | | | | |
| | **Authority required** | | | | | | | |
| | Initial treatment of HIV infection in combination with other antiretroviral agents in a patient with a CD4 count of less than 500 per cubic millimetre or symptomatic HIV disease | | | | | | | |
| | **Authority required** | | | | | | | |
| | Continuing treatment of HIV infection in combination with other antiretroviral agents where the patient has previously received PBS-subsidised therapy for HIV infection | | | | | | | |
| 1170N | rilpivirine 25 mg tablet, 30 | 2 | 5 | .. | *571.51 | | Edurant | JC |
| | ***Antivirals for treatment of HIV infections, combinations*** | | | | | | | |
| | **ABACAVIR + LAMIVUDINE** | | | | | | | |
| | **Authority required** | | | | | | | |
| | Initial treatment of HIV infection in combination with other antiretroviral agents in a patient over 12 years of age, weighing 40 kg or more, with a CD4 count of less than 500 per cubic millimetre or symptomatic HIV disease | | | | | | | |
| | **Authority required** | | | | | | | |
| | Continuing treatment of HIV infection in combination with other antiretroviral agents where the patient over 12 years of age, weighing 40 kg or more, has previously received PBS-subsidised therapy for HIV infection | | | | | | | |
| 6458X | abacavir 600 mg + lamivudine 300 mg tablet, 30 | 2 | 5 | .. | *1084.41 | | Kivexa | VI |
| | **ABACAVIR + LAMIVUDINE + ZIDOVUDINE** | | | | | | | |
| | **Authority required** | | | | | | | |
| | Initial treatment of HIV infection in a patient over 12 years of age, weighing 40 kg or more, with a CD4 count of less than 500 per cubic millimetre or | | | | | | | |

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|---|---|---|---|---|---|---|---|---|
| | symptomatic HIV disease | | | | | | | |
| | **Authority required** | | | | | | | |
| | Continuing treatment of HIV infection where the patient over 12 years of age, weighing 40 kg or more, has previously received PBS-subsidised therapy for HIV infection | | | | | | | |
| 6327B | abacavir 300 mg + lamivudine 150 mg + zidovudine 300 mg tablet, 60 | 2 | 5 | .. | *1661.29 | | Trizivir | VI |
| | **EMTRICITABINE + RILPIVIRINE + TENOFOVIR** | | | | | | | |
| | **Authority required** | | | | | | | |
| | Initial treatment of HIV infection in a patient with a CD4 count of less than 500 per cubic millimetre or symptomatic HIV disease | | | | | | | |
| | **Authority required** | | | | | | | |
| | Continuing treatment of HIV infection where the patient has previously received PBS-subsidised therapy for HIV infection | | | | | | | |
| 1490K | emtricitabine 200 mg + rilpivirine 25 mg + tenofovir disoproxil fumarate 300 mg tablet, 30 | 2 | 5 | .. | *2119.99 | | Eviplera | GI |
| | **LAMIVUDINE + ZIDOVUDINE** | | | | | | | |
| | **Authority required** | | | | | | | |
| | Initial treatment of HIV infection in combination with other antiretroviral agents in a patient with a CD4 count of less than 500 per cubic millimetre or symptomatic HIV disease | | | | | | | |
| | **Authority required** | | | | | | | |
| | Continuing treatment of HIV infection in combination with other antiretroviral agents where the patient has previously received PBS-subsidised therapy for HIV infection | | | | | | | |
| 6234D | lamivudine 150 mg + zidovudine 300 mg tablet, 60 | 2 | 5 | .. | *1013.71 | [a] | Combivir | VI |
| | | | | | | [a] | Lamivudine 150 mg + Zidovudine 300 mg Alphapharm | AF |
| | **LOPINAVIR + RITONAVIR** | | | | | | | |
| | **Authority required** | | | | | | | |
| | Initial treatment of HIV infection in combination with other antiretroviral agents in a patient with a CD4 count of less than 500 per cubic millimetre or symptomatic HIV disease | | | | | | | |
| | **Authority required** | | | | | | | |
| | Continuing treatment of HIV infection in combination with other antiretroviral agents where the patient has previously received PBS-subsidised therapy for HIV infection | | | | | | | |
| 9633B | lopinavir 100 mg + ritonavir 25 mg tablet, 60 | 2 | 5 | .. | *362.83 | | Kaletra | VE |
| 6495W | lopinavir 200 mg + ritonavir 50 mg tablet, 120 | 2 | 5 | .. | *1416.63 | | Kaletra | VE |
| 6341R | lopinavir 400 mg/5 mL + ritonavir 100 mg/5 mL oral liquid, 60 mL | 10 | 5 | .. | *1336.63 | | Kaletra | VE |
| | **TENOFOVIR + EMTRICITABINE** | | | | | | | |
| | **Authority required** | | | | | | | |
| | Initial treatment of HIV infection in combination with other antiretroviral agents in a patient with a CD4 count of less than 500 per cubic millimetre or symptomatic HIV disease | | | | | | | |
| | **Authority required** | | | | | | | |
| | Continuing treatment of HIV infection in combination with other antiretroviral agents where the patient has previously received PBS-subsidised therapy for HIV infection | | | | | | | |
| 6468K | tenofovir disoproxil fumarate 300 mg + emtricitabine 200 mg tablet, 30 | 2 | 5 | .. | *1576.83 | | Truvada | GI |
| | **TENOFOVIR + EMTRICITABINE + EFAVIRENZ** | | | | | | | |
| | **Authority required** | | | | | | | |
| | Initial treatment of HIV infection in a patient with a CD4 count of less than 500 per cubic millimetre or symptomatic HIV disease | | | | | | | |
| | **Authority required** | | | | | | | |
| | Continuing treatment of HIV infection where the patient has previously received PBS-subsidised therapy for HIV infection | | | | | | | |
| 9650X | tenofovir disoproxil fumarate 300 mg + emtricitabine 200 mg + efavirenz 600 mg tablet, 30 | 2 | 5 | .. | *2119.99 | | Atripla | GI |

## *Other antivirals*

**ENFUVIRTIDE**

**Authority required**

Treatment of HIV infection, in addition to optimised background therapy in combination with other antiretroviral agents in an antiretroviral experienced patient who, after each of at least three different antiretroviral regimens that have included one drug from at least 3 different antiretroviral classes, has experienced virological failure or clinical failure or genotypic resistance.

Virological failure is defined as a viral load greater than 400 copies per mL on two consecutive occasions, while clinical failure is linked to emerging

# HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|
| | signs and symptoms of progressing HIV infection or treatment-limiting toxicity | | | | | | |
| 6455R | enfuvirtide 90 mg injection [60 x 90 mg vials] (&) inert substance diluent [60 x 1.1 mL vials], 1 pack | 2 | 5 | .. | *4472.63 | Fuzeon | RO |
| | **MARAVIROC** | | | | | | |
| | **Authority required** | | | | | | |
| | Treatment, in addition to optimised background therapy in combination with other antiretroviral agents, of an antiretroviral experienced patient infected with only CCR5-tropic HIV-1, who, after each of at least three different antiretroviral regimens that have included one drug from at least 3 different antiretroviral classes, has experienced virological failure or clinical failure or genotypic resistance. A tropism assay to determine CCR5 only strain status is required prior to initiation. Individuals with CXCR4 tropism demonstrated at any time point are not eligible. | | | | | | |
| | Virological failure is defined as a viral load greater than 400 copies per mL on two consecutive occasions, while clinical failure is linked to emerging signs and symptoms of progressing HIV infection or treatment-limiting toxicity | | | | | | |
| 9572T | maraviroc 150 mg tablet, 60 | 2 | 5 | .. | *1882.03 | Celsentri | VI |
| 9573W | maraviroc 300 mg tablet, 60 | 2 | 5 | .. | *1882.03 | Celsentri | VI |
| | **RALTEGRAVIR** | | | | | | |
| | **Authority required** | | | | | | |
| | Initial treatment of HIV infection in combination with other antiretroviral agents in a patient with a CD4 count of less than 500 per cubic millimetre or symptomatic HIV disease | | | | | | |
| | **Authority required** | | | | | | |
| | Continuing treatment of HIV infection in combination with other antiretroviral agents where the patient has previously received PBS-subsidised therapy for HIV infection | | | | | | |
| 9629T | raltegravir 400 mg tablet, 60 | 2 | 5 | .. | *1377.73 | Isentress | MK |

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Brand Name and Manufacturer | |
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# ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

## ANTINEOPLASTIC AGENTS

### ANTIMETABOLITES

#### *Pyrimidine analogues*

**AZACITIDINE**

**Authority required**

Initial PBS-subsidised treatment of a patient with:

(1) Myelodysplastic syndrome classified as Intermediate-2 or high risk according to the International Prognostic Scoring System (IPSS); OR

(2) Chronic Myelomonocytic Leukaemia (10% to 29% marrow blasts without Myeloproliferative Disorder); OR

(3) Acute Myeloid Leukaemia with 20 to 30% marrow blasts and multi-lineage dysplasia, according to World Health Organisation (WHO) Classification.

Classification of a patient as Intermediate-2 requires a score of 1.5 to 2.0 on the IPSS, achieved with the possible combinations:

1. 11% to 30% marrow blasts with good karyotypic status (normal, -Y alone, del(5q) alone, del(20q) alone), and 0 to 1 cytopenias; OR
2. 11% to 20% marrow blasts with intermediate karyotypic status (other abnormalities), and 0 to 1 cytopenias; OR
3. 11% to 20% marrow blasts with good karyotypic status (normal, -Y alone, del(5q) alone, del(20q) alone), and 2 to 3 cytopenias; OR
4. 5% to 10% marrow blasts with poor karyotypic status (3 or more abnormalities or chromosome 7 anomalies), regardless of cytopenias; OR
5. 5% to 10% marrow blasts with intermediate karyotypic status (other abnormalities), and 2 to 3 cytopenias; OR
6. less than 5% marrow blasts with poor karyotypic status (3 or more abnormalities or chromosome 7 anomalies), and 2 to 3 cytopenias.

Classification of a patient as high risk requires a score of 2.5 or more on the IPSS, achieved with the possible combinations:

1. 21% to 30% marrow blasts with good karyotypic status (normal, -Y alone, del(5q) alone, del(20q) alone), and 2 to 3 cytopenias; OR
2. 21% to 30% marrow blasts with intermediate (other abnormalities) or poor karyotypic status (3 or more abnormalities or chromosome 7 anomalies), regardless of cytopenias; OR
3. 11% to 20% marrow blasts with poor karyotypic status (3 or more abnormalities or chromosome 7 anomalies), regardless of cytopenias; OR
4. 11% to 20% marrow blasts with intermediate karyotypic status (other abnormalities), and 2 to 3 cytopenias.

The first authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Azacitidine PBS Authority Application - Supporting Information Form; and

(c) a copy of the bone marrow biopsy report demonstrating that the patient has myelodysplastic syndrome, chronic myelomonocytic leukaemia or acute myeloid leukaemia; and

(d) a copy of the full blood examination report; and

(e) for myelodysplastic syndrome, a copy of the pathology report detailing the cytogenetics demonstrating intermediate-2 or high risk disease according to the International Prognostic Scoring System (IPSS); and

(f) a signed patient acknowledgment form.

No more than three cycles will be authorised

**Note**

Any queries concerning the arrangements to prescribe azacitidine may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe azacitidine should be forwarded to:

Medicare Australia

Prior Written Approval of Specialised Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

**Note**

Special Pricing Arrangements apply.

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| 6100C | azacitidine 100 mg injection, 1 x 100 mg vial | 14 | 2 | .. | *7746.67 | Vidaza | CJ |

**AZACITIDINE**

**Authority required**

Continuing treatment of a patient with:

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|
| | (1) Myelodysplastic syndrome classified as Intermediate-2 or high risk according to the International Prognostic Scoring System (IPSS); OR | | | | | | |
| | (2) Chronic Myelomonocytic Leukaemia (10% to 29% marrow blasts without Myeloproliferative Disorder); OR | | | | | | |
| | (3) Acute Myeloid Leukaemia with 20 to 30% blasts and multi-lineage dysplasia, according to World Health Organisation (WHO) Classification; | | | | | | |
| | who has previously been issued with an authority prescription for azacitidine and does not have progressive disease. | | | | | | |
| | Authority applications for continuing treatment may be made by telephone on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). | | | | | | |
| | Up to six cycles will be authorised | | | | | | |
| | **Note** | | | | | | |
| | Any queries concerning the arrangements to prescribe azacitidine may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). | | | | | | |
| | Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au. | | | | | | |
| | Written applications for authority to prescribe azacitidine should be forwarded to: | | | | | | |
| | Medicare Australia | | | | | | |
| | Prior Written Approval of Specialised Drugs | | | | | | |
| | Reply Paid 9826 | | | | | | |
| | GPO Box 9826 | | | | | | |
| | HOBART TAS 7001 | | | | | | |
| | **Note** | | | | | | |
| | Special Pricing Arrangements apply. | | | | | | |
| 6138C | azacitidine 100 mg injection, 1 x 100 mg vial | 14 | 5 | .. | *7746.67 | Vidaza | CJ |

## CYTOTOXIC ANTIBIOTICS AND RELATED SUBSTANCES

### *Anthracyclines and related substances*

**DOXORUBICIN HYDROCHLORIDE-PEGYLATED LIPOSOMAL**

**Authority required**

Treatment of AIDS-related Kaposi's sarcoma in patients with CD4 cell counts of less than 200 per cubic millimetre and extensive mucocutaneous involvement

**Authority required**

Treatment of AIDS-related Kaposi's sarcoma in patients with CD4 cell counts of less than 200 per cubic millimetre and extensive visceral involvement

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| 6249X | doxorubicin hydrochloride-pegylated liposomal 20 mg/10 mL injection, 1 x 10 mL vial | 4 | 5 | .. | *2538.59 | Caelyx | JC |
| | | | | | | Lipodox | ZF |

## IMMUNOSTIMULANTS

## IMMUNOSTIMULANTS

### *Colony stimulating factors*

**FILGRASTIM**

**Authority required**

For use in a patient undergoing induction and consolidation therapy for acute myeloid leukaemia

**Authority required**

Mobilisation of peripheral blood progenitor cells to facilitate harvest of such cells for autologous transplantation into a patient with a non-myeloid malignancy who has had myeloablative or myelosuppressive therapy

**Authority required**

A patient receiving chemotherapy for myeloma who has had a prior episode of febrile neutropenia, and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned

**Authority required**

A patient with severe congenital neutropenia (absolute neutrophil count of less than 100 million cells per litre measured on 3 occasions, with readings at least 2 weeks apart, and in whom a bone marrow examination has shown evidence of maturational arrest of the neutrophil lineage)

**Authority required**

A patient with severe chronic neutropenia (absolute neutrophil count of less than 1,000 million cells per litre measured on 3 occasions, with readings at least 2 weeks apart, or evidence of neutrophil dysfunction, and, either having experienced a life-threatening infectious episode requiring hospitalisation and treatment with intravenous antibiotics in the previous 12 months, or having recurrent clinically significant infections (a minimum of 3 in the previous 12 months))

**Authority required**

A patient with chronic cyclic neutropenia (absolute neutrophil count of less than 500 million cells per litre lasting for 3 days per cycle, measured over 3 separate cycles, and, either having experienced a life-threatening infectious episode requiring hospitalisation and treatment with intravenous

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| | antibiotics, or having recurrent clinically significant infections (a minimum of 3 in the previous 12 months)) | | | | | | |
| | **Authority required**<br>A patient with inoperable Stage III, IVa or IVb squamous cell carcinoma of the oral cavity, larynx, oropharynx or hypopharynx receiving neoadjuvant treatment with docetaxel in combination with cisplatin and fluorouracil who has had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned | | | | | | |
| | **Authority required**<br>Mobilisation of peripheral blood progenitor cells, in a normal volunteer, for use in allogeneic transplantation | | | | | | |
| | **Authority required**<br>A patient receiving marrow-ablative chemotherapy and subsequent bone marrow transplantation | | | | | | |
| | **Authority required**<br>A patient with a non-myeloid malignancy receiving marrow-ablative chemotherapy and subsequent autologous peripheral blood progenitor cell transplantation | | | | | | |
| | **Authority required**<br>A patient with breast cancer receiving standard dose adjuvant chemotherapy who has had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned | | | | | | |
| | **Authority required**<br>A patient receiving chemotherapy for B-cell chronic lymphocytic leukaemia with fludarabine and cyclophosphamide who has had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned | | | | | | |
| | **Authority required**<br>A patient receiving first-line chemotherapy for Hodgkin disease who has had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned | | | | | | |
| | **Authority required**<br>A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in acute lymphoblastic leukaemia | | | | | | |
| | **Authority required**<br>A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in breast cancer (adjuvant chemotherapy with docetaxel in combination with an anthracycline and cyclophosphamide) | | | | | | |
| | **Authority required**<br>A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in germ cell tumours | | | | | | |
| | **Authority required**<br>A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in infants and children with CNS tumours | | | | | | |
| | **Authority required**<br>A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in neuroblastoma | | | | | | |
| | **Authority required**<br>A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in non-Hodgkin lymphoma (aggressive grades; or low grade receiving an anthracycline-containing regimen) | | | | | | |
| | **Authority required**<br>A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in relapsed Hodgkin disease | | | | | | |
| | **Authority required**<br>A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in sarcoma | | | | | | |
| | **Authority required**<br>A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in Hodgkin disease (first-line chemotherapy with escalated BEACOPP) | | | | | | |
| 5830W | filgrastim 120 microgram/0.2 mL injection, 10 x 0.2 mL syringes | 2 | 11 | .. | *1052.85 | Nivestim | HH |
| 1082Y | filgrastim 300 microgram/0.5 mL injection, 10 x 0.5 mL syringes | 2 | 11 | .. | *2562.17 | TevaGrastim | AS |
| 6291D | filgrastim 300 microgram/0.5 mL injection, 10 x 0.5 mL syringes | 2 | 11 | .. | *2562.17 | Neupogen | AN |
| 9693E | filgrastim 300 microgram/0.5 mL injection, 10 x 0.5 mL syringes | 2 | 11 | .. | *2562.17 | Nivestim | HH |
| 6126K | filgrastim 300 microgram/mL injection, 10 x 1 mL vials | 2 | 11 | .. | *2562.17 | Neupogen | AN |
| 6292E | filgrastim 480 microgram/0.5 mL injection, 10 x 0.5 mL | 2 | 11 | .. | *4079.21 | Neupogen | AN |

# HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

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|---|---|---|---|---|---|---|---|
| | syringes | | | | | | |
| 9695G | filgrastim 480 microgram/0.5 mL injection, 10 x 0.5 mL syringes | 2 | 11 | .. | *4079.21 | Nivestim | HH |
| 1113N | filgrastim 480 microgram/0.8 mL injection, 10 x 0.8 mL syringes | 2 | 11 | .. | *4079.21 | TevaGrastim | AS |
| 6127L | filgrastim 480 microgram/1.6 mL injection, 10 x 1.6 mL vials | 2 | 11 | .. | *4079.21 | Neupogen | AN |

**LENOGRASTIM**

**Authority required**

Mobilisation of peripheral blood progenitor cells to facilitate harvest of such cells for reinfusion into patients with non-myeloid malignancies who have had myeloablative or myelosuppressive therapy

**Authority required**

Mobilisation of peripheral blood progenitor cells, in normal volunteers, for use in allogeneic transplantation to facilitate harvest of such cells in healthy donors

**Authority required**

Patients with non-myeloid malignancies receiving marrow-ablative chemotherapy and subsequent peripheral blood progenitor cell or bone marrow transplantation

**Authority required**

Patients with breast cancer receiving standard dose adjuvant chemotherapy who have had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned

**Authority required**

Patients receiving first-line chemotherapy for Hodgkin's disease who have had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned

**Authority required**

Patients being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in relapsed Hodgkin's disease

**Authority required**

Patients being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in rhabdomyosarcoma

**Authority required**

Patients being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in Ewing's sarcoma

**Authority required**

Patients being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in germ cell tumours

**Authority required**

Patients being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in infants and children with CNS tumours

**Authority required**

Patients being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in neuroblastoma

**Authority required**

Patients being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in non-Hodgkin's lymphoma (intermediate or high grade)

**Authority required**

Patients being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in osteosarcoma

**Authority required**

Patients being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in acute lymphoblastic leukaemia

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| 6337M | LENOGRASTIM Powder for injection 13,400,000 i.u. (105 micrograms) vial, 10 | 2 | 11 | .. | *1071.63 | Granocyte 13 | HH |
| 6338N | LENOGRASTIM Powder for injection 33,600,000 i.u. (263 micrograms) vial, 10 | 2 | 11 | .. | *2613.83 | Granocyte 34 | HH |

**PEGFILGRASTIM**

**Authority required**

For use in a patient undergoing induction and consolidation therapy for acute myeloid leukaemia

**Authority required**

A patient with breast cancer receiving standard dose adjuvant chemotherapy who has had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned

**Authority required**

# HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

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|---|---|---|---|---|---|---|---|
| | A patient receiving chemotherapy for B-cell chronic lymphocytic leukaemia with fludarabine and cyclophosphamide who has had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned | | | | | | |
| | **Authority required**<br>A patient receiving first-line chemotherapy for Hodgkin disease who has had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned | | | | | | |
| | **Authority required**<br>A patient receiving chemotherapy for myeloma who has had a prior episode of febrile neutropenia, and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned | | | | | | |
| | **Authority required**<br>A patient with inoperable Stage III, IVa or IVb squamous cell carcinoma of the oral cavity, larynx, oropharynx or hypopharynx receiving neoadjuvant treatment with docetaxel in combination with cisplatin and fluorouracil who has had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned | | | | | | |
| | **Authority required**<br>A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in acute lymphoblastic leukaemia | | | | | | |
| | **Authority required**<br>A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in breast cancer (adjuvant chemotherapy with docetaxel in combination with an anthracycline and cyclophosphamide) | | | | | | |
| | **Authority required**<br>A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in germ cell tumours | | | | | | |
| | **Authority required**<br>A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in infants and children with CNS tumours | | | | | | |
| | **Authority required**<br>A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in neuroblastoma | | | | | | |
| | **Authority required**<br>A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in non-Hodgkin lymphoma (aggressive grades; or low grade receiving an anthracycline-containing regimen) | | | | | | |
| | **Authority required**<br>A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in relapsed Hodgkin disease | | | | | | |
| | **Authority required**<br>A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in sarcoma | | | | | | |
| | **Authority required**<br>A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in Hodgkin disease (first-line chemotherapy with escalated BEACOPP) | | | | | | |
| 6363X | pegfilgrastim 6 mg/0.6 mL injection, 1 x 0.6 mL syringe | 1 | 11 | .. | 1971.63 | Neulasta | AN |

## *Interferons*

**INTERFERON ALFA-2A**

**Authority required**
Use in the treatment of Philadelphia chromosome positive myelogenous leukaemia in the chronic phase

**Authority required**
Chronic hepatitis B in a patient without cirrhosis who satisfies all of the following criteria:

(1) Elevated HBV DNA levels - greater than 20,000 IU/mL (100,000 copies/mL) if HBeAg positive, or greater than 2,000 IU/mL (10,000 copies/mL) if HBeAg negative - in conjunction with documented chronic hepatitis B infection;

(2) Evidence of chronic liver injury as determined by:

(a) Confirmed elevated serum ALT; or

(b) Liver biopsy

**Authority required**
Chronic hepatitis B in a patient with cirrhosis who has detectable HBV DNA.

Persons with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy

**Caution**

# HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

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| | Treatment with interferon alfa has been associated with depression and suicide in some patients. Patients with a history of suicidal ideation or depressive illness should be warned of the risks. Psychiatric status during therapy should be monitored. | | | | | | |
| 6210W | interferon alfa-2a 3 million international units/0.5 mL injection, 1 x 0.5 mL syringe | 30 | 5 | .. | *936.33 | Roferon-A | RO |
| 6211X | interferon alfa-2a 4.5 million international units/0.5 mL injection, 1 x 0.5 mL syringe | 30 | 5 | .. | *1387.53 | Roferon-A | RO |
| 6212Y | interferon alfa-2a 6 million international units/0.5 mL injection, 1 x 0.5 mL syringe | 30 | 5 | .. | *1833.93 | Roferon-A | RO |
| 6213B | interferon alfa-2a 9 million international units/0.5 mL injection, 1 x 0.5 mL syringe | 30 | 5 | .. | *2727.93 | Roferon-A | RO |
| | **INTERFERON ALFA-2B** | | | | | | |
| | **Authority required** | | | | | | |
| | Adjunctive therapy of malignant melanoma following surgery in patients with nodal involvement | | | | | | |
| | **Authority required** | | | | | | |
| | Use in the treatment of Philadelphia chromosome positive myelogenous leukaemia in the chronic phase | | | | | | |
| | **Authority required** | | | | | | |
| | Chronic hepatitis B in a patient without cirrhosis who satisfies all of the following criteria: | | | | | | |
| | (1) Elevated HBV DNA levels - greater than 20,000 IU/mL (100,000 copies/mL) if HBeAg positive, or greater than 2,000 IU/mL (10,000 copies/mL) if HBeAg negative - in conjunction with documented chronic hepatitis B infection; | | | | | | |
| | (2) Evidence of chronic liver injury as determined by: | | | | | | |
| | (a) Confirmed elevated serum ALT; or | | | | | | |
| | (b) Liver biopsy | | | | | | |
| | **Authority required** | | | | | | |
| | Chronic hepatitis B in a patient with cirrhosis who has detectable HBV DNA. | | | | | | |
| | Persons with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy | | | | | | |
| | **Caution** | | | | | | |
| | Treatment with interferon alfa has been associated with depression and suicide in some patients. Patients with a history of suicidal ideation or depressive illness should be warned of the risks. Psychiatric status during therapy should be monitored. | | | | | | |
| 6246R | interferon alfa-2b 10 million international units/mL injection, 5 x 1 mL vials | 3 | 5 | .. | *1536.12 | Intron A | MK |
| 6253D | interferon alfa-2b 18 million international units/1.2 mL injection, 1 x 1.2 mL cartridge | 2 | 5 | .. | *378.41 | Intron A Redipen | MK |
| 6218G | interferon alfa-2b 18 million international units/3 mL injection, 1 x 3 mL vial | 15 | 5 | .. | *2727.78 | Intron A | MK |
| 6219H | interferon alfa-2b 25 million international units/2.5 mL injection, 1 x 2.5 mL vial | 15 | 5 | .. | *3770.43 | Intron A | MK |
| 6254E | interferon alfa-2b 30 million international units/1.2 mL injection, 1 x 1.2 mL cartridge | 2 | 5 | .. | *626.27 | Intron A Redipen | MK |
| 6255F | interferon alfa-2b 60 million international units/1.2 mL injection, 1 x 1.2 mL cartridge | 2 | 5 | .. | *1238.23 | Intron A Redipen | MK |
| | **INTERFERON GAMMA-1B** | | | | | | |
| | **Authority required** | | | | | | |
| | Treatment of chronic granulomatous disease in patients with frequent and severe infections despite adequate prophylaxis with antimicrobial agents | | | | | | |
| 6148N | interferon gamma-1b 2 million international units (100 microgram/0.5 mL) injection, 6 x 0.5 mL vials | 2 | 11 | .. | *2768.43 | Imukin | BY |
| | **PEGINTERFERON ALFA-2A** | | | | | | |
| | **Authority required** | | | | | | |
| | Treatment, as sole PBS-subsidised therapy, in a patient with chronic hepatitis B without cirrhosis who satisfies all of the following criteria: | | | | | | |
| | (1) Elevated HBV DNA levels - greater than 20,000 IU/mL (100,000 copies/mL) if HBeAg positive, or greater than 2,000 IU/mL (10,000 copies/mL) if HBeAg negative - in conjunction with documented chronic hepatitis B infection; | | | | | | |
| | (2) Evidence of chronic liver injury as determined by: | | | | | | |
| | (a) Confirmed elevated serum ALT; or | | | | | | |
| | (b) Liver biopsy; | | | | | | |
| | (3) Has received no prior peginterferon alfa therapy for the treatment of hepatitis B | | | | | | |
| | **Authority required** | | | | | | |
| | Treatment, as sole PBS-subsidised therapy, in a patient with chronic hepatitis B with cirrhosis who has detectable HBV DNA. | | | | | | |
| | Persons with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy. | | | | | | |

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| | Treatment is limited to 1 course of treatment for a duration of up to 48 weeks | | | | | | |
| | **Authority required**<br>Treatment, managed by an accredited treatment centre, of chronic hepatitis C in patients 18 years or older who have compensated liver disease and who have received no prior interferon alfa or peginterferon alfa treatment for hepatitis C and have a contraindication to ribavirin, who satisfy all of the following criteria:<br>(1) Documented chronic hepatitis C infection (repeatedly anti-HCV positive and HCV RNA positive);<br>(2) Female patients of child-bearing age are not pregnant, not breast-feeding, and are using an effective form of contraception.<br>The treatment course is limited to up to 48 weeks.<br>Patients may only continue treatment after the first 12 weeks if the result of an HCV RNA quantitative assay (performed at the same laboratory using the same test) shows that the plasma HCV RNA has become undetectable or the viral load has decreased by at least a 2 log drop | | | | | | |
| | **Caution**<br>Treatment with peginterferon alfa has been associated with depression and suicide in some patients. Patients with a history of suicidal ideation or depressive illness should be warned of the risks. Psychiatric status during therapy should be monitored. | | | | | | |
| | **Note**<br>Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C:<br>(a) a nurse educator/counsellor for patients; and<br>(b) 24 hour access by patients to medical advice; and<br>(c) an established liver clinic; and<br>(d) facilities for safe liver biopsy. | | | | | | |
| 6439X | peginterferon alfa-2a 135 microgram/0.5 mL injection, 4 x 0.5 mL syringes | 2 | 5 | .. | *2378.43 | Pegasys | RO |
| 6449K | peginterferon alfa-2a 180 microgram/0.5 mL injection, 4 x 0.5 mL syringes | 2 | 5 | .. | *2747.09 | Pegasys | RO |
| | **PEGINTERFERON ALFA-2A (&) RIBAVIRIN**<br>**Authority required**<br>Chronic genotype 1 hepatitis C infection<br>**The Treatment criteria is:**<br>Must be treated in an accredited treatment centre,<br>**AND the Clinical criteria is:**<br>Patient must have compensated liver disease,<br>**AND the Clinical criteria is:**<br>Patient must have failed prior treatment with interferon based therapies (non-pegylated or pegylated),<br>**AND the Clinical criteria is:**<br>Patient must have received prior treatment with interferon alfa or peginterferon alfa for hepatitis C if using peginterferon and ribavirin in triple combination therapy with telaprevir; OR<br>Patient must have received no more than one prior treatment with interferon alfa or peginterferon alfa for hepatitis C if using peginterferon and ribavirin without an NS3 protease inhibitor, or, in triple combination therapy with boceprevir,<br>**AND the Clinical criteria is:**<br>The treatment must be limited to a maximum duration of 24 weeks in patients using peginterferon and ribavirin in triple combination therapy with telaprevir who were prior treatment relapsers and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at weeks 4 and 12; OR<br>The treatment must be limited to a maximum duration of 36 weeks in patients using peginterferon and ribavirin in triple combination therapy with boceprevir who were prior treatment partial responders or relapsers and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at weeks 8 and 12; OR<br>The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin without an NS3 protease inhibitor; OR<br>The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin in triple combination therapy with boceprevir who: (i) were prior treatment null responders; or (ii) were prior treatment partial responders or relapsers and in whom plasma HCV RNA is detectable by an HCV RNA qualitative assay at week 8, and undetectable by an HCV RNA qualitative assay at week 12; or (iii) have hepatic cirrhosis; OR<br>The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin in triple combination therapy with telaprevir who: (i) were prior treatment partial or null responders; or (ii) were prior treatment relapsers and for whom the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is detectable but less than or equal to 1000 IU/mL; or (iii) have hepatic cirrhosis,<br>**AND the Clinical criteria is:**<br>The treatment must cease in patients using peginterferon and ribavirin without an NS3 protease inhibitor if HCV RNA is detectable by an HCV RNA qualitative assay at week 12, | | | | | | |

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**AND the Clinical criteria is:**

The treatment must cease in patients using peginterferon and ribavirin in combination with boceprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 12,

**AND the Clinical criteria is:**

The treatment must cease in patients using peginterferon and ribavirin in combination with boceprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24,

**AND the Clinical criteria is:**

The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is greater than 1000 IU/mL,

**AND the Clinical criteria is:**

The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 12,

**AND the Clinical criteria is:**

The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24,

**AND the Population criteria is:**

Patient must be aged 18 years or older,

**AND the Population criteria is:**

Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

Evidence of chronic genotype 1 hepatitis C infection (repeatedly anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records.

**Note**

No increase in the maximum quantity or number of units may be authorised.

**Note**

No increase in the maximum number of repeats may be authorised.

**Note**

Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C:

(a) a nurse educator/counsellor for patients; and

(b) 24-hour access by patients to medical advice; and

(c) an established liver clinic.

**Authority required**

Chronic genotype 1 hepatitis C infection

**The Treatment criteria is:**

Must be treated in an accredited treatment centre,

**AND the Clinical criteria is:**

Patient must have compensated liver disease,

**AND the Clinical criteria is:**

Patient must not have received prior interferon alfa or peginterferon alfa treatment for hepatitis C,

**AND the Clinical criteria is:**

The treatment must be limited to a maximum duration of 24 weeks in patients using peginterferon and ribavirin in triple combination therapy with telaprevir and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at weeks 4 and 12; OR

The treatment must be limited to a maximum duration of 28 weeks in patients using peginterferon and ribavirin in triple combination therapy with boceprevir and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at weeks 8 and 24; OR

The treatment must be limited to a maximum duration of 48 weeks in patients: (i) using peginterferon and ribavirin in triple combination therapy with boceprevir and in whom plasma HCV RNA is detectable by an HCV RNA qualitative assay at week 8, and undetectable by an HCV RNA qualitative assay at week 24; or (ii) using peginterferon and ribavirin in triple combination therapy with boceprevir who have hepatic cirrhosis; OR

The treatment must be limited to a maximum duration of 48 weeks in patients: (i) using peginterferon and ribavirin in triple combination therapy with telaprevir and for whom the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is detectable but less than or equal to 1000 IU/mL; or (ii) using peginterferon and ribavirin in triple combination therapy with telaprevir who have hepatic cirrhosis; OR

The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin without an NS3 protease inhibitor,

**AND the Clinical criteria is:**

The treatment must cease in patients using peginterferon and ribavirin without an NS3 protease inhibitor unless the results of an HCV RNA quantitative assay at week 12 (performed at the same laboratory using the same test) show that plasma HCV RNA has become undetectable or the viral load has decreased by at least a 2 log drop,

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**AND the Clinical criteria is:**

The treatment must cease in patients using peginterferon and ribavirin in combination with boceprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24,

**AND the Clinical criteria is:**

The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is greater than 1000 IU/mL,

**AND the Clinical criteria is:**

The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 12,

**AND the Clinical criteria is:**

The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24,

**AND the Population criteria is:**

Patient must be aged 18 years or older,

**AND the Population criteria is:**

Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

Evidence of chronic hepatitis C infection (repeated anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records.

For patients using peginterferon and ribavirin without an NS3 protease inhibitor who are viral negative at week 12, an HCV RNA qualitative assay at week 24 is unnecessary.

**Note**

No increase in the maximum quantity or number of units may be authorised.

**Note**

No increase in the maximum number of repeats may be authorised.

**Note**

Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C:

(a) a nurse educator/counsellor for patients; and

(b) 24-hour access by patients to medical advice; and

(c) an established liver clinic.

**Authority required**

Chronic non-genotype 1 hepatitis C infection

**The Treatment criteria is:**

Must be treated in an accredited treatment centre,

**AND the Clinical criteria is:**

The treatment must be the sole PBS-subsidised treatment for hepatitis C,

**AND the Clinical criteria is:**

Patient must have compensated liver disease,

**AND the Clinical criteria is:**

The condition must be genotype 2, 3, 4, 5 or 6 hepatitis C,

**AND the Clinical criteria is:**

Patient must have failed prior treatment with interferon based therapies (non-pegylated or pegylated),

**AND the Clinical criteria is:**

Patient must have received no more than one prior treatment with interferon alfa or peginterferon alfa for hepatitis C,

**AND the Clinical criteria is:**

The treatment must be limited to a maximum duration of 48 weeks,

**AND the Clinical criteria is:**

The treatment must cease if HCV RNA is detectable by an HCV RNA qualitative assay at week 12,

**AND the Population criteria is:**

Patient must be aged 18 years or older,

**AND the Population criteria is:**

Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

Evidence of chronic hepatitis C infection (repeated anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records.

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**Note**

No increase in the maximum quantity or number of units may be authorised.

**Note**

No increase in the maximum number of repeats may be authorised.

**Note**

Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C:

(a) a nurse educator/counsellor for patients; and

(b) 24-hour access by patients to medical advice; and

(c) an established liver clinic.

**Authority required**

Chronic non-genotype 1 hepatitis C infection

**The Treatment criteria is:**

Must be treated in an accredited treatment centre,

**AND the Clinical criteria is:**

The treatment must be the sole PBS-subsidised treatment for hepatitis C,

**AND the Clinical criteria is:**

Patient must have compensated liver disease,

**AND the Clinical criteria is:**

Patient must not have received prior interferon alfa or peginterferon alfa treatment for hepatitis C,

**AND the Clinical criteria is:**

The condition must be genotype 2, 3, 4, 5 or 6 hepatitis C,

**AND the Clinical criteria is:**

The treatment must be limited to a maximum duration of 48 weeks for patients with genotype 4, 5 or 6 hepatitis C; OR

The treatment must be limited to a maximum duration of 24 weeks for patients with genotype 2 or 3 hepatitis C without hepatic cirrhosis or bridging fibrosis; OR

The treatment must be limited to a maximum duration of 48 weeks for patients with genotype 2 or 3 hepatitis C with hepatic cirrhosis or bridging fibrosis,

**AND the Clinical criteria is:**

The treatment must cease in patients with genotype 4, 5, or 6 hepatitis C unless the results of an HCV RNA quantitative assay at week 12 (performed at the same laboratory using the same test) shows that plasma HCV RNA has become undetectable or the viral load has decreased by at least a 2 log drop,

**AND the Clinical criteria is:**

The treatment must cease in patients eligible for 48 weeks of treatment if HCV RNA is detectable by an HCV RNA qualitative assay at week 24,

**AND the Population criteria is:**

Patient must be aged 18 years or older,

**AND the Population criteria is:**

Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

Evidence of chronic hepatitis C infection (repeated anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records.

For patients with genotype 4, 5, or 6 who are viral negative at week 12, an HCV RNA qualitative assay at week 24 is unnecessary.

For patients with genotype 2 or 3 without cirrhosis, an HCV RNA assay at week 12 is unnecessary because of the high likelihood of early viral response by week 12.

For patients who are eligible for 24 weeks of treatment, a maximum of 2 repeats may be prescribed.

For patients who are eligible for 48 weeks of treatment, a maximum of 5 repeats may be prescribed.

**Caution**

Ribavirin is a category X drug and must not be given to pregnant women. Pregnancy in female patients or in the partners of male patients must be avoided during treatment and during the 6 months period after cessation of treatment.

**Caution**

Treatment with peginterferon alfa has been associated with depression and suicide in some patients. Patients with a history of suicidal ideation or depressive illness should be warned of the risks. Psychiatric status during therapy should be monitored.

**Note**

Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C:

(a) a nurse educator/counsellor for patients; and

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| | (b) 24-hour access by patients to medical advice; and<br>(c) an established liver clinic. | | | | | | |
| 6392K | peginterferon alfa-2a 135 microgram/0.5 mL injection [4 x 0.5 mL syringes] (&) ribavirin 200 mg tablet [168 tablets], 1 pack | 2 | 5 | .. | *3119.47 | Pegasys RBV | RO |
| 6394M | peginterferon alfa-2a 180 microgram/0.5 mL injection [4 x 0.5 mL syringes] (&) ribavirin 200 mg tablet [112 tablets], 1 pack | 2 | 5 | .. | *3131.91 | Pegasys RBV | RO |
| 6395N | peginterferon alfa-2a 180 microgram/0.5 mL injection [4 x 0.5 mL syringes] (&) ribavirin 200 mg tablet [140 tablets], 1 pack | 2 | 5 | .. | *3292.45 | Pegasys RBV | RO |
| 6396P | peginterferon alfa-2a 180 microgram/0.5 mL injection [4 x 0.5 mL syringes] (&) ribavirin 200 mg tablet [168 tablets], 1 pack | 2 | 5 | .. | *3452.99 | Pegasys RBV | RO |

**PEGINTERFERON ALFA-2B (&) RIBAVIRIN**

**Authority required**

Chronic genotype 1 hepatitis C infection

**The Treatment criteria is:**

Must be treated in an accredited treatment centre,

**AND the Clinical criteria is:**

The treatment must be the sole PBS-subsidised treatment for hepatitis C,

**AND the Clinical criteria is:**

Patient must have compensated liver disease,

**AND the Clinical criteria is:**

Patient must have failed prior treatment with interferon based therapies (non-pegylated or pegylated),

**AND the Clinical criteria is:**

Patient must have received no more than one prior treatment with interferon alfa or peginterferon alfa for hepatitis C,

**AND the Clinical criteria is:**

The treatment must be limited to a maximum duration of 48 weeks,

**AND the Clinical criteria is:**

The treatment must cease if HCV RNA is detectable by an HCV RNA qualitative assay at week 12,

**AND the Population criteria is:**

Patient must weigh at least 27 kg,

**AND the Population criteria is:**

Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

Evidence of chronic genotype 1 hepatitis C infection (repeatedly anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records.

**Note**

No increase in the maximum quantity or number of units may be authorised.

**Note**

No increase in the maximum number of repeats may be authorised.

**Note**

Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C:

(a) a nurse educator/counsellor for patients; and

(b) 24-hour access by patients to medical advice; and

(c) an established liver clinic.

**Authority required**

Chronic genotype 1 hepatitis C infection

**The Treatment criteria is:**

Must be treated in an accredited treatment centre,

**AND the Clinical criteria is:**

The treatment must be the sole PBS-subsidised treatment for hepatitis C,

**AND the Clinical criteria is:**

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Patient must have compensated liver disease,

**AND the Clinical criteria is:**

Patient must not have received prior interferon alfa or peginterferon alfa treatment for hepatitis C,

**AND the Clinical criteria is:**

The treatment must be limited to a maximum duration of 48 weeks,

**AND the Clinical criteria is:**

The treatment must cease unless the results of an HCV RNA quantitative assay at week 12 (performed at the same laboratory using the same test) show that plasma HCV RNA has become undetectable or the viral load has decreased by at least a 2 log drop,

**AND the Population criteria is:**

Patient must weigh at least 27 kg,

**AND the Population criteria is:**

Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

Evidence of chronic hepatitis C infection (repeated anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records.

For patients who are viral negative at week 12, an HCV RNA qualitative assay at week 24 is unnecessary.

**Note**

No increase in the maximum quantity or number of units may be authorised.

**Note**

No increase in the maximum number of repeats may be authorised.

**Note**

Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C:

(a) a nurse educator/counsellor for patients; and

(b) 24-hour access by patients to medical advice; and

(c) an established liver clinic.

**Authority required**

Chronic non-genotype 1 hepatitis C infection

**The Treatment criteria is:**

Must be treated in an accredited treatment centre,

**AND the Clinical criteria is:**

The treatment must be the sole PBS-subsidised treatment for hepatitis C,

**AND the Clinical criteria is:**

Patient must have compensated liver disease,

**AND the Clinical criteria is:**

The condition must be genotype 2, 3, 4, 5 or 6 hepatitis C,

**AND the Clinical criteria is:**

Patient must have failed prior treatment with interferon based therapies (non-pegylated or pegylated),

**AND the Clinical criteria is:**

Patient must have received no more than one prior treatment with interferon alfa or peginterferon alfa for hepatitis C,

**AND the Clinical criteria is:**

The treatment must be limited to a maximum duration of 48 weeks,

**AND the Clinical criteria is:**

The treatment must cease if HCV RNA is detectable by an HCV RNA qualitative assay at week 12,

**AND the Population criteria is:**

Patient must weigh at least 27 kg,

**AND the Population criteria is:**

Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

Evidence of chronic hepatitis C infection (repeated anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records.

**Note**

No increase in the maximum quantity or number of units may be authorised.

**Note**

No increase in the maximum number of repeats may be authorised.

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**Note**

Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C:

(a) a nurse educator/counsellor for patients; and

(b) 24-hour access by patients to medical advice; and

(c) an established liver clinic.

**Authority required**

Chronic non-genotype 1 hepatitis C infection

**The Treatment criteria is:**

Must be treated in an accredited treatment centre,

**AND the Clinical criteria is:**

The treatment must be the sole PBS-subsidised treatment for hepatitis C,

**AND the Clinical criteria is:**

Patient must have compensated liver disease,

**AND the Clinical criteria is:**

Patient must not have received prior interferon alfa or peginterferon alfa treatment for hepatitis C,

**AND the Clinical criteria is:**

The condition must be genotype 2, 3, 4, 5 or 6 hepatitis C,

**AND the Clinical criteria is:**

The treatment must be limited to a maximum duration of 48 weeks for patients with genotype 4, 5 or 6 hepatitis C; OR

The treatment must be limited to a maximum duration of 24 weeks for patients with genotype 2 or 3 hepatitis C without hepatic cirrhosis or bridging fibrosis; OR

The treatment must be limited to a maximum duration of 48 weeks for patients with genotype 2 or 3 hepatitis C with hepatic cirrhosis or bridging fibrosis,

**AND the Clinical criteria is:**

The treatment must cease in patients with genotype 4, 5, or 6 hepatitis C unless the results of an HCV RNA quantitative assay at week 12 (performed at the same laboratory using the same test) shows that plasma HCV RNA has become undetectable or the viral load has decreased by at least a 2 log drop,

**AND the Clinical criteria is:**

The treatment must cease in patients eligible for 48 weeks of treatment if HCV RNA is detectable by an HCV RNA qualitative assay at week 24,

**AND the Population criteria is:**

Patient must weigh at least 27 kg,

**AND the Population criteria is:**

Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

Evidence of chronic hepatitis C infection (repeated anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records.

For patients with genotype 4, 5, or 6 who are viral negative at week 12, an HCV RNA qualitative assay at week 24 is unnecessary.

For patients with genotype 2 or 3 without cirrhosis, an HCV RNA assay at week 12 is unnecessary because of the high likelihood of early viral response by week 12.

For patients who are eligible for 24 weeks of treatment, a maximum of 2 repeats may be prescribed.

For patients who are eligible for 48 weeks of treatment, a maximum of 5 repeats may be prescribed.

**Note**

Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C:

(a) a nurse educator/counsellor for patients; and

(b) 24-hour access by patients to medical advice; and

(c) an established liver clinic.

**Authority required**

Chronic genotype 1 hepatitis C infection

**The Treatment criteria is:**

Must be treated in an accredited treatment centre,

**AND the Clinical criteria is:**

Patient must have compensated liver disease,

**AND the Clinical criteria is:**

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Patient must have failed prior treatment with interferon based therapies (non-pegylated or pegylated),

**AND the Clinical criteria is:**

Patient must have received prior treatment with interferon alfa or peginterferon alfa for hepatitis C if using peginterferon and ribavirin in triple combination therapy with telaprevir; OR

Patient must have received no more than one prior treatment with interferon alfa or peginterferon alfa for hepatitis C if using peginterferon and ribavirin without an NS3 protease inhibitor, or, in triple combination therapy with boceprevir,

**AND the Clinical criteria is:**

The treatment must be limited to a maximum duration of 24 weeks in patients using peginterferon and ribavirin in triple combination therapy with telaprevir who were prior treatment relapsers and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at weeks 4 and 12; OR

The treatment must be limited to a maximum duration of 36 weeks in patients using peginterferon and ribavirin in triple combination therapy with boceprevir who were prior treatment partial responders or relapsers and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at weeks 8 and 12; OR

The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin without an NS3 protease inhibitor; OR

The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin in triple combination therapy with boceprevir who: (i) were prior treatment null responders; or (ii) were prior treatment partial responders or relapsers and in whom plasma HCV RNA is detectable by an HCV RNA qualitative assay at week 8, and undetectable by an HCV RNA qualitative assay at week 12; or (iii) have hepatic cirrhosis; OR

The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin in triple combination therapy with telaprevir who: (i) were prior treatment partial or null responders; or (ii) were prior treatment relapsers and for whom the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is detectable but less than or equal to 1000 IU/mL; or (iii) have hepatic cirrhosis,

**AND the Clinical criteria is:**

The treatment must cease in patients using peginterferon and ribavirin without an NS3 protease inhibitor if HCV RNA is detectable by an HCV RNA qualitative assay at week 12,

**AND the Clinical criteria is:**

The treatment must cease in patients using peginterferon and ribavirin in combination with boceprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 12,

**AND the Clinical criteria is:**

The treatment must cease in patients using peginterferon and ribavirin in combination with boceprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24,

**AND the Clinical criteria is:**

The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is greater than 1000 IU/mL,

**AND the Clinical criteria is:**

The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 12,

**AND the Clinical criteria is:**

The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24,

**AND the Population criteria is:**

Patient must be aged 18 years or older,

**AND the Population criteria is:**

Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

Evidence of chronic genotype 1 hepatitis C infection (repeatedly anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records.

**Note**
No increase in the maximum quantity or number of units may be authorised.

**Note**
No increase in the maximum number of repeats may be authorised.

**Note**
Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C:

(a) a nurse educator/counsellor for patients; and

(b) 24-hour access by patients to medical advice; and

(c) an established liver clinic.

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**Authority required**

Chronic genotype 1 hepatitis C infection

**The Treatment criteria is:**

Must be treated in an accredited treatment centre,

**AND the Clinical criteria is:**

Patient must have compensated liver disease,

**AND the Clinical criteria is:**

Patient must not have received prior interferon alfa or peginterferon alfa treatment for hepatitis C,

**AND the Clinical criteria is:**

The treatment must be limited to a maximum duration of 24 weeks in patients using peginterferon and ribavirin in triple combination therapy with telaprevir and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at weeks 4 and 12; OR

The treatment must be limited to a maximum duration of 28 weeks in patients using peginterferon and ribavirin in triple combination therapy with boceprevir and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at weeks 8 and 24; OR

The treatment must be limited to a maximum duration of 48 weeks in patients: (i) using peginterferon and ribavirin in triple combination therapy with boceprevir and in whom plasma HCV RNA is detectable by an HCV RNA qualitative assay at week 8, and undetectable by an HCV RNA qualitative assay at week 24; or (ii) using peginterferon and ribavirin in triple combination therapy with boceprevir who have hepatic cirrhosis; OR

The treatment must be limited to a maximum duration of 48 weeks in patients: (i) using peginterferon and ribavirin in triple combination therapy with telaprevir and for whom the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is detectable but less than or equal to 1000 IU/mL; or (ii) using peginterferon and ribavirin in triple combination therapy with telaprevir who have hepatic cirrhosis; OR

The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin without an NS3 protease inhibitor,

**AND the Clinical criteria is:**

The treatment must cease in patients using peginterferon and ribavirin without an NS3 protease inhibitor unless the results of an HCV RNA quantitative assay at week 12 (performed at the same laboratory using the same test) show that plasma HCV RNA has become undetectable or the viral load has decreased by at least a 2 log drop,

**AND the Clinical criteria is:**

The treatment must cease in patients using peginterferon and ribavirin in combination with boceprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24,

**AND the Clinical criteria is:**

The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is greater than 1000 IU/mL,

**AND the Clinical criteria is:**

The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 12,

**AND the Clinical criteria is:**

The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24,

**AND the Population criteria is:**

Patient must be aged 18 years or older,

**AND the Population criteria is:**

Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

Evidence of chronic hepatitis C infection (repeated anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records.

For patients using peginterferon and ribavirin without an NS3 protease inhibitor who are viral negative at week 12, an HCV RNA qualitative assay at week 24 is unnecessary.

**Note**

No increase in the maximum quantity or number of units may be authorised.

**Note**

No increase in the maximum number of repeats may be authorised.

**Note**

Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C:

(a) a nurse educator/counsellor for patients; and

(b) 24-hour access by patients to medical advice; and

(c) an established liver clinic.

**Authority required**

Chronic non-genotype 1 hepatitis C infection

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**The Treatment criteria is:**

Must be treated in an accredited treatment centre,

**AND the Clinical criteria is:**

The treatment must be the sole PBS-subsidised treatment for hepatitis C,

**AND the Clinical criteria is:**

Patient must have compensated liver disease,

**AND the Clinical criteria is:**

The condition must be genotype 2, 3, 4, 5 or 6 hepatitis C,

**AND the Clinical criteria is:**

Patient must have failed prior treatment with interferon based therapies (non-pegylated or pegylated),

**AND the Clinical criteria is:**

Patient must have received no more than one prior treatment with interferon alfa or peginterferon alfa for hepatitis C,

**AND the Clinical criteria is:**

The treatment must be limited to a maximum duration of 48 weeks,

**AND the Clinical criteria is:**

The treatment must cease if HCV RNA is detectable by an HCV RNA qualitative assay at week 12,

**AND the Population criteria is:**

Patient must be aged 18 years or older,

**AND the Population criteria is:**

Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

Evidence of chronic hepatitis C infection (repeated anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records.

**Note**

No increase in the maximum quantity or number of units may be authorised.

**Note**

No increase in the maximum number of repeats may be authorised.

**Note**

Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C:

(a) a nurse educator/counsellor for patients; and

(b) 24-hour access by patients to medical advice; and

(c) an established liver clinic.

**Authority required**

Chronic non-genotype 1 hepatitis C infection

**The Treatment criteria is:**

Must be treated in an accredited treatment centre,

**AND the Clinical criteria is:**

The treatment must be the sole PBS-subsidised treatment for hepatitis C,

**AND the Clinical criteria is:**

Patient must have compensated liver disease,

**AND the Clinical criteria is:**

Patient must not have received prior interferon alfa or peginterferon alfa treatment for hepatitis C,

**AND the Clinical criteria is:**

The condition must be genotype 2, 3, 4, 5 or 6 hepatitis C,

**AND the Clinical criteria is:**

The treatment must be limited to a maximum duration of 48 weeks for patients with genotype 4, 5 or 6 hepatitis C; OR

The treatment must be limited to a maximum duration of 24 weeks for patients with genotype 2 or 3 hepatitis C without hepatic cirrhosis or bridging fibrosis; OR

The treatment must be limited to a maximum duration of 48 weeks for patients with genotype 2 or 3 hepatitis C with hepatic cirrhosis or bridging fibrosis,

**AND the Clinical criteria is:**

The treatment must cease in patients with genotype 4, 5, or 6 hepatitis C unless the results of an HCV RNA quantitative assay at week 12 (performed at the same laboratory using the same test) shows that plasma HCV RNA has become undetectable or the viral load has decreased by at least a 2 log

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| | drop,<br>**AND the Clinical criteria is:**<br>The treatment must cease in patients eligible for 48 weeks of treatment if HCV RNA is detectable by an HCV RNA qualitative assay at week 24,<br>**AND the Population criteria is:**<br>Patient must be aged 18 years or older,<br>**AND the Population criteria is:**<br>Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.<br>Evidence of chronic hepatitis C infection (repeated anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records.<br>For patients with genotype 4, 5, or 6 who are viral negative at week 12, an HCV RNA qualitative assay at week 24 is unnecessary.<br>For patients with genotype 2 or 3 without cirrhosis, an HCV RNA assay at week 12 is unnecessary because of the high likelihood of early viral response by week 12.<br>For patients who are eligible for 24 weeks of treatment, a maximum of 2 repeats may be prescribed.<br>For patients who are eligible for 48 weeks of treatment, a maximum of 5 repeats may be prescribed.<br>**Caution**<br>Ribavirin is a category X drug and must not be given to pregnant women. Pregnancy in female patients or in the partners of male patients must be avoided during treatment and during the 6 months period after cessation of treatment.<br>**Caution**<br>Treatment with peginterferon alfa has been associated with depression and suicide in some patients. Patients with a history of suicidal ideation or depressive illness should be warned of the risks. Psychiatric status during therapy should be monitored.<br>**Note**<br>Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C:<br>(a) a nurse educator/counsellor for patients; and<br>(b) 24-hour access by patients to medical advice; and<br>(c) an established liver clinic. | | | | | | |
| 6405D | peginterferon alfa-2b 100 microgram injection [4 x 100 microgram cartridges] (&) ribavirin 200 mg capsule [112 capsules] (&) inert substance diluent [4 x 0.5 mL cartridges], 1 pack | 2 | 5 | .. | *3146.25 | Pegatron | MK |
| 6400W | peginterferon alfa-2b 50 microgram injection [4 x 50 microgram cartridges] (&) ribavirin 200 mg capsule [112 capsules] (&) inert substance diluent [4 x 0.5 mL cartridges], 1 pack | 2 | 5 | .. | *2166.37 | Pegatron | MK |
| 6401X | peginterferon alfa-2b 80 microgram injection [4 x 80 microgram cartridges] (&) ribavirin 200 mg capsule [84 capsules] (&) inert substance diluent [4 x 0.5 mL cartridges], 1 pack | 2 | 5 | .. | *2469.35 | Pegatron | MK |
| | **PEGINTERFERON ALFA-2B (&) RIBAVIRIN**<br>**Authority required**<br>Chronic genotype 1 hepatitis C infection<br>**The Treatment criteria is:**<br>Must be treated in an accredited treatment centre,<br>**AND the Clinical criteria is:**<br>Patient must have compensated liver disease,<br>**AND the Clinical criteria is:**<br>Patient must have failed prior treatment with interferon based therapies (non-pegylated or pegylated),<br>**AND the Clinical criteria is:**<br>Patient must have received prior treatment with interferon alfa or peginterferon alfa for hepatitis C if using peginterferon and ribavirin in triple combination therapy with telaprevir; OR<br>Patient must have received no more than one prior treatment with interferon alfa or peginterferon alfa for hepatitis C if using peginterferon and ribavirin without an NS3 protease inhibitor, or, in triple combination therapy with boceprevir,<br>**AND the Clinical criteria is:**<br>The treatment must be limited to a maximum duration of 24 weeks in patients using peginterferon and ribavirin in triple combination therapy with telaprevir who were prior treatment relapsers and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at weeks 4 and 12; OR<br>The treatment must be limited to a maximum duration of 36 weeks in patients using peginterferon and ribavirin in triple combination therapy with boceprevir who were prior treatment partial responders or relapsers and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay | | | | | | |

# HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Brand Name and Manufacturer |
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at weeks 8 and 12; OR

The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin without an NS3 protease inhibitor; OR

The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin in triple combination therapy with boceprevir who: (i) were prior treatment null responders; or (ii) were prior treatment partial responders or relapsers and in whom plasma HCV RNA is detectable by an HCV RNA qualitative assay at week 8, and undetectable by an HCV RNA qualitative assay at week 12; or (iii) have hepatic cirrhosis; OR

The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin in triple combination therapy with telaprevir who: (i) were prior treatment partial or null responders; or (ii) were prior treatment relapsers and for whom the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is detectable but less than or equal to 1000 IU/mL; or (iii) have hepatic cirrhosis,

**AND the Clinical criteria is:**

The treatment must cease in patients using peginterferon and ribavirin without an NS3 protease inhibitor if HCV RNA is detectable by an HCV RNA qualitative assay at week 12,

**AND the Clinical criteria is:**

The treatment must cease in patients using peginterferon and ribavirin in combination with boceprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 12,

**AND the Clinical criteria is:**

The treatment must cease in patients using peginterferon and ribavirin in combination with boceprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24,

**AND the Clinical criteria is:**

The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is greater than 1000 IU/mL,

**AND the Clinical criteria is:**

The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 12,

**AND the Clinical criteria is:**

The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24,

**AND the Population criteria is:**

Patient must be aged 18 years or older,

**AND the Population criteria is:**

Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

Evidence of chronic genotype 1 hepatitis C infection (repeatedly anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records.

**Note**

No increase in the maximum quantity or number of units may be authorised.

**Note**

No increase in the maximum number of repeats may be authorised.

**Note**

Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C:

(a) a nurse educator/counsellor for patients; and

(b) 24-hour access by patients to medical advice; and

(c) an established liver clinic.

**Authority required**

Chronic genotype 1 hepatitis C infection

**The Treatment criteria is:**

Must be treated in an accredited treatment centre,

**AND the Clinical criteria is:**

Patient must have compensated liver disease,

**AND the Clinical criteria is:**

Patient must not have received prior interferon alfa or peginterferon alfa treatment for hepatitis C,

**AND the Clinical criteria is:**

The treatment must be limited to a maximum duration of 24 weeks in patients using peginterferon and ribavirin in triple combination therapy with telaprevir and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at weeks 4 and 12; OR

# HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

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The treatment must be limited to a maximum duration of 28 weeks in patients using peginterferon and ribavirin in triple combination therapy with boceprevir and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at weeks 8 and 24; OR

The treatment must be limited to a maximum duration of 48 weeks in patients: (i) using peginterferon and ribavirin in triple combination therapy with boceprevir and in whom plasma HCV RNA is detectable by an HCV RNA qualitative assay at week 8, and undetectable by an HCV RNA qualitative assay at week 24; or (ii) using peginterferon and ribavirin in triple combination therapy with boceprevir who have hepatic cirrhosis; OR

The treatment must be limited to a maximum duration of 48 weeks in patients: (i) using peginterferon and ribavirin in triple combination therapy with telaprevir and for whom the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is detectable but less than or equal to 1000 IU/mL; or (ii) using peginterferon and ribavirin in triple combination therapy with telaprevir who have hepatic cirrhosis; OR

The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin without an NS3 protease inhibitor,

**AND the Clinical criteria is:**

The treatment must cease in patients using peginterferon and ribavirin without an NS3 protease inhibitor unless the results of an HCV RNA quantitative assay at week 12 (performed at the same laboratory using the same test) show that plasma HCV RNA has become undetectable or the viral load has decreased by at least a 2 log drop,

**AND the Clinical criteria is:**

The treatment must cease in patients using peginterferon and ribavirin in combination with boceprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24,

**AND the Clinical criteria is:**

The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is greater than 1000 IU/mL,

**AND the Clinical criteria is:**

The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 12,

**AND the Clinical criteria is:**

The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24,

**AND the Population criteria is:**

Patient must be aged 18 years or older,

**AND the Population criteria is:**

Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

Evidence of chronic hepatitis C infection (repeated anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records.

For patients using peginterferon and ribavirin without an NS3 protease inhibitor who are viral negative at week 12, an HCV RNA qualitative assay at week 24 is unnecessary.

**Note**

No increase in the maximum quantity or number of units may be authorised.

**Note**

No increase in the maximum number of repeats may be authorised.

**Note**

Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C:

(a) a nurse educator/counsellor for patients; and

(b) 24-hour access by patients to medical advice; and

(c) an established liver clinic.

**Authority required**

Chronic non-genotype 1 hepatitis C infection

**The Treatment criteria is:**

Must be treated in an accredited treatment centre,

**AND the Clinical criteria is:**

The treatment must be the sole PBS-subsidised treatment for hepatitis C,

**AND the Clinical criteria is:**

Patient must have compensated liver disease,

**AND the Clinical criteria is:**

The condition must be genotype 2, 3, 4, 5 or 6 hepatitis C,

**AND the Clinical criteria is:**

Patient must have failed prior treatment with interferon based therapies (non-pegylated or pegylated),

# HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Brand Name and Manufacturer |
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**AND the Clinical criteria is:**

Patient must have received no more than one prior treatment with interferon alfa or peginterferon alfa for hepatitis C,

**AND the Clinical criteria is:**

The treatment must be limited to a maximum duration of 48 weeks,

**AND the Clinical criteria is:**

The treatment must cease if HCV RNA is detectable by an HCV RNA qualitative assay at week 12,

**AND the Population criteria is:**

Patient must be aged 18 years or older,

**AND the Population criteria is:**

Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

Evidence of chronic hepatitis C infection (repeated anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records.

**Note**

No increase in the maximum quantity or number of units may be authorised.

**Note**

No increase in the maximum number of repeats may be authorised.

**Note**

Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C:

(a) a nurse educator/counsellor for patients; and

(b) 24-hour access by patients to medical advice; and

(c) an established liver clinic.

**Authority required**

Chronic non-genotype 1 hepatitis C infection

**The Treatment criteria is:**

Must be treated in an accredited treatment centre,

**AND the Clinical criteria is:**

The treatment must be the sole PBS-subsidised treatment for hepatitis C,

**AND the Clinical criteria is:**

Patient must have compensated liver disease,

**AND the Clinical criteria is:**

Patient must not have received prior interferon alfa or peginterferon alfa treatment for hepatitis C,

**AND the Clinical criteria is:**

The condition must be genotype 2, 3, 4, 5 or 6 hepatitis C,

**AND the Clinical criteria is:**

The treatment must be limited to a maximum duration of 48 weeks for patients with genotype 4, 5 or 6 hepatitis C; OR

The treatment must be limited to a maximum duration of 24 weeks for patients with genotype 2 or 3 hepatitis C without hepatic cirrhosis or bridging fibrosis; OR

The treatment must be limited to a maximum duration of 48 weeks for patients with genotype 2 or 3 hepatitis C with hepatic cirrhosis or bridging fibrosis,

**AND the Clinical criteria is:**

The treatment must cease in patients with genotype 4, 5, or 6 hepatitis C unless the results of an HCV RNA quantitative assay at week 12 (performed at the same laboratory using the same test) shows that plasma HCV RNA has become undetectable or the viral load has decreased by at least a 2 log drop,

**AND the Clinical criteria is:**

The treatment must cease in patients eligible for 48 weeks of treatment if HCV RNA is detectable by an HCV RNA qualitative assay at week 24,

**AND the Population criteria is:**

Patient must be aged 18 years or older,

**AND the Population criteria is:**

Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

Evidence of chronic hepatitis C infection (repeated anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records.

For patients with genotype 4, 5, or 6 who are viral negative at week 12, an HCV RNA qualitative assay at week 24 is unnecessary.

For patients with genotype 2 or 3 without cirrhosis, an HCV RNA assay at week 12 is unnecessary because of the high likelihood of early viral

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| | response by week 12. | | | | | | |
| | For patients who are eligible for 24 weeks of treatment, a maximum of 2 repeats may be prescribed. | | | | | | |
| | For patients who are eligible for 48 weeks of treatment, a maximum of 5 repeats may be prescribed. | | | | | | |
| | **Caution**<br>Ribavirin is a category X drug and must not be given to pregnant women. Pregnancy in female patients or in the partners of male patients must be avoided during treatment and during the 6 months period after cessation of treatment. | | | | | | |
| | **Caution**<br>Treatment with peginterferon alfa has been associated with depression and suicide in some patients. Patients with a history of suicidal ideation or depressive illness should be warned of the risks. Psychiatric status during therapy should be monitored. | | | | | | |
| | **Note**<br>Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C:<br>(a) a nurse educator/counsellor for patients; and<br>(b) 24-hour access by patients to medical advice; and<br>(c) an established liver clinic. | | | | | | |
| 6407F | peginterferon alfa-2b 120 microgram injection [4 x 120 microgram cartridges] (&) ribavirin 200 mg capsule [140 capsules] (&) inert substance diluent [4 x 0.5 mL cartridges], 1 pack | 2 | 5 | .. | *3538.21 | Pegatron | MK |
| 6409H | peginterferon alfa-2b 150 microgram injection [4 x 150 microgram cartridges] (&) ribavirin 200 mg capsule [140 capsules] (&) inert substance diluent [4 x 0.5 mL cartridges], 1 pack | 2 | 5 | .. | *4126.15 | Pegatron | MK |
| 6410J | peginterferon alfa-2b 150 microgram injection [4 x 150 microgram cartridges] (&) ribavirin 200 mg capsule [168 capsules] (&) inert substance diluent [4 x 0.5 mL cartridges], 1 pack | 2 | 5 | .. | *4126.15 | Pegatron | MK |
| 9634C | peginterferon alfa-2b 150 microgram injection [4 x 150 microgram cartridges] (&) ribavirin 200 mg capsule [196 capsules] (&) inert substance diluent [4 x 0.5 mL cartridges], 1 pack | 2 | 5 | .. | *4411.11 | Pegatron | MK |
| 6402Y | peginterferon alfa-2b 80 microgram injection [4 x 80 microgram cartridges] (&) ribavirin 200 mg capsule [140 capsules] (&) inert substance diluent [4 x 0.5 mL cartridges], 1 pack | 2 | 5 | .. | *2754.29 | Pegatron | MK |

## IMMUNOSUPPRESSANTS

## IMMUNOSUPPRESSANTS

### *Selective immunosuppressants*

**ABATACEPT**

**Authority required**

Initial 1 (new patient or patient re-commencing after a break of more than 24 months)

Initial PBS-subsidised treatment with abatacept, in combination with methotrexate at a dose of at least 7.5 mg weekly, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of adults who:

(a) have severe active rheumatoid arthritis; and

(b) have received no PBS-subsidised treatment with a bDMARD for this condition in the previous 24 months; and

(c) have failed, in the 24 months immediately prior to the date of application, to achieve an adequate response to at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs), which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be:

— hydroxychloroquine at a dose of at least 200 mg daily; or

— leflunomide at a dose of at least 10 mg daily; or

— sulfasalazine at a dose of at least 2 g daily.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, then the 6 months of intensive DMARD treatment must include at least 3 months continuous treatment with each of at least 2 of the DMARDs:

— hydroxychloroquine at a dose of at least 200 mg daily; and/or

— leflunomide at a dose of at least 10 mg daily; and/or

— sulfasalazine at a dose of at least 2 g daily.

The application must include details of the contraindication or intolerance to methotrexate. Details of the toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose can be found on the Medicare Australia website [www.medicareaustralia.gov.au]. The maximum tolerated dose of methotrexate must

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be documented in the application, if applicable.

If 3 or more of methotrexate, hydroxychloroquine, leflunomide and sulfasalazine are contraindicated according to the relevant TGA-approved product information or cannot be tolerated at the doses specified above, then one or more of the following DMARDs may be used in place of these agents in order to satisfy the requirement for a trial of 6 months of intensive DMARD therapy with at least 2 DMARDs taken continuously for at least 3 months each:

— azathioprine at a dose of at least 1 mg/kg per day; and/or

— cyclosporin at a dose of at least 2 mg/kg/day; and/or

— sodium aurothiomalate at a dose of 50 mg weekly.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances. Details of the toxicities, including severity, which will be accepted as a reason for substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial can be found on the Medicare Australia website [www.medicareaustralia.gov.au].

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance and dose for each DMARD must be provided in the authority application. Details of the toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy can be found on the Medicare Australia website [www.medicareaustralia.gov.au].

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L;

AND either

(i) a total active joint count of at least 20 active (swollen and tender) joints; or

(ii) at least 4 active joints from the following list of major joints:

— elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

— shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reason this criterion cannot be satisfied.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and

(3) a signed patient acknowledgement.

A maximum of 16 weeks of treatment will be authorised under this restriction.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion. Up to a maximum of 4 repeats may be authorised. Where fewer than 4 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Assessment of a patient's response to an initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with abatacept.

Patients who fail to demonstrate a response to treatment with abatacept under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition

**Authority required**

Initial 2 (change or re-commencement after break of less than 24 months)

Initial course of PBS-subsidised treatment with abatacept, in combination with methotrexate at a dose of at least 7.5 mg weekly, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of adults who:

(a) have a documented history of severe active rheumatoid arthritis; and

(b) have received prior PBS-subsidised bDMARD treatment for this condition and are eligible to receive further bDMARD therapy.

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The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].

Applications for patients who have received PBS-subsidised treatment with abatacept and who wish to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised abatacept treatment, within the timeframes specified below.

A maximum of 16 weeks of treatment will be authorised under this restriction.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion. Up to a maximum of 4 repeats may be authorised.

Where fewer than 4 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Where the most recent course of PBS-subsidised abatacept treatment was approved under either of the initial 1 or 2 treatment restrictions, patients must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be provided to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised abatacept treatment was approved under the continuing treatment criteria, patients must have been assessed for response, and the assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Patients who fail to demonstrate a response to treatment with abatacept under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition

**Authority required**

Continuing treatment

Continuing PBS-subsidised treatment with abatacept, in combination with methotrexate at a dose of at least 7.5 mg weekly, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of adults:

(a) who have a documented history of severe active rheumatoid arthritis; and

(b) who have demonstrated an adequate response to treatment with abatacept; and

(c) whose most recent course of PBS-subsidised bDMARD treatment was with abatacept.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(i) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(ii) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

— elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

— shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].

A maximum of 24 weeks of treatment will be approved under this restriction.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion. Up to a maximum of 5 repeats may be authorised.

Where fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

All applications for continuing treatment with abatacept must include a measurement of response to the prior course of therapy. This assessment must be provided to Medicare Australia no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with abatacept, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.

Patients who fail to demonstrate a response to treatment with abatacept under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition

**Note**

Any queries concerning the arrangements to prescribe abatacept may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Further prescribing information (including Authority Application Forms) is on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe abatacept should be forwarded to:

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Medicare Australia

Prior Written Approval of Specialised Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

**Note**

TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying anti-rheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab) and the T-cell co-stimulation modulator (abatacept).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

PBS-subsidised abatacept, golimumab, infliximab and rituximab must be used in combination with methotrexate at a dose of at least 7.5 mg weekly. Where a patient cannot tolerate 7.5 mg of methotrexate weekly, they are eligible to receive PBS-subsidised adalimumab, certolizumab pegol, etanercept and tocilizumab.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:

— a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,

— a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and

— once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact Medicare Australia on 1800 700 270.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or

(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or

(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or

(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab and tocilizumab, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to Medicare Australia within 4 weeks.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

Abatacept patients:

Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no

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|---|---|---|---|---|---|---|---|

repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients:

A further application may be submitted to Medicare Australia 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Rituximab patients:

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.

Abatacept patients:

Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

**Note**

(3) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and Medicare Australia will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

**Note**

Special Pricing Arrangements apply.

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| 9621J | abatacept 250 mg injection, 1 x 250 mg vial | 1 | .. | .. | 531.24 | Orencia | BQ |

# HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|
| | **EVEROLIMUS** | | | | | | | |
| | **Authority required** | | | | | | | |
| | Management of rejection, under the supervision and direction of a transplant unit, in patients receiving this drug for prophylaxis of renal allograft rejection. Management includes initiation, stabilisation and review of therapy as required | | | | | | | |
| | **Authority required** | | | | | | | |
| | Management of rejection, under the supervision and direction of a transplant unit, in patients receiving this drug for prophylaxis of cardiac allograft rejection. Management includes initiation, stabilisation and review of therapy as required | | | | | | | |
| | **Caution** | | | | | | | |
| | Careful monitoring of patients is mandatory. | | | | | | | |
| 9582H | everolimus 1 mg tablet, 60 | 4 | 5 | .. | *3891.43 | | Certican | NV |
| 6459Y | everolimus 250 microgram tablet, 60 | 2 | 5 | .. | *506.45 | | Certican | NV |
| 6460B | everolimus 500 microgram tablet, 60 | 2 | 5 | .. | *1006.27 | | Certican | NV |
| 6461C | everolimus 750 microgram tablet, 60 | 4 | 5 | .. | *2930.23 | | Certican | NV |
| | **MYCOPHENOLATE** | | | | | | | |
| | **Authority required** | | | | | | | |
| | Prophylaxis of renal allograft rejection | | | | | | | |
| | Treatment Phase: Management | | | | | | | |
| | **The Clinical criteria is:** | | | | | | | |
| | The treatment must be under the supervision and direction of a transplant unit. | | | | | | | |
| | **Authority required** | | | | | | | |
| | WHO Class III, IV or V lupus nephritis | | | | | | | |
| | Treatment Phase: Management | | | | | | | |
| | **The Clinical criteria is:** | | | | | | | |
| | The condition must be proven by biopsy, | | | | | | | |
| | **AND the Treatment criteria is:** | | | | | | | |
| | Must be treated by a nephrologist or in consultation with a nephrologist. | | | | | | | |
| | The name of the consulting nephrologist must be included in the patient medical records. | | | | | | | |
| | **Caution** | | | | | | | |
| | Careful monitoring of patients is mandatory. | | | | | | | |
| | **Note** | | | | | | | |
| | Management includes initiation, stabilisation and review of therapy as required. | | | | | | | |
| 6369F | mycophenolate 180 mg tablet: enteric, 120 tablets | 2 | 5 | .. | *395.01 | | Myfortic | NV |
| 6370G | mycophenolate 360 mg tablet: enteric, 120 tablets | 2 | 5 | .. | *783.37 | | Myfortic | NV |
| | **MYCOPHENOLATE** | | | | | | | |
| | **Authority required** | | | | | | | |
| | Management of rejection, under the supervision and direction of a transplant unit, in patients receiving this drug for prophylaxis of renal allograft rejection. Management includes initiation, stabilisation and review of therapy as required | | | | | | | |
| | **Authority required** | | | | | | | |
| | Management of rejection, under the supervision and direction of a transplant unit, in patients receiving this drug for prophylaxis of cardiac allograft rejection. Management includes initiation, stabilisation and review of therapy as required | | | | | | | |
| | **Caution** | | | | | | | |
| | Careful monitoring of patients is mandatory. | | | | | | | |
| | **Note** | | | | | | | |
| | For item codes 6208R and 1837Q, pharmaceutical benefits that have the form capsule 250 mg are equivalent for the purposes of substitution. | | | | | | | |
| 1837Q | mycophenolate Capsule 250 mg, 50 | 12 | 5 | .. | *977.55 | [a] | Ceptolate | AF |
| 6208R | mycophenolate mofetil 250 mg capsule, 100 | 6 | 5 | .. | *977.55 | [a] | APO-Mycophenolate | TX |
| | | | | | | [a] | CellCept | RO |
| | | | | | | [a] | Imulate | QA |
| | | | | | | [a] | Mycophenolate Sandoz | SZ |
| | | | | | | [a] | Pharmacor Mycophenolate 250 | CR |
| | **MYCOPHENOLATE** | | | | | | | |
| | **Authority required** | | | | | | | |
| | Management of rejection, under the supervision and direction of a transplant unit, in patients receiving this drug for prophylaxis of renal allograft rejection. Management includes initiation, stabilisation and review of therapy as required | | | | | | | |
| | **Authority required** | | | | | | | |

# HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|
| | Management of rejection, under the supervision and direction of a transplant unit, in patients receiving this drug for prophylaxis of cardiac allograft rejection. Management includes initiation, stabilisation and review of therapy as required | | | | | | | |
| | **Caution**<br>Careful monitoring of patients is mandatory. | | | | | | | |
| 6364Y | mycophenolate mofetil 1 g/5 mL oral liquid: powder for, 165 mL | 2 | 5 | .. | *#517.83 | | CellCept | RO |
| 6209T | mycophenolate mofetil 500 mg tablet, 50 | 6 | 5 | .. | *977.49 | [a] | APO-Mycophenolate | TX |
| | | | | | | [a] | CellCept | RO |
| | | | | | | [a] | Ceptolate | AF |
| | | | | | | [a] | Imulate | QA |
| | | | | | | [a] | Mycophenolate Sandoz | SZ |
| | | | | | | [a] | Pharmacor Mycophenolate 500 | CR |
| | **NATALIZUMAB**<br>**Authority required**<br>Initial treatment, as monotherapy, by a neurologist, of clinically definite relapsing-remitting multiple sclerosis in an ambulatory (without assistance or support) patient 18 years of age or older, who has experienced at least 2 documented attacks of neurological dysfunction, believed to be due to multiple sclerosis, in the preceding 2 years.<br>The diagnosis must be confirmed by magnetic resonance imaging of the brain and/or spinal cord and the date of the scan included in the authority application, unless the authority application is accompanied by written certification provided by a radiologist that an MRI scan is contraindicated because of the risk of physical (not psychological) injury to the patient | | | | | | | |
| | **Authority required**<br>Continuing treatment, as monotherapy, of clinically definite relapsing-remitting multiple sclerosis in a patient previously issued with an authority prescription for this drug who does not show continuing progression of disability while on treatment with this drug, and who has demonstrated compliance with, and an ability to tolerate, this therapy | | | | | | | |
| | **Caution**<br>Progressive multifocal leukoencephalopathy has been reported with this drug. | | | | | | | |
| | **Note**<br>Neurologists prescribing natalizumab under the PBS listing must be registered with the Tysabri Australian Prescribing Program. | | | | | | | |
| | **Note**<br>Special Pricing Arrangements apply. | | | | | | | |
| 9624M | natalizumab 300 mg/15 mL injection, 1 x 15 mL vial | 1 | 5 | .. | 2085.09 | | Tysabri | BD |
| | **SIROLIMUS**<br>**Authority required**<br>Management of rejection, under the supervision and direction of a transplant unit, in patients receiving this drug for prophylaxis of renal allograft rejection. Management includes initiation, stabilisation and review of therapy as required | | | | | | | |
| | **Caution**<br>Careful monitoring of patients is mandatory. | | | | | | | |
| 6436R | sirolimus 1 mg tablet, 100 | 2 | 5 | .. | *1493.29 | | Rapamune | PF |
| 6437T | sirolimus 1 mg/mL oral liquid, 60 mL | 2 | 5 | .. | *980.07 | | Rapamune | PF |
| 6457W | sirolimus 2 mg tablet, 100 | 2 | 5 | .. | *2939.97 | | Rapamune | PF |
| 9748C | sirolimus 500 microgram tablet, 100 | 2 | 5 | .. | *758.91 | | Rapamune | PF |

## *Tumor necrosis factor alpha (TNF-) inhibitors*

**ADALIMUMAB**

**Authority required**

Initial 1 (new patient or patient recommencing after a break of more than 12 months).

Initial treatment by a paediatric rheumatologist, or under the supervision of a paediatric rheumatology treatment centre, of a patient under 18 years:

(a) who has severe active juvenile idiopathic arthritis; AND

(b) whose parent or authorised guardian has signed a patient acknowledgement; AND

(c) who has not received PBS-subsidised treatment with adalimumab or etanercept for this condition in the previous 12 months; AND

(d) who has demonstrated either:

(i) severe intolerance of, or toxicity due to, methotrexate (see below for definition of severe intolerance and toxicity); or

(ii) failure to achieve an adequate response to 1 or more of the following treatment regimens:

— oral or parenteral methotrexate at a dose of at least 20 mg per square metre weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; or

— oral methotrexate at a dose of at least 10 mg per square metre weekly together with at least 1 other DMARD, alone or in combination with corticosteroids, for a minimum of 3 months. (Note: use of alternative DMARDs in children is dependent on approval by the Therapeutic Goods

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Administration as age restrictions may apply.)

Severe intolerance is defined as intractable nausea and vomiting and general malaise unresponsive to manoeuvres, including reducing or omitting concomitant NSAIDs on the day of methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses over 24 hours.

Toxicity is defined as evidence of hepatotoxicity with repeated elevations of transaminases, bone marrow suppression temporally related to methotrexate use, pneumonitis, or serious sepsis.

If treatment with methotrexate alone or in combination with another DMARD is contraindicated according to the relevant TGA-approved Product Information, please provide details at time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, please provide details of this toxicity at the time of application.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

(a) an active joint count of at least 20 active (swollen and tender) joints; OR

(b) at least 4 active joints from the following list:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count assessment should be performed preferably whilst still on DMARD treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and

(3) an acknowledgement signed by a parent or authorised guardian.

A maximum of 16 weeks of treatment will be authorised under this restriction.

At the time of authority application, medical practitioners should request the appropriate number of injections of appropriate strength, based on the weight of the patient, to provide sufficient for two doses. Up to a maximum of 3 repeats will be authorised.

Where fewer than 3 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Assessment of a patient's response to an initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 4 weeks from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with adalimumab.

If a patient fails to respond to treatment 3 times (twice with one agent and once with the other) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle. A patient may re-trial adalimumab after a minimum of 12 months have elapsed between the date the last PBS-subsidised bDMARD was stopped and the date of the first application under a new treatment cycle

**Authority required**

Initial 2 (change or re-commencement after break of less than 12 months).

Initial PBS-subsidised treatment with adalimumab by a paediatric rheumatologist, or under the supervision of a paediatric rheumatology treatment centre, of a patient under 18 years who:

(a) has a documented history of severe active juvenile idiopathic arthritis; and

(b) in this treatment cycle, has received prior PBS-subsidised treatment with adalimumab or etanercept for this condition; and

(c) has not failed PBS-subsidised therapy with adalimumab for this condition more than once in the current treatment cycle.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].

Applications for a patient who has received PBS-subsidised treatment with adalimumab in this treatment cycle and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised adalimumab treatment, within the timeframes specified below.

A maximum of 16 weeks of treatment will be authorised under this restriction.

At the time of authority application, medical practitioners should request the appropriate number of injections of appropriate strength, based on the weight of the patient, to provide sufficient for two doses. Up to a maximum of 3 repeats will be authorised.

Where fewer than 3 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment with adalimumab may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

# HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

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|---|---|---|---|---|---|---|

Where the most recent course of PBS-subsidised adalimumab treatment was approved under either of the Initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be provided to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised adalimumab treatment was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to that particular course of bDMARD.

If a patient fails to respond to treatment 3 times (twice with one agent and once with the other) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle. A patient may re-trial adalimumab after a minimum of 12 months have elapsed between the date the last PBS-subsidised bDMARD was stopped and the date of the first application under a new treatment cycle

**Authority required**

Initial 3 ('grandfather' patients).

Initial PBS-subsidised supply for continuing treatment with adalimumab, by a paediatric rheumatologist, or under the supervision of a paediatric rheumatology treatment centre, of a patient under 18 years who:

(a) has a documented history of severe active juvenile idiopathic arthritis; and

(b) was receiving treatment with adalimumab prior to 1 March 2010; and

(c) has demonstrated a response as specified in the criteria for continuing PBS-subsidised treatment with adalimumab; and

(d) is receiving treatment with adalimumab at the time of application.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and

(3) an acknowledgement signed by a parent or authorised guardian.

A maximum of 24 weeks of treatment will be authorised under this restriction.

At the time of authority application, medical practitioners should request the appropriate number of injections of appropriate strength, based on the weight of the patient, to provide sufficient for two doses. Up to a maximum of 5 repeats will be authorised.

Where fewer than 5 repeats are initially requested with the authority prescription, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

The assessment of the patient's response to this initial course of PBS-subsidised therapy must be made within the 4 weeks prior to completion of the course in order to ensure continuity of treatment.

A patient ceasing treatment or swapping to an alternate agent and wishing to demonstrate a response to treatment, must be assessed no earlier than 12 weeks from the commencement of PBS-subsidised treatment. This assessment must be provided to Medicare Australia no later than 4 weeks from the date that 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.

A patient may only qualify for PBS-subsidised treatment under this restriction once

**Authority required**

Continuing treatment.

Continuing PBS-subsidised treatment with adalimumab, by a rheumatologist or under the supervision of a paediatric rheumatology treatment centre, of a patient:

(a) who has a documented history of severe active juvenile idiopathic arthritis; and

(b) who has demonstrated an adequate response to treatment with adalimumab; and

(c) whose most recent course of PBS-subsidised bDMARD treatment in this treatment cycle was with adalimumab.

An adequate response to treatment is defined as:

(i) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(ii) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

— elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

— shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].

A maximum of 24 weeks of treatment will be approved under this restriction.

At the time of authority application, medical practitioners should request the appropriate number of injections of appropriate strength, based on

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|

the weight of the patient, to provide sufficient for two doses. Up to a maximum of 5 repeats will be authorised.

Where fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

All applications for continuing treatment with adalimumab must include a measurement of response to the prior course of therapy. This assessment must be provided to Medicare Australia no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with adalimumab, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.

If a patient fails to respond to treatment 3 times (twice with one agent and once with the other) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle. A patient may re-trial adalimumab after a minimum of 12 months have elapsed between the date the last PBS-subsidised bDMARD was stopped and the date of the first application under a new treatment cycle

**Note**

Any queries concerning the arrangements to prescribe adalimumab may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe adalimumab should be forwarded to:

Medicare Australia

Prior Written Approval of Specialised Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

**Note**

TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab and etanercept for a patient who has severe active juvenile idiopathic arthritis. Where the term bDMARD appears in the following NOTES and restrictions, it refers to adalimumab and etanercept only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 2 bDMARDs at any 1 time.

From 1 November 2010, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to the alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

— continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy, and

— fail to respond, or to sustain a response to one PBS-subsidised bDMARD twice and the other PBS-subsidised bDMARD once only.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 12 month break in PBS-subsidised biological therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 November 2010 is considered to be in their first cycle as of 1 November 2010. A patient who has had a break in bDMARD treatment of at least 12 months immediately prior to making a new application, on or after 1 November 2010, will commence a new treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 12 months may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 12 months must commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 November 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or

(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 12 months (Initial 1); or

(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or

(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 12 months in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

# HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|
| | For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course. | | | | | | |
| | (b) Continuing treatment. | | | | | | |
| | Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. | | | | | | |
| | It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply. | | | | | | |
| | Assessments of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased. | | | | | | |
| | Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD. | | | | | | |
| | (2) Swapping therapy. | | | | | | |
| | Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to the alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 12 months. | | | | | | |
| | A patient may trial the 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 twice within the current treatment cycle. | | | | | | |
| | To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction. | | | | | | |
| | To avoid confusion, an application for a patient who wishes to swap to the alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing. | | | | | | |
| | (3) Baseline measurements to determine response. | | | | | | |
| | Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and Medicare Australia will assess response according to the revised baseline measurement. | | | | | | |
| | (4) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy. | | | | | | |
| | A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 12 months, must requalify for treatment under the Initial 1 treatment restriction. | | | | | | |
| | (5) Patients 'grandfathered' onto PBS-subsidised treatment with adalimumab. | | | | | | |
| | A patient who commenced treatment with adalimumab for severe active juvenile idiopathic arthritis prior to 1 March 2010 and who continues to receive treatment at the time of application, may qualify for treatment under the initial 'grandfather' treatment restriction. | | | | | | |
| | A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment with adalimumab will be authorised under this criterion. | | | | | | |
| | Following completion of the initial PBS-subsidised course, further applications for treatment with adalimumab will be assessed under the continuing treatment restriction. | | | | | | |
| | 'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must qualify for initial treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 12 month break in PBS-subsidised therapy' above for further details. | | | | | | |
| | (6) Withdrawal of treatment after sustained remission. | | | | | | |
| | Withdrawal of treatment with bDMARDs should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be submitted to Medicare Australia at the time treatment is ceased. | | | | | | |
| 9678J | adalimumab 20 mg/0.4 mL injection, 2 x 0.4 mL syringes | 1 | .. | .. | 1676.63 | Humira | VE |
| 9680L | adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL cartridges | 1 | .. | .. | 1676.63 | Humira | VE |
| 9679K | adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes | 1 | .. | .. | 1676.63 | Humira | VE |
| | **ETANERCEPT** | | | | | | |
| | **Authority required** | | | | | | |
| | Continuing treatment. | | | | | | |
| | Continuing PBS-subsidised treatment with etanercept, by a rheumatologist or under the supervision of a paediatric rheumatology treatment centre, of a patient 18 years or older: | | | | | | |
| | (a) who has a documented history of severe active juvenile idiopathic arthritis; and | | | | | | |
| | (b) who has demonstrated an adequate response to treatment with etanercept; and | | | | | | |
| | (c) whose most recent course of PBS-subsidised bDMARD treatment in this treatment cycle was with etanercept. | | | | | | |

# HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|

An adequate response to treatment is defined as:

(i) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(ii) a reduction in the number of the following active joints, from at least 4, by at least 50%:

— elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

— shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].

A maximum of 24 weeks of treatment will be approved under this restriction.

Where fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

All applications for continuing treatment with etanercept must include a measurement of response to the prior course of therapy. This assessment must be provided to Medicare Australia no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with etanercept, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.

If a patient fails to respond to treatment 3 times (twice with one agent and once with the other) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle.

Where a patient with severe active juvenile idiopathic arthritis continues treatment with etanercept and is 18 years or older, etanercept 50 mg may be prescribed

**Note**

Any queries concerning the arrangements to prescribe etanercept may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe etanercept should be forwarded to:

Medicare Australia

Prior Written Approval of Specialised Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

**Note**

TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab and etanercept for a patient who has severe active juvenile idiopathic arthritis. Where the term bDMARD appears in the following NOTES and restrictions, it refers to adalimumab and etanercept only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 2 bDMARDs at any 1 time.

From 1 November 2010, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to the alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

— continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy, and

— fail to respond, or to sustain a response to one PBS-subsidised bDMARD twice and the other PBS-subsidised bDMARD once only.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 12 month break in PBS-subsidised biological therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 November 2010 is considered to be in their first cycle as of 1 November 2010. A patient who has had a break in bDMARD treatment of at least 12 months immediately prior to making a new application, on or after 1 November 2010, will commence a new treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 12 months may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 12 months must commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 November 2010.

(a) Initial treatment.

# HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|
| | Applications for initial treatment should be made where: | | | | | | |
| | (i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or | | | | | | |
| | (ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 12 months (Initial 1); or | | | | | | |
| | (iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or | | | | | | |
| | (iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 12 months in PBS-subsidised therapy with that agent (Initial 2). | | | | | | |
| | Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy. | | | | | | |
| | A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased. | | | | | | |
| | Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD. | | | | | | |
| | For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course. | | | | | | |
| | (b) Continuing treatment. | | | | | | |
| | Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. | | | | | | |
| | It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply. | | | | | | |
| | Assessments of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased. | | | | | | |
| | Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD. | | | | | | |
| | (2) Swapping therapy. | | | | | | |
| | Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to the alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 12 months. | | | | | | |
| | A patient may trial the 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 twice within the current treatment cycle. | | | | | | |
| | To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction. | | | | | | |
| | To avoid confusion, an application for a patient who wishes to swap to the alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing. | | | | | | |
| | (3) Baseline measurements to determine response. | | | | | | |
| | Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and Medicare Australia will assess response according to the revised baseline measurement. | | | | | | |
| | (4) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy. | | | | | | |
| | A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 12 months, must requalify for treatment under the Initial 1 treatment restriction. | | | | | | |
| | (5) Patients 'grandfathered' onto PBS-subsidised treatment with adalimumab. | | | | | | |
| | A patient who commenced treatment with adalimumab for severe active juvenile idiopathic arthritis prior to 1 March 2010 and who continues to receive treatment at the time of application, may qualify for treatment under the initial 'grandfather' treatment restriction. | | | | | | |
| | A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment with adalimumab will be authorised under this criterion. | | | | | | |
| | Following completion of the initial PBS-subsidised course, further applications for treatment with adalimumab will be assessed under the continuing treatment restriction. | | | | | | |
| | 'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must qualify for initial treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 12 month break in PBS-subsidised therapy' above for further details. | | | | | | |
| | (6) Withdrawal of treatment after sustained remission. | | | | | | |
| | Withdrawal of treatment with bDMARDs should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be submitted to Medicare Australia at the time treatment is ceased. | | | | | | |
| 9641K | ETANERCEPT Injection 50 mg in 1 mL single use auto-injector, 4, 1 | 1 | .. | .. | 1676.64 | Enbrel | PF |

# HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|
| 9615C | ETANERCEPT Injections 50 mg in 1 mL single use pre-filled syringes, 4, 1 | 1 | .. | .. | 1676.64 | Enbrel | PF |

**ETANERCEPT**

**Authority required**

Initial 1 (new patient or patient recommencing after a break of more than 12 months).

Initial treatment by a paediatric rheumatologist, or under the supervision of a paediatric rheumatology treatment centre, of a patient under 18 years:

(a) who has severe active juvenile idiopathic arthritis; AND

(b) whose parent or authorised guardian has signed a patient acknowledgement; AND

(c) who has not received PBS-subsidised treatment with adalimumab or etanercept for this condition in the previous 12 months; AND

(d) who has demonstrated either:

(i) severe intolerance of, or toxicity due to, methotrexate (see below for definition of severe intolerance and toxicity); or

(ii) failure to achieve an adequate response to 1 or more of the following treatment regimens:

— oral or parenteral methotrexate at a dose of at least 20 mg per square metre weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; or

— oral methotrexate at a dose of at least 10 mg per square metre weekly together with at least 1 other DMARD, alone or in combination with corticosteroids, for a minimum of 3 months. (Note: use of alternative DMARDs in children is dependent on approval by the Therapeutic Goods Administration as age restrictions may apply.)

Severe intolerance is defined as intractable nausea and vomiting and general malaise unresponsive to manoeuvres, including reducing or omitting concomitant NSAIDs on the day of methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses over 24 hours.

Toxicity is defined as evidence of hepatotoxicity with repeated elevations of transaminases, bone marrow suppression temporally related to methotrexate use, pneumonitis, or serious sepsis.

If treatment with methotrexate alone or in combination with another DMARD is contraindicated according to the relevant TGA-approved Product Information, please provide details at time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, please provide details of this toxicity at the time of application.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

(a) an active joint count of at least 20 active (swollen and tender) joints; OR

(b) at least 4 active joints from the following list:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count assessment should be performed preferably whilst still on DMARD treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and

(3) an acknowledgement signed by a parent or authorised guardian.

A maximum of 16 weeks of treatment will be authorised under this restriction.

Where fewer than 3 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Assessment of a patient's response to an initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 4 weeks from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with etanercept.

If a patient fails to respond to treatment 3 times (twice with one agent and once with the other) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle. A patient may re-trial etanercept after a minimum of 12 months have elapsed between the date the last PBS-subsidised bDMARD was stopped and the date of the first application under a new treatment cycle

**Authority required**

Initial 2 (change or re-commencement after break of less than 12 months).

Initial PBS-subsidised treatment with etanercept by a paediatric rheumatologist, or under the supervision of a paediatric rheumatology treatment centre, of a patient under 18 years who:

# HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|

(a) has a documented history of severe active juvenile idiopathic arthritis; and

(b) in this treatment cycle, has received prior PBS-subsidised treatment with adalimumab or etanercept for this condition; and

(c) has not failed PBS-subsidised therapy with etanercept for this condition more than once in the current treatment cycle.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].

Applications for a patient who has received PBS-subsidised treatment with etanercept in this treatment cycle and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised etanercept treatment, within the timeframes specified below.

A maximum of 16 weeks of treatment will be authorised under this restriction.

Where fewer than 3 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment with etanercept may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Where the most recent course of PBS-subsidised etanercept treatment was approved under either of the Initial 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 provided to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised etanercept treatment was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to that particular course of bDMARD.

If a patient fails to respond to treatment 3 times (twice with one agent and once with the other) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle. A patient may re-trial etanercept after a minimum of 12 months have elapsed between the date the last PBS-subsidised bDMARD was stopped and the date of the first application under a new treatment cycle

**Authority required**

Continuing treatment.

Continuing PBS-subsidised treatment with etanercept, by a rheumatologist or under the supervision of a paediatric rheumatology treatment centre, of a patient:

(a) who has a documented history of severe active juvenile idiopathic arthritis; and

(b) who has demonstrated an adequate response to treatment with etanercept; and

(c) whose most recent course of PBS-subsidised bDMARD treatment in this treatment cycle was with etanercept.

An adequate response to treatment is defined as:

(i) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(ii) a reduction in the number of the following active joints, from at least 4, by at least 50%:

— elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

— shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].

A maximum of 24 weeks of treatment will be approved under this restriction.

Where fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

All applications for continuing treatment with etanercept must include a measurement of response to the prior course of therapy. This assessment must be provided to Medicare Australia no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with etanercept, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.

If a patient fails to respond to treatment 3 times (twice with one agent and once with the other) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle. A patient may re-trial etanercept after a minimum of 12 months have elapsed between the date the last PBS-subsidised bDMARD was stopped and the date of the first application under a new treatment cycle

**Note**

Any queries concerning the arrangements to prescribe etanercept may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe etanercept should be forwarded to:

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|

Medicare Australia

Prior Written Approval of Specialised Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

**Note**

TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab and etanercept for a patient who has severe active juvenile idiopathic arthritis. Where the term bDMARD appears in the following NOTES and restrictions, it refers to adalimumab and etanercept only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 2 bDMARDs at any 1 time.

From 1 November 2010, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to the alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

— continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy, and

— fail to respond, or to sustain a response to one PBS-subsidised bDMARD twice and the other PBS-subsidised bDMARD once only.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 12 month break in PBS-subsidised biological therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 November 2010 is considered to be in their first cycle as of 1 November 2010. A patient who has had a break in bDMARD treatment of at least 12 months immediately prior to making a new application, on or after 1 November 2010, will commence a new treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 12 months may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 12 months must commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 November 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or

(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 12 months (Initial 1); or

(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or

(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 12 months in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to the alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in

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therapy of more than 12 months.

A patient may trial the 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 twice within the current treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to the alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and Medicare Australia will assess response according to the revised baseline measurement.

(4) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 12 months, must requalify for treatment under the Initial 1 treatment restriction.

(5) Patients 'grandfathered' onto PBS-subsidised treatment with adalimumab.

A patient who commenced treatment with adalimumab for severe active juvenile idiopathic arthritis prior to 1 March 2010 and who continues to receive treatment at the time of application, may qualify for treatment under the initial 'grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment with adalimumab will be authorised under this criterion.

Following completion of the initial PBS-subsidised course, further applications for treatment with adalimumab will be assessed under the continuing treatment restriction.

'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must qualify for initial treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 12 month break in PBS-subsidised therapy' above for further details.

(6) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with bDMARDs should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be submitted to Medicare Australia at the time treatment is ceased.

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| 6367D | etanercept 25 mg injection [4 x 25 mg vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack | 1 | .. | .. | 854.23 | Enbrel | PF |

**INFLIXIMAB**

**Authority required**

Initial 1 (new patient or patient re-commencing after a break of more than 24 months)

Initial PBS-subsidised treatment with infliximab, in combination with methotrexate at a dose of at least 7.5 mg weekly, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of adults who:

(a) have severe active rheumatoid arthritis; and

(b) have received no PBS-subsidised treatment with a bDMARD for this condition in the previous 24 months; and

(c) have failed, in the 24 months immediately prior to the date of application, to achieve an adequate response to at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs), which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be:

— hydroxychloroquine at a dose of at least 200 mg daily; or

— leflunomide at a dose of at least 10 mg daily; or

— sulfasalazine at a dose of at least 2 g daily.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, then the 6 months of intensive DMARD treatment must include at least 3 months continuous treatment with each of at least 2 of the DMARDs:

— hydroxychloroquine at a dose of at least 200 mg daily; and/or

— leflunomide at a dose of at least 10 mg daily; and/or

— sulfasalazine at a dose of at least 2 g daily.

The application must include details of the contraindication or intolerance to methotrexate. Details of the toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose can be found on the Medicare Australia website [www.medicareaustralia.gov.au]. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

If 3 or more of methotrexate, hydroxychloroquine, leflunomide and sulfasalazine are contraindicated according to the relevant TGA-approved product information or cannot be tolerated at the doses specified above, then one or more of the following DMARDs may be used in place of these agents in order to satisfy the requirement for a trial of 6 months of intensive DMARD therapy with at least 2 DMARDs taken continuously for at least 3 months each:

— azathioprine at a dose of at least 1 mg/kg per day; and/or

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— cyclosporin at a dose of at least 2 mg/kg/day; and/or

— sodium aurothiomalate at a dose of 50 mg weekly.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances. Details of the toxicities, including severity, which will be accepted as a reason for substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial can be found on the Medicare Australia website [www.medicareaustralia.gov.au].

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance and dose for each DMARD must be provided in the authority application. Details of the toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy can be found on the Medicare Australia website [www.medicareaustralia.gov.au].

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L;

AND either

(i) a total active joint count of at least 20 active (swollen and tender) joints; or

(ii) at least 4 active joints from the following list of major joints:

— elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

— shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reason this criterion cannot be satisfied.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and

(3) a signed patient acknowledgement.

A maximum of 22 weeks of treatment will be authorised under this restriction.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 3 mg per kg. Up to a maximum of 3 repeats may be authorised. Where fewer than 3 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 22 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Assessment of a patient's response to an initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab.

Patients who fail to demonstrate a response to treatment with infliximab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition

**Authority required**

Initial 2 (change or re-commencement after break of less than 24 months)

Initial course of PBS-subsidised treatment with infliximab, in combination with methotrexate at a dose of at least 7.5 mg weekly, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of adults who:

(a) have a documented history of severe active rheumatoid arthritis; and

(b) have received prior PBS-subsidised bDMARD treatment for this condition and are eligible to receive further bDMARD therapy.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].

Applications for patients who have received PBS-subsidised treatment with infliximab and who wish to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised infliximab treatment, within the timeframes

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specified below.

A maximum of 22 weeks of treatment will be authorised under this restriction.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 3 mg per kg. Up to a maximum of 3 repeats may be authorised.

Where fewer than 3 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 22 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Where the most recent course of PBS-subsidised infliximab treatment was approved under either of the initial 1 or 2 treatment restrictions, patients must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be provided to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised infliximab treatment was approved under the continuing treatment criteria, patients must have been assessed for response, and the assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Patients who fail to demonstrate a response to treatment with infliximab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition

**Authority required**

Continuing treatment

Continuing PBS-subsidised treatment with infliximab, in combination with methotrexate at a dose of at least 7.5 mg weekly, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of adults:

(a) who have a documented history of severe active rheumatoid arthritis; and

(b) who have demonstrated an adequate response to treatment with infliximab; and

(c) whose most recent course of PBS-subsidised bDMARD treatment was with infliximab.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(i) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(ii) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

— elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

— shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].

A maximum of 24 weeks of treatment will be approved under this restriction.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 3 mg per kg. Up to a maximum of 2 repeats may be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

All applications for continuing treatment with infliximab must include a measurement of response to the prior course of therapy. This assessment must be provided to Medicare Australia no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with infliximab, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.

Patients who fail to demonstrate a response to treatment with infliximab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition

**Note**

Any queries concerning the arrangements to prescribe infliximab may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe infliximab should be forwarded to:

Medicare Australia

Prior Written Approval of Specialised Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

**Note**

# HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

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TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying anti-rheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab) and the T-cell co-stimulation modulator (abatacept).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

PBS-subsidised abatacept, golimumab, infliximab and rituximab must be used in combination with methotrexate at a dose of at least 7.5 mg weekly. Where a patient cannot tolerate 7.5 mg of methotrexate weekly, they are eligible to receive PBS-subsidised adalimumab, certolizumab pegol, etanercept and tocilizumab.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:

— a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,

— a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and

— once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact Medicare Australia on 1800 700 270.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or

(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or

(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or

(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab and tocilizumab, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to Medicare Australia within 4 weeks.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

Abatacept patients:

Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients:

A further application may be submitted to Medicare Australia 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24

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weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Rituximab patients:

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.

Abatacept patients:

Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

**Note**

(3) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and Medicare Australia will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

**Note**

Special Pricing Arrangements apply.

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| 6397Q | infliximab 100 mg injection, 1 x 100 mg vial | 1 | .. | .. | 788.40 | Remicade | JC |

**INFLIXIMAB**

**Authority required**

Initial 1 (new patients)

Initial PBS-subsidised treatment with infliximab, by a rheumatologist, of an adult with active ankylosing spondylitis who has radiographically (plain X-ray) confirmed Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis and who has not received any PBS-subsidised treatment with either adalimumab, etanercept, golimumab or infliximab in this treatment cycle; AND

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(a) who has 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) [for further information on the BASMI please refer to the Medicare Australia website at www.medicareaustralia.gov.au]; or

(iii) limitation of chest expansion relative to normal values for age and gender [for chest expansion normal values please refer to the Medicare Australia website at www.medicareaustralia.gov.au]; AND

(b) who has 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.

The application must include details of the NSAIDs trialled, their doses and duration of treatment. If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used.

If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication.

If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance. Details of the toxicities, including severity, which will be accepted for the purposes of administering this restriction can be found on the Medicare Australia website [www.medicareaustralia.gov.au].

For details on the appropriate minimum exercise program that will be accepted for the purposes of administering this restriction, please refer to the Medicare Australia website at www.medicareaustralia.gov.au.

The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of the initial application:

(a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale; AND

(b) an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 10 mg per L.

The BASDAI must be determined at the completion of the 3 month NSAID and exercise trial, but prior to ceasing NSAID treatment. The BASDAI must be no more than 1 month old at the time of initial application.

Both ESR and CRP measures should be provided with the initial treatment application and both must be no more than 1 month old. If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reason this criterion cannot be satisfied.

Authority applications 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 [www.medicareaustralia.gov.au] which must include the following:

(i) a copy of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and

(ii) a completed BASDAI Assessment Form [www.medicareaustralia.gov.au]; and

(iii) a completed Exercise Program Self Certification Form included in the supporting information form; and

(iv) a signed patient acknowledgment form.

The assessment of the patient's response to the initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted to Medicare Australia no later than 4 weeks from the cessation of that treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

A maximum of 18 weeks of treatment with infliximab will be approved under this criterion.

At the time of the authority application, the doctor should request the appropriate number of vials, based on the weight of the patient, to provide for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised.

Where fewer than 3 repeats are initially requested with the authority prescription, authority approvals for sufficient repeats to complete a maximum of 18 weeks of treatment may be requested by telephone.

Patients who fail to demonstrate a response to treatment with infliximab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. Patients may re-trial infliximab after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised TNF-alfa antagonist was approved in this cycle and the date of the first application under a new cycle

**Authority required**

Initial 2 (change or re-commencement for all patients)

Initial PBS-subsidised treatment with infliximab, by a rheumatologist, of an adult with a documented history of active ankylosing spondylitis who, in this treatment cycle, has received prior PBS-subsidised TNF-alfa antagonist treatment for this condition and is eligible to receive further TNF-alfa antagonist therapy, and has not failed PBS-subsidised therapy with infliximab in the current treatment cycle.

Where the most recent course of PBS-subsidised TNF-alfa antagonist treatment was approved under either of the initial treatment restrictions (i.e. for patients with no prior PBS-subsidised TNF-alfa antagonist therapy or, under this restriction, for patients who have received previous PBS-subsidised TNF-alfa antagonist 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 Medicare Australia 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 infliximab treatment was approved under the continuing treatment criteria, patients must have been assessed for response, and the assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Authority applications must be made in writing and must include:

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Brand Name and Manufacturer |
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(a) a completed authority prescription form; and

(b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form [www.medicareaustralia.gov.au].

A maximum of 18 weeks of treatment with infliximab will be approved under this criterion.

At the time of the authority application, the doctor should request the appropriate number of vials, based on the weight of the patient, to provide for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised.

Where fewer than 3 repeats are initially requested with the authority prescription, authority approvals for sufficient repeats to complete a maximum of 18 weeks of treatment may be requested by telephone.

Patients who fail to demonstrate a response to treatment with infliximab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. Patients may re-trial infliximab after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised TNF-alfa antagonist was approved in this cycle and the date of the first application under a new cycle

**Authority required**

Continuing treatment for all patients

Continuing PBS-subsidised treatment, by a rheumatologist, of an adult with a documented history of active ankylosing spondylitis who:

(a) has demonstrated an adequate response to treatment with infliximab; and

(b) whose most recent course of PBS-subsidised therapy in this treatment cycle was with infliximab.

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.

Authority applications 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 [www.medicareaustralia.gov.au].

All measurements provided must be no more than 1 month old at the time of application.

A maximum of 24 weeks of treatment with infliximab will be authorised under this criterion.

At the time of the authority application, the doctor should request the appropriate number of vials, based on the weight of the patient, to provide for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised.

Where fewer than 3 repeats are initially requested with the authority prescription, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone.

All applications for continuing treatment with infliximab must include a measurement of response to the prior course of therapy. This assessment must be provided to Medicare Australia no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment following an initial treatment course it must be made following a minimum of 12 weeks of treatment with infliximab. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

Patients who fail to demonstrate a response to treatment with infliximab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. Patients may re-trial infliximab after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised TNF-alfa antagonist was approved in this cycle and the date of the first application under a new cycle

**Note**

Any queries concerning the arrangements to prescribe infliximab may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe infliximab should be forwarded to:

Medicare Australia

Prior Written Approval of Specialised Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

**Note**

TREATMENT OF ADULT PATIENTS WITH ACTIVE ANKYLOSING SPONDYLITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept, golimumab and infliximab for adult patients with active ankylosing spondylitis. Where the term 'tumour necrosis factor (TNF) alfa antagonist' appears in the following NOTES and restrictions, it refers to adalimumab, etanercept, golimumab and infliximab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 4 TNF-alfa antagonists at any 1 time.

From 1 March 2007, under the PBS, all patients will be able to commence a treatment cycle where they may trial PBS-subsidised TNF-alfa antagonists without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a TNF-alfa antagonist while they continue to show a

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Brand Name and Manufacturer |
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response to therapy.

A patient who received PBS-subsidised TNF-alfa antagonist treatment prior to 1 March 2007 is considered to be in their first cycle as of 1 March 2007.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised TNF-alfa antagonist more than once. A patient who, prior to 1 March 2007, was authorised to receive PBS-subsidised initial treatment for ankylosing spondylitis with the same agent twice, is exempt from this condition in respect of applications approved prior to 1 March 2007.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised TNF-alfa antagonist therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised TNF-alfa antagonist treatment in the most recent cycle to the date of the first application for initial treatment with a TNF-alfa antagonist under the new treatment cycle.

A patient who has failed fewer than 3 TNF-alfa antagonists in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 TNF-alfa antagonists in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised TNF-alfa antagonist therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised TNF-alfa antagonist treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or

(ii) a patient has received prior PBS-subsidised (initial or continuing) TNF-alfa antagonist therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to re-commence treatment with a specific TNF-alfa antagonist following a break in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept and golimumab and 18 weeks of treatment for infliximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.

For second and subsequent courses of PBS-subsidised TNF-alfa antagonist treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific TNF-alfa antagonist, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing TNF-alfa antagonist treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted TNF-alfa antagonist supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised TNF-alfa antagonist is approved, a patient may swap to an alternate TNF-alfa antagonist 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 TNF-alfa antagonist at any time, regardless of whether they are receiving therapy (initial or continuing) with a TNF-alfa antagonist at the time of the application. However, they cannot swap to a particular TNF-alfa antagonist if they have failed to respond to prior treatment with that drug within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate TNF-alfa antagonist should be accompanied by the approved authority prescription or remaining repeats for the TNF-alfa antagonist the patient is ceasing.

(3) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a TNF-alfa antagonist. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and Medicare Australia will assess response according to these revised baseline measurements.

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For a new patient, the BASDAI used to determine the baseline must be measured while the patient is receiving NSAID therapy and completing their exercise program.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response.

(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised TNF-alfa antagonist therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have received treatment with 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.

(5) Patients 'grandfathered' onto PBS-subsidised treatment with golimumab.

A patient who commenced treatment with golimumab for active ankylosing spondylitis prior to 1 March 2010 and who continues to receive treatment at the time of application, may qualify for treatment under the initial 'grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment with golimumab will be authorised under this criterion.

Following completion of the initial PBS-subsidised course, further applications for treatment with golimumab will be assessed under the continuing treatment restriction.

'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must requalify for initial treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' above for further details.

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| 6448J | infliximab 100 mg injection, 1 x 100 mg vial | 1 | .. | .. | 788.40 | Remicade | JC |

**INFLIXIMAB**

**Authority required**

Initial 1

Initial PBS-subsidised treatment with infliximab, by a rheumatologist or clinical immunologist with expertise in the management of psoriatic arthritis, of adults who:

(1) have severe active psoriatic arthritis; and

(2) have received no prior PBS-subsidised biological treatment for this condition in this Treatment Cycle; and

(3) have failed to achieve an adequate response to:

(a) methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months; and

(b) sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months; or

(c) leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months.

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity to necessitate permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of acceptable toxicities, including severity, can be found on the Medicare Australia website (www.medicareaustralia.gov.au).

The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either

(i) an active joint count of at least 20 active (swollen and tender) joints; or

(ii) at least 4 active joints from the following list of major joints:

— elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

— shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and

(3) a signed patient acknowledgement.

A maximum of 22 weeks treatment will be authorised under this restriction.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats may be authorised.

Where fewer than 3 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum

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of 22 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

The assessment of the patient's response to the initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted to Medicare Australia no later than 4 weeks from the cessation of that treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

Patients who fail to demonstrate a response to treatment with infliximab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug, in this Treatment Cycle. Patients may re-trial infliximab after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle

**Authority required**

Initial 2

Initial PBS-subsidised treatment with infliximab, by a rheumatologist or clinical immunologist with expertise in the management of psoriatic arthritis, of adults who:

(1) have a documented history of severe active psoriatic arthritis; and

(2) have received prior PBS-subsidised biological treatment for this condition in this Treatment Cycle and are eligible to receive further biological therapy; and

(3) have not failed treatment with infliximab during the current Treatment Cycle.

Applications for patients who have received PBS-subsidised treatment with infliximab within this Treatment Cycle and who wish to re-commence therapy with this drug within this same Cycle, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised infliximab treatment, within the timeframes specified below.

A maximum of 22 weeks treatment will be authorised under this restriction.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats may be authorised.

Where fewer than 3 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 22 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Where the most recent course of PBS-subsidised infliximab treatment was approved under either of the initial treatment restrictions (i.e. for patients with no prior PBS-subsidised biological therapy or, under this restriction, for patients who have received previous PBS-subsidised biological therapy), patients must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be provided to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised infliximab treatment was approved under the continuing treatment criteria, patients must have been assessed for response, and the assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].

Patients who fail to demonstrate a response to treatment with infliximab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug, in this Treatment Cycle. Patients may re-trial infliximab after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle

**Authority required**

Continuing treatment

Continuing PBS-subsidised treatment with infliximab, by a rheumatologist or clinical immunologist with expertise in the management of psoriatic arthritis, of adults:

(1) who have a documented history of severe active psoriatic arthritis; and

(2) whose most recent course of PBS-subsidised biological agent for this condition in the current Treatment Cycle was with infliximab; and

(3) who, at the time of application, demonstrate an adequate response to treatment with infliximab.

An adequate response to treatment with infliximab is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following:

(i) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(ii) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

— elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

— shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].

# HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Brand Name and Manufacturer |
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A maximum of 24 weeks of treatment will be approved under this restriction.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats may be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

All applications for continuing treatment with infliximab must include a measurement of response to the prior course of therapy. This assessment must be provided to Medicare Australia no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with infliximab, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with the initial treatment course.

Patients who fail to demonstrate a response to treatment with infliximab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug, in this Treatment Cycle. Patients may re-trial infliximab after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle

**Note**

Any queries concerning the arrangements to prescribe infliximab may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe infliximab should be forwarded to:

Medicare Australia

Prior Written Approval of Specialised Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

**Note**

TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents (adalimumab, etanercept, golimumab and infliximab) for adult patients with severe active psoriatic arthritis.

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological agents at any 1 time. Where the term 'biological agents' appears in the following NOTES and restrictions, it only refers to adalimumab, etanercept, golimumab and infliximab.

From 1 August 2006, all patients will be able to commence a 'Biological Treatment Cycle' (Cycle), where they may trial biological agents without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

Following demonstration of response to initial treatment, these biological agents are available under the PBS for continuing treatment as set out in the continuing treatment restriction for each agent.

Once patients have either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological therapy before they are eligible to commence another Cycle [further details are under '(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' below].

The 5-year break in therapy will be measured from the date the last approval for PBS-subsidised treatment was granted in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Cycle.

Within the same Cycle, patients are not allowed to fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for any biological agent, they must change to an alternate agent which they have not previously failed, if they wish to continue PBS-subsidised biological treatment.

Patients for whom a break in PBS-subsidised therapy of less than 5 years has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.

Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle.

There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.

How to prescribe biological agents for the treatment of severe active psoriatic arthritis after 1 August 2010.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); and

(ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; and

(iii) patients wish to re-commence treatment with a specific biological agent following a break in PBS-subsidised therapy with that specific agent (Initial 2).

All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 16 weeks of therapy for all agents except for infliximab, for which a maximum of 22 weeks will be authorised. It is recommended that patients be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological agent supply.

# HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Brand Name and Manufacturer | |
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Patients must be assessed for response to any course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.

Grandfather patients — golimumab only.

Applications for patients who commenced treatment with golimumab prior to 1 March 2010 may apply for initial PBS-subsidised treatment as continuing therapy under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with any biological agent prior to PBS listing of that agent.

Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment for all agents. Approval will be based on the criteria included in the relevant restriction.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological agent, patients may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. Patients are eligible to receive continuing biological treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

Patients must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.

(3) Swapping therapy.

Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate biological agent without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements.

Patients may swap to an alternate biological agent at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological agent at the time of the application or not.

Patients may alternate between therapy with any biological agent of their choice (1 at a time) providing:

(i) they have not received PBS-subsidised treatment with that particular biological agent previously; or

(ii) they have demonstrated an adequate response to that particular biological agent if they have previously trialled it on the PBS; or

(iii) they have not previously failed to respond to treatment 3 times in this Treatment Cycle.

To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the biological agent the patient is ceasing.

(4) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements of the indices of disease severity submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment authority is submitted within a treatment Cycle and Medicare Australia will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.

(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

Patients who wish to trial a second or subsequent treatment Cycle following a break in PBS-subsidised biological therapy of at least 5 years, must re-qualify for initial treatment with respect to both the indices of disease severity. Patients must have received treatment with methotrexate and sulfasalazine or leflunomide, at an adequate dose, for a minimum of 3 months at the time the ESR or CRP levels and the active joint counts are measured.

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| 6496X | infliximab 100 mg injection, 1 x 100 mg vial | 1 | .. | .. | 788.40 | Remicade | JC |

**INFLIXIMAB**

**Authority required**

Initial treatment of Crohn disease in a paediatric patient.

Initial PBS-subsidised treatment by a gastroenterologist, paediatrician or consultant physician as specified in the NOTE below, of a patient aged 6 to 17 years inclusive with moderate to severe refractory Crohn disease who satisfies the following criteria:

(a) has confirmed Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or consultant physician as specified in the NOTE below; and

(b) whose parent or authorised guardian has signed a patient acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and

(c) has failed to achieve an adequate response to 2 of the following 3 conventional prior therapies including:

(i) a tapered course of steroids, starting at a dose of at least 1 mg per kg or 40 mg (whichever is the lesser) prednisolone (or equivalent), over a 6

# HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

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week period;

(ii) an 8 week course of enteral nutrition;

(iii) immunosuppressive therapy including:

— azathioprine at a dose of at least 2 mg per kg daily for 3 or more months; or

— 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months; or

— methotrexate at a dose of at least 10 mg per square metre weekly for 3 or more months.

NOTE: Prescribers must be gastoenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of the accepted toxicities including severity can be found on the Medicare Australia website (www.medicareaustralia.gov.au).

The following initiation criterion indicates failure to achieve an adequate response and must be demonstrated in all patients at the time of the application:

(a) severity of disease activity which results in a Paediatric Crohn Disease Activity Index (PCDAI) Score greater than or equal to 30 as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.

(b) The most recent PCDAI assessment must be no more than 1 month old at the time of application.

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) the completed current Paediatric Crohn Disease Activity Index (PCDAI) calculation sheet including the date of assessment of the patient's condition; and

(ii) details of previous systemic drug therapy [dosage, date of commencement and duration of therapy], or dates of enteral nutrition; and

(iii) the signed patient acknowledgement.

A maximum quantity and number of repeats to provide for an initial course of infliximab consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete the 3 doses of infliximab may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

A PCDAI assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab.

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment

**Authority required**

Continuing treatment of Crohn disease in a patient initiated on PBS-subsidised treatment as a paediatric patient.

Continuing PBS-subsidised treatment with infliximab by a gastroenterologist, paediatrician, consultant physician as specified in the NOTE below or other consultant physician in consultation with a gastroenterologist, of a patient who:

(a) has a documented history of moderate to severe refractory Crohn disease; and

(b) has demonstrated or sustained an adequate response to treatment with infliximab.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

An adequate response to infliximab treatment is defined as a reduction in Paediatric Crohn Disease Activity Index (PCDAI) Score by at least 15 points as compared to baseline AND a total PCDAI score of 30 points or less.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) the completed Paediatric Crohn Disease Activity Index (PCDAI) calculation sheet along with the date of the assessment of the patient's condition.

The PCDAI assessment must be no more than 1 month old at the time of application.

# HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

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If the application is the first application for continuing treatment with infliximab, a PCDAI assessment of the patient's response must be made up to 12 weeks after the first dose so that there is adequate time for a response to be demonstrated.

The assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion.

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with infliximab.

Patients are eligible to receive continuing infliximab treatment in courses of up to 24 weeks providing they continue to sustain the response.

Patients who fail to demonstrate or sustain a response to treatment with infliximab for Crohn disease as specified in the criteria for continuing treatment with infliximab, will not be eligible to receive PBS-subsidised treatment with this drug within 12 months of the date on which treatment was ceased.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats will be authorised. No applications for increased repeats will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday)

**Authority required**

Initial PBS-subsidised treatment of Crohn disease in a paediatric patient who has previously received non-PBS-subsidised therapy with infliximab.

Initial PBS-subsidised supply for continuing treatment with infliximab by a gastroenterologist, paediatrician, consultant physician as specified in the NOTE below or other consultant physician in consultation with a gastroenterologist, of a patient aged 6 to 17 years inclusive who:

(a) has a documented history of moderate to severe refractory Crohn disease and was receiving treatment with infliximab prior to 4 July 2007; and

(b) had a Paediatric Crohn Disease Activity Index (PCDAI) Score of greater than 30 prior to commencing treatment with infliximab. Where a baseline CDAI assessment is not available, please call Medicare Australia on 1800 700 270 to discuss; and

(c) whose parent or authorised guardian has signed a patient acknowledgement indicating that they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and

(d) has demonstrated or sustained an adequate response to treatment with infliximab. For advice please contact Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

An adequate response to infliximab treatment is defined as a reduction in Paediatric Crohn Disease Activity Index (PCDAI) Score by at least 15 points as compared to baseline AND a total PCDAI score of 30 points or less.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) the completed current and baseline Paediatric Crohn Disease Activity Index (PCDAI) calculation sheet along with the date of the assessment of the patient's condition; and

(ii) the signed patient acknowledgement.

The current PCDAI assessment must be no more than 1 month old at the time of application. The baseline PCDAI assessment must be from immediately prior to commencing treatment with infliximab.

The assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion.

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with infliximab.

Patients are eligible to receive continuing infliximab treatment in courses of up to 24 weeks providing they continue to sustain the response.

Patients who fail to demonstrate or sustain a response to treatment with infliximab for Crohn disease as specified in the criteria for continuing treatment with infliximab, will not be eligible to recommence PBS-subsidised treatment with this drug within 12 months of the date on which treatment was ceased.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats will be authorised. No applications for increased repeats will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Patients may qualify for PBS-subsidised treatment under this restriction once only

**Note**

Any queries concerning the arrangements to prescribe infliximab may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m.

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| | to 5 p.m. EST Monday to Friday). | | | | | | |
| | Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au. | | | | | | |
| | Written applications for authority to prescribe infliximab should be forwarded to: | | | | | | |
| | Medicare Australia | | | | | | |
| | Prior Written Approval of Specialised Drugs | | | | | | |
| | Reply Paid 9826 | | | | | | |
| | GPO Box 9826 | | | | | | |
| | HOBART TAS 7001 | | | | | | |
| 9612X | infliximab 100 mg injection, 1 x 100 mg vial | 1 | .. | .. | 788.40 | Remicade | JC |

**INFLIXIMAB**

**Authority required**

Initial 1 (new patients)

Initial treatment of Crohn disease in a patient assessed by CDAI.

Initial PBS-subsidised treatment with infliximab by a gastroenterologist or a consultant physician as specified in the NOTE below, of a patient with severe refractory Crohn disease who satisfies the following criteria:

(a) has confirmed Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician as specified in the NOTE below; and

(b) has signed a patient acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and

(c) has failed to achieve an adequate response to prior systemic therapy including:

(i) a tapered course of steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period; and

(ii) immunosuppressive therapy including:

— azathioprine at a dose of at least 2 mg per kg daily for 3 or more months; or

— 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months; or

— methotrexate at a dose of at least 15 mg weekly for 3 or more months.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of the accepted toxicities including severity can be found on the Medicare Australia website (www.medicareaustralia.gov.au).

The following initiation criterion indicates failure to achieve an adequate response and must be demonstrated in all patients at the time of the application:

(a) have a severity of disease activity which results in a Crohn Disease Activity Index (CDAI) Score greater than or equal to 300 as assessed.

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.

The most recent CDAI assessment must be no more than 1 month old at the time of application.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) the completed current Crohn Disease Activity Index (CDAI) calculation sheet including the date of assessment of the patient's condition; and

(ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and

(iii) the signed patient acknowledgement.

A maximum quantity and number of repeats to provide for an initial course of infliximab consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete the 3 doses of infliximab may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

A CDAI assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare

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Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab.

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment

**Authority required**

Initial 2

Change or re-commencement of treatment of Crohn disease in a patient assessed by CDAI.

Initial PBS-subsidised treatment with infliximab by a gastroenterologist or a consultant physician as specified in the NOTE below of a patient who:

(a) has a documented history of severe refractory Crohn disease; and

(b) in this treatment cycle, has received prior PBS-subsidised treatment with infliximab or adalimumab for this condition; and

(c) has not failed PBS-subsidised therapy with infliximab for this condition more than once in the current treatment cycle.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

To demonstrate a response to treatment the application must be accompanied by the results of the most recent course of TNF-alfa antagonist therapy within the timeframes specified in the relevant restriction.

Where the most recent course of PBS-subsidised TNF-alfa antagonist treatment was approved under an initial treatment restriction, the patient must have been assessed for response to that course following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

If the response assessment to the previous course of TNF-alfa antagonist treatment is not submitted as detailed above, the patient will be deemed to have failed therapy with that particular course of TNF-alfa antagonist.

Authority applications must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) the completed current Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient's condition; and

(ii) details of prior TNF alfa antagonist treatment including details of date and duration of treatment.

A maximum quantity and number of repeats to provide for an initial course of infliximb consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete the 3 doses of infliximab may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

A CDAI assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab.

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment

**Authority required**

Continuing treatment of Crohn disease in a patient assessed by CDAI.

Continuing PBS-subsidised treatment with infliximab by a gastroenterologist, a consultant physician as specified in the NOTE below or other consultant physician in consultation with a gastroenterologist, of a patient who:

(a) has a documented history of severe refractory Crohn disease; and

(b) has demonstrated or sustained an adequate response to treatment with infliximab.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

An adequate response to infliximab treatment is defined as a reduction in Crohn Disease Activity Index (CDAI) Score to a level no greater than 150.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) the completed Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient's condition.

The CDAI assessment must be no more than 1 month old at the time of application.

If the application is the first application for continuing treatment with infliximab, a CDAI assessment of the patient's response must be made up to 12 weeks after the first dose so that there is adequate time for a response to be demonstrated.

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The assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion.

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with infliximab.

Patients are eligible to receive continuing infliximab treatment in courses of up to 24 weeks providing they continue to sustain the response.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats will be authorised. No applications for increased repeats will be authorised.

Where fewer than 2 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday)

**Authority required**

Initial 1

Initial treatment of Crohn disease in a patient with short gut syndrome or an ostomy patient.

Initial PBS-subsidised treatment with infliximab by a gastroenterologist, or consultant physician as specified in the NOTE below of a patient who satisfies the following criteria:

(a) has confirmed Crohn disease defined by standard clinical, endoscopic and/or imaging features, including histological evidence with the diagnosis confirmed by a gastroenterologist or consultant physician as specified in the NOTE below; and

(b) has diagnostic imaging or surgical evidence of short gut syndrome or has an ileostomy or colostomy; and

(c) has evidence of intestinal inflammation; and

(d) has signed a patient acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and

(e) has failed to achieve an adequate response to prior systemic drug therapy including:

(i) a tapered course of steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period; and

(ii) immunosuppressive therapy including:

— azathioprine at a dose of at least 2 mg per kg daily for 3 or more months; or

— 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months; or

— methotrexate at a dose of at least 15 mg weekly for 3 or more months.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of the accepted toxicities including severity can be found on the Medicare Australia website (www.medicareaustralia.gov.au).

The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the application:

(a) have evidence of intestinal inflammation, including:

(i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; AND/OR

(ii) faeces: higher than normal lactoferrin or calprotectin level; AND/OR

(iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery;

AND/OR

(b) be assessed clinically as being in a high faecal output state;

AND/OR

(c) be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of infliximab.

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.

Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the continuing treatment restriction. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

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(i) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and

(ii) reports and dates of the pathology or diagnostic imaging test(s) nominated as the response criterion, if relevant; and

(iii) date of the most recent clinical assessment; and

(iv) the signed patient acknowledgement.

All assessments, pathology tests and diagnostic imaging studies must be made within 1 month of the date of application.

A maximum quantity and number of repeats to provide for an initial course of infliximab consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete the 3 doses of infliximab may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

The assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab.

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment

**Authority required**

Initial 2

Change or re-commencement of treatment of Crohn disease in a patient with short gut syndrome, an ostomy patient or a patient with extensive small intestine disease.

Initial PBS-subsidised treatment with infliximab by a gastroenterologist or a consultant physician as specified in the NOTE below of a patient who:

(a) has a documented history of severe refractory Crohn disease; and

(b) in this treatment cycle, has received prior PBS-subsidised treatment with infliximab or adalimumab for this condition; and

(c) has not failed PBS-subsidised therapy with infliximab for this condition more than once in the current treatment cycle.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

To demonstrate a response to treatment the application must be accompanied by the results of the most recent course of TNF-alfa antagonist therapy within the timeframes specified in the relevant restriction.

Where the most recent course of PBS-subsidised TNF-alfa antagonist treatment was approved under an initial treatment restriction, the patient must have been assessed for response to that course following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

If the response assessment to the previous course of TNF-alfa antagonist treatment is not submitted as detailed above, the patient will be deemed to have failed therapy with that particular course of TNF-alfa antagonist.

Authority applications must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) reports and dates of the pathology or diagnostic imaging test(s) nominated as the response criteria, if relevant; and

(ii). details of prior TNF alfa antagonist treatment including details of date and duration of treatment.

A maximum quantity and number of repeats to provide for an initial course of infliximab consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

The assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of therapy so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab.

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment

**Authority required**

Continuing treatment of Crohn disease in a patient with short gut syndrome or an ostomy patient.

Continuing PBS-subsidised treatment with infliximab by a gastroenterologist, a consultant physician as specified in the NOTE below or other

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consultant physician in consultation with a gastroenterologist, of a patient who:

(a) has a documented history of severe refractory Crohn disease with intestinal inflammation and with short gut syndrome or with an ileostomy or colostomy; and

(b) has demonstrated or sustained an adequate response to treatment with infliximab.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

An adequate response to infliximab treatment is defined as:

(a) improvement of intestinal inflammation as demonstrated by:

(i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; AND/OR

(ii) faeces: normalisation of lactoferrin or calprotectin level; AND/OR

(iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or

(b) reversal of high faecal output state; or

(c) avoidance of the need for surgery or total parenteral nutrition (TPN).

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) the reports and dates of the pathology or diagnostic imaging test(s) used to assess response to therapy or the date of clinical assessment.

The patient's assessment must be no more than 1 month old at the time of application.

If the application is the first application for continuing treatment with infliximab, an assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.

The assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion.

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with infliximab.

Patients are eligible to receive continuing infliximab treatment in courses of up to 24 weeks providing they continue to sustain the response.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats will be authorised. No applications for increased repeats will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday)

**Authority required**

Initial 1

Initial treatment of Crohn disease in a patient with extensive small intestine disease.

Initial PBS-subsidised treatment with infliximab by a gastroenterologist or a consultant physician as specified in the NOTE below, of a patient with severe refractory Crohn disease who satisfies the following criteria:

(a) has confirmed Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or consultant physician as specified in the NOTE below; and

(b) has extensive small intestinal disease with radiological evidence of intestinal inflammation affecting more than 50 cm of the small intestine; and

(c) has signed a patient acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and

(d) has failed to achieve an adequate response to prior systemic therapy including:

(i) a tapered course of steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period; and

(ii) immunosuppressive therapy including:

— azathioprine at a dose of at least 2 mg per kg daily for 3 or more months; or

— 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months; or

— methotrexate at a dose of at least 15 mg weekly for 3 or more months.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, please

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provide details of the degree of this toxicity at the time of application. Details of the accepted toxicities including severity can be found on the Medicare Australia website (www.medicareaustralia.gov.au).

The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the application:

(a) have severity of disease activity which results in a Crohn Disease Activity Index (CDAI) Score greater than or equal to 220;

AND/OR

(b) have evidence of active intestinal inflammation, including:

(i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; AND/OR

(ii) faeces: higher than normal lactoferrin or calprotectin level; AND/OR

(iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery;

AND/OR

(c) be assessed clinically as being in a high faecal output state;

AND/OR

(d) be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of infliximab.

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.

Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the continuing treatment restriction. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and

(ii) (1) reports and dates of the pathology or diagnostic imaging test(s) nominated as the response criterion, if relevant; or

(2) the completed current Crohn Disease Activity Index (CDAI) calculation sheet including the dates of assessment of the patient's condition, if relevant; and

(iii) date of the most recent clinical assessment; and

(iv) the signed patient acknowledgement.

All assessments, pathology tests and diagnostic imaging studies must be made within 1 month of the date of application.

A maximum quantity and number of repeats to provide for an initial course of infliximab consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete the 3 doses of infliximab may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

The assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab.

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment

**Authority required**

Continuing treatment of Crohn disease in a patient with extensive small intestine disease.

Continuing PBS-subsidised treatment with infliximab by a gastroenterologist, or consultant physician as specified in the NOTE below or other consultant physician in consultation with a gastroenterologist, of a patient who:

(a) has a documented history of severe refractory Crohn disease with extensive intestinal inflammation affecting more than 50 cm of the small intestine; and

(b) has demonstrated or sustained an adequate response to treatment with infliximab.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

An adequate response to infliximab treatment is defined as:

(a) a reduction in Crohn Disease Activity Index (CDAI) Score to no greater than 150; or

# HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

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(b) improvement of intestinal inflammation as demonstrated by:

(i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; AND/OR

(ii) faeces: normalisation of lactoferrin or calprotectin level; AND/OR

(iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or

(c) reversal of high faecal output state; or

(d) avoidance of the need for surgery or total parenteral nutrition (TPN).

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) the completed Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient's condition; or

(ii) the reports and dates of the pathology test or diagnostic imaging test(s) used to assess response to therapy; or

(iii) the date of clinical assessment.

All assessments must be no more than 1 month old at the time of application.

If the application is the first application for continuing treatment with infliximab, an assessment of the patient's response must be made up to 12 weeks after the first dose (6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.

The assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion.

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with infliximab.

Patients are eligible to receive continuing infliximab treatment in courses of up to 24 weeks providing they continue to sustain the response.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats will be authorised. No applications for increased repeats will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday)

**Authority required**

Initial 3 (grandfather)

Initial PBS-subsidised treatment of Crohn disease in a patient assessed by CDAI who has previously received non-PBS-subsidised therapy with infliximab.

Initial PBS-subsidised supply for continuing treatment with infliximab by a gastroenterologist, a consultant physician as specified in the NOTE below, or other consultant physician in consultation with a gastroenterologist of a patient who:

(a) has a documented history of severe refractory Crohn disease and was receiving treatment with infliximab prior to 7 March 2007; and

(b) had a Crohn Disease Activity Index (CDAI) Score of greater than or equal to 300 prior to commencing treatment with infliximab. Where a baseline CDAI assessment is not available, please call Medicare Australia on 1800 700 270 to discuss; and

(c) has signed a patient acknowledgement indicating that they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and

(d) has demonstrated or sustained an adequate response to treatment with infliximab. For advice please contact Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

An adequate response to infliximab treatment is defined as a reduction in Crohn Disease Activity Index (CDAI) Score to no greater than 150.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) the completed current and baseline Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient's condition; and

(ii) the signed patient acknowledgement.

The current CDAI assessment must be no more than 1 month old at the time of application. The baseline CDAI assessment must be from immediately prior to commencing treatment with infliximab.

The assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion.

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Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with infliximab.

Patients are eligible to receive continuing infliximab treatment in courses of up to 24 weeks providing they continue to sustain the response.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats will be authorised. No applications for increased repeats will be authorised.

Where fewer than 2 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Patients may qualify for PBS-subsidised treatment under this restriction once only

**Authority required**

Initial 3

Initial PBS-subsidised treatment of Crohn disease in a patient with short gut syndrome, an ostomy patient, or a patient with extensive small intestine disease, who has previously received non-PBS-subsidised therapy with infliximab.

Initial PBS-subsidised supply for continuing treatment with infliximab by a gastroenterologist, a consultant physician as specified in the NOTE below, or other consultant physician in consultation with a gastroenterologist, of a patient who:

(a) has a documented history of severe refractory Crohn disease and was receiving treatment with infliximab prior to 7 March 2007; and

(b) (1) has a history of extensive small intestinal disease with radiological evidence of intestinal inflammation affecting more than 50 cm of the small intestine; or

(2) has diagnostic imaging or surgical evidence of short gut syndrome or has an ileostomy or colostomy with a documented history of intestinal inflammation; and

(c) has signed a patient acknowledgement indicating that they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and

(d) has demonstrated or sustained an adequate response to treatment with infliximab according to the criteria included in the relevant continuation restriction. For advice please contact Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

The same criteria used to determine an inadequate response to prior treatment at baseline must be used to determine response to treatment and eligibility for continuing therapy, according to the criteria included in the continuing treatment restriction.

An adequate response to infliximab treatment is defined as:

(a) a reduction in Crohn Disease Activity Index (CDAI) Score to no greater than 150; or

(b) improvement of intestinal inflammation as demonstrated by:

(i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; AND/OR

(ii) faeces: normalisation of lactoferrin or calprotectin level; AND/OR

(iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or

(c) reversal of high faecal output state; or

(d) avoidance of the need for surgery or total parenteral nutrition (TPN).

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au) ] which includes the following:

(i) (1) the completed current and baseline Crohn Disease Activity Index (CDAI) Score calculation sheet, where relevant, including the date of the assessment of the patient's condition; or

(2) the reports and dates of the current and baseline pathology or diagnostic imaging test(s) in order to assess response to therapy; or

(3) the date of clinical assessment(s); and

(ii) the signed patient acknowledgement.

The patient's assessment must be no more than 1 month old at the time of application. The baseline CDAI assessments must be from immediately prior to commencing treatment with infliximab. Where a baseline assessment is not available, please call Medicare Australia on 1800 700 270 to discuss.

The assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion.

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with infliximab.

Patients are eligible to receive continuing infliximab treatment in courses of up to 24 weeks providing they continue to sustain the response.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient,

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to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats will be authorised. No applications for increased repeats will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Patients may qualify for PBS-subsidised treatment under this restriction once only

**Note**

Any queries concerning the arrangements to prescribe infliximab may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe infliximab should be forwarded to:

Medicare Australia

Prior Written Approval of Specialised Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

**Note**

TREATMENT OF ADULT PATIENTS WITH SEVERE REFRACTORY CROHN DISEASE

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab and infliximab for adult patients with severe refractory Crohn disease. Where the term 'tumour necrosis factor (TNF) alfa antagonist' appears in the following NOTES and restrictions, it refers to adalimumab and infliximab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 2 TNF-alfa antagonists at any 1 time.

From 1 August 2008, under the PBS, all patients will be able to commence a treatment cycle where they may trial each PBS-subsidised TNF-alfa antagonist without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a TNF-alfa antagonist while they continue to show a response to therapy.

A patient who received PBS-subsidised TNF-alfa antagonist treatment prior to 1 August 2008 is considered to be in their first cycle as of 1 August 2008.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised TNF-alfa antagonist more than twice.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised TNF-alfa antagonist therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised TNF-alfa antagonist treatment in the most recent cycle to the date of the first application for initial treatment with a TNF-alfa antagonist under the new treatment cycle.

A patient who has failed fewer than 3 trials of TNF-alfa antagonists in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of TNF-alfa antagonists in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised TNF-alfa antagonist therapy after 1 August 2008.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised TNF-alfa antagonist treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or

(ii) a patient has received prior PBS-subsidised (initial or continuing) TNF-alfa antagonist therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to re-commence treatment with a specific TNF-alfa antagonist following a break in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and 14 weeks of therapy for infliximab.

From 1 August 2008, a patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.

For second and subsequent courses of PBS-subsidised TNF-alfa antagonist treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

# HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

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Adalimumab only: Two completed authority prescriptions must be submitted with every initial application for adalimumab. One prescription must be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats. The second prescription must be written for 2 doses of 40 mg and 2 repeats.

(b) Continuing treatment. Following the completion of an initial treatment course with a specific TNF-alfa antagonist, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing TNF-alfa antagonist treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted TNF-alfa antagonist supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised TNF-alfa antagonist is approved, a patient may swap if eligible to the alternate TNF-alfa antagonist within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Crohn Disease Activity Index (CDAI) Score, evidence of intestinal inflammation), or the prior corticosteroid therapy and immunosuppressive therapy.

A patient may trial the alternate TNF-alfa antagonist at any time, regardless of whether they are receiving therapy (initial or continuing) with a TNF-alfa antagonist at the time of the application. However, they cannot swap to a particular TNF-alfa antagonist if they have failed to respond to prior treatment with that drug two times within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to the alternate TNF-alfa antagonist should be accompanied by the approved authority prescription or remaining repeats for the TNF-alfa antagonist the patient is ceasing.

(3) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements of the CDAI or evidence of intestinal inflammation submitted with the first authority application for a TNF-alfa antagonist. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and Medicare Australia will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications.

(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised TNF-alfa antagonist therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have received treatment with a corticosteroid and at least 1 immunosuppressive agent, at an adequate dose, for a minimum of 3 consecutive months immediately prior to the time the CDAI score or the indices of intestinal inflammation are measured.

(5) Patients 'grandfathered' onto PBS-subsidised treatment with adalimumab or infliximab.

A patient who commenced treatment with adalimumab for severe refractory Crohn disease prior to 9 November 2007 or infliximab prior to 7 March 2007 and who continues to receive treatment at the time of application, may qualify for treatment under the initial 'grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment with adalimumab or infliximab will be authorised under this criterion.

Following completion of the initial PBS-subsidised course, further applications for treatment with adalimumab or infliximab will be assessed under the continuing treatment restriction.

'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must requalify for initial treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' above for further details.

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|---|---|---|---|---|---|---|---|
| 9613Y | infliximab 100 mg injection, 1 x 100 mg vial | 1 | .. | .. | 788.40 | Remicade | JC |

**INFLIXIMAB**

**Authority required**

Initial treatment [Initial 1, Whole body (New patients — No prior biological agent)]

Initial treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over who:

(a) have severe chronic plaque psoriasis where lesions have been present for at least 6 months from the time of initial diagnosis; and

(b) have not received any prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle; and

(c) have signed a patient and prescriber acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment (whole body); and

(d) have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 3 of the following 4 treatments:

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Brand Name and Manufacturer |
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(i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; and/or

(ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; and/or

(iii) cyclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; and/or

(iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks.

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity to necessitate permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of acceptable toxicities including severity, associated with phototherapy, methotrexate, cyclosporin and acitretin, can be found on the Medicare Australia website (www.medicareaustralia.gov.au).

The following initiation criterion indicates failure to achieve an adequate response and must be demonstrated in all patients at the time of the application:

(a) A current Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.

(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 1 month following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than 1 month old at the time of application.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy]; and

(iii) the signed patient and prescriber acknowledgements.

A maximum of 22 weeks of treatment with infliximab will be authorised under this restriction.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised.

Where fewer than 3 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 22 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period beyond 22 weeks.

A PASI assessment of the patient's response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

It is recommended that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment

**Authority required**

Initial or re-Treatment [Initial 2, Whole body (Received prior biological agent under PBS)]

Treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over who:

(a) have a documented history of severe chronic plaque psoriasis; and

(b) have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle; and

(c) have not failed PBS-subsidised therapy with infliximab for the treatment of this condition in the current Treatment Cycle.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and

(ii) details of prior biological treatment, including dosage, date and duration of treatment.

Applications for patients who have demonstrated a response to PBS-subsidised infliximab treatment within this Treatment Cycle and who wish to re-commence infliximab treatment within the same Cycle following a break in therapy, will only be approved where evidence of the patient's response to their most recent course of PBS-subsidised infliximab treatment has been submitted to Medicare Australia within 1 month of cessation of treatment.

A maximum of 22 weeks of treatment with infliximab will be authorised under this restriction.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient,

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to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised.

Where fewer than 3 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 22 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period beyond 22 weeks.

A PASI assessment of the patient's response to this course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

It is recommended that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment.

Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may re-commence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle

**Authority required**

Continuing treatment (Whole body)

Continuing PBS-subsidised treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over:

(a) who have a documented history of severe chronic plaque psoriasis; and

(b) whose most recent course of PBS-subsidised biological treatment for this condition in this Treatment Cycle was with infliximab; and

(c) who have demonstrated an adequate response to their most recent course of treatment with infliximab.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the pre-biological treatment baseline value for this Treatment Cycle.

This assessment must be provided to Medicare Australia no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with infliximab, the assessment of response must be after a minimum of 12 weeks of treatment with an initial course.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) the completed Psoriasis Area and Severity Index (PASI) calculation sheet along with the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 1 month old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with infliximab.

A maximum of 24 weeks of treatment with infliximab will be authorised under this restriction.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for continuing authority applications, or for treatment that would otherwise extend the treatment period beyond 24 weeks.

A PASI assessment of the patient's response must be conducted within 4 weeks prior to completion of this course of treatment. This assessment, which will be used to determine eligibility for further continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

It is recommended that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment.

Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may re-commence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle

**Authority required**

Initial treatment [Initial 1, Face, hand, foot (New patients — No prior biological agent)]

Initial treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over who:

(a) have severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis; and

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(b) have not received any prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle; and

(c) have signed a patient and prescriber acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment (face, hand, foot); and

(d) have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 3 of the following 4 treatments:

(i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; and/or

(ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; and/or

(iii) cyclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; and/or

(iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks.

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity to necessitate permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of acceptable toxicities including severity, associated with phototherapy, methotrexate, cyclosporin and acitretin, can be found on the Medicare Australia website (www.medicareaustralia.gov.au).

The following initiation criterion indicates failure to achieve an adequate response and must be demonstrated in all patients at the time of the application:

(a) Chronic plaque psoriasis classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where:

(i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment; or

(ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.

(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 1 month following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than 1 month old at the time of application.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy]; and

(iii) the signed patient and prescriber acknowledgements.

A maximum of 22 weeks of treatment with infliximab will be authorised under this restriction.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised.

Where fewer than 3 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 22 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period beyond 22 weeks.

A PASI assessment of the patient's response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

It is recommended that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline

**Authority required**

Initial or re-Treatment [Initial 2, Face, hand, foot (Received prior biological agent under PBS)]

Treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over who:

(a) have a documented history of severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot; and

(b) have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle; and

(c) have not failed PBS-subsidised therapy with infliximab for the treatment of this condition in the current Treatment Cycle.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

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(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and

(ii) details of prior biological treatment, including dosage, date and duration of treatment.

Applications for patients who have demonstrated a response to PBS-subsidised infliximab treatment within this Treatment Cycle and who wish to re-commence infliximab treatment within the same Cycle following a break in therapy, will only be approved where evidence of the patient's response to their most recent course of PBS-subsidised infliximab treatment has been submitted to Medicare Australia within 1 month of cessation of treatment.

A maximum of 22 weeks of treatment with infliximab will be authorised under this restriction.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised.

Where fewer than 3 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 22 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period beyond 22 weeks.

A PASI assessment of the patient's response to this course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

It is recommended that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may re-commence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle

**Authority required**

Continuing treatment (Face, hand, foot)

Continuing PBS-subsidised treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over:

(a) who have a documented history of severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot; and

(b) whose most recent course of PBS-subsidised biological treatment for this condition in this Treatment Cycle was with infliximab; and

(c) who have demonstrated an adequate response to treatment with infliximab.

An adequate response to infliximab treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the pre-biological treatment baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the pre-biological treatment baseline value.

This assessment must be provided to Medicare Australia no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with infliximab, the assessment of response must be after a minimum of 12 weeks of treatment with an initial course.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) the completed Psoriasis Area and Severity Index (PASI) calculation sheet and face, hand, foot area diagrams along with the date of the assessment of the patient's condition [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].

The most recent PASI assessment must be no more than 1 month old at the time of application.

A maximum of 24 weeks of treatment with infliximab will be authorised under this restriction.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for continuing authority applications, or for treatment that would otherwise extend the treatment period beyond 24 weeks.

A PASI assessment of the patient's response must be conducted within 4 weeks prior to completion of this course of treatment. This assessment, which will be used to determine eligibility for further continuing treatment must be submitted to Medicare Australia no later than 1 month from the date of completion of this course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab. In circumstances where it is not possible to submit a

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response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

It is recommended that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment.

The PASI assessment for continuing treatment must be performed on the same affected area assessed at baseline.

Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may re-commence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle

**Note**

Any queries concerning the arrangements to prescribe infliximab may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe infliximab should be forwarded to:

Medicare Australia

Prior Written Approval of Specialised Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

**Note**

TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, etanercept, infliximab and ustekinumab, for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological agents' appears in the following NOTES and restrictions, it only refers to adalimumab, etanercept, infliximab and ustekinumab.

From 1 March 2010, all patients will be able to commence a 'Biological Treatment Cycle' (Cycle), where they may trial adalimumab, etanercept, infliximab or ustekinumab without having to meet the initial treatment criteria, that is they will not need to experience a disease flare when swapping to an alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

A patient who received PBS-subsidised biological agent treatment for chronic plaque psoriasis prior to 1 March 2010 is considered to be in their first Cycle as of 1 March 2010.

Patients are eligible for PBS-subsidised treatment with only 1 biological agent at any 1 time.

Within the same Treatment Cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for a PBS-subsidised biological agent, they must change to an alternate agent if they wish to continue PBS-subsidised biological treatment. A patient who, prior to 1 March 2010, was authorised to receive PBS-subsidised initial treatment for chronic plaque psoriasis with the same agent twice, is exempt from this condition in respect of applications approved prior to 1 March 2010.

Patients must be assessed for response to each course of continuing treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a Treatment Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological agent therapy before they are eligible to commence the next Cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological agent treatment in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Treatment Cycle.

Patients for whom a break in PBS-subsidised therapy of less than 5 years duration has occurred, and, who have failed therapy fewer than 3 times within a particular Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.

Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle.

There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.

How to prescribe biological agents for the treatment of severe chronic plaque psoriasis after 1 March 2010.

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Application for approval for initial treatment.

Applications for a course of initial treatment should be made in the following situations:

(i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); or

(ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under '(4) Swapping therapy' below]; or

(iii) patients who wish to re-commence treatment following a break in PBS-subsidised therapy with that agent (Initial 2).

All applications for initial treatment will be limited to provide for a maximum of 16 weeks of treatment in the case of adalimumab and etanercept, 22 weeks of treatment in the case of infliximab and 28 weeks of treatment in the case of ustekinumab.

(2) Assessment of response to initial treatment.

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When prescribing initial treatment with a biological agent, a PASI assessment must be conducted after at least 12 weeks of treatment. This assessment must be submitted to Medicare Australia within 1 month of the completion of this initial treatment course. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

(3) Application for continuing treatment.

Following the completion of an initial treatment course of a biological agent to which an adequate response has been demonstrated, patients may qualify to receive up to 24 weeks of continuing treatment with that biological agent. Patients are eligible to continue to receive continuous treatment with 24 week courses providing they continue to sustain a response.

For second and subsequent courses of PBS-subsidised treatment with adalimumab, etanercept, infliximab or ustekinumab it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

Where a response assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to sustain a response to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

(4) Swapping therapy.

Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate agent within the same Treatment Cycle without having to requalify with respect to disease severity (i.e. a PASI score of greater than 15), or prior treatment requirements.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

Patients may trial an alternate biological agent at any time, regardless of whether they are receiving therapy with a biological agent at the time of the application or not. However, they cannot swap to a particular agent if they have failed to respond to treatment with that particular agent within the same Cycle.

Patients who commenced treatment with adalimumab prior to 1 June 2009 or ustekinumab prior to 1 March 2010 access these interchangeability arrangements in the same way as patients who have not.

To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the agent being ceased.

(5) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated, based on the baseline PASI assessment submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment authority is submitted within a Treatment Cycle and subsequent response will be assessed according to this revised PASI score.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatment applications.

(6) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

Patients who wish to trial a second or subsequent Biological Treatment Cycle, following a break in PBS-subsidised biological therapy of at least 5 years, must requalify for initial treatment according to the criteria of the relevant restriction and index of disease severity. Patients must have had at least 1 prior treatment, as listed in the criteria, for a minimum of 6 weeks, and must have a PASI assessment conducted preferably whilst still on treatment, but no later than 1 month following cessation of treatment. The PASI assessment must be no older than 1 month at the time of application.

**Note**

No applications for increased repeats will be authorised.

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| 9617E | infliximab 100 mg injection, 1 x 100 mg vial | 1 | .. | .. | 788.40 | Remicade | JC |

**INFLIXIMAB**

**Authority required**

Initial 1

Initial treatment of complex refractory FISTULISING CROHN DISEASE.

Initial PBS-subsidised treatment with infliximab by a gastroenterologist or a consultant physician as specified in the NOTE below, of a patient with complex refractory fistulising Crohn disease who:

(a) has confirmed Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician as specified in the NOTE below; and

(b) has an externally draining enterocutaneous or rectovaginal fistula; and

(c) has signed a patient acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criteria for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

# HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

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Authority applications must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Fistulising Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) a completed current Fistula Assessment Form including the date of assessment of the patient's condition; and

(ii) a signed patient acknowledgement.

The most recent fistula assessment must be no more than 1 month old at the time of application.

A maximum quantity and number of repeats to provide for an initial course of infliximab consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6 will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete 3 doses of infliximab may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

An assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (up to 6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.

This assessment must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab.

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment

**Authority required**

Initial 2

Change or re-commencement of treatment of complex refractory FISTULISING CROHN DISEASE.

Initial PBS-subsidised treatment with infliximab of complex refractory fistulising Crohn disease by a gastroenterologist or a consultant physician as specified in the NOTE below, of a patient with complex refractory fistulising Crohn disease who:

(a) has a documented history of complex refractory fistulising Crohn disease; and

(b) in this treatment cycle, has received prior PBS-subsidised treatment with adalimumab or infliximab for a draining enterocutaneous or rectovaginal fistula; and

(c) has not failed PBS-subsidised therapy with infliximab for this condition more than once in the current treatment cycle.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

To demonstrate a response to treatment the application must be accompanied by the results of the most recent course of TNF-alfa antagonist therapy within the timeframes specified in the relevant restriction.

Where the most recent course of PBS-subsidised TNF-alfa antagonist treatment was approved under an initial treatment restriction, the patient must have been assessed for response to that course following a minimum of 12 weeks therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

If the response assessment to the previous course of TNF-alfa antagonist treatment is not submitted as detailed above, the patient will be deemed to have failed therapy with that particular course of TNF-alfa antagonist.

Authority applications must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Fistulising Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) a completed current Fistula Assessment Form including the date of assessment of the patient's condition; and

(ii) details of prior TNF-alfa antagonist treatment including details of date and duration of treatment.

The most recent fistula assessment must be no more than 1 month old at the time of application.

A maximum quantity and number of repeats to provide for an initial course of infliximab consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete 3 doses of infliximab may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

An assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (up to 6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.

This assessment must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab.

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 12 week assessment, to ensure

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continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment

**Authority required**

Initial 3 (grandfather)

Initial PBS-subsidised treatment of complex refractory FISTULISING CROHN DISEASE in a patient who has previously received non-PBS-subsidised therapy with infliximab.

Initial PBS-subsidised supply for continuing treatment with infliximab by a gastroenterologist, a consultant physician as specified in the NOTE below, or other consultant physician in consultation with a gastroenterologist of a patient who satisfies the following criteria:

(a) has a documented history of complex refractory fistulising Crohn disease and was receiving treatment with infliximab prior to 1 March 2010; and

(b) had a draining enterocutaneous or rectovaginal fistula(e) prior to commencing treatment with infliximab; and

(c) has signed a patient acknowledgement indicating that they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criteria for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and

(d) is receiving treatment with infliximab at the time of application; and

(e) has demonstrated or sustained an adequate response to treatment with infliximab.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

An adequate response to infliximab treatment is defined as:

(a) a decrease from baseline in the number of open draining fistulae of greater than or equal to 50%; and/or

(b) a marked reduction in drainage of all fistula(e) from baseline, together with less pain and induration as reported by the patient.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Fistulising Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) a completed current and baseline Fistula Assessment form including the date of assessment of the patient's condition; and

(ii) a signed patient acknowledgement.

The current fistula assessment must be no more than 1 month old at the time of application.

The baseline fistula assessment must be from immediately prior to commencing treatment with infliximab.

An assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criteria.

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with infliximab.

Patients are eligible to receive continuing infliximab treatment in courses of up to 24 weeks providing they continue to sustain the response.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats will be authorised. No applications for increased repeats will be authorised.

Where fewer than 2 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Patients may qualify for PBS-subsidised treatment under this restriction once only

**Authority required**

Continuing treatment of complex refractory FISTULISING CROHN DISEASE.

Continuing PBS-subsidised treatment with infliximab by a gastroenterologist, a consultant physician as specified in the NOTE below or other consultant physician in consultation with a gastroenterologist, of a patient who:

(a) has a documented history of complex refractory fistulising Crohn disease; and

(b) has demonstrated or sustained an adequate response to treatment with infliximab.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

An adequate response is defined as:

(a) a decrease from baseline in the number of open draining fistulae of greater than or equal to 50%; and/or

(b) a marked reduction in drainage of all fistula(e) from baseline, together with less pain and induration as reported by the patient.

Authority applications must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Fistulising Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes a completed Fistula Assessment form including the date of the assessment of the patient's condition.

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Brand Name and Manufacturer |
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The fistula assessment must be no more than 1 month old at the time of application.

If the application is the first application for continuing treatment with infliximab, an assessment of the patient's response must be made up to 12 weeks after the first dose so that there is adequate time for a response to be demonstrated.

An assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criteria.

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with infliximab.

Patients are eligible to receive continuing infliximab treatment in courses of up to 24 weeks providing they continue to sustain the response.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats will be authorised. No applications for increased repeats will be authorised.

Where fewer than 2 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday)

**Note**

Any queries concerning the arrangements to prescribe infliximab may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe infliximab should be forwarded to:

Medicare Australia

Prior Written Approval of Specialised Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

**Note**

TREATMENT OF COMPLEX REFRACTORY FISTULISING CROHN DISEASE

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab and infliximab for patients with complex refractory fistulising Crohn disease. Where the term 'tumour necrosis factor (TNF) alfa antagonist' appears in the following NOTES and restrictions, it refers to adalimumab and infliximab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 2 TNF-alfa antagonists at any 1 time.

From 1 April 2011, under the PBS, all patients will be able to commence a treatment cycle where they may trial each PBS-subsidised TNF-alfa antagonist without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a TNF-alfa antagonist while they continue to show a response to therapy.

A patient who received PBS-subsidised TNF-alfa antagonist treatment prior to 1 April 2011 is considered to be in their first cycle as of 1 April 2011.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised TNF-alfa antagonist more than twice.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised TNF-alfa antagonist therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised TNF-alfa antagonist treatment in the most recent cycle to the date of the first application for initial treatment with a TNF-alfa antagonist under the new treatment cycle.

A patient who has failed fewer than 3 trials of TNF-alfa antagonists in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of TNF-alfa antagonists in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised TNF-alfa antagonist therapy after 1 April 2011.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised TNF-alfa antagonist treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or

(ii) a patient has received prior PBS-subsidised (initial or continuing) TNF-alfa antagonist therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to re-commence treatment with a specific TNF-alfa antagonist following a break in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and 14 weeks of therapy for infliximab.

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From 1 April 2011, a patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.

For second and subsequent courses of PBS-subsidised TNF-alfa antagonist treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

Adalimumab only: Two completed authority prescriptions must be submitted with every initial application for adalimumab. One prescription must be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats. The second prescription must be written for 2 doses of 40 mg and 2 repeats.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific TNF-alfa antagonist, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing TNF-alfa antagonist treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted TNF-alfa antagonist supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised TNF-alfa antagonist is approved, a patient may swap if eligible to the alternate TNF-alfa antagonist within the same treatment cycle.

A patient may trial the alternate TNF-alfa antagonist at any time, regardless of whether they are receiving therapy (initial or continuing) with a TNF-alfa antagonist at the time of the application. However, they cannot swap to a particular TNF-alfa antagonist if they have failed to respond to prior treatment with that drug two times within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to the alternate TNF-alfa antagonist should be accompanied by the approved authority prescription or remaining repeats for the TNF-alfa antagonist the patient is ceasing.

(3) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements submitted with the first authority application for a TNF-alfa antagonist. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and Medicare Australia will assess response according to these revised baseline measurements.

(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised TNF-alfa antagonist therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity.

(5) Patients 'grandfathered' onto PBS-subsidised treatment with adalimumab or infliximab.

A patient who commenced treatment with adalimumab for complex refractory fistulising Crohn disease prior to 4 November 2010 or infliximab prior to 1 March 2010 and who continues to receive treatment at the time of application, may qualify for treatment under the initial 'grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment with adalimumab or infliximab will be authorised under this criterion.

Following completion of the initial PBS-subsidised course, further applications for treatment with adalimumab or infliximab will be assessed under the continuing treatment restriction.

'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must requalify for initial treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' above for further details.

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| 9674E | infliximab 100 mg injection, 1 x 100 mg vial | 1 | .. | .. | 788.40 | Remicade | JC |

## *Interleukin inhibitors*

**TOCILIZUMAB**

**Authority required**

Initial 1 (new and recommencing patients after a break of more than 12 months)

Initial treatment by a rheumatologist, or under the supervision of a paediatric rheumatology treatment centre, of a patient under 18 years who:

(a) has been diagnosed with systemic juvenile idiopathic arthritis; AND

(b) has polyarticular course disease and either:

(i) failure to achieve an adequate response to the following treatment regimen (see (1) below for definition of failure to achieve an adequate

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response):

— oral or parenteral methotrexate at a dose of at least 15 mg per square metre weekly, alone or in combination with oral or intra-articular corticosteroids for a minimum of 3 months; or

(ii) severe intolerance of, or toxicity due to, methotrexate (see (2) below for definition of severe intolerance and toxicity); OR

(c) has refractory systemic symptoms, demonstrated by:

— an inability to decrease and maintain the dose of prednisolone (or equivalent) below 0.5 mg per kg per day following a minimum of 2 months of therapy; AND

(d) has not received PBS-subsidised treatment with tocilizumab for this condition in the previous 12 months.

(1) The following criteria indicate failure to achieve an adequate response to prior methotrexate therapy and must be demonstrated in all patients at the time of the initial application:

(a) in a patient with polyarticular course disease:

(i) an active joint count of at least 20 active (swollen and tender) joints; OR

(ii) at least 4 active joints from the following list:

— elbow, wrist, knee and/or ankle (assessed as swollen and tender); AND/OR

— shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

(b) in a patient with refractory systemic symptoms:

(i) an active joint count of at least 2 active joints; AND

(ii) persistent fever greater than 38 degrees Celsius for at least 5 out of 14 consecutive days; AND/OR

(iii) a C-reactive protein (CRP) level and platelet count above the upper limits of normal (ULN).

(2) Severe intolerance to methotrexate is defined as intractable nausea and vomiting and general malaise unresponsive to manoeuvres, including reducing or omitting concomitant NSAIDs on the day of methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses over 24 hours.

Toxicity to methotrexate is defined as evidence of hepatotoxicity with repeated elevations of transaminases, bone marrow suppression temporally related to methotrexate use, pneumonia, or serious sepsis.

If treatment with methotrexate alone or in combination with other treatments is contraindicated according to the relevant TGA-approved Product Information, please provide details at time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, please provide details of this toxicity at the time of application.

The baseline measurements of joint count, fever and/or CRP level and platelet count must be performed preferably whilst on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be provided for all subsequent continuing treatment applications.

The authority application must be made in writing and must include:

(1) completed authority prescription form(s); and

(2) a completed Systemic Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) the date of assessment of severe active systemic juvenile idiopathic arthritis;

(ii) details of prior treatment including dose and duration of treatment;

(iii) pathology reports detailing CRP and platelet count where appropriate; and

(3) a signed patient or authorised guardian acknowledgement form.

The most recent systemic juvenile idiopathic arthritis assessment must be no more than 1 month old at the time of application.

A maximum of 16 weeks of treatment will be authorised under this restriction.

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for two infusions (one month supply). A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised.

Where fewer than 3 repeats are requested at the time of initial application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Assessment of a patient's response to an initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 4 weeks from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with tocilizumab.

If a patient fails to respond to 2 courses of treatment in a treatment cycle they will not be eligible to receive further PBS-subsidised tocilizumab therapy in that treatment cycle. A patient may re-trial tocilizumab after a minimum of 12 months have elapsed between the date the last PBS-subsidised treatment was stopped and the date of the first application under a new treatment cycle

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**Authority required**

Initial 2 (retrial or recommencement of treatment after a break of less than 12 months)

Initial PBS-subsidised treatment by a rheumatologist, or under the supervision of a paediatric rheumatology treatment centre, of a patient who:

(a) has a documented history of systemic juvenile idiopathic arthritis; AND

(b) has received PBS-subsidised treatment with tocilizumab for this condition in the previous 12 months; AND

(c) has not failed PBS-subsidised therapy with tocilizumab for this condition more than once in the current treatment cycle.

The authority application must be made in writing and must include:

(1) completed authority prescription form(s); and

(2) a completed Systemic Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) pathology reports detailing CRP and platelet count where appropriate.

Applications for a patient who has received PBS-subsidised treatment with tocilizumab in this treatment cycle and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised tocilizumab treatment, within the timeframes specified below.

A maximum of 16 weeks of treatment will be authorised under this restriction.

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for two infusions (one month supply). A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised.

Where fewer than 3 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment with tocilizumab may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

An assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criteria. Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with tocilizumab.

Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to that course of tocilizumab.

If a patient fails to respond to 2 courses of treatment they will not be eligible to receive further PBS-subsidised tocilizumab therapy in this treatment cycle. A patient may re-trial tocilizumab after a minimum of 12 months have elapsed between the date the last PBS-subsidised treatment was stopped and the date of the first application under a new treatment cycle

**Authority required**

Initial 3 ('grandfather' patients)

Initial treatment by a rheumatologist, or under the supervision of a paediatric rheumatology treatment centre, of a patient who:

(a) has a documented history of systemic juvenile idiopathic arthritis; and

(b) was receiving treatment with tocilizumab prior 1 November 2011; and

(c) has demonstrated a response as specified in the criteria for continuing PBS-subsidised treatment with tocilizumab; and

(d) is receiving treatment with tocilizumab at the time of application.

To ensure consistency in determining response, the same indices of disease severity used to establish the baseline must be provided for all subsequent continuing treatment applications.

The authority application must be made in writing and must include:

(1) completed authority prescription form(s); and

(2) a completed Systemic Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) pathology reports detailing CRP and platelet count where appropriate; and

(3) a signed patient or authorised guardian acknowledgement form.

The most recent systemic juvenile idiopathic arthritis assessment must be no more than 1 month old at the time of application.

The baseline systemic juvenile idiopathic arthritis assessment must be provided and must be from immediately prior to commencing treatment with tocilizumab. (See NOTE (3) above for definition of baseline measurements to determine response.)

An assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criteria.

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with tocilizumab.

Patients are eligible to receive continuing tocilizumab treatment in courses of up to 24 weeks providing they continue to sustain the response.

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for two infusions (one months supply). A separate authority prescription form must be completed for each strength requested. Up to a maximum of 5 repeats will be authorised.

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Where fewer than 5 repeats are initially requested with the authority prescription, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

A patient may only qualify for PBS-subsidised treatment under this restriction once

**Authority required**

Continuing treatment

Continuing treatment with tocilizumab, by a rheumatologist or under the supervision of a paediatric rheumatology treatment centre, of a patient who:

(a) has a documented history of systemic juvenile idiopathic arthritis; AND

(b) has demonstrated an adequate response to treatment with tocilizumab.

An adequate response to treatment is defined as:

(a) in a patient with polyarticular course disease:

(i) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(ii) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

— elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

— shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

(b) in a patient with refractory systemic symptoms:

(i) absence of fever greater than 38 degrees Celsius in the preceding seven days; AND/OR

(ii) a reduction in the CRP level and platelet count by at least 30% from baseline; AND/OR

(iii) a reduction in the dose of corticosteroid by at least 30% from baseline.

The authority application must be made in writing and must include:

(1) completed authority prescription form(s); and

(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) baseline and current pathology reports detailing CRP and platelet count where appropriate.

The most recent systemic juvenile idiopathic arthritis assessment must be no more than 1 month old at the time of application.

Where the most recent course of PBS-subsidised tocilizumab treatment was approved under the Initial treatment restriction, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be provided to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised tocilizumab treatment was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Patients are eligible to receive continuing tocilizumab treatment in courses of up to 24 weeks providing they continue to sustain the response.

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for two infusions (one month supply). A separate authority prescription form must be completed for each strength requested. Up to a maximum of 5 repeats will be authorised.

Where fewer than 5 repeats are requested at the time of initial application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

If a patient fails to respond to 2 courses of treatment they will not be eligible to receive further PBS-subsidised tocilizumab therapy in this treatment cycle. A patient may re-trial tocilizumab after a minimum of 12 months have elapsed between the date the last PBS-subsidised treatment was stopped and the date of the first application under a new treatment cycle

**Note**

Any queries concerning the arrangements to prescribe tocilizumab may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Further prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe tocilizumab should be forwarded to:

Medicare Australia

Prior Written Approval of Specialised Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

**Note**

TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

# HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

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The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying anti-rheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab) and the T-cell co-stimulation modulator (abatacept).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

PBS-subsidised abatacept, golimumab, infliximab and rituximab must be used in combination with methotrexate at a dose of at least 7.5 mg weekly. Where a patient cannot tolerate 7.5 mg of methotrexate weekly, they are eligible to receive PBS-subsidised adalimumab, certolizumab pegol, etanercept and tocilizumab.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:

— a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,

— a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and

— once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact Medicare Australia on 1800 700 270.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or

(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or

(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or

(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab and tocilizumab, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to Medicare Australia within 4 weeks.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

Abatacept patients:

Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients:

A further application may be submitted to Medicare Australia 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible

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to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Rituximab patients:

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.

Abatacept patients:

Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

**Note**

(3) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and Medicare Australia will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

**Note**

TREATMENT OF PATIENTS WITH SEVERE ACTIVE SYSTEMIC JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of tocilizumab for a patient who has severe active systemic juvenile idiopathic arthritis (sJIA).

From 1 May 2012, a patient receiving PBS-subsidised tocilizumab therapy is considered to be in a treatment cycle. Under these arrangements, within a single treatment cycle, a patient may:

— continue to receive long-term treatment with PBS-subsidised tocilizumab while they continue to show a response to therapy, and

— fail to respond, or to sustain a response, to PBS-subsidised tocilizumab twice.

Once a patient has either failed or ceased to respond to 2 courses of treatment, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 12 month break in PBS-subsidised tocilizumab therapy before they are eligible to receive further PBS-subsidised tocilizumab therapy. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised tocilizumab

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treatment was stopped to the date of the first application for initial treatment with tocilizumab under the new treatment cycle.

A patient who was receiving PBS-subsidised tocilizumab treatment immediately prior to 1 May 2012 is considered to be in their first cycle as of 1 May 2012. A patient who has had a break in tocilizumab treatment of at least 12 months immediately prior to making a new application, on or after 1 May 2012, will commence a new treatment cycle.

A patient who has failed their first course of tocilizumab in a treatment cycle and who has a break in therapy of less than 12 months may commence a second course of treatment within the same treatment cycle.

A patient who has failed their first course of tocilizumab in a treatment cycle and who has a break in therapy of more than 12 months must commence a new treatment cycle.

(1) How to prescribe PBS-subsidised tocilizumab therapy after 1 May 2012.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised tocilizumab treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or

(ii) a patient wishes to re-commence treatment with tocilizumab following a break in PBS-subsidised therapy of more than 12 months (Initial 1); or

(iii) a patient has received the first course of PBS-subsidised (initial or continuing) tocilizumab therapy in a treatment cycle and is deemed to have failed to respond or sustain a response and the treating physician wishes to trial a second course (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with tocilizumab for that course.

For second and subsequent courses of PBS-subsidised tocilizumab, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with tocilizumab, a patient may qualify to receive up to 24 weeks of continuing treatment with tocilizumab providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing tocilizumab treatment in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted tocilizumab supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with tocilizumab.

(2) Treatment cycle.

Once initial treatment with PBS-subsidised tocilizumab is approved, a patient deemed to have failed to respond to the first course of treatment may have a second course without having to requalify with respect to the indices of disease severity (joint count, fever and/or CRP level and platelet count) or the prior therapy requirements, except if the patient has had a break in therapy of more than 12 months.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

(3) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated based on the relevant baseline measurements of the joint count, fever and/or CRP level and platelet count submitted with the first authority application for tocilizumab.

Where a patient is deemed to have failed to respond or to sustain a response to the first course of therapy in a treatment cycle, prescribers may provide new baseline measurements for the second course of treatment within that cycle. Medicare Australia will assess response according to these revised baseline measurements. If new baseline measurements are not submitted with the initial application for the second course of treatment, then those submitted with the first course will be used by Medicare Australia to assess response to the second course.

(4) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised tocilizumab therapy of at least 12 months, must requalify for treatment under the Initial 1 treatment restriction.

(5) Patients 'grandfathered' onto PBS-subsidised treatment with tocilizumab.

A patient who commenced treatment with tocilizumab for severe active systemic juvenile idiopathic arthritis prior to 1 November 2011 and who continues to receive treatment at the time of application, may qualify for treatment under the initial 'grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment with tocilizumab will be authorised under this criterion.

Following completion of the initial PBS-subsidised course, further applications for treatment with tocilizumab will be assessed under the continuing treatment restriction.

'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must qualify for initial treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 12 month break in PBS-subsidised

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| | therapy' above for further details. | | | | | | |
| | (6) Withdrawal of treatment after sustained remission. | | | | | | |
| | Withdrawal of treatment with tocilizumab should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be submitted to Medicare Australia at the time treatment is ceased. | | | | | | |
| | **Note** | | | | | | |
| | Special Pricing Arrangements apply. | | | | | | |
| 1423X | tocilizumab 200 mg/10 mL injection, 1 x 10 mL vial | 1 | .. | .. | 492.52 | Actemra | RO |
| 1464C | tocilizumab 400 mg/20 mL injection, 1 x 20 mL vial | 1 | .. | .. | 978.41 | Actemra | RO |
| 1419Q | tocilizumab 80 mg/4 mL injection, 1 x 4 mL vial | 1 | .. | .. | 200.99 | Actemra | RO |
| | **TOCILIZUMAB** | | | | | | |
| | **Authority required** | | | | | | |
| | Initial 1 (new patient or patient re-commencing after a break of more than 24 months) | | | | | | |
| | Initial PBS-subsidised treatment with tocilizumab, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of adults who: | | | | | | |
| | (a) have severe active rheumatoid arthritis; and | | | | | | |
| | (b) have received no PBS-subsidised treatment with a bDMARD for this condition in the previous 24 months; and | | | | | | |
| | (c) have failed, in the 24 months immediately prior to the date of application, to achieve an adequate response to at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs), which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: | | | | | | |
| | — hydroxychloroquine at a dose of at least 200 mg daily; or | | | | | | |
| | — leflunomide at a dose of at least 10 mg daily; or | | | | | | |
| | — sulfasalazine at a dose of at least 2 g daily. | | | | | | |
| | If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, then the 6 months of intensive DMARD treatment must include at least 3 months continuous treatment with each of at least 2 of the DMARDs: | | | | | | |
| | — hydroxychloroquine at a dose of at least 200 mg daily; and/or | | | | | | |
| | — leflunomide at a dose of at least 10 mg daily; and/or | | | | | | |
| | — sulfasalazine at a dose of at least 2 g daily. | | | | | | |
| | The application must include details of the contraindication or intolerance to methotrexate. Details of the toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose can be found on the Medicare Australia website [www.medicareaustralia.gov.au]. The maximum tolerated dose of methotrexate must be documented in the application, if applicable. | | | | | | |
| | If 3 or more of methotrexate, hydroxychloroquine, leflunomide and sulfasalazine are contraindicated according to the relevant TGA-approved product information or cannot be tolerated at the doses specified above, then one or more of the following DMARDs may be used in place of these agents in order to satisfy the requirement for a trial of 6 months of intensive DMARD therapy with at least 2 DMARDs taken continuously for at least 3 months each: | | | | | | |
| | — azathioprine at a dose of at least 1 mg/kg per day; and/or | | | | | | |
| | — cyclosporin at a dose of at least 2 mg/kg/day; and/or | | | | | | |
| | — sodium aurothiomalate at a dose of 50 mg weekly. | | | | | | |
| | The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances. Details of the toxicities, including severity, which will be accepted as a reason for substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial can be found on the Medicare Australia website [www.medicareaustralia.gov.au]. | | | | | | |
| | The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs. | | | | | | |
| | If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance and dose for each DMARD must be provided in the authority application. Details of the toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy can be found on the Medicare Australia website [www.medicareaustralia.gov.au]. | | | | | | |
| | The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application: | | | | | | |
| | an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; | | | | | | |
| | AND either | | | | | | |
| | (i) a total active joint count of at least 20 active (swollen and tender) joints; or | | | | | | |
| | (ii) at least 4 active joints from the following list of major joints: | | | | | | |
| | — elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or | | | | | | |
| | — shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are | | | | | | |

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due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reason this criterion cannot be satisfied.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and

(3) a signed patient acknowledgement.

A maximum of 16 weeks of treatment will be authorised under this restriction.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials of appropriate strength, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 8 mg per kg. A separate authority prescription form must be completed for each strength requested.

Up to a maximum of 3 repeats of each strength may be authorised. Where fewer than 3 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Assessment of a patient's response to an initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with tocilizumab.

Patients who fail to demonstrate a response to treatment with tocilizumab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition

**Authority required**

Initial 2 (change or re-commencement after break of less than 24 months)

Initial course of PBS-subsidised treatment with tocilizumab, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of adults who:

(a) have a documented history of severe active rheumatoid arthritis; and

(b) have received prior PBS-subsidised bDMARD treatment for this condition and are eligible to receive further bDMARD therapy.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].

Applications for patients who have received PBS-subsidised treatment with tocilizumab and who wish to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised tocilizumab treatment, within the timeframes specified below.

A maximum of 16 weeks of treatment will be authorised under this restriction.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials of appropriate strength, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 8 mg per kg. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats of each strength may be authorised.

Where fewer than 3 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Where the most recent course of PBS-subsidised tocilizumab treatment was approved under either of the initial 1 or 2 treatment restrictions, patients must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be provided to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised tocilizumab treatment was approved under the continuing treatment criteria, patients must have been assessed for response, and the assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Patients who fail to demonstrate a response to treatment with tocilizumab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition

**Authority required**

Continuing treatment

Continuing PBS-subsidised treatment with tocilizumab, by a rheumatologist or clinical immunologist with expertise in the management of

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rheumatoid arthritis, of adults:

(a) who have a documented history of severe active rheumatoid arthritis; and

(b) who have demonstrated an adequate response to treatment with tocilizumab; and

(c) whose most recent course of PBS-subsidised bDMARD treatment was with tocilizumab.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(i) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(ii) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

— elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

— shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].

A maximum of 24 weeks of treatment will be approved under this restriction.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials of appropriate strength, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 8 mg per kg. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 5 repeats of each strength may be authorised.

Where fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

All applications for continuing treatment with tocilizumab must include a measurement of response to the prior course of therapy. This assessment must be provided to Medicare Australia no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with tocilizumab, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.

Patients who fail to demonstrate a response to treatment with tocilizumab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition

**Note**

Any queries concerning the arrangements to prescribe tocilizumab may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Further prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe tocilizumab should be forwarded to:

Medicare Australia

Prior Written Approval of Specialised Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

**Note**

TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying anti-rheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab) and the T-cell co-stimulation modulator (abatacept).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

PBS-subsidised abatacept, golimumab, infliximab and rituximab must be used in combination with methotrexate at a dose of at least 7.5 mg weekly. Where a patient cannot tolerate 7.5 mg of methotrexate weekly, they are eligible to receive PBS-subsidised adalimumab, certolizumab pegol, etanercept and tocilizumab.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:

— a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,

— a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and

— once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Brand Name and Manufacturer |
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for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact Medicare Australia on 1800 700 270.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or

(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or

(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or

(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab and tocilizumab, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to Medicare Australia within 4 weeks.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

Abatacept patients:

Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients:

A further application may be submitted to Medicare Australia 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Rituximab patients:

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the

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requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.

Abatacept patients:

Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

**Note**

(3) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and Medicare Australia will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

**Note**

Special Pricing Arrangements apply.

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| 9672C | tocilizumab 200 mg/10 mL injection, 1 x 10 mL vial | 1 | .. | .. | 492.52 | Actemra | RO |
| 9673D | tocilizumab 400 mg/20 mL injection, 1 x 20 mL vial | 1 | .. | .. | 978.41 | Actemra | RO |
| 9671B | tocilizumab 80 mg/4 mL injection, 1 x 4 mL vial | 1 | .. | .. | 200.99 | Actemra | RO |

## *Calcineurin inhibitors*

**CYCLOSPORIN**

**Authority required**

Management of rejection in patients following organ or tissue transplantation, under the supervision and direction of a transplant unit. Management includes initiation, stabilisation and review of therapy as required

**Authority required**

Management (which includes initiation, stabilisation and review of therapy) by dermatologists or clinical immunologists of patients with severe atopic dermatitis for whom other systemic therapies are ineffective or inappropriate

**Authority required**

Management (which includes initiation, stabilisation and review of therapy) by dermatologists of patients with severe psoriasis for whom other systemic therapies are ineffective or inappropriate and in whom the disease has caused significant interference with quality of life

**Authority required**

Management (which includes initiation, stabilisation and review of therapy) by nephrologists of patients with nephrotic syndrome in patients in whom steroids and cytostatic drugs have failed or are not tolerated or are considered inappropriate and in whom renal function is unimpaired

**Authority required**

Management (which includes initiation, stabilisation and review of therapy) by rheumatologists or clinical immunologists of patients with severe active rheumatoid arthritis for whom classical slow-acting anti-rheumatic agents (including methotrexate) are ineffective or inappropriate

**Caution**

Careful monitoring of patients is mandatory.

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| 6232B | cyclosporin 10 mg capsule, 60 | 2 | 5 | .. | *85.03 | Neoral 10 | NV |

# HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|
| 6354K | cyclosporin 100 mg capsule, 30 | 4 | 5 | .. | *683.75 | [a] | Cyclosporin Sandoz | SZ |
| | | | | | | [a] | Neoral 100 | NV |
| 6125J | cyclosporin 100 mg/mL oral liquid, 50 mL | 4 | 5 | .. | *1309.79 | | Neoral | NV |
| 6352H | cyclosporin 25 mg capsule, 30 | 4 | 5 | .. | *166.35 | [a] | Cyclosporin Sandoz | SZ |
| | | | | | | [a] | Neoral 25 | NV |
| 6353J | cyclosporin 50 mg capsule, 30 | 4 | 5 | .. | *338.95 | [a] | Cyclosporin Sandoz | SZ |
| | | | | | | [a] | Neoral 50 | NV |

**CYCLOSPORIN**

**Authority required**

For use by organ or tissue transplant recipients

**Caution**

Careful monitoring of patients is mandatory.

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 6109M | cyclosporin 50 mg/mL injection, 10 x 1 mL ampoules | 1 | .. | .. | 64.73 | | Sandimmun | NV |

**TACROLIMUS**

**Authority required**

Management of rejection in patients following organ or tissue transplantation, under the supervision and direction of a transplant unit. Management includes initiation, stabilisation and review of therapy as required

**Caution**

Careful monitoring of patients is mandatory.

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 6216E | tacrolimus 1 mg capsule, 100 | 2 | 5 | .. | *688.53 | [a] | Prograf | JC |
| | | | | | | [a] | Tacrolimus Sandoz | SZ |
| 9682N | tacrolimus 1 mg capsule: modified release, 60 capsules | 2 | 5 | .. | *415.77 | | Prograf XL | JC |
| 6217F | tacrolimus 5 mg capsule, 50 | 2 | 5 | .. | *1685.01 | [a] | Prograf | JC |
| | | | | | | [a] | Tacrolimus Sandoz | SZ |
| 9683P | tacrolimus 5 mg capsule: modified release, 30 capsules | 2 | 5 | .. | *1029.51 | | Prograf XL | JC |
| 6328C | tacrolimus 500 microgram capsule, 100 | 2 | 5 | .. | *347.59 | [a] | Prograf | JC |
| | | | | | | [a] | Tacrolimus Sandoz | SZ |
| 9681M | tacrolimus 500 microgram capsule: modified release, 30 capsules | 2 | 5 | .. | *108.99 | | Prograf XL | JC |

## *Other immunosuppressants*

**LENALIDOMIDE**

**Authority required**

Multiple myeloma

Treatment Phase: Initial PBS-subsidised treatment

**The Clinical criteria is:**

The condition must be confirmed by a histological diagnosis,

**AND the Clinical criteria is:**

The treatment must be as monotherapy; OR

The treatment must be in combination with dexamethasone,

**AND the Clinical criteria is:**

Patient must have progressive disease after at least one prior therapy,

**AND the Clinical criteria is:**

Patient must have undergone or be ineligible for a primary stem cell transplant,

**AND the Clinical criteria is:**

Patient must have experienced treatment failure after a trial of at least four (4) weeks of thalidomide at a dose of at least 100 mg daily or have failed to achieve at least a minimal response after eight (8) or more weeks of thalidomide-based therapy for progressive disease,

**AND the Clinical criteria is:**

Patient must not be receiving concomitant PBS-subsidised bortezomib.

Progressive disease is defined as at least 1 of the following:

(a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or

(b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or

(c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase of the difference between involved free light chain and uninvolved free light chain; or

(d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or

(e) an increase in the size or number of lytic bone lesions (not including compression fractures); or

# HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

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(f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or

(g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.

Thalidomide treatment failure is defined as:

(1) confirmed disease progression during thalidomide treatment or within 6 months of discontinuing thalidomide treatment; or

(2) severe intolerance or toxicity unresponsive to clinically appropriate dose adjustment.

Severe intolerance due to thalidomide is defined as unacceptable somnolence or sedation interfering with activities of daily living.

Toxicity from thalidomide is defined as peripheral neuropathy (Grade 2 or greater, interfering with function), drug-related seizures, serious Grade 3 or 4 drug-related dermatological reactions, such as Stevens-Johnson Syndrome, or other Grade 3 or 4 toxicity.

Failure to achieve at least a minimal response after 8 or more weeks of thalidomide-based therapy for progressive disease is defined as:

(1) less than a 25% reduction in serum or urine M protein; or

(2) in oligo-secretory and non-secretory myeloma patients only, less than a 25% reduction in the difference between involved and uninvolved serum free light chain levels.

If the dosing requirement for thalidomide cannot be met, the application must state the reasons why this criterion cannot be satisfied.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Multiple Myeloma lenalidomide Authority Application - Supporting Information Form, which includes details of the histological diagnosis of multiple myeloma, prior treatments including name(s) of drug(s) and date of most recent treatment cycle and record of prior stem cell transplant or ineligibility for prior stem cell transplant; details of thalidomide treatment failure; details of the basis of the diagnosis of progressive disease or failure to respond; and nomination of which disease activity parameters will be used to assess response; and

(3) duration of thalidomide and daily dose prescribed; and

(4) a signed patient acknowledgment.

To enable confirmation of eligibility for treatment, current diagnostic reports of at least one of the following must be provided:

(a) the level of serum monoclonal protein; or

(b) Bence-Jones proteinuria - the results of 24-hour urinary light chain M protein excretion; or

(c) the serum level of free kappa and lambda light chains; or

(d) bone marrow aspirate or trephine; or

(e) if present, the size and location of lytic bone lesions (not including compression fractures); or

(f) if present, the size and location of all soft tissue plasmacytomas by clinical or radiographic examination i.e. MRI or CT-scan; or

(g) if present, the level of hypercalcaemia, corrected for albumin concentration.

As these parameters will be used to determine response, results for either (a) or (b) or (c) should be provided for all patients. Where the patient has oligo-secretory or non-secretory multiple myeloma, either (c) or (d) or if relevant (e), (f) or (g) should be provided. Where the prescriber plans to assess response in patients with oligo-secretory or non-secretory multiple myeloma with free light chain assays, evidence of the oligo-secretory or non-secretory nature of the multiple myeloma (current serum M protein less than 10 g per L) must be provided.

Patients receiving lenalidomide under the PBS listing must be registered in the i-access risk management program.

**Note**

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

**Note**

Special Pricing Arrangements apply.

**Authority required**

Multiple myeloma

Treatment Phase: Continuing PBS-subsidised treatment

**The Clinical criteria is:**

Patient must have previously received an authority prescription for lenalidomide,

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|
| | **AND the Clinical criteria is:** | | | | | | |
| | Patient must not have progressive disease, | | | | | | |
| | **AND the Clinical criteria is:** | | | | | | |
| | The treatment must be as monotherapy; OR | | | | | | |
| | The treatment must be in combination with dexamethasone. | | | | | | |
| | Progressive disease is defined as at least 1 of the following: | | | | | | |
| | (a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or | | | | | | |
| | (b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or | | | | | | |
| | (c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase of the difference between involved free light chain and uninvolved free light chain; or | | | | | | |
| | (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or | | | | | | |
| | (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or | | | | | | |
| | (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or | | | | | | |
| | (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause). | | | | | | |
| | Patients receiving lenalidomide under the PBS listing must be registered in the i-access risk management program. | | | | | | |
| | **Note**<br>Authority applications for continuing treatment may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). | | | | | | |
| | **Note**<br>Written applications for authority to prescribe should be forwarded to: | | | | | | |
| | Department of Human Services | | | | | | |
| | Prior Written Approval of Complex Drugs | | | | | | |
| | Reply Paid 9826 | | | | | | |
| | GPO Box 9826 | | | | | | |
| | HOBART TAS 7001 | | | | | | |
| | **Note**<br>Special Pricing Arrangements apply. | | | | | | |
| 9643M | lenalidomide 10 mg capsule, 21 | 1 | .. | .. | 5689.96 | Revlimid | CJ |
| 9644N | lenalidomide 15 mg capsule, 21 | 1 | .. | .. | 6628.24 | Revlimid | CJ |
| 9645P | lenalidomide 25 mg capsule, 21 | 1 | .. | .. | 6980.83 | Revlimid | CJ |
| 9642L | lenalidomide 5 mg capsule, 21 | 1 | .. | .. | 5439.01 | Revlimid | CJ |
| | **RITUXIMAB** | | | | | | |
| | **Authority required**<br>Initial 1 (patient re-commencing after a break of more than 24 months) | | | | | | |
| | Initial PBS-subsidised treatment with rituximab, in combination with methotrexate at a dose of at least 7.5 mg weekly, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of adults who: | | | | | | |
| | (a) have severe active rheumatoid arthritis; and | | | | | | |
| | (b) have failed to respond to at least 1 PBS-subsidised TNF-alfa antagonist; and | | | | | | |
| | (c) have received no PBS-subsidised treatment with a bDMARD for this condition in the previous 24 months; and | | | | | | |
| | (d) have failed, in the 24 months immediately prior to the date of application, to achieve an adequate response to at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs), which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: | | | | | | |
| | — hydroxychloroquine at a dose of at least 200 mg daily; or | | | | | | |
| | — leflunomide at a dose of at least 10 mg daily; or | | | | | | |
| | — sulfasalazine at a dose of at least 2 g daily. | | | | | | |
| | If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, then the 6 months of intensive DMARD treatment must include at least 3 months continuous treatment with each of at least 2 of the DMARDs: | | | | | | |
| | — hydroxychloroquine at a dose of at least 200 mg daily; and/or | | | | | | |
| | — leflunomide at a dose of at least 10 mg daily; and/or | | | | | | |
| | — sulfasalazine at a dose of at least 2 g daily. | | | | | | |
| | The application must include details of the contraindication or intolerance to methotrexate. Details of the toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose can be found on the Medicare Australia website [www.medicareaustralia.gov.au]. The maximum tolerated dose of methotrexate must be documented in the application, if applicable. | | | | | | |

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If 3 or more of methotrexate, hydroxychloroquine, leflunomide and sulfasalazine are contraindicated according to the relevant TGA-approved product information or cannot be tolerated at the doses specified above, then one or more of the following DMARDs may be used in place of these agents in order to satisfy the requirement for a trial of 6 months of intensive DMARD therapy with at least 2 DMARDs taken continuously for at least 3 months each:

— azathioprine at a dose of at least 1 mg/kg per day; and/or

— cyclosporin at a dose of at least 2 mg/kg/day; and/or

— sodium aurothiomalate at a dose of 50 mg weekly.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances. Details of the toxicities, including severity, which will be accepted as a reason for substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial can be found on the Medicare Australia website [www.medicareaustralia.gov.au].

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance and dose for each DMARD must be provided in the authority application. Details of the toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy can be found on the Medicare Australia website [www.medicareaustralia.gov.au].

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L;

AND either

(i) a total active joint count of at least 20 active (swollen and tender) joints; or

(ii) at least 4 active joints from the following list of major joints:

— elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

— shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reason this criterion cannot be satisfied.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and

(3) a signed patient acknowledgement.

A maximum of two infusions will be authorised under this restriction.

Assessment of a patient's response to an initial course of treatment must be made at least 12 weeks after the first infusion so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia within 4 weeks of the date it was conducted. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with rituximab.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction.

Patients who fail to demonstrate a response to treatment with rituximab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Patients who fail to demonstrate a response to rituximab treatment and who qualify to trial an alternate bDMARD according to the interchangeability arrangements for bDMARDs for the treatment of severe rheumatoid arthritis, may do so without having to have a 22 week treatment-free period

**Authority required**

Initial 2 (change or re-commencement after break of less than 24 months)

Initial course of PBS-subsidised treatment with rituximab, in combination with methotrexate at a dose of at least 7.5 mg weekly, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of adults who:

(a) have a documented history of severe active rheumatoid arthritis; and

(b) have failed to respond to at least 1 PBS-subsidised TNF-alfa antagonist; and

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(c) have received prior PBS-subsidised bDMARD treatment for this condition and are eligible to receive further bDMARD therapy.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].

Applications for patients who have received PBS-subsidised treatment with rituximab and who wish to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised rituximab treatment, within the timeframes specified below.

A maximum of two infusions will be authorised under this restriction.

Where the most recent course of PBS-subsidised rituximab treatment was approved under either of the initial 1 or 2 treatment restrictions patients must be assessed for response at least 12 weeks after the first infusion. This assessment must be provided to Medicare Australia no later than 4 weeks from the date of assessment.

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent provided they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The demonstration of response must be submitted to Medicare Australia within 4 weeks of assessment.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction.

Patients who fail to demonstrate a response to treatment with rituximab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Patients who fail to demonstrate a response to rituximab treatment and who qualify to trial an alternate bDMARD according to the interchangeability arrangements for bDMARDs for the treatment of severe rheumatoid arthritis, may do so without having to have a 22 week treatment-free period

**Authority required**

Continuing treatment

Continuing PBS-subsidised treatment with rituximab, in combination with methotrexate at a dose of at least 7.5 mg weekly, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of adults:

(a) who have a documented history of severe active rheumatoid arthritis; and

(b) who have demonstrated an adequate response to treatment with rituximab; and

(c) whose most recent course of PBS-subsidised bDMARD treatment was with rituximab.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(i) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(ii) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

— elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

— shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].

A maximum of two infusions will be authorised under this restriction.

Patients may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The demonstration of response must be submitted to Medicare Australia within 4 weeks of assessment.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction.

Patients who fail to demonstrate a response to treatment with rituximab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition

**Note**

Any queries concerning the arrangements to prescribe rituximab may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Further prescribing information (including Authority Application Forms) is on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe rituximab should be forwarded to:

Medicare Australia

Prior Written Approval of Specialised Drugs

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

**Note**

TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying anti-rheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab) and the T-cell co-stimulation modulator (abatacept).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

PBS-subsidised abatacept, golimumab, infliximab and rituximab must be used in combination with methotrexate at a dose of at least 7.5 mg weekly. Where a patient cannot tolerate 7.5 mg of methotrexate weekly, they are eligible to receive PBS-subsidised adalimumab, certolizumab pegol, etanercept and tocilizumab.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:

— a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,

— a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and

— once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact Medicare Australia on 1800 700 270.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or

(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or

(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or

(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab and tocilizumab, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to Medicare Australia within 4 weeks.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

Abatacept patients:

Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

# HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|
| | Rituximab patients: | | | | | | |
| | A further application may be submitted to Medicare Australia 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate. | | | | | | |
| | (b) Continuing treatment. | | | | | | |
| | Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. | | | | | | |
| | It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply. | | | | | | |
| | Assessments of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased. | | | | | | |
| | Rituximab patients: | | | | | | |
| | A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction. | | | | | | |
| | Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD. | | | | | | |
| | (2) Swapping therapy. | | | | | | |
| | Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled. | | | | | | |
| | Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent. | | | | | | |
| | A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug. | | | | | | |
| | Abatacept patients: | | | | | | |
| | Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation. | | | | | | |
| | In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment. | | | | | | |
| | To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction. | | | | | | |
| | PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period. | | | | | | |
| | To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing. | | | | | | |
| | **Note** | | | | | | |
| | (3) Baseline measurements to determine response. | | | | | | |
| | Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and Medicare Australia will assess response according to these revised baseline measurements. | | | | | | |
| | To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. | | | | | | |
| | Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. | | | | | | |
| | **Note** | | | | | | |
| | Special Pricing Arrangements apply. | | | | | | |
| 9611W | rituximab 500 mg/50 mL injection, 1 x 50 mL vial | 1 | .. | .. | 2310.20 | Mabthera | RO |
| | **THALIDOMIDE** | | | | | | |

# HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|
| | **Authority required**<br>Multiple myeloma | | | | | | |
| | **Caution**<br>Thalidomide is a category X drug and must not be given to pregnant women. Pregnancy in female patients or in the partners of male patients must be avoided during treatment and for 1 month after cessation of treatment. | | | | | | |
| | **Note**<br>Patients receiving thalidomide under the PBS listing must be registered in the i-access risk management program. | | | | | | |
| 9684Q | thalidomide 100 mg capsule, 28 | 2 | .. | .. | *1726.63 | Thalomid | CJ |
| 6469L | thalidomide 50 mg capsule, 28 | 4 | .. | .. | *1726.63 | Thalomid | CJ |

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|

# MUSCULO-SKELETAL SYSTEM

## MUSCLE RELAXANTS

### MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS

#### *Other centrally acting agents*

**BACLOFEN**

**Authority required**

Severe chronic spasticity, where oral antispastic agents have failed or have caused unacceptable side effects, in patients with chronic spasticity of cerebral origin

**Authority required**

Severe chronic spasticity, where oral antispastic agents have failed or have caused unacceptable side effects, in patients with chronic spasticity due to multiple sclerosis

**Authority required**

Severe chronic spasticity, where oral antispastic agents have failed or have caused unacceptable side effects, in patients with chronic spasticity due to spinal cord injury

**Authority required**

Severe chronic spasticity, where oral antispastic agents have failed or have caused unacceptable side effects, in patients with chronic spasticity due to spinal cord disease

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 6284R | baclofen 10 mg/5 mL injection: intrathecal, 1 x 5 mL ampoule | 10 | .. | .. | *1530.33 | | Lioresal Intrathecal | NV |

## DRUGS FOR TREATMENT OF BONE DISEASES

### DRUGS AFFECTING BONE STRUCTURE AND MINERALIZATION

#### *Bisphosphonates*

**IBANDRONIC ACID**

**Authority required**

Bone metastases from breast cancer

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 9619G | ibandronic acid 6 mg/6 mL injection, 1 x 6 mL vial | 1 | 11 | .. | 361.64 | | Bondronat | RO |

**PAMIDRONATE DISODIUM**

**Authority required**

Treatment of hypercalcaemia of malignancy refractory to anti-neoplastic therapy

**Note**

Pharmaceutical benefits that have the form disodium pamidronate powder for I.V. infusion 15 mg (after reconstitution) and pharmaceutical benefits that have the form disodium pamidronate concentrated injection 15 mg are equivalent for the purposes of substitution.

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 6290C | pamidronate disodium 15 mg injection [4 x 15 mg vials] (&) inert substance diluent [4 x 5 mL ampoules], 1 pack | 1 | 2 | .. | 115.79 | [a] | Aredia 15 mg | NV |
| 6286W | pamidronate disodium 15 mg/5 mL injection, 1 x 5 mL vial | 4 | 2 | .. | *115.79 | [a] | Pamisol | HH |

**PAMIDRONATE DISODIUM**

**Authority required**

Treatment of hypercalcaemia of malignancy refractory to anti-neoplastic therapy

**Note**

Pharmaceutical benefits that have the form disodium pamidronate powder for I.V. infusion 30 mg (after reconstitution) and pharmaceutical benefits that have the form disodium pamidronate concentrated injection 30 mg are equivalent for the purposes of substitution.

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 6279L | pamidronate disodium 30 mg injection [2 x 30 mg vials] (&) inert substance diluent [2 x 10 mL ampoules], 1 pack | 1 | 2 | .. | 115.79 | [a] | Aredia 30 mg | NV |
| 6287X | pamidronate disodium 30 mg/10 mL injection, 1 x 10 mL vial | 2 | 2 | .. | *115.79 | [a] | Pamidronate Strides | YA |
| | | | | | | [a] | Pamisol | HH |

**PAMIDRONATE DISODIUM**

**Authority required**

Treatment of hypercalcaemia of malignancy refractory to anti-neoplastic therapy

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 6288Y | pamidronate disodium 60 mg/10 mL injection, 1 x 10 mL vial | 1 | 2 | .. | 115.78 | | Pamisol | HH |

# HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|
| | **PAMIDRONATE DISODIUM** | | | | | | | |
| | **Authority required** | | | | | | | |
| | Treatment of hypercalcaemia of malignancy refractory to anti-neoplastic therapy | | | | | | | |
| | **Authority required** | | | | | | | |
| | Multiple myeloma | | | | | | | |
| | **Authority required** | | | | | | | |
| | Bone metastases from breast cancer | | | | | | | |
| | **Note** | | | | | | | |
| | Pharmaceutical benefits that have the form disodium pamidronate powder for I.V. infusion 90 mg (after reconstitution) and pharmaceutical benefits that have the form disodium pamidronate concentrated injection 90 mg are equivalent for the purposes of substitution. | | | | | | | |
| 6223M | pamidronate disodium 90 mg injection [1 x 90 mg vial] (&) inert substance diluent [1 x 10 mL ampoule], 1 pack | 1 | 11 | .. | 170.36 | [a] | Aredia 90 mg | NV |
| 6289B | pamidronate disodium 90 mg/10 mL injection, 1 x 10 mL vial | 1 | 11 | .. | 170.36 | [a] | Pamidronate Strides | YA |
| | | | | | | [a] | Pamisol | HH |
| | **ZOLEDRONIC ACID** | | | | | | | |
| | **Authority required** | | | | | | | |
| | Multiple myeloma | | | | | | | |
| | **Authority required** | | | | | | | |
| | Bone metastases from breast cancer | | | | | | | |
| | **Authority required** | | | | | | | |
| | Bone metastases from castration-resistant prostate cancer | | | | | | | |
| | **Authority required** | | | | | | | |
| | Treatment of hypercalcaemia of malignancy refractory to anti-neoplastic therapy | | | | | | | |
| | **Note** | | | | | | | |
| | Special Pricing Arrangements apply. | | | | | | | |
| 6371H | zoledronic acid 4 mg/5 mL injection, 1 x 5 mL vial | 1 | 11 | .. | 474.63 | | Zometa | NV |

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|

# NERVOUS SYSTEM

## ANTI-PARKINSON DRUGS

### DOPAMINERGIC AGENTS

#### *Dopa and dopa derivatives*

**LEVODOPA + CARBIDOPA ANHYDROUS**

**Authority required**

Management of advanced Parkinson disease in a patient with severe disabling motor fluctuations not adequately controlled by oral therapy.

Treatment must be commenced in a hospital-based movement disorder clinic

**Note**

Patients should have adequate cognitive function to manage administration with a portable continuous infusion pump.

A positive clinical response to Duodopa administered via a temporary nasoduodenal tube should be confirmed before a permanent percutaneous endoscopic gastrostomy (PEG) tube is inserted.

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 9744W | levodopa 20 mg/mL + carbidopa monohydrate 5 mg/mL gel: intestinal, 7 x 100 mL bags | 8 | 5 | .. | *11582.63 | | Duodopa | VE |

#### *Dopamine agonists*

**APOMORPHINE**

**Authority required**

Parkinson's disease in patients severely disabled by motor fluctuations which do not respond to other therapy

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 9607P | apomorphine hydrochloride 20 mg/2 mL injection, 5 x 2 mL ampoules | 72 | 5 | .. | *5652.87 | | Apomine | HH |
| 9647R | apomorphine hydrochloride 50 mg/10 mL injection: subcutaneous infusion, 5 x 10 mL syringes | 36 | 5 | .. | *7053.99 | | Apomine PFS | HH |
| 9640J | apomorphine hydrochloride 50 mg/5 mL injection, 5 x 5 mL ampoules | 36 | 5 | .. | *7053.99 | | Apomine | HH |

## PSYCHOLEPTICS

### ANTIPSYCHOTICS

#### *Diazepines, oxazepines, thiazepines and oxepines*

**CLOZAPINE**

**Authority required**

Schizophrenia in patients who are non-responsive to other neuroleptic agents

**Authority required**

Schizophrenia in patients who are intolerant of other neuroleptic agents

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 6102E | clozapine 100 mg tablet, 100 | 2 | .. | .. | *354.41 | [a] | Clopine 100 | HH |
| | | | | | | [a] | Clozaril 100 | NV |
| 6418T | clozapine 200 mg tablet, 100 | 2 | .. | .. | *702.21 | | Clopine 200 | HH |
| 6101D | clozapine 25 mg tablet, 100 | 2 | .. | .. | *99.81 | [a] | Clopine 25 | HH |
| | | | | | | [a] | Clozaril 25 | NV |
| 6417R | clozapine 50 mg tablet, 100 | 2 | .. | .. | *192.13 | | Clopine 50 | HH |
| 9632Y | clozapine 50 mg/mL oral liquid, 100 mL | 1 | .. | .. | 147.03 | | Clopine Suspension | HH |

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|

# RESPIRATORY SYSTEM

## DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES

### OTHER SYSTEMIC DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES

#### *Other systemic drugs for obstructive airway diseases*

**OMALIZUMAB**

**Authority required**

Initial treatment of uncontrolled severe allergic asthma

Initial PBS-subsidised treatment with omalizumab by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma, of a patient aged 12 years or older with uncontrolled severe allergic asthma who has been under the care of this physician for at least 12 months, and satisfies the following criteria:

(a) has a diagnosis of asthma confirmed and documented by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma, defined by standard clinical features, including:

(i) forced expiratory volume (FEV1) reversibility greater than or equal to 12% and greater than or equal to 200 mL at baseline within 30 minutes after administration of salbutamol (200 to 400 micrograms), or

(ii) airway hyperresponsiveness defined as a greater than 20% decline in FEV1 during a direct bronchial provocation test or greater than 15% decline during an indirect bronchial provocation test, or

(iii) peak expiratory flow (PEF) variability of greater than 15% between the two highest and two lowest peak expiratory flow rates during 14 days; and

(b) duration of asthma of at least 1 year; and

(c) FEV1 less than or equal to 80% predicted, documented on 3 or more occasions in the previous 12 months; and

(d) past or current evidence of atopy, documented by skin prick testing or RAST; and

(e) total serum human immunoglobulin E (IgE) greater than or equal to 76 IU/mL; and

(f) has signed a patient acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criteria for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and

(g) has failed to achieve adequate control with optimised asthma therapy, despite formal assessment of and adherence to correct inhaler technique, which has been documented (see NOTE). Optimised asthma therapy includes:

(i) adherence to maximal inhaled therapy, including high dose inhaled corticosteroid (budesonide 1600 micrograms per day or fluticasone propionate 1000 micrograms per day or equivalent), plus long-acting beta-2 agonist therapy (at least salmeterol 50 micrograms bd or eformoterol 12 micrograms bd) for at least 12 months, unless contraindicated or not tolerated, AND

(ii) oral corticosteroids (at least 10 mg per day prednisolone (or equivalent)) for at least 6 weeks, unless contraindicated or not tolerated.

If the requirement for treatment with optimised asthma therapy cannot be met because of contraindications according to the relevant TGA-approved Product Information and/or intolerances of a severity necessitating permanent treatment withdrawal, details of the contraindication and/or intolerance must be provided in the authority application. Details of the accepted toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement of treatment with optimised asthma therapy can be found on the Medicare Australia website [www.medicareaustralia.gov.au].

The initial IgE assessment must be no more than 12 months old at the time of application. A re-assessment of free IgE can only be made at least 12 months after the last dose of omalizumab. For patients re-commencing omalizumab within 12 months of the last dose the previous pre-omalizumab IgE level should be used.

The IgE pathology report must be provided with the authority application.

The following initiation criteria indicate failure to achieve adequate control and must be demonstrated in all patients at the time of the application:

(a) an Asthma Control Questionnaire (ACQ-5) score of at least 2.0, as assessed in the previous month, AND

(b) while on oral corticosteroids and in the past 12 months, experienced at least 1 admission to hospital for a severe asthma exacerbation, OR 1 severe asthma exacerbation, requiring documented use of systemic corticosteroids (oral corticosteroids initiated or increased for at least 3 days, or parenteral corticosteroids) prescribed/supervised by a physician.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Allergic Asthma PBS Authority Application - Supporting Information Form (may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)) which includes the following:

(i) details of prior optimised asthma drug therapy (dosage, date of commencement and duration of therapy); and

(ii) details of severe exacerbation/s experienced while on oral corticosteroids (date and treatment); and

(iii) the signed patient acknowledgement; and

(c) a completed Asthma Control Questionnaire (ACQ-5) calculation sheet including the date of assessment of the patient's symptoms. (For copies of the ACQ please contact Novartis Medical Information on 1800 671 203 or medinfo.phauno@novartis.com)

At the time of the authority application, medical practitioners should request the appropriate maximum quantity and number of repeats to provide for an initial course of omalizumab consisting of the recommended number of doses for the baseline IgE level and body weight of the patient (refer

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to the TGA-approved Product Information) to be administered every 2 or 4 weeks.

Where fewer than the required number of repeats to complete 28 weeks of treatment are requested at the time of the application, authority approvals for sufficient repeats to complete 28 weeks of omalizumab therapy may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period beyond 28 weeks.

The Asthma Control Questionnaire (5 item version) assessment of the patient's response to this initial course of treatment, and the assessment of oral corticosteroid dose, must be made at around 24 to 26 weeks after the first dose so that there is adequate time for a response to be demonstrated and for the application for continuing therapy to be processed.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia within 4 weeks of the date of assessment, and no later than 2 weeks prior to the patient completing their current treatment course, to avoid an interruption to supply. Where a response assessment is not undertaken and submitted to Medicare Australia within this timeframe, the patient will be deemed to have failed to respond to treatment with omalizumab. It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 24 to 26 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised omalizumab treatment.

A patient who fails to respond to a course of PBS-subsidised omalizumab for the treatment of uncontrolled severe allergic asthma will not be eligible to receive further PBS-subsidised treatment with omalizumab for this condition within 6 months of the date on which treatment was ceased

**Authority required**

Continuing treatment

Continuing PBS-subsidised treatment with omalizumab, by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma, of a patient who:

(a) has a documented history of severe allergic asthma; and

(b) has demonstrated or sustained an adequate response to treatment with omalizumab.

An adequate response to omalizumab treatment is defined as:

(a) a reduction in the Asthma Control Questionnaire (ACQ-5) score of at least 0.5 from baseline, OR

(b) maintenance oral corticosteroid dose reduced by at least 25% from baseline, and no deterioration in ACQ-5 score from baseline.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Allergic Asthma PBS Authority Application - Supporting Information Form (may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)) which includes details of maintenance oral corticosteroid dose; and

(c) a completed Asthma Control Questionnaire (ACQ-5) calculation sheet including the date of assessment of the patient's symptoms. (For copies of the ACQ please contact Novartis Medical Information on 1800 671 203 or medinfo.phauno@novartis.com)

All applications for continuing treatment with omalizumab must include a measurement of response to the prior course of therapy. The Asthma Control Questionnaire (5 item version) assessment of the patient's response to the prior course of treatment, and the assessment of oral corticosteroid dose, must be made at around 20 to 22 weeks after the first dose so that there is adequate time for a response to be demonstrated and for the application for continuing therapy to be processed.

The first assessment should, where possible, be completed by the same physician who initiated treatment with omalizumab. If the same physician cannot assess the patient please call Medicare Australia on 1800 700 270.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia within 4 weeks of the date of assessment, and no later than 2 weeks prior to the patient completing their current treatment course, to avoid an interruption to supply. Where a response assessment is not undertaken and submitted to Medicare Australia within this timeframe, the patient will be deemed to have failed to respond to treatment with omalizumab.

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 20 to 22 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised omalizumab treatment.

Patients are eligible to receive continuing courses of omalizumab treatment of up to 24 weeks providing they continue to demonstrate an adequate response to treatment.

At the time of the authority application, medical practitioners should request the appropriate maximum quantity and number of repeats to provide for a continuing course of omalizumab consisting of the recommended number of doses for the baseline IgE level and body weight of the patient (refer to the TGA-approved Product Information), sufficient for 24 weeks of therapy.

Where fewer than the required number of repeats to complete 24 weeks of treatment are requested at the time of the application, authority approvals for sufficient repeats to complete 24 weeks of omalizumab therapy may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

A patient who fails to respond to a course of PBS-subsidised omalizumab for the treatment of uncontrolled severe allergic asthma will not be eligible to receive further PBS-subsidised treatment with omalizumab for this condition within 6 months of the date on which treatment was ceased

**Authority required**

Initial PBS-subsidised treatment of severe allergic asthma in a patient who has previously received non-PBS-subsidised therapy with omalizumab (grandfather patients)

Initial PBS-subsidised supply for continuing treatment with omalizumab by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma, of a patient aged 12 years or older with severe allergic asthma who satisfies the following criteria:

(a) has a diagnosis of asthma confirmed and documented by a respiratory physician, clinical immunologist, allergist or general physician

# HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

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experienced in the management of patients with severe asthma, defined by standard clinical features, including:

(i) forced expiratory volume (FEV1) reversibility greater than or equal to 12% and greater than or equal to 200 mL at baseline within 30 minutes after administration of salbutamol (200 to 400 micrograms), or

(ii) airway hyperresponsiveness defined as a greater than 20% decline in FEV1 during a direct bronchial provocation test or greater than 15% decline during an indirect bronchial provocation test, or

(iii) peak expiratory flow (PEF) variability of greater than 15% between the two highest and two lowest peak expiratory flow rates during 14 days; and

(b) duration of asthma of at least 1 year; and

(c) past or current evidence of atopy, documented by skin prick testing or RAST; and

(d) has signed a patient acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criteria for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment for grandfathered patients; and

(e) prior to omalizumab therapy had failed to achieve adequate control with optimised asthma therapy. Optimised asthma therapy includes:

(i) adherence to maximal inhaled therapy, including high dose inhaled corticosteroid (budesonide 1600 micrograms per day or fluticasone propionate 1000 micrograms per day or equivalent), plus long-acting beta-2 agonist therapy (at least salmeterol 50 micrograms bd or eformoterol 12 micrograms bd) for at least 12 months, and

(ii) may have included maintenance dose oral corticosteroids; and

(f) has demonstrated an adequate response to treatment with omalizumab.

A review of the patient's records should be conducted to extract pre- and post-omalizumab data on symptoms, quality of life, medication doses, exacerbations and hospitalisations. Examples of parameters to establish response include:

(i) a reduction in Asthma Control Questionnaire (ACQ-5) score of at least 0.5;

(ii) an improvement of at least 0.5 in the Asthma Quality of Life Questionnaire (AQLQ or mini-AQLQ);

(iii) maintenance oral corticosteroid dose reduced by at least 25% from baseline; and/or

(iv) a reduction in the number of hospitalisations or severe exacerbations requiring use of systemic corticosteroids, compared to the 12 months prior to commencement of omalizumab.

Where baseline assessments are not available, please call Medicare Australia on 1800 700 270 to discuss.

If the requirement for treatment with optimised asthma therapy cannot be met because of contraindications according to the relevant TGA-approved Product Information and/or intolerances of a severity necessitating permanent treatment withdrawal, details of the contraindication and/or intolerance must be provided in the authority application. Details of the accepted contraindications and toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement of treatment with optimised asthma therapy can be found on the Medicare Australia website [www.medicareaustralia.gov.au].

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Allergic Asthma PBS Authority Application - Supporting Information Form (may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)) which includes the following:

(i) details of prior optimised asthma drug therapy (dosage, date of commencement and duration of therapy); and

(ii) details of pre- and post-omalizumab data on symptoms, quality of life, medication doses, exacerbations and hospitalisations; and

(iii) the signed patient acknowledgement.

At the time of the authority application, medical practitioners should request the appropriate maximum quantity and number of repeats to provide for an initial course of omalizumab consisting of the recommended number of doses for the baseline IgE level and body weight of the patient (refer to the TGA-approved Product Information) to be administered every 2 or 4 weeks.

Where fewer than the required number of repeats to complete 24 weeks of treatment are requested at the time of the application, authority approvals for sufficient repeats to complete 24 weeks of omalizumab therapy may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period beyond 24 weeks.

An assessment of the patient's continued response to this course of PBS-subsidised treatment must be made at around 20 to 22 weeks after the first dose so that there is adequate time for a response to be demonstrated and for the application for continuing therapy to be processed. The same parameters used to establish response to non-PBS-subsidised therapy with omalizumab should be used for the assessment.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia within 4 weeks of the date of assessment, and no later than 2 weeks prior to the patient completing their current treatment course, to avoid an interruption to supply. Where a response assessment is not undertaken and submitted to Medicare Australia within this timeframe, the patient will be deemed to have failed to respond to treatment with omalizumab.

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 20 to 22 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised omalizumab treatment.

Patients are eligible to receive continuing courses of omalizumab treatment of up to 24 weeks providing they continue to demonstrate an adequate response to treatment.

Patients may qualify for PBS-subsidised treatment under this restriction once only. A patient who fails to respond to a course of PBS-subsidised omalizumab for the treatment of uncontrolled severe allergic asthma will not be eligible to receive further PBS-subsidised treatment with omalizumab for this condition within 6 months of the date on which treatment was ceased

# HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

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**Note**

Any queries concerning the arrangements to prescribe omalizumab may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe omalizumab should be forwarded to:

Medicare Australia

Prior Written Approval of Specialised Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

**Note**

TREATMENT OF ADULT AND ADOLESCENT PATIENTS WITH UNCONTROLLED SEVERE ALLERGIC ASTHMA

Patients are eligible to commence an 'omalizumab treatment cycle' (initial treatment course with or without continuing treatment course/s) if they satisfy the eligibility criteria as detailed under the initial treatment restriction.

Once a patient has either failed to achieve or maintain a response to omalizumab, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 6 month break in PBS-subsidised omalizumab therapy before they are eligible to commence the next cycle. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised omalizumab treatment is stopped to the date of the first application for initial treatment with omalizumab under the new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised omalizumab therapy.

(a) Initial treatment.

Applications for initial treatment should be made where a patient has received no prior PBS-subsidised omalizumab treatment in this treatment cycle and wishes to commence such therapy.

Initial treatment authorisations will be limited to provide for a maximum of 28 weeks of therapy with omalizumab.

A patient must be assessed for response to a course of Initial PBS-subsidised treatment following a minimum of 24 weeks of therapy with omalizumab, and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date of assessment.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with omalizumab.

For second and subsequent courses of PBS-subsidised omalizumab treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of the initial treatment course with omalizumab, a patient may qualify to receive up to a further 24 weeks of continuing treatment with omalizumab providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing omalizumab treatment in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted omalizumab supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia within 4 weeks of the date of assessment, and no later than 2 weeks prior to the patient completing their current treatment course, to avoid an interruption to supply.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with omalizumab.

(2) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements of the Asthma Control Questionnaire (ACQ; 5 item version) and oral corticosteroid dose, submitted with the Initial authority application for omalizumab. However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and Medicare Australia will assess response according to these revised baseline measurements.

(3) Re-commencement of treatment after a 6 month break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised omalizumab therapy of at least 6 months, must re-qualify for initial treatment with respect to the indices of disease severity (oral corticosteroid dose, Asthma Control Questionnaire (ACQ-5) score, and relevant exacerbation history). Patients must have received optimised standard therapy, at adequate doses and for the minimum period specified, immediately prior to the time the new baseline assessments are performed.

(4) Patients 'grandfathered' onto PBS-subsidised treatment with omalizumab.

A patient who commenced treatment with omalizumab for uncontrolled severe allergic asthma prior to 1 November 2010 and who continues to receive treatment at the time of application, may qualify for treatment under the Initial 'grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment with omalizumab will be authorised under this criterion.

Following completion of the Initial PBS-subsidised course, further applications for treatment with omalizumab will be assessed under the continuing treatment restriction.

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| | 'Grandfather' arrangements will only apply for the first treatment cycle (initial treatment course with or without continuing treatment course/s). For the second and subsequent cycles, a 'Grandfathered' patient must re-qualify for Initial treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 6 month break in PBS-subsidised therapy' above for further details.<br>(5) Monitoring of patients.<br>Anaphylaxis and anaphylactoid reactions have been reported following first or subsequent administration of omalizumab (see Product Information). Patients should be monitored post-injection, and medications for the treatment of anaphylactic reactions should be available for immediate use following administration of omalizumab. Patients should be informed that such reactions are possible and prompt medical attention should be sought if allergic reactions occur.<br>**Note**<br>Formal assessment and correction of inhaler technique should be performed in accordance with the National Asthma Council (NAC) Information Paper for Health Professionals on Inhaler Technique (available at www.medicareaustralia.gov.au or www.nationalasthma.org.au); the assessment and adherence to correct technique should be documented in the patient's medical records. Patients can obtain support with inhaler technique through their local Asthma Foundation (1800 645 130).<br>**Note**<br>Special Pricing Arrangements apply. | | | | | | |
| 9746Y | omalizumab 150 mg injection [1 x 150 mg vial] (&) inert substance diluent [1 x 1.2 mL ampoule], 1 pack | 1 | .. | .. | 448.63 | Xolair | NV |

## COUGH AND COLD PREPARATIONS

### EXPECTORANTS, EXCL. COMBINATIONS WITH COUGH SUPPRESSANTS

#### *Mucolytics*

**DORNASE ALFA**

**Authority required**

Use by cystic fibrosis patients who satisfy all of the following criteria:

(1) are 5 years of age or older;

(2) have a FVC greater than 40% predicted for age, gender and height;

(3) have evidence of chronic suppurative lung disease (cough and sputum most days of the week, or greater than 3 respiratory tract infections of more than 2 weeks' duration in any 12 months, or objective evidence of obstructive airways disease);

(4) are participating in a 4 week trial as detailed below or have achieved a 10% or greater improvement in FEV1 (compared to baseline established prior to dornase alfa treatment) after a 4 week trial.

In order for patients to be eligible for participation in the HSD program, the following conditions must be met:

(1) Patients must be assessed at cystic fibrosis clinics/centres which are under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis and the prescribing of dornase alfa under the HSD program is limited to such physicians. If attendance at such units is not possible because of geographical isolation, management (including prescribing) may be by specialist physician or paediatrician in consultation with such a unit;

(2) The measurement of lung function is to be conducted by independent (other than the treating doctor) experienced personnel at established lung function testing laboratories, unless this is not possible because of geographical isolation;

(3) Prior to dornase alfa therapy, a baseline measurement of FEV1 must be undertaken during a stable period of the disease;

(4) Initial therapy is limited to 4 weeks' treatment with dornase alfa at a dose of 2.5 mg daily;

(5) At or towards the end of the initial 4 weeks' trial, patients must be reassessed and a further FEV1 measurement be undertaken (single test under conditions as above). Patients who achieve a 10% or greater improvement in FEV1 (compared to baseline established prior to dornase alfa treatment) are eligible for continued subsidy under the HSD program at a dose of 2.5 mg daily;

(6) Patients who fail to meet a 10% or greater improvement in FEV1 after the initial 4 weeks' treatment at a dose of 2.5 mg daily, may have 1 further trial in the next 12 months but not before 3 months after the initial trial;

(7) Following an initial 6 months' therapy, a global assessment must be undertaken involving the patient, the patient's family (in the case of paediatric patients) and the treating physician(s) to establish that all agree that dornase alfa treatment is continuing to produce worthwhile benefits. (Dornase alfa therapy should cease if there is not general agreement of benefit as there is always the possibility of harm from unnecessary use.) Further reassessments are to be undertaken at six-monthly intervals;

(8) Other aspects of treatment, such as physiotherapy, must be continued;

(9) Where there is documented evidence that a patient already receiving dornase alfa therapy would have met the criteria for subsidy (i.e. satisfied the criteria for the 4 week trial and achieved a 10% or greater improvement in FEV1) then the patient is eligible to continue treatment under the HSD program. Where such evidence is not available, patients will need to satisfy the initiation and continuation criteria as for new patients. (Four weeks is considered a suitable wash-out period)

**Authority required**

Treatment of cystic fibrosis in a patient less than 5 years of age who has:

(1) A severe clinical course with frequent respiratory exacerbations or chronic respiratory symptoms (including chronic or recurrent cough, wheeze or tachypnoea) requiring frequent hospital admissions more frequently than 3 times per year; or

(2) Significant bronchiectasis on chest high resolution computed tomography scan; or

(3) Severe cystic fibrosis bronchiolitis with persistent wheeze non-responsive to conventional medicines; or

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| | (4) Severe physiological deficit measure by forced oscillation technique or multiple breath nitrogen washout and failure to respond to conventional therapy. | | | | | | |
| | In order for the patient to be eligible for participation in the HSD program, the following conditions must be met: | | | | | | |
| | (1) The patient must be assessed at a cystic fibrosis clinic/centre which is under the supervision of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis, and the prescribing of dornase alfa under the HSD program is limited to such physicians. If attendance at such a unit is not possible because of geographical isolation, management (including prescribing) may be by specialist physician or paediatrician in consultation with such a unit; | | | | | | |
| | (2) Following an initial 6 months therapy, a comprehensive assessment must be undertaken and documented involving the patient, the patient's family, the treating physician and an additional independent member of the cystic fibrosis treatment team to establish agreement that dornase alfa treatment is continuing to produce worthwhile benefit. Treatment with dornase alfa should cease if there is not agreement of benefit as there is always the possibility of harm from unnecessary use. Further reassessments are to be undertaken and documented yearly | | | | | | |
| | **Authority required**<br>Grandfather — continuing for patients five years or older | | | | | | |
| | Continuation of treatment of cystic fibrosis in a patient 5 years of age or older, who initiated treatment with dornase alfa at an age of less than 5 years and for whom a comprehensive assessment, involving the patient's family, the treating physician and an additional independent member of the cystic fibrosis treatment team, documents agreement that dornase alfa treatment is continuing to produce worthwhile benefit. Further reassessments are to be undertaken and documented yearly. Treatment with dornase alfa should cease if there is not agreement of benefit as there is always the possibility of harm from unnecessary use | | | | | | |
| | **Authority required**<br>Grandfather — for patients less than five years of age who initiated dornase alfa prior to listing | | | | | | |
| | Treatment of cystic fibrosis in a patient less than 5 years of age who initiated treatment with dornase alfa prior to 1 November 2009 and for whom a comprehensive assessment, involving the patient's family, the treating physician and an additional independent member of the cystic fibrosis treatment team, documents agreement that dornase alfa treatment is continuing to produce worthwhile benefit. Further reassessments are to be undertaken and documented yearly. Treatment with dornase alfa should cease if there is not agreement of benefit as there is always the possibility of harm from unnecessary use | | | | | | |
| | **Note**<br>Dornase alfa is not PBS-subsidised for use in combination with PBS-subsidised mannitol. | | | | | | |
| | It is highly desirable that all patients be included in the national cystic fibrosis patient database. | | | | | | |
| 6120D | dornase alfa 2.5 mg/2.5 mL inhalation: solution, 30 x 2.5 mL ampoules | 2 | 5 | .. | *2406.63 | Pulmozyme | RO |
| | **MANNITOL**<br>**Authority required**<br>Treatment of cystic fibrosis in a patient who satisfies all of the following criteria: | | | | | | |
| | (1) Prior to mannitol therapy, the patient must have been assessed for bronchial hyperresponsiveness as per the TGA approved PI mannitol initiation dose assessment. If the patient has a negative hyperresponsiveness test they may be eligible for PBS subsidised treatment with mannitol; | | | | | | |
| | (2) Is 6 years of age or older; | | | | | | |
| | (3) Has a FEV1 greater than 30% predicted for age, gender and height; | | | | | | |
| | (4) Is intolerant or inadequately responsive to dornase alfa; | | | | | | |
| | (5) Has evidence of chronic suppurative lung disease (cough and sputum most days of the week, or greater than 3 respiratory tract infections of more than 2 weeks' duration in any 12 months, or objective evidence of obstructive airways disease); | | | | | | |
| | (6) Is participating in a 4 week trial, as detailed below, or has achieved a 10% or greater improvement in FEV1 (compared to baseline established prior to mannitol treatment) after a 4 week trial. | | | | | | |
| | In order for patients to be eligible for participation in the HSD program, the following conditions must be met: | | | | | | |
| | (1) Patients must be assessed at cystic fibrosis clinics/centres which are under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis and the prescribing of mannitol therapy under the HSD program is limited to such physicians. If attendance at such units is not possible because of geographical isolation, management (including prescribing) may be by specialist physician or paediatrician in consultation with such a unit; | | | | | | |
| | (2) The measurement of lung function is to be conducted by independent (other than the treating doctor) experienced personnel at established lung function testing laboratories, unless this is not possible because of geographical isolation; | | | | | | |
| | (3) Prior to mannitol therapy, a baseline measurement of FEV1 must be undertaken during a stable period of the disease; | | | | | | |
| | (4) Initial therapy is limited to 4 weeks' treatment with mannitol at a dose of 400 mg twice daily; | | | | | | |
| | (5) At or towards the end of the initial 4 weeks' trial, patients must be reassessed and a further FEV1 measurement be undertaken (single test under conditions as above). Patients who achieve a 10% or greater improvement in FEV1 (compared to baseline established prior to mannitol treatment) are eligible for continued subsidy under the HSD program at a dose of 400mg twice daily; | | | | | | |
| | (6) Patients who fail to meet a 10% or greater improvement in FEV1 after the initial 4 weeks' treatment at a dose of 400 mg twice daily, may have 1 further trial in the next 12 months but not before 3 months after the initial trial; | | | | | | |
| | (7) Following an initial 6 months' therapy, a global assessment must be undertaken involving the patient, the patient's family (in the case of paediatric patients) and the treating physician(s) to establish that all agree that mannitol powder for inhalation treatment is continuing to produce worthwhile benefits. (Mannitol therapy should cease if there is not general agreement of benefit as there is always the possibility of harm from unnecessary use.) Further reassessments are to be undertaken at six-monthly intervals; | | | | | | |

# HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|
| | (8) Other aspects of treatment, such as physiotherapy, must be continued;<br>(9) Where there is documented evidence that a patient already receiving mannitol therapy would have met the criteria for subsidy (i.e. satisfied the criteria for the 4 week trial and achieved a 10% or greater improvement in FEV1) then the patient is eligible to continue treatment under the HSD program. Where such evidence is not available, patients will need to satisfy the initiation and continuation criteria as for new patients. (Four weeks is considered a suitable wash-out period)<br>**Authority required**<br>Grandfather — for patients who initiated mannitol treatment prior to 1 August 2012<br>Continuation of treatment of cystic fibrosis in a patient 6 years of age or older, who initiated treatment with mannitol prior to 1 August 2012 and for whom a comprehensive assessment, involving the patient's family, the treating physician and an additional independent member of the cystic fibrosis team, documents agreement that mannitol treatment is continuing to produce worthwhile benefit. Further reassessments are to be undertaken and documented yearly. Treatment with mannitol should cease if there is not agreement of benefit as there is always the possibility of harm from unnecessary use<br>**Note**<br>Mannitol is not PBS-subsidised for use in combination with PBS-subsidised dornase alfa.<br>It is highly desirable that all patients be included in the national cystic fibrosis patient database. | | | | | | |
| 2008Q | MANNITOL Pack containing 280 capsules containing powder for inhalation 40 mg and 2 inhalers, 1 | 4 | 5 | .. | *1782.63 | bronchitol | XA |

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|

# SENSORY ORGANS

## OPHTHALMOLOGICALS

### ANTIINFECTIVES

#### *Antivirals*

**GANCICLOVIR**

**Authority required**

Cytomegalovirus retinitis in severely immunocompromised patients

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| 6256G | ganciclovir 4.5 mg implant, 1 | 1 | .. | .. | 6046.63 | Vitrasert | BU |

# HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|

# VARIOUS

## ALL OTHER THERAPEUTIC PRODUCTS

### ALL OTHER THERAPEUTIC PRODUCTS

#### *Iron chelating agents*

**DEFERASIROX**

**Authority required**

Chronic iron overload in patients with disorders of erythropoiesis

**Note**

Special Pricing Arrangements apply.

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 6499C | deferasirox 125 mg tablet: dispersible, 28 | 6 | 5 | .. | *1448.13 | | Exjade | NV |
| 6500D | deferasirox 250 mg tablet: dispersible, 28 | 6 | 5 | .. | *2849.55 | | Exjade | NV |
| 9600G | deferasirox 500 mg tablet: dispersible, 28 | 6 | 5 | .. | *5652.45 | | Exjade | NV |

**DEFERIPRONE**

**Authority required**

Iron overload in patients with thalassaemia major who are unable to take desferrioxamine therapy

**Authority required**

Iron overload in patients with thalassaemia major in whom desferrioxamine therapy has proven ineffective

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 9638G | deferiprone 100 mg/mL oral liquid, 250 mL | 5 | 5 | .. | *1173.03 | | Ferriprox | OA |
| 6416Q | deferiprone 500 mg tablet, 100 | 6 | 5 | .. | *2750.01 | | Ferriprox | OA |

**DESFERRIOXAMINE**

**Authority required**

Disorders of erythropoiesis associated with treatment-related chronic iron overload

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 6270B | desferrioxamine mesylate 2 g injection, 1 x 2 g vial | 60 | 5 | .. | *1990.83 | a | Hospira Pty Limited | HH |
| | | | | B19.80 | *2010.63 | a | Desferal 2 g | NV |
| 6113R | desferrioxamine mesylate 500 mg injection, 10 x 500 mg vials | 40 | 5 | .. | *3287.43 | a | Hospira Pty Limited | HH |
| | | | | B268.80 | *3556.23 | a | Desferal 500 mg | NV |

#### *Drugs for treatment of hyperkalemia and hyperphosphatemia*

**LANTHANUM**

**Authority required**

Management of hyperphosphataemia in a patient with chronic kidney disease on dialysis whose serum phosphate is not controlled on calcium and where serum phosphate is greater than 1.6 mmol per L at the commencement of therapy.

Management includes initiation, stabilisation and review of therapy as required

**Authority required**

Management of hyperphosphataemia in a patient with chronic kidney disease on dialysis whose serum phosphate is not controlled on calcium and where the serum calcium times phosphate product is greater than 4.0 at the commencement of therapy.

Management includes initiation, stabilisation and review of therapy as required

**Note**

Not to be used in combination with sevelamer.

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 9637F | LANTHANUM Tablet, chewable, 1000 mg (as carbonate hydrate), 90 | 2 | 5 | .. | *932.25 | | Fosrenol | ZI |
| 9635D | LANTHANUM Tablet, chewable, 500 mg (as carbonate hydrate), 90 | 2 | 5 | .. | *551.11 | | Fosrenol | ZI |
| 9636E | LANTHANUM Tablet, chewable, 750 mg (as carbonate hydrate), 90 | 2 | 5 | .. | *828.81 | | Fosrenol | ZI |

**SEVELAMER**

**Authority required**

Management of hyperphosphataemia in a patient with chronic kidney disease on dialysis whose serum phosphate is not controlled on calcium and where serum phosphate is greater than 1.6 mmol per L at the commencement of therapy.

Management includes initiation, stabilisation and review of therapy as required

**Authority required**

Management of hyperphosphataemia in a patient with chronic kidney disease on dialysis whose serum phosphate is not controlled on calcium and where the serum calcium times phosphate product is greater than 4.0 at the commencement of therapy.

Management includes initiation, stabilisation and review of therapy as required

# HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|
| | **Note**<br>Not to be used in combination with lanthanum. | | | | | | |
| 9620H | sevelamer hydrochloride 800 mg tablet, 180 | 2 | 5 | .. | *651.43 | Renagel | GZ |

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|

# BLOOD AND BLOOD FORMING ORGANS

## ANTIHEMORRHAGICS

### VITAMIN K AND OTHER HEMOSTATICS

#### *Other systemic hemostatics*

**ELTROMBOPAG**

**Authority required**

Initial (new patients)

Initial treatment, as the sole PBS-subsidised thrombopoietin receptor agonist (TRA), of severe thrombocytopenia in an adult patient with severe chronic immune (idiopathic) thrombocytopenic purpura (ITP) who is:

(1) Splenectomised and:

(a) has had an inadequate response to, or is intolerant to, corticosteroid therapy post splenectomy; and

(b) has had an inadequate response to, or is intolerant to, immunoglobulin therapy post splenectomy;

OR

(2) Not splenectomised and:

(a) has had an inadequate response, or is intolerant to, corticosteroid therapy at a dose equivalent to 0.5-2 mg/kg/day of prednisone for at least 4-6 weeks; and

(b) has had an inadequate response, or is intolerant to, immunoglobulin therapy; and

(c) in whom splenectomy is contraindicated for medical reasons.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of initial application:

(a) a platelet count of less than or equal to 20,000 million per L;

OR

(b) a platelet count of 20-30,000 million per L, where the patient is experiencing significant bleeding or has a history of significant bleeding in this platelet range.

The authority application must be made in writing and must include:

(1) a completed authority prescription form,

(2) a signed patient acknowledgement,

(3) a completed Idiopathic Thrombocytopenic Purpura Initial PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)],

(4) a copy of a full blood count pathology report supporting the diagnosis of ITP, and

(5) where the application is sought on the basis of a medical contraindication to surgery, a signed and dated letter from the clinician making this assessment which includes the date upon which the patient was assessed for surgery and the clinical grounds upon which surgery is contraindicated.

The full blood count must be no more than 1 month old at the time of application.

A maximum of 24 weeks of treatment with eltrombopag will be authorised under this criterion

**Authority required**

Initial (grandfather patients)

Initial treatment, as the sole PBS-subsidised thrombopoietin receptor agonist (TRA), of severe thrombocytopenia in an adult patient with severe chronic immune (idiopathic) thrombocytopenic purpura (ITP) who was receiving treatment with eltrombopag prior to 1 November 2011 and in whom the criteria for initial treatment can be demonstrated to have been met at the time eltrombopag was commenced.

The authority application must be made in writing and must include:

(1) a completed authority prescription form,

(2) a signed patient acknowledgement,

(3) a completed Idiopathic Thrombocytopenic Purpura Initial PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)], and

(4) where the application is sought on the basis of a medical contraindication to surgery, a signed and dated letter from the clinician making this assessment which includes the date upon which the patient was assessed for surgery and the clinical grounds upon which surgery is contraindicated.

A maximum of 24 weeks of treatment with eltrombopag will be authorised under this criterion

**Authority required**

Continuing therapy or re-initiation after a break in therapy

First period of PBS-subsidised continuing treatment or re-initiation of interrupted PBS-subsidised treatment, as the sole PBS-subsidised thrombopoietin receptor agonist (TRA), of severe thrombocytopenia in an adult patient with chronic immune (idiopathic) thrombocytopenic purpura (ITP) who has displayed a sustained platelet response to treatment with eltrombopag during the initial period of PBS-subsidised treatment.

For the purposes of this restriction, a sustained platelet response is defined as:

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|
| | (a) use of rescue medication (corticosteroids or immunoglobulins) on no more than one occasion during the initial period of PBS-subsidised eltrombopag, | | | | | | |
| | AND either of the following: | | | | | | |
| | (b) a platelet count greater than or equal to 50,000 million per L on at least four (4) occasions, each at least one week apart; | | | | | | |
| | OR | | | | | | |
| | (c) a platelet count greater than 30,000 million per L and which is double the baseline (pre-treatment) platelet count on at least four (4) occasions, each at least one week apart. | | | | | | |
| | Applications for the first period of continuing PBS-subsidised treatment or re-initiation of interrupted treatment must be made in writing and must include: | | | | | | |
| | (1) a completed authority prescription form, and | | | | | | |
| | (2) a completed Idiopathic Thrombocytopenic Purpura Continuing PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)], and | | | | | | |
| | (3) copies of the platelet count pathology reports (unless previously provided for patients re-initiating therapy). | | | | | | |
| | The most recent platelet count must be no more than one month old at the time of application. | | | | | | |
| | A maximum of 24 weeks of treatment with eltrombopag will be authorised under this criterion. | | | | | | |
| | Where fewer than 5 repeats are initially requested with the authority prescription, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be made by telephone | | | | | | |
| | **Authority required** | | | | | | |
| | Second and subsequent applications for continuing therapy | | | | | | |
| | Continuing treatment, as the sole PBS-subsidised thrombopoietin receptor agonist (TRA), of severe thrombocytopenia in an adult patient with chronic immune (idiopathic) thrombocytopenic purpura (ITP) who has previously received PBS-subsidised therapy with eltrombopag and who continues to display a response to treatment with eltrombopag. | | | | | | |
| | For the purposes of this restriction, a continuing response to treatment with eltrombopag is defined as: | | | | | | |
| | (a) use of rescue medication (corticosteroids or immunoglobulins) on no more than one occasion during the most recent 24 week period of PBS-subsidised treatment with eltrombopag, | | | | | | |
| | AND either of the following: | | | | | | |
| | (b) a platelet count greater than or equal to 50,000 million per L | | | | | | |
| | OR | | | | | | |
| | (c) a platelet count greater than 30,000 million per L and which is double the baseline platelet count. | | | | | | |
| | Platelet counts must be no more than 1 month old at the time of application. | | | | | | |
| | Authority applications for second and subsequent periods of continuing therapy may be made by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) | | | | | | |
| | **Note** | | | | | | |
| | Eltrombopag is not PBS-subsidised as an alternative to splenectomy. | | | | | | |
| | Any queries concerning the arrangements to prescribe eltrombopag may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). | | | | | | |
| | Written applications for authority to prescribe eltrombopag should be forwarded to: | | | | | | |
| | Medicare Australia | | | | | | |
| | Prior Written Approval of Specialised Drugs | | | | | | |
| | Reply Paid 9826 | | | | | | |
| | GPO Box 9826 | | | | | | |
| | HOBART TAS 7001 | | | | | | |
| | Further prescribing information is on the Medicare Australia website at www.medicareaustralia.gov.au. | | | | | | |
| | **Note** | | | | | | |
| | Patients will be able to trial either eltrombopag and/or romiplostim within the initial 24 weeks treatment period. Patients who fail to demonstrate a response to treatment with either eltrombopag and/or romiplostim under the initial restriction will not be eligible to receive further PBS-subsidised treatment with either of these drugs. | | | | | | |
| | No applications for increased repeats will be authorised. | | | | | | |
| | **Note** | | | | | | |
| | No applications for increased repeats will be authorised. | | | | | | |
| 5825N | eltrombopag 25 mg tablet, 28 | 1 | 5 | .. | 1512.00 | Revolade | GK |
| 5826P | eltrombopag 50 mg tablet, 28 | 1 | 5 | .. | 3024.00 | Revolade | GK |
| | **ROMIPLOSTIM** | | | | | | |
| | **Authority required** | | | | | | |
| | Initial (new patients) | | | | | | |

# HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|

Initial treatment, as the sole PBS-subsidised thrombopoietin receptor agonist (TRA), of severe thrombocytopenia in an adult patient with severe chronic immune (idiopathic) thrombocytopenic purpura (ITP) who is:

(1) Splenectomised and:

(a) has had an inadequate response to, or is intolerant to, corticosteroid therapy post splenectomy; and

(b) has had an inadequate response to, or is intolerant to, immunoglobulin therapy post splenectomy;

OR

(2) Not splenectomised and:

(a) has had an inadequate response, or is intolerant to, corticosteroid therapy at a dose equivalent to 0.5-2 mg/kg/day of prednisone for at least 4-6 weeks; and

(b) has had an inadequate response, or is intolerant to, immunoglobulin therapy; and

(c) in whom splenectomy is contraindicated for medical reasons.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of initial application:

(a) a platelet count of less than or equal to 20,000 million per L;

OR

(b) a platelet count of 20-30,000 million per L, where the patient is experiencing significant bleeding or has a history of significant bleeding in this platelet range.

The authority application must be made in writing and must include:

(1) a completed authority prescription form,

(2) a signed patient acknowledgement,

(3) a completed Idiopathic Thrombocytopenic Purpura Initial PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)],

(4) a copy of a full blood count pathology report supporting the diagnosis of ITP, and

(5) where the application is sought on the basis of a medical contraindication to surgery, a signed and dated letter from the clinician making this assessment which includes the date upon which the patient was assessed for surgery and the clinical grounds upon which surgery is contraindicated.

The full blood count must be no more than 1 month old at the time of application.

At the time of the written authority application, medical practitioners should request the appropriate quantity of vials of appropriate strength to provide sufficient drug for a single treatment at a dose of 1 microgram/kg. Up to 1 repeat may be requested with the initial written application.

Subsequently during the initial period of dose titration, authority applications for a single dose and up to 1 repeat may be made by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). The dose (microgram/kg/week) must be provided at the time of application.

Once a patient's dose has been stable for a period of 4 weeks, authority approvals for sufficient vials of appropriate strength based on the weight of the patient and dose (microgram/kg/week) for up to 4 weeks of treatment and up to 4 repeats may be granted, as long as the total period of treatment authorised under this restriction does not exceed 24 weeks.

Authority approval will not be given for doses of higher than 10 micrograms/kg/week

**Authority required**

Initial (grandfather patients)

Initial PBS-subsidised treatment, as the sole PBS-subsidised thrombopoietin receptor agonist (TRA), of severe thrombocytopenia in an adult patient with severe chronic immune (idiopathic) thrombocytopenic purpura (ITP) who was receiving treatment with romiplostim prior to 1 April 2011 and in whom the criteria for initial treatment can be demonstrated to have been met at the time romiplostim was commenced.

The authority application must be made in writing and must include:

(1) a completed authority prescription form,

(2) a signed patient acknowledgement,

(3) a completed Idiopathic Thrombocytopenic Purpura Initial PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)], and

(4) where the application is sought on the basis of a medical contraindication to surgery, a signed and dated letter from the clinician making this assessment which includes the date upon which the patient was assessed for surgery and the clinical grounds upon which surgery is contraindicated.

For patients whose dose of romiplostim had been stable for at least 4 weeks at the time of the initial application for PBS-subsidy, the medical practitioner should request sufficient number of vials based on the weight of the patient and dose (microgram/kg/week) to provide up to 4 weeks of treatment. Up to a maximum of 5 repeats may be authorised.

Where the patient is in the titration phase of treatment with romiplostim, medical practitioners should request the appropriate quantity of vials of appropriate strength to provide sufficient drug for a single treatment at a dose of 1 microgram/kg. Up to 1 repeat may be requested with the initial written application.

Subsequently during the initial period of dose titration, authority applications for a single dose and up to 1 repeat may be made by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). The dose (microgram/kg/week) must be provided at the time of application.

Once a patient's dose has been stable for a period of 4 weeks, authority approvals for sufficient vials of appropriate strength based on the weight of the patient and dose (microgram/kg/week) for up to 4 weeks of treatment and up to 4 repeats may be granted, as long as the total period of

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|

treatment authorised under this restriction does not exceed 24 weeks.

Authority approval will not be given for doses of higher than 10 micrograms/kg/week

**Authority required**

Continuing therapy or re-initiation after a break in therapy

First period of PBS-subsidised continuing treatment or re-initiation of interrupted PBS-subsidised treatment, as the sole PBS-subsidised thrombopoietin receptor agonist (TRA), of severe thrombocytopenia in an adult patient with chronic immune (idiopathic) thrombocytopenic purpura (ITP) who has displayed a sustained platelet response to treatment with romiplostim during the initial period of PBS-subsidised treatment.

For the purposes of this restriction, a sustained platelet response is defined as:

(a) use of rescue medication (corticosteroids or immunoglobulins) on no more than one occasion during the initial period of PBS-subsidised romiplostim,

AND either of the following:

(b) a platelet count greater than or equal to 50,000 million per L on at least four (4) occasions, each at least one week apart;

OR

(c) a platelet count greater than 30,000 million per L and which is double the baseline (pre-treatment) platelet count on at least four (4) occasions, each at least one week apart.

Applications for the first period of continuing PBS-subsidised treatment or re-initiation of interrupted treatment must be made in writing and must include:

(1) a completed authority prescription form, and

(2) a completed Idiopathic Thrombocytopenic Purpura Continuing PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)], and

(3) copies of the platelet count pathology reports (unless previously provided for patients re-initiating therapy).

The most recent platelet count must be no more than one month old at the time of application.

The medical practitioner should request sufficient number of vials of appropriate strength based on the weight of the patient and dose (microgram/kg/week) to provide 4 weeks of treatment. Up to a maximum of 5 repeats may be authorised.

Where fewer than 5 repeats are initially requested with the authority prescription, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be made by telephone.

Authority approval will not be given for doses of higher than 10 micrograms/kg/week

**Authority required**

Second and subsequent applications for continuing therapy

Continuing treatment, as the sole PBS-subsidised thrombopoietin receptor agonist (TRA), of severe thrombocytopenia in an adult patient with chronic immune (idiopathic) thrombocytopenic purpura (ITP) who has previously received PBS-subsidised therapy with romiplostim and who continues to display a response to treatment with romiplostim.

For the purposes of this restriction, a continuing response to treatment with romiplostim is defined as:

(a) use of rescue medication (corticosteroids or immunoglobulins) on no more than one occasion during the most recent 24 week period of PBS-subsidised treatment with romiplostim,

AND either of the following:

(b) a platelet count greater than or equal to 50,000 million per L

OR

(c) a platelet count greater than 30,000 million per L and which is double the baseline platelet count.

Platelet counts must be no more than 1 month old at the time of application.

Authority applications for second and subsequent periods of continuing therapy may be made by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

The medical practitioner should request sufficient number of vials of appropriate strength based on the weight of the patient and dose (microgram/kg/week) to provide 4 weeks of treatment. Up to a maximum of 5 repeats may be authorised.

Authority approval will not be given for doses of higher than 10 micrograms/kg/week

**Note**

Romiplostim is not PBS-subsidised as an alternative to splenectomy.

Any queries concerning the arrangements to prescribe romiplostim may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written applications for authority to prescribe romiplostim should be forwarded to:

Medicare Australia

Prior Written Approval of Specialised Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|
| | Further prescribing information is on the Medicare Australia website at www.medicareaustralia.gov.au. | | | | | | |
| | **Note**<br>Patients will be able to trial either eltrombopag and/or romiplostim within the initial 24 weeks treatment period. Patients who fail to demonstrate a response to treatment with either eltrombopag and/or romiplostim under the initial restriction will not be eligible to receive further PBS-subsidised treatment with either of these drugs. | | | | | | |
| | **Note**<br>Special Pricing Arrangements apply. | | | | | | |
| 9696H | romiplostim 250 microgram injection, 1 x 250 microgram vial | 1 | .. | .. | 977.50 | Nplate | AN |
| 9698K | romiplostim 500 microgram injection, 1 x 500 microgram vial | 1 | .. | .. | 1955.00 | Nplate | AN |

## ANTIANEMIC PREPARATIONS

### OTHER ANTIANEMIC PREPARATIONS

### *Other antianemic preparations*

**DARBEPOETIN ALFA**

**Authority required (STREAMLINED)**

***3334***

Treatment of anaemia requiring transfusion, defined as a haemoglobin level of less than 100 g per L, where intrinsic renal disease, as assessed by a nephrologist, is the primary cause of the anaemia

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| 5637Q | darbepoetin alfa 10 microgram/0.4 mL injection, 4 x 0.4 mL syringes | 2 | 5 | .. | *356.08 | Aranesp | AN |
| 5649H | darbepoetin alfa 100 microgram/0.5 mL injection, 1 x 0.5 mL syringe | 8 | 5 | .. | *2620.48 | Aranesp SureClick | AN |
| 5651K | darbepoetin alfa 100 microgram/0.5 mL injection, 4 x 0.5 mL syringes | 2 | 5 | .. | *2620.50 | Aranesp | AN |
| 5650J | darbepoetin alfa 150 microgram/0.3 mL injection, 1 x 0.3 mL syringe | 8 | 5 | .. | *3904.48 | Aranesp SureClick | AN |
| 5643B | darbepoetin alfa 150 microgram/0.3 mL injection, 4 x 0.3 mL syringes | 2 | 5 | .. | *3904.50 | Aranesp | AN |
| 5645D | darbepoetin alfa 20 microgram/0.5 mL injection, 1 x 0.5 mL syringe | 8 | 5 | .. | *670.64 | Aranesp SureClick | AN |
| 5638R | darbepoetin alfa 20 microgram/0.5 mL injection, 4 x 0.5 mL syringes | 2 | 5 | .. | *670.62 | Aranesp | AN |
| 5639T | darbepoetin alfa 30 microgram/0.3 mL injection, 4 x 0.3 mL syringes | 2 | 5 | .. | *917.46 | Aranesp | AN |
| 5646E | darbepoetin alfa 40 microgram/0.4 mL injection, 1 x 0.4 mL syringe | 8 | 5 | .. | *1113.60 | Aranesp SureClick | AN |
| 5640W | darbepoetin alfa 40 microgram/0.4 mL injection, 4 x 0.4 mL syringes | 2 | 5 | .. | *1113.60 | Aranesp | AN |
| 5641X | darbepoetin alfa 50 microgram/0.5 mL injection, 4 x 0.5 mL syringes | 2 | 5 | .. | *1376.78 | Aranesp | AN |
| 5647F | darbepoetin alfa 60 microgram/0.3 mL injection, 1 x 0.3 mL syringe | 8 | 5 | .. | *1616.64 | Aranesp SureClick | AN |
| 5642Y | darbepoetin alfa 60 microgram/0.3 mL injection, 4 x 0.3 mL syringes | 2 | 5 | .. | *1616.66 | Aranesp | AN |
| 5648G | darbepoetin alfa 80 microgram/0.4 mL injection, 1 x 0.4 mL syringe | 8 | 5 | .. | *2128.00 | Aranesp SureClick | AN |
| 5644C | darbepoetin alfa 80 microgram/0.4 mL injection, 4 x 0.4 mL syringes | 2 | 5 | .. | *2128.00 | Aranesp | AN |

**EPOETIN ALFA**

**Authority required (STREAMLINED)**

***3334***

Treatment of anaemia requiring transfusion, defined as a haemoglobin level of less than 100 g per L, where intrinsic renal disease, as assessed by a nephrologist, is the primary cause of the anaemia

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| 5722E | epoetin alfa 10 000 international units/mL injection, 6 x 1 mL syringes | 2 | 5 | .. | *1970.30 | Eprex 10000 | JC |
| 5714R | epoetin alfa 1000 international units/0.5 mL injection, 6 x 0.5 mL syringes | 2 | 5 | .. | *279.30 | Eprex 1000 | JC |
| 5713Q | epoetin alfa 20 000 international units/0.5 mL injection, 6 x 0.5 mL syringes | 2 | 5 | .. | *3876.00 | Eprex 20,000 | JC |
| 5719B | epoetin alfa 2000 international units/0.5 mL injection, 6 x 0.5 mL syringes | 2 | 5 | .. | *516.80 | Eprex 2000 | JC |
| 5720C | epoetin alfa 3000 international units/0.3 mL injection, 6 x 0.3 mL syringes | 2 | 5 | .. | *666.90 | Eprex 3000 | JC |

# HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|
| 5718Y | epoetin alfa 40 000 international units/mL injection, 1 x 1 mL syringe | 2 | 5 | .. | *1254.00 | Eprex 40,000 | JC |
| 5721D | epoetin alfa 4000 international units/0.4 mL injection, 6 x 0.4 mL syringes | 2 | 5 | .. | *849.30 | Eprex 4000 | JC |
| 5715T | epoetin alfa 5000 international units/0.5 mL injection, 6 x 0.5 mL syringes | 2 | 5 | .. | *1057.34 | Eprex 5000 | JC |
| 5716W | epoetin alfa 6000 international units/0.6 mL injection, 6 x 0.6 mL syringes | 2 | 5 | .. | *1255.14 | Eprex 6000 | JC |
| 5717X | epoetin alfa 8000 international units/0.8 mL injection, 6 x 0.8 mL syringes | 2 | 5 | .. | *1627.92 | Eprex 8000 | JC |
| | **EPOETIN BETA** | | | | | | |
| | **Authority required (STREAMLINED)** | | | | | | |
| | ***3334*** | | | | | | |
| | Treatment of anaemia requiring transfusion, defined as a haemoglobin level of less than 100 g per L, where intrinsic renal disease, as assessed by a nephrologist, is the primary cause of the anaemia | | | | | | |
| 5729M | epoetin beta 10 000 international units/0.6 mL injection, 6 x 0.6 mL syringes | 2 | 5 | .. | *1970.30 | NeoRecormon | RO |
| 5724G | epoetin beta 2000 international units/0.3 mL injection, 6 x 0.3 mL syringes | 2 | 5 | .. | *516.80 | NeoRecormon | RO |
| 5725H | epoetin beta 3000 international units/0.3 mL injection, 6 x 0.3 mL syringes | 2 | 5 | .. | *666.90 | NeoRecormon | RO |
| 5726J | epoetin beta 4000 international units/0.3 mL injection, 6 x 0.3 mL syringes | 2 | 5 | .. | *849.30 | NeoRecormon | RO |
| 5727K | epoetin beta 5000 international units/0.3 mL injection, 6 x 0.3 mL syringes | 2 | 5 | .. | *1057.36 | NeoRecormon | RO |
| 5728L | epoetin beta 6000 international units/0.3 mL injection, 6 x 0.3 mL syringes | 2 | 5 | .. | *1255.14 | NeoRecormon | RO |
| | **EPOETIN LAMBDA** | | | | | | |
| | **Authority required (STREAMLINED)** | | | | | | |
| | ***3334*** | | | | | | |
| | Treatment of anaemia requiring transfusion, defined as a haemoglobin level of less than 100 g per L, where intrinsic renal disease, as assessed by a nephrologist, is the primary cause of the anaemia | | | | | | |
| | **Note** | | | | | | |
| | Epoetin lambda should only be administered by the intravenous route. | | | | | | |
| 9596C | epoetin lambda 10 000 international units/mL injection, 6 x 1 mL syringes | 2 | 5 | .. | *1866.60 | Novicrit | NV |
| 9668W | epoetin lambda 1000 international units/0.5 mL injection, 6 x 0.5 mL syringes | 2 | 5 | .. | *264.60 | Novicrit | NV |
| 9669X | epoetin lambda 2000 international units/mL injection, 6 x 1 mL syringes | 2 | 5 | .. | *489.60 | Novicrit | NV |
| 9670Y | epoetin lambda 3000 international units/0.3 mL injection, 6 x 0.3 mL syringes | 2 | 5 | .. | *631.80 | Novicrit | NV |
| 9587N | epoetin lambda 4000 international units/0.4 mL injection, 6 x 0.4 mL syringes | 2 | 5 | .. | *804.60 | Novicrit | NV |
| 9589Q | epoetin lambda 5000 international units/0.5 mL injection, 6 x 0.5 mL syringes | 2 | 5 | .. | *1001.70 | Novicrit | NV |
| 9591T | epoetin lambda 6000 international units/0.6 mL injection, 6 x 0.6 mL syringes | 2 | 5 | .. | *1189.08 | Novicrit | NV |
| 9594Y | epoetin lambda 8000 international units/0.8 mL injection, 6 x 0.8 mL syringes | 2 | 5 | .. | *1542.24 | Novicrit | NV |
| | **METHOXY POLYETHYLENE GLYCOL-EPOETIN BETA** | | | | | | |
| | **Authority required (STREAMLINED)** | | | | | | |
| | ***3334*** | | | | | | |
| | Treatment of anaemia requiring transfusion, defined as a haemoglobin level of less than 100 g per L, where intrinsic renal disease, as assessed by a nephrologist, is the primary cause of the anaemia | | | | | | |
| 5797D | methoxy polyethylene glycol-epoetin beta 100 microgram/0.3 mL injection, 1 x 0.3 mL syringe | 2 | 5 | .. | *1158.82 | Mircera | RO |
| 5798E | methoxy polyethylene glycol-epoetin beta 120 microgram/0.3 mL injection, 1 x 0.3 mL syringe | 2 | 5 | .. | *1341.64 | Mircera | RO |
| 5799F | methoxy polyethylene glycol-epoetin beta 200 microgram/0.3 mL injection, 1 x 0.3 mL syringe | 2 | 5 | .. | *1924.30 | Mircera | RO |
| 5794Y | methoxy polyethylene glycol-epoetin beta 30 microgram/0.3 mL injection, 1 x 0.3 mL syringe | 2 | 5 | .. | *369.18 | Mircera | RO |
| 5800G | methoxy polyethylene glycol-epoetin beta 360 microgram/0.6 mL injection, 1 x 0.6 mL syringe | 2 | 5 | .. | *3326.52 | Mircera | RO |
| 5795B | methoxy polyethylene glycol-epoetin beta 50 | 2 | 5 | .. | *615.30 | Mircera | RO |

# HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

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|---|---|---|---|---|---|---|---|
| 5796C | microgram/0.3 mL injection, 1 x 0.3 mL syringe<br>methoxy polyethylene glycol-epoetin beta 75<br>microgram/0.3 mL injection, 1 x 0.3 mL syringe | 2 | 5 | .. | *896.02 | Mircera | RO |

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|

# CARDIOVASCULAR SYSTEM

## ANTIHYPERTENSIVES

### OTHER ANTIHYPERTENSIVES

#### *Other antihypertensives*

**AMBRISENTAN**

**Authority required**

Initial (new patients)

Application for initial PBS-subsidised treatment with ambrisentan of patients who have not received prior PBS-subsidised treatment with a PAH agent and who have been assessed by a physician from a designated hospital to have:

(a) WHO Functional Class III primary pulmonary hypertension and a mean right atrial pressure of 8 mmHg or less, as measured by RHC, or, where a RHC cannot be performed on clinical grounds, right ventricular function as assessed by ECHO; OR

(b) WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease and a mean right atrial pressure of 8 mmHg or less, as measured by RHC, or, where a RHC cannot be performed on clinical grounds, right ventricular function as assessed by ECHO.

Patients must have failed to respond [see Note for definition of response] to 6 or more weeks of appropriate vasodilator treatment unless intolerance or a contraindication to such treatment exists.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form [www.medicareaustralia.gov.au] which includes results from the 3 tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6MWT; and

(3) a signed patient acknowledgment form.

Details of prior vasodilator treatment, including the dose and duration of treatment, must be provided at the time of application. Where the patient has an adverse event to a vasodilator or where vasodilator treatment is contraindicated, details on the nature of the adverse event or contraindication according to the TGA-approved Product Information must also be provided with the application.

Where fewer than 3 tests (see requirement 2 above) are able to be performed on clinical grounds, a patient specific reason outlining why the particular test/s could not be conducted must be provided with the authority application [see Note for test requirements].

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. A maximum of 5 repeats may be requested. Where fewer than 5 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 6 months of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday)

**Authority required**

Initial (new patients)

Application for initial PBS-subsidised treatment with ambrisentan of patients who have not received prior PBS-subsidised treatment with a PAH agent and who have been assessed by a physician from a designated hospital to have:

(a) WHO Functional Class III primary pulmonary hypertension and a mean right atrial pressure greater than 8 mmHg, as measured by RHC, or, where a RHC cannot be performed on clinical grounds, right ventricular function as assessed by ECHO; OR

(b) WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease and a mean right atrial pressure greater than 8 mmHg, as measured by RHC, or, where a RHC cannot be performed on clinical grounds, right ventricular function as assessed by ECHO; OR

(c) WHO Functional Class IV primary pulmonary hypertension; OR

(d) WHO Functional Class IV pulmonary arterial hypertension secondary to connective tissue disease.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form [www.medicareaustralia.gov.au] which includes results from the 3 tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6MWT; and

(3) a signed patient acknowledgment form.

Where fewer than 3 tests (see requirement 2 above) are able to be performed on clinical grounds, a patient specific reason outlining why the particular test/s could not be conducted must be provided with the authority application [see Note for test requirements].

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. A maximum of 5 repeats may be requested. Where fewer than 5 repeats are requested at the time of

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|---|---|---|---|---|---|---|

application, authority approvals for sufficient repeats to complete a maximum of 6 months of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday)

**Authority required**

Initial (change or re-commencement for all patients)

Application for initial treatment with ambrisentan of patients with one of the following:

(a) primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease who wish to re-commence PBS-subsidised ambrisentan after a break in therapy and who have demonstrated a response to their most recent course of PBS-subsidised treatment with ambrisentan; OR

(b) primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease and whose most recent course of PBS-subsidised treatment was with an alternate PAH agent other than ambrisentan.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form [www.medicareaustralia.gov.au] which includes the results on which approval for the first application for PBS-subsidised PAH agent was granted; and

(3) the date of the first application for PBS-subsidised treatment with a PAH agent; and

(4) the results of the patient's response to treatment with their last course of PBS-subsidised PAH agent.

Where fewer than 3 tests (see requirement 2 above) are able to be performed on clinical grounds, a patient specific reason outlining why the particular test/s could not be conducted must be provided with the authority application [see Note for test requirements].

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. A maximum of 5 repeats may be requested. Where fewer than 5 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 6 months of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday)

**Authority required**

Continuing treatment (all patients)

Continuing PBS-subsidised treatment with ambrisentan of patients who have received approval for initial PBS-subsidised treatment with ambrisentan and who have been assessed by a physician from a designated hospital to have achieved a response to their most recent course of ambrisentan treatment [see Note for definition of response].

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form [www.medicareaustralia.gov.au] which includes results from the 3 tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6MWT.

The results of the same tests as conducted at baseline should be provided with each written continuing treatment application (i.e. every 6 months), except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be provided with the application.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. A maximum of 5 repeats will be authorised. Where fewer than 5 repeats are initially requested under this criterion, authority approvals for sufficient repeats to complete a maximum of 6 months of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday)

**Caution**

Ambrisentan is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 3 months following cessation of treatment with this drug.

**Note**

Any queries concerning the arrangements to prescribe ambrisentan may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written applications for authority to prescribe PAH agents should be forwarded to:

Medicare Australia

Prior Written Approval of Specialised Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

**Note**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of agents for primary pulmonary hypertension and pulmonary arterial hypertension. Where the term PAH agents appears in the following notes and restrictions it refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan and tadalafil.

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|---|---|---|---|---|---|---|

Patients are eligible for PBS-subsidised treatment with only 1 of the above PAH agents at any 1 time. Eligible patients may only swap between PAH agents if they have not failed prior PBS-subsidised treatment with that agent.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of that predicted.

The following provides some explanatory notes regarding the availability of PBS-subsidised treatment of patients with:

(a) bosentan monohydrate, of primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, or pulmonary arterial hypertension associated with a congential systemic-to-pulmonary shunt (including Eisenmenger's physiology), in patients with disease of WHO Functional Class III or IV severity; AND

(b) iloprost trometamol, of:

— primary pulmonary hypertension, or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class III severity and who have failed to respond to prior PBS-subsidised treatment with an alternate PAH agent; AND

— primary pulmonary hypertension, or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class IV severity; AND

— drug-induced pulmonary arterial hypertension, in patients with disease of WHO Functional Class III and IV severity; AND

(c) epoprostenol sodium, of:

— primary pulmonary hypertension, or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class III severity and who have failed to respond to prior PBS-subsidised treatment with an alternate PAH agent; AND

— primary pulmonary hypertension, or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class IV severity; AND

(d) sildenafil citrate, of primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class III severity; AND

(e) ambrisentan, of primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class III or IV severity; AND

(f) tadalafil, of primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class III severity.

From 1 April 2012, patients can access PAH agents through the PBS according to the relevant restrictions. Once these patients are approved initial treatment with 1 of these 6 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary. (New baselines may be submitted where the patient has failed to respond to their current treatment.)

1. Definition of primary pulmonary hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease, including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology).

Primary pulmonary hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease, including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary capillary wedge pressure (PCWP) less than 18 mmHg; or

(ii) mPAP greater than 30 mmHg with exercise and PCWP less than 18 mmHg; or

(iii) where a right heart catheter cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

2. Definition of WHO Functional Class III or IV disease severity.

(a) WHO Functional Class III disease severity is defined as follows:

Patients with pulmonary hypertension resulting in marked limitation of physical activity who are comfortable at rest and on ordinary physical activity experience dyspnoea or fatigue, chest pain or near syncope.

(b) WHO Functional Class IV disease severity is defined as follows:

Patients with the inability to carry out any physical activity without symptoms. These patients manifest signs of right heart failure. Dyspnoea and/or fatigue may even be present at rest. Discomfort is increased by any physical activity.

3. Designated hospitals.

Refer to the Medicare Australia website at www.medicareaustralia.gov.au for a list of designated hospitals.

4. Test requirements to establish baseline for initiation of treatment and response to treatment for continuation of treatment.

(a) Initiation of treatment.

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment, plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

(1) RHC plus ECHO composite assessments;

(2) RHC composite assessment plus 6MWT;

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|---|---|---|---|---|---|---|

(3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted to Medicare Australia for consideration based on the results of the following test combinations, which are listed in descending order of preference:

(1) ECHO composite assessment plus 6MWT;

(2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test/s could not be conducted must be provided with the authority application.

(b) Continuation of treatment.

The following list outlines the preferred test combination, in descending order, for the purposes of continuation of PBS-subsidised treatment:

(1) RHC plus ECHO composite assessments plus 6MWT;

(2) RHC plus ECHO composite assessments;

(3) RHC composite assessment plus 6MWT;

(4) ECHO composite assessment plus 6MWT;

(5) RHC composite assessment only;

(6) ECHO composite assessment only.

The results of the same tests as conducted at baseline should be provided with each written continuing treatment application (i.e. every 6 months), except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be provided with the application. The test(s) results provided with the application for continuing treatment must be no more than 2 months old at the time of application.

**Note**

5. Definition of response to a PAH agent or prior vasodilator treatment.

For patients with 2 or more baseline tests, response to treatment is defined as 2 or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least 1 of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

6. Authority approval requirements.

(a) Initiation of PBS-subsidised treatment with a PAH agent, where the patient has not received prior PBS-subsidised treatment with that agent.

All applications for initial treatment must be made in writing, must include a completed authority prescription and must be submitted to Medicare Australia for authorisation. The total duration of initial PBS-subsidised treatment that will be approved with this first written application is up to 6 months, based on the dosage recommendations in the TGA-approved Product Information.

Bosentan only:

Approvals for the first authority prescription will be limited to 1 month of therapy with the 62.5 mg strength tablet, with the quantity approved based on the dosage recommendations in the Therapeutic Goods Administration (TGA)-approved Product Information. No repeats will be authorised for this prescription. The second authority prescription may be written for either the 62.5 mg tablet or the 125 mg tablet strengths. Where the 62.5 mg tablet strength is required, please contact Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) for further advice. Approvals for the second authority prescription will be limited to 1 month of treatment, with the quantity approved based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 4 repeats. The approved second authority prescription will be returned to the prescriber by Medicare Australia 2 weeks after the date of the approval of the first authority prescription, to allow for the uninterrupted completion of the 6 month initial treatment course. Medicare Australia will contact prescribers prior to dispatch of the second authority prescription to confirm the tablet strength required for the patient.

(b) Continuation of treatment.

Written applications for continuing treatment for patients who have demonstrated an adequate response to their current treatment must be submitted to Medicare Australia for authorisation every 6 months. Approvals will be limited to provide sufficient supply for up to a maximum of 6 months of treatment, based on the dosage recommendations in the TGA-approved Product Information.

The assessment of the patient's response to the first and subsequent 6 month courses of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated. Applications for continuing treatment with a PAH agent should be made prior to the completion of the 6 month treatment course to ensure continuity for those patients who respond to treatment, as assessed by the treating physician.

(c) Swapping between PAH agents.

For eligible patients, applications to swap between these 6 drugs must be made under the relevant initial treatment restriction. Patients should be assessed for response to the treatment they are ceasing at the time the application to swap therapy is being made. Patients who fail to demonstrate a response or for whom no assessment results are submitted with the application to swap therapy may not re-commence PBS-subsidised treatment with the drug they are ceasing.

It is important that patients are assessed for response to every course of treatment approved within the timeframes specified in the relevant

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restriction, in order to maximise the choice of treatment.

To avoid confusion, applications for patients who wish to swap to an alternate treatment should be accompanied by the previously approved authority prescription, or remaining repeats, for the treatment the patient is ceasing.

(d) Cessation of treatment — bosentan patients only.

Patients who fail to demonstrate a response to PBS-subsidised bosentan monohydrate treatment at the time where an assessment is required must cease PBS-subsidised bosentan monohydrate therapy.

For patients ceasing treatment, approval will only be granted to provide sufficient supply of the 62.5 mg tablet strength to allow gradual dose reduction over a period of no more than 1 month duration. Prescribers should telephone Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) to receive authorisation for this final supply and to ensure no unintended break in treatment occurs.

7. Re-treatment with a PAH agent.

Patients who do not respond to treatment are not eligible to receive further PBS-subsidised treatment with that agent under any circumstances.

8. Further information.

A tabulated representation of the above information and the restriction can be obtained from the Medicare Australia website at www.medicareaustralia.gov.au.

**Note**

Special Pricing Arrangements apply.

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| 5608E | ambrisentan 10 mg tablet, 30 | 1 | .. | .. | 2876.47 | Volibris | GK |
| 5607D | ambrisentan 5 mg tablet, 30 | 1 | .. | .. | 2876.47 | Volibris | GK |

**BOSENTAN**

**Authority required**

Initial (new patients)

Application for initial PBS-subsidised treatment with bosentan monohydrate of patients who have not received prior PBS-subsidised treatment with a PAH agent and who have been assessed by a physician from a designated hospital to have:

(a) WHO Functional Class III primary pulmonary hypertension and a mean right atrial pressure of 8 mmHg or less, as measured by RHC, or, where a RHC cannot be performed on clinical grounds, right ventricular function as assessed by ECHO; OR

(b) WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease and a mean right atrial pressure of 8 mmHg or less, as measured by RHC, or, where a RHC cannot be performed on clinical grounds, right ventricular function as assessed by ECHO.

Patients must have failed to respond [see Note for definition of response] to 6 or more weeks of appropriate vasodilator treatment unless intolerance or a contraindication to such treatment exists.

Applications for authorisation must be in writing and must include:

(1) two completed authority prescription forms [see Note for authority approval requirements]; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form [www.medicareaustralia.gov.au] which includes results from the 3 tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6MWT; and

(3) a signed patient acknowledgment form.

Details of prior vasodilator treatment, including the dose and duration of treatment, must be provided at the time of application. Where the patient has an adverse event to a vasodilator or where vasodilator treatment is contraindicated, details on the nature of the adverse event or contraindication according to the TGA-approved Product Information must also be provided with the application.

Where fewer than 3 tests (see requirement 2 above) are able to be performed on clinical grounds, a patient specific reason outlining why the particular test/s could not be conducted must be provided with the authority application [see Note for test requirements].

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. No repeats will be authorised for the first authority prescription issued under this criterion [see Note for full details of authority approval requirements]. A maximum of 4 repeats will be authorised for the second authority prescription issued under this criterion. Where fewer than 4 repeats are initially requested with the second authority prescription, authority approvals for sufficient repeats to complete a maximum of 6 months of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday)

**Authority required**

Initial (new patients)

Application for initial PBS-subsidised treatment with bosentan monohydrate of patients who have not received prior PBS-subsidised treatment with a PAH agent and who have been assessed by a physician from a designated hospital to have:

(a) WHO Functional Class III primary pulmonary hypertension and a mean right atrial pressure greater than 8 mmHg, as measured by RHC, or, where a RHC cannot be performed on clinical grounds, right ventricular function as assessed by ECHO; OR

(b) WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease and a mean right atrial pressure greater than 8 mmHg, as measured by RHC, or, where a RHC cannot be performed on clinical grounds, right ventricular function as assessed by ECHO; OR

(c) WHO Functional Class IV primary pulmonary hypertension; OR

# HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

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(d) WHO Functional Class IV pulmonary arterial hypertension secondary to connective tissue disease; OR

(e) WHO Functional Class III or IV pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology).

Applications for authorisation must be in writing and must include:

(1) two completed authority prescription forms [see Note for authority approval requirements]; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form [www.medicareaustralia.gov.au] which includes results from the 3 tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6MWT; and

(3) a signed patient acknowledgment form.

Where fewer than 3 tests (see requirement 2 above) are able to be performed on clinical grounds, a patient specific reason outlining why the particular test/s could not be conducted must be provided with the authority application [see Note for test requirements].

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. No repeats will be authorised for the first authority prescription issued under this criterion [see Note for full details of authority approval requirements]. A maximum of 4 repeats will be authorised for the second authority prescription issued under this criterion. Where fewer than 4 repeats are initially requested with the second authority prescription, authority approvals for sufficient repeats to complete a maximum of 6 months of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday)

**Authority required**

Initial (change or re-commencement for all patients)

Application for initial treatment with bosentan monohydrate of patients with one of the following:

(a) primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology), who wish to re-commence PBS-subsidised bosentan monohydrate after a break in therapy and who have demonstrated a response to their most recent course of PBS-subsidised treatment with bosentan monohydrate; OR

(b) primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease and whose most recent course of PBS-subsidised treatment was with an alternate PAH agent other than bosentan monohydrate.

Applications for authorisation must be in writing and must include:

(1) two completed authority prescription forms [see Note for authority approval requirements]; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form [www.medicareaustralia.gov.au] which includes the results on which approval for the first application for PBS-subsidised PAH agent was granted; and

(3) the date of the first application for PBS-subsidised treatment with a PAH agent; and

(4) the results of the patient's response to treatment with their last course of PBS-subsidised PAH agent.

Where fewer than 3 tests (see requirement 2 above) are able to be performed on clinical grounds, a patient specific reason outlining why the particular test/s could not be conducted must be provided with the authority application [see Note for test requirements].

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. No repeats will be authorised for the first authority prescription issued under this criterion [see Note for full details of authority approval requirements]. A maximum of 4 repeats will be authorised for the second authority prescription issued under this criterion. Where fewer than 4 repeats are initially requested with the second authority prescription, authority approvals for sufficient repeats to complete a maximum of 6 months of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday)

**Authority required**

Continuing treatment (all patients)

Continuing PBS-subsidised treatment with bosentan monohydrate of patients who have received approval for initial PBS-subsidised treatment with bosentan monohydrate and who have been assessed by a physician from a designated hospital to have achieved a response to their most recent course of bosentan monohydrate treatment [see Note for definition of response].

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form [www.medicareaustralia.gov.au] which includes results from the 3 tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6MWT.

The results of the same tests as conducted at baseline should be provided with each written continuing treatment application (i.e. every 6 months), except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be provided with the application.

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The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. A maximum of 5 repeats will be authorised.

Where fewer than 5 repeats are initially requested under this criterion, authority approvals for sufficient repeats to complete a maximum of 6 months of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday)

**Authority required**

Cessation of treatment (all patients)

Final PBS-subsidised supply for patients with WHO Functional Class III or IV primary pulmonary hypertension or WHO Functional Class III or IV pulmonary arterial hypertension secondary to connective tissue disease or WHO Functional Class III or IV pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology), who have not responded to bosentan monohydrate therapy [see Note for definition of response], to allow for gradual cessation of treatment.

Applications for authorisation under this criterion should be made on the telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) [see Note on authority approval requirements].

Approval will only be granted for the 62.5 mg tablet strength. The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment.

Under no circumstances will telephone approvals be granted for treatment that would extend the final treatment period beyond 1 month

**Caution**

Bosentan monohydrate is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 3 months following cessation of treatment with this drug.

**Note**

Any queries concerning the arrangements to prescribe bosentan monohydrate may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written applications for authority to prescribe PAH agents should be forwarded to:

Medicare Australia

Prior Written Approval of Specialised Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

**Note**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of agents for primary pulmonary hypertension and pulmonary arterial hypertension. Where the term PAH agents appears in the following notes and restrictions it refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan and tadalafil.

Patients are eligible for PBS-subsidised treatment with only 1 of the above PAH agents at any 1 time. Eligible patients may only swap between PAH agents if they have not failed prior PBS-subsidised treatment with that agent.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of that predicted.

The following provides some explanatory notes regarding the availability of PBS-subsidised treatment of patients with:

(a) bosentan monohydrate, of primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, or pulmonary arterial hypertension associated with a congential systemic-to-pulmonary shunt (including Eisenmenger's physiology), in patients with disease of WHO Functional Class III or IV severity; AND

(b) iloprost trometamol, of:

— primary pulmonary hypertension, or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class III severity and who have failed to respond to prior PBS-subsidised treatment with an alternate PAH agent; AND

— primary pulmonary hypertension, or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class IV severity; AND

— drug-induced pulmonary arterial hypertension, in patients with disease of WHO Functional Class III and IV severity; AND

(c) epoprostenol sodium, of:

— primary pulmonary hypertension, or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class III severity and who have failed to respond to prior PBS-subsidised treatment with an alternate PAH agent; AND

— primary pulmonary hypertension, or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class IV severity; AND

(d) sildenafil citrate, of primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class III severity; AND

(e) ambrisentan, of primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class III or IV severity; AND

(f) tadalafil, of primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class III severity.

From 1 April 2012, patients can access PAH agents through the PBS according to the relevant restrictions. Once these patients are approved initial treatment with 1 of these 6 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate

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agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary. (New baselines may be submitted where the patient has failed to respond to their current treatment.)

1. Definition of primary pulmonary hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease, including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology).

Primary pulmonary hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease, including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary capillary wedge pressure (PCWP) less than 18 mmHg; or

(ii) mPAP greater than 30 mmHg with exercise and PCWP less than 18 mmHg; or

(iii) where a right heart catheter cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

2. Definition of WHO Functional Class III or IV disease severity.

(a) WHO Functional Class III disease severity is defined as follows:

Patients with pulmonary hypertension resulting in marked limitation of physical activity who are comfortable at rest and on ordinary physical activity experience dyspnoea or fatigue, chest pain or near syncope.

(b) WHO Functional Class IV disease severity is defined as follows:

Patients with the inability to carry out any physical activity without symptoms. These patients manifest signs of right heart failure. Dyspnoea and/or fatigue may even be present at rest. Discomfort is increased by any physical activity.

3. Designated hospitals.

Refer to the Medicare Australia website at www.medicareaustralia.gov.au for a list of designated hospitals.

4. Test requirements to establish baseline for initiation of treatment and response to treatment for continuation of treatment.

(a) Initiation of treatment.

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment, plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

(1) RHC plus ECHO composite assessments;

(2) RHC composite assessment plus 6MWT;

(3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted to Medicare Australia for consideration based on the results of the following test combinations, which are listed in descending order of preference:

(1) ECHO composite assessment plus 6MWT;

(2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test/s could not be conducted must be provided with the authority application.

(b) Continuation of treatment.

The following list outlines the preferred test combination, in descending order, for the purposes of continuation of PBS-subsidised treatment:

(1) RHC plus ECHO composite assessments plus 6MWT;

(2) RHC plus ECHO composite assessments;

(3) RHC composite assessment plus 6MWT;

(4) ECHO composite assessment plus 6MWT;

(5) RHC composite assessment only;

(6) ECHO composite assessment only.

The results of the same tests as conducted at baseline should be provided with each written continuing treatment application (i.e. every 6 months), except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be provided with the application. The test(s) results provided with the application for continuing treatment must be no more than 2 months old at the time of application.

**Note**

5. Definition of response to a PAH agent or prior vasodilator treatment.

For patients with 2 or more baseline tests, response to treatment is defined as 2 or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or

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improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least 1 of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

6. Authority approval requirements.

(a) Initiation of PBS-subsidised treatment with a PAH agent, where the patient has not received prior PBS-subsidised treatment with that agent.

All applications for initial treatment must be made in writing, must include a completed authority prescription and must be submitted to Medicare Australia for authorisation. The total duration of initial PBS-subsidised treatment that will be approved with this first written application is up to 6 months, based on the dosage recommendations in the TGA-approved Product Information.

Bosentan only:

Approvals for the first authority prescription will be limited to 1 month of therapy with the 62.5 mg strength tablet, with the quantity approved based on the dosage recommendations in the Therapeutic Goods Administration (TGA)-approved Product Information. No repeats will be authorised for this prescription. The second authority prescription may be written for either the 62.5 mg tablet or the 125 mg tablet strengths. Where the 62.5 mg tablet strength is required, please contact Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) for further advice. Approvals for the second authority prescription will be limited to 1 month of treatment, with the quantity approved based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 4 repeats. The approved second authority prescription will be returned to the prescriber by Medicare Australia 2 weeks after the date of the approval of the first authority prescription, to allow for the uninterrupted completion of the 6 month initial treatment course. Medicare Australia will contact prescribers prior to dispatch of the second authority prescription to confirm the tablet strength required for the patient.

(b) Continuation of treatment.

Written applications for continuing treatment for patients who have demonstrated an adequate response to their current treatment must be submitted to Medicare Australia for authorisation every 6 months. Approvals will be limited to provide sufficient supply for up to a maximum of 6 months of treatment, based on the dosage recommendations in the TGA-approved Product Information.

The assessment of the patient's response to the first and subsequent 6 month courses of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated. Applications for continuing treatment with a PAH agent should be made prior to the completion of the 6 month treatment course to ensure continuity for those patients who respond to treatment, as assessed by the treating physician.

(c) Swapping between PAH agents.

For eligible patients, applications to swap between these 6 drugs must be made under the relevant initial treatment restriction. Patients should be assessed for response to the treatment they are ceasing at the time the application to swap therapy is being made. Patients who fail to demonstrate a response or for whom no assessment results are submitted with the application to swap therapy may not re-commence PBS-subsidised treatment with the drug they are ceasing.

It is important that patients are assessed for response to every course of treatment approved within the timeframes specified in the relevant restriction, in order to maximise the choice of treatment.

To avoid confusion, applications for patients who wish to swap to an alternate treatment should be accompanied by the previously approved authority prescription, or remaining repeats, for the treatment the patient is ceasing.

(d) Cessation of treatment — bosentan patients only.

Patients who fail to demonstrate a response to PBS-subsidised bosentan monohydrate treatment at the time where an assessment is required must cease PBS-subsidised bosentan monohydrate therapy.

For patients ceasing treatment, approval will only be granted to provide sufficient supply of the 62.5 mg tablet strength to allow gradual dose reduction over a period of no more than 1 month duration. Prescribers should telephone Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) to receive authorisation for this final supply and to ensure no unintended break in treatment occurs.

7. Re-treatment with a PAH agent.

Patients who do not respond to treatment are not eligible to receive further PBS-subsidised treatment with that agent under any circumstances.

8. Further information.

A tabulated representation of the above information and the restriction can be obtained from the Medicare Australia website at www.medicareaustralia.gov.au.

**Note**

Special Pricing Arrangements apply.

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| 5619R | bosentan 125 mg tablet, 60 | 1 | .. | .. | 2876.47 | Tracleer | AT |
| 5618Q | bosentan 62.5 mg tablet, 60 | 1 | .. | .. | 2876.47 | Tracleer | AT |

**EPOPROSTENOL**

**Authority required**

Initial (new patients)

Application for initial PBS-subsidised treatment with epoprostenol sodium of patients who have not received prior PBS-subsidised treatment with a PAH agent and who have been assessed by a physician from a designated hospital to have:

(a) WHO Functional Class IV primary pulmonary hypertension; OR

(b) WHO Functional Class IV pulmonary arterial hypertension secondary to connective tissue disease.

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Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form [www.medicareaustralia.gov.au] which includes results from the 3 tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6MWT; and

(3) a signed patient acknowledgment form.

Where fewer than 3 tests (see requirement 2 above) are able to be performed on clinical grounds, a patient specific reason outlining why the particular test/s could not be conducted must be provided with the authority application [see Note for test requirements].

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. A maximum of 5 repeats may be requested. Where fewer than 5 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 6 months of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday)

**Authority required**

Initial (change or re-commencement for all patients)

Application for initial PBS-subsidised treatment with epoprostenol sodium of patients with one of the following:

(a) primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease who wish to re-commence PBS-subsidised epoprostenol sodium after a break in therapy and who have demonstrated a response to their most recent course of PBS-subsidised treatment with epoprostenol sodium; OR

(b) WHO Functional Class IV primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease and who have received prior treatment with a PBS-subsidised PAH agent other than epoprostenol sodium; OR

(c) WHO Functional Class III primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease and who have failed to respond to a prior PBS-subsidised PAH agent.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form [www.medicareaustralia.gov.au] which includes the results on which approval for the first application for PBS-subsidised PAH agent was granted; and

(3) the date of the first application for PBS-subsidised treatment with a PAH agent; and

(4) the results of the patient's response to treatment with their last course of PBS-subsidised PAH agent; and

(5) for WHO Functional Class III patients, where this is the first application for epoprostenol sodium, assessment details of the PBS-subsidised PAH agent they have failed to respond to.

Where fewer than 3 tests (see requirement 2 above) are able to be performed on clinical grounds, a patient specific reason outlining why the particular test/s could not be conducted must be provided with the authority application [see Note for test requirements].

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. A maximum of 5 repeats may be requested. Where fewer than 5 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 6 months of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday)

**Authority required**

Continuing treatment (all patients)

Continuing PBS-subsidised treatment with epoprostenol sodium of patients who have received approval for initial PBS-subsidised treatment with epoprostenol sodium, and who have been assessed by a physician from a designated hospital to have achieved a response to their most recent course of epoprostenol sodium treatment [see Note for definition of response].

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form [www.medicareaustralia.gov.au] which includes results from the 3 tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6MWT.

The results of the same tests as conducted at baseline should be provided with each written continuing treatment application (i.e. every 6 months), except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be provided with the application.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. A maximum of 5 repeats may be requested. Where fewer than 5 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 6 months of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday)

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**Note**

Any queries concerning the arrangements to prescribe epoprostenol sodium may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written applications for authority to prescribe PAH agents should be forwarded to:

Medicare Australia

Prior Written Approval of Specialised Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

**Note**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of agents for primary pulmonary hypertension and pulmonary arterial hypertension. Where the term PAH agents appears in the following notes and restrictions it refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan and tadalafil.

Patients are eligible for PBS-subsidised treatment with only 1 of the above PAH agents at any 1 time. Eligible patients may only swap between PAH agents if they have not failed prior PBS-subsidised treatment with that agent.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of that predicted.

The following provides some explanatory notes regarding the availability of PBS-subsidised treatment of patients with:

(a) bosentan monohydrate, of primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, or pulmonary arterial hypertension associated with a congential systemic-to-pulmonary shunt (including Eisenmenger's physiology), in patients with disease of WHO Functional Class III or IV severity; AND

(b) iloprost trometamol, of:

— primary pulmonary hypertension, or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class III severity and who have failed to respond to prior PBS-subsidised treatment with an alternate PAH agent; AND

— primary pulmonary hypertension, or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class IV severity; AND

— drug-induced pulmonary arterial hypertension, in patients with disease of WHO Functional Class III and IV severity; AND

(c) epoprostenol sodium, of:

— primary pulmonary hypertension, or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class III severity and who have failed to respond to prior PBS-subsidised treatment with an alternate PAH agent; AND

— primary pulmonary hypertension, or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class IV severity; AND

(d) sildenafil citrate, of primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class III severity; AND

(e) ambrisentan, of primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class III or IV severity; AND

(f) tadalafil, of primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class III severity.

From 1 April 2012, patients can access PAH agents through the PBS according to the relevant restrictions. Once these patients are approved initial treatment with 1 of these 6 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary. (New baselines may be submitted where the patient has failed to respond to their current treatment.)

1. Definition of primary pulmonary hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease, including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology).

Primary pulmonary hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease, including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary capillary wedge pressure (PCWP) less than 18 mmHg; or

(ii) mPAP greater than 30 mmHg with exercise and PCWP less than 18 mmHg; or

(iii) where a right heart catheter cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

2. Definition of WHO Functional Class III or IV disease severity.

(a) WHO Functional Class III disease severity is defined as follows:

Patients with pulmonary hypertension resulting in marked limitation of physical activity who are comfortable at rest and on ordinary physical activity experience dyspnoea or fatigue, chest pain or near syncope.

(b) WHO Functional Class IV disease severity is defined as follows:

# HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

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Patients with the inability to carry out any physical activity without symptoms. These patients manifest signs of right heart failure. Dyspnoea and/or fatigue may even be present at rest. Discomfort is increased by any physical activity.

3. Designated hospitals.

Refer to the Medicare Australia website at www.medicareaustralia.gov.au for a list of designated hospitals.

4. Test requirements to establish baseline for initiation of treatment and response to treatment for continuation of treatment.

(a) Initiation of treatment.

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment, plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

(1) RHC plus ECHO composite assessments;

(2) RHC composite assessment plus 6MWT;

(3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted to Medicare Australia for consideration based on the results of the following test combinations, which are listed in descending order of preference:

(1) ECHO composite assessment plus 6MWT;

(2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test/s could not be conducted must be provided with the authority application.

(b) Continuation of treatment.

The following list outlines the preferred test combination, in descending order, for the purposes of continuation of PBS-subsidised treatment:

(1) RHC plus ECHO composite assessments plus 6MWT;

(2) RHC plus ECHO composite assessments;

(3) RHC composite assessment plus 6MWT;

(4) ECHO composite assessment plus 6MWT;

(5) RHC composite assessment only;

(6) ECHO composite assessment only.

The results of the same tests as conducted at baseline should be provided with each written continuing treatment application (i.e. every 6 months), except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be provided with the application. The test(s) results provided with the application for continuing treatment must be no more than 2 months old at the time of application.

**Note**

5. Definition of response to a PAH agent or prior vasodilator treatment.

For patients with 2 or more baseline tests, response to treatment is defined as 2 or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least 1 of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

6. Authority approval requirements.

(a) Initiation of PBS-subsidised treatment with a PAH agent, where the patient has not received prior PBS-subsidised treatment with that agent.

All applications for initial treatment must be made in writing, must include a completed authority prescription and must be submitted to Medicare Australia for authorisation. The total duration of initial PBS-subsidised treatment that will be approved with this first written application is up to 6 months, based on the dosage recommendations in the TGA-approved Product Information.

Bosentan only:

Approvals for the first authority prescription will be limited to 1 month of therapy with the 62.5 mg strength tablet, with the quantity approved based on the dosage recommendations in the Therapeutic Goods Administration (TGA)-approved Product Information. No repeats will be authorised for this prescription. The second authority prescription may be written for either the 62.5 mg tablet or the 125 mg tablet strengths. Where the 62.5 mg tablet strength is required, please contact Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) for further advice. Approvals for the second authority prescription will be limited to 1 month of treatment, with the quantity approved based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 4 repeats. The approved second authority prescription will be returned to the prescriber by Medicare Australia 2 weeks after the date of the approval of the first authority prescription, to allow for the uninterrupted completion of the 6 month initial treatment course. Medicare Australia will contact prescribers prior to dispatch of the second authority prescription to confirm the tablet strength required for the patient.

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Brand Name and Manufacturer | |
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| | (b) Continuation of treatment.<br>Written applications for continuing treatment for patients who have demonstrated an adequate response to their current treatment must be submitted to Medicare Australia for authorisation every 6 months. Approvals will be limited to provide sufficient supply for up to a maximum of 6 months of treatment, based on the dosage recommendations in the TGA-approved Product Information.<br>The assessment of the patient's response to the first and subsequent 6 month courses of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated. Applications for continuing treatment with a PAH agent should be made prior to the completion of the 6 month treatment course to ensure continuity for those patients who respond to treatment, as assessed by the treating physician.<br>(c) Swapping between PAH agents.<br>For eligible patients, applications to swap between these 6 drugs must be made under the relevant initial treatment restriction. Patients should be assessed for response to the treatment they are ceasing at the time the application to swap therapy is being made. Patients who fail to demonstrate a response or for whom no assessment results are submitted with the application to swap therapy may not re-commence PBS-subsidised treatment with the drug they are ceasing.<br>It is important that patients are assessed for response to every course of treatment approved within the timeframes specified in the relevant restriction, in order to maximise the choice of treatment.<br>To avoid confusion, applications for patients who wish to swap to an alternate treatment should be accompanied by the previously approved authority prescription, or remaining repeats, for the treatment the patient is ceasing.<br>(d) Cessation of treatment — bosentan patients only.<br>Patients who fail to demonstrate a response to PBS-subsidised bosentan monohydrate treatment at the time where an assessment is required must cease PBS-subsidised bosentan monohydrate therapy.<br>For patients ceasing treatment, approval will only be granted to provide sufficient supply of the 62.5 mg tablet strength to allow gradual dose reduction over a period of no more than 1 month duration. Prescribers should telephone Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) to receive authorisation for this final supply and to ensure no unintended break in treatment occurs.<br>7. Re-treatment with a PAH agent.<br>Patients who do not respond to treatment are not eligible to receive further PBS-subsidised treatment with that agent under any circumstances.<br>8. Further information.<br>A tabulated representation of the above information and the restriction can be obtained from the Medicare Australia website at www.medicareaustralia.gov.au. | | | | | | |
| 5035B | EPOPROSTENOL SODIUM Powder for I.V. infusion 1.5 mg (base) infusion administration set, 1 | 1 | .. | .. | 79.23 | Flolan Kit | GK |
| 5030R | EPOPROSTENOL SODIUM Powder for I.V. infusion 500 micrograms (base) infusion administration set, 1 | 1 | .. | .. | 39.62 | Flolan Kit | GK |
| | **ILOPROST**<br>**Authority required**<br>Initial (new patients)<br>Application for initial PBS-subsidised treatment with iloprost trometamol of patients who have not received prior PBS-subsidised treatment with iloprost and who have been assessed by a physician from a designated hospital to have:<br>WHO Functional Class III drug-induced pulmonary arterial hypertension and a mean right atrial pressure of 8 mmHg or less, as measured by RHC, or, where a RHC cannot be performed on clinical grounds, right ventricular function as assessed by ECHO.<br>Patients must have failed to respond [see Note for definition of response] to 6 or more weeks of appropriate vasodilator treatment unless intolerance or a contraindication to such treatment exists.<br>Applications for authorisation must be in writing and must include:<br>(1) a completed authority prescription form; and<br>(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form [www.medicareaustralia.gov.au] which includes results from the 3 tests below, where available:<br>(i) RHC composite assessment; and<br>(ii) ECHO composite assessment; and<br>(iii) 6MWT; and<br>(3) a signed patient acknowledgment form.<br>Details of prior vasodilator treatment, including the dose and duration of treatment, must be provided at the time of application. Where the patient has an adverse event to a vasodilator or where vasodilator treatment is contraindicated, details on the nature of the adverse event or contraindication according to the TGA-approved Product Information must also be provided with the application.<br>Where fewer than 3 tests (see requirement 2 above) are able to be performed on clinical grounds, a patient specific reason outlining why the particular test/s could not be conducted must be provided with the authority application [see Note for test requirements].<br>The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. A maximum of 5 repeats may be requested. Where fewer than 5 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 6 months of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday)<br>**Authority required** | | | | | | |

# HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Brand Name and Manufacturer |
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Initial (new patients)

Application for initial PBS-subsidised treatment with iloprost trometamol of patients who have not received prior PBS-subsidised treatment with a PAH agent and who have been assessed by a physician from a designated hospital to have:

(a) WHO Functional Class III drug-induced pulmonary arterial hypertension and a mean right atrial pressure greater than 8 mmHg, as measured by RHC, or, where a RHC cannot be performed on clinical grounds, right ventricular function as assessed by ECHO; OR

(b) WHO Functional Class IV primary pulmonary hypertension; OR

(c) WHO Functional Class IV pulmonary arterial hypertension secondary to connective tissue disease; OR

(d) WHO Functional Class IV drug-induced pulmonary arterial hypertension.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form [www.medicareaustralia.gov.au] which includes results from the 3 tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6MWT; and

(3) a signed patient acknowledgment form.

Where fewer than 3 tests (see requirement 2 above) are able to be performed on clinical grounds, a patient specific reason outlining why the particular test/s could not be conducted must be provided with the authority application [see Note for test requirements].

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. A maximum of 5 repeats may be requested. Where fewer than 5 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 6 months of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday)

**Authority required**

Initial (change or re-commencement for all patients)

Application for initial PBS-subsidised treatment with iloprost trometamol of patients with one of the following:

(a) primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease who wish to re-commence PBS-subsidised iloprost trometamol after a break in therapy and who have demonstrated a response to their most recent course of PBS-subsidised treatment with iloprost trometamol; OR

(b) WHO Functional Class IV primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease and who have received prior treatment with a PBS-subsidised PAH agent other than iloprost trometamol; OR

(c) WHO Functional Class III primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease and who have failed to respond to a prior PBS-subsidised PAH agent.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form [www.medicareaustralia.gov.au] which includes the results on which approval for the first application for PBS-subsidised PAH agent was granted; and

(3) the date of the first application for PBS-subsidised treatment with a PAH agent; and

(4) the results of the patient's response to treatment with their last course of PBS-subsidised PAH agent; and

(5) for WHO Functional Class III patients, where this is the first application for iloprost trometamol, assessment details of the PBS-subsidised PAH agent they have failed to respond to.

Where fewer than 3 tests (see requirement 2 above) are able to be performed on clinical grounds, a patient specific reason outlining why the particular test/s could not be conducted must be provided with the authority application [see Note for test requirements].

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. A maximum of 5 repeats may be requested. Where fewer than 5 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 6 months of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday)

**Authority required**

Continuing treatment (all patients)

Continuing PBS-subsidised treatment with iloprost trometamol of patients who have received approval for initial PBS-subsidised treatment with iloprost trometamol, and who have been assessed by a physician from a designated hospital to have achieved a response to their most recent course of iloprost trometamol treatment [see Note for definition of response].

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form [www.medicareaustralia.gov.au] which includes results from the 3 tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Brand Name and Manufacturer |
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(iii) 6MWT.

The results of the same tests as conducted at baseline should be provided with each written continuing treatment application (i.e. every 6 months), except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be provided with the application.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. A maximum of 5 repeats may be requested. Where fewer than 5 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 6 months of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday)

**Note**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of agents for primary pulmonary hypertension and pulmonary arterial hypertension. Where the term PAH agents appears in the following notes and restrictions it refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan and tadalafil.

Patients are eligible for PBS-subsidised treatment with only 1 of the above PAH agents at any 1 time. Eligible patients may only swap between PAH agents if they have not failed prior PBS-subsidised treatment with that agent.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of that predicted.

The following provides some explanatory notes regarding the availability of PBS-subsidised treatment of patients with:

(a) bosentan monohydrate, of primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, or pulmonary arterial hypertension associated with a congential systemic-to-pulmonary shunt (including Eisenmenger's physiology), in patients with disease of WHO Functional Class III or IV severity; AND

(b) iloprost trometamol, of:

— primary pulmonary hypertension, or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class III severity and who have failed to respond to prior PBS-subsidised treatment with an alternate PAH agent; AND

— primary pulmonary hypertension, or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class IV severity; AND

— drug-induced pulmonary arterial hypertension, in patients with disease of WHO Functional Class III and IV severity; AND

(c) epoprostenol sodium, of:

— primary pulmonary hypertension, or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class III severity and who have failed to respond to prior PBS-subsidised treatment with an alternate PAH agent; AND

— primary pulmonary hypertension, or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class IV severity; AND

(d) sildenafil citrate, of primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class III severity; AND

(e) ambrisentan, of primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class III or IV severity; AND

(f) tadalafil, of primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class III severity.

From 1 April 2012, patients can access PAH agents through the PBS according to the relevant restrictions. Once these patients are approved initial treatment with 1 of these 6 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary. (New baselines may be submitted where the patient has failed to respond to their current treatment.)

1. Definition of primary pulmonary hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease, including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology).

Primary pulmonary hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease, including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary capillary wedge pressure (PCWP) less than 18 mmHg; or

(ii) mPAP greater than 30 mmHg with exercise and PCWP less than 18 mmHg; or

(iii) where a right heart catheter cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

2. Definition of WHO Functional Class III or IV disease severity.

(a) WHO Functional Class III disease severity is defined as follows:

Patients with pulmonary hypertension resulting in marked limitation of physical activity who are comfortable at rest and on ordinary physical activity experience dyspnoea or fatigue, chest pain or near syncope.

(b) WHO Functional Class IV disease severity is defined as follows:

Patients with the inability to carry out any physical activity without symptoms. These patients manifest signs of right heart failure. Dyspnoea

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and/or fatigue may even be present at rest. Discomfort is increased by any physical activity.

3. Designated hospitals.

Refer to the Medicare Australia website at www.medicareaustralia.gov.au for a list of designated hospitals.

4. Test requirements to establish baseline for initiation of treatment and response to treatment for continuation of treatment.

(a) Initiation of treatment.

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment, plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

(1) RHC plus ECHO composite assessments;

(2) RHC composite assessment plus 6MWT;

(3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted to Medicare Australia for consideration based on the results of the following test combinations, which are listed in descending order of preference:

(1) ECHO composite assessment plus 6MWT;

(2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test/s could not be conducted must be provided with the authority application.

(b) Continuation of treatment.

The following list outlines the preferred test combination, in descending order, for the purposes of continuation of PBS-subsidised treatment:

(1) RHC plus ECHO composite assessments plus 6MWT;

(2) RHC plus ECHO composite assessments;

(3) RHC composite assessment plus 6MWT;

(4) ECHO composite assessment plus 6MWT;

(5) RHC composite assessment only;

(6) ECHO composite assessment only.

The results of the same tests as conducted at baseline should be provided with each written continuing treatment application (i.e. every 6 months), except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be provided with the application. The test(s) results provided with the application for continuing treatment must be no more than 2 months old at the time of application.

**Note**

5. Definition of response to a PAH agent or prior vasodilator treatment.

For patients with 2 or more baseline tests, response to treatment is defined as 2 or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least 1 of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

6. Authority approval requirements.

(a) Initiation of PBS-subsidised treatment with a PAH agent, where the patient has not received prior PBS-subsidised treatment with that agent.

All applications for initial treatment must be made in writing, must include a completed authority prescription and must be submitted to Medicare Australia for authorisation. The total duration of initial PBS-subsidised treatment that will be approved with this first written application is up to 6 months, based on the dosage recommendations in the TGA-approved Product Information.

Bosentan only:

Approvals for the first authority prescription will be limited to 1 month of therapy with the 62.5 mg strength tablet, with the quantity approved based on the dosage recommendations in the Therapeutic Goods Administration (TGA)-approved Product Information. No repeats will be authorised for this prescription. The second authority prescription may be written for either the 62.5 mg tablet or the 125 mg tablet strengths. Where the 62.5 mg tablet strength is required, please contact Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) for further advice. Approvals for the second authority prescription will be limited to 1 month of treatment, with the quantity approved based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 4 repeats. The approved second authority prescription will be returned to the prescriber by Medicare Australia 2 weeks after the date of the approval of the first authority prescription, to allow for the uninterrupted completion of the 6 month initial treatment course. Medicare Australia will contact prescribers prior to dispatch of the second authority prescription to confirm the tablet strength required for the patient.

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Brand Name and Manufacturer | |
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(b) Continuation of treatment.

Written applications for continuing treatment for patients who have demonstrated an adequate response to their current treatment must be submitted to Medicare Australia for authorisation every 6 months. Approvals will be limited to provide sufficient supply for up to a maximum of 6 months of treatment, based on the dosage recommendations in the TGA-approved Product Information.

The assessment of the patient's response to the first and subsequent 6 month courses of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated. Applications for continuing treatment with a PAH agent should be made prior to the completion of the 6 month treatment course to ensure continuity for those patients who respond to treatment, as assessed by the treating physician.

(c) Swapping between PAH agents.

For eligible patients, applications to swap between these 6 drugs must be made under the relevant initial treatment restriction. Patients should be assessed for response to the treatment they are ceasing at the time the application to swap therapy is being made. Patients who fail to demonstrate a response or for whom no assessment results are submitted with the application to swap therapy may not re-commence PBS-subsidised treatment with the drug they are ceasing.

It is important that patients are assessed for response to every course of treatment approved within the timeframes specified in the relevant restriction, in order to maximise the choice of treatment.

To avoid confusion, applications for patients who wish to swap to an alternate treatment should be accompanied by the previously approved authority prescription, or remaining repeats, for the treatment the patient is ceasing.

(d) Cessation of treatment — bosentan patients only.

Patients who fail to demonstrate a response to PBS-subsidised bosentan monohydrate treatment at the time where an assessment is required must cease PBS-subsidised bosentan monohydrate therapy.

For patients ceasing treatment, approval will only be granted to provide sufficient supply of the 62.5 mg tablet strength to allow gradual dose reduction over a period of no more than 1 month duration. Prescribers should telephone Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) to receive authorisation for this final supply and to ensure no unintended break in treatment occurs.

7. Re-treatment with a PAH agent.

Patients who do not respond to treatment are not eligible to receive further PBS-subsidised treatment with that agent under any circumstances.

8. Further information.

A tabulated representation of the above information and the restriction can be obtained from the Medicare Australia website at www.medicareaustralia.gov.au.

**Note**

Any queries concerning the arrangements to prescribe iloprost trometamol may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written applications for authority to prescribe PAH agents should be forwarded to:

Medicare Australia

Prior Written Approval of Specialised Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

**Note**

Special Pricing Arrangements apply.

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| 5751Q | iloprost 20 microgram/2 mL inhalation: solution, 30 x 2 mL ampoules | 1 | .. | .. | 1076.00 | Ventavis | BN |

**SILDENAFIL**

**Authority required**

Initial (new patients)

Application for initial PBS-subsidised treatment with sildenafil citrate of patients who have not received prior PBS-subsidised treatment with a PAH agent and who have been assessed by a physician from a designated hospital to have:

(a) WHO Functional Class III primary pulmonary hypertension and a mean right atrial pressure of 8 mmHg or less, as measured by RHC, or, where a RHC cannot be performed on clinical grounds, right ventricular function as assessed by ECHO; OR

(b) WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease and a mean right atrial pressure of 8 mmHg or less, as measured by RHC, or, where a RHC cannot be performed on clinical grounds, right ventricular function as assessed by ECHO.

Patients must have failed to respond [see Note for definition of response] to 6 or more weeks of appropriate vasodilator treatment unless intolerance or a contraindication to such treatment exists.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form [www.medicareaustralia.gov.au] which includes results from the 3 tests below, where available:

(i) RHC composite assessment; and

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Brand Name and Manufacturer |
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(ii) ECHO composite assessment; and

(iii) 6MWT; and

(3) a signed patient acknowledgment form.

Details of prior vasodilator treatment, including the dose and duration of treatment, must be provided at the time of application. Where the patient has an adverse event to a vasodilator or where vasodilator treatment is contraindicated, details on the nature of the adverse event or contraindication according to the TGA-approved Product Information must also be provided with the application.

Where fewer than 3 tests (see requirement 2 above) are able to be performed on clinical grounds, a patient specific reason outlining why the particular test/s could not be conducted must be provided with the authority application [see Note for test requirements].

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. A maximum of 5 repeats may be requested. Where fewer than 5 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 6 months of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday)

**Authority required**

Initial (new patients)

Application for initial PBS-subsidised treatment with sildenafil citrate of patients who have not received prior PBS-subsidised treatment with a PAH agent and who have been assessed by a physician from a designated hospital to have:

(a) WHO Functional Class III primary pulmonary hypertension and a mean right atrial pressure greater than 8 mmHg, as measured by RHC, or, where a RHC cannot be performed on clinical grounds, right ventricular function as assessed by ECHO; OR

(b) WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease and a mean right atrial pressure greater than 8 mmHg, as measured by RHC, or, where a RHC cannot be performed on clinical grounds, right ventricular function as assessed by ECHO.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form [www.medicareaustralia.gov.au] which includes results from the 3 tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6MWT; and

(3) a signed patient acknowledgment form.

Where fewer than 3 tests (see requirement 2 above) are able to be performed on clinical grounds, a patient specific reason outlining why the particular test/s could not be conducted must be provided with the authority application [see Note for test requirements].

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. A maximum of 5 repeats may be requested. Where fewer than 5 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 6 months of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday)

**Authority required**

Initial (change or re-commencement for all patients)

Application for initial PBS-subsidised treatment with sildenafil citrate of patients with one of the following:

(a) WHO Functional Class III primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease who wish to re-commence PBS-subsidised sildenafil citrate after a break in therapy and who have demonstrated a response to their most recent course of PBS-subsidised treatment with sildenafil citrate; OR

(b) WHO Functional Class III primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease and whose most recent course of PBS-subsidised treatment was with a PAH agent other than sildenafil citrate.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form [www.medicareaustralia.gov.au] which includes the results on which approval for the first application for PBS-subsidised PAH agent was granted; and

(3) the date of the first application for PBS-subsidised treatment with a PAH agent; and

(4) the results of the patient's response to treatment with their last course of PBS-subsidised PAH agent.

Where fewer than 3 tests (see requirement 2 above) are able to be performed on clinical grounds, a patient specific reason outlining why the particular test/s could not be conducted must be provided with the authority application [see Note for test requirements].

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. A maximum of 5 repeats may be requested. Where fewer than 5 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 6 months of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday)

**Authority required**

Continuing treatment (all patients)

Continuing PBS-subsidised treatment with sildenafil citrate of patients who have received approval for initial PBS-subsidised treatment with sildenafil citrate, and who have been assessed by a physician from a designated hospital to have achieved a response to their most recent course of

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sildenafil citrate treatment [see Note for definition of response].

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form [www.medicareaustralia.gov.au] which includes results from the 3 tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6MWT.

The results of the same tests as conducted at baseline should be provided with each written continuing treatment application (i.e. every 6 months), except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be provided with the application.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. A maximum of 5 repeats may be requested. Where fewer than 5 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 6 months of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday)

**Note**

Any queries concerning the arrangements to prescribe sildenafil citrate may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written applications for authority to prescribe PAH agents should be forwarded to:

Medicare Australia

Prior Written Approval of Specialised Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

**Note**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of agents for primary pulmonary hypertension and pulmonary arterial hypertension. Where the term PAH agents appears in the following notes and restrictions it refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan and tadalafil.

Patients are eligible for PBS-subsidised treatment with only 1 of the above PAH agents at any 1 time. Eligible patients may only swap between PAH agents if they have not failed prior PBS-subsidised treatment with that agent.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of that predicted.

The following provides some explanatory notes regarding the availability of PBS-subsidised treatment of patients with:

(a) bosentan monohydrate, of primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, or pulmonary arterial hypertension associated with a congential systemic-to-pulmonary shunt (including Eisenmenger's physiology), in patients with disease of WHO Functional Class III or IV severity; AND

(b) iloprost trometamol, of:

— primary pulmonary hypertension, or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class III severity and who have failed to respond to prior PBS-subsidised treatment with an alternate PAH agent; AND

— primary pulmonary hypertension, or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class IV severity; AND

— drug-induced pulmonary arterial hypertension, in patients with disease of WHO Functional Class III and IV severity; AND

(c) epoprostenol sodium, of:

— primary pulmonary hypertension, or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class III severity and who have failed to respond to prior PBS-subsidised treatment with an alternate PAH agent; AND

— primary pulmonary hypertension, or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class IV severity; AND

(d) sildenafil citrate, of primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class III severity; AND

(e) ambrisentan, of primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class III or IV severity; AND

(f) tadalafil, of primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class III severity.

From 1 April 2012, patients can access PAH agents through the PBS according to the relevant restrictions. Once these patients are approved initial treatment with 1 of these 6 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary. (New

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baselines may be submitted where the patient has failed to respond to their current treatment.)

1. Definition of primary pulmonary hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease, including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology).

Primary pulmonary hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease, including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary capillary wedge pressure (PCWP) less than 18 mmHg; or

(ii) mPAP greater than 30 mmHg with exercise and PCWP less than 18 mmHg; or

(iii) where a right heart catheter cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

2. Definition of WHO Functional Class III or IV disease severity.

(a) WHO Functional Class III disease severity is defined as follows:

Patients with pulmonary hypertension resulting in marked limitation of physical activity who are comfortable at rest and on ordinary physical activity experience dyspnoea or fatigue, chest pain or near syncope.

(b) WHO Functional Class IV disease severity is defined as follows:

Patients with the inability to carry out any physical activity without symptoms. These patients manifest signs of right heart failure. Dyspnoea and/or fatigue may even be present at rest. Discomfort is increased by any physical activity.

3. Designated hospitals.

Refer to the Medicare Australia website at www.medicareaustralia.gov.au for a list of designated hospitals.

4. Test requirements to establish baseline for initiation of treatment and response to treatment for continuation of treatment.

(a) Initiation of treatment.

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment, plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

(1) RHC plus ECHO composite assessments;

(2) RHC composite assessment plus 6MWT;

(3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted to Medicare Australia for consideration based on the results of the following test combinations, which are listed in descending order of preference:

(1) ECHO composite assessment plus 6MWT;

(2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test/s could not be conducted must be provided with the authority application.

(b) Continuation of treatment.

The following list outlines the preferred test combination, in descending order, for the purposes of continuation of PBS-subsidised treatment:

(1) RHC plus ECHO composite assessments plus 6MWT;

(2) RHC plus ECHO composite assessments;

(3) RHC composite assessment plus 6MWT;

(4) ECHO composite assessment plus 6MWT;

(5) RHC composite assessment only;

(6) ECHO composite assessment only.

The results of the same tests as conducted at baseline should be provided with each written continuing treatment application (i.e. every 6 months), except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be provided with the application. The test(s) results provided with the application for continuing treatment must be no more than 2 months old at the time of application.

**Note**

5. Definition of response to a PAH agent or prior vasodilator treatment.

For patients with 2 or more baseline tests, response to treatment is defined as 2 or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or

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improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least 1 of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

6. Authority approval requirements.

(a) Initiation of PBS-subsidised treatment with a PAH agent, where the patient has not received prior PBS-subsidised treatment with that agent.

All applications for initial treatment must be made in writing, must include a completed authority prescription and must be submitted to Medicare Australia for authorisation. The total duration of initial PBS-subsidised treatment that will be approved with this first written application is up to 6 months, based on the dosage recommendations in the TGA-approved Product Information.

Bosentan only:

Approvals for the first authority prescription will be limited to 1 month of therapy with the 62.5 mg strength tablet, with the quantity approved based on the dosage recommendations in the Therapeutic Goods Administration (TGA)-approved Product Information. No repeats will be authorised for this prescription. The second authority prescription may be written for either the 62.5 mg tablet or the 125 mg tablet strengths. Where the 62.5 mg tablet strength is required, please contact Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) for further advice. Approvals for the second authority prescription will be limited to 1 month of treatment, with the quantity approved based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 4 repeats. The approved second authority prescription will be returned to the prescriber by Medicare Australia 2 weeks after the date of the approval of the first authority prescription, to allow for the uninterrupted completion of the 6 month initial treatment course. Medicare Australia will contact prescribers prior to dispatch of the second authority prescription to confirm the tablet strength required for the patient.

(b) Continuation of treatment.

Written applications for continuing treatment for patients who have demonstrated an adequate response to their current treatment must be submitted to Medicare Australia for authorisation every 6 months. Approvals will be limited to provide sufficient supply for up to a maximum of 6 months of treatment, based on the dosage recommendations in the TGA-approved Product Information.

The assessment of the patient's response to the first and subsequent 6 month courses of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated. Applications for continuing treatment with a PAH agent should be made prior to the completion of the 6 month treatment course to ensure continuity for those patients who respond to treatment, as assessed by the treating physician.

(c) Swapping between PAH agents.

For eligible patients, applications to swap between these 6 drugs must be made under the relevant initial treatment restriction. Patients should be assessed for response to the treatment they are ceasing at the time the application to swap therapy is being made. Patients who fail to demonstrate a response or for whom no assessment results are submitted with the application to swap therapy may not re-commence PBS-subsidised treatment with the drug they are ceasing.

It is important that patients are assessed for response to every course of treatment approved within the timeframes specified in the relevant restriction, in order to maximise the choice of treatment.

To avoid confusion, applications for patients who wish to swap to an alternate treatment should be accompanied by the previously approved authority prescription, or remaining repeats, for the treatment the patient is ceasing.

(d) Cessation of treatment — bosentan patients only.

Patients who fail to demonstrate a response to PBS-subsidised bosentan monohydrate treatment at the time where an assessment is required must cease PBS-subsidised bosentan monohydrate therapy.

For patients ceasing treatment, approval will only be granted to provide sufficient supply of the 62.5 mg tablet strength to allow gradual dose reduction over a period of no more than 1 month duration. Prescribers should telephone Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) to receive authorisation for this final supply and to ensure no unintended break in treatment occurs.

7. Re-treatment with a PAH agent.

Patients who do not respond to treatment are not eligible to receive further PBS-subsidised treatment with that agent under any circumstances.

8. Further information.

A tabulated representation of the above information and the restriction can be obtained from the Medicare Australia website at www.medicareaustralia.gov.au.

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| 9547L | sildenafil 20 mg tablet, 90 | 1 | .. | .. | 898.43 | Revatio | PF |

**TADALAFIL**

**Authority required**

Initial (new patients)

Application for initial PBS-subsidised treatment with tadalafil of patients who have not received prior PBS-subsidised treatment with a PAH agent and who have been assessed by a physician from a designated hospital to have:

(a) WHO Functional Class III primary pulmonary hypertension and a mean right atrial pressure of 8 mmHg or less, as measured by RHC, or, where a RHC cannot be performed on clinical grounds, right ventricular function as assessed by ECHO; OR

(b) WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease and a mean right atrial pressure of 8 mmHg or less, as measured by RHC, or, where a RHC cannot be performed on clinical grounds, right ventricular function as assessed by ECHO.

Patients must have failed to respond [see Note for definition of response] to 6 or more weeks of appropriate vasodilator treatment unless intolerance or a contraindication to such treatment exists.

Applications for authorisation must be in writing and must include:

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(1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form [www.medicareaustralia.gov.au] which includes results from the 3 tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6MWT; and

(3) a signed patient acknowledgment form.

Details of prior vasodilator treatment, including the dose and duration of treatment, must be provided at the time of application. Where the patient has an adverse event to a vasodilator or where vasodilator treatment is contraindicated, details on the nature of the adverse event or contraindication according to the TGA-approved Product Information must also be provided with the application.

Where fewer than 3 tests (see requirement 2 above) are able to be performed on clinical grounds, a patient specific reason outlining why the particular test/s could not be conducted must be provided with the authority application [see Note for test requirements].

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. A maximum of 5 repeats may be requested. Where fewer than 5 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 6 months of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday)

**Authority required**

Initial (new patients)

Application for initial PBS-subsidised treatment with tadalafil of patients who have not received prior PBS-subsidised treatment with a PAH agent and who have been assessed by a physician from a designated hospital to have:

(a) WHO Functional Class III primary pulmonary hypertension and a mean right atrial pressure greater than 8 mmHg, as measured by RHC, or, where a RHC cannot be performed on clinical grounds, right ventricular function as assessed by ECHO; OR

(b) WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease and a mean right atrial pressure greater than 8 mmHg, as measured by RHC, or, where a RHC cannot be performed on clinical grounds, right ventricular function as assessed by ECHO;

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form [www.medicareaustralia.gov.au] which includes results from the 3 tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6MWT; and

(3) a signed patient acknowledgment form.

Where fewer than 3 tests (see requirement 2 above) are able to be performed on clinical grounds, a patient specific reason outlining why the particular test/s could not be conducted must be provided with the authority application [see Note for test requirements].

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. A maximum of 5 repeats may be requested. Where fewer than 5 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 6 months of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday)

**Authority required**

Initial (change or re-commencement for all patients)

Application for initial treatment with tadalafil of patients with one of the following:

(a) WHO Functional Class III primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease who wish to re-commence PBS-subsidised tadalafil after a break in therapy and who have demonstrated a response to their most recent course of PBS-subsidised treatment with tadalafil; OR

(b) WHO Functional Class III primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease and whose most recent course of PBS-subsidised treatment was with a PAH agent other than tadalafil.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form [www.medicareaustralia.gov.au] which includes the results on which approval for the first application for PBS-subsidised PAH agent was granted; and

(3) the date of the first application for PBS-subsidised treatment with a PAH agent; and

(4) the results of the patient's response to treatment with their last course of PBS-subsidised PAH agent.

Where fewer than 3 tests (see requirement 2 above) are able to be performed on clinical grounds, a patient specific reason outlining why the particular test/s could not be conducted must be provided with the authority application [see Note for test requirements].

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. A maximum of 5 repeats may be requested. Where fewer than 5 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 6 months of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday)

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**Authority required**

Continuing treatment (all patients)

Continuing PBS-subsidised treatment with tadalafil of patients who have received approval for initial PBS-subsidised treatment with tadalafil, and who have been assessed by a physician from a designated hospital to have achieved a response to their most recent course of tadalafil treatment [see Note for definition of response].

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form [www.medicareaustralia.gov.au] which includes results from the 3 tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6MWT.

The results of the same tests as conducted at baseline should be provided with each written continuing treatment application (i.e. every 6 months), except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be provided with the application.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. A maximum of 5 repeats will be authorised. Where fewer than 5 repeats are initially requested under this criterion, authority approvals for sufficient repeats to complete a maximum of 6 months of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday)

**Note**

Any queries concerning the arrangements to prescribe tadalafil may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written applications for authority to prescribe PAH agents should be forwarded to:

Medicare Australia

Prior Written Approval of Specialised Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

**Note**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of agents for primary pulmonary hypertension and pulmonary arterial hypertension. Where the term PAH agents appears in the following notes and restrictions it refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan and tadalafil.

Patients are eligible for PBS-subsidised treatment with only 1 of the above PAH agents at any 1 time. Eligible patients may only swap between PAH agents if they have not failed prior PBS-subsidised treatment with that agent.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of that predicted.

The following provides some explanatory notes regarding the availability of PBS-subsidised treatment of patients with:

(a) bosentan monohydrate, of primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, or pulmonary arterial hypertension associated with a congential systemic-to-pulmonary shunt (including Eisenmenger's physiology), in patients with disease of WHO Functional Class III or IV severity; AND

(b) iloprost trometamol, of:

— primary pulmonary hypertension, or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class III severity and who have failed to respond to prior PBS-subsidised treatment with an alternate PAH agent; AND

— primary pulmonary hypertension, or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class IV severity; AND

— drug-induced pulmonary arterial hypertension, in patients with disease of WHO Functional Class III and IV severity; AND

(c) epoprostenol sodium, of:

— primary pulmonary hypertension, or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class III severity and who have failed to respond to prior PBS-subsidised treatment with an alternate PAH agent; AND

— primary pulmonary hypertension, or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class IV severity; AND

(d) sildenafil citrate, of primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class III severity; AND

(e) ambrisentan, of primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class III or IV severity; AND

(f) tadalafil, of primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class III severity.

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From 1 April 2012, patients can access PAH agents through the PBS according to the relevant restrictions. Once these patients are approved initial treatment with 1 of these 6 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary. (New baselines may be submitted where the patient has failed to respond to their current treatment.)

1. Definition of primary pulmonary hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease, including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology).

Primary pulmonary hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease, including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary capillary wedge pressure (PCWP) less than 18 mmHg; or

(ii) mPAP greater than 30 mmHg with exercise and PCWP less than 18 mmHg; or

(iii) where a right heart catheter cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

2. Definition of WHO Functional Class III or IV disease severity.

(a) WHO Functional Class III disease severity is defined as follows:

Patients with pulmonary hypertension resulting in marked limitation of physical activity who are comfortable at rest and on ordinary physical activity experience dyspnoea or fatigue, chest pain or near syncope.

(b) WHO Functional Class IV disease severity is defined as follows:

Patients with the inability to carry out any physical activity without symptoms. These patients manifest signs of right heart failure. Dyspnoea and/or fatigue may even be present at rest. Discomfort is increased by any physical activity.

3. Designated hospitals.

Refer to the Medicare Australia website at www.medicareaustralia.gov.au for a list of designated hospitals.

4. Test requirements to establish baseline for initiation of treatment and response to treatment for continuation of treatment.

(a) Initiation of treatment.

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment, plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

(1) RHC plus ECHO composite assessments;

(2) RHC composite assessment plus 6MWT;

(3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted to Medicare Australia for consideration based on the results of the following test combinations, which are listed in descending order of preference:

(1) ECHO composite assessment plus 6MWT;

(2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test/s could not be conducted must be provided with the authority application.

(b) Continuation of treatment.

The following list outlines the preferred test combination, in descending order, for the purposes of continuation of PBS-subsidised treatment:

(1) RHC plus ECHO composite assessments plus 6MWT;

(2) RHC plus ECHO composite assessments;

(3) RHC composite assessment plus 6MWT;

(4) ECHO composite assessment plus 6MWT;

(5) RHC composite assessment only;

(6) ECHO composite assessment only.

The results of the same tests as conducted at baseline should be provided with each written continuing treatment application (i.e. every 6 months), except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be provided with the application. The test(s) results provided with the application for continuing treatment must be no more than 2 months old at the time of application.

**Note**

5. Definition of response to a PAH agent or prior vasodilator treatment.

For patients with 2 or more baseline tests, response to treatment is defined as 2 or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

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|---|---|---|---|---|---|---|---|
| | For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.<br>For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.<br>For patients aged less than 18 years, response to treatment is defined as at least 1 of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.<br>6. Authority approval requirements.<br>(a) Initiation of PBS-subsidised treatment with a PAH agent, where the patient has not received prior PBS-subsidised treatment with that agent.<br>All applications for initial treatment must be made in writing, must include a completed authority prescription and must be submitted to Medicare Australia for authorisation. The total duration of initial PBS-subsidised treatment that will be approved with this first written application is up to 6 months, based on the dosage recommendations in the TGA-approved Product Information.<br>Bosentan only:<br>Approvals for the first authority prescription will be limited to 1 month of therapy with the 62.5 mg strength tablet, with the quantity approved based on the dosage recommendations in the Therapeutic Goods Administration (TGA)-approved Product Information. No repeats will be authorised for this prescription. The second authority prescription may be written for either the 62.5 mg tablet or the 125 mg tablet strengths. Where the 62.5 mg tablet strength is required, please contact Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) for further advice. Approvals for the second authority prescription will be limited to 1 month of treatment, with the quantity approved based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 4 repeats. The approved second authority prescription will be returned to the prescriber by Medicare Australia 2 weeks after the date of the approval of the first authority prescription, to allow for the uninterrupted completion of the 6 month initial treatment course. Medicare Australia will contact prescribers prior to dispatch of the second authority prescription to confirm the tablet strength required for the patient.<br>(b) Continuation of treatment.<br>Written applications for continuing treatment for patients who have demonstrated an adequate response to their current treatment must be submitted to Medicare Australia for authorisation every 6 months. Approvals will be limited to provide sufficient supply for up to a maximum of 6 months of treatment, based on the dosage recommendations in the TGA-approved Product Information.<br>The assessment of the patient's response to the first and subsequent 6 month courses of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated. Applications for continuing treatment with a PAH agent should be made prior to the completion of the 6 month treatment course to ensure continuity for those patients who respond to treatment, as assessed by the treating physician.<br>(c) Swapping between PAH agents.<br>For eligible patients, applications to swap between these 6 drugs must be made under the relevant initial treatment restriction. Patients should be assessed for response to the treatment they are ceasing at the time the application to swap therapy is being made. Patients who fail to demonstrate a response or for whom no assessment results are submitted with the application to swap therapy may not re-commence PBS-subsidised treatment with the drug they are ceasing.<br>It is important that patients are assessed for response to every course of treatment approved within the timeframes specified in the relevant restriction, in order to maximise the choice of treatment.<br>To avoid confusion, applications for patients who wish to swap to an alternate treatment should be accompanied by the previously approved authority prescription, or remaining repeats, for the treatment the patient is ceasing.<br>(d) Cessation of treatment — bosentan patients only.<br>Patients who fail to demonstrate a response to PBS-subsidised bosentan monohydrate treatment at the time where an assessment is required must cease PBS-subsidised bosentan monohydrate therapy.<br>For patients ceasing treatment, approval will only be granted to provide sufficient supply of the 62.5 mg tablet strength to allow gradual dose reduction over a period of no more than 1 month duration. Prescribers should telephone Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) to receive authorisation for this final supply and to ensure no unintended break in treatment occurs.<br>7. Re-treatment with a PAH agent.<br>Patients who do not respond to treatment are not eligible to receive further PBS-subsidised treatment with that agent under any circumstances.<br>8. Further information.<br>A tabulated representation of the above information and the restriction can be obtained from the Medicare Australia website at www.medicareaustralia.gov.au. | | | | | | |
| 1308W | tadalafil 20 mg tablet, 56 | 1 | .. | .. | 838.53 | Adcirca | LY |

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|

# SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS

## PITUITARY AND HYPOTHALAMIC HORMONES AND ANALOGUES

### HYPOTHALAMIC HORMONES

#### *Somatostatin and analogues*

**LANREOTIDE**

**Authority required (STREAMLINED)**

***3388***

Active acromegaly in a patient with persistent elevation of mean growth hormone levels of greater than 2.5 micrograms per litre AND

(a) after failure of other therapy including dopamine agonists; or

(b) as interim treatment while awaiting the effects of radiotherapy and where treatment with dopamine agonists has failed; or

(c) if the patient is unfit for or unwilling to undergo surgery and where radiotherapy is contraindicated.

In a patient treated with radiotherapy, treatment must cease if there is biochemical evidence of remission (normal IGF1) after lanreotide has been withdrawn for at least 4 weeks (8 weeks after the last dose). Lanreotide should be withdrawn every 2 years in the 10 years after radiotherapy for assessment of remission.

Treatment must cease if IGF1 is not lower after 3 months treatment

**Authority required (STREAMLINED)**

***3389***

Functional carcinoid tumour causing intractable symptoms. The patient must have experienced on average over 1 week, 3 or more episodes per day of diarrhoea and/or flushing, which persisted despite the use of anti-histamines, anti-serotonin agents and anti-diarrhoea agents, and surgery or antineoplastic therapy must have failed or be inappropriate.

Treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 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

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| 5779E | lanreotide 120 mg/0.5 mL injection, 1 x 0.5 mL syringe | 2 | 11 | .. | *4480.00 | Somatuline Autogel | IS |
| 5777C | lanreotide 60 mg/0.3 mL injection: modified release, 1 x 0.3 mL syringe | 2 | 11 | .. | *2690.00 | Somatuline Autogel | IS |
| 5778D | lanreotide 90 mg/0.3 mL injection: modified release, 1 x 0.3 mL syringe | 2 | 11 | .. | *3580.00 | Somatuline Autogel | IS |

**LANREOTIDE**

**Authority required (STREAMLINED)**

***3387***

Active acromegaly in a patient with persistent elevation of mean growth hormone levels of greater than 2.5 micrograms per litre AND

(a) after failure of other therapy including dopamine agonists; or

(b) as interim treatment while awaiting the effects of radiotherapy and where treatment with dopamine agonists has failed; or

(c) if the patient is unfit for or unwilling to undergo surgery and where radiotherapy is contraindicated.

In a patient treated with radiotherapy, treatment must cease if there is biochemical evidence of remission (normal IGF1) after lanreotide has been withdrawn for at least 4 weeks (6 weeks after the last dose). Lanreotide should be withdrawn every 2 years in the 10 years after radiotherapy for assessment of remission.

Treatment must cease if IGF1 is not lower after 3 months treatment

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| 5776B | lanreotide 30 mg injection: modified release [1 x 30 mg vial] (&) inert substance diluent [1 x 2 mL ampoule], 1 pack | 2 | 11 | .. | *1500.00 | Somatuline LA | IS |

**OCTREOTIDE**

**Authority required (STREAMLINED)**

***3409***

Acromegaly in a patient controlled on Sandostatin subcutaneous injections.

In a patient treated with radiotherapy, treatment must cease if there is biochemical evidence of remission (normal IGF1) after octreotide has been withdrawn for at least 4 weeks (8 weeks after the last dose). Octreotide should be withdrawn every 2 years in the 10 years after radiotherapy for assessment of remission.

Treatment must cease if IGF1 is not lower after 3 months of treatment

**Authority required (STREAMLINED)**

***3410***

Functional carcinoid tumour or vasoactive intestinal peptide secreting tumour (VIPoma) with symptom control on Sandostatin subcutaneous

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|
| | injections. | | | | | | | |
| | Treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 3 months' therapy at a dose of 30 mg every 28 days and having allowed adequate rescue therapy with Sandostatin subcutaneous injections. Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose | | | | | | | |
| 9511N | octreotide 10 mg injection: modified release [1 x 10 mg vial] (&) inert substance diluent [1 x 2.5 mL syringe], 1 pack | 1 | 11 | .. | 1306.86 | | Sandostatin LAR | NV |
| 9512P | octreotide 20 mg injection: modified release [1 x 20 mg vial] (&) inert substance diluent [1 x 2.5 mL syringe], 1 pack | 1 | 11 | .. | 1739.81 | | Sandostatin LAR | NV |
| 9513Q | octreotide 30 mg injection: modified release [1 x 30 mg vial] (&) inert substance diluent [1 x 2.5 mL syringe], 1 pack | 1 | 11 | .. | 2177.46 | | Sandostatin LAR | NV |
| | **OCTREOTIDE** | | | | | | | |
| | **Authority required (STREAMLINED)** | | | | | | | |
| | ***3407*** | | | | | | | |
| | Active acromegaly in a patient with persistent elevation of mean growth hormone levels of greater than 2.5 micrograms per litre AND | | | | | | | |
| | (a) after failure of other therapy including dopamine agonists; or | | | | | | | |
| | (b) as interim treatment while awaiting the effects of radiotherapy and where treatment with dopamine agonists has failed; or | | | | | | | |
| | (c) if the patient is unfit for or unwilling to undergo surgery and where radiotherapy is contraindicated. | | | | | | | |
| | In a patient treated with radiotherapy, treatment must cease if there is biochemical evidence of remission (normal IGF1) after octreotide has been withdrawn for at least 4 weeks. Octreotide should be withdrawn every 2 years in the 10 years after radiotherapy for assessment of remission. | | | | | | | |
| | Treatment must cease if IGF1 is not lower after 3 months treatment at a dose of 100 micrograms 3 times daily | | | | | | | |
| | **Authority required (STREAMLINED)** | | | | | | | |
| | ***3408*** | | | | | | | |
| | Functional carcinoid tumour or vasoactive intestinal peptide secreting tumour (VIPoma) causing intractable symptoms. The patient must have experienced on average over 1 week, 3 or more episodes per day of diarrhoea and/or flushing, which persisted despite the use of anti-histamines, anti-serotonin agents and anti-diarrhoea agents, and surgery or antineoplastic therapy must have failed or be inappropriate. | | | | | | | |
| | Treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 2 months' therapy. Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose | | | | | | | |
| 9509L | octreotide 100 microgram/mL injection, 5 x 1 mL ampoules | 18 | 11 | .. | *1236.42 | [a] | Hospira Pty Limited | HH |
| | | | | | | [a] | Octreotide (SUN) | ZF |
| | | | | | | [a] | Octreotide MaxRx | GQ |
| | | | | | | [a] | Sandostatin 0.1 | NV |
| 9508K | octreotide 50 microgram/mL injection, 5 x 1 mL ampoules | 18 | 11 | .. | *619.02 | [a] | Hospira Pty Limited | HH |
| | | | | | | [a] | Octreotide (SUN) | ZF |
| | | | | | | [a] | Octreotide MaxRx | GQ |
| | | | | | | [a] | Sandostatin 0.05 | NV |
| 9510M | octreotide 500 microgram/mL injection, 5 x 1 mL ampoules | 18 | 11 | .. | *6194.52 | [a] | Hospira Pty Limited | HH |
| | | | | | | [a] | Octreotide (SUN) | ZF |
| | | | | | | [a] | Octreotide MaxRx | GQ |
| | | | | | | [a] | Sandostatin 0.5 | NV |

## CALCIUM HOMEOSTASIS

### ANTI-PARATHYROID AGENTS

#### *Other anti-parathyroid agents*

**CINACALCET**

**Authority required (STREAMLINED)**

***3323***

Management, including initiation and stabilisation, by a nephrologist, of a patient with chronic kidney disease on dialysis who has sustained secondary hyperparathyroidism with iPTH of at least 50 pmol per L, not responding to conventional therapy

**Authority required (STREAMLINED)**

***3324***

Management, including initiation and stabilisation, by a nephrologist, of a patient with chronic kidney disease on dialysis who has sustained secondary hyperparathyroidism with iPTH of at least 15 pmol per L and less than 50 pmol per L AND an (adjusted) serum calcium concentration at least 2.6 mmol per L, not responding to conventional treatment

**Note**

# HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|
| | During the titration phase, intact PTH should be monitored 4 weekly (measured at least 12 hours post dose) and dose titrated until an appropriate iPTH concentration is achieved. During the titration phase, approval will be limited to sufficient supply for 4 weeks treatment at a time, with doses between 30 and 180 mg per day according to the patient's response and tolerability.<br>During the maintenance phase, approval will be limited to provide sufficient quantity for 4 weeks treatment up to a maximum of 6 months supply for doses between 30 and 180 mg per day according to the patient's response and tolerability. Intact PTH should be monitored quarterly (measured at least 12 hours post dose) and dose adjusted as necessary to maintain an appropriate iPTH concentration.<br>"Sustained" means the abnormality was detected on at least 2 blood samples collected over a period of 2 to 4 months.<br>**Note**<br>Special Pricing Arrangements apply. | | | | | | |
| 5621W | cinacalcet 30 mg tablet, 28 | 2 | 5 | .. | *593.72 | Sensipar | AN |
| 5622X | cinacalcet 60 mg tablet, 28 | 2 | 5 | .. | *1187.44 | Sensipar | AN |
| 5623Y | cinacalcet 90 mg tablet, 28 | 2 | 5 | .. | *1781.16 | Sensipar | AN |

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|

# ANTIINFECTIVES FOR SYSTEMIC USE

## ANTIBACTERIALS FOR SYSTEMIC USE

### MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS

#### *Macrolides*

**AZITHROMYCIN**

**Authority required (STREAMLINED)**

***3317***

Prophylaxis against Mycobacterium avium complex infections in HIV-positive patients with CD4 cell counts of less than 75 per cubic millimetre

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 5616N | azithromycin 600 mg tablet, 8 | 2 | 5 | .. | *113.96 | | Zithromax | PF |

**CLARITHROMYCIN**

**Authority required (STREAMLINED)**

***3325***

Treatment of Mycobacterium avium complex infections

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 5625C | clarithromycin 250 mg tablet, 100 | 1 | 2 | .. | 23.71 | | Klacid | AB |
| 5624B | clarithromycin 500 mg tablet, 100 | 1 | 2 | .. | 47.30 | | Klacid | AB |

## ANTIMYCOBACTERIALS

### DRUGS FOR TREATMENT OF TUBERCULOSIS

#### *Antibiotics*

**RIFABUTIN**

**Authority required (STREAMLINED)**

***3415***

Treatment of Mycobacterium avium complex infections in HIV-positive patients

**Authority required (STREAMLINED)**

***3317***

Prophylaxis against Mycobacterium avium complex infections in HIV-positive patients with CD4 cell counts of less than 75 per cubic millimetre

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 9541E | rifabutin 150 mg capsule, 30 | 4 | 5 | .. | *588.00 | | Mycobutin | PF |

## ANTIVIRALS FOR SYSTEMIC USE

### DIRECT ACTING ANTIVIRALS

#### *Nucleosides and nucleotides excl. reverse transcriptase inhibitors*

**CIDOFOVIR**

**Authority required (STREAMLINED)**

***3322***

Treatment of cytomegalovirus retinitis in patients with AIDS

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 5620T | cidofovir 375 mg/5 mL injection, 1 x 5 mL vial | 4 | 3 | .. | *3600.00 | | Vistide | GI |

**GANCICLOVIR**

**Authority required (STREAMLINED)**

***3379***

Cytomegalovirus retinitis in severely immunocompromised patients

**Authority required (STREAMLINED)**

***3380***

Prophylaxis of cytomegalovirus disease in bone marrow transplant patients at risk of cytomegalovirus disease

**Authority required (STREAMLINED)**

***3381***

Prophylaxis of cytomegalovirus disease in solid organ transplant patients at risk of cytomegalovirus disease

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 5749N | ganciclovir 500 mg injection, 5 x 500 mg vials | 2 | 1 | .. | *560.00 | | Cymevene | RO |

**VALACICLOVIR**

**Authority required (STREAMLINED)**

***3419***

Prophylaxis of cytomegalovirus (CMV) infection and disease following renal transplantation in patients at risk of CMV disease

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 9568N | valaciclovir 500 mg tablet, 100 | 5 | 2 | .. | *2100.00 | [a] | APO-Valaciclovir | TX |
| | | | | | | [a] | Valaciclovir RBX | RA |

# HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|
| | | | | | | [a] Valtrex | AS |
| | | | | | | [a] Zelitrex | GM |
| | **VALGANCICLOVIR** | | | | | | |
| | **Authority required (STREAMLINED)** | | | | | | |
| | ***3420*** | | | | | | |
| | Cytomegalovirus retinitis in patients with acquired immunodeficiency syndrome | | | | | | |
| | **Authority required (STREAMLINED)** | | | | | | |
| | ***3421*** | | | | | | |
| | Prophylaxis of cytomegalovirus infection and disease in solid organ transplant patients at risk of cytomegalovirus disease | | | | | | |
| 9569P | valganciclovir 450 mg tablet, 60 | 2 | 5 | .. | *4491.60 | Valcyte | RO |
| 9655E | valganciclovir 50 mg/mL oral liquid: powder for, 100 mL | 11 | 5 | .. | *4574.79 | Valcyte | RO |

## *Phosphonic acid derivatives*

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| | **FOSCARNET** | | | | | | |
| | **Authority required (STREAMLINED)** | | | | | | |
| | ***3322*** | | | | | | |
| | Treatment of cytomegalovirus retinitis in patients with AIDS | | | | | | |
| | **Authority required (STREAMLINED)** | | | | | | |
| | ***3378*** | | | | | | |
| | Treatment of aciclovir-resistant herpes simplex virus infection in immunocompromised patients with HIV infection | | | | | | |
| 5747L | FOSCARNET SODIUM I.V. infusion 24 mg per mL, 250 mL bottle, 6 | 1 | 1 | .. | 1177.50 | Foscavir | IX |

## *Protease inhibitors*

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| | **ATAZANAVIR** | | | | | | |
| | **Authority required (STREAMLINED)** | | | | | | |
| | ***3588*** | | | | | | |
| | Initial treatment of HIV infection in combination with other antiretroviral agents in a patient with a CD4 count of less than 500 per cubic millimetre or symptomatic HIV disease | | | | | | |
| | **Authority required (STREAMLINED)** | | | | | | |
| | ***3589*** | | | | | | |
| | Continuing treatment of HIV infection in combination with other antiretroviral agents where the patient has previously received PBS-subsidised therapy for HIV infection | | | | | | |
| 5615M | atazanavir 100 mg capsule, 60 | 2 | 5 | .. | *695.88 | Reyataz | BQ |
| 5613K | atazanavir 150 mg capsule, 60 | 2 | 5 | .. | *1043.82 | Reyataz | BQ |
| 5614L | atazanavir 200 mg capsule, 60 | 2 | 5 | .. | *1391.76 | Reyataz | BQ |
| 5612J | atazanavir 300 mg capsule, 30 | 2 | 5 | .. | *1043.82 | Reyataz | BQ |

**BOCEPREVIR**

**Authority required (STREAMLINED)**

***4182***

Chronic genotype 1 hepatitis C infection

**The Treatment criteria is:**

Must be treated in an accredited treatment centre,

**AND the Clinical criteria is:**

Patient must have compensated liver disease,

**AND the Clinical criteria is:**

Patient must have received no more than one prior treatment with interferon alfa or peginterferon alfa for hepatitis C,

**AND the Clinical criteria is:**

The treatment must be in combination with peginterferon alfa and ribavirin,

**AND the Clinical criteria is:**

The treatment must be limited to a maximum duration of 32 weeks in patients without hepatic cirrhosis who were partial responders or relapsers to the prior course of interferon based therapy for hepatitis C; OR

The treatment must be limited to a maximum duration of 44 weeks in patients without hepatic cirrhosis who were null responders to the prior course of interferon based therapy for hepatitis C; OR

The treatment must be limited to a maximum duration of 44 weeks for all patients with hepatic cirrhosis,

**AND the Clinical criteria is:**

The treatment must cease after the first 8 weeks of boceprevir treatment if plasma HCV RNA is detectable by an HCV RNA qualitative assay at treatment week 12,

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|---|---|---|---|---|---|---|---|

**AND the Clinical criteria is:**

The treatment must cease after the first 20 weeks of boceprevir treatment if plasma HCV RNA is detectable by an HCV RNA qualitative assay at treatment week 24,

**AND the Population criteria is:**

Patient must be 18 years or older,

**AND the Population criteria is:**

Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

Chronic genotype 1 hepatitis C infection (repeated anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records.

Patients who have received prior treatment with an NS3/4A protease inhibitor are not eligible to receive PBS-subsidised boceprevir, except where the patient has developed an intolerance to the other NS3/4A protease inhibitor of a severity necessitating permanent treatment withdrawal. Details of the intolerance must be documented in the patient's medical records.

For patients without hepatic cirrhosis who were partial responders or relapsers to the prior course of interferon based therapy, a maximum of 7 repeats may be prescribed.

For patients without hepatic cirrhosis who were null responders to the prior course of interferon based therapy, a maximum of 10 repeats may be prescribed.

For patients with hepatic cirrhosis, a maximum of 10 repeats may be prescribed.

**Authority required (STREAMLINED)**

***4202***

Chronic genotype 1 hepatitis C infection

**The Treatment criteria is:**

Must be treated in an accredited treatment centre,

**AND the Clinical criteria is:**

Patient must have compensated liver disease,

**AND the Clinical criteria is:**

Patient must not have received prior interferon alfa or peginterferon alfa treatment for hepatitis C,

**AND the Clinical criteria is:**

The treatment must be in combination with peginterferon alfa and ribavirin,

**AND the Clinical criteria is:**

The treatment must be limited to a maximum duration of 24 weeks in patients without hepatic cirrhosis; OR

The treatment must be limited to a maximum duration of 44 weeks in patients with hepatic cirrhosis,

**AND the Clinical criteria is:**

The treatment must cease after the first 20 weeks of boceprevir treatment if plasma HCV RNA is detectable by an HCV RNA qualitative assay at treatment week 24,

**AND the Population criteria is:**

Patient must be 18 years or older,

**AND the Population criteria is:**

Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

Evidence of chronic genotype 1 hepatitis C infection (repeated anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records.

Patients who have received prior treatment with an NS3/4A protease inhibitor are not eligible to receive PBS-subsidised boceprevir, except where the patient has developed an intolerance to the other NS3/4A protease inhibitor of a severity necessitating permanent treatment withdrawal. Details of the intolerance must be documented in the patient's medical records.

For patients without hepatic cirrhosis, a maximum of 5 repeats may be prescribed.

For patients with hepatic cirrhosis, a maximum of 10 repeats may be prescribed.

**Note**

No increase in the maximum quantity or number of units may be authorised.

**Note**

Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C:

(a) a nurse educator/counsellor for patients; and

(b) 24-hour access by patients to medical advice; and

(c) an established liver clinic.

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| 2433C | Boceprevir 200 mg capsule, 336 capsules | 1 | 10 | .. | 3920.00 | Victrelis | MK |

# HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|
| | **DARUNAVIR**<br>**Authority required (STREAMLINED)**<br>***3595***<br>Treatment of HIV infection, in addition to optimised background therapy in combination with other antiretroviral agents, and co-administered with 100 mg ritonavir twice daily in an antiretroviral experienced patient who, after at least one antiretroviral regimen, has experienced virological failure or clinical failure or genotypic resistance.<br>Virological failure is defined as a viral load greater than 400 copies per mL on two consecutive occasions, while clinical failure is linked to emerging signs and symptoms of progressing HIV infection or treatment-limiting toxicity | | | | | | |
| 5653M | darunavir 150 mg tablet, 240 | 1 | 5 | .. | 1048.71 | Prezista | JC |
| 3392M | darunavir 600 mg tablet, 60 | 2 | 5 | .. | *2097.42 | Prezista | JC |
| | **DARUNAVIR**<br>**Authority required (STREAMLINED)**<br>***3941***<br>Treatment of HIV infection, in addition to optimised background therapy in combination with other antiretroviral agents, and co-administered with 100 mg ritonavir in an antiretroviral experienced patient who, after at least one antiretroviral regimen, has experienced virological failure or clinical failure or genotypic resistance, and who has not demonstrated darunavir resistance associated mutations detected on resistance testing.<br>Virological failure is defined as a viral load greater than 400 copies per mL on two consecutive occasions, while clinical failure is linked to emerging signs and symptoms of progressing HIV infection or treatment-limiting toxicity | | | | | | |
| 5821J | darunavir 400 mg tablet, 60 | 2 | 5 | .. | *1398.28 | Prezista | JC |
| | **FOSAMPRENAVIR**<br>**Authority required (STREAMLINED)**<br>***3588***<br>Initial treatment of HIV infection in combination with other antiretroviral agents in a patient with a CD4 count of less than 500 per cubic millimetre or symptomatic HIV disease<br>**Authority required (STREAMLINED)**<br>***3589***<br>Continuing treatment of HIV infection in combination with other antiretroviral agents where the patient has previously received PBS-subsidised therapy for HIV infection | | | | | | |
| 5745J | fosamprenavir 50 mg/mL oral liquid, 225 mL | 8 | 5 | .. | *812.48 | Telzir | VI |
| 5746K | fosamprenavir 700 mg tablet, 60 | 2 | 5 | .. | *758.32 | Telzir | VI |
| | **INDINAVIR**<br>**Authority required (STREAMLINED)**<br>***3588***<br>Initial treatment of HIV infection in combination with other antiretroviral agents in a patient with a CD4 count of less than 500 per cubic millimetre or symptomatic HIV disease<br>**Authority required (STREAMLINED)**<br>***3589***<br>Continuing treatment of HIV infection in combination with other antiretroviral agents where the patient has previously received PBS-subsidised therapy for HIV infection | | | | | | |
| 5752R | indinavir 400 mg capsule, 180 | 2 | 5 | .. | *910.00 | Crixivan 400 mg | MK |
| | **RITONAVIR**<br>**Authority required (STREAMLINED)**<br>***3588***<br>Initial treatment of HIV infection in combination with other antiretroviral agents in a patient with a CD4 count of less than 500 per cubic millimetre or symptomatic HIV disease<br>**Authority required (STREAMLINED)**<br>***3589***<br>Continuing treatment of HIV infection in combination with other antiretroviral agents where the patient has previously received PBS-subsidised therapy for HIV infection | | | | | | |
| 9660K | ritonavir 100 mg tablet, 30 | 24 | 5 | .. | *982.80 | Norvir | VE |
| 9542F | ritonavir 600 mg/7.5 mL oral liquid, 90 mL | 10 | 5 | .. | *910.00 | Norvir | VE |
| | **SAQUINAVIR**<br>**Authority required (STREAMLINED)**<br>***3588***<br>Initial treatment of HIV infection in combination with other antiretroviral agents in a patient with a CD4 count of less than 500 per cubic millimetre or symptomatic HIV disease<br>**Authority required (STREAMLINED)**<br>***3589***<br>Continuing treatment of HIV infection in combination with other antiretroviral agents where the patient has previously received PBS-subsidised | | | | | | |

# HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|
| | therapy for HIV infection | | | | | | |
| 9545J | saquinavir 500 mg tablet, 120 | 2 | 5 | .. | *1011.12 | Invirase | RO |

**TELAPREVIR**

**Authority required (STREAMLINED)**

***4186***

Chronic genotype 1 hepatitis C infection

**The Treatment criteria is:**

Must be treated in an accredited treatment centre,

**AND the Clinical criteria is:**

Patient must have compensated liver disease,

**AND the Clinical criteria is:**

Patient must not have received prior treatment with interferon alfa or peginterferon alfa for hepatitis C,

**AND the Clinical criteria is:**

The treatment must be in combination with peginterferon alfa and ribavirin,

**AND the Clinical criteria is:**

The treatment must be limited to a maximum duration of 12 weeks,

**AND the Clinical criteria is:**

The treatment must cease if the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is greater than 1000 IU/mL,

**AND the Population criteria is:**

Patient must be 18 years or older,

**AND the Population criteria is:**

Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

Evidence of chronic genotype 1 hepatitis C infection (repeatedly anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records.

Patients who have received prior treatment with an NS3/4A protease inhibitor are not eligible to receive PBS-subsidised telaprevir, except where the patient has developed an intolerance to the other NS3/4A protease inhibitor of a severity necessitating permanent treatment withdrawal. Details of the intolerance must be documented in the patient's medical records.

**Authority required (STREAMLINED)**

***4191***

Chronic genotype 1 hepatitis C infection

**The Treatment criteria is:**

Must be treated in an accredited treatment centre,

**AND the Clinical criteria is:**

Patient must have compensated liver disease,

**AND the Clinical criteria is:**

Patient must have received prior treatment with interferon alfa or peginterferon alfa for hepatitis C,

**AND the Clinical criteria is:**

The treatment must be in combination with peginterferon alfa and ribavirin,

**AND the Clinical criteria is:**

The treatment must be limited to a maximum duration of 12 weeks,

**AND the Clinical criteria is:**

The treatment must cease if the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is greater than 1000 IU/mL,

**AND the Population criteria is:**

Patient must be 18 years or older,

**AND the Population criteria is:**

Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

Evidence of chronic genotype 1 hepatitis C infection (repeatedly anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records.

Patients who have received prior treatment with an NS3/4A protease inhibitor are not eligible to receive PBS-subsidised telaprevir, except where the patient has developed an intolerance to the other NS3/4A protease inhibitor of a severity necessitating permanent treatment withdrawal. Details of the intolerance must be documented in the patient's medical records.

**Note**

# HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|
| | No increase in the maximum quantity or number of units may be authorised. | | | | | | |
| | **Note**<br>No increase in the maximum number of repeats may be authorised. | | | | | | |
| | **Note**<br>Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C:<br>(a) a nurse educator/counsellor for patients; and<br>(b) 24-hour access by patients to medical advice; and<br>(c) an established liver clinic. | | | | | | |
| 2437G | telaprevir 375 mg tablet, 42 | 6 | .. | .. | *14865.72 | Incivo | JC |
| | **TIPRANAVIR**<br>**Authority required (STREAMLINED)**<br>***3601***<br>Treatment of HIV infection, in addition to optimised background therapy in combination with other antiretroviral agents, and co-administered with 200 mg ritonavir twice daily in an antiretroviral experienced patient who, after each of at least three different antiretroviral regimens that have included one drug from at least 3 different antiretroviral classes, has experienced virological failure or clinical failure or genotypic resistance.<br>Virological failure is defined as a viral load greater than 400 copies per mL on two consecutive occasions, while clinical failure is linked to emerging signs and symptoms of progressing HIV infection or treatment-limiting toxicity<br>**Note**<br>Special Pricing Arrangements apply. | | | | | | |
| 9567M | tipranavir 250 mg capsule, 120 | 2 | 5 | .. | *2142.00 | Aptivus | BY |

## *Nucleoside and nucleotide reverse transcriptase inhibitors*

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| | **ABACAVIR**<br>**Authority required (STREAMLINED)**<br>***3588***<br>Initial treatment of HIV infection in combination with other antiretroviral agents in a patient with a CD4 count of less than 500 per cubic millimetre or symptomatic HIV disease<br>**Authority required (STREAMLINED)**<br>***3589***<br>Continuing treatment of HIV infection in combination with other antiretroviral agents where the patient has previously received PBS-subsidised therapy for HIV infection | | | | | | |
| 5602W | abacavir 20 mg/mL oral liquid, 240 mL | 8 | 5 | .. | *657.12 | Ziagen | VI |
| 5601T | abacavir 300 mg tablet, 60 | 2 | 5 | .. | *564.00 | Ziagen | VI |
| | **ADEFOVIR DIPIVOXIL**<br>**Authority required (STREAMLINED)**<br>***3973***<br>Chronic hepatitis B in a patient without cirrhosis who has failed antihepadnaviral therapy and who satisfies all of the following criteria:<br>(a) Repeatedly elevated serum ALT levels while on concurrent antihepadnaviral therapy of greater than or equal to 6 months duration in conjunction with documented chronic hepatitis B infection; or<br>(b) Repeatedly elevated HBV DNA levels one log greater than the nadir value or failure to achieve a 1 log reduction in HBV DNA within 3 months, whilst on previous antihepadnaviral therapy except in patients with evidence of poor compliance<br>**Authority required (STREAMLINED)**<br>***3974***<br>Chronic hepatitis B in a patient with cirrhosis who has failed antihepadnaviral therapy and who has detectable HBV DNA.<br>Persons with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy<br>**Note**<br>Patients may receive treatment in combination with lamivudine but not with other PBS-subsidised antihepadnaviral therapy. | | | | | | |
| 5606C | adefovir dipivoxil 10 mg tablet, 30 | 2 | 5 | .. | *1250.00 | Hepsera | GI |
| | **DIDANOSINE**<br>**Authority required (STREAMLINED)**<br>***3588***<br>Initial treatment of HIV infection in combination with other antiretroviral agents in a patient with a CD4 count of less than 500 per cubic millimetre or symptomatic HIV disease<br>**Authority required (STREAMLINED)**<br>***3589***<br>Continuing treatment of HIV infection in combination with other antiretroviral agents where the patient has previously received PBS-subsidised therapy for HIV infection | | | | | | |

# HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|
| 5663C | didanosine 125 mg capsule: enteric, 30 | 2 | 5 | .. | *280.86 | | Videx EC | BQ |
| 5664D | didanosine 200 mg capsule: enteric, 30 | 2 | 5 | .. | *326.80 | | Videx EC | BQ |
| 5665E | didanosine 250 mg capsule: enteric, 30 | 2 | 5 | .. | *408.48 | | Videx EC | BQ |
| 5666F | didanosine 400 mg capsule: enteric, 30 | 2 | 5 | .. | *653.58 | | Videx EC | BQ |

**EMTRICITABINE**

**Authority required (STREAMLINED)**

***3588***

Initial treatment of HIV infection in combination with other antiretroviral agents in a patient with a CD4 count of less than 500 per cubic millimetre or symptomatic HIV disease

**Authority required (STREAMLINED)**

***3589***

Continuing treatment of HIV infection in combination with other antiretroviral agents where the patient has previously received PBS-subsidised therapy for HIV infection

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 5709L | emtricitabine 200 mg capsule, 30 | 2 | 5 | .. | *564.00 | | Emtriva | GI |

**ENTECAVIR**

**Authority required (STREAMLINED)**

***3964***

Chronic hepatitis B in a patient without cirrhosis who has failed lamivudine and who satisfies all of the following criteria:

(a) Repeatedly elevated serum ALT levels while on concurrent antihepadnaviral therapy of greater than or equal to 6 months duration in conjunction with documented chronic hepatitis B infection; or

(b) Repeatedly elevated HBV DNA levels one log greater than the nadir value or failure to achieve a 1 log reduction in HBV DNA within 3 months, whilst on previous antihepadnaviral therapy except in patients with evidence of poor compliance

**Authority required (STREAMLINED)**

***3966***

Chronic hepatitis B in a patient with cirrhosis who has failed lamivudine and who has detectable HBV DNA.

Persons with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy

**Note**

PBS-subsidised entecavir monohydrate must be used as monotherapy.

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 5712P | entecavir monohydrate 1 mg tablet, 30 | 2 | 5 | .. | *1250.00 | | Baraclude | BQ |

**ENTECAVIR**

**Authority required (STREAMLINED)**

***3961***

Chronic hepatitis B in a patient without cirrhosis who satisfies all of the following criteria:

(1) Elevated HBV DNA levels - greater than 20,000 IU/mL (100,000 copies/mL) if HBeAg positive, or greater than 2,000 IU/mL (10,000 copies/mL) if HBeAg negative - in conjunction with documented chronic hepatitis B infection;

(2) Evidence of chronic liver injury as determined by:

(a) Confirmed elevated serum ALT; or

(b) Liver biopsy

**Authority required (STREAMLINED)**

***3962***

Chronic hepatitis B in a patient with cirrhosis who has detectable HBV DNA.

Persons with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy

**Note**

PBS-subsidised entecavir monohydrate must be used as monotherapy.

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 5711N | entecavir monohydrate 500 microgram tablet, 30 | 2 | 5 | .. | *768.60 | | Baraclude | BQ |

**LAMIVUDINE**

**Authority required (STREAMLINED)**

***3588***

Initial treatment of HIV infection in combination with other antiretroviral agents in a patient with a CD4 count of less than 500 per cubic millimetre or symptomatic HIV disease

**Authority required (STREAMLINED)**

***3589***

Continuing treatment of HIV infection in combination with other antiretroviral agents where the patient has previously received PBS-subsidised therapy for HIV infection

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 5773W | lamivudine 10 mg/mL oral liquid, 240 mL | 8 | 5 | .. | *691.84 | | 3TC | VI |
| 5772T | lamivudine 150 mg tablet, 60 | 2 | 5 | .. | *473.78 | [a] | 3TC | VI |

# HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|
| | | | | | | [a] | Lamivudine Alphapharm | AF |
| | | | | | | [a] | Lamivudine RBX | RA |
| 5774X | lamivudine 300 mg tablet, 30 | 2 | 5 | .. | *473.78 | [a] | 3TC | VI |
| | | | | | | [a] | Lamivudine Alphapharm | AF |
| | | | | | | [a] | Lamivudine RBX | RA |

**LAMIVUDINE**

**Authority required (STREAMLINED)**

***3961***

Chronic hepatitis B in a patient without cirrhosis who satisfies all of the following criteria:

(1) Elevated HBV DNA levels - greater than 20,000 IU/mL (100,000 copies/mL) if HBeAg positive, or greater than 2,000 IU/mL (10,000 copies/mL) if HBeAg negative - in conjunction with documented chronic hepatitis B infection;

(2) Evidence of chronic liver injury as determined by:

(a) Confirmed elevated serum ALT; or

(b) Liver biopsy

**Authority required (STREAMLINED)**

***3962***

Chronic hepatitis B in a patient with cirrhosis who has detectable HBV DNA.

Persons with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 5770Q | lamivudine 100 mg tablet, 28 | 2 | 5 | .. | *250.94 | [a] | Zeffix | AS |
| | | | | | | [a] | Zetlam | AF |
| 5771R | lamivudine 5 mg/mL oral liquid, 240 mL | 5 | 5 | .. | *349.55 | | Zeffix | AS |

**STAVUDINE**

**Authority required (STREAMLINED)**

***3588***

Initial treatment of HIV infection in combination with other antiretroviral agents in a patient with a CD4 count of less than 500 per cubic millimetre or symptomatic HIV disease

**Authority required (STREAMLINED)**

***3589***

Continuing treatment of HIV infection in combination with other antiretroviral agents where the patient has previously received PBS-subsidised therapy for HIV infection

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| 9553T | stavudine 20 mg capsule, 60 | 2 | 5 | .. | *560.00 | Zerit | BQ |
| 9554W | stavudine 30 mg capsule, 60 | 2 | 5 | .. | *667.36 | Zerit | BQ |
| 9556Y | stavudine 40 mg capsule, 60 | 2 | 5 | .. | *889.80 | Zerit | BQ |

**TELBIVUDINE**

**Authority required (STREAMLINED)**

***3969***

Treatment, as sole PBS-subsidised therapy, in a patient with chronic hepatitis B without cirrhosis who is nucleoside analogue naive and satisfies all of the following criteria:

(1) Elevated HBV DNA levels - greater than 20,000 IU/mL (100,000 copies/mL) if HBeAg positive, or greater than 2,000 IU/mL (10,000 copies/mL) if HBeAg negative - in conjunction with documented hepatitis B infection;

(2) Evidence of chronic liver injury as determined by:

(a) Confirmed elevated serum ALT; or

(b) Liver biopsy

**Authority required (STREAMLINED)**

***3970***

Treatment, as sole PBS-subsidised therapy, in a patient with chronic hepatitis B with cirrhosis who is nucleoside analogue naive and who has detectable HBV DNA.

Persons with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| 9562G | telbivudine 600 mg tablet, 28 | 2 | 5 | .. | *501.76 | Sebivo | NV |

**TENOFOVIR**

**Authority required (STREAMLINED)**

***3588***

Initial treatment of HIV infection in combination with other antiretroviral agents in a patient with a CD4 count of less than 500 per cubic millimetre or symptomatic HIV disease

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|
| | **Authority required (STREAMLINED)**<br>***3589***<br>Continuing treatment of HIV infection in combination with other antiretroviral agents where the patient has previously received PBS-subsidised therapy for HIV infection | | | | | | |
| | **Authority required (STREAMLINED)**<br>***3969***<br>Treatment, as sole PBS-subsidised therapy, in a patient with chronic hepatitis B without cirrhosis who is nucleoside analogue naive and satisfies all of the following criteria:<br>(1) Elevated HBV DNA levels - greater than 20,000 IU/mL (100,000 copies/mL) if HBeAg positive, or greater than 2,000 IU/mL (10,000 copies/mL) if HBeAg negative - in conjunction with documented hepatitis B infection;<br>(2) Evidence of chronic liver injury as determined by:<br>(a) Confirmed elevated serum ALT; or<br>(b) Liver biopsy | | | | | | |
| | **Authority required (STREAMLINED)**<br>***3970***<br>Treatment, as sole PBS-subsidised therapy, in a patient with chronic hepatitis B with cirrhosis who is nucleoside analogue naive and who has detectable HBV DNA.<br>Persons with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy | | | | | | |
| | **Authority required (STREAMLINED)**<br>***3973***<br>Chronic hepatitis B in a patient without cirrhosis who has failed antihepadnaviral therapy and who satisfies all of the following criteria:<br>(a) Repeatedly elevated serum ALT levels while on concurrent antihepadnaviral therapy of greater than or equal to 6 months duration in conjunction with documented chronic hepatitis B infection; or<br>(b) Repeatedly elevated HBV DNA levels one log greater than the nadir value or failure to achieve a 1 log reduction in HBV DNA within 3 months, whilst on previous antihepadnaviral therapy except in patients with evidence of poor compliance | | | | | | |
| | **Authority required (STREAMLINED)**<br>***3974***<br>Chronic hepatitis B in a patient with cirrhosis who has failed antihepadnaviral therapy and who has detectable HBV DNA.<br>Persons with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy | | | | | | |
| | **Note**<br>Patients may receive treatment in combination with lamivudine but not with other PBS-subsidised antihepadnaviral therapy. | | | | | | |
| 9563H | tenofovir disoproxil fumarate 300 mg tablet, 30 | 2 | 5 | .. | *966.20 | Viread | GI |
| | **ZIDOVUDINE**<br>**Authority required (STREAMLINED)**<br>***3588***<br>Initial treatment of HIV infection in combination with other antiretroviral agents in a patient with a CD4 count of less than 500 per cubic millimetre or symptomatic HIV disease | | | | | | |
| | **Authority required (STREAMLINED)**<br>***3589***<br>Continuing treatment of HIV infection in combination with other antiretroviral agents where the patient has previously received PBS-subsidised therapy for HIV infection | | | | | | |
| 9651Y | zidovudine 100 mg capsule, 100 | 4 | 5 | .. | *821.84 | Retrovir | VI |
| 9652B | zidovudine 250 mg capsule, 40 | 6 | 5 | .. | *1232.76 | Retrovir | VI |
| 9570Q | zidovudine 50 mg/5 mL oral liquid, 200 mL | 15 | 5 | .. | *673.20 | Retrovir | VI |
| | ***Non-nucleoside reverse transcriptase inhibitors*** | | | | | | |
| | **EFAVIRENZ**<br>**Authority required (STREAMLINED)**<br>***3588***<br>Initial treatment of HIV infection in combination with other antiretroviral agents in a patient with a CD4 count of less than 500 per cubic millimetre or symptomatic HIV disease | | | | | | |
| | **Authority required (STREAMLINED)**<br>***3589***<br>Continuing treatment of HIV infection in combination with other antiretroviral agents where the patient has previously received PBS-subsidised therapy for HIV infection | | | | | | |
| 5708K | efavirenz 200 mg tablet, 90 | 2 | 5 | .. | *543.16 | Stocrin | MK |
| 5707J | efavirenz 30 mg/mL oral liquid, 180 mL | 7 | 5 | .. | *570.29 | Stocrin | MK |
| 5706H | efavirenz 600 mg tablet, 30 | 2 | 5 | .. | *543.16 | Stocrin | MK |

# HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|
| | **ETRAVIRINE** | | | | | | | |
| | **Authority required (STREAMLINED)** | | | | | | | |
| | ***3597*** | | | | | | | |
| | Treatment of HIV infection, in addition to optimised background therapy in combination with other antiretroviral agents in an antiretroviral experienced patient who, after each of at least three different antiretroviral regimens that have included one drug from at least 3 different antiretroviral classes, has experienced virological failure or clinical failure or genotypic resistance. | | | | | | | |
| | Virological failure is defined as a viral load greater than 400 copies per mL on two consecutive occasions, while clinical failure is linked to emerging signs and symptoms of progressing HIV infection or treatment-limiting toxicity | | | | | | | |
| 5084N | etravirine 200 mg tablet, 60 | 2 | 5 | .. | *1233.00 | | Intelence | JC |
| | **NEVIRAPINE** | | | | | | | |
| | **Authority required (STREAMLINED)** | | | | | | | |
| | ***3588*** | | | | | | | |
| | Initial treatment of HIV infection in combination with other antiretroviral agents in a patient with a CD4 count of less than 500 per cubic millimetre or symptomatic HIV disease | | | | | | | |
| | **Authority required (STREAMLINED)** | | | | | | | |
| | ***3589*** | | | | | | | |
| | Continuing treatment of HIV infection in combination with other antiretroviral agents where the patient has previously received PBS-subsidised therapy for HIV infection | | | | | | | |
| 9507J | nevirapine 10 mg/mL oral liquid, 240 mL | 10 | 5 | .. | *1350.00 | | Viramune | BY |
| 9506H | nevirapine 200 mg tablet, 60 | 2 | 5 | .. | *456.26 | [a] | Nevirapine Alphapharm | AF |
| | | | | | | [a] | Nevirapine RBX | RA |
| | | | | | | [a] | Viramune | BY |
| | **NEVIRAPINE** | | | | | | | |
| | **Authority required (STREAMLINED)** | | | | | | | |
| | ***3995*** | | | | | | | |
| | Initial treatment of HIV infection in combination with other antiretroviral agents in a patient who has been stabilised on nevirapine immediate release with a CD4 count of less than 500 per cubic millimetre or symptomatic HIV disease | | | | | | | |
| | **Authority required (STREAMLINED)** | | | | | | | |
| | ***3589*** | | | | | | | |
| | Continuing treatment of HIV infection in combination with other antiretroviral agents where the patient has previously received PBS-subsidised therapy for HIV infection | | | | | | | |
| 1132N | nevirapine 400 mg tablet: modified release, 30 tablets | 2 | 5 | .. | *456.26 | | Viramune XR | BY |
| | **RILPIVIRINE** | | | | | | | |
| | **Authority required (STREAMLINED)** | | | | | | | |
| | ***3588*** | | | | | | | |
| | Initial treatment of HIV infection in combination with other antiretroviral agents in a patient with a CD4 count of less than 500 per cubic millimetre or symptomatic HIV disease | | | | | | | |
| | **Authority required (STREAMLINED)** | | | | | | | |
| | ***3589*** | | | | | | | |
| | Continuing treatment of HIV infection in combination with other antiretroviral agents where the patient has previously received PBS-subsidised therapy for HIV infection | | | | | | | |
| 1173R | rilpivirine 25 mg tablet, 30 | 2 | 5 | .. | *543.16 | | Edurant | JC |

## *Antivirals for treatment of HIV infections, combinations*

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | **ABACAVIR + LAMIVUDINE** | | | | | | | |
| | **Authority required (STREAMLINED)** | | | | | | | |
| | ***3592*** | | | | | | | |
| | Initial treatment of HIV infection in combination with other antiretroviral agents in a patient over 12 years of age, weighing 40 kg or more, with a CD4 count of less than 500 per cubic millimetre or symptomatic HIV disease | | | | | | | |
| | **Authority required (STREAMLINED)** | | | | | | | |
| | ***3593*** | | | | | | | |
| | Continuing treatment of HIV infection in combination with other antiretroviral agents where the patient over 12 years of age, weighing 40 kg or more, has previously received PBS-subsidised therapy for HIV infection | | | | | | | |
| 5603X | abacavir 600 mg + lamivudine 300 mg tablet, 30 | 2 | 5 | .. | *1037.78 | | Kivexa | VI |
| | **ABACAVIR + LAMIVUDINE + ZIDOVUDINE** | | | | | | | |
| | **Authority required (STREAMLINED)** | | | | | | | |
| | ***3981*** | | | | | | | |
| | Initial treatment of HIV infection in a patient over 12 years of age, weighing 40 kg or more, with a CD4 count of less than 500 per cubic millimetre or symptomatic HIV disease | | | | | | | |
| | **Authority required (STREAMLINED)** | | | | | | | |

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|
| | ***3982*** | | | | | | | |
| | Continuing treatment of HIV infection where the patient over 12 years of age, weighing 40 kg or more, has previously received PBS-subsidised therapy for HIV infection | | | | | | | |
| 5604Y | abacavir 300 mg + lamivudine 150 mg + zidovudine 300 mg tablet, 60 | 2 | 5 | .. | *1614.66 | | Trizivir | VI |
| | **EMTRICITABINE + RILPIVIRINE + TENOFOVIR** | | | | | | | |
| | **Authority required (STREAMLINED)** | | | | | | | |
| | ***3985*** | | | | | | | |
| | Initial treatment of HIV infection in a patient with a CD4 count of less than 500 per cubic millimetre or symptomatic HIV disease | | | | | | | |
| | **Authority required (STREAMLINED)** | | | | | | | |
| | ***3986*** | | | | | | | |
| | Continuing treatment of HIV infection where the patient has previously received PBS-subsidised therapy for HIV infection | | | | | | | |
| 1491L | emtricitabine 200 mg + rilpivirine 25 mg + tenofovir disoproxil fumarate 300 mg tablet, 30 | 2 | 5 | .. | *2073.36 | | Eviplera | GI |
| | **LAMIVUDINE + ZIDOVUDINE** | | | | | | | |
| | **Authority required (STREAMLINED)** | | | | | | | |
| | ***3588*** | | | | | | | |
| | Initial treatment of HIV infection in combination with other antiretroviral agents in a patient with a CD4 count of less than 500 per cubic millimetre or symptomatic HIV disease | | | | | | | |
| | **Authority required (STREAMLINED)** | | | | | | | |
| | ***3589*** | | | | | | | |
| | Continuing treatment of HIV infection in combination with other antiretroviral agents where the patient has previously received PBS-subsidised therapy for HIV infection | | | | | | | |
| 5775Y | lamivudine 150 mg + zidovudine 300 mg tablet, 60 | 2 | 5 | .. | *968.34 | [a] | Combivir | VI |
| | | | | | | [a] | Lamivudine 150 mg + Zidovudine 300 mg Alphapharm | AF |
| | **LOPINAVIR + RITONAVIR** | | | | | | | |
| | **Authority required (STREAMLINED)** | | | | | | | |
| | ***3588*** | | | | | | | |
| | Initial treatment of HIV infection in combination with other antiretroviral agents in a patient with a CD4 count of less than 500 per cubic millimetre or symptomatic HIV disease | | | | | | | |
| | **Authority required (STREAMLINED)** | | | | | | | |
| | ***3589*** | | | | | | | |
| | Continuing treatment of HIV infection in combination with other antiretroviral agents where the patient has previously received PBS-subsidised therapy for HIV infection | | | | | | | |
| 5790R | lopinavir 100 mg + ritonavir 25 mg tablet, 60 | 2 | 5 | .. | *342.50 | | Kaletra | VE |
| 5791T | lopinavir 200 mg + ritonavir 50 mg tablet, 120 | 2 | 5 | .. | *1370.00 | | Kaletra | VE |
| 5789Q | lopinavir 400 mg/5 mL + ritonavir 100 mg/5 mL oral liquid, 60 mL | 10 | 5 | .. | *1290.00 | | Kaletra | VE |
| | **TENOFOVIR + EMTRICITABINE** | | | | | | | |
| | **Authority required (STREAMLINED)** | | | | | | | |
| | ***3588*** | | | | | | | |
| | Initial treatment of HIV infection in combination with other antiretroviral agents in a patient with a CD4 count of less than 500 per cubic millimetre or symptomatic HIV disease | | | | | | | |
| | **Authority required (STREAMLINED)** | | | | | | | |
| | ***3589*** | | | | | | | |
| | Continuing treatment of HIV infection in combination with other antiretroviral agents where the patient has previously received PBS-subsidised therapy for HIV infection | | | | | | | |
| 9564J | tenofovir disoproxil fumarate 300 mg + emtricitabine 200 mg tablet, 30 | 2 | 5 | .. | *1530.20 | | Truvada | GI |
| | **TENOFOVIR + EMTRICITABINE + EFAVIRENZ** | | | | | | | |
| | **Authority required (STREAMLINED)** | | | | | | | |
| | ***3985*** | | | | | | | |
| | Initial treatment of HIV infection in a patient with a CD4 count of less than 500 per cubic millimetre or symptomatic HIV disease | | | | | | | |
| | **Authority required (STREAMLINED)** | | | | | | | |
| | ***3986*** | | | | | | | |
| | Continuing treatment of HIV infection where the patient has previously received PBS-subsidised therapy for HIV infection | | | | | | | |
| 9565K | tenofovir disoproxil fumarate 300 mg + emtricitabine 200 mg + efavirenz 600 mg tablet, 30 | 2 | 5 | .. | *2073.36 | | Atripla | GI |

# HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

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|---|---|---|---|---|---|---|---|
| | ***Other antivirals*** | | | | | | |
| | **ENFUVIRTIDE** | | | | | | |
| | **Authority required (STREAMLINED)** | | | | | | |
| | ***3597*** | | | | | | |
| | Treatment of HIV infection, in addition to optimised background therapy in combination with other antiretroviral agents in an antiretroviral experienced patient who, after each of at least three different antiretroviral regimens that have included one drug from at least 3 different antiretroviral classes, has experienced virological failure or clinical failure or genotypic resistance. | | | | | | |
| | Virological failure is defined as a viral load greater than 400 copies per mL on two consecutive occasions, while clinical failure is linked to emerging signs and symptoms of progressing HIV infection or treatment-limiting toxicity | | | | | | |
| 5710M | enfuvirtide 90 mg injection [60 x 90 mg vials] (&) inert substance diluent [60 x 1.1 mL vials], 1 pack | 2 | 5 | .. | *4426.00 | Fuzeon | RO |
| | **MARAVIROC** | | | | | | |
| | **Authority required (STREAMLINED)** | | | | | | |
| | ***3599*** | | | | | | |
| | Treatment, in addition to optimised background therapy in combination with other antiretroviral agents, of an antiretroviral experienced patient infected with only CCR5-tropic HIV-1, who, after each of at least three different antiretroviral regimens that have included one drug from at least 3 different antiretroviral classes, has experienced virological failure or clinical failure or genotypic resistance. A tropism assay to determine CCR5 only strain status is required prior to initiation. Individuals with CXCR4 tropism demonstrated at any time point are not eligible. | | | | | | |
| | Virological failure is defined as a viral load greater than 400 copies per mL on two consecutive occasions, while clinical failure is linked to emerging signs and symptoms of progressing HIV infection or treatment-limiting toxicity | | | | | | |
| 5792W | maraviroc 150 mg tablet, 60 | 2 | 5 | .. | *1835.40 | Celsentri | VI |
| 5793X | maraviroc 300 mg tablet, 60 | 2 | 5 | .. | *1835.40 | Celsentri | VI |
| | **RALTEGRAVIR** | | | | | | |
| | **Authority required (STREAMLINED)** | | | | | | |
| | ***3588*** | | | | | | |
| | Initial treatment of HIV infection in combination with other antiretroviral agents in a patient with a CD4 count of less than 500 per cubic millimetre or symptomatic HIV disease | | | | | | |
| | **Authority required (STREAMLINED)** | | | | | | |
| | ***3589*** | | | | | | |
| | Continuing treatment of HIV infection in combination with other antiretroviral agents where the patient has previously received PBS-subsidised therapy for HIV infection | | | | | | |
| 9523F | raltegravir 400 mg tablet, 60 | 2 | 5 | .. | *1331.10 | Isentress | MK |

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|---|---|---|---|---|---|---|---|

# ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

## ANTINEOPLASTIC AGENTS

### ANTIMETABOLITES

#### *Pyrimidine analogues*

**AZACITIDINE**

**Authority required**

Initial PBS-subsidised treatment of a patient with:

(1) Myelodysplastic syndrome classified as Intermediate-2 or high risk according to the International Prognostic Scoring System (IPSS); OR

(2) Chronic Myelomonocytic Leukaemia (10% to 29% marrow blasts without Myeloproliferative Disorder); OR

(3) Acute Myeloid Leukaemia with 20 to 30% marrow blasts and multi-lineage dysplasia, according to World Health Organisation (WHO) Classification.

Classification of a patient as Intermediate-2 requires a score of 1.5 to 2.0 on the IPSS, achieved with the possible combinations:

1. 11% to 30% marrow blasts with good karyotypic status (normal, -Y alone, del(5q) alone, del(20q) alone), and 0 to 1 cytopenias; OR
2. 11% to 20% marrow blasts with intermediate karyotypic status (other abnormalities), and 0 to 1 cytopenias; OR
3. 11% to 20% marrow blasts with good karyotypic status (normal, -Y alone, del(5q) alone, del(20q) alone), and 2 to 3 cytopenias; OR
4. 5% to 10% marrow blasts with poor karyotypic status (3 or more abnormalities or chromosome 7 anomalies), regardless of cytopenias; OR
5. 5% to 10% marrow blasts with intermediate karyotypic status (other abnormalities), and 2 to 3 cytopenias; OR
6. less than 5% marrow blasts with poor karyotypic status (3 or more abnormalities or chromosome 7 anomalies), and 2 to 3 cytopenias.

Classification of a patient as high risk requires a score of 2.5 or more on the IPSS, achieved with the possible combinations:

1. 21% to 30% marrow blasts with good karyotypic status (normal, -Y alone, del(5q) alone, del(20q) alone), and 2 to 3 cytopenias; OR
2. 21% to 30% marrow blasts with intermediate (other abnormalities) or poor karyotypic status (3 or more abnormalities or chromosome 7 anomalies), regardless of cytopenias; OR
3. 11% to 20% marrow blasts with poor karyotypic status (3 or more abnormalities or chromosome 7 anomalies), regardless of cytopenias; OR
4. 11% to 20% marrow blasts with intermediate karyotypic status (other abnormalities), and 2 to 3 cytopenias.

The first authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Azacitidine PBS Authority Application - Supporting Information Form; and

(c) a copy of the bone marrow biopsy report demonstrating that the patient has myelodysplastic syndrome, chronic myelomonocytic leukaemia or acute myeloid leukaemia; and

(d) a copy of the full blood examination report; and

(e) for myelodysplastic syndrome, a copy of the pathology report detailing the cytogenetics demonstrating intermediate-2 or high risk disease according to the International Prognostic Scoring System (IPSS); and

(f) a signed patient acknowledgment form.

No more than three cycles will be authorised

**Note**

Any queries concerning the arrangements to prescribe azacitidine may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe azacitidine should be forwarded to:

Medicare Australia

Prior Written Approval of Specialised Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

**Note**

Special Pricing Arrangements apply.

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| 9597D | azacitidine 100 mg injection, 1 x 100 mg vial | 14 | 2 | .. | *7700.00 | Vidaza | CJ |

**AZACITIDINE**

**Authority required**

Continuing treatment of a patient with:

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|---|---|---|---|---|---|---|---|
| | (1) Myelodysplastic syndrome classified as Intermediate-2 or high risk according to the International Prognostic Scoring System (IPSS); OR | | | | | | |
| | (2) Chronic Myelomonocytic Leukaemia (10% to 29% marrow blasts without Myeloproliferative Disorder); OR | | | | | | |
| | (3) Acute Myeloid Leukaemia with 20 to 30% blasts and multi-lineage dysplasia, according to World Health Organisation (WHO) Classification; | | | | | | |
| | who has previously been issued with an authority prescription for azacitidine and does not have progressive disease. | | | | | | |
| | Authority applications for continuing treatment may be made by telephone on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). | | | | | | |
| | Up to six cycles will be authorised | | | | | | |
| | **Note** | | | | | | |
| | Any queries concerning the arrangements to prescribe azacitidine may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). | | | | | | |
| | Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au. | | | | | | |
| | Written applications for authority to prescribe azacitidine should be forwarded to: | | | | | | |
| | Medicare Australia | | | | | | |
| | Prior Written Approval of Specialised Drugs | | | | | | |
| | Reply Paid 9826 | | | | | | |
| | GPO Box 9826 | | | | | | |
| | HOBART TAS 7001 | | | | | | |
| | **Note** | | | | | | |
| | Special Pricing Arrangements apply. | | | | | | |
| 9598E | azacitidine 100 mg injection, 1 x 100 mg vial | 14 | 5 | .. | *7700.00 | Vidaza | CJ |

## CYTOTOXIC ANTIBIOTICS AND RELATED SUBSTANCES

### *Anthracyclines and related substances*

**DOXORUBICIN HYDROCHLORIDE-PEGYLATED LIPOSOMAL**

**Authority required (STREAMLINED)**

***3348***

Treatment of AIDS-related Kaposi's sarcoma in patients with CD4 cell counts of less than 200 per cubic millimetre and extensive mucocutaneous involvement

**Authority required (STREAMLINED)**

***3349***

Treatment of AIDS-related Kaposi's sarcoma in patients with CD4 cell counts of less than 200 per cubic millimetre and extensive visceral involvement

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| 5705G | doxorubicin hydrochloride-pegylated liposomal 20 mg/10 mL injection, 1 x 10 mL vial | 4 | 5 | .. | *2491.96 | Caelyx | JC |
| | | | | | | Lipodox | ZF |

## IMMUNOSTIMULANTS

## IMMUNOSTIMULANTS

### *Colony stimulating factors*

**FILGRASTIM**

**Authority required (STREAMLINED)**

***3357***

For use in a patient undergoing induction and consolidation therapy for acute myeloid leukaemia

**Authority required (STREAMLINED)**

***3358***

Mobilisation of peripheral blood progenitor cells to facilitate harvest of such cells for autologous transplantation into a patient with a non-myeloid malignancy who has had myeloablative or myelosuppressive therapy

**Authority required (STREAMLINED)**

***3359***

Mobilisation of peripheral blood progenitor cells, in a normal volunteer, for use in allogeneic transplantation

**Authority required (STREAMLINED)**

***3360***

A patient receiving marrow-ablative chemotherapy and subsequent bone marrow transplantation

**Authority required (STREAMLINED)**

***3361***

A patient with a non-myeloid malignancy receiving marrow-ablative chemotherapy and subsequent autologous peripheral blood progenitor cell transplantation

**Authority required (STREAMLINED)**

***3368***

# HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

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|---|---|---|---|---|---|---|

A patient with chronic cyclic neutropenia (absolute neutrophil count of less than 500 million cells per litre lasting for 3 days per cycle, measured over 3 separate cycles, and, either having experienced a life-threatening infectious episode requiring hospitalisation and treatment with intravenous antibiotics, or having recurrent clinically significant infections (a minimum of 3 in the previous 12 months))

**Authority required (STREAMLINED)**

***3369***

A patient with inoperable Stage III, IVa or IVb squamous cell carcinoma of the oral cavity, larynx, oropharynx or hypopharynx receiving neoadjuvant treatment with docetaxel in combination with cisplatin and fluorouracil who has had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned

**Authority required (STREAMLINED)**

***3362***

A patient with breast cancer receiving standard dose adjuvant chemotherapy who has had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned

**Authority required (STREAMLINED)**

***3363***

A patient receiving chemotherapy for B-cell chronic lymphocytic leukaemia with fludarabine and cyclophosphamide who has had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned

**Authority required (STREAMLINED)**

***3364***

A patient receiving first-line chemotherapy for Hodgkin disease who has had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned

**Authority required (STREAMLINED)**

***3365***

A patient receiving chemotherapy for myeloma who has had a prior episode of febrile neutropenia, and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned

**Authority required (STREAMLINED)**

***3366***

A patient with severe congenital neutropenia (absolute neutrophil count of less than 100 million cells per litre measured on 3 occasions, with readings at least 2 weeks apart, and in whom a bone marrow examination has shown evidence of maturational arrest of the neutrophil lineage)

**Authority required (STREAMLINED)**

***3367***

A patient with severe chronic neutropenia (absolute neutrophil count of less than 1,000 million cells per litre measured on 3 occasions, with readings at least 2 weeks apart, or evidence of neutrophil dysfunction, and, either having experienced a life-threatening infectious episode requiring hospitalisation and treatment with intravenous antibiotics in the previous 12 months, or having recurrent clinically significant infections (a minimum of 3 in the previous 12 months))

**Authority required (STREAMLINED)**

***3370***

A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in acute lymphoblastic leukaemia

**Authority required (STREAMLINED)**

***3371***

A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in breast cancer (adjuvant chemotherapy with docetaxel in combination with an anthracycline and cyclophosphamide)

**Authority required (STREAMLINED)**

***3372***

A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in germ cell tumours

**Authority required (STREAMLINED)**

***3373***

A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in infants and children with CNS tumours

**Authority required (STREAMLINED)**

***3374***

A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in neuroblastoma

**Authority required (STREAMLINED)**

***3375***

A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in non-Hodgkin lymphoma

# HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

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|---|---|---|---|---|---|---|---|
| | (aggressive grades; or low grade receiving an anthracycline-containing regimen) | | | | | | |
| | **Authority required (STREAMLINED)** | | | | | | |
| | ***3376*** | | | | | | |
| | A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in relapsed Hodgkin disease | | | | | | |
| | **Authority required (STREAMLINED)** | | | | | | |
| | ***3377*** | | | | | | |
| | A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in sarcoma | | | | | | |
| | **Authority required (STREAMLINED)** | | | | | | |
| | ***3834*** | | | | | | |
| | A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in Hodgkin disease (first-line chemotherapy with escalated BEACOPP) | | | | | | |
| 5829T | filgrastim 120 microgram/0.2 mL injection, 10 x 0.2 mL syringes | 2 | 11 | .. | *1006.22 | Nivestim | HH |
| 1123D | filgrastim 300 microgram/0.5 mL injection, 10 x 0.5 mL syringes | 2 | 11 | .. | *2515.54 | TevaGrastim | AS |
| 5742F | filgrastim 300 microgram/0.5 mL injection, 10 x 0.5 mL syringes | 2 | 11 | .. | *2515.54 | Neupogen | AN |
| 9692D | filgrastim 300 microgram/0.5 mL injection, 10 x 0.5 mL syringes | 2 | 11 | .. | *2515.54 | Nivestim | HH |
| 5741E | filgrastim 300 microgram/mL injection, 10 x 1 mL vials | 2 | 11 | .. | *2515.54 | Neupogen | AN |
| 5744H | filgrastim 480 microgram/0.5 mL injection, 10 x 0.5 mL syringes | 2 | 11 | .. | *4032.58 | Neupogen | AN |
| 9694F | filgrastim 480 microgram/0.5 mL injection, 10 x 0.5 mL syringes | 2 | 11 | .. | *4032.58 | Nivestim | HH |
| 1126G | filgrastim 480 microgram/0.8 mL injection, 10 x 0.8 mL syringes | 2 | 11 | .. | *4032.58 | TevaGrastim | AS |
| 5743G | filgrastim 480 microgram/1.6 mL injection, 10 x 1.6 mL vials | 2 | 11 | .. | *4032.58 | Neupogen | AN |
| | **LENOGRASTIM** | | | | | | |
| | **Authority required (STREAMLINED)** | | | | | | |
| | ***3395*** | | | | | | |
| | Patients with breast cancer receiving standard dose adjuvant chemotherapy who have had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned | | | | | | |
| | **Authority required (STREAMLINED)** | | | | | | |
| | ***3396*** | | | | | | |
| | Patients receiving first-line chemotherapy for Hodgkin's disease who have had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned | | | | | | |
| | **Authority required (STREAMLINED)** | | | | | | |
| | ***3392*** | | | | | | |
| | Mobilisation of peripheral blood progenitor cells to facilitate harvest of such cells for reinfusion into patients with non-myeloid malignancies who have had myeloablative or myelosuppressive therapy | | | | | | |
| | **Authority required (STREAMLINED)** | | | | | | |
| | ***3393*** | | | | | | |
| | Mobilisation of peripheral blood progenitor cells, in normal volunteers, for use in allogeneic transplantation to facilitate harvest of such cells in healthy donors | | | | | | |
| | **Authority required (STREAMLINED)** | | | | | | |
| | ***3394*** | | | | | | |
| | Patients with non-myeloid malignancies receiving marrow-ablative chemotherapy and subsequent peripheral blood progenitor cell or bone marrow transplantation | | | | | | |
| | **Authority required (STREAMLINED)** | | | | | | |
| | ***3397*** | | | | | | |
| | Patients being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in acute lymphoblastic leukaemia | | | | | | |
| | **Authority required (STREAMLINED)** | | | | | | |
| | ***3398*** | | | | | | |
| | Patients being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in Ewing's sarcoma | | | | | | |
| | **Authority required (STREAMLINED)** | | | | | | |
| | ***3399*** | | | | | | |
| | Patients being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in germ cell tumours | | | | | | |
| | **Authority required (STREAMLINED)** | | | | | | |

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|---|---|---|---|---|---|---|---|
| | ***3400*** | | | | | | |
| | Patients being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in infants and children with CNS tumours | | | | | | |
| | **Authority required (STREAMLINED)** | | | | | | |
| | ***3401*** | | | | | | |
| | Patients being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in neuroblastoma | | | | | | |
| | **Authority required (STREAMLINED)** | | | | | | |
| | ***3402*** | | | | | | |
| | Patients being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in non-Hodgkin's lymphoma (intermediate or high grade) | | | | | | |
| | **Authority required (STREAMLINED)** | | | | | | |
| | ***3403*** | | | | | | |
| | Patients being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in osteosarcoma | | | | | | |
| | **Authority required (STREAMLINED)** | | | | | | |
| | ***3404*** | | | | | | |
| | Patients being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in relapsed Hodgkin's disease | | | | | | |
| | **Authority required (STREAMLINED)** | | | | | | |
| | ***3405*** | | | | | | |
| | Patients being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in rhabdomyosarcoma | | | | | | |
| 5787N | LENOGRASTIM Powder for injection 13,400,000 i.u. (105 micrograms) vial, 10 | 2 | 11 | .. | *1025.00 | Granocyte 13 | HH |
| 5788P | LENOGRASTIM Powder for injection 33,600,000 i.u. (263 micrograms) vial, 10 | 2 | 11 | .. | *2567.20 | Granocyte 34 | HH |
| | **PEGFILGRASTIM** | | | | | | |
| | **Authority required (STREAMLINED)** | | | | | | |
| | ***3357*** | | | | | | |
| | For use in a patient undergoing induction and consolidation therapy for acute myeloid leukaemia | | | | | | |
| | **Authority required (STREAMLINED)** | | | | | | |
| | ***3362*** | | | | | | |
| | A patient with breast cancer receiving standard dose adjuvant chemotherapy who has had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned | | | | | | |
| | **Authority required (STREAMLINED)** | | | | | | |
| | ***3363*** | | | | | | |
| | A patient receiving chemotherapy for B-cell chronic lymphocytic leukaemia with fludarabine and cyclophosphamide who has had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned | | | | | | |
| | **Authority required (STREAMLINED)** | | | | | | |
| | ***3364*** | | | | | | |
| | A patient receiving first-line chemotherapy for Hodgkin disease who has had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned | | | | | | |
| | **Authority required (STREAMLINED)** | | | | | | |
| | ***3365*** | | | | | | |
| | A patient receiving chemotherapy for myeloma who has had a prior episode of febrile neutropenia, and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned | | | | | | |
| | **Authority required (STREAMLINED)** | | | | | | |
| | ***3369*** | | | | | | |
| | A patient with inoperable Stage III, IVa or IVb squamous cell carcinoma of the oral cavity, larynx, oropharynx or hypopharynx receiving neoadjuvant treatment with docetaxel in combination with cisplatin and fluorouracil who has had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned | | | | | | |
| | **Authority required (STREAMLINED)** | | | | | | |
| | ***3370*** | | | | | | |
| | A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in acute lymphoblastic leukaemia | | | | | | |
| | **Authority required (STREAMLINED)** | | | | | | |
| | ***3371*** | | | | | | |

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|---|---|---|---|---|---|---|---|
| | A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in breast cancer (adjuvant chemotherapy with docetaxel in combination with an anthracycline and cyclophosphamide) | | | | | | |
| | **Authority required (STREAMLINED)** | | | | | | |
| | ***3372*** | | | | | | |
| | A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in germ cell tumours | | | | | | |
| | **Authority required (STREAMLINED)** | | | | | | |
| | ***3373*** | | | | | | |
| | A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in infants and children with CNS tumours | | | | | | |
| | **Authority required (STREAMLINED)** | | | | | | |
| | ***3374*** | | | | | | |
| | A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in neuroblastoma | | | | | | |
| | **Authority required (STREAMLINED)** | | | | | | |
| | ***3375*** | | | | | | |
| | A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in non-Hodgkin lymphoma (aggressive grades; or low grade receiving an anthracycline-containing regimen) | | | | | | |
| | **Authority required (STREAMLINED)** | | | | | | |
| | ***3376*** | | | | | | |
| | A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in relapsed Hodgkin disease | | | | | | |
| | **Authority required (STREAMLINED)** | | | | | | |
| | ***3377*** | | | | | | |
| | A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in sarcoma | | | | | | |
| | **Authority required (STREAMLINED)** | | | | | | |
| | ***3834*** | | | | | | |
| | A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in Hodgkin disease (first-line chemotherapy with escalated BEACOPP) | | | | | | |
| 9514R | pegfilgrastim 6 mg/0.6 mL injection, 1 x 0.6 mL syringe | 1 | 11 | .. | 1925.00 | Neulasta | AN |
| | ***Interferons*** | | | | | | |
| | **INTERFERON ALFA-2A** | | | | | | |
| | **Authority required (STREAMLINED)** | | | | | | |
| | ***3382*** | | | | | | |
| | Use in the treatment of Philadelphia chromosome positive myelogenous leukaemia in the chronic phase | | | | | | |
| | **Authority required (STREAMLINED)** | | | | | | |
| | ***3961*** | | | | | | |
| | Chronic hepatitis B in a patient without cirrhosis who satisfies all of the following criteria: | | | | | | |
| | (1) Elevated HBV DNA levels - greater than 20,000 IU/mL (100,000 copies/mL) if HBeAg positive, or greater than 2,000 IU/mL (10,000 copies/mL) if HBeAg negative - in conjunction with documented chronic hepatitis B infection; | | | | | | |
| | (2) Evidence of chronic liver injury as determined by: | | | | | | |
| | (a) Confirmed elevated serum ALT; or | | | | | | |
| | (b) Liver biopsy | | | | | | |
| | **Authority required (STREAMLINED)** | | | | | | |
| | ***3962*** | | | | | | |
| | Chronic hepatitis B in a patient with cirrhosis who has detectable HBV DNA. | | | | | | |
| | Persons with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy | | | | | | |
| | **Caution** | | | | | | |
| | Treatment with interferon alfa has been associated with depression and suicide in some patients. Patients with a history of suicidal ideation or depressive illness should be warned of the risks. Psychiatric status during therapy should be monitored. | | | | | | |
| 5759D | interferon alfa-2a 3 million international units/0.5 mL injection, 1 x 0.5 mL syringe | 30 | 5 | .. | *894.00 | Roferon-A | RO |
| 5760E | interferon alfa-2a 4.5 million international units/0.5 mL injection, 1 x 0.5 mL syringe | 30 | 5 | .. | *1341.00 | Roferon-A | RO |
| 5761F | interferon alfa-2a 6 million international units/0.5 mL injection, 1 x 0.5 mL syringe | 30 | 5 | .. | *1787.40 | Roferon-A | RO |
| 5762G | interferon alfa-2a 9 million international units/0.5 mL injection, 1 x 0.5 mL syringe | 30 | 5 | .. | *2681.40 | Roferon-A | RO |
| | **INTERFERON ALFA-2B** | | | | | | |
| | **Authority required (STREAMLINED)** | | | | | | |
| | ***3384*** | | | | | | |
| | Adjunctive therapy of malignant melanoma following surgery in patients with nodal involvement | | | | | | |

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|---|---|---|---|---|---|---|---|
| | **Authority required (STREAMLINED)** | | | | | | |
| | ***3382*** | | | | | | |
| | Use in the treatment of Philadelphia chromosome positive myelogenous leukaemia in the chronic phase | | | | | | |
| | **Authority required (STREAMLINED)** | | | | | | |
| | ***3961*** | | | | | | |
| | Chronic hepatitis B in a patient without cirrhosis who satisfies all of the following criteria: | | | | | | |
| | (1) Elevated HBV DNA levels - greater than 20,000 IU/mL (100,000 copies/mL) if HBeAg positive, or greater than 2,000 IU/mL (10,000 copies/mL) if HBeAg negative - in conjunction with documented chronic hepatitis B infection; | | | | | | |
| | (2) Evidence of chronic liver injury as determined by: | | | | | | |
| | (a) Confirmed elevated serum ALT; or | | | | | | |
| | (b) Liver biopsy | | | | | | |
| | **Authority required (STREAMLINED)** | | | | | | |
| | ***3962*** | | | | | | |
| | Chronic hepatitis B in a patient with cirrhosis who has detectable HBV DNA. | | | | | | |
| | Persons with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy | | | | | | |
| | **Caution** | | | | | | |
| | Treatment with interferon alfa has been associated with depression and suicide in some patients. Patients with a history of suicidal ideation or depressive illness should be warned of the risks. Psychiatric status during therapy should be monitored. | | | | | | |
| 5768N | interferon alfa-2b 10 million international units/mL injection, 5 x 1 mL vials | 3 | 5 | .. | *1489.50 | Intron A | MK |
| 5763H | interferon alfa-2b 18 million international units/1.2 mL injection, 1 x 1.2 mL cartridge | 2 | 5 | .. | *357.48 | Intron A Redipen | MK |
| 5766L | interferon alfa-2b 18 million international units/3 mL injection, 1 x 3 mL vial | 15 | 5 | .. | *2681.10 | Intron A | MK |
| 5767M | interferon alfa-2b 25 million international units/2.5 mL injection, 1 x 2.5 mL vial | 15 | 5 | .. | *3723.75 | Intron A | MK |
| 5764J | interferon alfa-2b 30 million international units/1.2 mL injection, 1 x 1.2 mL cartridge | 2 | 5 | .. | *595.80 | Intron A Redipen | MK |
| 5765K | interferon alfa-2b 60 million international units/1.2 mL injection, 1 x 1.2 mL cartridge | 2 | 5 | .. | *1191.60 | Intron A Redipen | MK |
| | **INTERFERON GAMMA-1B** | | | | | | |
| | **Authority required (STREAMLINED)** | | | | | | |
| | ***3385*** | | | | | | |
| | Treatment of chronic granulomatous disease in patients with frequent and severe infections despite adequate prophylaxis with antimicrobial agents | | | | | | |
| 5769P | interferon gamma-1b 2 million international units (100 microgram/0.5 mL) injection, 6 x 0.5 mL vials | 2 | 11 | .. | *2721.80 | Imukin | BY |
| | **PEGINTERFERON ALFA-2A** | | | | | | |
| | **Authority required (STREAMLINED)** | | | | | | |
| | ***3977*** | | | | | | |
| | Treatment, as sole PBS-subsidised therapy, in a patient with chronic hepatitis B without cirrhosis who satisfies all of the following criteria: | | | | | | |
| | (1) Elevated HBV DNA levels - greater than 20,000 IU/mL (100,000 copies/mL) if HBeAg positive, or greater than 2,000 IU/mL (10,000 copies/mL) if HBeAg negative - in conjunction with documented chronic hepatitis B infection; | | | | | | |
| | (2) Evidence of chronic liver injury as determined by: | | | | | | |
| | (a) Confirmed elevated serum ALT; or | | | | | | |
| | (b) Liver biopsy; | | | | | | |
| | (3) Has received no prior peginterferon alfa therapy for the treatment of hepatitis B | | | | | | |
| | **Authority required (STREAMLINED)** | | | | | | |
| | ***3978*** | | | | | | |
| | Treatment, as sole PBS-subsidised therapy, in a patient with chronic hepatitis B with cirrhosis who has detectable HBV DNA. | | | | | | |
| | Persons with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy. | | | | | | |
| | Treatment is limited to 1 course of treatment for a duration of up to 48 weeks | | | | | | |
| | **Authority required (STREAMLINED)** | | | | | | |
| | ***3412*** | | | | | | |
| | Treatment, managed by an accredited treatment centre, of chronic hepatitis C in patients 18 years or older who have compensated liver disease and who have received no prior interferon alfa or peginterferon alfa treatment for hepatitis C and have a contraindication to ribavirin, who satisfy all of the following criteria: | | | | | | |
| | (1) Documented chronic hepatitis C infection (repeatedly anti-HCV positive and HCV RNA positive); | | | | | | |

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| | (2) Female patients of child-bearing age are not pregnant, not breast-feeding, and are using an effective form of contraception. | | | | | | |
| | The treatment course is limited to up to 48 weeks. | | | | | | |
| | Patients may only continue treatment after the first 12 weeks if the result of an HCV RNA quantitative assay (performed at the same laboratory using the same test) shows that the plasma HCV RNA has become undetectable or the viral load has decreased by at least a 2 log drop | | | | | | |
| | **Caution**<br>Treatment with peginterferon alfa has been associated with depression and suicide in some patients. Patients with a history of suicidal ideation or depressive illness should be warned of the risks. Psychiatric status during therapy should be monitored. | | | | | | |
| | **Note**<br>Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C: | | | | | | |
| | (a) a nurse educator/counsellor for patients; and | | | | | | |
| | (b) 24 hour access by patients to medical advice; and | | | | | | |
| | (c) an established liver clinic; and | | | | | | |
| | (d) facilities for safe liver biopsy. | | | | | | |
| 9515T | peginterferon alfa-2a 135 microgram/0.5 mL injection, 4 x 0.5 mL syringes | 2 | 5 | .. | *2331.80 | Pegasys | RO |
| 9516W | peginterferon alfa-2a 180 microgram/0.5 mL injection, 4 x 0.5 mL syringes | 2 | 5 | .. | *2700.46 | Pegasys | RO |
| | **PEGINTERFERON ALFA-2A (&) RIBAVIRIN**<br>**Authority required (STREAMLINED)**<br>***4184***<br>Chronic genotype 1 hepatitis C infection | | | | | | |
| | **The Treatment criteria is:** | | | | | | |
| | Must be treated in an accredited treatment centre, | | | | | | |
| | **AND the Clinical criteria is:** | | | | | | |
| | Patient must have compensated liver disease, | | | | | | |
| | **AND the Clinical criteria is:** | | | | | | |
| | Patient must have failed prior treatment with interferon based therapies (non-pegylated or pegylated), | | | | | | |
| | **AND the Clinical criteria is:** | | | | | | |
| | Patient must have received prior treatment with interferon alfa or peginterferon alfa for hepatitis C if using peginterferon and ribavirin in triple combination therapy with telaprevir; OR | | | | | | |
| | Patient must have received no more than one prior treatment with interferon alfa or peginterferon alfa for hepatitis C if using peginterferon and ribavirin without an NS3 protease inhibitor, or, in triple combination therapy with boceprevir, | | | | | | |
| | **AND the Clinical criteria is:** | | | | | | |
| | The treatment must be limited to a maximum duration of 24 weeks in patients using peginterferon and ribavirin in triple combination therapy with telaprevir who were prior treatment relapsers and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at weeks 4 and 12; OR | | | | | | |
| | The treatment must be limited to a maximum duration of 36 weeks in patients using peginterferon and ribavirin in triple combination therapy with boceprevir who were prior treatment partial responders or relapsers and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at weeks 8 and 12; OR | | | | | | |
| | The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin without an NS3 protease inhibitor; OR | | | | | | |
| | The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin in triple combination therapy with boceprevir who: (i) were prior treatment null responders; or (ii) were prior treatment partial responders or relapsers and in whom plasma HCV RNA is detectable by an HCV RNA qualitative assay at week 8, and undetectable by an HCV RNA qualitative assay at week 12; or (iii) have hepatic cirrhosis; OR | | | | | | |
| | The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin in triple combination therapy with telaprevir who: (i) were prior treatment partial or null responders; or (ii) were prior treatment relapsers and for whom the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is detectable but less than or equal to 1000 IU/mL; or (iii) have hepatic cirrhosis, | | | | | | |
| | **AND the Clinical criteria is:** | | | | | | |
| | The treatment must cease in patients using peginterferon and ribavirin without an NS3 protease inhibitor if HCV RNA is detectable by an HCV RNA qualitative assay at week 12, | | | | | | |
| | **AND the Clinical criteria is:** | | | | | | |
| | The treatment must cease in patients using peginterferon and ribavirin in combination with boceprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 12, | | | | | | |
| | **AND the Clinical criteria is:** | | | | | | |
| | The treatment must cease in patients using peginterferon and ribavirin in combination with boceprevir if HCV RNA is detectable by an HCV RNA | | | | | | |

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qualitative assay at week 24,

**AND the Clinical criteria is:**

The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is greater than 1000 IU/mL,

**AND the Clinical criteria is:**

The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 12,

**AND the Clinical criteria is:**

The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24,

**AND the Population criteria is:**

Patient must be aged 18 years or older,

**AND the Population criteria is:**

Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

Evidence of chronic genotype 1 hepatitis C infection (repeatedly anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records.

**Note**

No increase in the maximum quantity or number of units may be authorised.

**Note**

No increase in the maximum number of repeats may be authorised.

**Note**

Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C:

(a) a nurse educator/counsellor for patients; and

(b) 24-hour access by patients to medical advice; and

(c) an established liver clinic.

**Authority required (STREAMLINED)**

***4197***

Chronic genotype 1 hepatitis C infection

**The Treatment criteria is:**

Must be treated in an accredited treatment centre,

**AND the Clinical criteria is:**

Patient must have compensated liver disease,

**AND the Clinical criteria is:**

Patient must not have received prior interferon alfa or peginterferon alfa treatment for hepatitis C,

**AND the Clinical criteria is:**

The treatment must be limited to a maximum duration of 24 weeks in patients using peginterferon and ribavirin in triple combination therapy with telaprevir and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at weeks 4 and 12; OR

The treatment must be limited to a maximum duration of 28 weeks in patients using peginterferon and ribavirin in triple combination therapy with boceprevir and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at weeks 8 and 24; OR

The treatment must be limited to a maximum duration of 48 weeks in patients: (i) using peginterferon and ribavirin in triple combination therapy with boceprevir and in whom plasma HCV RNA is detectable by an HCV RNA qualitative assay at week 8, and undetectable by an HCV RNA qualitative assay at week 24; or (ii) using peginterferon and ribavirin in triple combination therapy with boceprevir who have hepatic cirrhosis; OR

The treatment must be limited to a maximum duration of 48 weeks in patients: (i) using peginterferon and ribavirin in triple combination therapy with telaprevir and for whom the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is detectable but less than or equal to 1000 IU/mL; or (ii) using peginterferon and ribavirin in triple combination therapy with telaprevir who have hepatic cirrhosis; OR

The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin without an NS3 protease inhibitor,

**AND the Clinical criteria is:**

The treatment must cease in patients using peginterferon and ribavirin without an NS3 protease inhibitor unless the results of an HCV RNA quantitative assay at week 12 (performed at the same laboratory using the same test) show that plasma HCV RNA has become undetectable or the viral load has decreased by at least a 2 log drop,

**AND the Clinical criteria is:**

The treatment must cease in patients using peginterferon and ribavirin in combination with boceprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24,

**AND the Clinical criteria is:**

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|---|---|---|---|---|---|---|

The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is greater than 1000 IU/mL,

**AND the Clinical criteria is:**

The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 12,

**AND the Clinical criteria is:**

The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24,

**AND the Population criteria is:**

Patient must be aged 18 years or older,

**AND the Population criteria is:**

Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

Evidence of chronic hepatitis C infection (repeated anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records.

For patients using peginterferon and ribavirin without an NS3 protease inhibitor who are viral negative at week 12, an HCV RNA qualitative assay at week 24 is unnecessary.

**Note**

No increase in the maximum quantity or number of units may be authorised.

**Note**

No increase in the maximum number of repeats may be authorised.

**Note**

Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C:

(a) a nurse educator/counsellor for patients; and

(b) 24-hour access by patients to medical advice; and

(c) an established liver clinic.

**Authority required (STREAMLINED)**

***4206***

Chronic non-genotype 1 hepatitis C infection

**The Treatment criteria is:**

Must be treated in an accredited treatment centre,

**AND the Clinical criteria is:**

The treatment must be the sole PBS-subsidised treatment for hepatitis C,

**AND the Clinical criteria is:**

Patient must have compensated liver disease,

**AND the Clinical criteria is:**

The condition must be genotype 2, 3, 4, 5 or 6 hepatitis C,

**AND the Clinical criteria is:**

Patient must have failed prior treatment with interferon based therapies (non-pegylated or pegylated),

**AND the Clinical criteria is:**

Patient must have received no more than one prior treatment with interferon alfa or peginterferon alfa for hepatitis C,

**AND the Clinical criteria is:**

The treatment must be limited to a maximum duration of 48 weeks,

**AND the Clinical criteria is:**

The treatment must cease if HCV RNA is detectable by an HCV RNA qualitative assay at week 12,

**AND the Population criteria is:**

Patient must be aged 18 years or older,

**AND the Population criteria is:**

Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

Evidence of chronic hepatitis C infection (repeated anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records.

**Note**

No increase in the maximum quantity or number of units may be authorised.

**Note**

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|---|---|---|---|---|---|---|

No increase in the maximum number of repeats may be authorised.

**Note**

Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C:

(a) a nurse educator/counsellor for patients; and

(b) 24-hour access by patients to medical advice; and

(c) an established liver clinic.

**Authority required (STREAMLINED)**

***4187***

Chronic non-genotype 1 hepatitis C infection

**The Treatment criteria is:**

Must be treated in an accredited treatment centre,

**AND the Clinical criteria is:**

The treatment must be the sole PBS-subsidised treatment for hepatitis C,

**AND the Clinical criteria is:**

Patient must have compensated liver disease,

**AND the Clinical criteria is:**

Patient must not have received prior interferon alfa or peginterferon alfa treatment for hepatitis C,

**AND the Clinical criteria is:**

The condition must be genotype 2, 3, 4, 5 or 6 hepatitis C,

**AND the Clinical criteria is:**

The treatment must be limited to a maximum duration of 48 weeks for patients with genotype 4, 5 or 6 hepatitis C; OR

The treatment must be limited to a maximum duration of 24 weeks for patients with genotype 2 or 3 hepatitis C without hepatic cirrhosis or bridging fibrosis; OR

The treatment must be limited to a maximum duration of 48 weeks for patients with genotype 2 or 3 hepatitis C with hepatic cirrhosis or bridging fibrosis,

**AND the Clinical criteria is:**

The treatment must cease in patients with genotype 4, 5, or 6 hepatitis C unless the results of an HCV RNA quantitative assay at week 12 (performed at the same laboratory using the same test) shows that plasma HCV RNA has become undetectable or the viral load has decreased by at least a 2 log drop,

**AND the Clinical criteria is:**

The treatment must cease in patients eligible for 48 weeks of treatment if HCV RNA is detectable by an HCV RNA qualitative assay at week 24,

**AND the Population criteria is:**

Patient must be aged 18 years or older,

**AND the Population criteria is:**

Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

Evidence of chronic hepatitis C infection (repeated anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records.

For patients with genotype 4, 5, or 6 who are viral negative at week 12, an HCV RNA qualitative assay at week 24 is unnecessary.

For patients with genotype 2 or 3 without cirrhosis, an HCV RNA assay at week 12 is unnecessary because of the high likelihood of early viral response by week 12.

For patients who are eligible for 24 weeks of treatment, a maximum of 2 repeats may be prescribed.

For patients who are eligible for 48 weeks of treatment, a maximum of 5 repeats may be prescribed.

**Caution**

Ribavirin is a category X drug and must not be given to pregnant women. Pregnancy in female patients or in the partners of male patients must be avoided during treatment and during the 6 months period after cessation of treatment.

**Caution**

Treatment with peginterferon alfa has been associated with depression and suicide in some patients. Patients with a history of suicidal ideation or depressive illness should be warned of the risks. Psychiatric status during therapy should be monitored.

**Note**

Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C:

(a) a nurse educator/counsellor for patients; and

(b) 24-hour access by patients to medical advice; and

(c) an established liver clinic.

# HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|
| 9524G | peginterferon alfa-2a 135 microgram/0.5 mL injection [4 x 0.5 mL syringes] (&) ribavirin 200 mg tablet [168 tablets], 1 pack | 2 | 5 | .. | *3072.84 | Pegasys RBV | RO |
| 9525H | peginterferon alfa-2a 180 microgram/0.5 mL injection [4 x 0.5 mL syringes] (&) ribavirin 200 mg tablet [112 tablets], 1 pack | 2 | 5 | .. | *3085.28 | Pegasys RBV | RO |
| 9526J | peginterferon alfa-2a 180 microgram/0.5 mL injection [4 x 0.5 mL syringes] (&) ribavirin 200 mg tablet [140 tablets], 1 pack | 2 | 5 | .. | *3245.82 | Pegasys RBV | RO |
| 9527K | peginterferon alfa-2a 180 microgram/0.5 mL injection [4 x 0.5 mL syringes] (&) ribavirin 200 mg tablet [168 tablets], 1 pack | 2 | 5 | .. | *3406.36 | Pegasys RBV | RO |

**PEGINTERFERON ALFA-2B (&) RIBAVIRIN**

**Authority required (STREAMLINED)**

***4189***

Chronic genotype 1 hepatitis C infection

**The Treatment criteria is:**

Must be treated in an accredited treatment centre,

**AND the Clinical criteria is:**

The treatment must be the sole PBS-subsidised treatment for hepatitis C,

**AND the Clinical criteria is:**

Patient must have compensated liver disease,

**AND the Clinical criteria is:**

Patient must have failed prior treatment with interferon based therapies (non-pegylated or pegylated),

**AND the Clinical criteria is:**

Patient must have received no more than one prior treatment with interferon alfa or peginterferon alfa for hepatitis C,

**AND the Clinical criteria is:**

The treatment must be limited to a maximum duration of 48 weeks,

**AND the Clinical criteria is:**

The treatment must cease if HCV RNA is detectable by an HCV RNA qualitative assay at week 12,

**AND the Population criteria is:**

Patient must weigh at least 27 kg,

**AND the Population criteria is:**

Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

Evidence of chronic genotype 1 hepatitis C infection (repeatedly anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records.

**Note**

No increase in the maximum quantity or number of units may be authorised.

**Note**

No increase in the maximum number of repeats may be authorised.

**Note**

Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C:

(a) a nurse educator/counsellor for patients; and

(b) 24-hour access by patients to medical advice; and

(c) an established liver clinic.

**Authority required (STREAMLINED)**

***4198***

Chronic genotype 1 hepatitis C infection

**The Treatment criteria is:**

Must be treated in an accredited treatment centre,

**AND the Clinical criteria is:**

The treatment must be the sole PBS-subsidised treatment for hepatitis C,

**AND the Clinical criteria is:**

Patient must have compensated liver disease,

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|---|---|---|---|---|---|---|

**AND the Clinical criteria is:**

Patient must not have received prior interferon alfa or peginterferon alfa treatment for hepatitis C,

**AND the Clinical criteria is:**

The treatment must be limited to a maximum duration of 48 weeks,

**AND the Clinical criteria is:**

The treatment must cease unless the results of an HCV RNA quantitative assay at week 12 (performed at the same laboratory using the same test) show that plasma HCV RNA has become undetectable or the viral load has decreased by at least a 2 log drop,

**AND the Population criteria is:**

Patient must weigh at least 27 kg,

**AND the Population criteria is:**

Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

Evidence of chronic hepatitis C infection (repeated anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records.

For patients who are viral negative at week 12, an HCV RNA qualitative assay at week 24 is unnecessary.

**Note**

No increase in the maximum quantity or number of units may be authorised.

**Note**

No increase in the maximum number of repeats may be authorised.

**Note**

Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C:

(a) a nurse educator/counsellor for patients; and

(b) 24-hour access by patients to medical advice; and

(c) an established liver clinic.

**Authority required (STREAMLINED)**

***4199***

Chronic non-genotype 1 hepatitis C infection

**The Treatment criteria is:**

Must be treated in an accredited treatment centre,

**AND the Clinical criteria is:**

The treatment must be the sole PBS-subsidised treatment for hepatitis C,

**AND the Clinical criteria is:**

Patient must have compensated liver disease,

**AND the Clinical criteria is:**

The condition must be genotype 2, 3, 4, 5 or 6 hepatitis C,

**AND the Clinical criteria is:**

Patient must have failed prior treatment with interferon based therapies (non-pegylated or pegylated),

**AND the Clinical criteria is:**

Patient must have received no more than one prior treatment with interferon alfa or peginterferon alfa for hepatitis C,

**AND the Clinical criteria is:**

The treatment must be limited to a maximum duration of 48 weeks,

**AND the Clinical criteria is:**

The treatment must cease if HCV RNA is detectable by an HCV RNA qualitative assay at week 12,

**AND the Population criteria is:**

Patient must weigh at least 27 kg,

**AND the Population criteria is:**

Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

Evidence of chronic hepatitis C infection (repeated anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records.

**Note**

No increase in the maximum quantity or number of units may be authorised.

**Note**

No increase in the maximum number of repeats may be authorised.

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**Note**

Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C:

(a) a nurse educator/counsellor for patients; and

(b) 24-hour access by patients to medical advice; and

(c) an established liver clinic.

**Authority required (STREAMLINED)**

***4192***

Chronic non-genotype 1 hepatitis C infection

**The Treatment criteria is:**

Must be treated in an accredited treatment centre,

**AND the Clinical criteria is:**

The treatment must be the sole PBS-subsidised treatment for hepatitis C,

**AND the Clinical criteria is:**

Patient must have compensated liver disease,

**AND the Clinical criteria is:**

Patient must not have received prior interferon alfa or peginterferon alfa treatment for hepatitis C,

**AND the Clinical criteria is:**

The condition must be genotype 2, 3, 4, 5 or 6 hepatitis C,

**AND the Clinical criteria is:**

The treatment must be limited to a maximum duration of 48 weeks for patients with genotype 4, 5 or 6 hepatitis C; OR

The treatment must be limited to a maximum duration of 24 weeks for patients with genotype 2 or 3 hepatitis C without hepatic cirrhosis or bridging fibrosis; OR

The treatment must be limited to a maximum duration of 48 weeks for patients with genotype 2 or 3 hepatitis C with hepatic cirrhosis or bridging fibrosis,

**AND the Clinical criteria is:**

The treatment must cease in patients with genotype 4, 5, or 6 hepatitis C unless the results of an HCV RNA quantitative assay at week 12 (performed at the same laboratory using the same test) shows that plasma HCV RNA has become undetectable or the viral load has decreased by at least a 2 log drop,

**AND the Clinical criteria is:**

The treatment must cease in patients eligible for 48 weeks of treatment if HCV RNA is detectable by an HCV RNA qualitative assay at week 24,

**AND the Population criteria is:**

Patient must weigh at least 27 kg,

**AND the Population criteria is:**

Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

Evidence of chronic hepatitis C infection (repeated anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records.

For patients with genotype 4, 5, or 6 who are viral negative at week 12, an HCV RNA qualitative assay at week 24 is unnecessary.

For patients with genotype 2 or 3 without cirrhosis, an HCV RNA assay at week 12 is unnecessary because of the high likelihood of early viral response by week 12.

For patients who are eligible for 24 weeks of treatment, a maximum of 2 repeats may be prescribed.

For patients who are eligible for 48 weeks of treatment, a maximum of 5 repeats may be prescribed.

**Note**

Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C:

(a) a nurse educator/counsellor for patients; and

(b) 24-hour access by patients to medical advice; and

(c) an established liver clinic.

**Authority required (STREAMLINED)**

***4184***

Chronic genotype 1 hepatitis C infection

**The Treatment criteria is:**

Must be treated in an accredited treatment centre,

**AND the Clinical criteria is:**

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Patient must have compensated liver disease,

**AND the Clinical criteria is:**

Patient must have failed prior treatment with interferon based therapies (non-pegylated or pegylated),

**AND the Clinical criteria is:**

Patient must have received prior treatment with interferon alfa or peginterferon alfa for hepatitis C if using peginterferon and ribavirin in triple combination therapy with telaprevir; OR

Patient must have received no more than one prior treatment with interferon alfa or peginterferon alfa for hepatitis C if using peginterferon and ribavirin without an NS3 protease inhibitor, or, in triple combination therapy with boceprevir,

**AND the Clinical criteria is:**

The treatment must be limited to a maximum duration of 24 weeks in patients using peginterferon and ribavirin in triple combination therapy with telaprevir who were prior treatment relapsers and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at weeks 4 and 12; OR

The treatment must be limited to a maximum duration of 36 weeks in patients using peginterferon and ribavirin in triple combination therapy with boceprevir who were prior treatment partial responders or relapsers and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at weeks 8 and 12; OR

The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin without an NS3 protease inhibitor; OR

The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin in triple combination therapy with boceprevir who: (i) were prior treatment null responders; or (ii) were prior treatment partial responders or relapsers and in whom plasma HCV RNA is detectable by an HCV RNA qualitative assay at week 8, and undetectable by an HCV RNA qualitative assay at week 12; or (iii) have hepatic cirrhosis; OR

The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin in triple combination therapy with telaprevir who: (i) were prior treatment partial or null responders; or (ii) were prior treatment relapsers and for whom the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is detectable but less than or equal to 1000 IU/mL; or (iii) have hepatic cirrhosis,

**AND the Clinical criteria is:**

The treatment must cease in patients using peginterferon and ribavirin without an NS3 protease inhibitor if HCV RNA is detectable by an HCV RNA qualitative assay at week 12,

**AND the Clinical criteria is:**

The treatment must cease in patients using peginterferon and ribavirin in combination with boceprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 12,

**AND the Clinical criteria is:**

The treatment must cease in patients using peginterferon and ribavirin in combination with boceprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24,

**AND the Clinical criteria is:**

The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is greater than 1000 IU/mL,

**AND the Clinical criteria is:**

The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 12,

**AND the Clinical criteria is:**

The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24,

**AND the Population criteria is:**

Patient must be aged 18 years or older,

**AND the Population criteria is:**

Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

Evidence of chronic genotype 1 hepatitis C infection (repeatedly anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records.

**Note**

No increase in the maximum quantity or number of units may be authorised.

**Note**

No increase in the maximum number of repeats may be authorised.

**Note**

Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C:

(a) a nurse educator/counsellor for patients; and

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(b) 24-hour access by patients to medical advice; and

(c) an established liver clinic.

**Authority required (STREAMLINED)**

***4197***

Chronic genotype 1 hepatitis C infection

**The Treatment criteria is:**

Must be treated in an accredited treatment centre,

**AND the Clinical criteria is:**

Patient must have compensated liver disease,

**AND the Clinical criteria is:**

Patient must not have received prior interferon alfa or peginterferon alfa treatment for hepatitis C,

**AND the Clinical criteria is:**

The treatment must be limited to a maximum duration of 24 weeks in patients using peginterferon and ribavirin in triple combination therapy with telaprevir and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at weeks 4 and 12; OR

The treatment must be limited to a maximum duration of 28 weeks in patients using peginterferon and ribavirin in triple combination therapy with boceprevir and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at weeks 8 and 24; OR

The treatment must be limited to a maximum duration of 48 weeks in patients: (i) using peginterferon and ribavirin in triple combination therapy with boceprevir and in whom plasma HCV RNA is detectable by an HCV RNA qualitative assay at week 8, and undetectable by an HCV RNA qualitative assay at week 24; or (ii) using peginterferon and ribavirin in triple combination therapy with boceprevir who have hepatic cirrhosis; OR

The treatment must be limited to a maximum duration of 48 weeks in patients: (i) using peginterferon and ribavirin in triple combination therapy with telaprevir and for whom the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is detectable but less than or equal to 1000 IU/mL; or (ii) using peginterferon and ribavirin in triple combination therapy with telaprevir who have hepatic cirrhosis; OR

The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin without an NS3 protease inhibitor,

**AND the Clinical criteria is:**

The treatment must cease in patients using peginterferon and ribavirin without an NS3 protease inhibitor unless the results of an HCV RNA quantitative assay at week 12 (performed at the same laboratory using the same test) show that plasma HCV RNA has become undetectable or the viral load has decreased by at least a 2 log drop,

**AND the Clinical criteria is:**

The treatment must cease in patients using peginterferon and ribavirin in combination with boceprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24,

**AND the Clinical criteria is:**

The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is greater than 1000 IU/mL,

**AND the Clinical criteria is:**

The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 12,

**AND the Clinical criteria is:**

The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24,

**AND the Population criteria is:**

Patient must be aged 18 years or older,

**AND the Population criteria is:**

Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

Evidence of chronic hepatitis C infection (repeated anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records.

For patients using peginterferon and ribavirin without an NS3 protease inhibitor who are viral negative at week 12, an HCV RNA qualitative assay at week 24 is unnecessary.

**Note**

No increase in the maximum quantity or number of units may be authorised.

**Note**

No increase in the maximum number of repeats may be authorised.

**Note**

Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C:

(a) a nurse educator/counsellor for patients; and

(b) 24-hour access by patients to medical advice; and

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(c) an established liver clinic.

**Authority required (STREAMLINED)**

***4206***

Chronic non-genotype 1 hepatitis C infection

**The Treatment criteria is:**

Must be treated in an accredited treatment centre,

**AND the Clinical criteria is:**

The treatment must be the sole PBS-subsidised treatment for hepatitis C,

**AND the Clinical criteria is:**

Patient must have compensated liver disease,

**AND the Clinical criteria is:**

The condition must be genotype 2, 3, 4, 5 or 6 hepatitis C,

**AND the Clinical criteria is:**

Patient must have failed prior treatment with interferon based therapies (non-pegylated or pegylated),

**AND the Clinical criteria is:**

Patient must have received no more than one prior treatment with interferon alfa or peginterferon alfa for hepatitis C,

**AND the Clinical criteria is:**

The treatment must be limited to a maximum duration of 48 weeks,

**AND the Clinical criteria is:**

The treatment must cease if HCV RNA is detectable by an HCV RNA qualitative assay at week 12,

**AND the Population criteria is:**

Patient must be aged 18 years or older,

**AND the Population criteria is:**

Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

Evidence of chronic hepatitis C infection (repeated anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records.

**Note**

No increase in the maximum quantity or number of units may be authorised.

**Note**

No increase in the maximum number of repeats may be authorised.

**Note**

Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C:

(a) a nurse educator/counsellor for patients; and

(b) 24-hour access by patients to medical advice; and

(c) an established liver clinic.

**Authority required (STREAMLINED)**

***4187***

Chronic non-genotype 1 hepatitis C infection

**The Treatment criteria is:**

Must be treated in an accredited treatment centre,

**AND the Clinical criteria is:**

The treatment must be the sole PBS-subsidised treatment for hepatitis C,

**AND the Clinical criteria is:**

Patient must have compensated liver disease,

**AND the Clinical criteria is:**

Patient must not have received prior interferon alfa or peginterferon alfa treatment for hepatitis C,

**AND the Clinical criteria is:**

The condition must be genotype 2, 3, 4, 5 or 6 hepatitis C,

**AND the Clinical criteria is:**

The treatment must be limited to a maximum duration of 48 weeks for patients with genotype 4, 5 or 6 hepatitis C; OR

The treatment must be limited to a maximum duration of 24 weeks for patients with genotype 2 or 3 hepatitis C without hepatic cirrhosis or bridging fibrosis; OR

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| | The treatment must be limited to a maximum duration of 48 weeks for patients with genotype 2 or 3 hepatitis C with hepatic cirrhosis or bridging fibrosis,<br>**AND the Clinical criteria is:**<br>The treatment must cease in patients with genotype 4, 5, or 6 hepatitis C unless the results of an HCV RNA quantitative assay at week 12 (performed at the same laboratory using the same test) shows that plasma HCV RNA has become undetectable or the viral load has decreased by at least a 2 log drop,<br>**AND the Clinical criteria is:**<br>The treatment must cease in patients eligible for 48 weeks of treatment if HCV RNA is detectable by an HCV RNA qualitative assay at week 24,<br>**AND the Population criteria is:**<br>Patient must be aged 18 years or older,<br>**AND the Population criteria is:**<br>Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.<br>Evidence of chronic hepatitis C infection (repeated anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records.<br>For patients with genotype 4, 5, or 6 who are viral negative at week 12, an HCV RNA qualitative assay at week 24 is unnecessary.<br>For patients with genotype 2 or 3 without cirrhosis, an HCV RNA assay at week 12 is unnecessary because of the high likelihood of early viral response by week 12.<br>For patients who are eligible for 24 weeks of treatment, a maximum of 2 repeats may be prescribed.<br>For patients who are eligible for 48 weeks of treatment, a maximum of 5 repeats may be prescribed.<br>**Caution**<br>Ribavirin is a category X drug and must not be given to pregnant women. Pregnancy in female patients or in the partners of male patients must be avoided during treatment and during the 6 months period after cessation of treatment.<br>**Caution**<br>Treatment with peginterferon alfa has been associated with depression and suicide in some patients. Patients with a history of suicidal ideation or depressive illness should be warned of the risks. Psychiatric status during therapy should be monitored.<br>**Note**<br>Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C:<br>(a) a nurse educator/counsellor for patients; and<br>(b) 24-hour access by patients to medical advice; and<br>(c) an established liver clinic. | | | | | | |
| 9534T | peginterferon alfa-2b 100 microgram injection [4 x 100 microgram cartridges] (&) ribavirin 200 mg capsule [112 capsules] (&) inert substance diluent [4 x 0.5 mL cartridges], 1 pack | 2 | 5 | .. | *3099.62 | Pegatron | MK |
| 9529M | peginterferon alfa-2b 50 microgram injection [4 x 50 microgram cartridges] (&) ribavirin 200 mg capsule [112 capsules] (&) inert substance diluent [4 x 0.5 mL cartridges], 1 pack | 2 | 5 | .. | *2119.74 | Pegatron | MK |
| 9530N | peginterferon alfa-2b 80 microgram injection [4 x 80 microgram cartridges] (&) ribavirin 200 mg capsule [84 capsules] (&) inert substance diluent [4 x 0.5 mL cartridges], 1 pack | 2 | 5 | .. | *2422.72 | Pegatron | MK |
| | **PEGINTERFERON ALFA-2B (&) RIBAVIRIN**<br>**Authority required (STREAMLINED)**<br>***4184***<br>Chronic genotype 1 hepatitis C infection<br>**The Treatment criteria is:**<br>Must be treated in an accredited treatment centre,<br>**AND the Clinical criteria is:**<br>Patient must have compensated liver disease,<br>**AND the Clinical criteria is:**<br>Patient must have failed prior treatment with interferon based therapies (non-pegylated or pegylated),<br>**AND the Clinical criteria is:**<br>Patient must have received prior treatment with interferon alfa or peginterferon alfa for hepatitis C if using peginterferon and ribavirin in triple combination therapy with telaprevir; OR<br>Patient must have received no more than one prior treatment with interferon alfa or peginterferon alfa for hepatitis C if using peginterferon and ribavirin without an NS3 protease inhibitor, or, in triple combination therapy with boceprevir, | | | | | | |

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**AND the Clinical criteria is:**

The treatment must be limited to a maximum duration of 24 weeks in patients using peginterferon and ribavirin in triple combination therapy with telaprevir who were prior treatment relapsers and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at weeks 4 and 12; OR

The treatment must be limited to a maximum duration of 36 weeks in patients using peginterferon and ribavirin in triple combination therapy with boceprevir who were prior treatment partial responders or relapsers and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at weeks 8 and 12; OR

The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin without an NS3 protease inhibitor; OR

The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin in triple combination therapy with boceprevir who: (i) were prior treatment null responders; or (ii) were prior treatment partial responders or relapsers and in whom plasma HCV RNA is detectable by an HCV RNA qualitative assay at week 8, and undetectable by an HCV RNA qualitative assay at week 12; or (iii) have hepatic cirrhosis; OR

The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin in triple combination therapy with telaprevir who: (i) were prior treatment partial or null responders; or (ii) were prior treatment relapsers and for whom the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is detectable but less than or equal to 1000 IU/mL; or (iii) have hepatic cirrhosis,

**AND the Clinical criteria is:**

The treatment must cease in patients using peginterferon and ribavirin without an NS3 protease inhibitor if HCV RNA is detectable by an HCV RNA qualitative assay at week 12,

**AND the Clinical criteria is:**

The treatment must cease in patients using peginterferon and ribavirin in combination with boceprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 12,

**AND the Clinical criteria is:**

The treatment must cease in patients using peginterferon and ribavirin in combination with boceprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24,

**AND the Clinical criteria is:**

The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is greater than 1000 IU/mL,

**AND the Clinical criteria is:**

The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 12,

**AND the Clinical criteria is:**

The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24,

**AND the Population criteria is:**

Patient must be aged 18 years or older,

**AND the Population criteria is:**

Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

Evidence of chronic genotype 1 hepatitis C infection (repeatedly anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records.

**Note**

No increase in the maximum quantity or number of units may be authorised.

**Note**

No increase in the maximum number of repeats may be authorised.

**Note**

Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C:

(a) a nurse educator/counsellor for patients; and

(b) 24-hour access by patients to medical advice; and

(c) an established liver clinic.

**Authority required (STREAMLINED)**

***4197***

Chronic genotype 1 hepatitis C infection

**The Treatment criteria is:**

Must be treated in an accredited treatment centre,

**AND the Clinical criteria is:**

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Patient must have compensated liver disease,

**AND the Clinical criteria is:**

Patient must not have received prior interferon alfa or peginterferon alfa treatment for hepatitis C,

**AND the Clinical criteria is:**

The treatment must be limited to a maximum duration of 24 weeks in patients using peginterferon and ribavirin in triple combination therapy with telaprevir and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at weeks 4 and 12; OR

The treatment must be limited to a maximum duration of 28 weeks in patients using peginterferon and ribavirin in triple combination therapy with boceprevir and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at weeks 8 and 24; OR

The treatment must be limited to a maximum duration of 48 weeks in patients: (i) using peginterferon and ribavirin in triple combination therapy with boceprevir and in whom plasma HCV RNA is detectable by an HCV RNA qualitative assay at week 8, and undetectable by an HCV RNA qualitative assay at week 24; or (ii) using peginterferon and ribavirin in triple combination therapy with boceprevir who have hepatic cirrhosis; OR

The treatment must be limited to a maximum duration of 48 weeks in patients: (i) using peginterferon and ribavirin in triple combination therapy with telaprevir and for whom the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is detectable but less than or equal to 1000 IU/mL; or (ii) using peginterferon and ribavirin in triple combination therapy with telaprevir who have hepatic cirrhosis; OR

The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin without an NS3 protease inhibitor,

**AND the Clinical criteria is:**

The treatment must cease in patients using peginterferon and ribavirin without an NS3 protease inhibitor unless the results of an HCV RNA quantitative assay at week 12 (performed at the same laboratory using the same test) show that plasma HCV RNA has become undetectable or the viral load has decreased by at least a 2 log drop,

**AND the Clinical criteria is:**

The treatment must cease in patients using peginterferon and ribavirin in combination with boceprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24,

**AND the Clinical criteria is:**

The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is greater than 1000 IU/mL,

**AND the Clinical criteria is:**

The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 12,

**AND the Clinical criteria is:**

The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24,

**AND the Population criteria is:**

Patient must be aged 18 years or older,

**AND the Population criteria is:**

Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

Evidence of chronic hepatitis C infection (repeated anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records.

For patients using peginterferon and ribavirin without an NS3 protease inhibitor who are viral negative at week 12, an HCV RNA qualitative assay at week 24 is unnecessary.

**Note**

No increase in the maximum quantity or number of units may be authorised.

**Note**

No increase in the maximum number of repeats may be authorised.

**Note**

Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C:

(a) a nurse educator/counsellor for patients; and

(b) 24-hour access by patients to medical advice; and

(c) an established liver clinic.

**Authority required (STREAMLINED)**

***4206***

Chronic non-genotype 1 hepatitis C infection

**The Treatment criteria is:**

Must be treated in an accredited treatment centre,

**AND the Clinical criteria is:**

The treatment must be the sole PBS-subsidised treatment for hepatitis C,

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**AND the Clinical criteria is:**

Patient must have compensated liver disease,

**AND the Clinical criteria is:**

The condition must be genotype 2, 3, 4, 5 or 6 hepatitis C,

**AND the Clinical criteria is:**

Patient must have failed prior treatment with interferon based therapies (non-pegylated or pegylated),

**AND the Clinical criteria is:**

Patient must have received no more than one prior treatment with interferon alfa or peginterferon alfa for hepatitis C,

**AND the Clinical criteria is:**

The treatment must be limited to a maximum duration of 48 weeks,

**AND the Clinical criteria is:**

The treatment must cease if HCV RNA is detectable by an HCV RNA qualitative assay at week 12,

**AND the Population criteria is:**

Patient must be aged 18 years or older,

**AND the Population criteria is:**

Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

Evidence of chronic hepatitis C infection (repeated anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records.

**Note**

No increase in the maximum quantity or number of units may be authorised.

**Note**

No increase in the maximum number of repeats may be authorised.

**Note**

Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C:

(a) a nurse educator/counsellor for patients; and

(b) 24-hour access by patients to medical advice; and

(c) an established liver clinic.

**Authority required (STREAMLINED)**

***4187***

Chronic non-genotype 1 hepatitis C infection

**The Treatment criteria is:**

Must be treated in an accredited treatment centre,

**AND the Clinical criteria is:**

The treatment must be the sole PBS-subsidised treatment for hepatitis C,

**AND the Clinical criteria is:**

Patient must have compensated liver disease,

**AND the Clinical criteria is:**

Patient must not have received prior interferon alfa or peginterferon alfa treatment for hepatitis C,

**AND the Clinical criteria is:**

The condition must be genotype 2, 3, 4, 5 or 6 hepatitis C,

**AND the Clinical criteria is:**

The treatment must be limited to a maximum duration of 48 weeks for patients with genotype 4, 5 or 6 hepatitis C; OR

The treatment must be limited to a maximum duration of 24 weeks for patients with genotype 2 or 3 hepatitis C without hepatic cirrhosis or bridging fibrosis; OR

The treatment must be limited to a maximum duration of 48 weeks for patients with genotype 2 or 3 hepatitis C with hepatic cirrhosis or bridging fibrosis,

**AND the Clinical criteria is:**

The treatment must cease in patients with genotype 4, 5, or 6 hepatitis C unless the results of an HCV RNA quantitative assay at week 12 (performed at the same laboratory using the same test) shows that plasma HCV RNA has become undetectable or the viral load has decreased by at least a 2 log drop,

**AND the Clinical criteria is:**

The treatment must cease in patients eligible for 48 weeks of treatment if HCV RNA is detectable by an HCV RNA qualitative assay at week 24,

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| | **AND the Population criteria is:**<br>Patient must be aged 18 years or older,<br>**AND the Population criteria is:**<br>Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.<br>Evidence of chronic hepatitis C infection (repeated anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records.<br>For patients with genotype 4, 5, or 6 who are viral negative at week 12, an HCV RNA qualitative assay at week 24 is unnecessary.<br>For patients with genotype 2 or 3 without cirrhosis, an HCV RNA assay at week 12 is unnecessary because of the high likelihood of early viral response by week 12.<br>For patients who are eligible for 24 weeks of treatment, a maximum of 2 repeats may be prescribed.<br>For patients who are eligible for 48 weeks of treatment, a maximum of 5 repeats may be prescribed.<br>**Caution**<br>Ribavirin is a category X drug and must not be given to pregnant women. Pregnancy in female patients or in the partners of male patients must be avoided during treatment and during the 6 months period after cessation of treatment.<br>**Caution**<br>Treatment with peginterferon alfa has been associated with depression and suicide in some patients. Patients with a history of suicidal ideation or depressive illness should be warned of the risks. Psychiatric status during therapy should be monitored.<br>**Note**<br>Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C:<br>(a) a nurse educator/counsellor for patients; and<br>(b) 24-hour access by patients to medical advice; and<br>(c) an established liver clinic. | | | | | | |
| 9536X | peginterferon alfa-2b 120 microgram injection [4 x 120 microgram cartridges] (&) ribavirin 200 mg capsule [140 capsules] (&) inert substance diluent [4 x 0.5 mL cartridges], 1 pack | 2 | 5 | .. | *3491.58 | Pegatron | MK |
| 9538B | peginterferon alfa-2b 150 microgram injection [4 x 150 microgram cartridges] (&) ribavirin 200 mg capsule [140 capsules] (&) inert substance diluent [4 x 0.5 mL cartridges], 1 pack | 2 | 5 | .. | *4079.52 | Pegatron | MK |
| 9539C | peginterferon alfa-2b 150 microgram injection [4 x 150 microgram cartridges] (&) ribavirin 200 mg capsule [168 capsules] (&) inert substance diluent [4 x 0.5 mL cartridges], 1 pack | 2 | 5 | .. | *4079.52 | Pegatron | MK |
| 9540D | peginterferon alfa-2b 150 microgram injection [4 x 150 microgram cartridges] (&) ribavirin 200 mg capsule [196 capsules] (&) inert substance diluent [4 x 0.5 mL cartridges], 1 pack | 2 | 5 | .. | *4364.48 | Pegatron | MK |
| 9531P | peginterferon alfa-2b 80 microgram injection [4 x 80 microgram cartridges] (&) ribavirin 200 mg capsule [140 capsules] (&) inert substance diluent [4 x 0.5 mL cartridges], 1 pack | 2 | 5 | .. | *2707.66 | Pegatron | MK |

## IMMUNOSUPPRESSANTS

## IMMUNOSUPPRESSANTS

### *Selective immunosuppressants*

**ABATACEPT**

**Authority required**

Initial 1 (new patient or patient re-commencing after a break of more than 24 months)

Initial PBS-subsidised treatment with abatacept, in combination with methotrexate at a dose of at least 7.5 mg weekly, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of adults who:

(a) have severe active rheumatoid arthritis; and

(b) have received no PBS-subsidised treatment with a bDMARD for this condition in the previous 24 months; and

(c) have failed, in the 24 months immediately prior to the date of application, to achieve an adequate response to at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs), which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be:

— hydroxychloroquine at a dose of at least 200 mg daily; or

— leflunomide at a dose of at least 10 mg daily; or

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— sulfasalazine at a dose of at least 2 g daily.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, then the 6 months of intensive DMARD treatment must include at least 3 months continuous treatment with each of at least 2 of the DMARDs:

— hydroxychloroquine at a dose of at least 200 mg daily; and/or

— leflunomide at a dose of at least 10 mg daily; and/or

— sulfasalazine at a dose of at least 2 g daily.

The application must include details of the contraindication or intolerance to methotrexate. Details of the toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose can be found on the Medicare Australia website [www.medicareaustralia.gov.au]. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

If 3 or more of methotrexate, hydroxychloroquine, leflunomide and sulfasalazine are contraindicated according to the relevant TGA-approved product information or cannot be tolerated at the doses specified above, then one or more of the following DMARDs may be used in place of these agents in order to satisfy the requirement for a trial of 6 months of intensive DMARD therapy with at least 2 DMARDs taken continuously for at least 3 months each:

— azathioprine at a dose of at least 1 mg/kg per day; and/or

— cyclosporin at a dose of at least 2 mg/kg/day; and/or

— sodium aurothiomalate at a dose of 50 mg weekly.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances. Details of the toxicities, including severity, which will be accepted as a reason for substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial can be found on the Medicare Australia website [www.medicareaustralia.gov.au].

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance and dose for each DMARD must be provided in the authority application. Details of the toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy can be found on the Medicare Australia website [www.medicareaustralia.gov.au].

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L;

AND either

(i) a total active joint count of at least 20 active (swollen and tender) joints; or

(ii) at least 4 active joints from the following list of major joints:

— elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

— shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reason this criterion cannot be satisfied.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and

(3) a signed patient acknowledgement.

A maximum of 16 weeks of treatment will be authorised under this restriction.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion. Up to a maximum of 4 repeats may be authorised. Where fewer than 4 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Assessment of a patient's response to an initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with

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abatacept.

Patients who fail to demonstrate a response to treatment with abatacept under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition

**Authority required**

Initial 2 (change or re-commencement after break of less than 24 months)

Initial course of PBS-subsidised treatment with abatacept, in combination with methotrexate at a dose of at least 7.5 mg weekly, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of adults who:

(a) have a documented history of severe active rheumatoid arthritis; and

(b) have received prior PBS-subsidised bDMARD treatment for this condition and are eligible to receive further bDMARD therapy.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].

Applications for patients who have received PBS-subsidised treatment with abatacept and who wish to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised abatacept treatment, within the timeframes specified below.

A maximum of 16 weeks of treatment will be authorised under this restriction.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion. Up to a maximum of 4 repeats may be authorised.

Where fewer than 4 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Where the most recent course of PBS-subsidised abatacept treatment was approved under either of the initial 1 or 2 treatment restrictions, patients must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be provided to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised abatacept treatment was approved under the continuing treatment criteria, patients must have been assessed for response, and the assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Patients who fail to demonstrate a response to treatment with abatacept under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition

**Authority required**

Continuing treatment

Continuing PBS-subsidised treatment with abatacept, in combination with methotrexate at a dose of at least 7.5 mg weekly, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of adults:

(a) who have a documented history of severe active rheumatoid arthritis; and

(b) who have demonstrated an adequate response to treatment with abatacept; and

(c) whose most recent course of PBS-subsidised bDMARD treatment was with abatacept.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(i) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(ii) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

— elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

— shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].

A maximum of 24 weeks of treatment will be approved under this restriction.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion. Up to a maximum of 5 repeats may be authorised.

Where fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

All applications for continuing treatment with abatacept must include a measurement of response to the prior course of therapy. This assessment must be provided to Medicare Australia no later than 4 weeks from the cessation of that treatment course. If the application is the first application

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for continuing treatment with abatacept, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.

Patients who fail to demonstrate a response to treatment with abatacept under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition

**Note**

Any queries concerning the arrangements to prescribe abatacept may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Further prescribing information (including Authority Application Forms) is on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe abatacept should be forwarded to:

Medicare Australia

Prior Written Approval of Specialised Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

**Note**

TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying anti-rheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab) and the T-cell co-stimulation modulator (abatacept).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

PBS-subsidised abatacept, golimumab, infliximab and rituximab must be used in combination with methotrexate at a dose of at least 7.5 mg weekly. Where a patient cannot tolerate 7.5 mg of methotrexate weekly, they are eligible to receive PBS-subsidised adalimumab, certolizumab pegol, etanercept and tocilizumab.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:

— a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,

— a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and

— once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact Medicare Australia on 1800 700 270.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or

(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or

(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or

(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab and tocilizumab, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to Medicare

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Australia within 4 weeks.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

Abatacept patients:

Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients:

A further application may be submitted to Medicare Australia 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Rituximab patients:

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.

Abatacept patients:

Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

**Note**

(3) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and Medicare Australia will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of

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| | 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.<br><br>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.<br><br>**Note**<br>Special Pricing Arrangements apply. | | | | | | |
| 5605B | abatacept 250 mg injection, 1 x 250 mg vial | 1 | .. | .. | 504.43 | Orencia | BQ |
| | **EVEROLIMUS**<br>**Authority required (STREAMLINED)**<br>***3355***<br>Management of rejection, under the supervision and direction of a transplant unit, in patients receiving this drug for prophylaxis of renal allograft rejection. Management includes initiation, stabilisation and review of therapy as required<br><br>**Authority required (STREAMLINED)**<br>***3356***<br>Management of rejection, under the supervision and direction of a transplant unit, in patients receiving this drug for prophylaxis of cardiac allograft rejection. Management includes initiation, stabilisation and review of therapy as required<br><br>**Caution**<br>Careful monitoring of patients is mandatory. | | | | | | |
| 5737Y | everolimus 1 mg tablet, 60 | 4 | 5 | .. | *3844.80 | Certican | NV |
| 5738B | everolimus 250 microgram tablet, 60 | 2 | 5 | .. | *480.60 | Certican | NV |
| 5739C | everolimus 500 microgram tablet, 60 | 2 | 5 | .. | *961.20 | Certican | NV |
| 5740D | everolimus 750 microgram tablet, 60 | 4 | 5 | .. | *2883.60 | Certican | NV |
| | **MYCOPHENOLATE**<br>**Authority required (STREAMLINED)**<br>***4084***<br>Prophylaxis of renal allograft rejection<br><br>Treatment Phase: Management<br><br>**The Clinical criteria is:**<br><br>The treatment must be under the supervision and direction of a transplant unit.<br><br>**Authority required (STREAMLINED)**<br>***4095***<br>WHO Class III, IV or V lupus nephritis<br><br>Treatment Phase: Management<br><br>**The Clinical criteria is:**<br><br>The condition must be proven by biopsy,<br><br>**AND the Treatment criteria is:**<br><br>Must be treated by a nephrologist or in consultation with a nephrologist.<br><br>The name of the consulting nephrologist must be included in the patient medical records.<br><br>**Caution**<br>Careful monitoring of patients is mandatory.<br><br>**Note**<br>Management includes initiation, stabilisation and review of therapy as required. | | | | | | |
| 9503E | mycophenolate 180 mg tablet: enteric, 120 tablets | 2 | 5 | .. | *373.44 | Myfortic | NV |
| 9504F | mycophenolate 360 mg tablet: enteric, 120 tablets | 2 | 5 | .. | *746.86 | Myfortic | NV |
| | **MYCOPHENOLATE**<br>**Authority required (STREAMLINED)**<br>***3355***<br>Management of rejection, under the supervision and direction of a transplant unit, in patients receiving this drug for prophylaxis of renal allograft rejection. Management includes initiation, stabilisation and review of therapy as required<br><br>**Authority required (STREAMLINED)**<br>***3356***<br>Management of rejection, under the supervision and direction of a transplant unit, in patients receiving this drug for prophylaxis of cardiac allograft rejection. Management includes initiation, stabilisation and review of therapy as required<br><br>**Caution**<br>Careful monitoring of patients is mandatory. | | | | | | |

# HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | | Brand Name and Manufacturer | |
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| | **Note**<br>For item codes 9501C and 1839T, pharmaceutical benefits that have the form capsule 250 mg are equivalent for the purposes of substitution. | | | | | | | |
| 1839T | mycophenolate Capsule 250 mg, 50 | 12 | 5 | .. | *933.60 | [a] | Ceptolate | AF |
| 9501C | mycophenolate mofetil 250 mg capsule, 100 | 6 | 5 | .. | *933.60 | [a] | APO-Mycophenolate | TX |
| | | | | | | [a] | CellCept | RO |
| | | | | | | [a] | Imulate | QA |
| | | | | | | [a] | Mycophenolate Sandoz | SZ |
| | | | | | | [a] | Pharmacor Mycophenolate 250 | CR |
| | **MYCOPHENOLATE**<br>**Authority required (STREAMLINED)**<br>***3355***<br>Management of rejection, under the supervision and direction of a transplant unit, in patients receiving this drug for prophylaxis of renal allograft rejection. Management includes initiation, stabilisation and review of therapy as required | | | | | | | |
| | **Authority required (STREAMLINED)**<br>***3356***<br>Management of rejection, under the supervision and direction of a transplant unit, in patients receiving this drug for prophylaxis of cardiac allograft rejection. Management includes initiation, stabilisation and review of therapy as required | | | | | | | |
| | **Caution**<br>Careful monitoring of patients is mandatory. | | | | | | | |
| 9500B | mycophenolate mofetil 1 g/5 mL oral liquid: powder for, 165 mL | 2 | 5 | .. | *489.02 | | CellCept | RO |
| 9502D | mycophenolate mofetil 500 mg tablet, 50 | 6 | 5 | .. | *933.54 | [a] | APO-Mycophenolate | TX |
| | | | | | | [a] | CellCept | RO |
| | | | | | | [a] | Ceptolate | AF |
| | | | | | | [a] | Imulate | QA |
| | | | | | | [a] | Mycophenolate Sandoz | SZ |
| | | | | | | [a] | Pharmacor Mycophenolate 500 | CR |
| | **NATALIZUMAB**<br>**Authority required (STREAMLINED)**<br>***3425***<br>Treatment, as monotherapy, by a neurologist, of clinically definite relapsing-remitting multiple sclerosis in an ambulatory (without assistance or support) patient 18 years of age or older, who has experienced at least 2 documented attacks of neurological dysfunction, believed to be due to multiple sclerosis, in the preceding 2 years.<br>The diagnosis must be confirmed by magnetic resonance imaging of the brain and/or spinal cord and the date of the scan included in the patient's medical notes, unless written certification provided by a radiologist that an MRI scan is contraindicated because of the risk of physical (not psychological) injury to the patient is included in the patient's medical notes.<br>Natalizumab must be ceased if there is continuing progression of disability while on treatment with natalizumab. For continued treatment the patient must demonstrate compliance with, and an ability to tolerate, natalizumab | | | | | | | |
| | **Caution**<br>Progressive multifocal leukoencephalopathy has been reported with this drug. | | | | | | | |
| | **Note**<br>Neurologists prescribing natalizumab under the PBS listing must be registered with the Tysabri Australian Prescribing Program. | | | | | | | |
| | **Note**<br>Special Pricing Arrangements apply. | | | | | | | |
| 9505G | natalizumab 300 mg/15 mL injection, 1 x 15 mL vial | 1 | 5 | .. | 2038.46 | | Tysabri | BD |
| | **SIROLIMUS**<br>**Authority required (STREAMLINED)**<br>***3355***<br>Management of rejection, under the supervision and direction of a transplant unit, in patients receiving this drug for prophylaxis of renal allograft rejection. Management includes initiation, stabilisation and review of therapy as required | | | | | | | |
| | **Caution**<br>Careful monitoring of patients is mandatory. | | | | | | | |
| 9549N | sirolimus 1 mg tablet, 100 | 2 | 5 | .. | *1446.66 | | Rapamune | PF |
| 9550P | sirolimus 1 mg/mL oral liquid, 60 mL | 2 | 5 | .. | *936.00 | | Rapamune | PF |
| 9548M | sirolimus 2 mg tablet, 100 | 2 | 5 | .. | *2893.34 | | Rapamune | PF |
| 9747B | sirolimus 500 microgram tablet, 100 | 2 | 5 | .. | *723.34 | | Rapamune | PF |

## *Tumor necrosis factor alpha (TNF-) inhibitors*

# HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|

**ADALIMUMAB**

**Authority required**

Initial 1 (new patient or patient recommencing after a break of more than 12 months).

Initial treatment by a paediatric rheumatologist, or under the supervision of a paediatric rheumatology treatment centre, of a patient under 18 years:

(a) who has severe active juvenile idiopathic arthritis; AND

(b) whose parent or authorised guardian has signed a patient acknowledgement; AND

(c) who has not received PBS-subsidised treatment with adalimumab or etanercept for this condition in the previous 12 months; AND

(d) who has demonstrated either:

(i) severe intolerance of, or toxicity due to, methotrexate (see below for definition of severe intolerance and toxicity); or

(ii) failure to achieve an adequate response to 1 or more of the following treatment regimens:

— oral or parenteral methotrexate at a dose of at least 20 mg per square metre weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; or

— oral methotrexate at a dose of at least 10 mg per square metre weekly together with at least 1 other DMARD, alone or in combination with corticosteroids, for a minimum of 3 months. (Note: use of alternative DMARDs in children is dependent on approval by the Therapeutic Goods Administration as age restrictions may apply.)

Severe intolerance is defined as intractable nausea and vomiting and general malaise unresponsive to manoeuvres, including reducing or omitting concomitant NSAIDs on the day of methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses over 24 hours.

Toxicity is defined as evidence of hepatotoxicity with repeated elevations of transaminases, bone marrow suppression temporally related to methotrexate use, pneumonitis, or serious sepsis.

If treatment with methotrexate alone or in combination with another DMARD is contraindicated according to the relevant TGA-approved Product Information, please provide details at time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, please provide details of this toxicity at the time of application.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

(a) an active joint count of at least 20 active (swollen and tender) joints; OR

(b) at least 4 active joints from the following list:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count assessment should be performed preferably whilst still on DMARD treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and

(3) an acknowledgement signed by a parent or authorised guardian.

A maximum of 16 weeks of treatment will be authorised under this restriction.

At the time of authority application, medical practitioners should request the appropriate number of injections of appropriate strength, based on the weight of the patient, to provide sufficient for two doses. Up to a maximum of 3 repeats will be authorised.

Where fewer than 3 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Assessment of a patient's response to an initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 4 weeks from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with adalimumab.

If a patient fails to respond to treatment 3 times (twice with one agent and once with the other) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle. A patient may re-trial adalimumab after a minimum of 12 months have elapsed between the date the last PBS-subsidised bDMARD was stopped and the date of the first application under a new treatment cycle

**Authority required**

Initial 2 (change or re-commencement after break of less than 12 months).

Initial PBS-subsidised treatment with adalimumab by a paediatric rheumatologist, or under the supervision of a paediatric rheumatology treatment centre, of a patient under 18 years who:

# HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|

(a) has a documented history of severe active juvenile idiopathic arthritis; and

(b) in this treatment cycle, has received prior PBS-subsidised treatment with adalimumab or etanercept for this condition; and

(c) has not failed PBS-subsidised therapy with adalimumab for this condition more than once in the current treatment cycle.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].

Applications for a patient who has received PBS-subsidised treatment with adalimumab in this treatment cycle and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised adalimumab treatment, within the timeframes specified below.

A maximum of 16 weeks of treatment will be authorised under this restriction.

At the time of authority application, medical practitioners should request the appropriate number of injections of appropriate strength, based on the weight of the patient, to provide sufficient for two doses. Up to a maximum of 3 repeats will be authorised.

Where fewer than 3 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment with adalimumab may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Where the most recent course of PBS-subsidised adalimumab treatment was approved under either of the Initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be provided to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised adalimumab treatment was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to that particular course of bDMARD.

If a patient fails to respond to treatment 3 times (twice with one agent and once with the other) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle. A patient may re-trial adalimumab after a minimum of 12 months have elapsed between the date the last PBS-subsidised bDMARD was stopped and the date of the first application under a new treatment cycle

**Authority required**

Initial 3 ('grandfather' patients).

Initial PBS-subsidised supply for continuing treatment with adalimumab, by a paediatric rheumatologist, or under the supervision of a paediatric rheumatology treatment centre, of a patient under 18 years who:

(a) has a documented history of severe active juvenile idiopathic arthritis; and

(b) was receiving treatment with adalimumab prior to 1 March 2010; and

(c) has demonstrated a response as specified in the criteria for continuing PBS-subsidised treatment with adalimumab; and

(d) is receiving treatment with adalimumab at the time of application.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and

(3) an acknowledgement signed by a parent or authorised guardian.

A maximum of 24 weeks of treatment will be authorised under this restriction.

At the time of authority application, medical practitioners should request the appropriate number of injections of appropriate strength, based on the weight of the patient, to provide sufficient for two doses. Up to a maximum of 5 repeats will be authorised.

Where fewer than 5 repeats are initially requested with the authority prescription, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

The assessment of the patient's response to this initial course of PBS-subsidised therapy must be made within the 4 weeks prior to completion of the course in order to ensure continuity of treatment.

A patient ceasing treatment or swapping to an alternate agent and wishing to demonstrate a response to treatment, must be assessed no earlier than 12 weeks from the commencement of PBS-subsidised treatment. This assessment must be provided to Medicare Australia no later than 4 weeks from the date that 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.

A patient may only qualify for PBS-subsidised treatment under this restriction once

**Authority required**

Continuing treatment.

Continuing PBS-subsidised treatment with adalimumab, by a rheumatologist or under the supervision of a paediatric rheumatology treatment centre, of a patient:

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Brand Name and Manufacturer |
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(a) who has a documented history of severe active juvenile idiopathic arthritis; and

(b) who has demonstrated an adequate response to treatment with adalimumab; and

(c) whose most recent course of PBS-subsidised bDMARD treatment in this treatment cycle was with adalimumab.

An adequate response to treatment is defined as:

(i) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(ii) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

— elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

— shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].

A maximum of 24 weeks of treatment will be approved under this restriction.

At the time of authority application, medical practitioners should request the appropriate number of injections of appropriate strength, based on the weight of the patient, to provide sufficient for two doses. Up to a maximum of 5 repeats will be authorised.

Where fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

All applications for continuing treatment with adalimumab must include a measurement of response to the prior course of therapy. This assessment must be provided to Medicare Australia no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with adalimumab, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.

If a patient fails to respond to treatment 3 times (twice with one agent and once with the other) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle. A patient may re-trial adalimumab after a minimum of 12 months have elapsed between the date the last PBS-subsidised bDMARD was stopped and the date of the first application under a new treatment cycle

**Note**

Any queries concerning the arrangements to prescribe adalimumab may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe adalimumab should be forwarded to:

Medicare Australia

Prior Written Approval of Specialised Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

**Note**

TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab and etanercept for a patient who has severe active juvenile idiopathic arthritis. Where the term bDMARD appears in the following NOTES and restrictions, it refers to adalimumab and etanercept only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 2 bDMARDs at any 1 time.

From 1 November 2010, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to the alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

— continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy, and

— fail to respond, or to sustain a response to one PBS-subsidised bDMARD twice and the other PBS-subsidised bDMARD once only.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 12 month break in PBS-subsidised biological therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 November 2010 is considered to be in their first cycle as of 1 November 2010. A patient who has had a break in bDMARD treatment of at least 12 months immediately prior to making a new application, on or after 1 November 2010, will commence a new treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 12 months may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 12 months must

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commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 November 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or

(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 12 months (Initial 1); or

(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or

(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 12 months in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to the alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 12 months.

A patient may trial the 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 twice within the current treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to the alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and Medicare Australia will assess response according to the revised baseline measurement.

(4) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 12 months, must requalify for treatment under the Initial 1 treatment restriction.

(5) Patients 'grandfathered' onto PBS-subsidised treatment with adalimumab.

A patient who commenced treatment with adalimumab for severe active juvenile idiopathic arthritis prior to 1 March 2010 and who continues to receive treatment at the time of application, may qualify for treatment under the initial 'grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment with adalimumab will be authorised under this criterion.

Following completion of the initial PBS-subsidised course, further applications for treatment with adalimumab will be assessed under the continuing treatment restriction.

'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must qualify for initial treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 12 month break in PBS-subsidised therapy' above for further details.

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| | (6) Withdrawal of treatment after sustained remission. | | | | | | |
| | Withdrawal of treatment with bDMARDs should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be submitted to Medicare Australia at the time treatment is ceased. | | | | | | |
| 9661L | adalimumab 20 mg/0.4 mL injection, 2 x 0.4 mL syringes | 1 | .. | .. | 1630.00 | Humira | VE |
| 9663N | adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL cartridges | 1 | .. | .. | 1630.00 | Humira | VE |
| 9662M | adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes | 1 | .. | .. | 1630.00 | Humira | VE |

**ETANERCEPT**

**Authority required**

Continuing treatment.

Continuing PBS-subsidised treatment with etanercept, by a rheumatologist or under the supervision of a paediatric rheumatology treatment centre, of a patient 18 years or older:

(a) who has a documented history of severe active juvenile idiopathic arthritis; and

(b) who has demonstrated an adequate response to treatment with etanercept; and

(c) whose most recent course of PBS-subsidised bDMARD treatment in this treatment cycle was with etanercept.

An adequate response to treatment is defined as:

(i) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(ii) a reduction in the number of the following active joints, from at least 4, by at least 50%:

— elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

— shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].

A maximum of 24 weeks of treatment will be approved under this restriction.

Where fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

All applications for continuing treatment with etanercept must include a measurement of response to the prior course of therapy. This assessment must be provided to Medicare Australia no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with etanercept, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.

If a patient fails to respond to treatment 3 times (twice with one agent and once with the other) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle.

Where a patient with severe active juvenile idiopathic arthritis continues treatment with etanercept and is 18 years or older, etanercept 50 mg may be prescribed

**Note**

Any queries concerning the arrangements to prescribe etanercept may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe etanercept should be forwarded to:

Medicare Australia

Prior Written Approval of Specialised Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

**Note**

TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab and etanercept for a patient who has severe active juvenile idiopathic arthritis. Where the term bDMARD appears in the following NOTES and restrictions, it refers to adalimumab and etanercept only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 2 bDMARDs at any 1 time.

From 1 November 2010, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to the alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a

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patient may:

— continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy, and

— fail to respond, or to sustain a response to one PBS-subsidised bDMARD twice and the other PBS-subsidised bDMARD once only.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 12 month break in PBS-subsidised biological therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 November 2010 is considered to be in their first cycle as of 1 November 2010. A patient who has had a break in bDMARD treatment of at least 12 months immediately prior to making a new application, on or after 1 November 2010, will commence a new treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 12 months may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 12 months must commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 November 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or

(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 12 months (Initial 1); or

(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or

(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 12 months in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to the alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 12 months.

A patient may trial the 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 twice within the current treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to the alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and Medicare Australia will assess response according to the revised baseline measurement.

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Brand Name and Manufacturer | |
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| | (4) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.<br>A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 12 months, must requalify for treatment under the Initial 1 treatment restriction.<br>(5) Patients 'grandfathered' onto PBS-subsidised treatment with adalimumab.<br>A patient who commenced treatment with adalimumab for severe active juvenile idiopathic arthritis prior to 1 March 2010 and who continues to receive treatment at the time of application, may qualify for treatment under the initial 'grandfather' treatment restriction.<br>A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment with adalimumab will be authorised under this criterion.<br>Following completion of the initial PBS-subsidised course, further applications for treatment with adalimumab will be assessed under the continuing treatment restriction.<br>'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must qualify for initial treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 12 month break in PBS-subsidised therapy' above for further details.<br>(6) Withdrawal of treatment after sustained remission.<br>Withdrawal of treatment with bDMARDs should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be submitted to Medicare Australia at the time treatment is ceased. | | | | | | |
| 5735W | ETANERCEPT Injection 50 mg in 1 mL single use auto-injector, 4, 1 | 1 | .. | .. | 1630.01 | Enbrel | PF |
| 5733R | ETANERCEPT Injections 50 mg in 1 mL single use pre-filled syringes, 4, 1 | 1 | .. | .. | 1630.01 | Enbrel | PF |

**ETANERCEPT**

**Authority required**

Initial 1 (new patient or patient recommencing after a break of more than 12 months).

Initial treatment by a paediatric rheumatologist, or under the supervision of a paediatric rheumatology treatment centre, of a patient under 18 years:

(a) who has severe active juvenile idiopathic arthritis; AND

(b) whose parent or authorised guardian has signed a patient acknowledgement; AND

(c) who has not received PBS-subsidised treatment with adalimumab or etanercept for this condition in the previous 12 months; AND

(d) who has demonstrated either:

(i) severe intolerance of, or toxicity due to, methotrexate (see below for definition of severe intolerance and toxicity); or

(ii) failure to achieve an adequate response to 1 or more of the following treatment regimens:

— oral or parenteral methotrexate at a dose of at least 20 mg per square metre weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; or

— oral methotrexate at a dose of at least 10 mg per square metre weekly together with at least 1 other DMARD, alone or in combination with corticosteroids, for a minimum of 3 months. (Note: use of alternative DMARDs in children is dependent on approval by the Therapeutic Goods Administration as age restrictions may apply.)

Severe intolerance is defined as intractable nausea and vomiting and general malaise unresponsive to manoeuvres, including reducing or omitting concomitant NSAIDs on the day of methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses over 24 hours.

Toxicity is defined as evidence of hepatotoxicity with repeated elevations of transaminases, bone marrow suppression temporally related to methotrexate use, pneumonitis, or serious sepsis.

If treatment with methotrexate alone or in combination with another DMARD is contraindicated according to the relevant TGA-approved Product Information, please provide details at time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, please provide details of this toxicity at the time of application.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

(a) an active joint count of at least 20 active (swollen and tender) joints; OR

(b) at least 4 active joints from the following list:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count assessment should be performed preferably whilst still on DMARD treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare

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Australia website (www.medicareaustralia.gov.au)]; and

(3) an acknowledgement signed by a parent or authorised guardian.

A maximum of 16 weeks of treatment will be authorised under this restriction.

Where fewer than 3 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Assessment of a patient's response to an initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 4 weeks from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with etanercept.

If a patient fails to respond to treatment 3 times (twice with one agent and once with the other) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle. A patient may re-trial etanercept after a minimum of 12 months have elapsed between the date the last PBS-subsidised bDMARD was stopped and the date of the first application under a new treatment cycle

**Authority required**

Initial 2 (change or re-commencement after break of less than 12 months).

Initial PBS-subsidised treatment with etanercept by a paediatric rheumatologist, or under the supervision of a paediatric rheumatology treatment centre, of a patient under 18 years who:

(a) has a documented history of severe active juvenile idiopathic arthritis; and

(b) in this treatment cycle, has received prior PBS-subsidised treatment with adalimumab or etanercept for this condition; and

(c) has not failed PBS-subsidised therapy with etanercept for this condition more than once in the current treatment cycle.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].

Applications for a patient who has received PBS-subsidised treatment with etanercept in this treatment cycle and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised etanercept treatment, within the timeframes specified below.

A maximum of 16 weeks of treatment will be authorised under this restriction.

Where fewer than 3 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment with etanercept may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Where the most recent course of PBS-subsidised etanercept treatment was approved under either of the Initial 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 provided to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised etanercept treatment was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to that particular course of bDMARD.

If a patient fails to respond to treatment 3 times (twice with one agent and once with the other) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle. A patient may re-trial etanercept after a minimum of 12 months have elapsed between the date the last PBS-subsidised bDMARD was stopped and the date of the first application under a new treatment cycle

**Authority required**

Continuing treatment.

Continuing PBS-subsidised treatment with etanercept, by a rheumatologist or under the supervision of a paediatric rheumatology treatment centre, of a patient:

(a) who has a documented history of severe active juvenile idiopathic arthritis; and

(b) who has demonstrated an adequate response to treatment with etanercept; and

(c) whose most recent course of PBS-subsidised bDMARD treatment in this treatment cycle was with etanercept.

An adequate response to treatment is defined as:

(i) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(ii) a reduction in the number of the following active joints, from at least 4, by at least 50%:

— elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

— shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

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(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].

A maximum of 24 weeks of treatment will be approved under this restriction.

Where fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

All applications for continuing treatment with etanercept must include a measurement of response to the prior course of therapy. This assessment must be provided to Medicare Australia no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with etanercept, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.

If a patient fails to respond to treatment 3 times (twice with one agent and once with the other) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle. A patient may re-trial etanercept after a minimum of 12 months have elapsed between the date the last PBS-subsidised bDMARD was stopped and the date of the first application under a new treatment cycle

**Note**

Any queries concerning the arrangements to prescribe etanercept may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe etanercept should be forwarded to:

Medicare Australia

Prior Written Approval of Specialised Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

**Note**

TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab and etanercept for a patient who has severe active juvenile idiopathic arthritis. Where the term bDMARD appears in the following NOTES and restrictions, it refers to adalimumab and etanercept only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 2 bDMARDs at any 1 time.

From 1 November 2010, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to the alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

— continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy, and

— fail to respond, or to sustain a response to one PBS-subsidised bDMARD twice and the other PBS-subsidised bDMARD once only.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 12 month break in PBS-subsidised biological therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 November 2010 is considered to be in their first cycle as of 1 November 2010. A patient who has had a break in bDMARD treatment of at least 12 months immediately prior to making a new application, on or after 1 November 2010, will commence a new treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 12 months may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 12 months must commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 November 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or

(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 12 months (Initial 1); or

(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or

(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 12 months in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

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Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to the alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 12 months.

A patient may trial the 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 twice within the current treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to the alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and Medicare Australia will assess response according to the revised baseline measurement.

(4) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 12 months, must requalify for treatment under the Initial 1 treatment restriction.

(5) Patients 'grandfathered' onto PBS-subsidised treatment with adalimumab.

A patient who commenced treatment with adalimumab for severe active juvenile idiopathic arthritis prior to 1 March 2010 and who continues to receive treatment at the time of application, may qualify for treatment under the initial 'grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment with adalimumab will be authorised under this criterion.

Following completion of the initial PBS-subsidised course, further applications for treatment with adalimumab will be assessed under the continuing treatment restriction.

'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must qualify for initial treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 12 month break in PBS-subsidised therapy' above for further details.

(6) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with bDMARDs should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be submitted to Medicare Australia at the time treatment is ceased.

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|---|---|---|---|---|---|---|---|
| 5734T | etanercept 25 mg injection [4 x 25 mg vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack | 1 | .. | .. | 815.00 | Enbrel | PF |

**INFLIXIMAB**

**Authority required**

Initial 1 (new patients)

Initial PBS-subsidised treatment with infliximab, by a rheumatologist, of an adult with active ankylosing spondylitis who has radiographically (plain X-ray) confirmed Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis and who has not received any PBS-subsidised treatment with either adalimumab, etanercept, golimumab or infliximab in this treatment cycle; AND

(a) who has 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) [for further information on the BASMI please

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refer to the Medicare Australia website at www.medicareaustralia.gov.au]; or

(iii) limitation of chest expansion relative to normal values for age and gender [for chest expansion normal values please refer to the Medicare Australia website at www.medicareaustralia.gov.au]; AND

(b) who has 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.

The application must include details of the NSAIDs trialled, their doses and duration of treatment. If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used.

If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication.

If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance. Details of the toxicities, including severity, which will be accepted for the purposes of administering this restriction can be found on the Medicare Australia website [www.medicareaustralia.gov.au].

For details on the appropriate minimum exercise program that will be accepted for the purposes of administering this restriction, please refer to the Medicare Australia website at www.medicareaustralia.gov.au.

The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of the initial application:

(a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale; AND

(b) an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 10 mg per L.

The BASDAI must be determined at the completion of the 3 month NSAID and exercise trial, but prior to ceasing NSAID treatment. The BASDAI must be no more than 1 month old at the time of initial application.

Both ESR and CRP measures should be provided with the initial treatment application and both must be no more than 1 month old. If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reason this criterion cannot be satisfied.

Authority applications 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 [www.medicareaustralia.gov.au] which must include the following:

(i) a copy of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and

(ii) a completed BASDAI Assessment Form [www.medicareaustralia.gov.au]; and

(iii) a completed Exercise Program Self Certification Form included in the supporting information form; and

(iv) a signed patient acknowledgment form.

The assessment of the patient's response to the initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted to Medicare Australia no later than 4 weeks from the cessation of that treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

A maximum of 18 weeks of treatment with infliximab will be approved under this criterion.

At the time of the authority application, the doctor should request the appropriate number of vials, based on the weight of the patient, to provide for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised.

Where fewer than 3 repeats are initially requested with the authority prescription, authority approvals for sufficient repeats to complete a maximum of 18 weeks of treatment may be requested by telephone.

Patients who fail to demonstrate a response to treatment with infliximab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. Patients may re-trial infliximab after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised TNF-alfa antagonist was approved in this cycle and the date of the first application under a new cycle

**Authority required**

Initial 2 (change or re-commencement for all patients)

Initial PBS-subsidised treatment with infliximab, by a rheumatologist, of an adult with a documented history of active ankylosing spondylitis who, in this treatment cycle, has received prior PBS-subsidised TNF-alfa antagonist treatment for this condition and is eligible to receive further TNF-alfa antagonist therapy, and has not failed PBS-subsidised therapy with infliximab in the current treatment cycle.

Where the most recent course of PBS-subsidised TNF-alfa antagonist treatment was approved under either of the initial treatment restrictions (i.e. for patients with no prior PBS-subsidised TNF-alfa antagonist therapy or, under this restriction, for patients who have received previous PBS-subsidised TNF-alfa antagonist 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 Medicare Australia 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 infliximab treatment was approved under the continuing treatment criteria, patients must have been assessed for response, and the assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Authority applications 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 [www.medicareaustralia.gov.au].

A maximum of 18 weeks of treatment with infliximab will be approved under this criterion.

At the time of the authority application, the doctor should request the appropriate number of vials, based on the weight of the patient, to provide

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for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised.

Where fewer than 3 repeats are initially requested with the authority prescription, authority approvals for sufficient repeats to complete a maximum of 18 weeks of treatment may be requested by telephone.

Patients who fail to demonstrate a response to treatment with infliximab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. Patients may re-trial infliximab after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised TNF-alfa antagonist was approved in this cycle and the date of the first application under a new cycle

**Authority required**

Continuing treatment for all patients

Continuing PBS-subsidised treatment, by a rheumatologist, of an adult with a documented history of active ankylosing spondylitis who:

(a) has demonstrated an adequate response to treatment with infliximab; and

(b) whose most recent course of PBS-subsidised therapy in this treatment cycle was with infliximab.

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.

Authority applications 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 [www.medicareaustralia.gov.au].

All measurements provided must be no more than 1 month old at the time of application.

A maximum of 24 weeks of treatment with infliximab will be authorised under this criterion.

At the time of the authority application, the doctor should request the appropriate number of vials, based on the weight of the patient, to provide for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised.

Where fewer than 3 repeats are initially requested with the authority prescription, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone.

All applications for continuing treatment with infliximab must include a measurement of response to the prior course of therapy. This assessment must be provided to Medicare Australia no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment following an initial treatment course it must be made following a minimum of 12 weeks of treatment with infliximab. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

Patients who fail to demonstrate a response to treatment with infliximab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. Patients may re-trial infliximab after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised TNF-alfa antagonist was approved in this cycle and the date of the first application under a new cycle

**Note**

Any queries concerning the arrangements to prescribe infliximab may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe infliximab should be forwarded to:

Medicare Australia

Prior Written Approval of Specialised Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

**Note**

TREATMENT OF ADULT PATIENTS WITH ACTIVE ANKYLOSING SPONDYLITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept, golimumab and infliximab for adult patients with active ankylosing spondylitis. Where the term 'tumour necrosis factor (TNF) alfa antagonist' appears in the following NOTES and restrictions, it refers to adalimumab, etanercept, golimumab and infliximab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 4 TNF-alfa antagonists at any 1 time.

From 1 March 2007, under the PBS, all patients will be able to commence a treatment cycle where they may trial PBS-subsidised TNF-alfa antagonists without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a TNF-alfa antagonist while they continue to show a response to therapy.

A patient who received PBS-subsidised TNF-alfa antagonist treatment prior to 1 March 2007 is considered to be in their first cycle as of 1 March 2007.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised TNF-alfa antagonist more than once. A patient who, prior to 1 March 2007, was authorised to receive PBS-subsidised initial treatment for ankylosing spondylitis with the same

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agent twice, is exempt from this condition in respect of applications approved prior to 1 March 2007.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised TNF-alfa antagonist therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised TNF-alfa antagonist treatment in the most recent cycle to the date of the first application for initial treatment with a TNF-alfa antagonist under the new treatment cycle.

A patient who has failed fewer than 3 TNF-alfa antagonists in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 TNF-alfa antagonists in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised TNF-alfa antagonist therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised TNF-alfa antagonist treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or

(ii) a patient has received prior PBS-subsidised (initial or continuing) TNF-alfa antagonist therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to re-commence treatment with a specific TNF-alfa antagonist following a break in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept and golimumab and 18 weeks of treatment for infliximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.

For second and subsequent courses of PBS-subsidised TNF-alfa antagonist treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific TNF-alfa antagonist, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing TNF-alfa antagonist treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted TNF-alfa antagonist supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised TNF-alfa antagonist is approved, a patient may swap to an alternate TNF-alfa antagonist 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 TNF-alfa antagonist at any time, regardless of whether they are receiving therapy (initial or continuing) with a TNF-alfa antagonist at the time of the application. However, they cannot swap to a particular TNF-alfa antagonist if they have failed to respond to prior treatment with that drug within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate TNF-alfa antagonist should be accompanied by the approved authority prescription or remaining repeats for the TNF-alfa antagonist the patient is ceasing.

(3) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a TNF-alfa antagonist. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and Medicare Australia will assess response according to these revised baseline measurements.

For a new patient, the BASDAI used to determine the baseline must be measured while the patient is receiving NSAID therapy and completing their exercise program.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response.

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| | (4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.<br>A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised TNF-alfa antagonist therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have received treatment with 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.<br>(5) Patients 'grandfathered' onto PBS-subsidised treatment with golimumab.<br>A patient who commenced treatment with golimumab for active ankylosing spondylitis prior to 1 March 2010 and who continues to receive treatment at the time of application, may qualify for treatment under the initial 'grandfather' treatment restriction.<br>A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment with golimumab will be authorised under this criterion.<br>Following completion of the initial PBS-subsidised course, further applications for treatment with golimumab will be assessed under the continuing treatment restriction.<br>'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must requalify for initial treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' above for further details. | | | | | | |
| 5753T | infliximab 100 mg injection, 1 x 100 mg vial | 1 | .. | .. | 751.70 | Remicade | JC |
| | **INFLIXIMAB**<br>**Authority required**<br>Initial 1 (new patients)<br>Initial treatment of Crohn disease in a patient assessed by CDAI.<br>Initial PBS-subsidised treatment with infliximab by a gastroenterologist or a consultant physician as specified in the NOTE below, of a patient with severe refractory Crohn disease who satisfies the following criteria:<br>(a) has confirmed Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician as specified in the NOTE below; and<br>(b) has signed a patient acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and<br>(c) has failed to achieve an adequate response to prior systemic therapy including:<br>(i) a tapered course of steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period; and<br>(ii) immunosuppressive therapy including:<br>— azathioprine at a dose of at least 2 mg per kg daily for 3 or more months; or<br>— 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months; or<br>— methotrexate at a dose of at least 15 mg weekly for 3 or more months.<br>NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].<br>If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application.<br>If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of the accepted toxicities including severity can be found on the Medicare Australia website (www.medicareaustralia.gov.au).<br>The following initiation criterion indicates failure to achieve an adequate response and must be demonstrated in all patients at the time of the application:<br>(a) have a severity of disease activity which results in a Crohn Disease Activity Index (CDAI) Score greater than or equal to 300 as assessed.<br>All tests and assessments should be performed preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.<br>The most recent CDAI assessment must be no more than 1 month old at the time of application.<br>Applications for authorisation must be made in writing and must include:<br>(a) a completed authority prescription form; and<br>(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:<br>(i) the completed current Crohn Disease Activity Index (CDAI) calculation sheet including the date of assessment of the patient's condition; and<br>(ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and<br>(iii) the signed patient acknowledgement.<br>A maximum quantity and number of repeats to provide for an initial course of infliximab consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.<br>Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete the 3 doses of infliximab may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend | | | | | | |

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the initial treatment period.

A CDAI assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab.

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment

**Authority required**

Initial 2

Change or re-commencement of treatment of Crohn disease in a patient assessed by CDAI.

Initial PBS-subsidised treatment with infliximab by a gastroenterologist or a consultant physician as specified in the NOTE below of a patient who:

(a) has a documented history of severe refractory Crohn disease; and

(b) in this treatment cycle, has received prior PBS-subsidised treatment with infliximab or adalimumab for this condition; and

(c) has not failed PBS-subsidised therapy with infliximab for this condition more than once in the current treatment cycle.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

To demonstrate a response to treatment the application must be accompanied by the results of the most recent course of TNF-alfa antagonist therapy within the timeframes specified in the relevant restriction.

Where the most recent course of PBS-subsidised TNF-alfa antagonist treatment was approved under an initial treatment restriction, the patient must have been assessed for response to that course following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

If the response assessment to the previous course of TNF-alfa antagonist treatment is not submitted as detailed above, the patient will be deemed to have failed therapy with that particular course of TNF-alfa antagonist.

Authority applications must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) the completed current Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient's condition; and

(ii) details of prior TNF alfa antagonist treatment including details of date and duration of treatment.

A maximum quantity and number of repeats to provide for an initial course of infliximb consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete the 3 doses of infliximab may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

A CDAI assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab.

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment

**Authority required**

Continuing treatment of Crohn disease in a patient assessed by CDAI.

Continuing PBS-subsidised treatment with infliximab by a gastroenterologist, a consultant physician as specified in the NOTE below or other consultant physician in consultation with a gastroenterologist, of a patient who:

(a) has a documented history of severe refractory Crohn disease; and

(b) has demonstrated or sustained an adequate response to treatment with infliximab.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

An adequate response to infliximab treatment is defined as a reduction in Crohn Disease Activity Index (CDAI) Score to a level no greater than 150.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

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(i) the completed Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient's condition.

The CDAI assessment must be no more than 1 month old at the time of application.

If the application is the first application for continuing treatment with infliximab, a CDAI assessment of the patient's response must be made up to 12 weeks after the first dose so that there is adequate time for a response to be demonstrated.

The assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion.

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with infliximab.

Patients are eligible to receive continuing infliximab treatment in courses of up to 24 weeks providing they continue to sustain the response.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats will be authorised. No applications for increased repeats will be authorised.

Where fewer than 2 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday)

**Authority required**

Initial 1

Initial treatment of Crohn disease in a patient with short gut syndrome or an ostomy patient.

Initial PBS-subsidised treatment with infliximab by a gastroenterologist, or consultant physician as specified in the NOTE below of a patient who satisfies the following criteria:

(a) has confirmed Crohn disease defined by standard clinical, endoscopic and/or imaging features, including histological evidence with the diagnosis confirmed by a gastroenterologist or consultant physician as specified in the NOTE below; and

(b) has diagnostic imaging or surgical evidence of short gut syndrome or has an ileostomy or colostomy; and

(c) has evidence of intestinal inflammation; and

(d) has signed a patient acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and

(e) has failed to achieve an adequate response to prior systemic drug therapy including:

(i) a tapered course of steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period; and

(ii) immunosuppressive therapy including:

— azathioprine at a dose of at least 2 mg per kg daily for 3 or more months; or

— 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months; or

— methotrexate at a dose of at least 15 mg weekly for 3 or more months.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of the accepted toxicities including severity can be found on the Medicare Australia website (www.medicareaustralia.gov.au).

The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the application:

(a) have evidence of intestinal inflammation, including:

(i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; AND/OR

(ii) faeces: higher than normal lactoferrin or calprotectin level; AND/OR

(iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery;

AND/OR

(b) be assessed clinically as being in a high faecal output state;

AND/OR

(c) be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of infliximab.

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.

Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the continuing treatment restriction. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy.

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Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and

(ii) reports and dates of the pathology or diagnostic imaging test(s) nominated as the response criterion, if relevant; and

(iii) date of the most recent clinical assessment; and

(iv) the signed patient acknowledgement.

All assessments, pathology tests and diagnostic imaging studies must be made within 1 month of the date of application.

A maximum quantity and number of repeats to provide for an initial course of infliximab consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete the 3 doses of infliximab may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

The assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab.

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment

**Authority required**

Initial 2

Change or re-commencement of treatment of Crohn disease in a patient with short gut syndrome, an ostomy patient or a patient with extensive small intestine disease.

Initial PBS-subsidised treatment with infliximab by a gastroenterologist or a consultant physician as specified in the NOTE below of a patient who:

(a) has a documented history of severe refractory Crohn disease; and

(b) in this treatment cycle, has received prior PBS-subsidised treatment with infliximab or adalimumab for this condition; and

(c) has not failed PBS-subsidised therapy with infliximab for this condition more than once in the current treatment cycle.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

To demonstrate a response to treatment the application must be accompanied by the results of the most recent course of TNF-alfa antagonist therapy within the timeframes specified in the relevant restriction.

Where the most recent course of PBS-subsidised TNF-alfa antagonist treatment was approved under an initial treatment restriction, the patient must have been assessed for response to that course following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

If the response assessment to the previous course of TNF-alfa antagonist treatment is not submitted as detailed above, the patient will be deemed to have failed therapy with that particular course of TNF-alfa antagonist.

Authority applications must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) reports and dates of the pathology or diagnostic imaging test(s) nominated as the response criteria, if relevant; and

(ii). details of prior TNF alfa antagonist treatment including details of date and duration of treatment.

A maximum quantity and number of repeats to provide for an initial course of infliximab consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

The assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of therapy so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab.

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 12 week assessment, to ensure

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continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment

**Authority required**

Continuing treatment of Crohn disease in a patient with short gut syndrome or an ostomy patient.

Continuing PBS-subsidised treatment with infliximab by a gastroenterologist, a consultant physician as specified in the NOTE below or other consultant physician in consultation with a gastroenterologist, of a patient who:

(a) has a documented history of severe refractory Crohn disease with intestinal inflammation and with short gut syndrome or with an ileostomy or colostomy; and

(b) has demonstrated or sustained an adequate response to treatment with infliximab.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

An adequate response to infliximab treatment is defined as:

(a) improvement of intestinal inflammation as demonstrated by:

(i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; AND/OR

(ii) faeces: normalisation of lactoferrin or calprotectin level; AND/OR

(iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or

(b) reversal of high faecal output state; or

(c) avoidance of the need for surgery or total parenteral nutrition (TPN).

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) the reports and dates of the pathology or diagnostic imaging test(s) used to assess response to therapy or the date of clinical assessment.

The patient's assessment must be no more than 1 month old at the time of application.

If the application is the first application for continuing treatment with infliximab, an assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.

The assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion.

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with infliximab.

Patients are eligible to receive continuing infliximab treatment in courses of up to 24 weeks providing they continue to sustain the response.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats will be authorised. No applications for increased repeats will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday)

**Authority required**

Initial 1

Initial treatment of Crohn disease in a patient with extensive small intestine disease.

Initial PBS-subsidised treatment with infliximab by a gastroenterologist or a consultant physician as specified in the NOTE below, of a patient with severe refractory Crohn disease who satisfies the following criteria:

(a) has confirmed Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or consultant physician as specified in the NOTE below; and

(b) has extensive small intestinal disease with radiological evidence of intestinal inflammation affecting more than 50 cm of the small intestine; and

(c) has signed a patient acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and

(d) has failed to achieve an adequate response to prior systemic therapy including:

(i) a tapered course of steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period; and

(ii) immunosuppressive therapy including:

— azathioprine at a dose of at least 2 mg per kg daily for 3 or more months; or

— 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months; or

— methotrexate at a dose of at least 15 mg weekly for 3 or more months.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or

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consultant physicians [general medicine specialising in gastroenterology (code 82)].

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of the accepted toxicities including severity can be found on the Medicare Australia website (www.medicareaustralia.gov.au).

The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the application:

(a) have severity of disease activity which results in a Crohn Disease Activity Index (CDAI) Score greater than or equal to 220;

AND/OR

(b) have evidence of active intestinal inflammation, including:

(i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; AND/OR

(ii) faeces: higher than normal lactoferrin or calprotectin level; AND/OR

(iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery;

AND/OR

(c) be assessed clinically as being in a high faecal output state;

AND/OR

(d) be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of infliximab.

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.

Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the continuing treatment restriction. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and

(ii) (1) reports and dates of the pathology or diagnostic imaging test(s) nominated as the response criterion, if relevant; or

(2) the completed current Crohn Disease Activity Index (CDAI) calculation sheet including the dates of assessment of the patient's condition, if relevant; and

(iii) date of the most recent clinical assessment; and

(iv) the signed patient acknowledgement.

All assessments, pathology tests and diagnostic imaging studies must be made within 1 month of the date of application.

A maximum quantity and number of repeats to provide for an initial course of infliximab consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete the 3 doses of infliximab may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

The assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab.

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment

**Authority required**

Continuing treatment of Crohn disease in a patient with extensive small intestine disease.

Continuing PBS-subsidised treatment with infliximab by a gastroenterologist, or consultant physician as specified in the NOTE below or other consultant physician in consultation with a gastroenterologist, of a patient who:

(a) has a documented history of severe refractory Crohn disease with extensive intestinal inflammation affecting more than 50 cm of the small intestine; and

(b) has demonstrated or sustained an adequate response to treatment with infliximab.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or

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consultant physicians [general medicine specialising in gastroenterology (code 82)].

An adequate response to infliximab treatment is defined as:

(a) a reduction in Crohn Disease Activity Index (CDAI) Score to no greater than 150; or

(b) improvement of intestinal inflammation as demonstrated by:

(i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; AND/OR

(ii) faeces: normalisation of lactoferrin or calprotectin level; AND/OR

(iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or

(c) reversal of high faecal output state; or

(d) avoidance of the need for surgery or total parenteral nutrition (TPN).

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) the completed Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient's condition; or

(ii) the reports and dates of the pathology test or diagnostic imaging test(s) used to assess response to therapy; or

(iii) the date of clinical assessment.

All assessments must be no more than 1 month old at the time of application.

If the application is the first application for continuing treatment with infliximab, an assessment of the patient's response must be made up to 12 weeks after the first dose (6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.

The assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion.

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with infliximab.

Patients are eligible to receive continuing infliximab treatment in courses of up to 24 weeks providing they continue to sustain the response.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats will be authorised. No applications for increased repeats will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday)

**Authority required**

Initial 3 (grandfather)

Initial PBS-subsidised treatment of Crohn disease in a patient assessed by CDAI who has previously received non-PBS-subsidised therapy with infliximab.

Initial PBS-subsidised supply for continuing treatment with infliximab by a gastroenterologist, a consultant physician as specified in the NOTE below, or other consultant physician in consultation with a gastroenterologist of a patient who:

(a) has a documented history of severe refractory Crohn disease and was receiving treatment with infliximab prior to 7 March 2007; and

(b) had a Crohn Disease Activity Index (CDAI) Score of greater than or equal to 300 prior to commencing treatment with infliximab. Where a baseline CDAI assessment is not available, please call Medicare Australia on 1800 700 270 to discuss; and

(c) has signed a patient acknowledgement indicating that they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and

(d) has demonstrated or sustained an adequate response to treatment with infliximab. For advice please contact Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

An adequate response to infliximab treatment is defined as a reduction in Crohn Disease Activity Index (CDAI) Score to no greater than 150.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) the completed current and baseline Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient's condition; and

(ii) the signed patient acknowledgement.

The current CDAI assessment must be no more than 1 month old at the time of application. The baseline CDAI assessment must be from

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immediately prior to commencing treatment with infliximab.

The assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion.

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with infliximab.

Patients are eligible to receive continuing infliximab treatment in courses of up to 24 weeks providing they continue to sustain the response.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats will be authorised. No applications for increased repeats will be authorised.

Where fewer than 2 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Patients may qualify for PBS-subsidised treatment under this restriction once only

**Authority required**

Initial 3

Initial PBS-subsidised treatment of Crohn disease in a patient with short gut syndrome, an ostomy patient, or a patient with extensive small intestine disease, who has previously received non-PBS-subsidised therapy with infliximab.

Initial PBS-subsidised supply for continuing treatment with infliximab by a gastroenterologist, a consultant physician as specified in the NOTE below, or other consultant physician in consultation with a gastroenterologist, of a patient who:

(a) has a documented history of severe refractory Crohn disease and was receiving treatment with infliximab prior to 7 March 2007; and

(b) (1) has a history of extensive small intestinal disease with radiological evidence of intestinal inflammation affecting more than 50 cm of the small intestine; or

(2) has diagnostic imaging or surgical evidence of short gut syndrome or has an ileostomy or colostomy with a documented history of intestinal inflammation; and

(c) has signed a patient acknowledgement indicating that they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and

(d) has demonstrated or sustained an adequate response to treatment with infliximab according to the criteria included in the relevant continuation restriction. For advice please contact Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

The same criteria used to determine an inadequate response to prior treatment at baseline must be used to determine response to treatment and eligibility for continuing therapy, according to the criteria included in the continuing treatment restriction.

An adequate response to infliximab treatment is defined as:

(a) a reduction in Crohn Disease Activity Index (CDAI) Score to no greater than 150; or

(b) improvement of intestinal inflammation as demonstrated by:

(i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; AND/OR

(ii) faeces: normalisation of lactoferrin or calprotectin level; AND/OR

(iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or

(c) reversal of high faecal output state; or

(d) avoidance of the need for surgery or total parenteral nutrition (TPN).

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au) ] which includes the following:

(i) (1) the completed current and baseline Crohn Disease Activity Index (CDAI) Score calculation sheet, where relevant, including the date of the assessment of the patient's condition; or

(2) the reports and dates of the current and baseline pathology or diagnostic imaging test(s) in order to assess response to therapy; or

(3) the date of clinical assessment(s); and

(ii) the signed patient acknowledgement.

The patient's assessment must be no more than 1 month old at the time of application. The baseline CDAI assessments must be from immediately prior to commencing treatment with infliximab. Where a baseline assessment is not available, please call Medicare Australia on 1800 700 270 to discuss.

The assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion.

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Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with infliximab.

Patients are eligible to receive continuing infliximab treatment in courses of up to 24 weeks providing they continue to sustain the response.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats will be authorised. No applications for increased repeats will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Patients may qualify for PBS-subsidised treatment under this restriction once only

**Note**

Any queries concerning the arrangements to prescribe infliximab may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe infliximab should be forwarded to:

Medicare Australia

Prior Written Approval of Specialised Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

**Note**

TREATMENT OF ADULT PATIENTS WITH SEVERE REFRACTORY CROHN DISEASE

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab and infliximab for adult patients with severe refractory Crohn disease. Where the term 'tumour necrosis factor (TNF) alfa antagonist' appears in the following NOTES and restrictions, it refers to adalimumab and infliximab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 2 TNF-alfa antagonists at any 1 time.

From 1 August 2008, under the PBS, all patients will be able to commence a treatment cycle where they may trial each PBS-subsidised TNF-alfa antagonist without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a TNF-alfa antagonist while they continue to show a response to therapy.

A patient who received PBS-subsidised TNF-alfa antagonist treatment prior to 1 August 2008 is considered to be in their first cycle as of 1 August 2008.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised TNF-alfa antagonist more than twice.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised TNF-alfa antagonist therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised TNF-alfa antagonist treatment in the most recent cycle to the date of the first application for initial treatment with a TNF-alfa antagonist under the new treatment cycle.

A patient who has failed fewer than 3 trials of TNF-alfa antagonists in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of TNF-alfa antagonists in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised TNF-alfa antagonist therapy after 1 August 2008.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised TNF-alfa antagonist treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or

(ii) a patient has received prior PBS-subsidised (initial or continuing) TNF-alfa antagonist therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to re-commence treatment with a specific TNF-alfa antagonist following a break in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and 14 weeks of therapy for infliximab.

From 1 August 2008, a patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to

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respond to treatment with that TNF-alfa antagonist.

For second and subsequent courses of PBS-subsidised TNF-alfa antagonist treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

Adalimumab only: Two completed authority prescriptions must be submitted with every initial application for adalimumab. One prescription must be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats. The second prescription must be written for 2 doses of 40 mg and 2 repeats.

(b) Continuing treatment. Following the completion of an initial treatment course with a specific TNF-alfa antagonist, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing TNF-alfa antagonist treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted TNF-alfa antagonist supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised TNF-alfa antagonist is approved, a patient may swap if eligible to the alternate TNF-alfa antagonist within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Crohn Disease Activity Index (CDAI) Score, evidence of intestinal inflammation), or the prior corticosteroid therapy and immunosuppressive therapy.

A patient may trial the alternate TNF-alfa antagonist at any time, regardless of whether they are receiving therapy (initial or continuing) with a TNF-alfa antagonist at the time of the application. However, they cannot swap to a particular TNF-alfa antagonist if they have failed to respond to prior treatment with that drug two times within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to the alternate TNF-alfa antagonist should be accompanied by the approved authority prescription or remaining repeats for the TNF-alfa antagonist the patient is ceasing.

(3) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements of the CDAI or evidence of intestinal inflammation submitted with the first authority application for a TNF-alfa antagonist. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and Medicare Australia will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications.

(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised TNF-alfa antagonist therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have received treatment with a corticosteroid and at least 1 immunosuppressive agent, at an adequate dose, for a minimum of 3 consecutive months immediately prior to the time the CDAI score or the indices of intestinal inflammation are measured.

(5) Patients 'grandfathered' onto PBS-subsidised treatment with adalimumab or infliximab.

A patient who commenced treatment with adalimumab for severe refractory Crohn disease prior to 9 November 2007 or infliximab prior to 7 March 2007 and who continues to receive treatment at the time of application, may qualify for treatment under the initial 'grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment with adalimumab or infliximab will be authorised under this criterion.

Following completion of the initial PBS-subsidised course, further applications for treatment with adalimumab or infliximab will be assessed under the continuing treatment restriction.

'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must requalify for initial treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' above for further details.

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| 5754W | infliximab 100 mg injection, 1 x 100 mg vial | 1 | .. | .. | 751.70 | Remicade | JC |

**INFLIXIMAB**

**Authority required**

Initial treatment of Crohn disease in a paediatric patient.

Initial PBS-subsidised treatment by a gastroenterologist, paediatrician or consultant physician as specified in the NOTE below, of a patient aged 6 to 17 years inclusive with moderate to severe refractory Crohn disease who satisfies the following criteria:

(a) has confirmed Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or consultant physician as specified in the NOTE below; and

(b) whose parent or authorised guardian has signed a patient acknowledgement indicating they understand and acknowledge that PBS-subsidised

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treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and

(c) has failed to achieve an adequate response to 2 of the following 3 conventional prior therapies including:

(i) a tapered course of steroids, starting at a dose of at least 1 mg per kg or 40 mg (whichever is the lesser) prednisolone (or equivalent), over a 6 week period;

(ii) an 8 week course of enteral nutrition;

(iii) immunosuppressive therapy including:

— azathioprine at a dose of at least 2 mg per kg daily for 3 or more months; or

— 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months; or

— methotrexate at a dose of at least 10 mg per square metre weekly for 3 or more months.

NOTE: Prescribers must be gastoenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of the accepted toxicities including severity can be found on the Medicare Australia website (www.medicareaustralia.gov.au).

The following initiation criterion indicates failure to achieve an adequate response and must be demonstrated in all patients at the time of the application:

(a) severity of disease activity which results in a Paediatric Crohn Disease Activity Index (PCDAI) Score greater than or equal to 30 as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.

(b) The most recent PCDAI assessment must be no more than 1 month old at the time of application.

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) the completed current Paediatric Crohn Disease Activity Index (PCDAI) calculation sheet including the date of assessment of the patient's condition; and

(ii) details of previous systemic drug therapy [dosage, date of commencement and duration of therapy], or dates of enteral nutrition; and

(iii) the signed patient acknowledgement.

A maximum quantity and number of repeats to provide for an initial course of infliximab consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete the 3 doses of infliximab may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

A PCDAI assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab.

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment

**Authority required**

Continuing treatment of Crohn disease in a patient initiated on PBS-subsidised treatment as a paediatric patient.

Continuing PBS-subsidised treatment with infliximab by a gastroenterologist, paediatrician, consultant physician as specified in the NOTE below or other consultant physician in consultation with a gastroenterologist, of a patient who:

(a) has a documented history of moderate to severe refractory Crohn disease; and

(b) has demonstrated or sustained an adequate response to treatment with infliximab.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

An adequate response to infliximab treatment is defined as a reduction in Paediatric Crohn Disease Activity Index (PCDAI) Score by at least 15 points as compared to baseline AND a total PCDAI score of 30 points or less.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

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(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) the completed Paediatric Crohn Disease Activity Index (PCDAI) calculation sheet along with the date of the assessment of the patient's condition.

The PCDAI assessment must be no more than 1 month old at the time of application.

If the application is the first application for continuing treatment with infliximab, a PCDAI assessment of the patient's response must be made up to 12 weeks after the first dose so that there is adequate time for a response to be demonstrated.

The assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion.

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with infliximab.

Patients are eligible to receive continuing infliximab treatment in courses of up to 24 weeks providing they continue to sustain the response.

Patients who fail to demonstrate or sustain a response to treatment with infliximab for Crohn disease as specified in the criteria for continuing treatment with infliximab, will not be eligible to receive PBS-subsidised treatment with this drug within 12 months of the date on which treatment was ceased.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats will be authorised. No applications for increased repeats will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday)

**Authority required**

Initial PBS-subsidised treatment of Crohn disease in a paediatric patient who has previously received non-PBS-subsidised therapy with infliximab.

Initial PBS-subsidised supply for continuing treatment with infliximab by a gastroenterologist, paediatrician, consultant physician as specified in the NOTE below or other consultant physician in consultation with a gastroenterologist, of a patient aged 6 to 17 years inclusive who:

(a) has a documented history of moderate to severe refractory Crohn disease and was receiving treatment with infliximab prior to 4 July 2007; and

(b) had a Paediatric Crohn Disease Activity Index (PCDAI) Score of greater than 30 prior to commencing treatment with infliximab. Where a baseline CDAI assessment is not available, please call Medicare Australia on 1800 700 270 to discuss; and

(c) whose parent or authorised guardian has signed a patient acknowledgement indicating that they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and

(d) has demonstrated or sustained an adequate response to treatment with infliximab. For advice please contact Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

An adequate response to infliximab treatment is defined as a reduction in Paediatric Crohn Disease Activity Index (PCDAI) Score by at least 15 points as compared to baseline AND a total PCDAI score of 30 points or less.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) the completed current and baseline Paediatric Crohn Disease Activity Index (PCDAI) calculation sheet along with the date of the assessment of the patient's condition; and

(ii) the signed patient acknowledgement.

The current PCDAI assessment must be no more than 1 month old at the time of application. The baseline PCDAI assessment must be from immediately prior to commencing treatment with infliximab.

The assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion.

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with infliximab.

Patients are eligible to receive continuing infliximab treatment in courses of up to 24 weeks providing they continue to sustain the response.

Patients who fail to demonstrate or sustain a response to treatment with infliximab for Crohn disease as specified in the criteria for continuing treatment with infliximab, will not be eligible to recommence PBS-subsidised treatment with this drug within 12 months of the date on which treatment was ceased.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats will be authorised. No applications for increased repeats will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24

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| | weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).<br>Patients may qualify for PBS-subsidised treatment under this restriction once only<br>**Note**<br>Any queries concerning the arrangements to prescribe infliximab may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).<br>Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.<br>Written applications for authority to prescribe infliximab should be forwarded to:<br>Medicare Australia<br>Prior Written Approval of Specialised Drugs<br>Reply Paid 9826<br>GPO Box 9826<br>HOBART TAS 7001 | | | | | | |
| 5755X | infliximab 100 mg injection, 1 x 100 mg vial | 1 | .. | .. | 751.70 | Remicade | JC |
| | **INFLIXIMAB**<br>**Authority required**<br>Initial 1<br>Initial PBS-subsidised treatment with infliximab, by a rheumatologist or clinical immunologist with expertise in the management of psoriatic arthritis, of adults who:<br>(1) have severe active psoriatic arthritis; and<br>(2) have received no prior PBS-subsidised biological treatment for this condition in this Treatment Cycle; and<br>(3) have failed to achieve an adequate response to:<br>(a) methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months; and<br>(b) sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months; or<br>(c) leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months.<br>If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application.<br>If intolerance to treatment develops during the relevant period of use, which is of a severity to necessitate permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of acceptable toxicities, including severity, can be found on the Medicare Australia website (www.medicareaustralia.gov.au).<br>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:<br>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<br>(i) an active joint count of at least 20 active (swollen and tender) joints; or<br>(ii) at least 4 active joints from the following list of major joints:<br>— elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or<br>— 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).<br>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.<br>The authority application must be made in writing and must include:<br>(1) a completed authority prescription form; and<br>(2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and<br>(3) a signed patient acknowledgement.<br>A maximum of 22 weeks treatment will be authorised under this restriction.<br>At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats may be authorised.<br>Where fewer than 3 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 22 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).<br>The assessment of the patient's response to the initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted to Medicare Australia no later than 4 weeks from the cessation of that treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.<br>Patients who fail to demonstrate a response to treatment with infliximab under this restriction will not be eligible to receive further PBS-subsidised | | | | | | |

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treatment with this drug, in this Treatment Cycle. Patients may re-trial infliximab after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle

**Authority required**

Initial 2

Initial PBS-subsidised treatment with infliximab, by a rheumatologist or clinical immunologist with expertise in the management of psoriatic arthritis, of adults who:

(1) have a documented history of severe active psoriatic arthritis; and

(2) have received prior PBS-subsidised biological treatment for this condition in this Treatment Cycle and are eligible to receive further biological therapy; and

(3) have not failed treatment with infliximab during the current Treatment Cycle.

Applications for patients who have received PBS-subsidised treatment with infliximab within this Treatment Cycle and who wish to re-commence therapy with this drug within this same Cycle, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised infliximab treatment, within the timeframes specified below.

A maximum of 22 weeks treatment will be authorised under this restriction.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats may be authorised.

Where fewer than 3 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 22 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Where the most recent course of PBS-subsidised infliximab treatment was approved under either of the initial treatment restrictions (i.e. for patients with no prior PBS-subsidised biological therapy or, under this restriction, for patients who have received previous PBS-subsidised biological therapy), patients must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be provided to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised infliximab treatment was approved under the continuing treatment criteria, patients must have been assessed for response, and the assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].

Patients who fail to demonstrate a response to treatment with infliximab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug, in this Treatment Cycle. Patients may re-trial infliximab after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle

**Authority required**

Continuing treatment

Continuing PBS-subsidised treatment with infliximab, by a rheumatologist or clinical immunologist with expertise in the management of psoriatic arthritis, of adults:

(1) who have a documented history of severe active psoriatic arthritis; and

(2) whose most recent course of PBS-subsidised biological agent for this condition in the current Treatment Cycle was with infliximab; and

(3) who, at the time of application, demonstrate an adequate response to treatment with infliximab.

An adequate response to treatment with infliximab is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following:

(i) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(ii) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

— elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

— shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].

A maximum of 24 weeks of treatment will be approved under this restriction.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats may be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

# HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

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All applications for continuing treatment with infliximab must include a measurement of response to the prior course of therapy. This assessment must be provided to Medicare Australia no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with infliximab, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with the initial treatment course.

Patients who fail to demonstrate a response to treatment with infliximab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug, in this Treatment Cycle. Patients may re-trial infliximab after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle

**Note**

Any queries concerning the arrangements to prescribe infliximab may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe infliximab should be forwarded to:

Medicare Australia

Prior Written Approval of Specialised Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

**Note**

TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents (adalimumab, etanercept, golimumab and infliximab) for adult patients with severe active psoriatic arthritis.

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological agents at any 1 time. Where the term 'biological agents' appears in the following NOTES and restrictions, it only refers to adalimumab, etanercept, golimumab and infliximab.

From 1 August 2006, all patients will be able to commence a 'Biological Treatment Cycle' (Cycle), where they may trial biological agents without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

Following demonstration of response to initial treatment, these biological agents are available under the PBS for continuing treatment as set out in the continuing treatment restriction for each agent.

Once patients have either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological therapy before they are eligible to commence another Cycle [further details are under '(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' below].

The 5-year break in therapy will be measured from the date the last approval for PBS-subsidised treatment was granted in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Cycle.

Within the same Cycle, patients are not allowed to fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for any biological agent, they must change to an alternate agent which they have not previously failed, if they wish to continue PBS-subsidised biological treatment.

Patients for whom a break in PBS-subsidised therapy of less than 5 years has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.

Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle.

There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.

How to prescribe biological agents for the treatment of severe active psoriatic arthritis after 1 August 2010.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); and

(ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; and

(iii) patients wish to re-commence treatment with a specific biological agent following a break in PBS-subsidised therapy with that specific agent (Initial 2).

All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 16 weeks of therapy for all agents except for infliximab, for which a maximum of 22 weeks will be authorised. It is recommended that patients be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological agent supply.

Patients must be assessed for response to any course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.

Grandfather patients — golimumab only.

Applications for patients who commenced treatment with golimumab prior to 1 March 2010 may apply for initial PBS-subsidised treatment as continuing therapy under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the

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same way as new patients who have not been treated with any biological agent prior to PBS listing of that agent.

Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment for all agents. Approval will be based on the criteria included in the relevant restriction.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological agent, patients may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. Patients are eligible to receive continuing biological treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

Patients must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.

(3) Swapping therapy.

Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate biological agent without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements.

Patients may swap to an alternate biological agent at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological agent at the time of the application or not.

Patients may alternate between therapy with any biological agent of their choice (1 at a time) providing:

(i) they have not received PBS-subsidised treatment with that particular biological agent previously; or

(ii) they have demonstrated an adequate response to that particular biological agent if they have previously trialled it on the PBS; or

(iii) they have not previously failed to respond to treatment 3 times in this Treatment Cycle.

To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the biological agent the patient is ceasing.

(4) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements of the indices of disease severity submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment authority is submitted within a treatment Cycle and Medicare Australia will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.

(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

Patients who wish to trial a second or subsequent treatment Cycle following a break in PBS-subsidised biological therapy of at least 5 years, must re-qualify for initial treatment with respect to both the indices of disease severity. Patients must have received treatment with methotrexate and sulfasalazine or leflunomide, at an adequate dose, for a minimum of 3 months at the time the ESR or CRP levels and the active joint counts are measured.

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|---|---|---|---|---|---|---|---|
| 5756Y | infliximab 100 mg injection, 1 x 100 mg vial | 1 | .. | .. | 751.70 | Remicade | JC |

**INFLIXIMAB**

**Authority required**

Initial 1 (new patient or patient re-commencing after a break of more than 24 months)

Initial PBS-subsidised treatment with infliximab, in combination with methotrexate at a dose of at least 7.5 mg weekly, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of adults who:

(a) have severe active rheumatoid arthritis; and

(b) have received no PBS-subsidised treatment with a bDMARD for this condition in the previous 24 months; and

(c) have failed, in the 24 months immediately prior to the date of application, to achieve an adequate response to at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs), which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be:

— hydroxychloroquine at a dose of at least 200 mg daily; or

— leflunomide at a dose of at least 10 mg daily; or

— sulfasalazine at a dose of at least 2 g daily.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, then the 6 months of intensive DMARD treatment must include at least 3 months continuous treatment with each of at least 2 of the DMARDs:

— hydroxychloroquine at a dose of at least 200 mg daily; and/or

— leflunomide at a dose of at least 10 mg daily; and/or

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— sulfasalazine at a dose of at least 2 g daily.

The application must include details of the contraindication or intolerance to methotrexate. Details of the toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose can be found on the Medicare Australia website [www.medicareaustralia.gov.au]. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

If 3 or more of methotrexate, hydroxychloroquine, leflunomide and sulfasalazine are contraindicated according to the relevant TGA-approved product information or cannot be tolerated at the doses specified above, then one or more of the following DMARDs may be used in place of these agents in order to satisfy the requirement for a trial of 6 months of intensive DMARD therapy with at least 2 DMARDs taken continuously for at least 3 months each:

— azathioprine at a dose of at least 1 mg/kg per day; and/or

— cyclosporin at a dose of at least 2 mg/kg/day; and/or

— sodium aurothiomalate at a dose of 50 mg weekly.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances. Details of the toxicities, including severity, which will be accepted as a reason for substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial can be found on the Medicare Australia website [www.medicareaustralia.gov.au].

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance and dose for each DMARD must be provided in the authority application. Details of the toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy can be found on the Medicare Australia website [www.medicareaustralia.gov.au].

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L;

AND either

(i) a total active joint count of at least 20 active (swollen and tender) joints; or

(ii) at least 4 active joints from the following list of major joints:

— elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

— shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reason this criterion cannot be satisfied.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and

(3) a signed patient acknowledgement.

A maximum of 22 weeks of treatment will be authorised under this restriction.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 3 mg per kg. Up to a maximum of 3 repeats may be authorised. Where fewer than 3 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 22 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Assessment of a patient's response to an initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab.

Patients who fail to demonstrate a response to treatment with infliximab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition

**Authority required**

Initial 2 (change or re-commencement after break of less than 24 months)

Initial course of PBS-subsidised treatment with infliximab, in combination with methotrexate at a dose of at least 7.5 mg weekly, by a

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rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of adults who:

(a) have a documented history of severe active rheumatoid arthritis; and

(b) have received prior PBS-subsidised bDMARD treatment for this condition and are eligible to receive further bDMARD therapy.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].

Applications for patients who have received PBS-subsidised treatment with infliximab and who wish to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised infliximab treatment, within the timeframes specified below.

A maximum of 22 weeks of treatment will be authorised under this restriction.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 3 mg per kg. Up to a maximum of 3 repeats may be authorised.

Where fewer than 3 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 22 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Where the most recent course of PBS-subsidised infliximab treatment was approved under either of the initial 1 or 2 treatment restrictions, patients must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be provided to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised infliximab treatment was approved under the continuing treatment criteria, patients must have been assessed for response, and the assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Patients who fail to demonstrate a response to treatment with infliximab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition

**Authority required**

Continuing treatment

Continuing PBS-subsidised treatment with infliximab, in combination with methotrexate at a dose of at least 7.5 mg weekly, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of adults:

(a) who have a documented history of severe active rheumatoid arthritis; and

(b) who have demonstrated an adequate response to treatment with infliximab; and

(c) whose most recent course of PBS-subsidised bDMARD treatment was with infliximab.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(i) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(ii) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

— elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

— shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].

A maximum of 24 weeks of treatment will be approved under this restriction.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 3 mg per kg. Up to a maximum of 2 repeats may be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

All applications for continuing treatment with infliximab must include a measurement of response to the prior course of therapy. This assessment must be provided to Medicare Australia no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with infliximab, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.

Patients who fail to demonstrate a response to treatment with infliximab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition

**Note**

Any queries concerning the arrangements to prescribe infliximab may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m.

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to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe infliximab should be forwarded to:

Medicare Australia

Prior Written Approval of Specialised Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

**Note**

TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying anti-rheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab) and the T-cell co-stimulation modulator (abatacept).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

PBS-subsidised abatacept, golimumab, infliximab and rituximab must be used in combination with methotrexate at a dose of at least 7.5 mg weekly. Where a patient cannot tolerate 7.5 mg of methotrexate weekly, they are eligible to receive PBS-subsidised adalimumab, certolizumab pegol, etanercept and tocilizumab.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:

— a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,

— a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and

— once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact Medicare Australia on 1800 700 270.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or

(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or

(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or

(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab and tocilizumab, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to Medicare Australia within 4 weeks.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

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Abatacept patients:

Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients:

A further application may be submitted to Medicare Australia 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Rituximab patients:

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.

Abatacept patients:

Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

**Note**

(3) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and Medicare Australia will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

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| | **Note**<br>Special Pricing Arrangements apply. | | | | | | |
| 5757B | infliximab 100 mg injection, 1 x 100 mg vial | 1 | .. | .. | 751.70 | Remicade | JC |

**INFLIXIMAB**

**Authority required**

Initial treatment [Initial 1, Whole body (New patients — No prior biological agent)]

Initial treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over who:

(a) have severe chronic plaque psoriasis where lesions have been present for at least 6 months from the time of initial diagnosis; and

(b) have not received any prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle; and

(c) have signed a patient and prescriber acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment (whole body); and

(d) have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 3 of the following 4 treatments:

(i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; and/or

(ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; and/or

(iii) cyclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; and/or

(iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks.

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity to necessitate permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of acceptable toxicities including severity, associated with phototherapy, methotrexate, cyclosporin and acitretin, can be found on the Medicare Australia website (www.medicareaustralia.gov.au).

The following initiation criterion indicates failure to achieve an adequate response and must be demonstrated in all patients at the time of the application:

(a) A current Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.

(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 1 month following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than 1 month old at the time of application.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy]; and

(iii) the signed patient and prescriber acknowledgements.

A maximum of 22 weeks of treatment with infliximab will be authorised under this restriction.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised.

Where fewer than 3 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 22 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period beyond 22 weeks.

A PASI assessment of the patient's response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

It is recommended that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment

**Authority required**

Initial or re-Treatment [Initial 2, Whole body (Received prior biological agent under PBS)]

Treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over who:

(a) have a documented history of severe chronic plaque psoriasis; and

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(b) have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle; and

(c) have not failed PBS-subsidised therapy with infliximab for the treatment of this condition in the current Treatment Cycle.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and

(ii) details of prior biological treatment, including dosage, date and duration of treatment.

Applications for patients who have demonstrated a response to PBS-subsidised infliximab treatment within this Treatment Cycle and who wish to re-commence infliximab treatment within the same Cycle following a break in therapy, will only be approved where evidence of the patient's response to their most recent course of PBS-subsidised infliximab treatment has been submitted to Medicare Australia within 1 month of cessation of treatment.

A maximum of 22 weeks of treatment with infliximab will be authorised under this restriction.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised.

Where fewer than 3 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 22 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period beyond 22 weeks.

A PASI assessment of the patient's response to this course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

It is recommended that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment.

Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may re-commence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle

**Authority required**

Continuing treatment (Whole body)

Continuing PBS-subsidised treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over:

(a) who have a documented history of severe chronic plaque psoriasis; and

(b) whose most recent course of PBS-subsidised biological treatment for this condition in this Treatment Cycle was with infliximab; and

(c) who have demonstrated an adequate response to their most recent course of treatment with infliximab.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the pre-biological treatment baseline value for this Treatment Cycle.

This assessment must be provided to Medicare Australia no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with infliximab, the assessment of response must be after a minimum of 12 weeks of treatment with an initial course.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) the completed Psoriasis Area and Severity Index (PASI) calculation sheet along with the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 1 month old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with infliximab.

A maximum of 24 weeks of treatment with infliximab will be authorised under this restriction.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for continuing authority applications, or for treatment that would otherwise extend the treatment period beyond 24 weeks.

# HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

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A PASI assessment of the patient's response must be conducted within 4 weeks prior to completion of this course of treatment. This assessment, which will be used to determine eligibility for further continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

It is recommended that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment.

Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may re-commence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle

**Authority required**

Initial treatment [Initial 1, Face, hand, foot (New patients — No prior biological agent)]

Initial treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over who:

(a) have severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis; and

(b) have not received any prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle; and

(c) have signed a patient and prescriber acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment (face, hand, foot); and

(d) have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 3 of the following 4 treatments:

(i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; and/or

(ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; and/or

(iii) cyclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; and/or

(iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks.

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity to necessitate permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of acceptable toxicities including severity, associated with phototherapy, methotrexate, cyclosporin and acitretin, can be found on the Medicare Australia website (www.medicareaustralia.gov.au).

The following initiation criterion indicates failure to achieve an adequate response and must be demonstrated in all patients at the time of the application:

(a) Chronic plaque psoriasis classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where:

(i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment; or

(ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.

(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 1 month following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than 1 month old at the time of application.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy]; and

(iii) the signed patient and prescriber acknowledgements.

A maximum of 22 weeks of treatment with infliximab will be authorised under this restriction.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised.

Where fewer than 3 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 22 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period beyond 22 weeks.

A PASI assessment of the patient's response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response

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assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

It is recommended that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline

**Authority required**

Initial or re-Treatment [Initial 2, Face, hand, foot (Received prior biological agent under PBS)]

Treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over who:

(a) have a documented history of severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot; and

(b) have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle; and

(c) have not failed PBS-subsidised therapy with infliximab for the treatment of this condition in the current Treatment Cycle.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and

(ii) details of prior biological treatment, including dosage, date and duration of treatment.

Applications for patients who have demonstrated a response to PBS-subsidised infliximab treatment within this Treatment Cycle and who wish to re-commence infliximab treatment within the same Cycle following a break in therapy, will only be approved where evidence of the patient's response to their most recent course of PBS-subsidised infliximab treatment has been submitted to Medicare Australia within 1 month of cessation of treatment.

A maximum of 22 weeks of treatment with infliximab will be authorised under this restriction.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised.

Where fewer than 3 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 22 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period beyond 22 weeks.

A PASI assessment of the patient's response to this course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

It is recommended that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may re-commence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle

**Authority required**

Continuing treatment (Face, hand, foot)

Continuing PBS-subsidised treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over:

(a) who have a documented history of severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot; and

(b) whose most recent course of PBS-subsidised biological treatment for this condition in this Treatment Cycle was with infliximab; and

(c) who have demonstrated an adequate response to treatment with infliximab.

An adequate response to infliximab treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the pre-biological treatment baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the pre-biological treatment baseline value.

This assessment must be provided to Medicare Australia no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with infliximab, the assessment of response must be after a minimum of 12 weeks of treatment with an initial course.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

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(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) the completed Psoriasis Area and Severity Index (PASI) calculation sheet and face, hand, foot area diagrams along with the date of the assessment of the patient's condition [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].

The most recent PASI assessment must be no more than 1 month old at the time of application.

A maximum of 24 weeks of treatment with infliximab will be authorised under this restriction.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for continuing authority applications, or for treatment that would otherwise extend the treatment period beyond 24 weeks.

A PASI assessment of the patient's response must be conducted within 4 weeks prior to completion of this course of treatment. This assessment, which will be used to determine eligibility for further continuing treatment must be submitted to Medicare Australia no later than 1 month from the date of completion of this course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

It is recommended that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment.

The PASI assessment for continuing treatment must be performed on the same affected area assessed at baseline.

Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may re-commence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle

**Note**

Any queries concerning the arrangements to prescribe infliximab may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe infliximab should be forwarded to:

Medicare Australia

Prior Written Approval of Specialised Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

**Note**

TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, etanercept, infliximab and ustekinumab, for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological agents' appears in the following NOTES and restrictions, it only refers to adalimumab, etanercept, infliximab and ustekinumab.

From 1 March 2010, all patients will be able to commence a 'Biological Treatment Cycle' (Cycle), where they may trial adalimumab, etanercept, infliximab or ustekinumab without having to meet the initial treatment criteria, that is they will not need to experience a disease flare when swapping to an alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

A patient who received PBS-subsidised biological agent treatment for chronic plaque psoriasis prior to 1 March 2010 is considered to be in their first Cycle as of 1 March 2010.

Patients are eligible for PBS-subsidised treatment with only 1 biological agent at any 1 time.

Within the same Treatment Cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for a PBS-subsidised biological agent, they must change to an alternate agent if they wish to continue PBS-subsidised biological treatment. A patient who, prior to 1 March 2010, was authorised to receive PBS-subsidised initial treatment for chronic plaque psoriasis with the same agent twice, is exempt from this condition in respect of applications approved prior to 1 March 2010.

Patients must be assessed for response to each course of continuing treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a Treatment Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological agent therapy before they are eligible to commence the next Cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological agent treatment in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Treatment Cycle.

Patients for whom a break in PBS-subsidised therapy of less than 5 years duration has occurred, and, who have failed therapy fewer than 3 times within a particular Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.

Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a

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particular Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle.

There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.

How to prescribe biological agents for the treatment of severe chronic plaque psoriasis after 1 March 2010.

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Application for approval for initial treatment.

Applications for a course of initial treatment should be made in the following situations:

(i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); or

(ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under '(4) Swapping therapy' below]; or

(iii) patients who wish to re-commence treatment following a break in PBS-subsidised therapy with that agent (Initial 2).

All applications for initial treatment will be limited to provide for a maximum of 16 weeks of treatment in the case of adalimumab and etanercept, 22 weeks of treatment in the case of infliximab and 28 weeks of treatment in the case of ustekinumab.

(2) Assessment of response to initial treatment.

When prescribing initial treatment with a biological agent, a PASI assessment must be conducted after at least 12 weeks of treatment. This assessment must be submitted to Medicare Australia within 1 month of the completion of this initial treatment course. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

(3) Application for continuing treatment.

Following the completion of an initial treatment course of a biological agent to which an adequate response has been demonstrated, patients may qualify to receive up to 24 weeks of continuing treatment with that biological agent. Patients are eligible to continue to receive continuous treatment with 24 week courses providing they continue to sustain a response.

For second and subsequent courses of PBS-subsidised treatment with adalimumab, etanercept, infliximab or ustekinumab it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

Where a response assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to sustain a response to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

(4) Swapping therapy.

Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate agent within the same Treatment Cycle without having to requalify with respect to disease severity (i.e. a PASI score of greater than 15), or prior treatment requirements.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

Patients may trial an alternate biological agent at any time, regardless of whether they are receiving therapy with a biological agent at the time of the application or not. However, they cannot swap to a particular agent if they have failed to respond to treatment with that particular agent within the same Cycle.

Patients who commenced treatment with adalimumab prior to 1 June 2009 or ustekinumab prior to 1 March 2010 access these interchangeability arrangements in the same way as patients who have not.

To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the agent being ceased.

(5) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated, based on the baseline PASI assessment submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment authority is submitted within a Treatment Cycle and subsequent response will be assessed according to this revised PASI score.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatment applications.

(6) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

Patients who wish to trial a second or subsequent Biological Treatment Cycle, following a break in PBS-subsidised biological therapy of at least 5 years, must requalify for initial treatment according to the criteria of the relevant restriction and index of disease severity. Patients must have had at least 1 prior treatment, as listed in the criteria, for a minimum of 6 weeks, and must have a PASI assessment conducted preferably whilst still on treatment, but no later than 1 month following cessation of treatment. The PASI assessment must be no older than 1 month at the time of application.

**Note**

No applications for increased repeats will be authorised.

# HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Brand Name and Manufacturer | |
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| 5758C | infliximab 100 mg injection, 1 x 100 mg vial | 1 | .. | .. | 751.70 | Remicade | JC |

**INFLIXIMAB**

**Authority required**

Initial 1

Initial treatment of complex refractory FISTULISING CROHN DISEASE.

Initial PBS-subsidised treatment with infliximab by a gastroenterologist or a consultant physician as specified in the NOTE below, of a patient with complex refractory fistulising Crohn disease who:

(a) has confirmed Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician as specified in the NOTE below; and

(b) has an externally draining enterocutaneous or rectovaginal fistula; and

(c) has signed a patient acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criteria for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

Authority applications must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Fistulising Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) a completed current Fistula Assessment Form including the date of assessment of the patient's condition; and

(ii) a signed patient acknowledgement.

The most recent fistula assessment must be no more than 1 month old at the time of application.

A maximum quantity and number of repeats to provide for an initial course of infliximab consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6 will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete 3 doses of infliximab may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

An assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (up to 6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.

This assessment must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab.

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment

**Authority required**

Initial 2

Change or re-commencement of treatment of complex refractory FISTULISING CROHN DISEASE.

Initial PBS-subsidised treatment with infliximab of complex refractory fistulising Crohn disease by a gastroenterologist or a consultant physician as specified in the NOTE below, of a patient with complex refractory fistulising Crohn disease who:

(a) has a documented history of complex refractory fistulising Crohn disease; and

(b) in this treatment cycle, has received prior PBS-subsidised treatment with adalimumab or infliximab for a draining enterocutaneous or rectovaginal fistula; and

(c) has not failed PBS-subsidised therapy with infliximab for this condition more than once in the current treatment cycle.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

To demonstrate a response to treatment the application must be accompanied by the results of the most recent course of TNF-alfa antagonist therapy within the timeframes specified in the relevant restriction.

Where the most recent course of PBS-subsidised TNF-alfa antagonist treatment was approved under an initial treatment restriction, the patient must have been assessed for response to that course following a minimum of 12 weeks therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

If the response assessment to the previous course of TNF-alfa antagonist treatment is not submitted as detailed above, the patient will be deemed to have failed therapy with that particular course of TNF-alfa antagonist.

Authority applications must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Fistulising Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Brand Name and Manufacturer |
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(i) a completed current Fistula Assessment Form including the date of assessment of the patient's condition; and

(ii) details of prior TNF-alfa antagonist treatment including details of date and duration of treatment.

The most recent fistula assessment must be no more than 1 month old at the time of application.

A maximum quantity and number of repeats to provide for an initial course of infliximab consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete 3 doses of infliximab may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

An assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (up to 6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.

This assessment must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab.

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment

**Authority required**

Initial 3 (grandfather)

Initial PBS-subsidised treatment of complex refractory FISTULISING CROHN DISEASE in a patient who has previously received non-PBS-subsidised therapy with infliximab.

Initial PBS-subsidised supply for continuing treatment with infliximab by a gastroenterologist, a consultant physician as specified in the NOTE below, or other consultant physician in consultation with a gastroenterologist of a patient who satisfies the following criteria:

(a) has a documented history of complex refractory fistulising Crohn disease and was receiving treatment with infliximab prior to 1 March 2010; and

(b) had a draining enterocutaneous or rectovaginal fistula(e) prior to commencing treatment with infliximab; and

(c) has signed a patient acknowledgement indicating that they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criteria for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and

(d) is receiving treatment with infliximab at the time of application; and

(e) has demonstrated or sustained an adequate response to treatment with infliximab.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

An adequate response to infliximab treatment is defined as:

(a) a decrease from baseline in the number of open draining fistulae of greater than or equal to 50%; and/or

(b) a marked reduction in drainage of all fistula(e) from baseline, together with less pain and induration as reported by the patient.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Fistulising Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) a completed current and baseline Fistula Assessment form including the date of assessment of the patient's condition; and

(ii) a signed patient acknowledgement.

The current fistula assessment must be no more than 1 month old at the time of application.

The baseline fistula assessment must be from immediately prior to commencing treatment with infliximab.

An assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criteria.

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with infliximab.

Patients are eligible to receive continuing infliximab treatment in courses of up to 24 weeks providing they continue to sustain the response.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats will be authorised. No applications for increased repeats will be authorised.

Where fewer than 2 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Patients may qualify for PBS-subsidised treatment under this restriction once only

**Authority required**

Continuing treatment of complex refractory FISTULISING CROHN DISEASE.

Continuing PBS-subsidised treatment with infliximab by a gastroenterologist, a consultant physician as specified in the NOTE below or other

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consultant physician in consultation with a gastroenterologist, of a patient who:

(a) has a documented history of complex refractory fistulising Crohn disease; and

(b) has demonstrated or sustained an adequate response to treatment with infliximab.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

An adequate response is defined as:

(a) a decrease from baseline in the number of open draining fistulae of greater than or equal to 50%; and/or

(b) a marked reduction in drainage of all fistula(e) from baseline, together with less pain and induration as reported by the patient.

Authority applications must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Fistulising Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes a completed Fistula Assessment form including the date of the assessment of the patient's condition.

The fistula assessment must be no more than 1 month old at the time of application.

If the application is the first application for continuing treatment with infliximab, an assessment of the patient's response must be made up to 12 weeks after the first dose so that there is adequate time for a response to be demonstrated.

An assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criteria.

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with infliximab.

Patients are eligible to receive continuing infliximab treatment in courses of up to 24 weeks providing they continue to sustain the response.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats will be authorised. No applications for increased repeats will be authorised.

Where fewer than 2 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday)

**Note**

Any queries concerning the arrangements to prescribe infliximab may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe infliximab should be forwarded to:

Medicare Australia

Prior Written Approval of Specialised Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

**Note**

TREATMENT OF COMPLEX REFRACTORY FISTULISING CROHN DISEASE

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab and infliximab for patients with complex refractory fistulising Crohn disease. Where the term 'tumour necrosis factor (TNF) alfa antagonist' appears in the following NOTES and restrictions, it refers to adalimumab and infliximab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 2 TNF-alfa antagonists at any 1 time.

From 1 April 2011, under the PBS, all patients will be able to commence a treatment cycle where they may trial each PBS-subsidised TNF-alfa antagonist without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a TNF-alfa antagonist while they continue to show a response to therapy.

A patient who received PBS-subsidised TNF-alfa antagonist treatment prior to 1 April 2011 is considered to be in their first cycle as of 1 April 2011.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised TNF-alfa antagonist more than twice.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised TNF-alfa antagonist therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised TNF-alfa antagonist treatment in the most recent cycle to the date of the first application for initial treatment with a TNF-alfa antagonist under the new treatment cycle.

A patient who has failed fewer than 3 trials of TNF-alfa antagonists in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of TNF-alfa antagonists in a treatment cycle and who has a break in therapy of more than 5 years, may

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commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised TNF-alfa antagonist therapy after 1 April 2011.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised TNF-alfa antagonist treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or

(ii) a patient has received prior PBS-subsidised (initial or continuing) TNF-alfa antagonist therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to re-commence treatment with a specific TNF-alfa antagonist following a break in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and 14 weeks of therapy for infliximab.

From 1 April 2011, a patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.

For second and subsequent courses of PBS-subsidised TNF-alfa antagonist treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

Adalimumab only: Two completed authority prescriptions must be submitted with every initial application for adalimumab. One prescription must be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats. The second prescription must be written for 2 doses of 40 mg and 2 repeats.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific TNF-alfa antagonist, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing TNF-alfa antagonist treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted TNF-alfa antagonist supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised TNF-alfa antagonist is approved, a patient may swap if eligible to the alternate TNF-alfa antagonist within the same treatment cycle.

A patient may trial the alternate TNF-alfa antagonist at any time, regardless of whether they are receiving therapy (initial or continuing) with a TNF-alfa antagonist at the time of the application. However, they cannot swap to a particular TNF-alfa antagonist if they have failed to respond to prior treatment with that drug two times within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to the alternate TNF-alfa antagonist should be accompanied by the approved authority prescription or remaining repeats for the TNF-alfa antagonist the patient is ceasing.

(3) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements submitted with the first authority application for a TNF-alfa antagonist. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and Medicare Australia will assess response according to these revised baseline measurements.

(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised TNF-alfa antagonist therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity.

(5) Patients 'grandfathered' onto PBS-subsidised treatment with adalimumab or infliximab.

A patient who commenced treatment with adalimumab for complex refractory fistulising Crohn disease prior to 4 November 2010 or infliximab prior to 1 March 2010 and who continues to receive treatment at the time of application, may qualify for treatment under the initial 'grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment with adalimumab or infliximab will be authorised under this criterion.

Following completion of the initial PBS-subsidised course, further applications for treatment with adalimumab or infliximab will be assessed under

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| | the continuing treatment restriction. | | | | | | |
| | 'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must requalify for initial treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' above for further details. | | | | | | |
| 9654D | infliximab 100 mg injection, 1 x 100 mg vial | 1 | .. | .. | 751.70 | Remicade | JC |

## *Interleukin inhibitors*

**TOCILIZUMAB**

**Authority required**

Initial 1 (new and recommencing patients after a break of more than 12 months)

Initial treatment by a rheumatologist, or under the supervision of a paediatric rheumatology treatment centre, of a patient under 18 years who:

(a) has been diagnosed with systemic juvenile idiopathic arthritis; AND

(b) has polyarticular course disease and either:

(i) failure to achieve an adequate response to the following treatment regimen (see (1) below for definition of failure to achieve an adequate response):

— oral or parenteral methotrexate at a dose of at least 15 mg per square metre weekly, alone or in combination with oral or intra-articular corticosteroids for a minimum of 3 months; or

(ii) severe intolerance of, or toxicity due to, methotrexate (see (2) below for definition of severe intolerance and toxicity); OR

(c) has refractory systemic symptoms, demonstrated by:

— an inability to decrease and maintain the dose of prednisolone (or equivalent) below 0.5 mg per kg per day following a minimum of 2 months of therapy; AND

(d) has not received PBS-subsidised treatment with tocilizumab for this condition in the previous 12 months.

(1) The following criteria indicate failure to achieve an adequate response to prior methotrexate therapy and must be demonstrated in all patients at the time of the initial application:

(a) in a patient with polyarticular course disease:

(i) an active joint count of at least 20 active (swollen and tender) joints; OR

(ii) at least 4 active joints from the following list:

— elbow, wrist, knee and/or ankle (assessed as swollen and tender); AND/OR

— shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

(b) in a patient with refractory systemic symptoms:

(i) an active joint count of at least 2 active joints; AND

(ii) persistent fever greater than 38 degrees Celsius for at least 5 out of 14 consecutive days; AND/OR

(iii) a C-reactive protein (CRP) level and platelet count above the upper limits of normal (ULN).

(2) Severe intolerance to methotrexate is defined as intractable nausea and vomiting and general malaise unresponsive to manoeuvres, including reducing or omitting concomitant NSAIDs on the day of methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses over 24 hours.

Toxicity to methotrexate is defined as evidence of hepatotoxicity with repeated elevations of transaminases, bone marrow suppression temporally related to methotrexate use, pneumonia, or serious sepsis.

If treatment with methotrexate alone or in combination with other treatments is contraindicated according to the relevant TGA-approved Product Information, please provide details at time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, please provide details of this toxicity at the time of application.

The baseline measurements of joint count, fever and/or CRP level and platelet count must be performed preferably whilst on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be provided for all subsequent continuing treatment applications.

The authority application must be made in writing and must include:

(1) completed authority prescription form(s); and

(2) a completed Systemic Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) the date of assessment of severe active systemic juvenile idiopathic arthritis;

(ii) details of prior treatment including dose and duration of treatment;

(iii) pathology reports detailing CRP and platelet count where appropriate; and

(3) a signed patient or authorised guardian acknowledgement form.

The most recent systemic juvenile idiopathic arthritis assessment must be no more than 1 month old at the time of application.

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A maximum of 16 weeks of treatment will be authorised under this restriction.

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for two infusions (one month supply). A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised.

Where fewer than 3 repeats are requested at the time of initial application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Assessment of a patient's response to an initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 4 weeks from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with tocilizumab.

If a patient fails to respond to 2 courses of treatment in a treatment cycle they will not be eligible to receive further PBS-subsidised tocilizumab therapy in that treatment cycle. A patient may re-trial tocilizumab after a minimum of 12 months have elapsed between the date the last PBS-subsidised treatment was stopped and the date of the first application under a new treatment cycle

**Authority required**

Initial 2 (retrial or recommencement of treatment after a break of less than 12 months)

Initial PBS-subsidised treatment by a rheumatologist, or under the supervision of a paediatric rheumatology treatment centre, of a patient who:

(a) has a documented history of systemic juvenile idiopathic arthritis; AND

(b) has received PBS-subsidised treatment with tocilizumab for this condition in the previous 12 months; AND

(c) has not failed PBS-subsidised therapy with tocilizumab for this condition more than once in the current treatment cycle.

The authority application must be made in writing and must include:

(1) completed authority prescription form(s); and

(2) a completed Systemic Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) pathology reports detailing CRP and platelet count where appropriate.

Applications for a patient who has received PBS-subsidised treatment with tocilizumab in this treatment cycle and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised tocilizumab treatment, within the timeframes specified below.

A maximum of 16 weeks of treatment will be authorised under this restriction.

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for two infusions (one month supply). A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised.

Where fewer than 3 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment with tocilizumab may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

An assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criteria. Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with tocilizumab.

Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to that course of tocilizumab.

If a patient fails to respond to 2 courses of treatment they will not be eligible to receive further PBS-subsidised tocilizumab therapy in this treatment cycle. A patient may re-trial tocilizumab after a minimum of 12 months have elapsed between the date the last PBS-subsidised treatment was stopped and the date of the first application under a new treatment cycle

**Authority required**

Initial 3 ('grandfather' patients)

Initial treatment by a rheumatologist, or under the supervision of a paediatric rheumatology treatment centre, of a patient who:

(a) has a documented history of systemic juvenile idiopathic arthritis; and

(b) was receiving treatment with tocilizumab prior 1 November 2011; and

(c) has demonstrated a response as specified in the criteria for continuing PBS-subsidised treatment with tocilizumab; and

(d) is receiving treatment with tocilizumab at the time of application.

To ensure consistency in determining response, the same indices of disease severity used to establish the baseline must be provided for all subsequent continuing treatment applications.

The authority application must be made in writing and must include:

(1) completed authority prescription form(s); and

(2) a completed Systemic Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

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(i) pathology reports detailing CRP and platelet count where appropriate; and

(3) a signed patient or authorised guardian acknowledgement form.

The most recent systemic juvenile idiopathic arthritis assessment must be no more than 1 month old at the time of application.

The baseline systemic juvenile idiopathic arthritis assessment must be provided and must be from immediately prior to commencing treatment with tocilizumab. (See NOTE (3) above for definition of baseline measurements to determine response.)

An assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criteria.

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with tocilizumab.

Patients are eligible to receive continuing tocilizumab treatment in courses of up to 24 weeks providing they continue to sustain the response.

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for two infusions (one months supply). A separate authority prescription form must be completed for each strength requested. Up to a maximum of 5 repeats will be authorised.

Where fewer than 5 repeats are initially requested with the authority prescription, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

A patient may only qualify for PBS-subsidised treatment under this restriction once

**Authority required**

Continuing treatment

Continuing treatment with tocilizumab, by a rheumatologist or under the supervision of a paediatric rheumatology treatment centre, of a patient who:

(a) has a documented history of systemic juvenile idiopathic arthritis; AND

(b) has demonstrated an adequate response to treatment with tocilizumab.

An adequate response to treatment is defined as:

(a) in a patient with polyarticular course disease:

(i) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(ii) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

— elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

— shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

(b) in a patient with refractory systemic symptoms:

(i) absence of fever greater than 38 degrees Celsius in the preceding seven days; AND/OR

(ii) a reduction in the CRP level and platelet count by at least 30% from baseline; AND/OR

(iii) a reduction in the dose of corticosteroid by at least 30% from baseline.

The authority application must be made in writing and must include:

(1) completed authority prescription form(s); and

(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) baseline and current pathology reports detailing CRP and platelet count where appropriate.

The most recent systemic juvenile idiopathic arthritis assessment must be no more than 1 month old at the time of application.

Where the most recent course of PBS-subsidised tocilizumab treatment was approved under the Initial treatment restriction, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be provided to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised tocilizumab treatment was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Patients are eligible to receive continuing tocilizumab treatment in courses of up to 24 weeks providing they continue to sustain the response.

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for two infusions (one month supply). A separate authority prescription form must be completed for each strength requested. Up to a maximum of 5 repeats will be authorised.

Where fewer than 5 repeats are requested at the time of initial application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

If a patient fails to respond to 2 courses of treatment they will not be eligible to receive further PBS-subsidised tocilizumab therapy in this treatment cycle. A patient may re-trial tocilizumab after a minimum of 12 months have elapsed between the date the last PBS-subsidised treatment was stopped and the date of the first application under a new treatment cycle

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**Note**

Any queries concerning the arrangements to prescribe tocilizumab may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Further prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe tocilizumab should be forwarded to:

Medicare Australia

Prior Written Approval of Specialised Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

**Note**

TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying anti-rheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab) and the T-cell co-stimulation modulator (abatacept).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

PBS-subsidised abatacept, golimumab, infliximab and rituximab must be used in combination with methotrexate at a dose of at least 7.5 mg weekly. Where a patient cannot tolerate 7.5 mg of methotrexate weekly, they are eligible to receive PBS-subsidised adalimumab, certolizumab pegol, etanercept and tocilizumab.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:

— a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,

— a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and

— once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact Medicare Australia on 1800 700 270.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or

(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or

(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or

(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab and tocilizumab, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to Medicare Australia within 4 weeks.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

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For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

Abatacept patients:

Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients:

A further application may be submitted to Medicare Australia 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Rituximab patients:

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.

Abatacept patients:

Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

**Note**

(3) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and Medicare Australia will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still

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on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

**Note**

TREATMENT OF PATIENTS WITH SEVERE ACTIVE SYSTEMIC JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of tocilizumab for a patient who has severe active systemic juvenile idiopathic arthritis (sJIA).

From 1 May 2012, a patient receiving PBS-subsidised tocilizumab therapy is considered to be in a treatment cycle. Under these arrangements, within a single treatment cycle, a patient may:

— continue to receive long-term treatment with PBS-subsidised tocilizumab while they continue to show a response to therapy, and

— fail to respond, or to sustain a response, to PBS-subsidised tocilizumab twice.

Once a patient has either failed or ceased to respond to 2 courses of treatment, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 12 month break in PBS-subsidised tocilizumab therapy before they are eligible to receive further PBS-subsidised tocilizumab therapy. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised tocilizumab treatment was stopped to the date of the first application for initial treatment with tocilizumab under the new treatment cycle.

A patient who was receiving PBS-subsidised tocilizumab treatment immediately prior to 1 May 2012 is considered to be in their first cycle as of 1 May 2012. A patient who has had a break in tocilizumab treatment of at least 12 months immediately prior to making a new application, on or after 1 May 2012, will commence a new treatment cycle.

A patient who has failed their first course of tocilizumab in a treatment cycle and who has a break in therapy of less than 12 months may commence a second course of treatment within the same treatment cycle.

A patient who has failed their first course of tocilizumab in a treatment cycle and who has a break in therapy of more than 12 months must commence a new treatment cycle.

(1) How to prescribe PBS-subsidised tocilizumab therapy after 1 May 2012.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised tocilizumab treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or

(ii) a patient wishes to re-commence treatment with tocilizumab following a break in PBS-subsidised therapy of more than 12 months (Initial 1); or

(iii) a patient has received the first course of PBS-subsidised (initial or continuing) tocilizumab therapy in a treatment cycle and is deemed to have failed to respond or sustain a response and the treating physician wishes to trial a second course (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with tocilizumab for that course.

For second and subsequent courses of PBS-subsidised tocilizumab, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with tocilizumab, a patient may qualify to receive up to 24 weeks of continuing treatment with tocilizumab providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing tocilizumab treatment in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted tocilizumab supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with tocilizumab.

(2) Treatment cycle.

Once initial treatment with PBS-subsidised tocilizumab is approved, a patient deemed to have failed to respond to the first course of treatment may have a second course without having to requalify with respect to the indices of disease severity (joint count, fever and/or CRP level and platelet count) or the prior therapy requirements, except if the patient has had a break in therapy of more than 12 months.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

(3) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated based on the relevant baseline measurements of the joint count, fever and/or CRP level and platelet count submitted with the first authority application for tocilizumab.

Where a patient is deemed to have failed to respond or to sustain a response to the first course of therapy in a treatment cycle, prescribers may provide new baseline measurements for the second course of treatment within that cycle. Medicare Australia will assess response according to these revised baseline measurements. If new baseline measurements are not submitted with the initial application for the second course of

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| | treatment, then those submitted with the first course will be used by Medicare Australia to assess response to the second course. | | | | | | |
| | (4) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy. | | | | | | |
| | A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised tocilizumab therapy of at least 12 months, must requalify for treatment under the Initial 1 treatment restriction. | | | | | | |
| | (5) Patients 'grandfathered' onto PBS-subsidised treatment with tocilizumab. | | | | | | |
| | A patient who commenced treatment with tocilizumab for severe active systemic juvenile idiopathic arthritis prior to 1 November 2011 and who continues to receive treatment at the time of application, may qualify for treatment under the initial 'grandfather' treatment restriction. | | | | | | |
| | A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment with tocilizumab will be authorised under this criterion. | | | | | | |
| | Following completion of the initial PBS-subsidised course, further applications for treatment with tocilizumab will be assessed under the continuing treatment restriction. | | | | | | |
| | 'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must qualify for initial treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 12 month break in PBS-subsidised therapy' above for further details. | | | | | | |
| | (6) Withdrawal of treatment after sustained remission. | | | | | | |
| | Withdrawal of treatment with tocilizumab should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be submitted to Medicare Australia at the time treatment is ceased. | | | | | | |
| | **Note** | | | | | | |
| | Special Pricing Arrangements apply. | | | | | | |
| 1481Y | tocilizumab 200 mg/10 mL injection, 1 x 10 mL vial | 1 | .. | .. | 467.20 | Actemra | RO |
| 1482B | tocilizumab 400 mg/20 mL injection, 1 x 20 mL vial | 1 | .. | .. | 934.40 | Actemra | RO |
| 1476Q | tocilizumab 80 mg/4 mL injection, 1 x 4 mL vial | 1 | .. | .. | 186.88 | Actemra | RO |
| | **TOCILIZUMAB** | | | | | | |
| | **Authority required** | | | | | | |
| | Initial 1 (new patient or patient re-commencing after a break of more than 24 months) | | | | | | |
| | Initial PBS-subsidised treatment with tocilizumab, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of adults who: | | | | | | |
| | (a) have severe active rheumatoid arthritis; and | | | | | | |
| | (b) have received no PBS-subsidised treatment with a bDMARD for this condition in the previous 24 months; and | | | | | | |
| | (c) have failed, in the 24 months immediately prior to the date of application, to achieve an adequate response to at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs), which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: | | | | | | |
| | — hydroxychloroquine at a dose of at least 200 mg daily; or | | | | | | |
| | — leflunomide at a dose of at least 10 mg daily; or | | | | | | |
| | — sulfasalazine at a dose of at least 2 g daily. | | | | | | |
| | If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, then the 6 months of intensive DMARD treatment must include at least 3 months continuous treatment with each of at least 2 of the DMARDs: | | | | | | |
| | — hydroxychloroquine at a dose of at least 200 mg daily; and/or | | | | | | |
| | — leflunomide at a dose of at least 10 mg daily; and/or | | | | | | |
| | — sulfasalazine at a dose of at least 2 g daily. | | | | | | |
| | The application must include details of the contraindication or intolerance to methotrexate. Details of the toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose can be found on the Medicare Australia website [www.medicareaustralia.gov.au]. The maximum tolerated dose of methotrexate must be documented in the application, if applicable. | | | | | | |
| | If 3 or more of methotrexate, hydroxychloroquine, leflunomide and sulfasalazine are contraindicated according to the relevant TGA-approved product information or cannot be tolerated at the doses specified above, then one or more of the following DMARDs may be used in place of these agents in order to satisfy the requirement for a trial of 6 months of intensive DMARD therapy with at least 2 DMARDs taken continuously for at least 3 months each: | | | | | | |
| | — azathioprine at a dose of at least 1 mg/kg per day; and/or | | | | | | |
| | — cyclosporin at a dose of at least 2 mg/kg/day; and/or | | | | | | |
| | — sodium aurothiomalate at a dose of 50 mg weekly. | | | | | | |
| | The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances. Details of the toxicities, including severity, which will be accepted as a reason for substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial can be found on the Medicare Australia website [www.medicareaustralia.gov.au]. | | | | | | |
| | The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs. | | | | | | |

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If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance and dose for each DMARD must be provided in the authority application. Details of the toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy can be found on the Medicare Australia website [www.medicareaustralia.gov.au].

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L;

AND either

(i) a total active joint count of at least 20 active (swollen and tender) joints; or

(ii) at least 4 active joints from the following list of major joints:

— elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

— shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reason this criterion cannot be satisfied.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and

(3) a signed patient acknowledgement.

A maximum of 16 weeks of treatment will be authorised under this restriction.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials of appropriate strength, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 8 mg per kg. A separate authority prescription form must be completed for each strength requested.

Up to a maximum of 3 repeats of each strength may be authorised. Where fewer than 3 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Assessment of a patient's response to an initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with tocilizumab.

Patients who fail to demonstrate a response to treatment with tocilizumab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition

**Authority required**

Initial 2 (change or re-commencement after break of less than 24 months)

Initial course of PBS-subsidised treatment with tocilizumab, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of adults who:

(a) have a documented history of severe active rheumatoid arthritis; and

(b) have received prior PBS-subsidised bDMARD treatment for this condition and are eligible to receive further bDMARD therapy.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].

Applications for patients who have received PBS-subsidised treatment with tocilizumab and who wish to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised tocilizumab treatment, within the timeframes specified below.

A maximum of 16 weeks of treatment will be authorised under this restriction.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials of appropriate strength, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 8 mg per kg. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats of each strength may be authorised.

Where fewer than 3 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum

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of 16 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Where the most recent course of PBS-subsidised tocilizumab treatment was approved under either of the initial 1 or 2 treatment restrictions, patients must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be provided to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised tocilizumab treatment was approved under the continuing treatment criteria, patients must have been assessed for response, and the assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Patients who fail to demonstrate a response to treatment with tocilizumab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition

**Authority required**

Continuing treatment

Continuing PBS-subsidised treatment with tocilizumab, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of adults:

(a) who have a documented history of severe active rheumatoid arthritis; and

(b) who have demonstrated an adequate response to treatment with tocilizumab; and

(c) whose most recent course of PBS-subsidised bDMARD treatment was with tocilizumab.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(i) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(ii) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

— elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

— shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].

A maximum of 24 weeks of treatment will be approved under this restriction.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials of appropriate strength, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 8 mg per kg. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 5 repeats of each strength may be authorised.

Where fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

All applications for continuing treatment with tocilizumab must include a measurement of response to the prior course of therapy. This assessment must be provided to Medicare Australia no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with tocilizumab, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.

Patients who fail to demonstrate a response to treatment with tocilizumab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition

**Note**

Any queries concerning the arrangements to prescribe tocilizumab may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Further prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe tocilizumab should be forwarded to:

Medicare Australia

Prior Written Approval of Specialised Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

**Note**

TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying anti-rheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and

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restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab) and the T-cell co-stimulation modulator (abatacept).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

PBS-subsidised abatacept, golimumab, infliximab and rituximab must be used in combination with methotrexate at a dose of at least 7.5 mg weekly. Where a patient cannot tolerate 7.5 mg of methotrexate weekly, they are eligible to receive PBS-subsidised adalimumab, certolizumab pegol, etanercept and tocilizumab.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:

— a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,

— a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and

— once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact Medicare Australia on 1800 700 270.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or

(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or

(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or

(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab and tocilizumab, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to Medicare Australia within 4 weeks.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

Abatacept patients:

Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients:

A further application may be submitted to Medicare Australia 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD

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supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Rituximab patients:

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.

Abatacept patients:

Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

**Note**

(3) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and Medicare Australia will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

**Note**

Special Pricing Arrangements apply.

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| 9658H | tocilizumab 200 mg/10 mL injection, 1 x 10 mL vial | 1 | .. | .. | 467.20 | Actemra | RO |
| 9659J | tocilizumab 400 mg/20 mL injection, 1 x 20 mL vial | 1 | .. | .. | 934.40 | Actemra | RO |
| 9657G | tocilizumab 80 mg/4 mL injection, 1 x 4 mL vial | 1 | .. | .. | 186.88 | Actemra | RO |

## *Calcineurin inhibitors*

**CYCLOSPORIN**

**Authority required (STREAMLINED)**

***3328***

Management of rejection in patients following organ or tissue transplantation, under the supervision and direction of a transplant unit. Management includes initiation, stabilisation and review of therapy as required

**Authority required (STREAMLINED)**

***3329***

# HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

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| | Management (which includes initiation, stabilisation and review of therapy) by dermatologists or clinical immunologists of patients with severe atopic dermatitis for whom other systemic therapies are ineffective or inappropriate | | | | | | | |
| | **Authority required (STREAMLINED)** | | | | | | | |
| | ***3330*** | | | | | | | |
| | Management (which includes initiation, stabilisation and review of therapy) by dermatologists of patients with severe psoriasis for whom other systemic therapies are ineffective or inappropriate and in whom the disease has caused significant interference with quality of life | | | | | | | |
| | **Authority required (STREAMLINED)** | | | | | | | |
| | ***3331*** | | | | | | | |
| | Management (which includes initiation, stabilisation and review of therapy) by nephrologists of patients with nephrotic syndrome in patients in whom steroids and cytostatic drugs have failed or are not tolerated or are considered inappropriate and in whom renal function is unimpaired | | | | | | | |
| | **Authority required (STREAMLINED)** | | | | | | | |
| | ***3332*** | | | | | | | |
| | Management (which includes initiation, stabilisation and review of therapy) by rheumatologists or clinical immunologists of patients with severe active rheumatoid arthritis for whom classical slow-acting anti-rheumatic agents (including methotrexate) are ineffective or inappropriate | | | | | | | |
| | **Caution** | | | | | | | |
| | Careful monitoring of patients is mandatory. | | | | | | | |
| 5632K | cyclosporin 10 mg capsule, 60 | 2 | 5 | .. | *74.40 | | Neoral 10 | NV |
| 5636P | cyclosporin 100 mg capsule, 30 | 4 | 5 | .. | *651.08 | a | Cyclosporin Sandoz | SZ |
| | | | | | | a | Neoral 100 | NV |
| 5633L | cyclosporin 100 mg/mL oral liquid, 50 mL | 4 | 5 | .. | *1263.16 | | Neoral | NV |
| 5634M | cyclosporin 25 mg capsule, 30 | 4 | 5 | .. | *153.56 | a | Cyclosporin Sandoz | SZ |
| | | | | | | a | Neoral 25 | NV |
| 5635N | cyclosporin 50 mg capsule, 30 | 4 | 5 | .. | *319.52 | a | Cyclosporin Sandoz | SZ |
| | | | | | | a | Neoral 50 | NV |
| | **CYCLOSPORIN** | | | | | | | |
| | **Authority required (STREAMLINED)** | | | | | | | |
| | ***3333*** | | | | | | | |
| | For use by organ or tissue transplant recipients | | | | | | | |
| | **Caution** | | | | | | | |
| | Careful monitoring of patients is mandatory. | | | | | | | |
| 5631J | cyclosporin 50 mg/mL injection, 10 x 1 mL ampoules | 1 | .. | .. | 54.10 | | Sandimmun | NV |
| | **TACROLIMUS** | | | | | | | |
| | **Authority required (STREAMLINED)** | | | | | | | |
| | ***3328*** | | | | | | | |
| | Management of rejection in patients following organ or tissue transplantation, under the supervision and direction of a transplant unit. Management includes initiation, stabilisation and review of therapy as required | | | | | | | |
| | **Caution** | | | | | | | |
| | Careful monitoring of patients is mandatory. | | | | | | | |
| 9560E | tacrolimus 1 mg capsule, 100 | 2 | 5 | .. | *655.68 | a | Prograf | JC |
| | | | | | | a | Tacrolimus Sandoz | SZ |
| 9665Q | tacrolimus 1 mg capsule: modified release, 60 capsules | 2 | 5 | .. | *393.40 | | Prograf XL | JC |
| 9561F | tacrolimus 5 mg capsule, 50 | 2 | 5 | .. | *1638.38 | a | Prograf | JC |
| | | | | | | a | Tacrolimus Sandoz | SZ |
| 9666R | tacrolimus 5 mg capsule: modified release, 30 capsules | 2 | 5 | .. | *983.54 | | Prograf XL | JC |
| 9558C | tacrolimus 500 microgram capsule, 100 | 2 | 5 | .. | *327.84 | a | Prograf | JC |
| | | | | | | a | Tacrolimus Sandoz | SZ |
| 9664P | tacrolimus 500 microgram capsule: modified release, 30 capsules | 2 | 5 | .. | *98.36 | | Prograf XL | JC |

## *Other immunosuppressants*

**LENALIDOMIDE**

**Authority required**

Multiple myeloma

Treatment Phase: Initial PBS-subsidised treatment

**The Clinical criteria is:**

The condition must be confirmed by a histological diagnosis,

**AND the Clinical criteria is:**

The treatment must be as monotherapy; OR

The treatment must be in combination with dexamethasone,

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**AND the Clinical criteria is:**

Patient must have progressive disease after at least one prior therapy,

**AND the Clinical criteria is:**

Patient must have undergone or be ineligible for a primary stem cell transplant,

**AND the Clinical criteria is:**

Patient must have experienced treatment failure after a trial of at least four (4) weeks of thalidomide at a dose of at least 100 mg daily or have failed to achieve at least a minimal response after eight (8) or more weeks of thalidomide-based therapy for progressive disease,

**AND the Clinical criteria is:**

Patient must not be receiving concomitant PBS-subsidised bortezomib.

Progressive disease is defined as at least 1 of the following:

(a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or

(b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or

(c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase of the difference between involved free light chain and uninvolved free light chain; or

(d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or

(e) an increase in the size or number of lytic bone lesions (not including compression fractures); or

(f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or

(g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.

Thalidomide treatment failure is defined as:

(1) confirmed disease progression during thalidomide treatment or within 6 months of discontinuing thalidomide treatment; or

(2) severe intolerance or toxicity unresponsive to clinically appropriate dose adjustment.

Severe intolerance due to thalidomide is defined as unacceptable somnolence or sedation interfering with activities of daily living.

Toxicity from thalidomide is defined as peripheral neuropathy (Grade 2 or greater, interfering with function), drug-related seizures, serious Grade 3 or 4 drug-related dermatological reactions, such as Stevens-Johnson Syndrome, or other Grade 3 or 4 toxicity.

Failure to achieve at least a minimal response after 8 or more weeks of thalidomide-based therapy for progressive disease is defined as:

(1) less than a 25% reduction in serum or urine M protein; or

(2) in oligo-secretory and non-secretory myeloma patients only, less than a 25% reduction in the difference between involved and uninvolved serum free light chain levels.

If the dosing requirement for thalidomide cannot be met, the application must state the reasons why this criterion cannot be satisfied.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Multiple Myeloma lenalidomide Authority Application - Supporting Information Form, which includes details of the histological diagnosis of multiple myeloma, prior treatments including name(s) of drug(s) and date of most recent treatment cycle and record of prior stem cell transplant or ineligibility for prior stem cell transplant; details of thalidomide treatment failure; details of the basis of the diagnosis of progressive disease or failure to respond; and nomination of which disease activity parameters will be used to assess response; and

(3) duration of thalidomide and daily dose prescribed; and

(4) a signed patient acknowledgment.

To enable confirmation of eligibility for treatment, current diagnostic reports of at least one of the following must be provided:

(a) the level of serum monoclonal protein; or

(b) Bence-Jones proteinuria - the results of 24-hour urinary light chain M protein excretion; or

(c) the serum level of free kappa and lambda light chains; or

(d) bone marrow aspirate or trephine; or

(e) if present, the size and location of lytic bone lesions (not including compression fractures); or

(f) if present, the size and location of all soft tissue plasmacytomas by clinical or radiographic examination i.e. MRI or CT-scan; or

(g) if present, the level of hypercalcaemia, corrected for albumin concentration.

As these parameters will be used to determine response, results for either (a) or (b) or (c) should be provided for all patients. Where the patient has oligo-secretory or non-secretory multiple myeloma, either (c) or (d) or if relevant (e), (f) or (g) should be provided. Where the prescriber plans to assess response in patients with oligo-secretory or non-secretory multiple myeloma with free light chain assays, evidence of the oligo-secretory or non-secretory nature of the multiple myeloma (current serum M protein less than 10 g per L) must be provided.

Patients receiving lenalidomide under the PBS listing must be registered in the i-access risk management program.

**Note**

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation

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8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

**Note**

Special Pricing Arrangements apply.

**Authority required**

Multiple myeloma

Treatment Phase: Continuing PBS-subsidised treatment

**The Clinical criteria is:**

Patient must have previously received an authority prescription for lenalidomide,

**AND the Clinical criteria is:**

Patient must not have progressive disease,

**AND the Clinical criteria is:**

The treatment must be as monotherapy; OR

The treatment must be in combination with dexamethasone.

Progressive disease is defined as at least 1 of the following:

(a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or

(b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or

(c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase of the difference between involved free light chain and uninvolved free light chain; or

(d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or

(e) an increase in the size or number of lytic bone lesions (not including compression fractures); or

(f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or

(g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Patients receiving lenalidomide under the PBS listing must be registered in the i-access risk management program.

**Note**

Authority applications for continuing treatment may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**Note**

Written applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

**Note**

Special Pricing Arrangements apply.

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| 5784K | lenalidomide 10 mg capsule, 21 | 1 | .. | .. | 5643.33 | Revlimid | CJ |
| 5785L | lenalidomide 15 mg capsule, 21 | 1 | .. | .. | 6581.61 | Revlimid | CJ |
| 5786M | lenalidomide 25 mg capsule, 21 | 1 | .. | .. | 6934.20 | Revlimid | CJ |
| 5783J | lenalidomide 5 mg capsule, 21 | 1 | .. | .. | 5392.38 | Revlimid | CJ |

**RITUXIMAB**

**Authority required**

Initial 1 (patient re-commencing after a break of more than 24 months)

Initial PBS-subsidised treatment with rituximab, in combination with methotrexate at a dose of at least 7.5 mg weekly, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of adults who:

(a) have severe active rheumatoid arthritis; and

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(b) have failed to respond to at least 1 PBS-subsidised TNF-alfa antagonist; and

(c) have received no PBS-subsidised treatment with a bDMARD for this condition in the previous 24 months; and

(d) have failed, in the 24 months immediately prior to the date of application, to achieve an adequate response to at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs), which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be:

— hydroxychloroquine at a dose of at least 200 mg daily; or

— leflunomide at a dose of at least 10 mg daily; or

— sulfasalazine at a dose of at least 2 g daily.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, then the 6 months of intensive DMARD treatment must include at least 3 months continuous treatment with each of at least 2 of the DMARDs:

— hydroxychloroquine at a dose of at least 200 mg daily; and/or

— leflunomide at a dose of at least 10 mg daily; and/or

— sulfasalazine at a dose of at least 2 g daily.

The application must include details of the contraindication or intolerance to methotrexate. Details of the toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose can be found on the Medicare Australia website [www.medicareaustralia.gov.au]. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

If 3 or more of methotrexate, hydroxychloroquine, leflunomide and sulfasalazine are contraindicated according to the relevant TGA-approved product information or cannot be tolerated at the doses specified above, then one or more of the following DMARDs may be used in place of these agents in order to satisfy the requirement for a trial of 6 months of intensive DMARD therapy with at least 2 DMARDs taken continuously for at least 3 months each:

— azathioprine at a dose of at least 1 mg/kg per day; and/or

— cyclosporin at a dose of at least 2 mg/kg/day; and/or

— sodium aurothiomalate at a dose of 50 mg weekly.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances. Details of the toxicities, including severity, which will be accepted as a reason for substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial can be found on the Medicare Australia website [www.medicareaustralia.gov.au].

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance and dose for each DMARD must be provided in the authority application. Details of the toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy can be found on the Medicare Australia website [www.medicareaustralia.gov.au].

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L;

AND either

(i) a total active joint count of at least 20 active (swollen and tender) joints; or

(ii) at least 4 active joints from the following list of major joints:

— elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

— shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reason this criterion cannot be satisfied.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and

(3) a signed patient acknowledgement.

A maximum of two infusions will be authorised under this restriction.

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Assessment of a patient's response to an initial course of treatment must be made at least 12 weeks after the first infusion so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia within 4 weeks of the date it was conducted. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with rituximab.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction.

Patients who fail to demonstrate a response to treatment with rituximab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Patients who fail to demonstrate a response to rituximab treatment and who qualify to trial an alternate bDMARD according to the interchangeability arrangements for bDMARDs for the treatment of severe rheumatoid arthritis, may do so without having to have a 22 week treatment-free period

**Authority required**

Initial 2 (change or re-commencement after break of less than 24 months)

Initial course of PBS-subsidised treatment with rituximab, in combination with methotrexate at a dose of at least 7.5 mg weekly, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of adults who:

(a) have a documented history of severe active rheumatoid arthritis; and

(b) have failed to respond to at least 1 PBS-subsidised TNF-alfa antagonist; and

(c) have received prior PBS-subsidised bDMARD treatment for this condition and are eligible to receive further bDMARD therapy.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].

Applications for patients who have received PBS-subsidised treatment with rituximab and who wish to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised rituximab treatment, within the timeframes specified below.

A maximum of two infusions will be authorised under this restriction.

Where the most recent course of PBS-subsidised rituximab treatment was approved under either of the initial 1 or 2 treatment restrictions patients must be assessed for response at least 12 weeks after the first infusion. This assessment must be provided to Medicare Australia no later than 4 weeks from the date of assessment.

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent provided they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The demonstration of response must be submitted to Medicare Australia within 4 weeks of assessment.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction.

Patients who fail to demonstrate a response to treatment with rituximab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Patients who fail to demonstrate a response to rituximab treatment and who qualify to trial an alternate bDMARD according to the interchangeability arrangements for bDMARDs for the treatment of severe rheumatoid arthritis, may do so without having to have a 22 week treatment-free period

**Authority required**

Continuing treatment

Continuing PBS-subsidised treatment with rituximab, in combination with methotrexate at a dose of at least 7.5 mg weekly, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of adults:

(a) who have a documented history of severe active rheumatoid arthritis; and

(b) who have demonstrated an adequate response to treatment with rituximab; and

(c) whose most recent course of PBS-subsidised bDMARD treatment was with rituximab.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(i) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(ii) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

— elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

— shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia

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website (www.medicareaustralia.gov.au)].

A maximum of two infusions will be authorised under this restriction.

Patients may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The demonstration of response must be submitted to Medicare Australia within 4 weeks of assessment.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction.

Patients who fail to demonstrate a response to treatment with rituximab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition

**Note**

Any queries concerning the arrangements to prescribe rituximab may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Further prescribing information (including Authority Application Forms) is on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe rituximab should be forwarded to:

Medicare Australia

Prior Written Approval of Specialised Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

**Note**

TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying anti-rheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab) and the T-cell co-stimulation modulator (abatacept).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

PBS-subsidised abatacept, golimumab, infliximab and rituximab must be used in combination with methotrexate at a dose of at least 7.5 mg weekly. Where a patient cannot tolerate 7.5 mg of methotrexate weekly, they are eligible to receive PBS-subsidised adalimumab, certolizumab pegol, etanercept and tocilizumab.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:

— a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,

— a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and

— once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact Medicare Australia on 1800 700 270.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or

(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or

(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or

(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab

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and tocilizumab, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to Medicare Australia within 4 weeks.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

Abatacept patients:

Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients:

A further application may be submitted to Medicare Australia 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Rituximab patients:

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.

Abatacept patients:

Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

**Note**

(3) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements

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| | any time that an initial treatment authority application is submitted and Medicare Australia will assess response according to these revised baseline measurements.<br><br>To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.<br><br>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.<br><br>**Note**<br>Special Pricing Arrangements apply. | | | | | | |
| 9544H | rituximab 500 mg/50 mL injection, 1 x 50 mL vial | 1 | .. | .. | 2263.57 | Mabthera | RO |
| | **THALIDOMIDE**<br>**Authority required (STREAMLINED)**<br>***3342***<br>Multiple myeloma<br><br>**Caution**<br>Thalidomide is a category X drug and must not be given to pregnant women. Pregnancy in female patients or in the partners of male patients must be avoided during treatment and for 1 month after cessation of treatment.<br><br>**Note**<br>Patients receiving thalidomide under the PBS listing must be registered in the i-access risk management program. | | | | | | |
| 9667T | thalidomide 100 mg capsule, 28 | 2 | .. | .. | *1680.00 | Thalomid | CJ |
| 9566L | thalidomide 50 mg capsule, 28 | 4 | .. | .. | *1680.00 | Thalomid | CJ |

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|

# MUSCULO-SKELETAL SYSTEM

## MUSCLE RELAXANTS

### MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS

#### *Other centrally acting agents*

**BACLOFEN**

**Authority required (STREAMLINED)**

***3318***

Severe chronic spasticity, where oral antispastic agents have failed or have caused unacceptable side effects, in patients with chronic spasticity of cerebral origin

**Authority required (STREAMLINED)**

***3319***

Severe chronic spasticity, where oral antispastic agents have failed or have caused unacceptable side effects, in patients with chronic spasticity due to multiple sclerosis

**Authority required (STREAMLINED)**

***3320***

Severe chronic spasticity, where oral antispastic agents have failed or have caused unacceptable side effects, in patients with chronic spasticity due to spinal cord injury

**Authority required (STREAMLINED)**

***3321***

Severe chronic spasticity, where oral antispastic agents have failed or have caused unacceptable side effects, in patients with chronic spasticity due to spinal cord disease

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 5617P | baclofen 10 mg/5 mL injection: intrathecal, 1 x 5 mL ampoule | 10 | .. | .. | *1483.70 | | Lioresal Intrathecal | NV |

## DRUGS FOR TREATMENT OF BONE DISEASES

### DRUGS AFFECTING BONE STRUCTURE AND MINERALIZATION

#### *Bisphosphonates*

**IBANDRONIC ACID**

**Authority required (STREAMLINED)**

***3343***

Bone metastases from breast cancer

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 5750P | ibandronic acid 6 mg/6 mL injection, 1 x 6 mL vial | 1 | 11 | .. | 341.36 | | Bondronat | RO |

**PAMIDRONATE DISODIUM**

**Authority required (STREAMLINED)**

***3341***

Treatment of hypercalcaemia of malignancy refractory to anti-neoplastic therapy

**Note**

Pharmaceutical benefits that have the form disodium pamidronate powder for I.V. infusion 15 mg (after reconstitution) and pharmaceutical benefits that have the form disodium pamidronate concentrated injection 15 mg are equivalent for the purposes of substitution.

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 5701C | pamidronate disodium 15 mg injection [4 x 15 mg vials] (&) inert substance diluent [4 x 5 mL ampoules], 1 pack | 1 | 2 | .. | 104.96 | [a] | Aredia 15 mg | NV |
| 5667G | pamidronate disodium 15 mg/5 mL injection, 1 x 5 mL vial | 4 | 2 | .. | *104.96 | [a] | Pamisol | HH |

**PAMIDRONATE DISODIUM**

**Authority required (STREAMLINED)**

***3341***

Treatment of hypercalcaemia of malignancy refractory to anti-neoplastic therapy

**Note**

Pharmaceutical benefits that have the form disodium pamidronate powder for I.V. infusion 30 mg (after reconstitution) and pharmaceutical benefits that have the form disodium pamidronate concentrated injection 30 mg are equivalent for the purposes of substitution.

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 5702D | pamidronate disodium 30 mg injection [2 x 30 mg vials] (&) inert substance diluent [2 x 10 mL ampoules], 1 pack | 1 | 2 | .. | 104.96 | [a] | Aredia 30 mg | NV |
| 5668H | pamidronate disodium 30 mg/10 mL injection, 1 x 10 mL vial | 2 | 2 | .. | *104.96 | [a] | Pamidronate Strides | YA |
| | | | | | | [a] | Pamisol | HH |

# HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

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|---|---|---|---|---|---|---|---|---|
| | **PAMIDRONATE DISODIUM**<br>**Authority required (STREAMLINED)**<br>***3341***<br>Treatment of hypercalcaemia of malignancy refractory to anti-neoplastic therapy | | | | | | | |
| 5669J | pamidronate disodium 60 mg/10 mL injection, 1 x 10 mL vial | 1 | 2 | .. | 104.95 | | Pamisol | HH |
| | **PAMIDRONATE DISODIUM**<br>**Authority required (STREAMLINED)**<br>***3341***<br>Treatment of hypercalcaemia of malignancy refractory to anti-neoplastic therapy<br>**Authority required (STREAMLINED)**<br>***3342***<br>Multiple myeloma<br>**Authority required (STREAMLINED)**<br>***3343***<br>Bone metastases from breast cancer<br>**Note**<br>Pharmaceutical benefits that have the form disodium pamidronate powder for I.V. infusion 90 mg (after reconstitution) and pharmaceutical benefits that have the form disodium pamidronate concentrated injection 90 mg are equivalent for the purposes of substitution. | | | | | | | |
| 5703E | pamidronate disodium 90 mg injection [1 x 90 mg vial] (&) inert substance diluent [1 x 10 mL ampoule], 1 pack | 1 | 11 | .. | 157.43 | [a] | Aredia 90 mg | NV |
| 5670K | pamidronate disodium 90 mg/10 mL injection, 1 x 10 mL vial | 1 | 11 | .. | 157.43 | [a] | Pamidronate Strides | YA |
| | | | | | | [a] | Pamisol | HH |
| | **ZOLEDRONIC ACID**<br>**Authority required (STREAMLINED)**<br>***3342***<br>Multiple myeloma<br>**Authority required (STREAMLINED)**<br>***3343***<br>Bone metastases from breast cancer<br>**Authority required (STREAMLINED)**<br>***4052***<br>Bone metastases from castration-resistant prostate cancer<br>**Authority required (STREAMLINED)**<br>***3341***<br>Treatment of hypercalcaemia of malignancy refractory to anti-neoplastic therapy<br>**Note**<br>Special Pricing Arrangements apply. | | | | | | | |
| 9653C | zoledronic acid 4 mg/5 mL injection, 1 x 5 mL vial | 1 | 11 | .. | 450.00 | | Zometa | NV |

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | | Brand Name and Manufacturer | |
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# NERVOUS SYSTEM

## ANTI-PARKINSON DRUGS

### DOPAMINERGIC AGENTS

#### *Dopa and dopa derivatives*

**LEVODOPA + CARBIDOPA ANHYDROUS**

**Authority required (STREAMLINED)**

***3704***

Management of advanced Parkinson disease in a patient with severe disabling motor fluctuations not adequately controlled by oral therapy.

Treatment must be commenced in a hospital-based movement disorder clinic

**Note**

Patients should have adequate cognitive function to manage administration with a portable continuous infusion pump.

A positive clinical response to Duodopa administered via a temporary nasoduodenal tube should be confirmed before a permanent percutaneous endoscopic gastrostomy (PEG) tube is inserted.

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 9743T | levodopa 20 mg/mL + carbidopa monohydrate 5 mg/mL gel: intestinal, 7 x 100 mL bags | 8 | 5 | .. | *11536.00 | | Duodopa | VE |

#### *Dopamine agonists*

**APOMORPHINE**

**Authority required (STREAMLINED)**

***3314***

Parkinson's disease in patients severely disabled by motor fluctuations which do not respond to other therapy

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 5609F | apomorphine hydrochloride 20 mg/2 mL injection, 5 x 2 mL ampoules | 72 | 5 | .. | *5605.92 | | Apomine | HH |
| 5611H | apomorphine hydrochloride 50 mg/10 mL injection: subcutaneous infusion, 5 x 10 mL syringes | 36 | 5 | .. | *7007.40 | | Apomine PFS | HH |
| 5610G | apomorphine hydrochloride 50 mg/5 mL injection, 5 x 5 mL ampoules | 36 | 5 | .. | *7007.40 | | Apomine | HH |

## PSYCHOLEPTICS

### ANTIPSYCHOTICS

#### *Diazepines, oxazepines, thiazepines and oxepines*

**CLOZAPINE**

**Authority required (STREAMLINED)**

***3326***

Schizophrenia in patients who are non-responsive to other neuroleptic agents

**Authority required (STREAMLINED)**

***3327***

Schizophrenia in patients who are intolerant of other neuroleptic agents

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 5629G | clozapine 100 mg tablet, 100 | 2 | .. | .. | *334.40 | [a] | Clopine 100 | HH |
| | | | | | | [a] | Clozaril 100 | NV |
| 5627E | clozapine 200 mg tablet, 100 | 2 | .. | .. | *668.82 | | Clopine 200 | HH |
| 5628F | clozapine 25 mg tablet, 100 | 2 | .. | .. | *89.18 | [a] | Clopine 25 | HH |
| | | | | | | [a] | Clozaril 25 | NV |
| 5626D | clozapine 50 mg tablet, 100 | 2 | .. | .. | *178.36 | | Clopine 50 | HH |
| 5630H | clozapine 50 mg/mL oral liquid, 100 mL | 1 | .. | .. | 135.00 | | Clopine Suspension | HH |

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# RESPIRATORY SYSTEM

## DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES

### OTHER SYSTEMIC DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES

#### *Other systemic drugs for obstructive airway diseases*

**OMALIZUMAB**

**Authority required**

Initial treatment of uncontrolled severe allergic asthma

Initial PBS-subsidised treatment with omalizumab by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma, of a patient aged 12 years or older with uncontrolled severe allergic asthma who has been under the care of this physician for at least 12 months, and satisfies the following criteria:

(a) has a diagnosis of asthma confirmed and documented by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma, defined by standard clinical features, including:

(i) forced expiratory volume (FEV1) reversibility greater than or equal to 12% and greater than or equal to 200 mL at baseline within 30 minutes after administration of salbutamol (200 to 400 micrograms), or

(ii) airway hyperresponsiveness defined as a greater than 20% decline in FEV1 during a direct bronchial provocation test or greater than 15% decline during an indirect bronchial provocation test, or

(iii) peak expiratory flow (PEF) variability of greater than 15% between the two highest and two lowest peak expiratory flow rates during 14 days; and

(b) duration of asthma of at least 1 year; and

(c) FEV1 less than or equal to 80% predicted, documented on 3 or more occasions in the previous 12 months; and

(d) past or current evidence of atopy, documented by skin prick testing or RAST; and

(e) total serum human immunoglobulin E (IgE) greater than or equal to 76 IU/mL; and

(f) has signed a patient acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criteria for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and

(g) has failed to achieve adequate control with optimised asthma therapy, despite formal assessment of and adherence to correct inhaler technique, which has been documented (see NOTE). Optimised asthma therapy includes:

(i) adherence to maximal inhaled therapy, including high dose inhaled corticosteroid (budesonide 1600 micrograms per day or fluticasone propionate 1000 micrograms per day or equivalent), plus long-acting beta-2 agonist therapy (at least salmeterol 50 micrograms bd or eformoterol 12 micrograms bd) for at least 12 months, unless contraindicated or not tolerated, AND

(ii) oral corticosteroids (at least 10 mg per day prednisolone (or equivalent)) for at least 6 weeks, unless contraindicated or not tolerated.

If the requirement for treatment with optimised asthma therapy cannot be met because of contraindications according to the relevant TGA-approved Product Information and/or intolerances of a severity necessitating permanent treatment withdrawal, details of the contraindication and/or intolerance must be provided in the authority application. Details of the accepted toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement of treatment with optimised asthma therapy can be found on the Medicare Australia website [www.medicareaustralia.gov.au].

The initial IgE assessment must be no more than 12 months old at the time of application. A re-assessment of free IgE can only be made at least 12 months after the last dose of omalizumab. For patients re-commencing omalizumab within 12 months of the last dose the previous pre-omalizumab IgE level should be used.

The IgE pathology report must be provided with the authority application.

The following initiation criteria indicate failure to achieve adequate control and must be demonstrated in all patients at the time of the application:

(a) an Asthma Control Questionnaire (ACQ-5) score of at least 2.0, as assessed in the previous month, AND

(b) while on oral corticosteroids and in the past 12 months, experienced at least 1 admission to hospital for a severe asthma exacerbation, OR 1 severe asthma exacerbation, requiring documented use of systemic corticosteroids (oral corticosteroids initiated or increased for at least 3 days, or parenteral corticosteroids) prescribed/supervised by a physician.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Allergic Asthma PBS Authority Application - Supporting Information Form (may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)) which includes the following:

(i) details of prior optimised asthma drug therapy (dosage, date of commencement and duration of therapy); and

(ii) details of severe exacerbation/s experienced while on oral corticosteroids (date and treatment); and

(iii) the signed patient acknowledgement; and

(c) a completed Asthma Control Questionnaire (ACQ-5) calculation sheet including the date of assessment of the patient's symptoms. (For copies of the ACQ please contact Novartis Medical Information on 1800 671 203 or medinfo.phauno@novartis.com)

At the time of the authority application, medical practitioners should request the appropriate maximum quantity and number of repeats to provide for an initial course of omalizumab consisting of the recommended number of doses for the baseline IgE level and body weight of the patient (refer

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to the TGA-approved Product Information) to be administered every 2 or 4 weeks.

Where fewer than the required number of repeats to complete 28 weeks of treatment are requested at the time of the application, authority approvals for sufficient repeats to complete 28 weeks of omalizumab therapy may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period beyond 28 weeks.

The Asthma Control Questionnaire (5 item version) assessment of the patient's response to this initial course of treatment, and the assessment of oral corticosteroid dose, must be made at around 24 to 26 weeks after the first dose so that there is adequate time for a response to be demonstrated and for the application for continuing therapy to be processed.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia within 4 weeks of the date of assessment, and no later than 2 weeks prior to the patient completing their current treatment course, to avoid an interruption to supply. Where a response assessment is not undertaken and submitted to Medicare Australia within this timeframe, the patient will be deemed to have failed to respond to treatment with omalizumab. It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 24 to 26 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised omalizumab treatment.

A patient who fails to respond to a course of PBS-subsidised omalizumab for the treatment of uncontrolled severe allergic asthma will not be eligible to receive further PBS-subsidised treatment with omalizumab for this condition within 6 months of the date on which treatment was ceased

**Authority required**

Continuing treatment

Continuing PBS-subsidised treatment with omalizumab, by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma, of a patient who:

(a) has a documented history of severe allergic asthma; and

(b) has demonstrated or sustained an adequate response to treatment with omalizumab.

An adequate response to omalizumab treatment is defined as:

(a) a reduction in the Asthma Control Questionnaire (ACQ-5) score of at least 0.5 from baseline, OR

(b) maintenance oral corticosteroid dose reduced by at least 25% from baseline, and no deterioration in ACQ-5 score from baseline.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Allergic Asthma PBS Authority Application - Supporting Information Form (may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)) which includes details of maintenance oral corticosteroid dose; and

(c) a completed Asthma Control Questionnaire (ACQ-5) calculation sheet including the date of assessment of the patient's symptoms. (For copies of the ACQ please contact Novartis Medical Information on 1800 671 203 or medinfo.phauno@novartis.com)

All applications for continuing treatment with omalizumab must include a measurement of response to the prior course of therapy. The Asthma Control Questionnaire (5 item version) assessment of the patient's response to the prior course of treatment, and the assessment of oral corticosteroid dose, must be made at around 20 to 22 weeks after the first dose so that there is adequate time for a response to be demonstrated and for the application for continuing therapy to be processed.

The first assessment should, where possible, be completed by the same physician who initiated treatment with omalizumab. If the same physician cannot assess the patient please call Medicare Australia on 1800 700 270.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia within 4 weeks of the date of assessment, and no later than 2 weeks prior to the patient completing their current treatment course, to avoid an interruption to supply. Where a response assessment is not undertaken and submitted to Medicare Australia within this timeframe, the patient will be deemed to have failed to respond to treatment with omalizumab.

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 20 to 22 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised omalizumab treatment.

Patients are eligible to receive continuing courses of omalizumab treatment of up to 24 weeks providing they continue to demonstrate an adequate response to treatment.

At the time of the authority application, medical practitioners should request the appropriate maximum quantity and number of repeats to provide for a continuing course of omalizumab consisting of the recommended number of doses for the baseline IgE level and body weight of the patient (refer to the TGA-approved Product Information), sufficient for 24 weeks of therapy.

Where fewer than the required number of repeats to complete 24 weeks of treatment are requested at the time of the application, authority approvals for sufficient repeats to complete 24 weeks of omalizumab therapy may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

A patient who fails to respond to a course of PBS-subsidised omalizumab for the treatment of uncontrolled severe allergic asthma will not be eligible to receive further PBS-subsidised treatment with omalizumab for this condition within 6 months of the date on which treatment was ceased

**Authority required**

Initial PBS-subsidised treatment of severe allergic asthma in a patient who has previously received non-PBS-subsidised therapy with omalizumab (grandfather patients)

Initial PBS-subsidised supply for continuing treatment with omalizumab by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma, of a patient aged 12 years or older with severe allergic asthma who satisfies the following criteria:

(a) has a diagnosis of asthma confirmed and documented by a respiratory physician, clinical immunologist, allergist or general physician

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experienced in the management of patients with severe asthma, defined by standard clinical features, including:

(i) forced expiratory volume (FEV1) reversibility greater than or equal to 12% and greater than or equal to 200 mL at baseline within 30 minutes after administration of salbutamol (200 to 400 micrograms), or

(ii) airway hyperresponsiveness defined as a greater than 20% decline in FEV1 during a direct bronchial provocation test or greater than 15% decline during an indirect bronchial provocation test, or

(iii) peak expiratory flow (PEF) variability of greater than 15% between the two highest and two lowest peak expiratory flow rates during 14 days; and

(b) duration of asthma of at least 1 year; and

(c) past or current evidence of atopy, documented by skin prick testing or RAST; and

(d) has signed a patient acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criteria for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment for grandfathered patients; and

(e) prior to omalizumab therapy had failed to achieve adequate control with optimised asthma therapy. Optimised asthma therapy includes:

(i) adherence to maximal inhaled therapy, including high dose inhaled corticosteroid (budesonide 1600 micrograms per day or fluticasone propionate 1000 micrograms per day or equivalent), plus long-acting beta-2 agonist therapy (at least salmeterol 50 micrograms bd or eformoterol 12 micrograms bd) for at least 12 months, and

(ii) may have included maintenance dose oral corticosteroids; and

(f) has demonstrated an adequate response to treatment with omalizumab.

A review of the patient's records should be conducted to extract pre- and post-omalizumab data on symptoms, quality of life, medication doses, exacerbations and hospitalisations. Examples of parameters to establish response include:

(i) a reduction in Asthma Control Questionnaire (ACQ-5) score of at least 0.5;

(ii) an improvement of at least 0.5 in the Asthma Quality of Life Questionnaire (AQLQ or mini-AQLQ);

(iii) maintenance oral corticosteroid dose reduced by at least 25% from baseline; and/or

(iv) a reduction in the number of hospitalisations or severe exacerbations requiring use of systemic corticosteroids, compared to the 12 months prior to commencement of omalizumab.

Where baseline assessments are not available, please call Medicare Australia on 1800 700 270 to discuss.

If the requirement for treatment with optimised asthma therapy cannot be met because of contraindications according to the relevant TGA-approved Product Information and/or intolerances of a severity necessitating permanent treatment withdrawal, details of the contraindication and/or intolerance must be provided in the authority application. Details of the accepted contraindications and toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement of treatment with optimised asthma therapy can be found on the Medicare Australia website [www.medicareaustralia.gov.au].

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Allergic Asthma PBS Authority Application - Supporting Information Form (may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)) which includes the following:

(i) details of prior optimised asthma drug therapy (dosage, date of commencement and duration of therapy); and

(ii) details of pre- and post-omalizumab data on symptoms, quality of life, medication doses, exacerbations and hospitalisations; and

(iii) the signed patient acknowledgement.

At the time of the authority application, medical practitioners should request the appropriate maximum quantity and number of repeats to provide for an initial course of omalizumab consisting of the recommended number of doses for the baseline IgE level and body weight of the patient (refer to the TGA-approved Product Information) to be administered every 2 or 4 weeks.

Where fewer than the required number of repeats to complete 24 weeks of treatment are requested at the time of the application, authority approvals for sufficient repeats to complete 24 weeks of omalizumab therapy may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period beyond 24 weeks.

An assessment of the patient's continued response to this course of PBS-subsidised treatment must be made at around 20 to 22 weeks after the first dose so that there is adequate time for a response to be demonstrated and for the application for continuing therapy to be processed. The same parameters used to establish response to non-PBS-subsidised therapy with omalizumab should be used for the assessment.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia within 4 weeks of the date of assessment, and no later than 2 weeks prior to the patient completing their current treatment course, to avoid an interruption to supply. Where a response assessment is not undertaken and submitted to Medicare Australia within this timeframe, the patient will be deemed to have failed to respond to treatment with omalizumab.

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 20 to 22 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised omalizumab treatment.

Patients are eligible to receive continuing courses of omalizumab treatment of up to 24 weeks providing they continue to demonstrate an adequate response to treatment.

Patients may qualify for PBS-subsidised treatment under this restriction once only. A patient who fails to respond to a course of PBS-subsidised omalizumab for the treatment of uncontrolled severe allergic asthma will not be eligible to receive further PBS-subsidised treatment with omalizumab for this condition within 6 months of the date on which treatment was ceased

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**Note**

Any queries concerning the arrangements to prescribe omalizumab may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe omalizumab should be forwarded to:

Medicare Australia

Prior Written Approval of Specialised Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

**Note**

TREATMENT OF ADULT AND ADOLESCENT PATIENTS WITH UNCONTROLLED SEVERE ALLERGIC ASTHMA

Patients are eligible to commence an 'omalizumab treatment cycle' (initial treatment course with or without continuing treatment course/s) if they satisfy the eligibility criteria as detailed under the initial treatment restriction.

Once a patient has either failed to achieve or maintain a response to omalizumab, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 6 month break in PBS-subsidised omalizumab therapy before they are eligible to commence the next cycle. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised omalizumab treatment is stopped to the date of the first application for initial treatment with omalizumab under the new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised omalizumab therapy.

(a) Initial treatment.

Applications for initial treatment should be made where a patient has received no prior PBS-subsidised omalizumab treatment in this treatment cycle and wishes to commence such therapy.

Initial treatment authorisations will be limited to provide for a maximum of 28 weeks of therapy with omalizumab.

A patient must be assessed for response to a course of Initial PBS-subsidised treatment following a minimum of 24 weeks of therapy with omalizumab, and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date of assessment.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with omalizumab.

For second and subsequent courses of PBS-subsidised omalizumab treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of the initial treatment course with omalizumab, a patient may qualify to receive up to a further 24 weeks of continuing treatment with omalizumab providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing omalizumab treatment in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted omalizumab supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia within 4 weeks of the date of assessment, and no later than 2 weeks prior to the patient completing their current treatment course, to avoid an interruption to supply.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with omalizumab.

(2) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements of the Asthma Control Questionnaire (ACQ; 5 item version) and oral corticosteroid dose, submitted with the Initial authority application for omalizumab. However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and Medicare Australia will assess response according to these revised baseline measurements.

(3) Re-commencement of treatment after a 6 month break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised omalizumab therapy of at least 6 months, must re-qualify for initial treatment with respect to the indices of disease severity (oral corticosteroid dose, Asthma Control Questionnaire (ACQ-5) score, and relevant exacerbation history). Patients must have received optimised standard therapy, at adequate doses and for the minimum period specified, immediately prior to the time the new baseline assessments are performed.

(4) Patients 'grandfathered' onto PBS-subsidised treatment with omalizumab.

A patient who commenced treatment with omalizumab for uncontrolled severe allergic asthma prior to 1 November 2010 and who continues to receive treatment at the time of application, may qualify for treatment under the Initial 'grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment with omalizumab will be authorised under this criterion.

Following completion of the Initial PBS-subsidised course, further applications for treatment with omalizumab will be assessed under the continuing treatment restriction.

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|
| | 'Grandfather' arrangements will only apply for the first treatment cycle (initial treatment course with or without continuing treatment course/s). For the second and subsequent cycles, a 'Grandfathered' patient must re-qualify for Initial treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 6 month break in PBS-subsidised therapy' above for further details.<br><br>(5) Monitoring of patients.<br><br>Anaphylaxis and anaphylactoid reactions have been reported following first or subsequent administration of omalizumab (see Product Information). Patients should be monitored post-injection, and medications for the treatment of anaphylactic reactions should be available for immediate use following administration of omalizumab. Patients should be informed that such reactions are possible and prompt medical attention should be sought if allergic reactions occur.<br><br>**Note**<br>Formal assessment and correction of inhaler technique should be performed in accordance with the National Asthma Council (NAC) Information Paper for Health Professionals on Inhaler Technique (available at www.medicareaustralia.gov.au or www.nationalasthma.org.au); the assessment and adherence to correct technique should be documented in the patient's medical records. Patients can obtain support with inhaler technique through their local Asthma Foundation (1800 645 130).<br><br>**Note**<br>Special Pricing Arrangements apply. | | | | | | |
| 9745X | omalizumab 150 mg injection [1 x 150 mg vial] (&) inert substance diluent [1 x 1.2 mL ampoule], 1 pack | 1 | .. | .. | 425.00 | Xolair | NV |

## COUGH AND COLD PREPARATIONS

### EXPECTORANTS, EXCL. COMBINATIONS WITH COUGH SUPPRESSANTS

#### *Mucolytics*

**DORNASE ALFA**

**Authority required (STREAMLINED)**

***3344***

Use by cystic fibrosis patients who satisfy all of the following criteria:

(1) are 5 years of age or older;

(2) have a FVC greater than 40% predicted for age, gender and height;

(3) have evidence of chronic suppurative lung disease (cough and sputum most days of the week, or greater than 3 respiratory tract infections of more than 2 weeks' duration in any 12 months, or objective evidence of obstructive airways disease);

(4) are participating in a 4 week trial as detailed below or have achieved a 10% or greater improvement in FEV1 (compared to baseline established prior to dornase alfa treatment) after a 4 week trial.

In order for patients to be eligible for participation in the HSD program, the following conditions must be met:

(1) Patients must be assessed at cystic fibrosis clinics/centres which are under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis and the prescribing of dornase alfa under the HSD program is limited to such physicians. If attendance at such units is not possible because of geographical isolation, management (including prescribing) may be by specialist physician or paediatrician in consultation with such a unit;

(2) The measurement of lung function is to be conducted by independent (other than the treating doctor) experienced personnel at established lung function testing laboratories, unless this is not possible because of geographical isolation;

(3) Prior to dornase alfa therapy, a baseline measurement of FEV1 must be undertaken during a stable period of the disease;

(4) Initial therapy is limited to 4 weeks' treatment with dornase alfa at a dose of 2.5 mg daily;

(5) At or towards the end of the initial 4 weeks' trial, patients must be reassessed and a further FEV1 measurement be undertaken (single test under conditions as above). Patients who achieve a 10% or greater improvement in FEV1 (compared to baseline established prior to dornase alfa treatment) are eligible for continued subsidy under the HSD program at a dose of 2.5 mg daily;

(6) Patients who fail to meet a 10% or greater improvement in FEV1 after the initial 4 weeks' treatment at a dose of 2.5 mg daily, may have 1 further trial in the next 12 months but not before 3 months after the initial trial;

(7) Following an initial 6 months' therapy, a global assessment must be undertaken involving the patient, the patient's family (in the case of paediatric patients) and the treating physician(s) to establish that all agree that dornase alfa treatment is continuing to produce worthwhile benefits. (Dornase alfa therapy should cease if there is not general agreement of benefit as there is always the possibility of harm from unnecessary use.) Further reassessments are to be undertaken at six-monthly intervals;

(8) Other aspects of treatment, such as physiotherapy, must be continued;

(9) Where there is documented evidence that a patient already receiving dornase alfa therapy would have met the criteria for subsidy (i.e. satisfied the criteria for the 4 week trial and achieved a 10% or greater improvement in FEV1) then the patient is eligible to continue treatment under the HSD program. Where such evidence is not available, patients will need to satisfy the initiation and continuation criteria as for new patients. (Four weeks is considered a suitable wash-out period)

**Authority required (STREAMLINED)**

***3345***

Treatment of cystic fibrosis in a patient less than 5 years of age who has:

(1) A severe clinical course with frequent respiratory exacerbations or chronic respiratory symptoms (including chronic or recurrent cough, wheeze or tachypnoea) requiring frequent hospital admissions more frequently than 3 times per year; or

# HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|

(2) Significant bronchiectasis on chest high resolution computed tomography scan; or

(3) Severe cystic fibrosis bronchiolitis with persistent wheeze non-responsive to conventional medicines; or

(4) Severe physiological deficit measure by forced oscillation technique or multiple breath nitrogen washout and failure to respond to conventional therapy.

In order for the patient to be eligible for participation in the HSD program, the following conditions must be met:

(1) The patient must be assessed at a cystic fibrosis clinic/centre which is under the supervision of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis, and the prescribing of dornase alfa under the HSD program is limited to such physicians. If attendance at such a unit is not possible because of geographical isolation, management (including prescribing) may be by specialist physician or paediatrician in consultation with such a unit;

(2) Following an initial 6 months therapy, a comprehensive assessment must be undertaken and documented involving the patient, the patient's family, the treating physician and an additional independent member of the cystic fibrosis treatment team to establish agreement that dornase alfa treatment is continuing to produce worthwhile benefit. Treatment with dornase alfa should cease if there is not agreement of benefit as there is always the possibility of harm from unnecessary use. Further reassessments are to be undertaken and documented yearly

**Authority required (STREAMLINED)**

***3346***

Grandfather — continuing for patients five years or older

Continuation of treatment of cystic fibrosis in a patient 5 years of age or older, who initiated treatment with dornase alfa at an age of less than 5 years and for whom a comprehensive assessment, involving the patient's family, the treating physician and an additional independent member of the cystic fibrosis treatment team, documents agreement that dornase alfa treatment is continuing to produce worthwhile benefit. Further reassessments are to be undertaken and documented yearly. Treatment with dornase alfa should cease if there is not agreement of benefit as there is always the possibility of harm from unnecessary use

**Authority required (STREAMLINED)**

***3347***

Grandfather — for patients less than five years of age who initiated dornase alfa prior to listing

Treatment of cystic fibrosis in a patient less than 5 years of age who initiated treatment with dornase alfa prior to 1 November 2009 and for whom a comprehensive assessment, involving the patient's family, the treating physician and an additional independent member of the cystic fibrosis treatment team, documents agreement that dornase alfa treatment is continuing to produce worthwhile benefit. Further reassessments are to be undertaken and documented yearly. Treatment with dornase alfa should cease if there is not agreement of benefit as there is always the possibility of harm from unnecessary use

**Note**

Dornase alfa is not PBS-subsidised for use in combination with PBS-subsidised mannitol.

It is highly desirable that all patients be included in the national cystic fibrosis patient database.

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| 5704F | dornase alfa 2.5 mg/2.5 mL inhalation: solution, 30 x 2.5 mL ampoules | 2 | 5 | .. | *2360.00 | Pulmozyme | RO |

**MANNITOL**

**Authority required (STREAMLINED)**

***4063***

Treatment of cystic fibrosis in a patient who satisfies all of the following criteria:

(1) Prior to mannitol therapy, the patient must have been assessed for bronchial hyperresponsiveness as per the TGA approved PI mannitol initiation dose assessment. If the patient has a negative hyperresponsiveness test they may be eligible for PBS subsidised treatment with mannitol;

(2) Is 6 years of age or older;

(3) Has a FEV1 greater than 30% predicted for age, gender and height;

(4) Is intolerant or inadequately responsive to dornase alfa;

(5) Has evidence of chronic suppurative lung disease (cough and sputum most days of the week, or greater than 3 respiratory tract infections of more than 2 weeks' duration in any 12 months, or objective evidence of obstructive airways disease);

(6) Is participating in a 4 week trial, as detailed below, or has achieved a 10% or greater improvement in FEV1 (compared to baseline established prior to mannitol treatment) after a 4 week trial.

In order for patients to be eligible for participation in the HSD program, the following conditions must be met:

(1) Patients must be assessed at cystic fibrosis clinics/centres which are under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis and the prescribing of mannitol therapy under the HSD program is limited to such physicians. If attendance at such units is not possible because of geographical isolation, management (including prescribing) may be by specialist physician or paediatrician in consultation with such a unit;

(2) The measurement of lung function is to be conducted by independent (other than the treating doctor) experienced personnel at established lung function testing laboratories, unless this is not possible because of geographical isolation;

(3) Prior to mannitol therapy, a baseline measurement of FEV1 must be undertaken during a stable period of the disease;

(4) Initial therapy is limited to 4 weeks' treatment with mannitol at a dose of 400 mg twice daily;

(5) At or towards the end of the initial 4 weeks' trial, patients must be reassessed and a further FEV1 measurement be undertaken (single test under conditions as above). Patients who achieve a 10% or greater improvement in FEV1 (compared to baseline established prior to mannitol treatment) are eligible for continued subsidy under the HSD program at a dose of 400mg twice daily;

(6) Patients who fail to meet a 10% or greater improvement in FEV1 after the initial 4 weeks' treatment at a dose of 400 mg twice daily, may have 1

# HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|
| | further trial in the next 12 months but not before 3 months after the initial trial;<br><br>(7) Following an initial 6 months' therapy, a global assessment must be undertaken involving the patient, the patient's family (in the case of paediatric patients) and the treating physician(s) to establish that all agree that mannitol powder for inhalation treatment is continuing to produce worthwhile benefits. (Mannitol therapy should cease if there is not general agreement of benefit as there is always the possibility of harm from unnecessary use.) Further reassessments are to be undertaken at six-monthly intervals;<br><br>(8) Other aspects of treatment, such as physiotherapy, must be continued;<br><br>(9) Where there is documented evidence that a patient already receiving mannitol therapy would have met the criteria for subsidy (i.e. satisfied the criteria for the 4 week trial and achieved a 10% or greater improvement in FEV1) then the patient is eligible to continue treatment under the HSD program. Where such evidence is not available, patients will need to satisfy the initiation and continuation criteria as for new patients. (Four weeks is considered a suitable wash-out period)<br><br>**Authority required (STREAMLINED)**<br>***4064***<br>Grandfather — for patients who initiated mannitol treatment prior to 1 August 2012<br><br>Continuation of treatment of cystic fibrosis in a patient 6 years of age or older, who initiated treatment with mannitol prior to 1 August 2012 and for whom a comprehensive assessment, involving the patient's family, the treating physician and an additional independent member of the cystic fibrosis team, documents agreement that mannitol treatment is continuing to produce worthwhile benefit. Further reassessments are to be undertaken and documented yearly. Treatment with mannitol should cease if there is not agreement of benefit as there is always the possibility of harm from unnecessary use<br><br>**Note**<br>Mannitol is not PBS-subsidised for use in combination with PBS-subsidised dornase alfa.<br><br>It is highly desirable that all patients be included in the national cystic fibrosis patient database. | | | | | | |
| 2015C | MANNITOL Pack containing 280 capsules containing powder for inhalation 40 mg and 2 inhalers, 1 | 4 | 5 | .. | *1736.00 | bronchitol | XA |

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|
| | **SENSORY ORGANS** | | | | | | |
| | OPHTHALMOLOGICALS | | | | | | |
| | **ANTIINFECTIVES** | | | | | | |
| | ***Antivirals*** | | | | | | |
| | **GANCICLOVIR** | | | | | | |
| | **Authority required (STREAMLINED)** | | | | | | |
| | ***3379*** | | | | | | |
| | Cytomegalovirus retinitis in severely immunocompromised patients | | | | | | |
| 5748M | ganciclovir 4.5 mg implant, 1 | 1 | .. | .. | 6000.00 | Vitrasert | BU |

# VARIOUS

ALL OTHER THERAPEUTIC PRODUCTS

## ALL OTHER THERAPEUTIC PRODUCTS

### *Iron chelating agents*

**DEFERASIROX**

**Authority required (STREAMLINED)**

***3828***

Chronic iron overload in patients with disorders of erythropoiesis

**Note**

Special Pricing Arrangements apply.

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|
| 5654N | deferasirox 125 mg tablet: dispersible, 28 | 6 | 5 | .. | *1401.48 | | Exjade | NV |
| 5655P | deferasirox 250 mg tablet: dispersible, 28 | 6 | 5 | .. | *2802.90 | | Exjade | NV |
| 5656Q | deferasirox 500 mg tablet: dispersible, 28 | 6 | 5 | .. | *5605.80 | | Exjade | NV |

**DEFERIPRONE**

**Authority required (STREAMLINED)**

***3338***

Iron overload in patients with thalassaemia major who are unable to take desferrioxamine therapy

**Authority required (STREAMLINED)**

***3339***

Iron overload in patients with thalassaemia major in whom desferrioxamine therapy has proven ineffective

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 5658T | deferiprone 100 mg/mL oral liquid, 250 mL | 5 | 5 | .. | *1126.40 | | Ferriprox | OA |
| 5657R | deferiprone 500 mg tablet, 100 | 6 | 5 | .. | *2703.36 | | Ferriprox | OA |

**DESFERRIOXAMINE**

**Authority required (STREAMLINED)**

***3340***

Disorders of erythropoiesis associated with treatment-related chronic iron overload

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 5661Y | desferrioxamine mesylate 2 g injection, 1 x 2 g vial | 60 | 5 | .. | *1944.00 | a | Hospira Pty Limited | HH |
| | | | | B19.80 | *1963.80 | a | Desferal 2 g | NV |
| 5662B | desferrioxamine mesylate 500 mg injection, 10 x 500 mg vials | 40 | 5 | .. | *3240.80 | a | Hospira Pty Limited | HH |
| | | | | B268.80 | *3509.60 | a | Desferal 500 mg | NV |

### *Drugs for treatment of hyperkalemia and hyperphosphatemia*

**LANTHANUM**

**Authority required (STREAMLINED)**

***3390***

Management of hyperphosphataemia in a patient with chronic kidney disease on dialysis whose serum phosphate is not controlled on calcium and where serum phosphate is greater than 1.6 mmol per L at the commencement of therapy.

Management includes initiation, stabilisation and review of therapy as required

**Authority required (STREAMLINED)**

***3391***

Management of hyperphosphataemia in a patient with chronic kidney disease on dialysis whose serum phosphate is not controlled on calcium and where the serum calcium times phosphate product is greater than 4.0 at the commencement of therapy.

Management includes initiation, stabilisation and review of therapy as required

**Note**

Not to be used in combination with sevelamer.

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 5782H | LANTHANUM Tablet, chewable, 1000 mg (as carbonate hydrate), 90 | 2 | 5 | .. | *890.02 | | Fosrenol | ZI |
| 5780F | LANTHANUM Tablet, chewable, 500 mg (as carbonate hydrate), 90 | 2 | 5 | .. | *523.54 | | Fosrenol | ZI |
| 5781G | LANTHANUM Tablet, chewable, 750 mg (as carbonate hydrate), 90 | 2 | 5 | .. | *790.56 | | Fosrenol | ZI |

**SEVELAMER**

**Authority required (STREAMLINED)**

***3390***

Management of hyperphosphataemia in a patient with chronic kidney disease on dialysis whose serum phosphate is not controlled on calcium and where serum phosphate is greater than 1.6 mmol per L at the commencement of therapy.

# HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|
| | Management includes initiation, stabilisation and review of therapy as required | | | | | | |
| | **Authority required (STREAMLINED)** | | | | | | |
| | ***3391*** | | | | | | |
| | Management of hyperphosphataemia in a patient with chronic kidney disease on dialysis whose serum phosphate is not controlled on calcium and where the serum calcium times phosphate product is greater than 4.0 at the commencement of therapy. | | | | | | |
| | Management includes initiation, stabilisation and review of therapy as required | | | | | | |
| | **Note** | | | | | | |
| | Not to be used in combination with lanthanum. | | | | | | |
| 9546K | sevelamer hydrochloride 800 mg tablet, 180 | 2 | 5 | .. | *620.00 | Renagel | GZ |

# SECTION 100 (BOTULINUM TOXIN PROGRAM)

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | Price ex manufacturer $ | Brand Name and Manufacturer | |
|---|---|---|---|---|---|
| | **BOTULINUM TOXIN TYPE A** | | | | |
| | **Criteria for availability**<br>Treatment of blepharospasm or hemifacial spasm in a patient 12 years or older | | | | |
| | **Criteria for availability**<br>Treatment of dynamic equinus foot deformity due to spasticity in an ambulant paediatric cerebral palsy patient aged from 2 to 17 years inclusive | | | | |
| | **Criteria for availability**<br>Continuing PBS-subsidised treatment of dynamic equinus foot deformity due to spasticity in an ambulant cerebral palsy patient 18 years of age or older who was commenced on PBS-subsidised treatment with botulinum toxin type A purified neurotoxin complex as a paediatric patient | | | | |
| | **Criteria for availability**<br>Treatment of spasmodic torticollis, either as monotherapy or as adjunctive therapy to current standard care | | | | |
| | **Criteria for availability**<br>Continuing PBS-subsidised treatment of moderate to severe spasticity of the upper limb in a cerebral palsy patient 18 years of age or older who was commenced on PBS-subsidised treatment with botulinum toxin type A purified neurotoxin complex as a paediatric patient | | | | |
| | **Criteria for availability**<br>Treatment of moderate to severe spasticity of the upper limb in a cerebral palsy patient aged from 2 to 17 years inclusive | | | | |
| | **Criteria for availability**<br>Treatment of moderate to severe spasticity [defined as MAS greater than or equal to 3 using modified Ashworth scale] of the upper limb in adults following a stroke, as second line therapy when standard management has failed (e.g. physiotherapy and/or oral spasticity agents) or as an adjunct to physical therapy.<br>Maximum number of treatments to be authorised is 4 (total Botox and Dysport) per upper limb per lifetime. Treatment should not be initiated until 3 months post-stroke in patients who do not have established severe contracture. Treatment should be discontinued if the patient does not respond (decrease of MAS greater than 1 in at least one joint) after two treatments.<br>The date of the stroke must be provided.<br>Contraindications to treatment include established severe contracture and known sensitivity to botulinum toxin | | | | |
| | **Criteria for availability**<br>Treatment of severe primary axillary hyperhidrosis in a patient 12 years or older who has failed or is intolerant to topical aluminium chloride hexahydrate after one to two months of treatment.<br>Maximum number of treatments per year is 3, with no less than 4 months to elapse between treatments | | | | |
| | **Note**<br>Arrangements to prescribe this item should be made by medical practitioners with Medicare Australia, contact telephone number 1800 700 270. | | | | |
| | **Note**<br>Contact Medicare Australia before commencing PBS-subsidised treatment in cerebral palsy patients who have been treated for moderate to severe spasticity of the upper limb with non-PBS-subsidised botulinum toxin prior to the age of 18. | | | | |
| | **Note**<br>The units used to express the potency of botulinum toxin preparations currently available for PBS subsidy are not equivalent. | | | | |
| 6103F | botulinum toxin type A 100 units injection, 1 x 100 units vial | 1 | 415.50 | Botox | AG |
| | **CLOSTRIDIUM BOTULINUM TYPE A TOXIN-HAEMAGGLUTININ COMPLEX** | | | | |
| | **Criteria for availability**<br>Treatment of dynamic equinus foot deformity due to spasticity in an ambulant paediatric cerebral palsy patient aged from 2 to 17 years inclusive | | | | |
| | **Criteria for availability**<br>Continuing PBS-subsidised treatment of dynamic equinus foot deformity due to spasticity in an ambulant cerebral palsy patient 18 years of age or older who was commenced on PBS-subsidised treatment with clostridium botulinum type A toxin-haemagglutinin complex as a paediatric patient | | | | |
| | **Criteria for availability**<br>Treatment of spasmodic torticollis, either as monotherapy or as adjunctive therapy to current standard care | | | | |
| | **Criteria for availability**<br>Treatment of blepharospasm or hemifacial spasm in an adult | | | | |
| | **Criteria for availability**<br>Treatment of moderate to severe spasticity [defined as MAS greater than or equal to 3 using modified Ashworth scale] of the upper limb in adults following a stroke, as second line therapy when standard management has failed (e.g. physiotherapy and/or oral spasticity agents) or as an adjunct to physical therapy.<br>Maximum number of treatments to be authorised is 4 (total Botox and Dysport) per upper limb per lifetime. Treatment should not be initiated until 3 months post-stroke in patients who do not have established severe contracture. Treatment should be discontinued if the patient does not respond (decrease of MAS greater than 1 in at least one joint) after two treatments.<br>The date of the stroke must be provided.<br>Contraindications to treatment include established severe contracture and known sensitivity to botulinum toxin | | | | |
| | **Note**<br>Arrangements to prescribe this item should be made by medical practitioners with Medicare Australia, contact telephone number 1800 700 270. | | | | |
| | **Note** | | | | |

# SECTION 100 (BOTULINUM TOXIN PROGRAM)

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | Price ex manufacturer $ | Brand Name and Manufacturer | |
|---|---|---|---|---|---|
| | The units used to express the potency of botulinum toxin preparations currently available for PBS subsidy are not equivalent. | | | | |
| 1152P | clostridium botulinum type A toxin-haemagglutinin complex 300 units injection, 1 x 300 units vial | 1 | 361.52 | Dysport | IS |
| 6293F | clostridium botulinum type A toxin-haemagglutinin complex 500 units injection, 1 x 500 units vial | 1 | 644.81 | Dysport | IS |

# SECTION 100 (HUMAN GROWTH HORMONE)

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | Price ex manufacturer $ | Brand Name and Manufacturer | |
|---|---|---|---|---|---|
| | **SOMATROPIN** | | | | |
| | **Criteria for availability** | | | | |
| | Short stature in accordance with the 'Guidelines for the Pharmaceutical Benefits Scheme Growth Hormone Program. The program also aims to correct neonatal hypoglycaemia due to biochemical growth hormone deficiency and improve body composition for children with Prader-Willi Syndrome. | | | | |
| | The Guidelines specify the eligibility criteria for the conditions that are eligible for treatment through the program which include: | | | | |
| | (i) short stature and slow growth; | | | | |
| | (ii) short stature associated with biochemical growth hormone deficiency; | | | | |
| | (iii) growth retardation secondary to intracranial lesion or cranial irradiation; | | | | |
| | (iv) neonates/infants at risk of hypoglycaemia secondary to growth hormone deficiency; | | | | |
| | (v) short stature associated with Turner Syndrome; | | | | |
| | (vi) short stature due to short stature homeobox (SHOX) gene disorders; | | | | |
| | (vii) short stature associated with chronic renal insufficiency; | | | | |
| | (viii) biochemical growth hormone deficiency and precocious puberty; | | | | |
| | (ix) Prader-Willi syndrome. | | | | |
| | Genotropin branded products are available for the treatment of Prader-Willi Syndrome in accordance with the Guidelines | | | | |
| | **Note** | | | | |
| | Growth hormone (Somatropin) for adults is currently not subsidised through the Pharmaceutical Benefits Scheme. | | | | |
| | These guidelines may be obtained from the Department of Health and Ageing's internet site at http://www.health.gov.au/hGH, or from: | | | | |
| | Growth Hormone Program | | | | |
| | Access and Systems Branch | | | | |
| | Department of Health and Ageing | | | | |
| | GPO Box 9848 | | | | |
| | CANBERRA ACT 2601 | | | | |
| | Contact telephone number (02) 6289 7274 | | | | |
| 6329D | SOMATROPIN (Recombinant human growth hormone) Injection 8 mg (24 i.u.) vial with 1.37 mL diluent cartridge (with preservative) (for use with one.click auto-injector), 1 | 1 | 396.00 | Saizen 8 mg click.easy | SG |
| 9586M | SOMATROPIN (Recombinant human growth hormone) Powder for injection 12 mg (36 i.u.) with diluent in pre-filled pen (with preservative), 1 | 1 | 594.00 | Genotropin GoQuick | PF |
| 9585L | SOMATROPIN (Recombinant human growth hormone) Powder for injection 5 mg (15 i.u.) with diluent in pre-filled pen (with preservative), 1 | 1 | 247.50 | Genotropin GoQuick | PF |
| 9628R | somatropin 1.8 international units (600 microgram) injection [7 x 600 microgram syringes] (&) inert substance diluent [7 x 0.25 mL syringes], 1 pack | 1 | 207.90 | Genotropin MiniQuick | PF |
| 6266T | somatropin 12 international units (4 mg) injection [1 x 4 mg vial] (&) inert substance diluent [1 vial], 1 pack | 1 | 198.00 | Zomacton | FP |
| 6330E | somatropin 15 international units (5 mg) injection [1 x 5 mg cartridge] (&) inert substance diluent [1 x 1 mL cartridge], 1 pack | 1 | 247.50 | Genotropin | PF |
| 6295H | somatropin 15 international units (5 mg/1.5 mL) injection, 1 x 1.5 mL cartridge | 1 | 247.50 | Norditropin SimpleXx | NO |
| 6476W | somatropin 15 international units (5 mg/1.5 mL) injection, 1 x 1.5 mL cartridge | 1 | 247.50 | Omnitrope | SZ |
| 6169Q | somatropin 18 international units (6 mg) injection [1 x 6 mg cartridge] (&) inert substance diluent [1 x 3.15 mL syringe], 1 pack | 1 | 297.00 | Humatrope | LY |
| 5822K | somatropin 18 international units (6 mg/1.03 mL) injection, 1 x 1.03 mL cartridge | 1 | 297.00 | Saizen | SG |
| 6313G | somatropin 2.4 international units (800 microgram) injection [7 x 800 microgram syringes] (&) inert substance diluent [7 x 0.25 mL syringes], 1 pack | 1 | 277.20 | Genotropin MiniQuick | PF |
| 6314H | somatropin 3 international units (1 mg) injection [7 x 1 mg syringes] (&) inert substance diluent [7 x 0.25 mL syringes], 1 pack | 1 | 346.50 | Genotropin MiniQuick | PF |
| 6315J | somatropin 3.6 international units (1.2 mg) injection [7 x 1.2 mg syringes] (&) inert substance diluent [7 x 0.25 mL syringes], 1 pack | 1 | 415.80 | Genotropin MiniQuick | PF |
| 6310D | somatropin 30 international units (10 mg) injection [1 x 10 mg vial] (&) inert substance diluent [1 x 1 mL syringe], 1 pack | 1 | 495.00 | Zomacton | FP |
| 6296J | somatropin 30 international units (10 mg/1.5 mL) injection, 1 x 1.5 mL cartridge | 1 | 495.00 | Norditropin SimpleXx | NO |
| 6311E | somatropin 30 international units (10 mg/1.5 mL) injection, 1 x 1.5 mL cartridge | 1 | 495.00 | Omnitrope | SZ |
| 9604L | somatropin 30 international units (10 mg/2 mL) injection, 1 x 2 mL | 1 | 495.00 | NutropinAq | IS |

# SECTION 100 (HUMAN GROWTH HORMONE)

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | Price ex manufacturer $ | Brand Name and Manufacturer | |
|---|---|---|---|---|---|
| | cartridge | | | | |
| 6312F | somatropin 36 international units (12 mg) injection [1 x 12 mg cartridge] (&) inert substance diluent [1 x 1 mL cartridge], 1 pack | 1 | 594.00 | Genotropin | PF |
| 6170R | somatropin 36 international units (12 mg) injection [1 x 12 mg cartridge] (&) inert substance diluent [1 x 3.15 mL syringe], 1 pack | 1 | 594.00 | Humatrope | LY |
| 5824M | somatropin 36 international units (12 mg/1.5 mL) injection, 1 x 1.5 mL cartridge | 1 | 594.00 | Saizen | SG |
| 6316K | somatropin 4.2 international units (1.4 mg) injection [7 x 1.4 mg syringes] (&) inert substance diluent [7 x 0.25 mL syringes], 1 pack | 1 | 485.10 | Genotropin MiniQuick | PF |
| 6317L | somatropin 4.8 international units (1.6 mg) injection [7 x 1.6 mg syringes] (&) inert substance diluent [7 x 0.25 mL syringes], 1 pack | 1 | 554.40 | Genotropin MiniQuick | PF |
| 6297K | somatropin 45 international units (15 mg/1.5 mL) injection, 1 x 1.5 mL cartridge | 1 | 742.50 | Norditropin SimpleXx | NO |
| 6318M | somatropin 5.4 international units (1.8 mg) injection [7 x 1.8 mg syringes] (&) inert substance diluent [7 x 0.25 mL syringes], 1 pack | 1 | 623.70 | Genotropin MiniQuick | PF |
| 6319N | somatropin 6 international units (2 mg) injection [7 x 2 mg syringes] (&) inert substance diluent [7 x 0.25 mL syringes], 1 pack | 1 | 693.00 | Genotropin MiniQuick | PF |
| 3388H | somatropin 60 international units (20 mg/2.5 mL) injection, 1 x 2.5 mL cartridge | 1 | 990.00 | Saizen | SG |
| 6345Y | somatropin 72 international units (24 mg) injection [1 x 24 mg cartridge] (&) inert substance diluent [1 x 3.15 mL syringe], 1 pack | 1 | 1188.00 | Humatrope | LY |

**SOMATROPIN**

**Criteria for availability**

Short stature in accordance with the 'Guidelines for the Pharmaceutical Benefits Scheme Growth Hormone Program. The program also aims to correct neonatal hypoglycaemia due to biochemical growth hormone deficiency and improve body composition for children with Prader-Willi Syndrome.

The Guidelines specify the eligibility criteria for the conditions that are eligible for treatment through the program which include:

(i) short stature and slow growth;

(ii) short stature associated with biochemical growth hormone deficiency;

(iii) growth retardation secondary to intracranial lesion or cranial irradiation;

(iv) neonates/infants at risk of hypoglycaemia secondary to growth hormone deficiency;

(v) short stature associated with Turner Syndrome;

(vi) short stature due to short stature homeobox (SHOX) gene disorders;

(vii) short stature associated with chronic renal insufficiency;

(viii) biochemical growth hormone deficiency and precocious puberty;

(ix) Prader-Willi syndrome.

Genotropin branded products are available for the treatment of Prader-Willi Syndrome in accordance with the Guidelines

**Note**

Growth hormone (Somatropin) for adults is currently not subsidised through the Pharmaceutical Benefits Scheme.

These guidelines may be obtained from the Department of Health and Ageing's internet site at http://www.health.gov.au/hGH, or from:

Growth Hormone Program

Access and Systems Branch

Department of Health and Ageing

GPO Box 9848

CANBERRA ACT 2601

Contact telephone number (02) 6289 7274

**Note**

Special Pricing Arrangements apply.

| | | | | | |
|---|---|---|---|---|---|
| 5818F | somatropin 15 international units (5 mg/1.5 mL) injection, 1 x 1.5 mL cartridge | 1 | 315.50 | Norditropin FlexPro | NO |
| 5819G | somatropin 30 international units (10 mg/1.5 mL) injection, 1 x 1.5 mL cartridge | 1 | 631.00 | Norditropin FlexPro | NO |
| 5820H | somatropin 45 international units (15 mg/1.5 mL) injection, 1 x 1.5 mL cartridge | 1 | 946.50 | Norditropin FlexPro | NO |

# SECTION 100 (IVF/GIFT TREATMENT)

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | Price ex manufacturer $ | Brand Name and Manufacturer | |
|---|---|---|---|---|---|
| | **CETRORELIX** | | | | |
| | **Criteria for availability** | | | | |
| | For the prevention of premature luteinisation and ovulation in patients undergoing controlled ovarian stimulation, followed by oocyte pick-up and assisted reproductive techniques as described in items 13200, 13201, 13202 or 13203 of the Medicare Benefits Schedule | | | | |
| | **Note** | | | | |
| | Supply of these items is through an accredited IVF/GIFT clinic. For enquiries relating to the IVF/GIFT Program, medical practitioners should contact Medicare Australia on 1800 700 270. | | | | |
| 9599F | cetrorelix 250 microgram injection [1 x 250 microgram vial] (&) inert substance diluent [1 x 1 mL syringe], 1 pack | 1 | 46.08 | Cetrotide | SG |
| | **CHORIOGONADOTROPIN ALFA** | | | | |
| | **Criteria for availability** | | | | |
| | Patients who are receiving medical treatment as described in items 13200, 13201, 13202 or 13203 of the Medicare Benefits Schedule | | | | |
| | **Note** | | | | |
| | Supply of this item is through an accredited IVF/GIFT clinic. For enquiries relating to the IVF/GIFT Program, medical practitioners should contact Medicare Australia on 1800 700 270. | | | | |
| | **Note** | | | | |
| | Special Pricing Arrangements apply. | | | | |
| 6182J | choriogonadotropin alfa 250 microgram/0.5 mL injection, 1 x 0.5 mL cartridge | 1 | 54.80 | Ovidrel | SG |
| 9631X | choriogonadotropin alfa 250 microgram/0.5 mL injection, 1 x 0.5 mL syringe | 1 | 54.80 | Ovidrel | SG |
| | **CORIFOLLITROPIN ALFA** | | | | |
| | **Criteria for availability** | | | | |
| | A patient who is receiving treatment as described in items 13200, 13201 or 13202 of the Medicare Benefits Schedule and who: | | | | |
| | (i) Has an antral follicle count of 20 or less; and | | | | |
| | (ii) Weighs 90 kg or less; and | | | | |
| | (iii) Is undergoing a gonadotrophin releasing hormone antagonist cycle | | | | |
| | **Note** | | | | |
| | Supply of these items is through an accredited IVF/GIFT clinic. For enquiries relating to the IVF/GIFT Program, medical practitioners should contact Medicare Australia on 1800 700 270. | | | | |
| 5816D | corifollitropin alfa 100 microgram/0.5 mL injection, 1 x 0.5 mL syringe | 1 | 410.14 | Elonva | MK |
| | **CORIFOLLITROPIN ALFA** | | | | |
| | **Criteria for availability** | | | | |
| | Controlled ovarian stimulation | | | | |
| | **The Treatment criteria is:** | | | | |
| | Patient must be undergoing treatment as described in items 13200, 13201 or 13202 of the Health Insurance (General Medical Services Table) Regulations, | | | | |
| | **AND the Treatment criteria is:** | | | | |
| | Patient must be undergoing a gonadotrophin releasing hormone antagonist cycle, | | | | |
| | **AND the Clinical criteria is:** | | | | |
| | Patient must have an antral follicle count of 20 or less. | | | | |
| | **Note** | | | | |
| | Supply of these items is through an accredited IVF/GIFT clinic. For enquiries relating to the IVF/GIFT Program, medical practitioners should contact the Department of Human Services on 1800 700 270. | | | | |
| 5817E | corifollitropin alfa 150 microgram/0.5 mL injection, 1 x 0.5 mL syringe | 1 | 673.51 | Elonva | MK |
| | **FOLLITROPIN ALFA** | | | | |
| | **Criteria for availability** | | | | |
| | Patients who are receiving medical treatment as described in items 13200, 13201, 13202 or 13203 of the Medicare Benefits Schedule | | | | |
| | **Note** | | | | |
| | Supply of these items is through an accredited IVF/GIFT clinic. For enquiries relating to the IVF/GIFT Program, medical practitioners should contact Medicare Australia on 1800 700 270. | | | | |
| 6431L | follitropin alfa 300 international units / 0.5 mL (21.84 microgram/0.5 mL) injection, 1 x 0.5 mL cartridge | 1 | 145.20 | Gonal-f Pen | SG |
| 6432M | follitropin alfa 450 international units / 0.75 mL (32.76 microgram/0.75 mL) injection, 1 x 0.75 mL cartridge | 1 | 217.80 | Gonal-f Pen | SG |
| 6433N | follitropin alfa 900 international units / 1.5 mL (65.52 microgram/1.5 mL) injection, 1 x 1.5 mL cartridge | 1 | 435.60 | Gonal-f Pen | SG |

# SECTION 100 (IVF/GIFT TREATMENT)

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | Price ex manufacturer $ | Brand Name and Manufacturer | |
|---|---|---|---|---|---|
| | **FOLLITROPIN BETA** | | | | |
| | **Criteria for availability** | | | | |
| | Patients who are receiving medical treatment as described in items 13200, 13201, 13202 or 13203 of the Medicare Benefits Schedule | | | | |
| | **Note** | | | | |
| | Supply of these items is through an accredited IVF/GIFT clinic. For enquiries relating to the IVF/GIFT Program, medical practitioners should contact Medicare Australia on 1800 700 270. | | | | |
| 6335K | follitropin beta 300 international units/0.36 mL injection, 1 x 0.36 mL cartridge | 1 | 150.00 | Puregon 300 IU/0.36 mL | MK |
| 6336L | follitropin beta 600 international units/0.72 mL injection, 1 x 0.72 mL cartridge | 1 | 292.72 | Puregon 600 IU/0.72 mL | MK |
| 6464F | follitropin beta 900 international units/1.08 mL injection, 1 x 1.08 mL cartridge | 1 | 435.15 | Puregon 900 IU/1.08 mL | MK |
| | **GANIRELIX** | | | | |
| | **Criteria for availability** | | | | |
| | For the prevention of premature luteinisation and ovulation in patients undergoing controlled ovarian stimulation, followed by oocyte pick-up and assisted reproductive techniques as described in items 13200, 13201, 13202 or 13203 of the Medicare Benefits Schedule | | | | |
| | **Note** | | | | |
| | Supply of these items is through an accredited IVF/GIFT clinic. For enquiries relating to the IVF/GIFT Program, medical practitioners should contact Medicare Australia on 1800 700 270. | | | | |
| 9583J | ganirelix 250 microgram/0.5 mL injection, 1 x 0.5 mL syringe | 1 | 46.08 | Orgalutran | MK |
| 9584K | ganirelix 250 microgram/0.5 mL injection, 5 x 0.5 mL syringes | 1 | 230.40 | Orgalutran | MK |
| | **GONADOTROPHIN CHORIONIC HUMAN** | | | | |
| | **Criteria for availability** | | | | |
| | Patients who are receiving medical treatment as described in items 13200, 13201, 13202 or 13203 of the Medicare Benefits Schedule | | | | |
| | **Note** | | | | |
| | Supply of these items is through an accredited IVF/GIFT clinic. For enquiries relating to the IVF/GIFT Program, medical practitioners should contact Medicare Australia on 1800 700 270. | | | | |
| 6178E | gonadotrophin chorionic human 1500 international units injection [3 x 1500 international units ampoules] (&) inert substance diluent [3 x 1 mL ampoules], 1 pack | 1 | 39.57 | Pregnyl | MK |
| 6181H | gonadotrophin chorionic human 5000 international units injection [1 x 5000 international units ampoule] (&) inert substance diluent [1 x 1 mL ampoule], 1 pack | 1 | 11.49 | Pregnyl | MK |
| | **GONADOTROPHIN-MENOPAUSAL HUMAN** | | | | |
| | **Criteria for availability** | | | | |
| | Patients who are receiving medical treatment as described in items 13200, 13201, 13202 or 13203 of the Medicare Benefits Schedule | | | | |
| | **Note** | | | | |
| | Supply of these items is through an accredited IVF/GIFT clinic. For enquiries relating to the IVF/GIFT Program, medical practitioners should contact Medicare Australia on 1800 700 270. | | | | |
| 2038G | gonadotrophin-menopausal human 1200 international units injection [1 x 1200 international units vial] (&) inert substance diluent [2 x 1 mL syringes], 1 pack | 1 | 531.18 | Menopur 1200 | FP |
| 2036E | gonadotrophin-menopausal human 600 international units injection [1 x 600 international units vial] (&) inert substance diluent [1 x 1 mL syringe], 1 pack | 1 | 265.59 | Menopur 600 | FP |
| | **NAFARELIN** | | | | |
| | **Criteria for availability** | | | | |
| | For the prevention of premature luteinisation and ovulation in patients undergoing controlled ovarian stimulation, followed by oocyte pick-up and assisted reproductive techniques as described in items 13200, 13201, 13202 or 13203 of the Medicare Benefits Schedule | | | | |
| | **Note** | | | | |
| | Supply of this item is through an accredited IVF/GIFT clinic. For enquiries relating to the IVF/GIFT Program, medical practitioners should contact Medicare Australia on 1800 700 270. | | | | |
| 5815C | nafarelin 2 mg/mL nasal spray, 60 actuations | 1 | 106.00 | Synarel | PF |
| | **PROGESTERONE** | | | | |
| | **Criteria for availability** | | | | |
| | For luteal phase support in patients who are receiving medical treatment as described in items 13200 or 13201 of the Medicare Benefits Schedule. The luteal phase is defined as the time span from embryo transfer until implantation confirmed by positive B-hCG measurement | | | | |
| | **Note** | | | | |
| | Supply of these items is through an accredited IVF/GIFT clinic. For enquiries relating to the IVF/GIFT Program, medical practitioners should contact Medicare Australia on 1800 700 270. | | | | |

# SECTION 100 (IVF/GIFT TREATMENT)

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | Price ex manufacturer $ | Brand Name and Manufacturer | |
|---|---|---|---|---|---|
| 9608Q | progesterone 100 mg pessary, 15 | 1 | 50.40 | Oripro | ON |
| 9609R | progesterone 200 mg pessary, 15 | 1 | 55.60 | Oripro | ON |

**PROGESTERONE**

**Criteria for availability**

For luteal phase support in patients who are receiving medical treatment as described in items 13200 or 13201 of the Medicare Benefits Schedule. The luteal phase is defined as the time span from embryo transfer until implantation confirmed by positive B-hCG measurement

**Note**

Supply of these items is through an accredited IVF/GIFT clinic. For enquiries relating to the IVF/GIFT Program, medical practitioners should contact Medicare Australia on 1800 700 270.

**Note**

Special Pricing Arrangements apply.

| | | | | | |
|---|---|---|---|---|---|
| 6366C | progesterone 8% (90 mg/1.125 g) gel, 15 applications | 1 | 148.50 | Crinone 8% | SG |

# OPIATE DEPENDENCE TREATMENT PROGRAM

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | Price ex manufacturer $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|
| | **BUPRENORPHINE** | | | | | |
| | **Criteria for availability** | | | | | |
| | Treatment of opiate dependence, including maintenance and detoxification (withdrawal), within a framework of medical, social and psychological treatment | | | | | |
| | **Note** | | | | | |
| | Treatment must be in accordance with the law of the relevant State or Territory. | | | | | |
| | **Note** | | | | | |
| | Shared Care Model: | | | | | |
| | For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners. | | | | | |
| 6308B *NP* | buprenorphine 2 mg tablet, 7 | 1 | 10.50 | | Subutex | RC |
| 6307Y *NP* | buprenorphine 400 microgram tablet, 7 | 1 | 6.16 | | Subutex | RC |
| 6309C *NP* | buprenorphine 8 mg tablet, 7 | 1 | 30.10 | | Subutex | RC |
| | **BUPRENORPHINE + NALOXONE** | | | | | |
| | **Criteria for availability** | | | | | |
| | Treatment of opiate dependence within a framework of medical, social and psychological treatment | | | | | |
| | **Caution** | | | | | |
| | Buprenorphine with naloxone soluble film and buprenorphine with naloxone sublingual tablet do not meet all the criteria for bioequivalence. Patients being switched between sublingual tablets and soluble films may therefore require a dosage adjustment. | | | | | |
| | **Note** | | | | | |
| | Treatment must be in accordance with the law of the relevant State or Territory. | | | | | |
| | **Note** | | | | | |
| | Shared Care Model: | | | | | |
| | For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners. | | | | | |
| 9749D *NP* | buprenorphine 2 mg + naloxone 500 microgram film: sublingual, 28 films | 1 | 46.20 | | Suboxone Film 2/0.5 | RC |
| 6470M *NP* | buprenorphine 2 mg + naloxone 500 microgram tablet: sublingual, 28 tablets | 1 | 46.20 | | Suboxone | RC |
| 9750E *NP* | buprenorphine 8 mg + naloxone 2 mg film: sublingual, 28 films | 1 | 132.44 | | Suboxone Film 8/2 | RC |
| 6471N *NP* | buprenorphine 8 mg + naloxone 2 mg tablet: sublingual, 28 tablets | 1 | 132.44 | | Suboxone | RC |
| | **METHADONE** | | | | | |
| | **Criteria for availability** | | | | | |
| | Treatment of opiate dependence in accordance with the law of the relevant State or Territory | | | | | |
| | **Caution** | | | | | |
| | The risk of drug dependence is high. | | | | | |
| | **Note** | | | | | |
| | Shared Care Model: | | | | | |
| | For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners. | | | | | |
| 6172W *NP* | methadone hydrochloride 5 mg/mL oral liquid, 1000 mL | 1 | 33.20 | [a] | Biodone Forte | MW |
| | | | | [a] | Sigma Methadone Syrup | QA |
| 6171T *NP* | methadone hydrochloride 5 mg/mL oral liquid, 200 mL | 1 | 7.91 | [a] | Biodone Forte | MW |
| | | | | [a] | Sigma Methadone Syrup | QA |

# Section 3 – Container Prices, Fees, Standard Packs and Prices for Ready Prepared Pharmaceutical Benefits

**CONTAINER PRICES FOR QUANTITIES OF READY PREPARED BENEFITS LESS THAN THE STANDARD PACK:**

| | | |
|---|---|---|
| Injectables | 150 mL vial | $0.81 |
| Other Items | 25 mL vial | $0.32 |

**(The 25 mL is the most commonly used size)**

**FEES:**

| | |
|---|---|
| Dispensing Fee for Ready Prepared Benefits | $6.63 |
| Dangerous Drug Fee | $2.71 |
| Additional Fee for Agreed Price Ready Prepared Benefits | $1.13 |

**NOTE** -

*Standard packs and prices (including mark-up, but without dispensing fee and dangerous drug fee) are for items against the price of which an asterisk (*) is shown in Section 2 of the Schedule.*

# (APPLY WASTAGE FACTOR IN CALCULATING BROKEN QUANTITY PRICES)

| Code | Name, Form/Strength | Pack and Price | | Manufacturer |
|---|---|---|---|---|
| 8048N | **abciximab 10 mg/5 mL injection, 1 x 5 mL vial** | 1@ | 482.23 | LY |
| 1003T | **aciclovir 200 mg tablet, 25** | 25@ | 19.51 | AF, GM, SZ |
| 1003T | **aciclovir 200 mg tablet, 25** | 25@ | 20.69 | GK |
| 2014B | **alginate sodium 500 mg/10 mL + calcium carbonate 160 mg/10 mL + sodium bicarbonate 267 mg/10 mL oral liquid, 500 mL** | 1@ | 4.13 | RC |
| 1557Y | **allopurinol 100 mg tablet, 100** | 100@ | 2.65 | AF |
| 2159P | **aluminium hydroxide dried 250 mg/5 mL + magnesium trisilicate 120 mg/5 mL + magnesium hydroxide 120 mg/5 mL oral liquid, 500 mL** | 1@ | 5.64 | FM |
| 2157M | **ALUMINIUM HYDROXIDE with MAGNESIUM HYDROXIDE Oral suspension 200 mg-200 mg per 5 mL, 500 mL, 1** | 1@ | 5.64 | JT |
| 3417W | **amino acid formula with fat, carbohydrate, vitamins, minerals and trace elements without methionine and supplemented with docosahexanoic acid oral liquid, 36 x 125 mL cans** | 1@ | 625.39 | SB |
| 9330C | **amino acid formula with fat, carbohydrate, vitamins, minerals and trace elements without phenylalanine and tyrosine, and supplemented with docosahexanoic acid oral liquid, 36 x 125 mL cans** | 1@ | 625.39 | SB |
| 8678R | **amino acid formula without phenylalanine 1 g tablet, 75** | 1@ | 59.19 | SB |
| 8554F | **amino acid formula without phenylalanine 500 mg capsule, 200** | 1@ | 79.37 | SB |
| 2347M | **amino acid formula without phenylalanine oral liquid: powder for, 30 x 20 g sachets** | 1@ | 208.07 | SB |
| 8479G | **amino acid formula with vitamins, minerals and long chain polyunsaturated fatty acids without phenylalanine oral liquid: powder for, 400 g** | 1@ | 87.15 | SB |
| 9438R | **amino acid formula with vitamins and minerals without lysine and low in tryptophan oral liquid: powder for, 30 x 24 g sachets** | 1@ | 526.99 | VF |
| 5484P | **amino acid formula with vitamins and minerals without lysine and low in tryptophan oral liquid: powder for, 30 x 25 g sachets** | 1@ | 787.00 | VF |
| 2650L | **amino acid formula with vitamins and minerals without lysine and low in tryptophan oral liquid: powder for, 400 g** | 1@ | 95.36 | SB |
| 2646G | **amino acid formula with vitamins and minerals without lysine and low in tryptophan oral liquid: powder for, 500 g** | 1@ | 222.29 | SB |
| 3444G | **amino acid formula with vitamins and minerals without methionine, threonine and valine and low in isoleucine oral liquid: powder for, 30 x 24 g sachets** | 1@ | 526.99 | VF |
| 3443F | **amino acid formula with vitamins and minerals without methionine, threonine and valine and low in isoleucine oral liquid: powder for, 30 x 25 g sachets** | 1@ | 772.99 | VF |
| 8058D | **amino acid formula with vitamins and minerals without methionine, threonine and valine and low in isoleucine oral liquid: powder for, 400 g** | 1@ | 95.36 | SB |
| 8059E | **amino acid formula with vitamins and minerals without methionine, threonine and valine and low in isoleucine oral liquid: powder for, 500 g** | 1@ | 222.29 | SB |
| 8061G | | 1@ | 337.29 | SB |
| 1923F | **AMINO ACID FORMULA with VITAMINS and MINERALS without METHIONINE, THREONINE and VALINE and low in ISOLEUCINE Oral liquid 130 mL, 30, 1** | 1@ | 772.99 | VF |
| 9133Q | **amino acid formula with vitamins and minerals without methionine oral liquid, 30 x 130 mL cans** | 1@ | 772.99 | VF |
| 2640Y | **amino acid formula with vitamins and minerals without methionine oral liquid, 30 x 174 mL pouches** | 1@ | 1018.99 | VF |
| 2639X | **amino acid formula with vitamins and minerals without methionine oral liquid, 30 x 87 mL pouches** | 1@ | 526.99 | VF |
| 8677Q | **amino acid formula with vitamins and minerals without methionine oral liquid: powder for, 30 x 24 g sachets** | 1@ | 526.99 | VF |
| 8744F | **amino acid formula with vitamins and minerals without methionine oral liquid: powder for, 30 x 25 g sachets** | 1@ | 772.99 | VF |
| 8417B | **amino acid formula with vitamins and minerals without methionine oral liquid: powder for, 400 g** | 1@ | 95.36 | SB |
| 8328H | **amino acid formula with vitamins and minerals without methionine oral liquid: powder for, 500 g** | 1@ | 222.29 | SB |
| 8416Y | | 1@ | 337.29 | SB |
| 1548L | **AMINO ACID FORMULA with VITAMINS and MINERALS without METHIONINE Oral liquid 125 mL, 30, 1** | 1@ | 1030.64 | SB |
| 9132P | **amino acid formula with vitamins and minerals without phenylalanine and tyrosine oral liquid, 30 x 130 mL cans** | 1@ | 772.99 | VF |
| 2701E | **amino acid formula with vitamins and minerals without phenylalanine** | 1@ | 1018.99 | VF |

# (APPLY WASTAGE FACTOR IN CALCULATING BROKEN QUANTITY PRICES)

| Code | Name, Form/Strength | Pack and Price | | Manufacturer |
|---|---|---|---|---|
| | **and tyrosine oral liquid, 30 x 174 mL pouches** | | | |
| 2674R | **amino acid formula with vitamins and minerals without phenylalanine and tyrosine oral liquid, 30 x 87 mL pouches** | 1@ | 526.99 | VF |
| 8631G | **amino acid formula with vitamins and minerals without phenylalanine and tyrosine oral liquid: powder for, 30 x 24 g sachets** | 1@ | 526.99 | VF |
| 8667E | **amino acid formula with vitamins and minerals without phenylalanine and tyrosine oral liquid: powder for, 30 x 25 g sachets** | 1@ | 772.99 | VF |
| 9395L | **amino acid formula with vitamins and minerals without phenylalanine and tyrosine oral liquid: powder for, 30 x 29 g sachets** | 1@ | 448.51 | SB |
| 8445L | **amino acid formula with vitamins and minerals without phenylalanine and tyrosine oral liquid: powder for, 400 g** | 1@ | 95.36 | SB |
| 3078B | **amino acid formula with vitamins and minerals without phenylalanine and tyrosine oral liquid: powder for, 500 g** | 1@ | 337.29 | SB |
| 8446M | | 1@ | 222.29 | SB |
| 1547K | **AMINO ACID FORMULA with VITAMINS and MINERALS without PHENYLALANINE and TYROSINE Oral liquid 125 mL, 30, 1** | 1@ | 1030.64 | SB |
| 8746H | **amino acid formula with vitamins and minerals without phenylalanine oral liquid, 18 x 250 mL cans** | 18@ | 261.37 | SB |
| 9021T | **amino acid formula with vitamins and minerals without phenylalanine oral liquid, 30 x 125 mL cans** | 1@ | 514.34 | SB |
| 8846N | **amino acid formula with vitamins and minerals without phenylalanine oral liquid, 30 x 130 mL cans** | 1@ | 385.48 | VF |
| 2474F | **amino acid formula with vitamins and minerals without phenylalanine oral liquid, 30 x 174 mL cans** | 1@ | 511.90 | VF |
| 5483N | **amino acid formula with vitamins and minerals without phenylalanine oral liquid, 30 x 85 g sachets** | 1@ | 263.05 | VF |
| 2382J | **amino acid formula with vitamins and minerals without phenylalanine oral liquid, 30 x 87 mL cans** | 1@ | 257.09 | VF |
| 9396M | **amino acid formula with vitamins and minerals without phenylalanine oral liquid, 36 x 125 mL cans** | 1@ | 315.86 | SB |
| 9397N | **amino acid formula with vitamins and minerals without phenylalanine oral liquid, 60 x 62.5 mL cans** | 1@ | 526.47 | SB |
| 8555G | **amino acid formula with vitamins and minerals without phenylalanine oral liquid: powder for, 30 x 24 g sachets** | 1@ | 263.05 | VF |
| 8591E | **amino acid formula with vitamins and minerals without phenylalanine oral liquid: powder for, 30 x 25 g sachets** | 1@ | 385.68 | VF |
| 8804J | **amino acid formula with vitamins and minerals without phenylalanine oral liquid: powder for, 30 x 27.8 g sachets** | 1@ | 514.34 | SB |
| 8613H | **amino acid formula with vitamins and minerals without phenylalanine oral liquid: powder for, 30 x 29 g sachets** | 1@ | 221.42 | SB |
| 8727H | **amino acid formula with vitamins and minerals without phenylalanine oral liquid: powder for, 30 x 50 g sachets** | 1@ | 501.88 | SB |
| 8545R | **amino acid formula with vitamins and minerals without phenylalanine oral liquid: powder for, 400 g** | 1@ | 105.27 | AB |
| 2738D | **amino acid formula with vitamins and minerals without phenylalanine oral liquid: powder for, 500 g** | 1@ | 109.70 | SB |
| 2739E | | 1@ | 168.25 | SB |
| 1411G | **AMINO ACID FORMULA with VITAMINS and MINERALS without PHENYLALANINE Sachets 18.2 g, 60, 1** | 1@ | 544.55 | SB |
| 1909L | **AMINO ACID FORMULA with VITAMINS and MINERALS without PHENYLALANINE Sachets 34 g, 30, 1** | 1@ | 511.90 | VF |
| 2375B | **amino acid formula with vitamins and minerals without valine, leucine and isoleucine oral liquid, 30 x 130 mL cans** | 1@ | 772.99 | VF |
| 2654Q | **amino acid formula with vitamins and minerals without valine, leucine and isoleucine oral liquid, 30 x 174 mL pouches** | 1@ | 1018.99 | VF |
| 2651M | **amino acid formula with vitamins and minerals without valine, leucine and isoleucine oral liquid, 30 x 87 mL pouches** | 1@ | 526.99 | VF |
| 8592F | **amino acid formula with vitamins and minerals without valine, leucine and isoleucine oral liquid: powder for, 30 x 24 g sachets** | 1@ | 526.99 | VF |
| 8632H | **amino acid formula with vitamins and minerals without valine, leucine and isoleucine oral liquid: powder for, 30 x 25 g sachets** | 1@ | 772.99 | VF |
| 8745G | **amino acid formula with vitamins and minerals without valine, leucine and isoleucine oral liquid: powder for, 30 x 29 g sachets** | 1@ | 448.51 | SB |
| 2380G | **amino acid formula with vitamins and minerals without valine, leucine and isoleucine oral liquid: powder for, 400 g** | 1@ | 95.36 | SB |

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| Code | Name, Form/Strength | Pack and Price | | Manufacturer |
|---|---|---|---|---|
| 8057C | **amino acid formula with vitamins and minerals without valine, leucine and isoleucine oral liquid: powder for, 500 g** | 1@ | 337.29 | SB |
| 8260R | | 1@ | 222.29 | SB |
| 8310J | | 1@ | 666.39 | SB |
| 1546J | **AMINO ACID FORMULA with VITAMINS and MINERALS without VALINE, LEUCINE and ISOLEUCINE Oral liquid 125 mL, 30, 1** | 1@ | 1030.64 | SB |
| 1914R | **AMINO ACID FORMULA with VITAMINS and MINERALS without VALINE, LEUCINE and ISOLEUCINE Sachets 34 g, 30, 1** | 1@ | 1021.93 | VF |
| 9499Y | **amino acid formula with vitamins and minerals without valine, leucine and isoleucine with fat, carbohydrate and trace elements and supplemented with docosahexanoic acid oral liquid, 36 cans** | 1@ | 625.39 | SB |
| 1180D | **amino acid synthetic formula oral liquid: powder for, 400 g** | 1@ | 44.34 | SB |
| 1192R | | 1@ | 44.34 | SB |
| 1521C | | 1@ | 43.77 | SB |
| 2250K | | 1@ | 43.77 | AB |
| 8574G | | 1@ | 44.34 | AB |
| 8575H | | 1@ | 44.34 | AB |
| 8754R | | 1@ | 44.34 | SB |
| 8755T | | 1@ | 44.34 | SB |
| 1545H | **amino acid synthetic formula supplemented with long chain polyunsaturated fatty acids and medium chain triglycerides oral liquid: powder for, 400 g** | 1@ | 44.65 | SB |
| 5466Q | | 1@ | 45.18 | SB |
| 5467R | | 1@ | 45.18 | SB |
| 2246F | **amino acid synthetic formula supplemented with long chain polyunsaturated fatty acids oral liquid: powder for, 400 g** | 1@ | 45.18 | SB |
| 2560R | | 1@ | 45.18 | SB |
| 9339M | | 1@ | 45.18 | AB |
| 9340N | | 1@ | 45.18 | AB |
| 8736T | **amisulpride 100 mg/mL oral liquid, 60 mL** | 1@ | 71.16 | SW |
| 9386B | **amylopectin modified long chain oral liquid: powder for, 30 x 60 g sachets** | 1@ | 186.47 | VF |
| 5482M | **arginine with carbohydrate containing 2 g arginine oral liquid: powder for, 30 x 4 g sachets** | 1@ | 191.10 | VF |
| 9437Q | **arginine with carbohydrate containing 500 mg arginine oral liquid: powder for, 30 x 4 g sachets** | 1@ | 127.40 | VF |
| 9092M | **atomoxetine 10 mg capsule, 28** | 28@ | 107.38 | LY |
| 9093N | **atomoxetine 18 mg capsule, 28** | 28@ | 107.38 | LY |
| 9094P | **atomoxetine 25 mg capsule, 28** | 28@ | 107.38 | LY |
| 9095Q | **atomoxetine 40 mg capsule, 28** | 28@ | 107.38 | LY |
| 9096R | **atomoxetine 60 mg capsule, 28** | 28@ | 107.38 | LY |
| 1140B | **Bacillus Calmette and Guerin-Connaught strain 660 million colony forming units injection [1 x 81 mg vial] (&) inert substance diluent [1 x 3 mL vial], 1 pack** | 1@ | 151.15 | SW |
| 2647H | **benzylpenicillin 3 g injection, 1 x 3 g vial** | 1@ | 7.26 | CS |
| 3399X | | 1@ | 7.26 | CS |
| 1775K | **benzylpenicillin 600 mg injection, 1 x 600 mg vial** | 1@ | 4.29 | CS |
| 3398W | | 1@ | 4.29 | CS |
| 2812B | **betamethasone (as valerate) 0.02% (200 microgram/g) cream, 100 g** | 1@ | 8.90 | FM, FR |
| 2812B | **betamethasone (as valerate) 0.02% (200 microgram/g) cream, 100 g** | 1@ | 10.13 | MK |
| 2812B | **betamethasone (as valerate) 0.02% (200 microgram/g) cream, 100 g** | 1@ | 12.34 | QA |
| 2544X | **biperiden hydrochloride 2 mg tablet, 100** | 100@ | 7.23 | LM |
| 1260H | **bisacodyl 10 mg suppository, 10** | 1@ | 4.84 | PP |
| 1260H | **bisacodyl 10 mg suppository, 10** | 1@ | 5.34 | BY |
| 5303D | | 1@ | 5.34 | BY |
| 5303D | | 1@ | 4.84 | PP |
| 5307H | | 1@ | 4.84 | PP |
| 5307H | | 1@ | 5.34 | BY |
| 1258F | **bisacodyl 10 mg suppository, 12** | 1@ | 3.97 | PP |
| 5304E | | 1@ | 3.97 | PP |
| 5308J | | 1@ | 3.97 | PP |
| 1443Y | **bromocriptine 2.5 mg tablet, 30** | 30@ | 12.50 | NV |
| 3116B | **CALCIUM Tablet (chewable) 500 mg (as carbonate), 60** | 60@ | 6.70 | IA |
| 2422L | **CARBAMAZEPINE Tablet 100 mg, 100** | 100@ | 7.52 | NV |
| 5039F | | 100@ | 7.52 | NV |

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| Code | Name, Form/Strength | Pack and Price | | Manufacturer |
|---|---|---|---|---|
| 1706T | **CARBAMAZEPINE Tablet 200 mg, 100** | 100@ | 12.77 | NV |
| 1724R | | 100@ | 12.77 | NV |
| 1153Q | **carbimazole 5 mg tablet, 100** | 100@ | 12.31 | LM |
| 8369L | **carbohydrate, fat, vitamins, minerals and trace elements oral liquid: powder for, 400 g** | 1@ | 38.97 | SB |
| 2058H | **carbomer 0.2% (1.2 mg/600 mg) + triglyceride lipids 1% (6 mg/600 mg) eye gel, 30 x 600 mg unit doses** | 1@ | 9.89 | BU |
| 2090B | | 1@ | 9.89 | BU |
| 5502N | **carbomer-974 0.3% (1.5 mg/500 mg) eye gel, 30 x 500 mg unit doses** | 1@ | 9.88 | AQ |
| 8514D | | 1@ | 9.88 | AQ |
| 5504Q | **carbomer-980 0.2% (2 mg/g) eye drops, 30 x 0.6 mL unit doses** | 1@ | 9.89 | AQ |
| 8578L | | 1@ | 9.89 | AQ |
| 5509Y | **carmellose sodium 0.25% (1.5 mg/0.6 mL) eye drops, 24 x 0.6 mL unit doses** | 1@ | 8.50 | CX |
| 8823J | | 1@ | 8.50 | CX |
| 5561Q | **carmellose sodium 0.5% (2 mg/0.4 mL) + glycerol 0.9% (3.6 mg/0.4 mL) eye drops, 30 x 0.4 mL unit doses** | 1@ | 9.88 | AG |
| 9307W | | 1@ | 9.88 | AG |
| 2338C | **carmellose sodium 0.5% (2 mg/0.4 mL) eye drops, 30 x 0.4 mL unit doses** | 1@ | 9.88 | AG |
| 5506T | | 1@ | 9.88 | AG |
| 2324H | **carmellose sodium 1% (4 mg/0.4 mL) eye drops, 30 x 0.4 mL unit doses** | 1@ | 9.88 | AG |
| 5505R | | 1@ | 9.88 | AG |
| 5510B | **carmellose sodium 1% (6 mg/0.6 mL) eye gel, 28 x 0.6 mL unit doses** | 1@ | 9.22 | CX |
| 8824K | | 1@ | 9.22 | CX |
| 8315P | **CEFEPIME Powder for injection 1 g (as hydrochloride), 1** | 1@ | 10.34 | HH, OE, SZ |
| 8316Q | **CEFEPIME Powder for injection 2 g (as hydrochloride), 1** | 1@ | 19.69 | HH, OE, SZ |
| 1085D | **cefotaxime 1 g injection, 1 x 1 g vial** | 1@ | 1.64 | SZ |
| 5048Q | | 1@ | 1.64 | SZ |
| 1086E | **cefotaxime 2 g injection, 1 x 2 g vial** | 1@ | 3.02 | SZ |
| 5049R | | 1@ | 3.02 | SZ |
| 1784X | **ceftriaxone 1 g injection, 1 x 1 g vial** | 1@ | 2.98 | AE, HH, PP, RO, SZ |
| 1785Y | **ceftriaxone 2 g injection, 1 x 2 g vial** | 1@ | 5.53 | AE, AF, HH, PP, RO, SZ |
| 1783W | **ceftriaxone 500 mg injection, 1 x 500 mg vial** | 1@ | 1.91 | AE, PP |
| 2655R | **cephalexin 250 mg capsule, 20** | 20@ | 1.29 | AF, CH, CR, GM, GQ, GX, LN, RA, SZ, TW |
| 2655R | **cephalexin 250 mg capsule, 20** | 20@ | 4.67 | AS |
| 1797N | **cephazolin 1 g injection, 5 x 1 g vials** | 5@ | 9.81 | AE, HH |
| 1799Q | | 5@ | 9.81 | AE, HH |
| 5479J | **cephazolin 2 g injection, 1 x 2 g vial** | 1@ | 4.36 | AF, SZ |
| 9326W | | 1@ | 4.36 | AF, SZ |
| 1256D | **cephazolin 500 mg injection, 5 x 500 mg vials** | 5@ | 7.37 | AE, HH |
| 5477G | | 5@ | 7.37 | AE, HH |
| 1163F | **chlorambucil 2 mg tablet, 25** | 25@ | 32.89 | AS |
| 1585K | **chlorthalidone 25 mg tablet, 50** | 50@ | 5.58 | LM |
| 2967E | **cholestyramine 4 g oral liquid: powder for, 50 x 4.7 g sachets** | 1@ | 32.76 | QA |
| 9249T | | 1@ | 32.76 | QA |
| 1217C | **ciprofloxacin 0.3% eye drops, 5 mL** | 1@ | 11.03 | IQ |
| 1217C | **ciprofloxacin 0.3% eye drops, 5 mL** | 1@ | 12.06 | AQ |
| 5564W | | 1@ | 11.03 | IQ |
| 5564W | | 1@ | 12.06 | AQ |
| 5481L | **citrulline with carbohydrate containing 1 g citrulline oral liquid: powder for, 30 x 4 g sachets** | 1@ | 127.40 | VF |
| 1808E | **clonazepam 2.5 mg/mL oral liquid, 10 mL** | 1@ | 4.31 | RO |
| 5339B | | 1@ | 4.31 | RO |
| 5342E | | 1@ | 4.31 | RO |
| 1806C | **clonazepam 2 mg tablet, 100** | 100@ | 14.25 | RO |
| 1806C | **clonazepam 2 mg tablet, 100** | 100@ | 12.32 | AF |
| 1805B | **clonazepam 500 microgram tablet, 100** | 100@ | 8.25 | RO |
| 1805B | **clonazepam 500 microgram tablet, 100** | 100@ | 6.54 | AF |
| 8785J | **CODEINE PHOSPHATE with PARACETAMOL Tablet 30 mg-500 mg, 20** | 20@ | 0.92 | AL, AV, FM, SZ, TX |
| 8785J | **CODEINE PHOSPHATE with PARACETAMOL Tablet 30 mg-500 mg, 20** | 20@ | 3.32 | SW |
| 8661W | **cyclosporin 100 mg/mL oral liquid, 50 mL** | 1@ | 353.12 | NV |
| 8660T | **cyclosporin 100 mg capsule, 30** | 30@ | 184.01 | NV, SZ |
| 8657P | **cyclosporin 10 mg capsule, 60** | 60@ | 44.00 | NV |

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| Code | Name, Form/Strength | Pack and | Price | Manufacturer |
|---|---|---|---|---|
| 8658Q | **cyclosporin 25 mg capsule, 30** | 30@ | 45.41 | NV, SZ |
| 8659R | **cyclosporin 50 mg capsule, 30** | 30@ | 94.48 | NV, SZ |
| 1270W | **cyproterone acetate 50 mg tablet, 50** | 50@ | 71.67 | BN |
| 1270W | **cyproterone acetate 50 mg tablet, 50** | 50@ | 70.35 | AF, GM, GX, HX, QA, SY, SZ |
| 9164H | **cystine with carbohydrate containing 500 mg cystine oral liquid: powder for, 30 x 4 g sachets** | 1@ | 127.40 | VF |
| 9319L | **dabigatran etexilate 110 mg capsule, 10** | 10@ | 15.59 | BY |
| 9323Q | | 10@ | 15.59 | BY |
| 9318K | **dabigatran etexilate 75 mg capsule, 10** | 10@ | 19.56 | BY |
| 9322P | | 10@ | 19.56 | BY |
| 8959M | **DALTEPARIN SODIUM (Low Molecular Weight Heparin Sodium-porcine mucous) Injection 15,000 units (anti-Xa) in 0.6 mL single dose pre-filled syringe, 10** | 10@ | 136.11 | PF |
| 8960N | **DALTEPARIN SODIUM (Low Molecular Weight Heparin Sodium-porcine mucous) Injection 18,000 units (anti-Xa) in 0.72 mL single dose pre-filled syringe, 10** | 10@ | 162.39 | PF |
| 1229Q | **dalteparin sodium 10 000 anti-Xa international units/mL injection, 10 x 1 mL syringes** | 10@ | 84.57 | PF |
| 8957K | | 10@ | 82.88 | PF |
| 1296F | **dalteparin sodium 12 500 anti-Xa international units/0.5 mL injection, 10 x 0.5 mL syringes** | 10@ | 117.43 | PF |
| 8958L | | 10@ | 114.43 | PF |
| 8603T | **dalteparin sodium 2500 anti-Xa international units/0.2 mL injection, 10 x 0.2 mL syringes** | 10@ | 49.16 | PF |
| 8641T | | 10@ | 49.16 | PF |
| 2816F | **dalteparin sodium 5000 anti-Xa international units/0.2 mL injection, 10 x 0.2 mL syringes** | 10@ | 51.23 | PF |
| 8642W | | 10@ | 51.23 | PF |
| 8643X | **dalteparin sodium 7500 anti-Xa international units/0.75 mL injection, 10 x 0.75 mL syringes** | 10@ | 61.96 | PF |
| 8956J | | 10@ | 61.96 | PF |
| 2129C | **desmopressin acetate 100 microgram/mL nasal drops, 2.5 mL** | 1@ | 30.95 | FP |
| 8711L | **desmopressin acetate 10 microgram/actuation nasal spray, 60 actuations** | 1@ | 77.31 | FP |
| 8662X | **desmopressin acetate 200 microgram tablet, 30** | 30@ | 57.83 | FP |
| 5521N | **dextran-70 0.1% + hypromellose 0.3% eye drops, 28 x 0.4 mL unit doses** | 1@ | 9.55 | AQ |
| 8299T | | 1@ | 9.55 | AQ |
| 1302M | **diclofenac sodium 100 mg suppository, 20** | 20@ | 9.25 | NV |
| 5079H | | 20@ | 9.25 | NV |
| 5363G | | 20@ | 9.25 | NV |
| 5366K | | 20@ | 9.25 | NV |
| 1299J | **diclofenac sodium 25 mg tablet: enteric, 50 tablets** | 50@ | 2.51 | AF, CH, GM, QA, SZ, TW, TX |
| 1299J | **diclofenac sodium 25 mg tablet: enteric, 50 tablets** | 50@ | 3.44 | NV |
| 5076E | | 50@ | 2.51 | AF, CH, GM, QA, SZ, TW, TX |
| 5076E | | 50@ | 3.44 | NV |
| 5361E | | 50@ | 2.51 | AF, CH, GM, QA, SZ, TW, TX |
| 5361E | | 50@ | 3.44 | NV |
| 5364H | | 50@ | 2.51 | AF, CH, GM, QA, SZ, TW, TX |
| 5364H | | 50@ | 3.44 | NV |
| 3164M | **digoxin 50 microgram/mL oral liquid, 60 mL** | 1@ | 17.35 | QA |
| 2703G | **doxycycline 100 mg capsule: modified release, 7 capsules** | 7@ | 1.52 | YT |
| 2703G | **doxycycline 100 mg capsule: modified release, 7 capsules** | 7@ | 4.32 | YN |
| 2702F | **doxycycline 100 mg tablet, 7** | 7@ | 1.52 | AF, GM, QA |
| 2714W | | 7@ | 1.52 | AF, GM, QA |
| 9107H | | 7@ | 1.52 | CH, GX, HX, SZ, TW |
| 9108J | | 7@ | 1.52 | CH, HX, SZ, TW |
| 5435C | **enoxaparin sodium 100 mg/mL injection, 10 x 1 mL syringes** | 10@ | 102.33 | SW |
| 8558K | **enoxaparin sodium 20 mg/0.2 mL injection, 10 x 0.2 mL syringes** | 10@ | 49.16 | SW |
| 8716R | | 10@ | 49.16 | SW |
| 9195Y | **enoxaparin sodium 40 mg/0.4 mL injection, 10 x 0.4 mL ampoules** | 10@ | 51.23 | SW |
| 9196B | | 10@ | 51.23 | SW |

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| Code | Name, Form/Strength | Pack and Price | | Manufacturer |
|---|---|---|---|---|
| 8510X | **enoxaparin sodium 40 mg/0.4 mL injection, 10 x 0.4 mL syringes** | 10@ | 51.23 | SW |
| 8639Q | | 10@ | 51.23 | SW |
| 8640R | **enoxaparin sodium 60 mg/0.6 mL injection, 10 x 0.6 mL syringes** | 10@ | 73.26 | SW |
| 5434B | **enoxaparin sodium 80 mg/0.8 mL injection, 10 x 0.8 mL syringes** | 10@ | 84.28 | SW |
| 8367J | **entacapone 200 mg tablet, 100** | 100@ | 137.70 | NV |
| 8397Y | **eprosartan 400 mg tablet, 28** | 28@ | 8.59 | AB |
| 8951D | | 28@ | 8.59 | AB |
| 8683B | **eptifibatide 20 mg/10 mL injection, 1 x 10 mL vial** | 1@ | 128.06 | MK |
| 8684C | **eptifibatide 75 mg/100 mL injection, 1 x 100 mL vial** | 1@ | 337.98 | MK |
| 1397M | **erythromycin (as lactobionate) 1 g injection, 1 x 1 g vial** | 1@ | 38.01 | LM |
| 5088T | | 1@ | 38.01 | LM |
| 9329B | **essential amino acids formula oral liquid: powder for, 2 x 200 g cans** | 1@ | 199.02 | SB |
| 2027Q | **essential amino acids formula with minerals and vitamin C oral liquid: powder for, 400 g** | 1@ | 125.55 | SB |
| 9385Y | **essential amino acids formula with vitamins and minerals oral liquid: powder for, 50 x 12.5 g sachets** | 1@ | 377.52 | VF |
| 1954W | **etanercept 25 mg injection [4 x 25 mg vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack** | 1@ | 883.97 | PF |
| 3445H | | 1@ | 883.97 | PF |
| 3448L | | 1@ | 883.97 | PF |
| 8637N | | 1@ | 883.97 | PF |
| 8638P | | 1@ | 883.97 | PF |
| 8778B | | 1@ | 883.97 | PF |
| 8779C | | 1@ | 883.97 | PF |
| 9035M | | 1@ | 883.97 | PF |
| 9036N | | 1@ | 883.97 | PF |
| 9037P | | 1@ | 883.97 | PF |
| 9429G | | 1@ | 883.97 | PF |
| 8748K | **ethacrynic acid 25 mg tablet, 100** | 100@ | 95.44 | FK |
| 9352F | **everolimus 1 mg tablet, 60** | 60@ | 1031.17 | NV |
| 8842J | **everolimus 750 microgram tablet, 60** | 60@ | 786.10 | NV |
| 5411T | **FENTANYL Lozenge 1200 micrograms (as citrate), 30** | 30@ | 285.15 | OA |
| 5412W | **FENTANYL Lozenge 1600 micrograms (as citrate), 30** | 30@ | 285.15 | OA |
| 5407N | **FENTANYL Lozenge 200 micrograms (as citrate), 30** | 30@ | 285.15 | OA |
| 5408P | **FENTANYL Lozenge 400 micrograms (as citrate), 30** | 30@ | 285.15 | OA |
| 5409Q | **FENTANYL Lozenge 600 micrograms (as citrate), 30** | 30@ | 285.15 | OA |
| 5410R | **FENTANYL Lozenge 800 micrograms (as citrate), 30** | 30@ | 285.15 | OA |
| 1473M | **fluconazole 100 mg/50 mL injection, 1 x 50 mL vial** | 1@ | 12.13 | AE, HX, PF, SZ |
| 1474N | **fluconazole 200 mg/100 mL injection, 1 x 100 mL vial** | 1@ | 22.85 | AE, AF, BX, HX, PF, SZ |
| 1433K | **fludrocortisone acetate 100 microgram tablet, 100** | 100@ | 20.04 | QA |
| 2958Q | **folic acid 500 microgram tablet, 100** | 100@ | 3.09 | AF, PP |
| 1437P | **folic acid 5 mg tablet, 100** | 100@ | 3.80 | AF |
| 8812T | **folinic acid 100 mg/10 mL injection, 1 x 10 mL vial** | 1@ | 9.91 | SZ |
| 9041W | **folinic acid 300 mg/30 mL injection, 1 x 30 mL vial** | 1@ | 28.96 | HH, SZ |
| 8740B | **folinic acid 50 mg/5 mL injection, 1 x 5 mL vial** | 1@ | 10.73 | HH |
| 1575X | **folinic acid 50 mg/5 mL injection, 5 x 5 mL ampoules** | 5@ | 53.64 | SZ |
| 8713N | **follitropin alfa 300 international units / 0.5 mL (21.84 microgram/0.5 mL) injection, 1 x 0.5 mL cartridge** | 1@ | 162.36 | SG |
| 8714P | **follitropin alfa 450 international units / 0.75 mL (32.76 microgram/0.75 mL) injection, 1 x 0.75 mL cartridge** | 1@ | 243.55 | SG |
| 8715Q | **follitropin alfa 900 international units / 1.5 mL (65.52 microgram/1.5 mL) injection, 1 x 1.5 mL cartridge** | 1@ | 487.09 | SG |
| 8565T | **follitropin beta 300 international units/0.36 mL injection, 1 x 0.36 mL cartridge** | 1@ | 167.73 | MK |
| 8566W | **follitropin beta 600 international units/0.72 mL injection, 1 x 0.72 mL cartridge** | 1@ | 327.32 | MK |
| 8871X | **follitropin beta 900 international units/1.08 mL injection, 1 x 1.08 mL cartridge** | 1@ | 486.58 | MK |
| 8775W | **FONDAPARINUX SODIUM Injection 2.5 mg in 0.5 mL single dose pre-filled syringe, 2** | 2@ | 37.05 | GK |
| 1810G | **frusemide 20 mg tablet, 50** | 50@ | 1.04 | FM |
| 1810G | **frusemide 20 mg tablet, 50** | 50@ | 2.00 | SW |
| 8444K | **gelatin-succinylated 20 g/500 mL injection, 1 x 500 mL bag** | 1@ | 13.11 | BR |
| 9445D | **glucose 10% (50 g/500 mL) injection, 1 x 500 mL bag** | 1@ | 2.29 | PK |

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| Code | Name, Form/Strength | Pack and Price | | Manufacturer |
|---|---|---|---|---|
| 9474P | **glucose 5% (12.5 g/250 mL) injection, 1 x 250 mL bag** | 1@ | 3.45 | BR, PK |
| 5005K | **glucose 5% (25 g/500 mL) injection, 1 x 500 mL bag** | 1@ | 2.29 | BR, PK |
| 9444C | | 1@ | 2.29 | BR, PK |
| 2245E | **glucose 5% (50 g/1000 mL) injection, 1 x 1000 mL bag** | 1@ | 3.28 | BR, BX, PK |
| 5106R | | 1@ | 3.28 | BR, BX, PK |
| 3106L | **glucose and ketone indicator urine strip: diagnostic, 50 diagnostic strips** | 1@ | 5.44 | RD |
| 3107M | | 1@ | 5.50 | BN |
| 9254C | | 1@ | 5.44 | RD |
| 9255D | | 1@ | 5.50 | BN |
| 2263D | **glucose indicator blood strip: diagnostic, 50 diagnostic strips** | 1@ | 23.38 | MS |
| 2673Q | | 1@ | 23.38 | JJ |
| 2697Y | | 1@ | 23.38 | JJ |
| 2860M | | 1@ | 23.38 | NA |
| 2890D | | 1@ | 23.38 | NA |
| 2914J | | 1@ | 19.74 | NA |
| 3406G | | 1@ | 23.38 | LB |
| 3407H | | 1@ | 23.38 | LB |
| 3441D | | 1@ | 23.38 | JJ |
| 3442E | | 1@ | 23.38 | JJ |
| 5043K | | 1@ | 23.38 | RD |
| 5053Y | | 1@ | 23.38 | RD |
| 8723D | | 1@ | 23.38 | BR |
| 8739Y | | 1@ | 23.38 | RD |
| 8749L | | 1@ | 23.38 | OZ |
| 8759B | | 1@ | 23.38 | LB |
| 8795X | | 1@ | 23.38 | PX |
| 9013J | | 1@ | 23.38 | OZ |
| 9261K | | 1@ | 23.38 | OZ |
| 9263M | | 1@ | 23.38 | OZ |
| 9265P | | 1@ | 23.38 | BR |
| 9267R | | 1@ | 23.38 | MS |
| 9274D | | 1@ | 23.38 | RD |
| 9276F | | 1@ | 23.38 | NA |
| 9277G | | 1@ | 23.38 | NA |
| 9278H | | 1@ | 23.38 | LB |
| 9279J | | 1@ | 19.74 | NA |
| 9281L | | 1@ | 23.38 | PX |
| 9297H | | 1@ | 23.38 | QB |
| 9298J | | 1@ | 23.38 | QB |
| 9471L | | 1@ | 23.38 | EH |
| 9472M | | 1@ | 23.38 | EH |
| 9485F | | 1@ | 23.38 | OI |
| 9486G | | 1@ | 23.38 | OI |
| 8806L | **glucose indicator blood strip: diagnostic, 51 diagnostic strips** | 1@ | 23.38 | RD |
| 9275E | | 1@ | 23.38 | RD |
| 3104J | **glucose indicator urine strip: diagnostic, 50 diagnostic strips** | 1@ | 6.70 | BN |
| 9253B | | 1@ | 6.70 | BN |
| 2556M | **glycerol 1.4 g suppository, 12** | 1@ | 4.49 | PP |
| 5312N | | 1@ | 4.49 | PP |
| 5315R | | 1@ | 4.49 | PP |
| 2557N | **glycerol 2.8 g suppository, 12** | 1@ | 4.66 | PP |
| 5313P | | 1@ | 4.66 | PP |
| 5316T | | 1@ | 4.66 | PP |
| 2555L | **glycerol 700 mg suppository, 12** | 1@ | 4.35 | PP |
| 5311M | | 1@ | 4.35 | PP |
| 5314Q | | 1@ | 4.35 | PP |
| 2712R | **glycomacropeptide and essential amino acids oral liquid, 12 x 500 mL bottles** | 1@ | 105.31 | QH |
| 2696X | **glycomacropeptide and essential amino acids with vitamins and minerals bar, 7 x 54 g** | 1@ | 61.43 | QH |
| 2644E | **glycomacropeptide and essential amino acids with vitamins and minerals bar, 7 x 81 g** | 1@ | 92.15 | QH |
| 2685H | **glycomacropeptide and essential amino acids with vitamins and minerals oral liquid: powder for, 28 x 49 g sachets** | 1@ | 368.34 | QH |
| 8728J | **granisetron 2 mg tablet, 1** | 1@ | 15.26 | RO |

# (APPLY WASTAGE FACTOR IN CALCULATING BROKEN QUANTITY PRICES)

| Code | Name, Form/Strength | Pack and Price | | Manufacturer |
|---|---|---|---|---|
| 1076P | **heparin sodium 35 000 international units/35 mL injection, 1 x 35 mL vial** | 1@ | 31.15 | HH |
| 2652N | **high fat formula with vitamins, minerals and trace elements and low in protein and carbohydrate (3:1 ratio long chain fat to carbohydrate plus protein) oral liquid: powder for, 300 g** | 1@ | 42.96 | SB |
| 9446E | **high fat formula with vitamins, minerals and trace elements and low in protein and carbohydrate oral liquid: powder for, 300 g** | 1@ | 42.96 | SB |
| 1640H | **hydralazine hydrochloride 25 mg tablet, 100** | 100@ | 5.44 | AF |
| 1639G | **hydralazine hydrochloride 50 mg tablet, 100** | 100@ | 6.30 | AF |
| 1486F | **hydrochlorothiazide 50 mg + amiloride hydrochloride 5 mg tablet, 50** | 50@ | 3.54 | AS |
| 1501B | **hydrocortisone (as sodium succinate) 100 mg injection [1 x 100 mg vial] (&) inert substance diluent [1 x 2 mL vial], 1 pack** | 1@ | 5.05 | PF |
| 1510L | | 1@ | 5.05 | PF |
| 5118J | | 1@ | 5.05 | PF |
| 1511M | **hydrocortisone (as sodium succinate) 250 mg injection [1 x 250 mg vial] (&) inert substance diluent [1 x 2 mL vial], 1 pack** | 1@ | 8.72 | PF |
| 5119K | | 1@ | 8.72 | PF |
| 1502C | **hydrocortisone acetate 10% (100 mg/g) enema, 21.1 g** | 1@ | 18.73 | AS |
| 9487H | **HYDROXYETHYL STARCH 130/0.4 I.V. infusion 30 g per 500 mL, 500 mL, 1** | 1@ | 13.11 | PK |
| 5317W | **hyoscine butylbromide 20 mg/mL injection, 5 x 1 mL ampoules** | 5@ | 17.02 | BY |
| 5318X | | 5@ | 17.02 | BY |
| 3190X | **ibuprofen 400 mg tablet, 30** | 30@ | 2.77 | AB |
| 5123P | | 30@ | 2.77 | AB |
| 5368M | | 30@ | 2.77 | AB |
| 5370P | | 30@ | 2.77 | AB |
| 2448W | **idarubicin hydrochloride 10 mg capsule, 1** | 1@ | 162.69 | PF |
| 2446R | **idarubicin hydrochloride 5 mg capsule, 1** | 1@ | 87.06 | PF |
| 2757D | **indomethacin 100 mg suppository, 20** | 20@ | 8.04 | AS |
| 5128X | | 20@ | 8.04 | AS |
| 5378C | | 20@ | 8.04 | AS |
| 5380E | | 20@ | 8.04 | AS |
| 2454E | **indomethacin 25 mg capsule, 50** | 50@ | 3.00 | AF |
| 2454E | **indomethacin 25 mg capsule, 50** | 50@ | 4.24 | AS |
| 5126T | | 50@ | 3.00 | AF |
| 5126T | | 50@ | 4.24 | AS |
| 5377B | | 50@ | 4.24 | AS |
| 5377B | | 50@ | 3.00 | AF |
| 5379D | | 50@ | 4.24 | AS |
| 5379D | | 50@ | 3.00 | AF |
| 8571D | **insulin aspart 100 international units/mL injection, 1 x 10 mL vial** | 1@ | 30.57 | NO |
| 8435Y | **insulin aspart 100 international units/mL injection, 5 x 3 mL cartridges** | 1@ | 51.56 | NF, NO |
| 8609D | **insulin aspart 30 international units/mL + insulin aspart protamine 70 international units/mL injection, 5 x 3 mL syringes** | 1@ | 51.56 | NF, NO |
| 9040T | **insulin detemir 100 international units/mL injection, 5 x 3 mL cartridges** | 1@ | 85.26 | NF, NO |
| 9039R | **insulin glargine 100 international units/mL injection, 5 x 3 mL cartridges** | 1@ | 85.26 | AV, SW |
| 9224L | **insulin glulisine 100 international units/mL injection, 1 x 10 mL vial** | 1@ | 30.57 | SW |
| 1921D | **insulin glulisine 100 international units/mL injection, 5 x 3 mL cartridges** | 1@ | 51.56 | AV, SW |
| 1711C | **insulin isophane bovine 100 international units/mL injection, 1 x 10 mL vial** | 1@ | 33.12 | AS |
| 1533Q | **insulin isophane human 100 international units/mL injection, 1 x 10 mL vial** | 1@ | 25.48 | LY, NO |
| 1761Q | **insulin isophane human 100 international units/mL injection, 5 x 3 mL cartridges** | 1@ | 43.58 | LY, NI, NO |
| 1763T | **insulin isophane human 70 international units/mL + insulin neutral human 30 international units/mL injection, 5 x 3 mL cartridges** | 1@ | 43.58 | LY, NI, NO |
| 8084L | **insulin lispro 100 international units/mL injection, 1 x 10 mL vial** | 1@ | 30.57 | LY |
| 8212F | **insulin lispro 100 international units/mL injection, 5 x 3 mL cartridges** | 1@ | 51.56 | KP, LY |
| 8390N | **insulin lispro 25 international units/mL + insulin lispro protamine 75 international units/mL injection, 5 x 3 mL cartridges** | 1@ | 51.56 | KP, LY |
| 8874C | **insulin lispro 50 international units/mL + insulin lispro protamine 50 international units/mL injection, 5 x 3 mL cartridges** | 1@ | 51.56 | KP, LY |
| 1713E | **insulin neutral bovine 100 international units/mL injection, 1 x 10 mL vial** | 1@ | 33.12 | AS |
| 1531N | **insulin neutral human 100 international units/mL injection, 1 x 10 mL vial** | 1@ | 25.48 | LY, NO |
| 1762R | **insulin neutral human 100 international units/mL injection, 5 x 3 mL cartridges** | 1@ | 43.58 | LY, NO |
| 1426C | **insulin neutral human 30 international units/mL + insulin isophane** | 1@ | 25.48 | LY |

# (APPLY WASTAGE FACTOR IN CALCULATING BROKEN QUANTITY PRICES)

| Code | Name, Form/Strength | Pack and | Price | Manufacturer |
|---|---|---|---|---|
| | **human 70 international units/mL injection, 1 x 10 mL vial** | | | |
| 2062M | **insulin neutral human 50 international units/mL + insulin isophane human 50 international units/mL injection, 5 x 3 mL cartridges** | 1@ | 43.58 | NO |
| 8180M | **interferon alfa-2a 3 million international units/0.5 mL injection, 1 x 0.5 mL syringe** | 1@ | 33.32 | RO |
| 8181N | | 1@ | 33.32 | RO |
| 8182P | **interferon alfa-2a 4.5 million international units/0.5 mL injection, 1 x 0.5 mL syringe** | 1@ | 51.66 | RO |
| 8551C | | 1@ | 51.66 | RO |
| 8183Q | **interferon alfa-2a 6 million international units/0.5 mL injection, 1 x 0.5 mL syringe** | 1@ | 67.66 | RO |
| 8552D | | 1@ | 67.66 | RO |
| 8184R | **interferon alfa-2a 9 million international units/0.5 mL injection, 1 x 0.5 mL syringe** | 1@ | 99.94 | RO |
| 8553E | | 1@ | 99.94 | RO |
| 8348J | **interferon alfa-2b 18 million international units/1.2 mL injection, 1 x 1.2 mL cartridge** | 1@ | 199.87 | MK |
| 8572E | | 1@ | 199.87 | MK |
| 8476D | **interferon alfa-2b 30 million international units/1.2 mL injection, 1 x 1.2 mL cartridge** | 1@ | 333.11 | MK |
| 8671J | **ipratropium bromide 20 microgram/actuation inhalation: pressurised, 200 actuations** | 1@ | 13.71 | BY |
| 1542E | **ipratropium bromide 250 microgram/mL inhalation: solution, 30 x 1 mL ampoules** | 1@ | 12.17 | AF, PF, QA, TX |
| 1542E | **ipratropium bromide 250 microgram/mL inhalation: solution, 30 x 1 mL ampoules** | 1@ | 12.44 | BY |
| 8238N | **ipratropium bromide 500 microgram/mL inhalation: solution, 30 x 1 mL ampoules** | 1@ | 14.38 | AF, PF, QA, TX |
| 8238N | **ipratropium bromide 500 microgram/mL inhalation: solution, 30 x 1 mL ampoules** | 1@ | 14.65 | BY |
| 9436P | **isoleucine with carbohydrate containing 1 g isoleucine oral liquid: powder for, 30 x 4 g sachets** | 1@ | 140.14 | VF |
| 9134R | **isoleucine with carbohydrate containing 50 mg isoleucine oral liquid: powder for, 30 x 4 g sachets** | 1@ | 127.40 | VF |
| 2588F | **isosorbide dinitrate 5 mg tablet: sublingual, 100** | 100@ | 4.07 | QA |
| 1588N | **ketoprofen 100 mg suppository, 20** | 20@ | 9.44 | SW |
| 5139L | | 20@ | 9.44 | SW |
| 9416N | **lactate sodium 0.322% (1.61 g/500 mL) + sodium chloride 0.6% (3 g/500 mL) + potassium chloride 0.04% (200 mg/500 mL) + calcium chloride dihydrate 0.027% (135 mg/500 mL) injection, 1 x 500 mL bag** | 1@ | 1.28 | BR, PK |
| 2286H | **lactate sodium 0.322% (3.22 g/1000 mL) + sodium chloride 0.6% (6 g/1000 mL) + potassium chloride 0.04% (400 mg/1000 mL) + calcium chloride dihydrate 0.027% (270 mg/1000 mL) injection, 1 x 1000 mL bag** | 1@ | 1.82 | BR, BX, PK |
| 5387M | **LACTULOSE Mixture 3.34 g per 5 mL, 500 mL, 1** | 1@ | 4.72 | AF, GM, GX, QA, SZ |
| 5387M | **LACTULOSE Mixture 3.34 g per 5 mL, 500 mL, 1** | 1@ | 5.73 | AB |
| 5388N | | 1@ | 5.73 | AB |
| 5388N | | 1@ | 4.72 | AF, GM, GX, QA, SZ |
| 9148L | **lapatinib 250 mg tablet, 70** | 70@ | 1690.52 | GK |
| 8798C | **levodopa 100 mg + carbidopa anhydrous 25 mg + entacapone 200 mg tablet, 100** | 100@ | 167.75 | NV |
| 9345W | **levodopa 125 mg + carbidopa anhydrous 31.25 mg + entacapone 200 mg tablet, 100** | 100@ | 173.77 | NV |
| 8799D | **levodopa 150 mg + carbidopa anhydrous 37.5 mg + entacapone 200 mg tablet, 100** | 100@ | 182.77 | NV |
| 9292C | **levodopa 200 mg + carbidopa anhydrous 50 mg + entacapone 200 mg tablet, 100** | 100@ | 196.60 | NV |
| 8970D | **levodopa 20 mg/mL + carbidopa monohydrate 5 mg/mL gel: intestinal, 7 x 100 mL bags** | 7@ | 1459.49 | VE |
| 8797B | **levodopa 50 mg + carbidopa anhydrous 12.5 mg + entacapone 200 mg tablet, 100** | 100@ | 152.73 | NV |
| 9344T | **levodopa 75 mg + carbidopa anhydrous 18.75 mg + entacapone 200 mg tablet, 100** | 100@ | 159.35 | NV |
| 8290H | **lithium carbonate 450 mg tablet: modified release, 100 tablets** | 100@ | 13.94 | AS |
| 8203R | **losartan potassium 50 mg tablet, 30** | 30@ | 8.99 | AF |
| 5389P | **macrogol-3350 13.12 g + sodium chloride 350.7 mg + potassium chloride** | 1@ | 14.13 | GM, NE |

# (APPLY WASTAGE FACTOR IN CALCULATING BROKEN QUANTITY PRICES)

| Code | Name, Form/Strength | Pack and Price | | Manufacturer |
|---|---|---|---|---|
| | **46.6 mg (0.63 mmol potassium) + sodium bicarbonate 178.5 mg solution, 30 sachets** | | | |
| 5390Q | | 1@ | 14.13 | GM, NE |
| 2351R | **macrogol-3350 1 g/g oral liquid: powder for, 30 x 17 g sachets** | 1@ | 14.13 | ON |
| 2353W | | 1@ | 14.13 | ON |
| 5426N | **macrogol-3350 1 g/g oral liquid: powder for, 510 g** | 1@ | 14.13 | KY |
| 5427P | | 1@ | 14.13 | KY |
| 1598D | **mercaptopurine 50 mg tablet, 25** | 25@ | 61.38 | AS |
| 8753Q | **mesalazine 1 g/100 mL enema, 7 x 100 mL** | 1@ | 82.45 | FP |
| 8768L | **mesalazine 1 g/application enema, 14 applications** | 1@ | 82.45 | OA |
| 3413P | **mesalazine 1 g tablet: modified release, 60 tablets** | 60@ | 162.13 | FP |
| 8616L | **mesalazine 2 g/60 mL enema, 7 x 60 mL** | 1@ | 82.45 | OA |
| 8617M | **mesalazine 4 g/60 mL enema, 7 x 60 mL** | 1@ | 109.87 | OA |
| 8598M | **mesalazine 500 mg granules: modified release, 100 x 500 mg sachets** | 100@ | 145.51 | OA |
| 8731M | **mesalazine 500 mg tablet: enteric, 100 tablets** | 100@ | 145.51 | OA |
| 2214M | **mesalazine 500 mg tablet: modified release, 100 tablets** | 100@ | 145.51 | FP |
| 1818Q | **METHOTREXATE Injection 50 mg in 2 mL, 1** | 1@ | 3.67 | WQ |
| 5423K | **methylnaltrexone bromide 12 mg/0.6 mL injection, 1 x 0.6 mL vial** | 1@ | 41.39 | LM |
| 2826R | **methysergide 1 mg tablet, 50** | 50@ | 19.27 | LM |
| 1638F | **metronidazole 500 mg/100 mL (0.5%) injection, 1 x 100 mL bag** | 1@ | 2.69 | BX |
| 5154G | | 1@ | 2.69 | BX |
| 2277W | **metronidazole 500 mg/100 mL (0.5%) injection, 5 x 100 mL bags** | 5@ | 13.48 | AE |
| 2298Y | | 5@ | 13.48 | AE |
| 9026C | **miconazole nitrate 2% (20 mg/g) cream, 15 g** | 1@ | 4.74 | JT |
| 8282X | **milk powder lactose free formula oral liquid: powder for, 900 g** | 1@ | 21.29 | PF |
| 8283Y | | 1@ | 21.29 | PF |
| 2349P | **milk powder lactose free formula predigested oral liquid: powder for, 900 g** | 1@ | 16.50 | NU |
| 2350Q | | 1@ | 16.50 | NU |
| 2357C | **milk powder lactose modified predigested oral liquid: powder for, 900 g** | 1@ | 22.13 | SJ |
| 2358D | | 1@ | 22.13 | SJ |
| 3092R | **milk powder synthetic low calcium oral liquid: powder for, 400 g** | 1@ | 46.87 | SB |
| 8630F | **milk protein and fat formula with vitamins and minerals carbohydrate free oral liquid: powder for, 225 g** | 1@ | 26.75 | SB |
| 8816B | **modafinil 100 mg tablet, 60** | 60@ | 170.28 | CS |
| 1836P | **mycophenolate Capsule 250 mg, 50** | 50@ | 87.00 | AF |
| 8649F | **mycophenolate mofetil 250 mg capsule, 100** | 100@ | 173.99 | CR, QA, RO, SZ, TX |
| 8650G | **mycophenolate mofetil 500 mg tablet, 50** | 50@ | 173.98 | AF, CR, QA, RO, SZ, TX |
| 2192J | **naloxone hydrochloride 400 microgram/mL injection, 1 x 1 mL syringe** | 1@ | 19.68 | UC |
| 2196N | | 1@ | 19.68 | UC |
| 1674D | **naproxen 250 mg tablet, 50** | 50@ | 3.46 | AF |
| 1674D | **naproxen 250 mg tablet, 50** | 50@ | 4.58 | RO |
| 5176K | | 50@ | 3.46 | AF |
| 5176K | | 50@ | 4.58 | RO |
| 5345H | | 50@ | 4.58 | RO |
| 5345H | | 50@ | 3.46 | AF |
| 5349M | | 50@ | 4.58 | RO |
| 5349M | | 50@ | 3.46 | AF |
| 8298R | **naratriptan 2.5 mg tablet, 2** | 2@ | 11.13 | AS |
| 9734H | | 2@ | 11.13 | AS |
| 9316H | **nebivolol 1.25 mg tablet, 28** | 28@ | 22.10 | FK |
| 2732T | **nitrazepam 5 mg tablet, 25** | 25@ | 1.39 | AF |
| 2732T | **nitrazepam 5 mg tablet, 25** | 25@ | 2.85 | VT |
| 5359C | | 25@ | 1.39 | AF |
| 5359C | | 25@ | 2.85 | VT |
| 5360D | | 25@ | 1.39 | AF |
| 5360D | | 25@ | 2.85 | VT |
| 1698J | **nystatin 100 000 international units/g cream, 15 g** | 1@ | 6.07 | FM |
| 5567B | **ofloxacin 0.3% (3 mg/mL) eye drops, 5 mL** | 1@ | 12.86 | AG |
| 8383F | | 1@ | 12.86 | AG |
| 9294E | **olanzapine 210 mg injection: modified release [1 x 210 mg vial] (&) inert substance diluent [1 x 3 mL vial], 1 pack** | 1@ | 246.68 | LY |
| 9295F | **olanzapine 300 mg injection: modified release [1 x 300 mg vial] (&) inert substance diluent [1 x 3 mL vial], 1 pack** | 1@ | 401.42 | LY |

# (APPLY WASTAGE FACTOR IN CALCULATING BROKEN QUANTITY PRICES)

| Code | Name, Form/Strength | Pack and | Price | Manufacturer |
|---|---|---|---|---|
| 3134Y | **oxazepam 15 mg tablet, 25** | 25@ | 1.24 | AF |
| 3134Y | **oxazepam 15 mg tablet, 25** | 25@ | 3.92 | QA |
| 5371Q | | 25@ | 3.92 | QA |
| 5371Q | | 25@ | 1.24 | AF |
| 5373T | | 25@ | 3.92 | QA |
| 5373T | | 25@ | 1.24 | AF |
| 3135B | **oxazepam 30 mg tablet, 25** | 25@ | 1.24 | AF, FM, TX |
| 3135B | **oxazepam 30 mg tablet, 25** | 25@ | 3.92 | QA |
| 5372R | | 25@ | 1.24 | AF, FM, TX |
| 5372R | | 25@ | 3.92 | QA |
| 5374W | | 25@ | 3.92 | QA |
| 5374W | | 25@ | 1.24 | AF, FM, TX |
| 8588B | **oxcarbazepine 60 mg/mL oral liquid, 250 mL** | 1@ | 65.85 | NV |
| 8461H | **pamidronate disodium 15 mg/5 mL injection, 1 x 5 mL vial** | 1@ | 31.03 | HH |
| 8462J | **pamidronate disodium 30 mg/10 mL injection, 1 x 10 mL vial** | 1@ | 62.07 | HH, YA |
| 8020D | **pancreatic extract 10 000 international units capsule: modified release, 100 capsules** | 100@ | 35.45 | AB |
| 9226N | | 100@ | 35.45 | AB |
| 8021E | **pancreatic extract 25 000 international units capsule: modified release, 100 capsules** | 100@ | 70.66 | AB |
| 9227P | | 100@ | 70.66 | AB |
| 9412J | **pancreatic extract 40 000 international units capsule: modified release, 100 capsules** | 100@ | 111.77 | AB |
| 9413K | | 100@ | 111.77 | AB |
| 5453B | **pancreatic extract 5000 international units/100 mg granules: enteric-coated, 20 g** | 1@ | 45.12 | AB |
| 5454C | | 1@ | 45.12 | AB |
| 8366H | **pancrelipase 25 000 units capsule, 100** | 100@ | 65.74 | TM |
| 9229R | | 100@ | 65.74 | TM |
| 5319Y | **paracetamol 500 mg suppository, 24** | 1@ | 19.51 | GC |
| 5320B | | 1@ | 19.51 | GC |
| 5224Y | **paracetamol 500 mg tablet, 100** | 100@ | 1.90 | FM, GM, GQ, SW, SZ, TX |
| 8784H | | 100@ | 1.90 | FM, GM, GQ, SW, SZ, TX |
| 5343F | **paracetamol 665 mg tablet: modified release, 96 tablets** | 96@ | 5.11 | GC |
| 5344G | | 96@ | 5.11 | GC |
| 8814X | | 96@ | 5.11 | GC |
| 2167C | **paraffin + retinyl palmitate 138 microgram/g (equivalent to 250 units/g vitamin A) eye ointment, 5 g** | 1@ | 7.41 | AE |
| 2202X | | 1@ | 7.41 | AE |
| 2222Y | | 1@ | 7.41 | AE |
| 1754H | **paraffin 1 g/g eye ointment, 3.5 g** | 1@ | 7.41 | IQ |
| 1754H | **paraffin 1 g/g eye ointment, 3.5 g** | 1@ | 8.68 | AQ |
| 5523Q | | 1@ | 8.68 | AQ |
| 5523Q | | 1@ | 7.41 | IQ |
| 9217D | | 1@ | 8.68 | AQ |
| 9217D | | 1@ | 7.41 | IQ |
| 1166J | **phenoxybenzamine hydrochloride 10 mg capsule, 30** | 1@ | 66.16 | GH |
| 5024K | **phenoxymethylpenicillin 125 mg/5 mL oral liquid: powder for, 100 mL** | 1@ | 3.88 | AE |
| 8976K | | 1@ | 3.88 | AE |
| 5012T | **phenoxymethylpenicillin 150 mg/5 mL oral liquid, 100 mL** | 1@ | 8.54 | QA |
| 5012T | **phenoxymethylpenicillin 150 mg/5 mL oral liquid, 100 mL** | 1@ | 7.59 | FM |
| 9143F | | 1@ | 8.54 | QA |
| 9143F | | 1@ | 7.59 | FM |
| 5029Q | **phenoxymethylpenicillin 250 mg/5 mL oral liquid: powder for, 100 mL** | 1@ | 5.16 | AE |
| 8977L | | 1@ | 5.16 | AE |
| 1703P | **phenoxymethylpenicillin 250 mg tablet, 25** | 25@ | 2.45 | QA |
| 1787C | | 25@ | 2.45 | QA |
| 3360W | | 25@ | 2.45 | QA |
| 3028J | **phenoxymethylpenicillin 500 mg tablet, 25** | 25@ | 3.62 | QA |
| 3361X | | 25@ | 3.62 | QA |
| 9384X | **phenylalanine with carbohydrate containing 50 mg phenylalanine oral liquid: powder for, 30 x 4 g sachets** | 1@ | 127.40 | VF |
| 5560P | **polyethylene glycol-400 0.25% (1 mg/0.4 mL) eye drops, 20 x 0.4 mL unit** | 1@ | 6.59 | AO |

# (APPLY WASTAGE FACTOR IN CALCULATING BROKEN QUANTITY PRICES)

| Code | Name, Form/Strength | Pack and Price | | Manufacturer |
|---|---|---|---|---|
| | **doses** | | | |
| 9493P | | 1@ | 6.59 | AO |
| 5532E | **polyethylene glycol-400 0.4% (3.2 mg/0.8 mL) + propylene glycol 0.3% (2.4 mg/0.8 mL) eye drops, 28 x 0.8 mL unit doses** | 1@ | 13.83 | AQ |
| 9170P | | 1@ | 13.83 | AQ |
| 9475Q | **polylactic acid 150 mg injection, 1 x 150 mg vial** | 1@ | 220.02 | SW |
| 9476R | | 1@ | 220.02 | SW |
| 2642C | **potassium chloride 600 mg (8 mmol potassium) tablet: modified release, 100 tablets** | 100@ | 4.70 | NV |
| 2642C | **potassium chloride 600 mg (8 mmol potassium) tablet: modified release, 100 tablets** | 100@ | 3.23 | NM |
| 1920C | **prednisolone (as sodium phosphate) 20 mg/100 mL enema, 7 x 100 mL** | 7@ | 51.23 | QA |
| 2554K | **prednisolone (as sodium phosphate) 5 mg suppository, 10** | 1@ | 11.76 | QA |
| 1948M | **promethazine hydrochloride 50 mg/2 mL injection, 5 x 2 mL ampoules** | 5@ | 11.91 | HH |
| 3374N | | 5@ | 11.91 | HH |
| 1953T | **propantheline bromide 15 mg tablet, 100** | 100@ | 10.02 | QA |
| 1955X | **propylthiouracil 50 mg tablet, 100** | 100@ | 21.61 | PL |
| 2676W | **protein hydrolysate formula with medium chain triglycerides oral liquid: powder for, 400 g** | 1@ | 20.69 | NT |
| 8259Q | **protein hydrolysate formula with medium chain triglycerides oral liquid: powder for, 450 g** | 1@ | 12.93 | NU |
| 2608G | **pyridostigmine bromide 180 mg tablet: modified release, 50 tablets** | 50@ | 71.40 | VT |
| 2724J | **PYRIDOSTIGMINE BROMIDE Tablet 10 mg, 50** | 50@ | 8.29 | VT |
| 8162N | **ranitidine 150 mg/10 mL oral liquid, 300 mL** | 1@ | 9.05 | AS |
| 1937Y | **ranitidine 150 mg tablet: effervescent, 30** | 30@ | 4.00 | AS |
| 8790P | **risperidone 1 mg tablet: orally disintegrating, 28** | 28@ | 13.63 | JC |
| 8792R | | 28@ | 13.63 | JC |
| 8780D | **risperidone 25 mg injection: modified release [1 x 25 mg vial] (&) inert substance diluent [1 x 2 mL syringe], 1 pack** | 1@ | 135.34 | JC |
| 8794W | **risperidone 2 mg tablet: orally disintegrating, 28** | 28@ | 26.17 | JC |
| 9080X | | 28@ | 26.17 | JC |
| 8781E | **risperidone 37.5 mg injection: modified release [1 x 37.5 mg vial] (&) inert substance diluent [1 x 2 mL syringe], 1 pack** | 1@ | 173.51 | JC |
| 9075P | **risperidone 3 mg tablet: orally disintegrating, 28** | 28@ | 38.90 | JC |
| 9076Q | **risperidone 4 mg tablet: orally disintegrating, 28** | 28@ | 51.83 | JC |
| 1842Y | **risperidone 500 microgram tablet, 20** | 20@ | 4.06 | JC, TX |
| 1846E | | 20@ | 4.06 | JC, TX |
| 8788M | **risperidone 500 microgram tablet: orally disintegrating, 28** | 28@ | 6.81 | JC |
| 8870W | | 28@ | 6.81 | JC |
| 8782F | **risperidone 50 mg injection: modified release [1 x 50 mg vial] (&) inert substance diluent [1 x 2 mL syringe], 1 pack** | 1@ | 211.28 | JC |
| 9313E | **rizatriptan 10 mg wafer, 2** | 2@ | 9.35 | MK |
| 2003K | **salbutamol 0.5% (5 mg/mL) inhalation: solution, 1 x 30 mL bottle** | 1@ | 5.42 | PF |
| 8288F | **salbutamol 100 microgram/actuation inhalation: pressurised, 200 actuations** | 1@ | 4.86 | GK |
| 8288F | **salbutamol 100 microgram/actuation inhalation: pressurised, 200 actuations** | 1@ | 3.69 | AL, IA, TX |
| 2000G | **salbutamol 2.5 mg/2.5 mL inhalation: solution, 30 x 2.5 mL ampoules** | 1@ | 5.13 | AF, CR, GM, GX, QA, SZ |
| 2000G | **salbutamol 2.5 mg/2.5 mL inhalation: solution, 30 x 2.5 mL ampoules** | 1@ | 5.72 | GK |
| 1099W | **salbutamol 200 microgram inhalation: powder for, 100 capsules** | 100@ | 4.82 | GK |
| 1103C | **salbutamol 2 mg/5 mL oral liquid, 150 mL** | 1@ | 7.89 | GK |
| 2001H | **salbutamol 5 mg/2.5 mL inhalation: solution, 30 x 2.5 mL ampoules** | 1@ | 5.42 | AF, CR, GM, GX, QA, SZ |
| 2001H | **salbutamol 5 mg/2.5 mL inhalation: solution, 30 x 2.5 mL ampoules** | 1@ | 5.99 | GK |
| 8354Q | **salbutamol Oral pressurised inhalation in breath actuated device 100 micrograms (base) per dose (200 doses), CFC-free formulation, 1** | 1@ | 16.09 | IA |
| 2997R | **salcatonin 100 international units/mL injection, 5 x 1 mL ampoules** | 5@ | 51.57 | NV |
| 2995P | **salcatonin 50 international units/mL injection, 5 x 1 mL ampoules** | 5@ | 33.54 | NV |
| 2281C | **sodium chloride 0.18% (1.8 g/1000 mL) + glucose 4% (40 g/1000 mL) injection, 1 x 1000 mL bag** | 1@ | 3.42 | BX |
| 5214K | | 1@ | 3.42 | BX |
| 2279Y | **sodium chloride 0.225% (1.125 g/500 mL) + glucose 3.75% (18.75 g/500 mL) injection, 1 x 500 mL bag** | 1@ | 4.47 | BX |
| 5215L | | 1@ | 4.47 | BX |

# (APPLY WASTAGE FACTOR IN CALCULATING BROKEN QUANTITY PRICES)

| Code | Name, Form/Strength | Pack and Price | | Manufacturer |
|---|---|---|---|---|
| 2278X | **sodium chloride 0.45% (2.25 g/500 mL) + glucose 2.5% (12.5 g/500 mL) injection, 1 x 500 mL bag** | 1@ | 4.47 | BX |
| 5216M | | 1@ | 4.47 | BX |
| 9473N | **sodium chloride 0.9% (2.25 g/250 mL) injection, 1 x 250 mL bag** | 1@ | 1.99 | BR, PK |
| 5021G | **sodium chloride 0.9% (4.5 g/500 mL) injection, 1 x 500 mL bag** | 1@ | 1.32 | BR, PK |
| 9392H | | 1@ | 1.32 | BR, PK |
| 2264E | **sodium chloride 0.9% (9 g/1000 mL) injection, 1 x 1000 mL bag** | 1@ | 1.90 | BR, BX, PK |
| 5212H | | 1@ | 1.90 | BR, BX, PK |
| 2260Y | **sodium chloride 3% (30 g/1000 mL) injection, 1 x 1000 mL bag** | 1@ | 2.85 | BX |
| 5213J | | 1@ | 2.85 | BX |
| 2266G | **sodium chloride 8.6 g/1000 mL + potassium chloride 300 mg/1000 mL + calcium chloride dihydrate 330 mg/1000 mL injection, 1 x 1000 mL bag** | 1@ | 5.90 | BX |
| 3199J | **sodium gluconate 5.02 g/1000 mL + sodium chloride 5.26 g/1000 mL + potassium chloride 370 mg/1000 mL + magnesium chloride 300 mg/1000 mL + sodium acetate trihydrate 3.68 g/1000 mL + glucose 5% (50 g/1000 mL) injection, 1 x 1000 mL bag** | 1@ | 7.77 | BX |
| 9380Q | **sorafenib 200 mg tablet, 60** | 60@ | 3225.33 | BN |
| 2091C | **sorbitol 3.125 g/5 mL + citrate sodium dihydrate 450 mg/5 mL + lauryl sulfoacetate sodium 45 mg/5 mL enema, 12 x 5 mL** | 1@ | 12.93 | AE, JT |
| 5331N | | 1@ | 12.93 | AE, JT |
| 5332P | | 1@ | 12.93 | AE, JT |
| 5545W | **soy lecithin 1% (10 mg/mL) + tocopherols 0.002% (20 microgram/mL) + vitamin A palmitate 0.025% (250 microgram/mL) eye spray, 100 actuations** | 1@ | 14.82 | RB |
| 9448G | | 1@ | 14.82 | RB |
| 8577K | **soy protein and fat formula with vitamins and minerals carbohydrate free oral liquid, 1 x 384 mL can** | 1@ | 5.53 | AB |
| 2093E | **sulfasalazine 500 mg tablet, 100** | 100@ | 21.93 | PF |
| 9208P | | 100@ | 21.93 | PF |
| 2096H | **SULFASALAZINE Tablet 500 mg (enteric coated), 100** | 100@ | 24.90 | PF |
| 2096H | **SULFASALAZINE Tablet 500 mg (enteric coated), 100** | 100@ | 23.92 | FZ |
| 9209Q | | 100@ | 24.90 | PF |
| 9209Q | | 100@ | 23.92 | FZ |
| 8885P | **SUMATRIPTAN Tablet (fast disintegrating) 50 mg (as succinate), 2** | 2@ | 7.53 | AS |
| 8144P | **SUMATRIPTAN Tablet 50 mg (as succinate), 2** | 2@ | 7.53 | AF, AS, CH, QA, TW, TX |
| 8144P | **SUMATRIPTAN Tablet 50 mg (as succinate), 2** | 2@ | 8.31 | LN |
| 1880Y | **tamoxifen 20 mg tablet, 30** | 30@ | 19.00 | AP |
| 2088X | **temazepam 10 mg tablet, 25** | 25@ | 1.04 | AF, FM, TX |
| 2088X | **temazepam 10 mg tablet, 25** | 25@ | 3.09 | QA |
| 5375X | | 25@ | 1.04 | AF, FM, TX |
| 5375X | | 25@ | 3.09 | QA |
| 5376Y | | 25@ | 1.04 | AF, FM, TX |
| 5376Y | | 25@ | 3.09 | QA |
| 8821G | **temozolomide 100 mg capsule, 5** | 5@ | 497.62 | MK, ON, QA, WQ |
| 9361Q | **temozolomide 140 mg capsule, 5** | 5@ | 674.36 | MK, ON, QA, WQ |
| 8820F | **temozolomide 20 mg capsule, 5** | 5@ | 120.24 | MK, ON, QA, WQ |
| 8819E | **temozolomide 5 mg capsule, 5** | 5@ | 42.75 | MK, ON, QA, WQ |
| 9160D | **terbinafine hydrochloride 1% (10 mg/g) cream, 15 g** | 1@ | 15.47 | NC |
| 8098F | **testosterone 100 mg implant, 1** | 1@ | 33.86 | MK |
| 8099G | **testosterone 200 mg implant, 1** | 1@ | 67.71 | MK |
| 2832C | **tetracosactrin 1 mg/mL injection: modified release, 1 x 1 mL ampoule** | 1@ | 12.97 | NV |
| 8222R | **tiagabine 10 mg tablet, 50** | 50@ | 66.21 | OA |
| 8223T | **tiagabine 15 mg tablet, 50** | 50@ | 95.24 | OA |
| 8221Q | **tiagabine 5 mg tablet, 50** | 50@ | 33.10 | OA |
| 1356J | **tobramycin 80 mg/2 mL injection, 5 x 2 mL vials** | 5@ | 29.30 | HH |
| 8872Y | **tobramycin Injection 80 mg (base) in 2 mL (without preservative), 5** | 5@ | 29.30 | PF |
| 2117K | **triamcinolone acetonide 0.02% (200 microgram/g) cream, 100 g** | 1@ | 5.88 | QA |
| 2117K | **triamcinolone acetonide 0.02% (200 microgram/g) cream, 100 g** | 1@ | 3.99 | FM |
| 2118L | **triamcinolone acetonide 0.02% (200 microgram/g) ointment, 100 g** | 1@ | 3.99 | FM |
| 2118L | **triamcinolone acetonide 0.02% (200 microgram/g) ointment, 100 g** | 1@ | 5.88 | QA |
| 9308X | **triglycerides long chain with glucose polymer oral liquid, 18 x 250 mL cans** | 1@ | 55.56 | VF |
| 9309Y | **triglycerides long chain with glucose polymer oral liquid, 6 x 1000 mL bottles** | 1@ | 74.40 | VF |

# (APPLY WASTAGE FACTOR IN CALCULATING BROKEN QUANTITY PRICES)

| Code | Name, Form/Strength | Pack and Price | | Manufacturer |
|---|---|---|---|---|
| 3136C | **triglycerides medium chain and long chain with glucose polymer oral liquid: powder for, 400 g** | 1@ | 36.14 | SB |
| 9383W | **triglycerides medium chain formula oral liquid: powder for, 30 x 16 g sachets** | 1@ | 61.80 | VF |
| 1938B | **triglycerides medium chain formula oral liquid: powder for, 400 g** | 1@ | 54.55 | VF |
| 8478F | | 1@ | 51.86 | SB |
| 8629E | **triglycerides medium chain formula oral liquid: powder for, 420 g** | 1@ | 57.63 | SB |
| 3128P | **triglycerides medium chain oil: oral, 500 mL** | 1@ | 22.98 | SB |
| 9327X | **triglycerides medium chain oral liquid, 1 x 250 mL bottle** | 1@ | 26.00 | SB |
| 2666H | **trimethoprim 300 mg tablet, 7** | 7@ | 1.96 | AF |
| 2666H | **trimethoprim 300 mg tablet, 7** | 7@ | 3.85 | QA |
| 9165J | **tyrosine with carbohydrate containing 1 g tyrosine oral liquid: powder for, 30 x 4 g sachets** | 1@ | 127.40 | VF |
| 8448P | **ursodeoxycholic acid 250 mg capsule, 100** | 100@ | 183.09 | OA |
| 8133C | **valaciclovir 500 mg tablet, 10** | 10@ | 49.68 | AF, AS, CH, GM, GN, QA, SZ, TW, TX |
| 9434M | **valine with carbohydrate containing 1 g valine oral liquid: powder for, 30 x 4 g sachets** | 1@ | 140.14 | VF |
| 9135T | **valine with carbohydrate containing 50 mg valine oral liquid: powder for, 30 x 4 g sachets** | 1@ | 127.40 | VF |
| 2294R | **valproate sodium 100 mg tablet, 100** | 100@ | 12.79 | SW |
| 2293Q | **valproate sodium 200 mg/5 mL oral liquid, 300 mL** | 1@ | 14.25 | SW |
| 2295T | | 1@ | 14.25 | SW |
| 2289L | **valproate sodium 200 mg tablet: enteric, 100** | 100@ | 11.76 | AF, QA, SZ, WA |
| 2289L | **valproate sodium 200 mg tablet: enteric, 100** | 100@ | 12.75 | SW |
| 2290M | **valproate sodium 500 mg tablet: enteric, 100** | 100@ | 23.49 | SW |
| 2290M | **valproate sodium 500 mg tablet: enteric, 100** | 100@ | 22.49 | AF, QA, SZ, WA |
| 3113W | **vancomycin 125 mg capsule, 20** | 20@ | 112.92 | AS |
| 2270L | **vancomycin 1 g injection, 1 x 1 g vial** | 1@ | 5.06 | AF, HH, SZ, WQ |
| 3114X | **vancomycin 250 mg capsule, 20** | 20@ | 216.81 | AS |
| 3130R | **vancomycin 500 mg injection, 1 x 500 mg vial** | 1@ | 2.52 | AF, AS, HH, SZ, WQ |
| 3131T | | 1@ | 2.52 | AF, AS, HH, SZ, WQ |
| 3323X | | 1@ | 2.52 | AF, AS, HH, SZ, WQ |
| 9129L | **varenicline 1 mg tablet, 56** | 56@ | 112.64 | PF |
| 9009E | **vinorelbine 20 mg capsule, 1** | 1@ | 78.64 | FB |
| 9010F | **vinorelbine 30 mg capsule, 1** | 1@ | 117.55 | FB |
| 9328Y | **vitamins, minerals and trace elements with carbohydrate oral liquid: powder for, 200 g** | 1@ | 64.00 | SB |
| 9382T | **whey protein formula supplemented with amino acids, long chain polyunsaturated fatty acids, vitamins and minerals, low in protein, phosphate, potassium and lactose oral liquid: powder for, 10 x 100 g sachets** | 1@ | 164.35 | VF |
| 8587Y | **whey protein formula supplemented with amino acids, vitamins and minerals, and low in protein, phosphate, potassium and lactose oral liquid: powder for, 400 g** | 1@ | 66.22 | SB |
| 8266C | **zolmitriptan 2.5 mg tablet, 2** | 2@ | 11.09 | AP |
| 9736K | | 2@ | 11.09 | AP |
| 9390F | **zonisamide 100 mg capsule, 56** | 56@ | 43.52 | SA |

# Section 4

## Drug Tariff

## Container Prices

## Standard Formulae Preparations

## Table of Codes, Maximum Quantities, and Number of Repeats for Extemporaneously Prepared Pharmaceutical Benefits

# Drug Tariff

| Drug | Standard | Recovery Prices | | | |
|---|---|---|---|---|---|
| | | 0.1 g/mL | 1 g/mL | 10 g/mL | 100 g/mL |
| | | $ | $ | $ | $ |
| Acacia Mucilage (by weight) | APF 15 | 0.01 | 0.08 | 0.67 | 5.93 |
| Acacia, powdered | BP | 0.02 | 0.15 | 1.18 | 10.53 |
| Acetic Acid (6 per cent) | BP | 0.01 | 0.02 | 0.14 | 1.22 |
| Acetic Acid (33 per cent) | BP | 0.01 | 0.06 | 0.46 | 4.08 |
| Acetone (use as additive only) | BP | 0.01 | 0.10 | 0.80 | 7.08 |
| Alum | BP | 0.01 | 0.07 | 0.57 | 5.07 |
| Aluminium Acetate Solution | BP | 0.02 | 0.17 | 1.33 | 11.80 |
| Anise Water Concentrated 1 in 40 (use as additive only) | BP | 0.01 | 0.07 | 0.53 | 4.74 |
| Aqueous Cream (for use only as a base combined with active ingredients) | APF | 0.01 | 0.03 | 0.20 | 1.82 |
| Ascorbic Acid (for use only as an ingredient of ferrous sulfate mixtures) | BP | 0.14 | 1.11 | 8.87 | 78.88 |
| Aspirin | BP | 0.07 | 0.55 | 4.40 | 39.10 |
| Belladonna Tincture | BP | 0.09 | 0.68 | 5.43 | 48.30 |
| Benzocaine | BP | 0.07 | 0.55 | 4.40 | 39.15 |
| Benzoic Acid | BP | 0.04 | 0.35 | 2.79 | 24.83 |
| Benzoic Acid Compound Ointment | APF | 0.02 | 0.12 | 0.96 | 8.58 |
| Benzoic Acid Solution | BP | 0.01 | 0.10 | 0.84 | 7.45 |
| Benzoin Compound Tincture | BP | 0.03 | 0.25 | 1.96 | 17.40 |
| Boric Acid (use as additive only) | BP | 0.01 | 0.06 | 0.44 | 3.91 |
| Boric Acid, Olive Oil and Zinc Oxide Ointment | QHF | 0.01 | 0.08 | 0.67 | 6.00 |
| Calcium Hydroxide | BP | 0.09 | 0.74 | 5.91 | 52.50 |
| Calcium Hydroxide Solution | BP | 0.01 | 0.02 | 0.15 | 1.32 |
| Castor Oil (use as additive only) | BP | 0.01 | 0.10 | 0.83 | 7.36 |
| Cetomacrogol Aqueous Cream (for use only as a base combined with active ingredients) | APF | 0.01 | 0.03 | 0.24 | 2.14 |
| Cetrimide Aqueous Cream (for use only as a base combined with active ingredients) | APF | 0.02 | 0.13 | 1.04 | 9.22 |
| Chlorhexidine Acetate (use as additive only) | BP | 0.63 | 5.02 | 40.16 | 356.94 |
| Chlorhexidine Aqueous Cream (for use only as a base combined with active ingredients) | APF | 0.03 | 0.21 | 1.68 | 14.96 |
| Chloroform (use as additive only) | BP | 0.08 | 0.65 | 5.16 | 45.83 |

| Drug | Standard | Recovery Prices | | | |
|---|---|---|---|---|---|
| | | 0.1 g/mL | 1 g/mL | 10 g/mL | 100 g/mL |
| | | $ | $ | $ | $ |
| Chloroform Spirit | BP | 0.01 | 0.08 | 0.60 | 5.29 |
| Chloroform Water Concentrated 1 in 40 | APF 15 | 0.01 | 0.09 | 0.75 | 6.64 |
| Citric Acid Monohydrate | BP | 0.02 | 0.17 | 1.35 | 11.99 |
| Coal Tar | BP | 0.14 | 1.08 | 8.65 | 76.85 |
| Coal Tar Solution | BP | 0.02 | 0.13 | 1.07 | 9.47 |
| Cocaine Hydrochloride | BP | 6.09 | 48.74 | 389.90 | 3465.77 |
| Coconut Oil | BP | 0.01 | 0.10 | 0.80 | 7.16 |
| Codeine Linctus | APF | 0.01 | 0.07 | 0.58 | 5.15 |
| Codeine Phosphate (may only be prescribed in linctuses, mixtures or mixtures for children) | BP | 2.59 | 20.69 | 165.50 | 1471.11 |
| Collodion Flexible | BP | 0.17 | 1.36 | 10.88 | 96.67 |
| Dithranol | BP | 4.59 | 36.73 | 293.85 | 2611.99 |
| Emulsifying Ointment (for use only as a base combined with active ingredients) | BP | 0.01 | 0.09 | 0.69 | 6.13 |
| Ephedrine Hydrochloride (may only be prescribed in nasal instillations) | BP | 1.03 | 8.24 | 65.88 | 585.60 |
| Ethanol (90 per cent) (use as additive only) | BP | 0.01 | 0.03 | 0.24 | 2.17 |
| Ethanol (96 per cent) (use as additive only) | BP | 0.01 | 0.04 | 0.29 | 2.54 |
| Ether Solvent (use as additive only) | BP | 0.16 | 1.28 | 10.21 | 90.72 |
| Eucalyptus Oil (use as additive only) | BP | 0.02 | 0.14 | 1.09 | 9.65 |
| Ferrous Sulfate | BP | 0.13 | 1.02 | 8.16 | 72.50 |
| Formaldehyde Solution | BP | 0.11 | 0.88 | 7.03 | 62.53 |
| Gentian Alkaline Mixture | APF | 0.01 | 0.07 | 0.52 | 4.63 |
| Glycerol | BP | 0.01 | 0.07 | 0.52 | 4.65 |
| Honey Purified (use as additive only) | BP 1993 | 0.01 | 0.02 | 0.16 | 1.45 |
| Hydroxybenzoate Compound Solution | APF | 0.07 | 0.59 | 4.72 | 41.96 |
| Iodine | BP | 0.26 | 2.05 | 16.43 | 146.07 |
| Iodine Alcoholic Solution | BP | 0.02 | 0.14 | 1.12 | 9.96 |
| Iodine Aqueous Oral Solution | BP | 0.04 | 0.29 | 2.29 | 20.37 |
| Kaolin Mixture | BPC 1968 | 0.01 | 0.10 | 0.83 | 7.37 |
| Kaolin and Opium Mixture | APF 14 | 0.01 | 0.09 | 0.69 | 6.10 |
| Lactic Acid | BP | 0.06 | 0.45 | 3.63 | 32.30 |
| Lavender Spike Oil | BPC 1968 | 0.11 | 0.87 | 6.95 | 61.75 |
| Liquorice Liquid Extract | BP | 0.03 | 0.25 | 1.99 | 17.70 |
| Magnesium Carbonate Light | BP | 0.03 | 0.25 | 1.98 | 17.57 |

| Drug | Standard | Recovery Prices | | | |
|---|---|---|---|---|---|
| | | 0.1 g/mL | 1 g/mL | 10 g/mL | 100 g/mL |
| | | $ | $ | $ | $ |
| Magnesium Sulfate (may only be prescribed for other than oral use) | BP | 0.01 | 0.02 | 0.12 | 1.09 |
| Magnesium Trisilicate | BP | 0.04 | 0.32 | 2.56 | 22.79 |
| Menthol, Racemic or Levomenthol | BP | 0.26 | 2.05 | 16.40 | 145.79 |
| Methyl Hydroxybenzoate | BP | 0.34 | 2.71 | 21.70 | 192.89 |
| Methyl Hydroxybenzoate Solution | APF | 0.04 | 0.28 | 2.27 | 20.14 |
| Methylated Industrial Spirit (use as additive only) | BP | 0.01 | 0.03 | 0.25 | 2.22 |
| Olive Oil (use as additive only) | BP | 0.01 | 0.10 | 0.83 | 7.35 |
| Paraffin Hard | BP | 0.02 | 0.19 | 1.51 | 13.43 |
| Paraffin Liquid (may only be prescribed for other than oral use) | BP | 0.01 | 0.03 | 0.25 | 2.22 |
| Paraffin Light Liquid | BP | 0.02 | 0.17 | 1.33 | 11.81 |
| Paraffin Soft White | BP | 0.01 | 0.05 | 0.36 | 3.23 |
| Paraffin Soft Yellow | BP | 0.01 | 0.07 | 0.52 | 4.60 |
| Peppermint Oil (use as additive only) | BP | 0.14 | 1.14 | 9.14 | 81.21 |
| Peppermint Water Concentrated 1 in 40 (use as additive only) | APF 16 | 0.04 | 0.29 | 2.30 | 20.47 |
| Phenobarbitone Sodium (may only be prescribed for the treatment of epilepsy) | BP | 10.67 | 85.38 | 683.00 | 6071.11 |
| Phenol Liquefied (not available for ear drops) | BP | 0.19 | 1.51 | 12.06 | 107.19 |
| Podophyllum Resin | BP | 2.05 | 16.39 | 131.08 | 1165.16 |
| Potassium Citrate | BP | 0.02 | 0.14 | 1.10 | 9.78 |
| Potassium Iodide | BP | 0.07 | 0.57 | 4.56 | 40.57 |
| Potassium Permanganate | BP | 0.04 | 0.32 | 2.55 | 22.68 |
| Propyl Hydroxybenzoate | BP | 0.27 | 2.17 | 17.36 | 154.31 |
| Propylene Glycol | BP | 0.01 | 0.09 | 0.74 | 6.58 |
| Red Syrup | APF 15 | 0.02 | 0.13 | 1.07 | 9.50 |
| Resorcinol | BP | 0.36 | 2.84 | 22.68 | 201.60 |
| Salicylic Acid | BP | 0.03 | 0.24 | 1.90 | 16.85 |
| Salicylic Acid Ointment | APF | 0.02 | 0.13 | 1.01 | 9.00 |
| Salicylic Acid Ointment | BP | 0.02 | 0.13 | 1.01 | 9.00 |
| Simple Ointment (white) (for use only as a base combined with active ingredients) | BP | 0.02 | 0.15 | 1.16 | 10.33 |
| Simple Ointment (yellow) (for use only as a base combined with active ingredients) | BP | 0.02 | 0.15 | 1.16 | 10.33 |
| Sodium Bicarbonate | BP | 0.01 | 0.08 | 0.67 | 5.99 |
| Sodium Chloride | BP | 0.02 | 0.14 | 1.14 | 10.13 |
| Sodium Chloride Solution | BP | 0.01 | 0.01 | 0.08 | 0.72 |

| Drug | Standard | Recovery Prices | | | |
|---|---|---|---|---|---|
| | | 0.1 g/mL | 1 g/mL | 10 g/mL | 100 g/mL |
| | | $ | $ | $ | $ |
| Sodium Citrate | BP | 0.02 | 0.16 | 1.29 | 11.43 |
| Sodium Thiosulfate (use as additive only) | BP | 0.03 | 0.23 | 1.86 | 16.52 |
| Starch | BP | 0.02 | 0.15 | 1.22 | 10.81 |
| Sulfur Ointment (for use only as a base combined with active ingredients) | BP 1980 | 0.02 | 0.15 | 1.20 | 10.63 |
| Sulfur Precipitated | BP 1980 | 0.02 | 0.17 | 1.33 | 11.81 |
| Syrup | BP | 0.01 | 0.03 | 0.23 | 2.07 |
| Talc Purified, sterilised | BP | 0.03 | 0.21 | 1.65 | 14.65 |
| Thymol | BP | 0.25 | 1.96 | 15.66 | 139.20 |
| Thymol Compound Mouth Wash | APF 15 | 0.01 | 0.11 | 0.87 | 7.74 |
| Tragacanth Compound Powder | BP 1980 | 0.08 | 0.60 | 4.76 | 42.31 |
| Tragacanth Mucilage | APF 13 | 0.01 | 0.04 | 0.31 | 2.74 |
| Tragacanth Mucilage | BPC 1973 | 0.01 | 0.03 | 0.25 | 2.19 |
| Tragacanth, powdered | BP | 0.13 | 1.06 | 8.51 | 75.60 |
| Trichloroacetic Acid | BP 1980 | 0.36 | 2.88 | 23.02 | 204.61 |
| Triethanolamine | BP | 0.06 | 0.44 | 3.53 | 31.42 |
| Water For Injections, sterilised (b) (extemporaneously prepared eye drops and eye lotions) | BP | — | — | 11.37 | 11.37 |
| Water Purified | BP | 0.01 | 0.01 | 0.07 | 0.58 |
| Wool Alcohols Ointment (white) (for use only as a base combined with active ingredients) | BP | 0.02 | 0.13 | 1.04 | 9.22 |
| Wool Alcohols Ointment (yellow) (for use only as a base combined with active ingredients) | BP | 0.02 | 0.13 | 1.04 | 9.22 |
| Wool Fat | BP | 0.02 | 0.13 | 1.00 | 8.85 |
| Wool Fat Hydrous | BP | 0.02 | 0.13 | 1.05 | 9.36 |
| Zinc Compound Paste | BP | 0.03 | 0.24 | 1.94 | 17.27 |
| Zinc Cream (for use only as a base combined with active ingredients) | BP | 0.01 | 0.08 | 0.62 | 5.49 |
| Zinc Oxide | BP | 0.02 | 0.15 | 1.16 | 10.35 |
| Zinc and Salicylic Acid Paste | BP | 0.02 | 0.16 | 1.31 | 11.62 |
| Zinc Sulfate | BP | 0.03 | 0.23 | 1.87 | 16.65 |

# Container Prices

| **Container Prices** | |
|---|---|
| | $ |
| DISPENSING BOTTLES – | |
| 25mL | 0.61 |
| 50mL | 0.56 |
| 100mL | 0.75 |
| 200mL | 0.98 |
| 500mL | 1.34 |
| POISON BOTTLES – | |
| 25mL | 0.66 |
| 50mL | 0.74 |
| 100mL | 0.77 |
| 200mL | 1.03 |
| 500mL | 1.34 |
| SCREW CAP JARS – | |
| 25g | 0.83 |
| 50g | 0.90 |
| 100g | 1.04 |
| 200g | 0.89 |
| 500g | 1.29 |
| DROPPER CONTAINERS – | |
| 15mL polythene | 0.84 |
| 15mL glass | 0.86 |
| **Dispensing Fee for Extemporaneously Prepared Benefits** | **8.67** |
| **Additional Fee for Agreed Price** | **1.48** |
| **Extemporaneously Prepared Benefits** | |

# Standard Formula Preparations

The following list is not intended to indicate in any way which particular formula an approved pharmacist should use in filling a prescription.

The prices shown in the column 'Dispensed Price for Max. Qty' are for the ingredients, the container and the dispensing fee. The prices shown in the column 'Maximum Recordable Value for Safety Net' are for the ingredients, the container and the dispensing fee and, where applicable, the additional fee for agreed price benefits.

**KEY TO REFERENCES:**

| | |
|---|---|
| **APF** | **Australian Pharmaceutical Formulary** |
| **BP** | **British Pharmacopoeia** |
| **BPC** | **British Pharmaceutical Codex** |
| **QHF** | **Queensland Hospital Formulary** |

| Code | Item | Reference | Dispensed Price for Max. Qty | Maximum Recordable Value for Safety Net |
|---|---|---|---|---|
| | | | $ | $ |
| | **CREAMS (Maximum Quantity 100 g and 1 Repeat)** | | | |
| 7502W | Salicylic Acid and Sulfur Aqueous | APF | 12.27 | 13.75 |
| | **DUSTING POWDERS (Maximum Quantity 100 g and 1 Repeat)** | | | |
| 7458M | Zinc, Starch and Talc | APF 15 & BPC 1973 | 23.75 | 25.23 |
| | **EAR DROPS (Maximum Quantity 15 mL and 2 Repeats)** | | | |
| 7642F | Aluminium Acetate | APF | 10.77 | 12.25 |
| 7643G | Aluminium Acetate | BP | 11.50 | 12.98 |
| 7314Y | Sodium Bicarbonate | APF & BP | 9.93 | 11.41 |
| 7313X | Spirit | APF | 9.74 | 11.22 |
| | **INHALATIONS (Maximum Quantity 50 mL and 1 Repeat)** | | | |
| 7484X | Benzoin and Menthol | APF | 21.25 | 22.73 |
| 7308P | Menthol | APF | 12.68 | 14.16 |
| 7310R | Menthol and Eucalyptus | BP 1980 | 13.31 | 14.79 |
| | **LINCTUSES CONTAINING CODEINE PHOSPHATE (Maximum Quantity 100 mL and 0 Repeats)** | | | |
| 7530H | Codeine | APF | 14.57 | 16.05 |
| | **LOTIONS (Maximum Quantity 200 mL and 2 Repeats)** | | | |
| 7709R | Aluminium Acetate Aqueous | APF | 12.14 | 13.62 |
| | **MIXTURES, OTHER (Maximum Quantity 200 mL and 4 Repeats)** | | | |
| 7604F | Gentian Alkaline | APF | 18.92 | 20.40 |
| 7348R | Kaolin | BPC 1968 | 24.39 | 25.87 |
| 7301G | Kaolin and Opium | APF 14 | 21.84 | 23.32 |
| 7342K | Magnesium Trisilicate | BPC 1968 | 17.44 | 18.92 |
| 7343L | Magnesium Trisilicate and Belladonna | BPC 1968 | 22.74 | 24.22 |

| Code | Item | Reference | Dispensed Price for Max. Qty<br>$ | Maximum Recordable Value for Safety Net<br>$ |
|---|---|---|---|---|
| | **MOUTH WASHES**<br>**(Maximum Quantity 200 mL and 1 Repeat)** | | | |
| 7457L | Thymol Compound | APF 15 | 25.18 | 26.66 |
| | **OINTMENTS**<br>**(Maximum Quantity 100 g and 1 Repeat)** | | | |
| 7914M | Benzoic Acid Compound | APF | 18.29 | 19.77 |
| 7914M | Benzoic Acid Compound (extemporaneous formula) | BP | 18.29 | 19.77 |
| 7902X | Boric Acid, Olive Oil and Zinc Oxide | QHF | 15.71 | 17.19 |
| 7926E | Salicylic Acid | APF | 18.71 | 20.19 |
| 7928G | Salicylic Acid (extemporaneous formula) | BP | 18.71 | 20.19 |
| | **PAINTS**<br>**(Maximum Quantity 25 mL and 1 Repeat)** | | | |
| 7567G | Podophyllin Compound | APF 16 & BP | 75.66 | 36.10 |
| 7568H | Salicylic Acid | APF | 37.11 | 36.10 |
| | **PASTES, OTHER**<br>**(Maximum Quantity 100 g and 1 Repeat)** | | | |
| 7558T | Zinc | APF | 26.98 | 28.46 |
| 7558T | Zinc Compound (extemporaneous formula) | BP | 26.98 | 28.46 |
| | **POWDER FOR INTERNAL USE**<br>**(Maximum Quantity 100 g and 2 Repeats)** | | | |
| 7545D | Magnesium Trisilicate | BP | 32.35 | 33.83 |

—CONTAINER RATES ARE INCLUDED—

# Table of Codes, Maximum Quantities, and Number of Repeats for Extemporaneously Prepared Benefits

| Code | Preparation | Maximum Quantity | Number of Repeats |
|---|---|---|---|
| 13Q | Creams | 100 g | 1 |
| 48M | Dusting Powders | 100 g | 1 |
| 15T | Ear Drops | 15 mL | 2 |
| 19B | Eye Drops containing Cocaine Hydrochloride | 15 mL | .. |
| 22E | Eye Drops, Other | 15 mL | 5 |
| 23F | Eye Lotions | 200 mL | 2 |
| 29M | Inhalations | 50 mL | 1 |
| 64J | Linctuses containing Codeine Phosphate | 100 mL | .. |
| 34T | Linctuses, Other | 100 mL | 2 |
| 39C | Lotions | 200 mL | 2 |
| 65K | Mixtures containing Codeine Phosphate | 200 mL | .. |
| 40D | Mixtures, Other | 200 mL | 4 |
| 66L | Mixtures for Children containing Codeine Phosphate | 100 mL | .. |
| 41E | Mixtures for Children, Other | 100 mL | 4 |
| 30N | Mouth Washes | 200 mL | 1 |
| 42F | Nasal Instillations | 15 mL | 2 |
| 43G | Ointments, Waxes | 100 g | 1 |
| 44H | Paints | 25 mL | 1 |
| 63H | Pastes containing Cocaine Hydrochloride | 25 g | .. |
| 45J | Pastes, Other | 100 g | 1 |
| 49N | Powders for Internal Use | 100 g | 2 |
| 52R | Solutions | 200 mL | 2 |

Special Note: Purified Water BP is the minimum requirement for water in all PBS extemporaneous preparations.

Australian Government

Department of Health and Ageing

# REPATRIATION SCHEDULE OF PHARMACEUTICAL BENEFITS

**1 August 2013**

## The benefits listed in this Schedule may only be prescribed to Department of Veterans' Affairs beneficiaries holding a:

- Repatriation Health Card For All Conditions (gold); or
- Repatriation Health Card For Specific Conditions (white); or
- Repatriation Pharmaceutical Benefits Card (orange);

# BENEFICIARIES' ENTITLEMENT CARDS AND ELIGIBILITY FOR REPATRIATION PHARMACEUTICAL BENEFITS

| | |
|---|---|
| **Gold card**<br><br>This card is issued to those veterans of Australia's defence force, their widows/widowers and dependants entitled to treatment for all medical conditions. | |
| **White card**<br><br>A White Card is issued to Australian veterans or mariners under the Veterans' Entitlements Act 1986 with:<br>• an accepted war or service-caused injury or disease;<br>• malignant cancer (neoplasia) whether war-caused or not;<br>• pulmonary tuberculosis whether war-caused or not;<br>• post-traumatic stress disorder whether war-caused or not; or<br>• anxiety and/or depression whether war-caused or not. | |
| **Orange card**<br><br>Orange Repatriation pharmaceutical benefits cards are issued to Commonwealth and allied veterans and mariners who:<br>• have qualifying service from World War I or II and<br>• are aged 70 or over and<br>• have been resident in Australia for 10 years or more. | |

For more information go to the Department of Veterans' Affairs website:
http://www.dva.gov.au/service_providers/treatment_cards/Pages/index.aspx

# RPBS Explanatory Notes

## Introduction

### *The Australian Repatriation System*

- The Australian Repatriation system is based primarily on the principle of compensation to veterans and eligible dependants for injury or death related to war service. In certain cases, treatment is also provided for accepted injuries or conditions that are not service-related or have occurred as a result of other than war service.
- Through the *Veterans' Entitlements Act 1986* the Department of Veterans' Affairs provides programs of compensation, income support and treatment for eligible veterans and their dependants. One of the defined benefits for eligible veterans is the Repatriation Pharmaceutical Benefits Scheme. This range of medications and dressings is more comprehensive than is available through the Pharmaceutical Benefits Scheme.

## RPBS prescribing provisions

- Unless otherwise stated, Repatriation Pharmaceutical Benefits Scheme (RPBS) prescriptions must conform with the requirements of Pharmaceutical Benefits Scheme (PBS) prescriptions, as detailed in Section 1 – Explanatory Notes in the *Schedule of Pharmaceutical Benefits* book. The prescriber shall ensure that a prescription contains the following details:
    - the category of benefit, i.e., RPBS, by placing a cross in the relevant box;
    - the patient's full name and address;
    - the prescription date;
    - the DVA file number of the patient as evidence of entitlement;
    - in the case of authority prescriptions, the Authority approval number or the four digit streamlined authority code;
    - the item, form, strength, quantity and directions;
    - the number of repeats, if applicable;
    - indicate when brand substitution is not permitted; and
    - the name, signature, the prescriber number and address of the prescriber.

### *Prior Approval Arrangements*

- The prior approval of the Department is required to prescribe the following:
    - ‘Authority required’ items (excluding ‘Authority required (STREAMLINED)’ items) listed in either the PBS or RPBS Schedule;
    - increased quantities and/or repeats of items listed in either the PBS or RPBS Schedule;
    - items listed under section 100 of the *National Health Act 1953*; and
    - other items not listed in either Schedule (non-Schedule items).
- The above items are to be prescribed on the common PBS/RPBS authority prescription form in accordance with the directions stated in the Explanatory Notes in the *Schedule of Pharmaceutical Benefits* (See also information regarding dental prescribing and prescribing by optometrists under the RPBS in these Notes.)
- All Authority required prescriptions and requests for non-Schedule items must receive prior approval from the Department. This can be achieved by either:
    - using the Department's national free call number 1800 552 580; or
    - by mailing the written authority prescription to the Veterans' Affairs Pharmaceutical Advisory Centre (VAPAC) at the reply paid address shown at the end of these RPBS Explanatory Notes.

Prior approval is not required from DVA to prescribe an Authority required (STREAMLINED) item (except where increased quantities and/or repeats are required). Instead the authority prescription form must include a four digit streamlined authority code.

- Some requests for prior approval (including some non-Schedule items) need to be referred by VAPAC to the Repatriation Pharmaceutical Reference Committee for consideration. In such cases a VAPAC pharmacist will advise the prescriber to submit a request in writing that provides the following information:
    - A current clinical report on the patient's condition (such as age, co-morbidities, renal, liver failure) and clinical reports including pathology, biochemistry, diagnostic and other investigations if appropriate.
    - Details of past and current therapy for the condition. Include details of PBS, RPBS and non-Schedule items utilised, and the results of those therapies.
    - Details of the proposed treatment regimen. Include intended dose and duration of treatment and objective measures of response.

- When the proposed use of the item is outside the TGA-approved indications for use in Australia, provide copies of articles from peer reviewed publications supporting the proposed treatment.
- Signed, informed patient consent where the item is to be used for a non-TGA-approved indication.
- For items without Australian marketing approval, a copy of the TGA Special Access Scheme approval to prescribe the drug.

- Requests for prior approval to prescribe a non-Schedule (PBS or RPBS) item that is of the same therapeutic class (ATC level 3) as an item that is listed on the Schedule, will not be approved unless unequivocal clinical evidence is presented to demonstrate that the requested item is essential for effective treatment of the nominated patient.
- A pharmacist should not supply an item prescribed on an RPBS Authority Prescription Form unless the form has been approved and stamped by VAPAC, or has been endorsed by the prescriber with a telephone Authority approval number provided by VAPAC. The Department of Human Services will not accept RPBS Authority prescriptions that have not been approved by the Department of Veterans' Affairs for payment.

***Palliative Care Drugs***

- The following medications may be available, or made available in increased quantities or doses under prior approval arrangements for use only in the palliative care of terminal disease:
  - clonazepam
  - cyclizine
  - dexamethasone
  - disodium pamidronate
  - fentanyl
  - glycopyrrolate
  - hyoscine butylbromide
  - hyoscine hydrobromide
  - ketamine
  - midazolam
  - octreotide
- For further information telephone VAPAC on 1800 552 580.

***Dental Prescribing***

- Under Department of Veterans' Affairs arrangements, financial responsibility for pharmaceutical benefits prescribed by a Local Dental Officer (LDO) is limited to treatment to which holders of the following cards are entitled:
  - a Gold Repatriation Health Card – For All Conditions; or
  - a White Repatriation Health Card – For Specific Conditions; or
  - an Orange Repatriation Pharmaceutical Benefits Card.
- Where possible the LDO shall prescribe in accordance with the provisions governing dental prescribing under the Pharmaceutical Benefits Scheme (PBS).
- Prescriptions for PBS Dental Schedule items for Gold, White and Orange Card holders are to be dispensed at the PBS concessional rate. Claims for payment by the dispensing pharmacist are to be included with other Repatriation prescriptions. The card holder is required to meet the cost of any applicable brand premium.
- When a non-PBS Dental Schedule item is prescribed for an eligible card holder, the LDO's private prescription form should be used. The dispensing pharmacist may charge the patient the full cost of the prescription. The patient may claim a refund for the full cost of a non-Schedule item from the Department if an itemised receipt (not a cash register receipt) and a copy of the prescription are provided.

***Prescribing by optometrists***

- Optometrists approved as ‘PBS prescribers’ may write RPBS prescriptions as outlined in Section 1 for medicines listed in Section 2 of the PBS Schedule as pharmaceutical benefits for optometrical use.
- Medicines in the optometrist list include non-Authority and Authority required items. Procedures for obtaining VAPAC approval to prescribe ‘Authority required’ optometrist items or increased quantities and/or repeats of optometrist items under the RPBS are the same as indicated under prior approval arrangements above.

- The list of medicines for prescribing by optometrists under the RPBS is the same as applies under the PBS. There are no optometrist listings in the RPBS Schedule for prescribing for veterans only. There is no provision for optometrist prescribers to request approval to prescribe items that are not included in the PBS optometrist list (non-Schedule items).
- Optometrist PBS/RPBS prescription forms are for use for prescribing non-Authority or Authority required optometrist items under the RPBS with one item per form only.

## Provisions governing pricing and payment for RPBS benefits

### *Introduction*

- Unless otherwise stated, the pricing and payment principles and arrangements for approved pharmacists supplying pharmaceutical benefits under the RPBS will be the same as those arrangements applying under the PBS.
- Where a pharmaceutical benefit that is not listed on the PBS or RPBS Schedule is dispensed on an RPBS Authority prescription, a pharmacist will price the benefit and enter the serial number, prescription identifying number and price on the sticker or stamp imprint affixed to the prescription.

### *Pricing of Schedule Items*

- Items supplied under the RPBS from the PBS Schedule, both ready-prepared and extemporaneously-prepared, will be paid on the same basis as benefits supplied under the PBS. Items supplied under the RPBS from the Repatriation Schedule, including wound dressings, will be paid on the basis of the price as given in the Repatriation Pharmaceutical Benefits section (Section 1 – RPBS Schedule, Drugs, Medicines and Dressings) of the *Schedule of Pharmaceutical Benefits*.

### *Pricing of Non-Schedule Ready Prepared Items*

- Non-Schedule ready-prepared items are to be priced on the basis of the invoiced, GST-exclusive wholesale price to pharmacists plus the appropriate PBS mark-up and the PBS dispensing fee. Where the item price to pharmacists is greater than $100.00, a copy of the invoice pertaining to the supply of that item is to be submitted together with the appropriate copy of the authority prescription as part of the claim for payment.

### *Pricing of Non-Schedule Extemporaneously Prepared Items*

- When an ingredient drug is not listed in the PBS Drug Tariff, the recovery price will be based on the invoiced wholesale price to pharmacists, increased by a mark-up of 100%, calculated in accordance with the directions contained in the pricing instructions for pricing of PBS extemporaneously-prepared benefits in this Schedule. The price paid by the pharmacist for the commercial pack from which the ingredient is used shall be endorsed on the prescription form.

### *Miscellaneous Pricing Rules*

- The price to pharmacists used as the basis of pricing will be the invoiced, GST-exclusive price from the wholesaler.
- If multiple quantities of a manufacturer's original pack are supplied, the PBS mark-up is applied to the price to pharmacist of each pack and then totalled. The PBS dispensing fee, and the PBS dangerous drug fee if applicable, are then added to the total of the marked-up prices.
- When the quantity prescribed corresponds with the quantity of a manufacturer's original pack, in no circumstances will the price payable for one pack exceed that payable for multiples or combinations of packs to supply the quantity prescribed.
- The list of ingredient drugs and prices included in the PBS Drug Tariff are common to both the PBS and RPBS. Certain restrictions apply regarding the prescribing and dispensing of some of these ingredient drugs as pharmaceutical benefits, e.g., use as additive only.
- For items prescribed generically, including non-Schedule and wound dressings, the pharmacist should indicate on the prescription the quantity and brand supplied. If prescriptions are not endorsed, the Department will pay the lowest priced acceptable product available.

## General

### *Packaging Material, Postage or Freight*

- Payment to a pharmacist for the costs of packaging materials, postage or freight required to supply a pharmaceutical benefit is to be paid by the patient, who may then claim reimbursement from the Department through the provision of a pharmacists itemised receipt.

### *Payment for Items Supplied at Short Intervals*

- For all items dispensed at specific short intervals of time, the Department will pay a separate PBS dispensing fee for each occasion that the drug is supplied and which is acknowledged on receipt by the patient or agent.
- The price payable on the items supplied will be based on the individual dose quantity supplied. Where applicable, a PBS dangerous drug fee and a minimum container charge will be payable for each supply.

### *Receipts for Patient Charges*

- Where a charge is paid by a patient in any of the circumstances of paragraphs 13 or 24, the pharmacist is required to provide a printed receipt to the patient with the details of the items or services provided, the amount paid, date of supply and the patients name and address. The patient may apply for reimbursement from the Department.

### *Special Patient Contributions*

- The Special Patient Contribution for items listed as Special Pharmaceutical Benefits in the PBS Schedule is not payable by veterans entitled to pharmaceutical benefits under the RPBS. Eligible veterans receiving Special Pharmaceutical Benefits under the RPBS are required to pay only the concessional patient contribution and any applicable brand premium. If a Safety Net Entitlement card is held, the veteran should receive a Special Pharmaceutical Benefit free of charge, subject to any brand premium applicable. The Department of Human Services will reimburse the dispensing pharmacist the total dispensed price, less the concessional patient contribution and/or brand premium if applicable.

### *Therapeutic Group Premiums — Authority Processing*

- Items attracting a therapeutic group premium are dual listed. Dispensing pharmacists are therefore required to select the appropriate code for those items that are dual listed as authority and non-authority items, in order to correctly charge the patient and claim from the Department of Human Services. Those authority prescriptions that grant exemption from a therapeutic group premium will have the letters 'TPX' at the beginning of the telephone Authority approval number, or, in the case of a written approval, will be stamped with the words "This prescription does not attract a therapeutic group premium".

# DEPARTMENT OF VETERANS' AFFAIRS

**Authority Prescription Applications**

Applications for authority to prescribe under the Repatriation Pharmaceutical Benefits Scheme (RPBS) should be sent to the Veterans' Affairs Pharmaceutical Advisory Centre (VAPAC) using the free postal service:

REPLY PAID 9998
VAPAC (Veterans' Affairs Pharmaceutical Advisory Centre)
Department of Veterans' Affairs
GPO Box 9998
BRISBANE QLD 4001

**For RPBS enquiries and telephone approvals 24 hours a day the Freecall number is:**

**1800 552 580**

**Departmental pharmacists answer applications for prior approval for non-Schedule items and Authority application calls.**

# SUMMARY OF CHANGES

There is NO changes in Repatriation Schedule of Pharmaceutical Benefits for this month.

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# Section 1

## Drugs, Medicines and Dressings

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|---|

# ALIMENTARY TRACT AND METABOLISM

## STOMATOLOGICAL PREPARATIONS

### STOMATOLOGICAL PREPARATIONS

#### *Antiinfectives and antiseptics for local oral treatment*

**CHLORHEXIDINE**

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 4161B | chlorhexidine gluconate 0.2% (2 mg/mL) mouthwash, 250 mL | ‡1 | .. | .. | 12.10 | 5.90 | | Plaqacide | OB |
| 4204G | chlorhexidine gluconate 0.2% (2 mg/mL) mouthwash, 300 mL | ‡1 | .. | .. | 15.49 | 5.90 | | Savacol Mouth and Throat Rinse | OM |

#### *Other agents for local oral treatment*

**CARMELLOSE SODIUM**

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 4569L | carmellose sodium 10 mg/mL oral spray, 100 mL | ‡1 | .. | .. | 13.36 | 5.90 | | Aquae | VT |
| 4568K | carmellose sodium 10 mg/mL oral spray, 25 mL | ‡1 | 1 | .. | 11.51 | 5.90 | | Aquae | VT |

## DRUGS FOR ACID RELATED DISORDERS

### ANTACIDS

#### *Calcium compounds*

**CALCIUM CARBONATE + GLYCINE**

**Note**

For patients with chronic renal failure.

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 4055K | calcium carbonate 420 mg + glycine 180 mg tablet: chewable, 100 | 2 | 5 | .. | *23.39 | 5.90 | | Titralac | MM |

#### *Combinations and complexes of aluminium, calcium and magnesium compounds*

**ALUMINIUM HYDROXIDE WITH MAGNESIUM HYDROXIDE AND SIMETHICONE**

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 4118R | ALUMINIUM HYDROXIDE with MAGNESIUM HYDROXIDE and SIMETHICONE Oral suspension 400 mg-400 mg-30 mg per 5 mL, 500 mL, 1 | 2 | 5 | .. | *22.85 | 5.90 | | Mylanta Double Strength | JT |
| 4453J | ALUMINIUM HYDROXIDE with MAGNESIUM HYDROXIDE and SIMETHICONE Tablet 400 mg-400 mg-40 mg, 100 | 2 | 5 | .. | *46.33 | 5.90 | | Mylanta Double Strength | JT |

## DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS

### DRUGS FOR FUNCTIONAL BOWEL DISORDERS

#### *Synthetic anticholinergics, esters with tertiary amino group*

**MEBEVERINE**

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 4328T | mebeverine hydrochloride 135 mg tablet, 90 | 1 | .. | .. | 27.12 | 5.90 | [a] | Colese | AF |
| | | | | .. | 32.30 | 5.90 | [a] | Colofac | AB |

### BELLADONNA AND DERIVATIVES, PLAIN

#### *Belladonna alkaloids, semisynthetic, quaternary ammonium compounds*

**HYOSCINE BUTYLBROMIDE**

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 4279F | hyoscine butylbromide 20 mg/mL injection, 5 x 1 mL ampoules | 1 | .. | .. | 24.42 | 5.90 | | Buscopan | BY |

## LAXATIVES

### LAXATIVES

#### *Softeners, emollients*

**DOCUSATE**

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 4200C | docusate sodium 50 mg tablet, 100 | 1 | 2 | .. | 14.52 | 5.90 | | Coloxyl 50 | FM |

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|---|
| | ***Contact laxatives*** | | | | | | | | |
| | **DOCUSATE + SENNOSIDE B** | | | | | | | | |
| 4028B | docusate sodium 50 mg + sennoside B 8 mg tablet, 100 | 1 | 2 | .. | 14.62 | 5.90 | | Soflax | GM |
| | **DOCUSATE + SENNOSIDES** | | | | | | | | |
| 4198Y | docusate sodium 50 mg + sennosides 11.27 mg tablet, 90 | 1 | 2 | .. | 13.39 | 5.90 | a | Co-Senna | PP |
| | | | | .. | 16.90 | 5.90 | a | Coloxyl with Senna | FM |
| | **SENNOSIDE B** | | | | | | | | |
| 4455L | sennoside B 7.5 mg tablet, 100 | 1 | 1 | .. | 12.81 | 5.90 | a | Senna-Gen | PP |
| | | | | .. | 14.07 | 5.90 | a | Senokot | RC |
| | ***Bulk producers*** | | | | | | | | |
| | **ISPAGHULA HUSK DRY** | | | | | | | | |
| 4285M | ispaghula husk dry 3.5 g oral liquid: powder for, 30 x 3.5 g sachets | ‡1 | 1 | .. | 17.85 | 5.90 | | Fybogel | RC |
| | **PSYLLIUM HUSK POWDER** | | | | | | | | |
| 4422R | PSYLLIUM HYDROPHILIC MUCILLOID Oral powder (non-flavoured) 336 g, 1 | ‡1 | 1 | .. | 21.88 | 5.90 | | Fibre Health Natural Granular | PP |
| | | | | | | | | Metamucil Natural Granular | PY |
| 4419N | PSYLLIUM HYDROPHILIC MUCILLOID Oral powder (orange-flavoured, sugar-free) 283 g, 1 | ‡1 | 1 | .. | 21.88 | 5.90 | | Metamucil Orange Smooth | PY |
| | **PSYLLIUM HUSK POWDER + STARCH-MAIZE HIGH AMYLOSE** | | | | | | | | |
| 4416K | psyllium husk powder 375 mg/g + starch-maize high amylose 375 mg/g oral liquid: powder for, 440 g | ‡1 | 1 | .. | 21.48 | 5.90 | | Nucolox | QA |
| | **RHAMNUS FRANGULA + STERCULIA** | | | | | | | | |
| 4558X | rhamnus frangula 80 mg/g + sterculia 620 mg/g granules, 500 g | ‡1 | 1 | .. | 26.58 | 5.90 | | Normacol Plus | NE |
| | ***Enemas*** | | | | | | | | |
| | **SORBITOL + CITRATE + LAURYL SULFOACETATE SODIUM** | | | | | | | | |
| 4462W | sorbitol 3.125 g/5 mL + citrate sodium dihydrate 450 mg/5 mL + lauryl sulfoacetate sodium 45 mg/5 mL enema, 4 x 5 mL | ‡1 | .. | .. | 12.31 | 5.90 | | Micolette | AE |
| | | | | | | | | Microlax | JT |
| | ***Other laxatives*** | | | | | | | | |
| | **GLYCEROL** | | | | | | | | |
| | **Restricted benefit** | | | | | | | | |
| | Short-term use when oral laxative therapy has failed or is inappropriate | | | | | | | | |
| 4246L | glycerol 2.8 g suppository, 12 | 3 | .. | .. | *20.61 | 5.90 | | Petrus Pharmaceuticals Pty Ltd | PP |

## ANTIOBESITY PREPARATIONS, EXCL. DIET PRODUCTS

## ANTIOBESITY PREPARATIONS, EXCL. DIET PRODUCTS

### *Peripherally acting antiobesity products*

**ORLISTAT**

**Authority required**

For the treatment of obese patients.

Total treatment will not exceed 12 months from initial application.

Patients are eligible for 1 continuous treatment in a lifetime.

The patient must be receiving, or enrolled to receive, professional dietetic and weight management advice (where this is available).

Initial treatment for patients who meet the following criteria to qualify:

(a) Body Mass Index (BMI) greater than or equal to 35 with no known co-morbidities; or

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|
| | (b) BMI greater than or equal to 30 with 1 or more of the following co-morbidities:<br>(i) diabetes;<br>(ii) ischaemic heart disease;<br>(iii) psychiatric conditions;<br>(iv) hypertension.<br>The prescriber must provide the following:<br>(a) initial body weight; and<br>(b) BMI.<br>Continuing treatment for patients who have previously been issued with an authority prescription for orlistat. After 3 months and up to 6 months following commencement of orlistat treatment, patient's initial body weight must have been reduced by 2.5 kg or 2.5% (whichever is the lesser).<br>Continuing treatment for patients who have previously been issued with an authority prescription for orlistat. After 6 months and up to 12 months following commencement of orlistat treatment, patient's initial body weight must have been reduced by 5 kg or 5% (whichever is the lesser)<br>**Note**<br>The patient should be ideally enrolled in an exercise program and be receiving supplemental vitamins. | | | | | | | |
| 4570M | orlistat 120 mg capsule, 84 | 1 | 2 | .. | 140.37 | 5.90 | Xenical | RO |

## VITAMINS

### VITAMIN B1, PLAIN AND IN COMBINATION WITH VITAMIN B6 AND B12

#### *Vitamin B1, plain*

**THIAMINE**

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 4043T | thiamine hydrochloride 100 mg tablet, 100 | 1 | 2 | .. | 10.32 | 5.90 | Betavit | PP |

### VITAMIN B-COMPLEX, INCL. COMBINATIONS

#### *Vitamin B-complex, plain*

**CYANOCOBALAMIN + FERRIC PYROPHOSPHATE + LYSINE + PYRIDOXINE + THIAMINE**

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 4493L | iron (as ferric pyrophosphate) 10 mg/10 mL + thiamine hydrochloride 10 mg/10 mL + pyridoxine hydrochloride 5 mg/10 mL + cyanocobalamin 25 microgram/10 mL + lysine hydrochloride 300 mg/10 mL oral liquid, 200 mL | ‡1 | 2 | .. | 13.55 | 5.90 | Accomin Adult Tonic | PF |

## MINERAL SUPPLEMENTS

### CALCIUM

#### *Calcium*

**CALCIUM**
**Restricted benefit**
Hyperphosphataemia in chronic renal failure

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 4094L | CALCIUM Tablet (chewable) 500 mg (as carbonate), 60 | 4 | 1 | .. | *33.43 | 5.90 | Cal-Sup | IA |
| 4142B | CALCIUM Tablet 600 mg (as carbonate), 120 | 2 | 1 | .. | *22.41 | 5.90 | CAL-600 | PP |

**CALCIUM**
**Restricted benefit**
Hypocalcaemia

**Restricted benefit**
Osteoporosis

**Restricted benefit**
Proven calcium malabsorption

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 4333C | CALCIUM Tablet (chewable) 500 mg (as carbonate), 60 | 2 | 1 | .. | *20.03 | 5.90 | Cal-Sup | IA |
| 4082W | CALCIUM Tablet 600 mg (as carbonate), 120 | 1 | 1 | .. | 14.52 | 5.90 | CAL-600 | PP |

### OTHER MINERAL SUPPLEMENTS

#### *Magnesium*

# ALIMENTARY TRACT AND METABOLISM

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|
| | **MAGNESIUM ASPARTATE DIHYDRATE**<br>**Restricted benefit**<br>Patients with documented hypomagnesaemia | | | | | | | |
| 4321K | magnesium aspartate dihydrate 500 mg (equivalent to 37.4 mg of magnesium) tablet, 50 | 1 | .. | .. | 13.91 | 5.90 | Mag-Sup | PP |
| | | | | .. | 14.60 | 5.90 | Magmin | BB |

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|---|

# BLOOD AND BLOOD FORMING ORGANS

## ANTITHROMBOTIC AGENTS

### ANTITHROMBOTIC AGENTS

#### *Platelet aggregation inhibitors excl. heparin*

**ASPIRIN**

**Note**

The enteric coated preparations are for patients with a significant risk of gastrointestinal bleeding.

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 4078P | aspirin 100 mg capsule: modified release, 84 capsules | 1 | 1 | .. | 14.83 | 5.90 | | Astrix | YN |
| 4077N | aspirin 100 mg tablet: enteric, 84 | 1 | 1 | .. | 13.92 | 5.90 | | Cartia | AS |

**ASPIRIN**

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 4076M | aspirin 100 mg tablet, 90 | 1 | 1 | .. | 15.88 | 5.90 | | Cardiprin 100 | RC |

**CLOPIDOGREL**

**Authority required**

For use in patients pre- and post-angioplasty

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 4179Y | clopidogrel 75 mg tablet, 28 | 1 | 3 | .. | 31.94 | 5.90 | [a] | APO-Clopidogrel | TX |
| | | | | | | | [a] | Chem mart Clopidogrel | CH |
| | | | | | | | [a] | Iscover | AV |
| | | | | | | | [a] | Plavix | SW |
| | | | | | | | [a] | Terry White Chemists Clopidogrel | TW |

## BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS

### IRRIGATING SOLUTIONS

#### *Salt solutions*

**SODIUM CHLORIDE**

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 4460R | sodium chloride 0.9% (4.5 g/500 mL) solution, 1 x 500 mL bottle | ‡1 | 2 | .. | 10.54 | 5.90 | | Baxter Healthcare Pty Ltd | BX |
| 4461T | sodium chloride 0.9% (9 g/1000 mL) solution, 1 x 1000 mL bottle | ‡1 | 2 | .. | 10.86 | 5.90 | | Baxter Healthcare Pty Ltd | BX |

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|

# CARDIOVASCULAR SYSTEM

## VASOPROTECTIVES

### AGENTS FOR TREATMENT OF HEMORRHOIDS AND ANAL FISSURES FOR TOPICAL USE

***Other agents for treatment of hemorrhoids and anal fissures for topical use***

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | **ZINC OXIDE + PERU BALSAM + BENZYL BENZOATE** | | | | | | | |
| 4039N | zinc oxide 10.75% (107.5 mg/g) + peru balsam 1.88% (18.8 mg/g) + benzyl benzoate 1.25% (12.5 mg/g) ointment, 50 g | ‡1 | 1 | .. | 14.65 | 5.90 | Anusol | JT |
| 4040P | zinc oxide 300 mg + peru balsam 50 mg + benzyl benzoate 33 mg suppository, 12 | ‡1 | 1 | .. | 13.56 | 5.90 | Anusol | JT |

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|

# DERMATOLOGICALS

## ANTIFUNGALS FOR DERMATOLOGICAL USE

### ANTIFUNGALS FOR TOPICAL USE

#### *Antibiotics*

**NYSTATIN**

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 4001N | nystatin 100 000 international units/g cream, 15 g | ‡1 | 1 | .. | 12.70 | 5.90 | Mycostatin | FM |

#### *Imidazole and triazole derivatives*

**CLOTRIMAZOLE**

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 4004R | clotrimazole 1% (10 mg/g) cream, 20 g | ‡1 | 1 | .. | 9.05 | 5.90 | Clonea | AF |

**KETOCONAZOLE**

**Restricted benefit**

Severe seborrhoeic dermatitis

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 4007X | ketoconazole 2% (20 mg/g) application, 100 mL | ‡1 | .. | .. | 19.58 | 5.90 | Sebizole | GM |
| 4008Y | ketoconazole 2% (20 mg/g) application, 60 mL | ‡1 | .. | .. | 18.52 | 5.90 | Nizoral 2% | JT |

**MICONAZOLE**

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 4341L | miconazole 2% (20 mg/mL) lotion, 30 mL | ‡1 | 1 | .. | 19.68 | 5.90 | Daktarin | JT |
| 4454K | miconazole nitrate 2% (20 mg/g) cream, 30 g | ‡1 | 1 | .. | 15.00 | 5.90 | Daktarin | JT |
| 3400Y | miconazole nitrate 2% (20 mg/g) cream, 40 g | ‡1 | 1 | .. | 13.89 | 5.90 | Resolve Thrush | EO |

#### *Other antifungals for topical use*

**AMOROLFINE**

**Restricted benefit**

Onychomycosis

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 4010C | amorolfine 5% (50 mg/mL) application, 5 mL | ‡1 | 1 | .. | 96.35 | 5.90 | Loceryl | GA |

**CICLOPIROX**

**Restricted benefit**

Severe seborrhoeic dermatitis

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 4106D | ciclopirox olamine 1.5% (15 mg/g) solution, 60 mL | ‡1 | .. | .. | 18.95 | 5.90 | Stieprox Liquid | GK |

**TERBINAFINE**

**Restricted benefit**

Tinea pedis

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 4463X | terbinafine 1% gel, 15 g | ‡1 | .. | .. | 23.56 | 5.90 | Lamisil DermGel | NC |
| 4473K | terbinafine hydrochloride 1% (10 mg/g) cream, 15 g | ‡1 | 1 | .. | 22.10 | 5.90 | Lamisil | NC |

**TOLNAFTATE**

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 4481W | tolnaftate 0.07% (700 microgram/g) spray, 100 g | ‡1 | .. | .. | 15.30 | 5.90 | Tinaderm | MK |

### ANTIFUNGALS FOR SYSTEMIC USE

#### *Antifungals for systemic use*

**TERBINAFINE**

**Authority required**

Onychomycosis due to dermatophyte infection proven by microscopy or culture and confirmed by an approved pathology provider

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 4011D | terbinafine 250 mg tablet, 42 | 1 | 1 | .. | 53.50 | 5.90 | [a] | GenRx Terbinafine | GX |
| | | | | | | | [a] | Lamisil (Novartis Pharmaceuticals Australia Pty Limited) | NV |
| | | | | | | | [a] | Tamsil | QA |

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|
| | | | | | | | [a] Terbinafine-DP | GN |
| | | | | | | | [a] Terbinafine Sandoz | SZ |
| | | | | | | | [a] Tinasil | AF |

## EMOLLIENTS AND PROTECTIVES

### EMOLLIENTS AND PROTECTIVES

#### *Silicone products*

**DIMETHICONE-350 + GLYCEROL**

**Restricted benefit**
For colostomy and ileostomy use

**Restricted benefit**
For use by paraplegic and quadriplegic patients

**Restricted benefit**
For use with surgical appliances

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 4551M | dimethicone-350 15% (150 mg/g) + glycerol 2% (20 mg/g) cream, 500 g | ǂ1 | .. | .. | 26.62 | 5.90 | Silic 15 | EO |
| 4556T | dimethicone-350 15% (150 mg/g) + glycerol 2% (20 mg/g) cream, 75 g | ǂ1 | .. | .. | 12.74 | 5.90 | Silic 15 | EO |

#### *Soft paraffin and fat products*

**WOOL ALCOHOLS**

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 4041Q | wool alcohols 6% (60 mg/g) ointment, 100 g | ǂ1 | 1 | .. | 14.39 | 5.90 | Eucerin | BE |

#### *Carbamide products*

**UREA**

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 4042R | urea 10% (100 mg/g) cream, 100 g | ǂ1 | 2 | .. | 12.40 | 5.90 | Aquacare H.P. | AG |
| | | | | .. | 12.66 | 5.90 | Urederm | VT |
| | | | | .. | 12.98 | 5.90 | Calmurid | OL |

#### *Other emollients and protectives*

**CARMELLOSE SODIUM + GELATIN + PECTIN**

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 4518T | carmellose sodium 16.7% + gelatin 16.7% + pectin 16.7% paste: oromucosal, 5 g | ǂ1 | .. | .. | 12.06 | 5.90 | Orabase | QA |

**SKIN EMOLLIENT**

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 4122Y | SKIN EMOLLIENT Bath oil 500 mL, 1 | ǂ1 | 2 | .. | 17.56 | 5.90 | Alpha Keri Bath Oil | MT |
| | | | | .. | 19.97 | 5.90 | QV Bath Oil | EO |
| | | | | .. | 20.06 | 5.90 | Hamilton Skin Therapy Oil | VT |
| 4107E | SKIN EMOLLIENT Lotion 500 mL, 1 | ǂ1 | 2 | .. | 17.56 | 5.90 | Alpha Keri Lotion | MT |

### PROTECTIVES AGAINST UV-RADIATION

#### *Protectives against UV-radiation for topical use*

**SUNSCREENS**

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 4544E | SUNSCREENS Cream 100 g, 1 | ǂ1 | 2 | .. | 16.28 | 5.90 | Hamilton Sunscreen Family Sunscreen Cream SPF 15 | VT |
| 4307Q | SUNSCREENS Cream 75 g, 1 | ǂ1 | 2 | .. | 17.24 | 5.90 | Sunsense Sensitive SPF 30+ | EO |
| 4546G | SUNSCREENS Lotion (non-alcoholic) 125 mL, 1 | ǂ1 | 2 | .. | 16.19 | 5.90 | Aquasun Lotion SPF 18 | PF |
| | | | | .. | 16.28 | 5.90 | Hamilton Sunscreen Family Sunscreen Milk SPF 15 | VT |
| | | | | .. | 17.20 | 5.90 | SunSense Ultra SPF 30+ | EO |
| 4543D | SUNSCREENS Solid stick 4.5 g, 1 | ǂ1 | 2 | .. | 12.51 | 5.90 | Hamilton Solastick 30+ | VT |

## ANTIPRURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC.

### ANTIPRURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC.

#### *Anesthetics for topical use*

**LIGNOCAINE**

# DERMATOLOGICALS

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|
| 4308R | lignocaine hydrochloride anhydrous 2% (20 mg/mL) oral liquid, 200 mL | ‡1 | .. | .. | 89.76 | 5.90 | Xylocaine Viscous | AP |

### *Other antipruritics*

**PINE TAR WITH TRIETHANOLAMINE LAURYL SULFATE**
**Note**
For patients who have failed to respond to simple moisturising agents.

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 4408B | PINE TAR with TRIETHANOLAMINE LAURYL SULFATE Solution 23 mg-60 mg per mL (2.3%-6%), 500 mL, 1 | ‡1 | 2 | .. | 23.13 | 5.90 | Pinetarsol | EO |

## ANTIPSORIATICS

### ANTIPSORIATICS FOR TOPICAL USE

### *Tars*

**COAL TAR SOLUTION + PHENOL + SULFUR-PRECIPITATED**

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 4505D | coal tar solution 5% + phenol 0.5% + sulfur-precipitated 0.5% gel, 30 g | ‡1 | 2 | .. | 16.23 | 5.90 | Egopsoryl-TA | EO |

## ANTIBIOTICS AND CHEMOTHERAPEUTICS FOR DERMATOLOGICAL USE

### ANTIBIOTICS FOR TOPICAL USE

### *Other antibiotics for topical use*

**MUPIROCIN**
**Restricted benefit**
For the topical treatment of secondarily infected traumatic skin lesions

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 4348W | mupirocin 2% (20 mg/g) cream, 15 g | ‡1 | .. | .. | 17.46 | 5.90 | Bactroban | GK |
| 4350Y | mupirocin 2% (20 mg/g) ointment, 15 g | ‡1 | .. | .. | 17.46 | 5.90 | Bactroban | GK |

### CHEMOTHERAPEUTICS FOR TOPICAL USE

### *Antivirals*

**PODOPHYLLOTOXIN**
**Authority required**
For the treatment of ano-genital warts

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 4390C | podophyllotoxin 0.15% (1.5 mg/g) cream, 5 g | ‡1 | .. | .. | 52.87 | 5.90 | Wartec Cream | GK |
| 4566H | podophyllotoxin 0.5% solution, 3.5 mL | ‡1 | .. | .. | 39.96 | 5.90 | Condyline Paint | NQ |

### *Other chemotherapeutics*

**INGENOL MEBUTATE**
**Authority required**
Solar keratosis

**The Clinical criteria is:**

Patient must require topical drug therapy on the face and scalp as field treatment for clinically visible and subclinical lesions where other standard treatments are inappropriate.

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 2464Q | ingenol mebutate 0.015% gel, 3 x 470 mg tubes | 1 | .. | .. | 139.47 | 5.90 | Picato | LO |

**INGENOL MEBUTATE**
**Authority required**
Solar (actinic) keratosis

**The Clinical criteria is:**

Patient must require topical drug therapy as field treatment for clinically visible and subclinical lesions where other standard treatments are inappropriate.

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 2468X | ingenol mebutate 0.05% gel, 2 x 470 mg tubes | 1 | .. | .. | 139.47 | 5.90 | Picato | LO |

## CORTICOSTEROIDS, DERMATOLOGICAL PREPARATIONS

### CORTICOSTEROIDS, PLAIN

### *Corticosteroids, potent (group III)*

# DERMATOLOGICALS

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|
| | **BETAMETHASONE VALERATE** | | | | | | | |
| 4131K | betamethasone (as valerate) 0.1% (1 mg/g) cream, 30 g | ‡1 | 2 | .. | 22.64 | 5.90 | Betnovate | QA |
| 4132L | betamethasone (as valerate) 0.1% (1 mg/g) ointment, 30 g | ‡1 | 2 | .. | 22.64 | 5.90 | Betnovate | QA |
| | **MOMETASONE** | | | | | | | |
| | **Note** | | | | | | | |
| | Application to large areas of skin for longer than four weeks is not recommended. | | | | | | | |
| 4342M | mometasone furoate 0.1% (1 mg/g) cream, 50 g | ‡1 | .. | .. | 33.69 | 5.90 | Elocon | MK |
| 4343N | mometasone furoate 0.1% (1 mg/g) ointment, 50 g | ‡1 | .. | .. | 33.69 | 5.90 | Elocon | MK |

## CORTICOSTEROIDS, COMBINATIONS WITH ANTIBIOTICS

### *Corticosteroids, moderately potent, combinations with antibiotics*

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | **TRIAMCINOLONE + NEOMYCIN SULFATE + GRAMICIDIN + NYSTATIN** | | | | | | | |
| | **Caution** | | | | | | | |
| | For the short-term treatment of localised infective eczema only. | | | | | | | |
| 4482X | triamcinolone acetonide 0.1% (1 mg/g) + neomycin sulfate 0.25% (2.5 mg/g) + gramicidin 0.025% (250 microgram/g) + nystatin 100 000 international units/g ointment, 15 g | ‡1 | .. | .. | 19.30 | 5.90 | Kenacomb | QA |

## ANTISEPTICS AND DISINFECTANTS

## ANTISEPTICS AND DISINFECTANTS

### *Iodine products*

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | **POVIDONE-IODINE** | | | | | | | |
| 4411E | povidone-iodine 10% (100 mg/mL) paint, 100 mL | ‡1 | .. | .. | 22.32 | 5.90 | Betadine Antiseptic Liquid | SW |

## OTHER DERMATOLOGICAL PREPARATIONS

## OTHER DERMATOLOGICAL PREPARATIONS

### *Antihidrotics*

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | **DIPHEMANIL** | | | | | | | |
| 4191N | diphemanil methylsulfate 2% (20 mg/g) powder: dusting, 50 g | ‡1 | 1 | .. | 17.95 | 5.90 | Prantal | MK |

### *Medicated shampoos*

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | **COAL TAR SOLUTION + TAR + SALICYLIC ACID** | | | | | | | |
| 4447C | coal tar solution 1% (10 mg/g) + tar 1% (10 mg/g) + salicylic acid 2% (20 mg/g) solution, 250 mL | ‡1 | 2 | .. | 19.05 | 5.90 | Sebitar | EO |
| | **SALICYLIC ACID + BENZALKONIUM CHLORIDE + ALCOHOL + COAL TAR SOLUTION + POLYOXYETHYLENE ETHERS** | | | | | | | |
| 4560B | SALICYLIC ACID with COAL TAR SOLUTION Scalp cleanser 20 mg-50 mg per mL (2%-5%), 200 mL, 1 | ‡1 | 2 | .. | 20.59 | 5.90 | Ionil-T | GA |
| | **SELENIUM SULFIDE** | | | | | | | |
| 4452H | selenium sulfide 2.5% (25 mg/mL) application, 125 mL | ‡1 | .. | .. | 14.35 | 5.90 | Selsun | DQ |
| | **TAR + CADE OIL + COAL TAR + ARACHIS OIL EXTRACT OF COAL TAR** | | | | | | | |
| 4405W | tar 0.3% (300 microgram/mL) + cade oil 0.03% (300 microgram/mL) + coal tar 0.01% (100 microgram/mL) + arachis oil extract of coal tar 0.3% (3 mg/mL) lotion, 300 mL | ‡1 | 2 | .. | 24.35 | 5.90 | Polytar | GK |

### *Wart and anti-corn preparations*

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | **LACTIC ACID + SALICYLIC ACID** | | | | | | | |

# DERMATOLOGICALS

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|---|
| 4386W | lactic acid 16.7% (167 mg/mL) + salicylic acid 16.7% (167 mg/mL) application, 15 mL | ‡1 | .. | .. | 18.36 | 5.90 | | Duofilm Solution | GK |
| | **SALICYLIC ACID** | | | | | | | | |
| 4389B | salicylic acid 27% gel, 15 g | ‡1 | .. | .. | 19.75 | 5.90 | | Duofilm Gel | GK |

## *Other dermatologicals*

**DICLOFENAC**

**Authority required**

For the management of actinic keratoses in patients where other standard treatments are inappropriate, and topical drug therapy is required as field treatment for clinically visible and subclinical lesions

**Note**

Maximum quantity of four tubes (original + 3 repeats) in 12 months.

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 4046Y | diclofenac sodium 3% (30 mg/g) gel, 25 g | ‡1 | 3 | .. | 58.40 | 5.90 | | Solaraze 3% Gel | CS |

**ICHTHAMMOL**

**Note**

For patients who have failed to respond to simple moisturising agents.

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 4281H | ichthammol Cream 5 mg-10 mg-10 mg per g (0.5%-1%-1%), 50 g, 1 | ‡1 | 2 | .. | 18.31 | 5.90 | | Egoderm Cream | EO |

**ICHTHAMMOL + ZINC OXIDE**

**Note**

For patients who have failed to respond to simple moisturising agents.

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 4280G | ichthammol 1% (10 mg/g) + zinc oxide 15% (150 mg/g) ointment, 50 g | ‡1 | 2 | .. | 18.31 | 5.90 | | Egoderm Ointment | EO |

**IMIQUIMOD**

**Authority required**

Treatment of solar keratosis on the face and scalp in patients where other standard treatments are inappropriate and topical drug therapy is required as field treatment for clinically visible and subclinical lesions

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 4134N | imiquimod 5% (12.5 mg/250 mg) cream, 12 x 250 mg sachets | 1 | 1 | .. | 135.59 | 5.90 | [a] | Aldara | IA |
| | | | | | | | [a] | APO-Imiquimod | TX |

**IMIQUIMOD**

**Authority required**

Primary treatment of histopathologically confirmed superficial basal cell carcinoma where other standard treatments are inappropriate and topical drug therapy is required

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 4559Y | imiquimod 5% (12.5 mg/250 mg) cream, 12 x 250 mg sachets | 1 | 1 | .. | 135.59 | 5.90 | [a] | Aldara | IA |
| | | | | | | | [a] | APO-Imiquimod | TX |

**PANTHENOL**

**Note**

To be used in conjunction with the scalp cleanser salicylic acid with coal tar solution and pine tar (code 4447C).

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 4510J | panthenol conditioner, 200 g | ‡1 | 2 | .. | 14.46 | 5.90 | | SebiRinse | EO |
| | **PARAFFIN LIGHT LIQUID + COCOAMPHODIACETATE DISODIUM** | | | | | | | | |
| 4549K | paraffin light liquid 3.5% (35 mg/mL) + cocoamphodiacetate disodium 3% (30 mg/mL) lotion, 500 mL | ‡1 | 2 | .. | 20.95 | 5.90 | | Hamilton Skin Therapy Wash | VT |
| | **ZINC OXIDE + MAIZE STARCH + CHLORPHENESIN + TALC-PURIFIED** | | | | | | | | |
| 4497Q | zinc oxide 25% (250 mg/g) + maize starch 55.85% (558.5 mg/g) + chlorphenesin 1% (10 mg/g) + talc-purified 18.07% (180.7 mg/g) powder: dusting, 100 g | ‡1 | 1 | .. | 12.46 | 5.90 | | Z.S.C. | QA |

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|

# GENITO URINARY SYSTEM AND SEX HORMONES

## GYNECOLOGICAL ANTIINFECTIVES AND ANTISEPTICS

### ANTIINFECTIVES AND ANTISEPTICS, EXCL. COMBINATIONS WITH CORTICOSTEROIDS

#### *Antibiotics*

**NYSTATIN**

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 4013F | nystatin 100 000 international units/5 g cream, 75 g | ‡1 | 1 | .. | 14.00 | 5.90 | Nilstat | QA |

#### *Imidazole derivatives*

**CLOTRIMAZOLE**

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 4016J | clotrimazole 1% (10 mg/g) cream, 35 g | ‡1 | .. | .. | 15.29 | 5.90 | APO-Clotrimazole 6 Day Cream | TX |
| 4017K | clotrimazole 2% (20 mg/g) cream, 20 g | ‡1 | .. | .. | 15.29 | 5.90 | APO-Clotrimazole 3 Day Cream | TX |

## OTHER GYNECOLOGICALS

### OTHER GYNECOLOGICALS

**ACETIC ACID + HYDROXYQUINOLINE + RICINOLEIC ACID**

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 4434J | hydroxyquinoline sulfate 0.025% (250 microgram/g) + acetic acid 0.94% (9.4 mg/g) + ricinoleic acid 0.75% (7.5 mg/g) gel, 100 g | ‡1 | .. | .. | 33.11 | 5.90 | Aci-Jel | CU |

## UROLOGICALS

### OTHER UROLOGICALS, INCL. ANTISPASMODICS

#### *Drugs used in erectile dysfunction*

**ALPROSTADIL**

**Authority required**

Specific accepted war-caused or service-related disabilities for males with vasculogenic, psychogenic or neurogenic erectile dysfunction.

Authorisation will not be given for any additional prescriptions within 6 months or for any increased quantities or repeats

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 4579B | alprostadil 10 microgram injection [2 x 10 microgram syringes] (&) inert substance diluent [2 x 0.6 mL syringes], 1 pack | 3 | 3 | .. | *105.69 | 5.90 | Caverject Impulse | PF |
| 4580C | alprostadil 20 microgram injection [2 x 20 microgram syringes] (&) inert substance diluent [2 x 0.6 mL syringes], 1 pack | 3 | 3 | .. | *133.02 | 5.90 | Caverject Impulse | PF |

**SILDENAFIL**

**Authority required**

Specific accepted war-caused or service-related disabilities for males with vasculogenic, psychogenic or neurogenic erectile dysfunction.

Authorisation will not be given for any additional prescriptions within 6 months or for any increased quantities or repeats

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 4586J | sildenafil 100 mg tablet, 4 | 1 | 5 | .. | 85.89 | 5.90 | Viagra | PF |
| 4584G | sildenafil 25 mg tablet, 4 | 1 | 5 | .. | 64.19 | 5.90 | Viagra | PF |
| 4585H | sildenafil 50 mg tablet, 4 | 1 | 5 | .. | 79.90 | 5.90 | Viagra | PF |

**TADALAFIL**

**Authority required**

Specific accepted war-caused or service-related disabilities for males with vasculogenic, psychogenic or neurogenic erectile dysfunction.

Authorisation will not be given for any additional prescriptions within 6 months or for any increased quantities or repeats

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 4596X | tadalafil 10 mg tablet, 4 | 1 | 5 | .. | 79.90 | 5.90 | Cialis | LY |
| 4597Y | tadalafil 20 mg tablet, 4 | 1 | 5 | .. | 83.45 | 5.90 | Cialis | LY |

**VARDENAFIL**

**Authority required**

Specific accepted war-caused or service-related disabilities for males with vasculogenic, psychogenic or neurogenic erectile dysfunction.

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|---|
| | Authorisation will not be given for any additional prescriptions within 6 months or for any increased quantities or repeats | | | | | | | | |
| 4290T | vardenafil 10 mg tablet, 4 | 1 | 5 | .. | 73.00 | 5.90 | | Levitra | BN |
| 4302K | vardenafil 20 mg tablet, 4 | 1 | 5 | .. | 83.73 | 5.90 | | Levitra | BN |

### *Other urologicals*

**BICARBONATE + CITRATE + TARTARIC ACID**

**Restricted benefit**

For relief of urinary symptoms when antibiotic or other therapy alone is inappropriate

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 4049D | sodium bicarbonate 1.76 g + citrate sodium 630 mg + citrate 720 mg + tartaric acid 890 mg oral liquid: powder for, 28 x 4 g sachets | ‡1 | 4 | .. | 13.76 | 5.90 | | Uracol | GM |
| | | | | | | | | Ural Sachets | QA |

## DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY

### *Alpha-adrenoreceptor antagonists*

**ALFUZOSIN**

**Authority required**

Treatment of benign prostatic hyperplasia where surgery is inappropriate, or where other drug treatment has failed or is contraindicated

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 4277D | alfuzosin hydrochloride 10 mg tablet: modified release, 30 tablets | 1 | 5 | .. | 63.57 | 5.90 | | Xatral SR | SW |

**TAMSULOSIN**

**Authority required**

Treatment of benign prostatic hyperplasia where surgery is inappropriate, or where other drug treatment has failed or is contraindicated

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 4070F | tamsulosin hydrochloride 400 microgram tablet: modified release, 30 tablets | 1 | 5 | .. | 63.57 | 5.90 | | Flomaxtra | CS |

**TERAZOSIN**

**Authority required**

Treatment of benign prostatic hyperplasia where surgery is inappropriate, or where other drug treatment has failed or is contraindicated

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 4396J | terazosin 1 mg tablet [7 tablets] (&) terazosin 2 mg tablet [7 tablets], 14 | ‡1 | .. | .. | 20.26 | 5.90 | | Hytrin | AB |
| 4399M | terazosin 10 mg tablet, 28 | 1 | 5 | .. | 86.27 | 5.90 | | Hytrin | AB |
| 4397K | terazosin 2 mg tablet, 28 | 1 | 5 | .. | 41.90 | 5.90 | | Hytrin | AB |
| 4398L | terazosin 5 mg tablet, 28 | 1 | 5 | .. | 58.40 | 5.90 | | Hytrin | AB |

### *Testosterone-5-alpha reductase inhibitors*

**FINASTERIDE**

**Authority required**

Treatment of benign prostatic hyperplasia where surgery is inappropriate, or where other drug treatment has failed or is contraindicated

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 4303L | finasteride 5 mg tablet, 28 | 1 | 5 | .. | 91.47 | 5.90 | [a] | Finpro | RZ |
| | | | | | | | [a] | Pharmacy Choice Finasteride | RI |
| 4233T | finasteride 5 mg tablet, 30 | 1 | 5 | .. | 97.53 | 5.90 | [a] | Finasteride RBX | RA |
| | | | | .. | 102.32 | 5.90 | [a] | APO-Finasteride | TX |
| | | | | | | | [a] | Finasta | SZ |
| | | | | | | | [a] | Finasteride Alphapharm | AF |
| | | | | | | | [a] | Finasteride-GA 5 | GM |
| | | | | | | | [a] | Pharmacor Finasteride 5 | CR |
| | | | | | | | [a] | Proscar | MK |

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|---|

# ANTIINFECTIVES FOR SYSTEMIC USE

## ANTIBACTERIALS FOR SYSTEMIC USE

### MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS

#### *Macrolides*

**AZITHROMYCIN**

**Restricted benefit**

Upper and lower respiratory tract infections

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 4115N | azithromycin 500 mg tablet, 3 | 1 | .. | .. | 31.72 | 5.90 | [a] | Azithromycin Sandoz | SZ |
| | | | | | | | [a] | Zithromax | PF |
| | | | | | | | [a] | Zitrocin | GM |
| | | | | | | | | Zedd 500 | QA |

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|

# ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

## ANTINEOPLASTIC AGENTS

### ANTIMETABOLITES

#### *Pyrimidine analogues*

**FLUOROURACIL**

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 4222F | fluorouracil 5% (50 mg/g) cream, 20 g | ‡1 | .. | .. | 60.83 | 5.90 | Efudix | VT |

## IMMUNOSUPPRESSANTS

### IMMUNOSUPPRESSANTS

#### *Tumor necrosis factor alpha (TNF-) inhibitors*

**INFLIXIMAB**

**Authority required**

Initial treatment, in combination with methotrexate, of specific accepted war-caused or service-related disability of refractory rheumatoid arthritis. Initial treatment may be prescribed by rheumatologists or consultant physicians for the reduction of signs and symptoms and prevention of structural joint damage in adult patients with active rheumatoid arthritis who satisfy all of the following criteria:

(1) (a) Proven raised erythrocyte sedimentation rate (ESR) and/or C-reactive protein (CRP); and

(1) (b) Proven erosive rheumatoid arthritis without end-stage disease;

(2) Failure of an adequate trial of methotrexate and 2 other disease modifying anti-rheumatic drugs (such as sulfasalazine, hydroxychloroquine, leflunomide or cyclosporin) — unless these drugs were contraindicated or intolerance had developed;

(3) No history of active tuberculosis requiring treatment in the last 3 years;

(4) No history of opportunistic infection in the last 2 months;

(5) Female patients of child-bearing age are not pregnant, not breast-feeding, and are using an effective form of contraception.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Infliximab (Remicade) RPBS Authority Application - Supporting Information form (contact the VAPAC on 1800 552 580 for a copy of the form)

**Authority required**

Continuing treatment, in combination with methotrexate, of specific accepted war-caused or service-related disability of refractory rheumatoid arthritis. Continuing treatment may be prescribed by rheumatologists or consultant physicians, following initial therapy of 3 doses, in patients who satisfy the following criteria:

(1) There is improvement in ESR and/or CRP; and

(2) An ACR20 (American College of Rheumatology) response is achieved by 14 weeks after the commencement of therapy.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Infliximab (Remicade) RPBS Authority Application - Supporting Information form (contact the VAPAC on 1800 552 580 for a copy of the form)

**Note**

Any queries concerning the arrangements to prescribe infliximab may be directed to the Veterans' Affairs Pharmaceutical Advisory Centre (VAPAC) on 1800 552 580.

Written applications for authority to prescribe infliximab should be forwarded to:

Reply Paid 9998

Veterans' Affairs Pharmaceutical Advisory Centre (VAPAC)

Department of Veterans' Affairs

GPO Box 9998

BRISBANE QLD 4001

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 4284L | infliximab 100 mg injection, 1 x 100 mg vial | 1 | 2 | .. | 847.19 | 5.90 | Remicade | JC |

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|---|

# MUSCULO-SKELETAL SYSTEM

## ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS

### ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS

#### *Acetic acid derivatives and related substances*

**DICLOFENAC + MISOPROSTOL**

**Authority required**

Patients requiring an NSAID in whom a risk of upper gastrointestinal complications is high or with a history of peptic ulcer disease

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 4190M | diclofenac sodium 50 mg + misoprostol 200 microgram tablet, 60 | 1 | 2 | .. | 37.99 | 5.90 | | Arthrotec 50 | PF |

## TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN

### TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN

#### *Preparations with salicylic acid derivatives*

**METHYL SALICYLATE**

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 4026X | methyl salicylate 25% (0.25 mL/mL) liniment, 100 mL | ‡1 | 1 | .. | 10.15 | 5.90 | | Gold Cross | BI |
| 4023R | methyl salicylate 50% (500 mg/g) ointment, 100 g | ‡1 | 1 | .. | 12.38 | 5.90 | | Gold Cross | BI |

**METHYL SALICYLATE + MENTHOL + EUCALYPTUS OIL**

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 4022Q | methyl salicylate 25% (250 mg/g) + menthol 4% (40 mg/g) + eucalyptus oil 10% (100 mg/g) cream, 100 g | ‡1 | 1 | .. | 14.23 | 5.90 | | Gold Cross | BI |

## DRUGS FOR TREATMENT OF BONE DISEASES

### DRUGS AFFECTING BONE STRUCTURE AND MINERALIZATION

#### *Bisphosphonates*

**RISEDRONATE**

**Authority required**

For preservation of bone mineral density in patients on long-term glucocorticoid therapy where patients are undergoing continuous treatment with a dose equal to or greater than 7.5 mg of prednisone or equivalent per day. Prescribers need to demonstrate that the patient has been on continuous therapy for 3 months or more and demonstrate that the patient is osteopenic (bone mineral density t-score of less than -1.0)

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 2191H | RISEDRONATE SODIUM Tablet 35 mg (enteric coated), 4 | 1 | 5 | .. | 45.60 | 5.90 | | Actonel EC | SW |
| 4444X | risedronate sodium 35 mg tablet, 4 | 1 | 5 | .. | 45.60 | 5.90 | [a] | Acris Once-a-Week | AF |
| | | | | | | | [a] | APO-Risedronate | TX |
| | | | | | | | [a] | Chem mart Risedronate | CH |
| | | | | | | | [a] | Risedronate-GA | GM |
| | | | | | | | [a] | Risedronate Sandoz | SZ |
| | | | | | | | [a] | Risedro once a week | QA |
| | | | | | | | [a] | Terry White Chemists Risedronate | TW |
| 4443W | risedronate sodium 5 mg tablet, 28 | 1 | 5 | .. | 45.60 | 5.90 | | Actonel | SW |

#### *Bisphosphonates, combinations*

**ALENDRONATE + COLECALCIFEROL**

**Authority required**

For preservation of bone mineral density in patients on long-term glucocorticoid therapy where patients are undergoing continuous treatment with a dose equal to or greater than 7.5 mg of prednisone or equivalent per day. Prescribers need to demonstrate that the patient has been on continuous therapy for 3 months or more and demonstrate that the patient is osteopenic (bone mineral density t-score of less than -1.0)

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 2224C | alendronate 70 mg + colecalciferol 140 microgram tablet, 4 | 1 | 5 | .. | 47.87 | 5.90 | [a] | Fosamax Plus 70 mg/140 mcg | MK |
| 2194L | alendronate 70 mg + colecalciferol 70 microgram tablet, 4 | 1 | 5 | .. | 45.38 | 5.90 | | Fosamax Plus | MK |

**ALENDRONATE + COLECALCIFEROL (&) CALCIUM CARBONATE**

**Authority required**

For preservation of bone mineral density in patients on long-term glucocorticoid therapy where patients are undergoing continuous treatment with

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|---|
| | a dose equal to or greater than 7.5 mg of prednisone or equivalent per day. Prescribers need to demonstrate that the patient has been on continuous therapy for 3 months or more and demonstrate that the patient is osteopenic (bone mineral density t-score of less than -1.0) | | | | | | | | |
| 2273P | alendronate 70 mg + colecalciferol 140 microgram tablet [4 tablets] (&) calcium (as carbonate) 500 mg tablet [48 tablets], 1 pack | ‡1 | 5 | .. | 45.38 | 5.90 | a | Fosamax Plus D-Cal | MK |
| | **RISEDRONATE (&) CALCIUM CARBONATE** | | | | | | | | |
| | **Authority required** | | | | | | | | |
| | For preservation of bone mineral density in patients on long-term glucocorticoid therapy where patients are undergoing continuous treatment with a dose equal to or greater than 7.5 mg of prednisone or equivalent per day. Prescribers need to demonstrate that the patient has been on continuous therapy for 3 months or more and demonstrate that the patient is osteopenic (bone mineral density t-score of less than -1.0) | | | | | | | | |
| 2220W | RISEDRONATE SODIUM and CALCIUM CARBONATE Pack containing 4 enteric coated tablets risedronate sodium 35 mg and 24 tablets calcium carbonate 1.25 g (equivalent to 500 mg calcium), 1 | ‡1 | 5 | .. | 45.60 | 5.90 | a | Actonel EC Combi | SW |
| 4059P | risedronate sodium 35 mg tablet [4 tablets] (&) calcium (as carbonate) 500 mg tablet [24 tablets], 28 | ‡1 | 5 | .. | 45.60 | 5.90 | a | Acris Combi | AF |
| | **RISEDRONATE (&) CALCIUM CARBONATE + COLECALCIFEROL** | | | | | | | | |
| | **Authority required** | | | | | | | | |
| | For preservation of bone mineral density in patients on long-term glucocorticoid therapy where patients are undergoing continuous treatment with a dose equal to or greater than 7.5 mg of prednisone or equivalent per day. Prescribers need to demonstrate that the patient has been on continuous therapy for 3 months or more and demonstrate that the patient is osteopenic (bone mineral density t-score of less than -1.0) | | | | | | | | |
| 2254P | 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 | 5 | .. | 45.60 | 5.90 | a | Actonel EC Combi D | SW |

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|---|

# NERVOUS SYSTEM

## ANALGESICS

### OPIOIDS

#### *Natural opium alkaloids*

**MORPHINE**

**Restricted benefit**

Chronic severe disabling pain not responding to non-narcotic analgesics

**Caution**

The risk of drug dependence is high.

**Note**

Authorities for increased maximum quantities and/or repeats will be granted only for

(i) chronic severe disabling pain associated with proven malignant neoplasia; or

(ii) chronic severe disabling pain where treatment has been initiated by a specialist with appropriate expertise in pain management.

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 4349X | morphine sulfate 200 mg tablet: modified release, 28 tablets | 1 | .. | .. | 122.07 | 5.90 | | MS Contin | MF |

### OTHER ANALGESICS AND ANTIPYRETICS

#### *Salicylic acid and derivatives*

**ASPIRIN + CODEINE**

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 4286N | aspirin 300 mg + codeine phosphate 8 mg tablet: dispersible, 40 | 1 | 2 | .. | 14.39 | 5.90 | | Aspalgin 40 | QA |

#### *Anilides*

**PARACETAMOL + CODEINE**

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 4170L | paracetamol 500 mg + codeine phosphate 15 mg tablet, 20 | 1 | 2 | .. | 9.94 | 5.90 | | Prodeine 15 | SW |
| 4275B | paracetamol 500 mg + codeine phosphate 8 mg tablet, 40 | 1 | 2 | .. | 10.90 | 5.90 | | Panamax Co. 40 | SW |
| 4171M | paracetamol 500 mg + codeine phosphate 8 mg tablet, 50 | 1 | 2 | .. | 13.07 | 5.90 | | Codalgin | FM |

#### *Other analgesics and antipyretics*

**GABAPENTIN**

**Authority required**

To be approved for the treatment of refractory neuropathic pain not controlled by other drugs

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 4591P | gabapentin 100 mg capsule, 100 | 1 | 5 | .. | 15.98 | 5.90 | [a] | APO-Gabapentin | TX |
| | | | | | | | [a] | Gabatine 100 | QA |
| | | | | | | | [a] | Neurontin | PF |
| | | | | | | | [a] | Nupentin 100 | AF |
| 4592Q | gabapentin 300 mg capsule, 100 | 1 | 5 | .. | 37.88 | 5.90 | [a] | DBL Gabapentin | HH |
| | | | | | | | [a] | Gabapentin 300 | CR |
| | | | | | | | [a] | Gabatine 300 | QA |
| | | | | | | | [a] | Gantin | GN |
| | | | | | | | [a] | GenRx Gabapentin | GX |
| | | | | | | | [a] | Neurontin | PF |
| | | | | | | | [a] | Nupentin 300 | AF |
| 4593R | gabapentin 400 mg capsule, 100 | 1 | 5 | .. | 48.18 | 5.90 | [a] | DBL Gabapentin | HH |
| | | | | | | | [a] | Gabapentin 400 | CR |
| | | | | | | | [a] | Gabatine 400 | QA |
| | | | | | | | [a] | Gantin | GN |
| | | | | | | | [a] | GenRx Gabapentin | GX |
| | | | | | | | [a] | Neurontin | PF |
| | | | | | | | [a] | Nupentin 400 | AF |
| 4594T | gabapentin 600 mg tablet, 100 | 1 | 5 | .. | 71.32 | 5.90 | [a] | Gabatine 600 | QA |
| | | | | | | | [a] | GenRx Gabapentin | GX |
| | | | | | | | [a] | Neurontin | PF |
| | | | | | | | [a] | Nupentin Tabs | AF |
| 4595W | gabapentin 800 mg tablet, 100 | 1 | 5 | .. | 92.87 | 5.90 | [a] | Gabatine 800 | QA |

# NERVOUS SYSTEM

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | [a] | Gantin | GN |
| | | | | | | | [a] | GenRx Gabapentin | GX |
| | | | | | | | [a] | Neurontin | PF |
| | | | | | | | [a] | Nupentin Tabs | AF |
| | **PREGABALIN**<br>**Authority required**<br>For the treatment of refractory neuropathic pain not controlled by other drugs | | | | | | | | |
| 4323M | pregabalin 150 mg capsule, 56 | 1 | 5 | .. | 70.50 | 5.90 | | Lyrica | PF |
| 4320J | pregabalin 25 mg capsule, 56 | 1 | 5 | .. | 26.31 | 5.90 | | Lyrica | PF |
| 4324N | pregabalin 300 mg capsule, 56 | 1 | 5 | .. | 101.92 | 5.90 | | Lyrica | PF |
| 4322L | pregabalin 75 mg capsule, 56 | 1 | 5 | .. | 48.98 | 5.90 | | Lyrica | PF |

## PSYCHOLEPTICS

### ANXIOLYTICS

#### *Benzodiazepine derivatives*

**BROMAZEPAM**
**Authority required**
Patients with terminal disease

**Authority required**
Patients with refractory phobic or anxiety states

**Note**
For short-term use and palliative care. This drug should not be used as the first line of treatment. Other PBS-listed benzodiazepines should have been adequately tried and found to be ineffective or inappropriate. Authorities for increased quantities and/or repeats may be granted to patients with terminal disease, and other patients who have been shown to be dependent on this item by an unsuccessful attempt at gradual withdrawal.

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 4150K | bromazepam 3 mg tablet, 30 | 2 | .. | .. | *29.69 | 5.90 | | Lexotan | RO |
| 4151L | bromazepam 6 mg tablet, 30 | 2 | .. | .. | *36.31 | 5.90 | | Lexotan | RO |

#### *Azaspirodecanedione derivatives*

**BUSPIRONE**
**Authority required**
For the short-term treatment of anxiety

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 4145E | buspirone hydrochloride 10 mg tablet, 50 | 1 | .. | .. | 55.05 | 5.90 | | Buspar | QA |
| 4144D | buspirone hydrochloride 5 mg tablet, 50 | 1 | .. | .. | 38.20 | 5.90 | | Buspar | QA |

### HYPNOTICS AND SEDATIVES

#### *Benzodiazepine derivatives*

**FLUNITRAZEPAM**
**Authority required**
Patients with terminal disease

**Authority required**
Patients with refractory phobic or anxiety states

**Note**
For short-term use and palliative care. This drug should not be used as the first line of treatment. Other PBS-listed benzodiazepines should have been adequately tried and found to be ineffective or inappropriate. Authorities for increased quantities and/or repeats may be granted to patients with terminal disease, and other patients who have been shown to be dependent on this item by an unsuccessful attempt at gradual withdrawal.

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 4216X | flunitrazepam 1 mg tablet, 30 | 1 | .. | .. | 13.94 | 5.90 | | Hypnodorm | AF |

#### *Benzodiazepine related drugs*

**ZOPICLONE**
**Restricted benefit**
For the short-term treatment of insomnia

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 4522B | zopiclone 7.5 mg tablet, 30 | 1 | .. | .. | 21.97 | 5.90 | [a] | Imrest | AF |
| | | | | .. | 25.12 | 5.90 | [a] | Imovane | SW |

## OTHER NERVOUS SYSTEM DRUGS

### DRUGS USED IN ADDICTIVE DISORDERS

#### *Drugs used in nicotine dependence*

# NERVOUS SYSTEM

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|
| | **NICOTINE** | | | | | | | |
| | **Authority required** | | | | | | | |
| | Patients who have indicated that they are ready to cease smoking and who have entered a support and counselling program | | | | | | | |
| | **Note** | | | | | | | |
| | Studies have shown that successful therapy with this drug is enhanced by patient participation in a support and counselling program. | | | | | | | |
| 4577X | nicotine 10 mg/16 hours patch, 7 | 2 | .. | .. | *54.99 | 5.90 | Nicorette Patch | JT |
| 4572P | nicotine 14 mg/24 hours patch, 7 | 2 | .. | .. | *54.77 | 5.90 | QuitX | AF |
| | | | | .. | *68.95 | 5.90 | Nicabate CQ 14 | GC |
| 4578Y | nicotine 15 mg/16 hours patch, 7 | 2 | 2 | .. | *60.17 | 5.90 | Nicorette Patch | JT |
| 4573Q | nicotine 21 mg/24 hours patch, 7 | 2 | 2 | .. | *57.89 | 5.90 | QuitX | AF |
| | | | | .. | *68.95 | 5.90 | Nicabate CQ 21 | GC |
| 4576W | nicotine 5 mg/16 hours patch, 7 | 2 | .. | .. | *51.01 | 5.90 | Nicorette Patch | JT |
| 4571N | nicotine 7 mg/24 hours patch, 7 | 2 | .. | .. | *51.61 | 5.90 | QuitX | AF |

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|

# ANTIPARASITIC PRODUCTS, INSECTICIDES AND REPELLENTS

## ANTHELMINTICS

### ANTINEMATODAL AGENTS

#### *Benzimidazole derivatives*

**MEBENDAZOLE**

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 4325P | mebendazole 100 mg tablet, 6 | 1 | .. | .. | 15.13 | 5.90 | Vermox | BI |

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|

# RESPIRATORY SYSTEM

## NASAL PREPARATIONS

### DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE

#### *Sympathomimetics, plain*

**OXYMETAZOLINE**

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 4378K | oxymetazoline hydrochloride 0.05% (500 microgram/mL) nasal spray, 15 mL | ‡1 | .. | .. | 17.36 | 5.90 | Drixine | MK |
| 4379L | oxymetazoline hydrochloride 0.05% (500 microgram/mL) nasal spray, 18 mL | ‡1 | .. | .. | 16.97 | 5.90 | Logicin Rapid Relief | QA |

#### *Antiallergic agents, excl. corticosteroids*

**CROMOGLYCATE**

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 4468E | cromoglycate sodium 2% (20 mg/mL) nasal spray, 26 mL | ‡1 | 5 | .. | 23.12 | 5.90 | Rynacrom | SW |

**LEVOCABASTINE**

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 4311X | levocabastine 0.05% (500 microgram/mL) nasal spray, 100 actuations | ‡1 | 2 | .. | 18.45 | 5.90 | Livostin | JT |

#### *Corticosteroids*

**BUDESONIDE**

**Restricted benefit**

Severe intractable rhinitis

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 4092J | budesonide 64 microgram/actuation nasal spray, 120 actuations | ‡1 | .. | .. | 35.47 | 5.90 | Budamax Aqueous | PM |

#### *Other nasal preparations*

**IPRATROPIUM**

**Restricted benefit**

Severe intractable rhinorrhoea, associated with perennial rhinitis, unresponsive to insufflated nasal steroids

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 4089F | ipratropium bromide anhydrous 21 microgram/actuation nasal spray, 180 actuations | ‡1 | 5 | .. | 23.80 | 5.90 | Atrovent Nasal Aqueous | BY |
| 4090G | ipratropium bromide anhydrous 42 microgram/actuation nasal spray, 180 actuations | ‡1 | 5 | .. | 30.68 | 5.90 | Atrovent Nasal Forte | BY |

### NASAL DECONGESTANTS FOR SYSTEMIC USE

#### *Sympathomimetics*

**PSEUDOEPHEDRINE**

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 4029C | pseudoephedrine hydrochloride 60 mg tablet, 12 | 1 | .. | .. | 11.23 | 5.90 | Logicin Sinus | QA |

## COUGH AND COLD PREPARATIONS

### EXPECTORANTS, EXCL. COMBINATIONS WITH COUGH SUPPRESSANTS

#### *Expectorants*

**AMMONIUM + SENEGA ROOT**

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 4074K | ammonium bicarbonate 25 mg/mL + senega root 25 mg/mL oral liquid, 200 mL | ‡1 | 4 | .. | 9.39 | 5.90 | Gold Cross | BI |

### COUGH SUPPRESSANTS, EXCL. COMBINATIONS WITH EXPECTORANTS

#### *Opium alkaloids and derivatives*

**PHOLCODINE**

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 4071G | pholcodine 1 mg/mL oral liquid, 100 mL | ‡1 | 2 | .. | 9.23 | 5.90 | Gold Cross | BI |
| | | | | .. | 14.82 | 5.90 | Duro-Tuss | IA |

ANTIHISTAMINES FOR SYSTEMIC USE

## ANTIHISTAMINES FOR SYSTEMIC USE

### *Piperazine derivatives*

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|---|
| | **CETIRIZINE** | | | | | | | | |
| 4175R | cetirizine hydrochloride 10 mg tablet, 30 | 1 | .. | .. | 29.86 | 5.90 | a | Alzene | AF |
| | | | | .. | 33.08 | 5.90 | | Zilarex | SZ |
| | | | | .. | 39.66 | 5.90 | a | Zyrtec | JT |

### *Other antihistamines for systemic use*

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | **FEXOFENADINE** | | | | | | | | |
| 4238C | fexofenadine hydrochloride 120 mg tablet, 30 | 1 | .. | .. | 29.63 | 5.90 | a | Xergic | AF |
| | | | | .. | 34.92 | 5.90 | a | Fexal | SZ |
| | | | | .. | 47.34 | 5.90 | a | Telfast 120 | SW |
| 4237B | fexofenadine hydrochloride 60 mg tablet, 20 | 3 | .. | .. | *55.20 | 5.90 | | Telfast | SW |
| | **LORATADINE** | | | | | | | | |
| 4313B | loratadine 10 mg tablet, 30 | 1 | .. | .. | 33.20 | 5.90 | a | Allereze | AF |
| | | | | .. | 43.86 | 5.90 | a | Lorano | SZ |
| | | | | .. | 46.13 | 5.90 | a | Claratyne | MK |

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|

# SENSORY ORGANS

## OPHTHALMOLOGICALS

### DECONGESTANTS AND ANTIALLERGICS

#### *Sympathomimetics used as decongestants*

**ANTAZOLINE + NAPHAZOLINE**

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 4032F | antazoline phosphate 0.5% + naphazoline hydrochloride 0.05% eye drops, 15 mL | ‡1 | 1 | .. | 15.01 | 5.90 | Albalon-A | AG |

**NAPHAZOLINE**

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 4035J | naphazoline hydrochloride 0.1% eye drops, 15 mL | ‡1 | 1 | .. | 15.30 | 5.90 | Albalon Liquifilm | AG |

#### *Other antiallergics*

**LEVOCABASTINE**

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 4310W | levocabastine 0.05% eye drops, 4 mL | ‡1 | 1 | .. | 18.45 | 5.90 | Livostin | JT |

## OTOLOGICALS

### OTHER OTOLOGICALS

#### *Indifferent preparations*

**CARBAMIDE PEROXIDE**

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 4176T | carbamide peroxide 6.5% (65 mg/mL) ear drops, 12 mL | ‡1 | .. | .. | 16.29 | 5.90 | Ear Clear for Ear Wax Removal | KY |

**DICHLOROBENZENE WITH CHLORBUTOL AND ARACHIS OIL**

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 4180B | DICHLOROBENZENE with CHLORBUTOL and ARACHIS OIL Ear drops, ortho-dichlorobenzene 140 mg per mL, para-dichlorobenzene 20 mg per mL, chlorbutol 50 mg per mL, arachis oil 573 mg per mL, 10 mL, 1 | ‡1 | .. | .. | 14.29 | 5.90 | Cerumol | UN |

**DOCUSATE**

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 4199B | docusate sodium 0.5% (5 mg/mL) ear drops, 10 mL | ‡1 | .. | .. | 14.68 | 5.90 | Waxsol | NE |

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|

# VARIOUS

## ALL OTHER THERAPEUTIC PRODUCTS

### ALL OTHER THERAPEUTIC PRODUCTS

***Drugs for treatment of hyperkalemia and hyperphosphatemia***

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | **POLYSTYRENE SULFONATE SODIUM** | | | | | | | |
| 4470G | polystyrene sulfonate sodium 999.3 mg/g powder, 454 g | ‡1 | 2 | .. | 71.33 | 5.90 | Resonium-A | SW |

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|

# REPATRIATION PHARMACEUTICAL BENEFITS SCHEME (RPBS)
# WOUND ASSESSMENT AND DRESSING IDENTIFICATION

It is essential to define the aetiology of the wound before selecting a dressing. Recommendations are based on wound type, colour of wound base, depth of wound, and amount of exudate.

This wound chart adheres to the MOIST WOUND concept of healing and wound dressings are described below as ABSORBING or MOISTURE DONATING.

Most wound healing products are designed to remain in situ for several days, with the exception of those for infected wounds which should be changed daily. The quantities and repeats listed in the Repatriation Schedule are considered to be adequate to manage the treatment of a wound for two weeks to one month, when an assessment of the wound's healing process should be undertaken.

## DRESSINGS

### PINK EPITHELIALISING WOUND

Aim: To protect and promote epithelialisation. Epithelialising wounds normally are superficial and only produce a light exudate.

| | | |
|---|---|---|
| (A) Covering | • Film;<br>• Film Island | • Gauze—Paraffin;<br>• Non-adherent |
| (B) Absorbing | • Foam (Light Exudate);<br>• Hydroactive (Superficial Wound—Light Exudate) | • Hydrocolloid (Superficial Wound—Light Exudate) |

### RED GRANULATING WOUND

Aims: (1) to protect the granulating tissue; (2) to encourage epithelialisation; (3) to absorb excess exudate.

| | | |
|---|---|---|
| LIGHT EXUDATE: | Superficial | Cavity |
| (A) Absorbing | • Foam (Light Exudate);<br>• Hydroactive (Superficial Wound—Light Exudate);<br>• Hydrocolloid (Superficial Wound—Light Exudate) | • Hydrocolloid (Cavity Wound) |
| (B) Moisture donating | • Hydrogel—Amorphous;<br>• Hydrogel—Sheet | • Hydrogel—Amorphous |
| HIGH EXUDATE: | Superficial | Cavity |
| (A) Absorbing | • Alginate (Superficial Wound);<br>• Foam—Heavy Exudate;<br>• Hydroactive (Superficial Wound—Moderate Exudate);<br>• Hydrocolloid (Superficial Wound—Moderate/High Exudate) | • Alginate (Cavity Wound);<br>• Foam—Moderate Exudate (see “cavity conforming” product);<br>• Hydroactive (Cavity Wound);<br>• Hydrocolloid (Cavity Wound) |
| (B) Moisture donating | NOT APPROPRIATE | |

# VARIOUS

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|

**YELLOW SLOUGHY WOUND**

Aims: (1) to remove slough; (2) to encourage granulation; (3) to absorb excess exudate.

| | | |
|---|---|---|
| LIGHT EXUDATE: | Superficial | Cavity |
| (A) Absorbing | • Cadexomer Iodine;<br>• Foam—Light Exudate;<br>• Foam with Charcoal;<br>• Hydroactive (Superficial Wound—Moderate Exudate);<br>• Hydrocolloid (Superficial Wound—Moderate Exudate) | • Cadexomer Iodine;<br>• Hydrocolloid (Cavity Wound) |
| (B) Moisture Donating | • Hydrogel—Amorphous;<br>• Hydrogel—Sheet | • Hydrogel—Amorphous |
| HIGH EXUDATE: | Superficial | Cavity |
| (A) Absorbing | • Alginate (Superficial Wound);<br>• Cadexomer Iodine;<br>• Foam—Heavy Exudate;<br>• Hydroactive (Superficial Wound—Moderate/High Exudate);<br>• Hydrocolloid (Superficial Wound—Moderate/High Exudate) | • Alginate (Cavity Wound);<br>• Cadexomer Iodine;<br>• Hydrocolloid (Cavity Wound) |
| (B) Moisture donating | NOT APPROPRIATE | |

**BLACK NECROTIC WOUND**

Aim: To remove eschar by — (1) sharp debridement, e.g., scissor/scalpel and/or (2) rehydration and autolytic debridement. (These wounds usually produce a LIGHT EXUDATE.)

| | | |
|---|---|---|
| DRY / LIGHT EXUDATE: | Superficial | Cavity |
| (A) Absorbing | • Hydroactive (Superficial Wound—Light Exudate);<br>• Hydrocolloid (Superficial Wound—Light/Moderate Exudate) | • Hydrocolloid (Cavity Wound) |
| (B) Moisture donating | • Hydrogel—Amorphous;<br>• Hydrogel—Sheet | • Hydrogel—Amorphous;<br>• Hydrogel—Sheet |

**INFECTED WOUNDS**

Aims: (1) to clear the infection with systemic antibiotics; (2) to absorb excess exudate; (3) to remove slough if present; (4) to decrease bacterial burden - by applying a Silver dressing or Cadexomer Iodine dressing.

**MALODOROUS WOUNDS**

Aims: (1) to clear infection if present; (2) to remove slough if present; (3) to clear colonising odour-producing bacteria **in** slough — by applying metronidazole gel, a Silver dressing or a Cadexomer Iodine dressing; (4) to absorb excess exudate.

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|

Products: Activated Charcoal; Alginate with Charcoal; Foam with Charcoal; Silver dressing; Cadexomer Iodine dressing.

**MINOR SKIN TRAUMA**

Aims: (1) to stop bleeding; (2) to prevent infection; (3) to minimise the surface defect; (4) to promote epithelialisation.

**ORDERING HARTMANN PRODUCTS**

Hartmann wound dressings are available through HARTMANN and Independence Australia only. If you would like to order Hartmann Wound Care products, please call HARTMANN customer service on 1800 805 839 or Independence Australia on 1300 788 855.

**ORDERING COLOPLAST PRODUCTS**

Coloplast dressings are available via a range of distributors. However, Coloplast's principal agreement to ensure correct RPBS Price to Pharmacy and ready supply has been secured with Independence Australia on 1300 788 855 and BrightSky on 1300 290 400. Please note that Coloplast is unable to guarantee ready supply or rebate for price differences on purchases outside these distributors.

**ORDERING MOLNLYCKE HEALTHCARE PRODUCTS**

Molnlycke Healthcare products are distributed through leading pharmacy distributors. To best ensure product availability at RPBS agreed prices, special arrangements have been made with API and Independence Australia Health Solutions (IAHS). IAHS orders can be placed on: Tel: 1300 788 855; or Email customerservice@independenceaustralia.com. Molnlycke Healthcare are not able to ensure product availability or pricing on listed products beyond these two suppliers.

## ALL OTHER NON-THERAPEUTIC PRODUCTS

## ALL OTHER NON-THERAPEUTIC PRODUCTS

**LUBRICATING AGENT**

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 4306P | lubricating agent jelly, 100 g | 1 | .. | .. | 12.85 | 5.90 | Lubri-Gel | PP |

### *Other non-therapeutic auxiliary products*

**BANDAGE ABSORBENT WOOL**

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 4653X | bandage absorbent wool 10 cm x 3 m bandage, 1 | 1 | .. | .. | 20.53 | 5.90 | Surepress 650948 | CC |

**BANDAGE CALICO**

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 4717G | bandage calico large bandage: triangular, 1 bandage | ‡1 | .. | .. | 13.70 | 5.90 | Handy 36361414 | BV |

**BANDAGE COMPRESSION**

**Note**

Treatment of varices and oedema associated with venous disease and lymphoedema; contraindicated in arterial disease.

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 4654Y | BANDAGE-COMPRESSION Bandage, short stretch, 8 cm x 2.6 m, 1 | 5 | .. | .. | *77.98 | 5.90 | Comprilan 01027-00 | BV |
| 4748X | bandage compression 10 cm x 3 m bandage: high stretch, 1 bandage | 5 | .. | .. | *73.13 | 5.90 | Surepress 650947 | CC |
| | | | | .. | *126.83 | 5.90 | Tensopress 71723-00 | BV |
| 4736G | bandage compression 7.5 cm x 3 m bandage: high stretch, 1 bandage | 5 | .. | .. | *94.53 | 5.90 | Tensopress 71723-01 | BV |
| 4656C | bandage compression 7.5 cm x 3.5 m bandage: high stretch, 1 bandage | 5 | .. | .. | *68.58 | 5.90 | Setopress 3504 | SS |

**BANDAGE COMPRESSION**

**Note**

Treatment of varices and oedema associated with venous disease and lymphoedema; contraindicated in arterial disease.

**Note**

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| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 4657D | bandage compression 10 cm x 3.5 m bandage: high stretch, 1 bandage | 5 | .. | .. | *78.78 | 5.90 | Setopress 3505 | MH |

**BANDAGE COMPRESSION**

**Note**

Treatment of varices and oedema associated with venous disease and lymphoedema; contraindicated in arterial disease.

**Note**

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| | prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS pricing from distributors other than those aforementioned. | | | | | | | |
| 4598B | bandage compression bandage: four layer, 1 bandage | 5 | .. | .. | *152.83 | 5.90 | Profore Lite 66050415 | SN |
| 4658E | bandage compression bandage: four layer, 1 bandage | 5 | .. | .. | *224.63 | 5.90 | Profore 66050016 | SN |
| | **BANDAGE COMPRESSION** | | | | | | | |
| | **Restricted benefit** | | | | | | | |
| | Initial treatment of venous ulcers | | | | | | | |
| | **Restricted benefit** | | | | | | | |
| | Continuation of treatment of venous ulcers where patient's ability to tolerate dressing has been demonstrated | | | | | | | |
| | **Note** | | | | | | | |
| | Treatment of varices and oedema associated with venous disease and lymphoedema; contraindicated in arterial disease. | | | | | | | |
| | **Note** | | | | | | | |
| | Bandage can be left in situ for up to 7 days as per manufacturer's instructions. | | | | | | | |
| 4050E | bandage compression bandage: two layer, 1 bandage | 1 | .. | .. | 42.89 | 5.90 | Coban 2 | MM |
| | **BANDAGE RETENTION COHESIVE HEAVY** | | | | | | | |
| 4813H | bandage retention cohesive heavy 10 cm x 1.3 m bandage, 1 | 2 | .. | .. | *21.29 | 5.90 | Peg 7423 | MM |
| 4660G | bandage retention cohesive heavy 10 cm x 2 m bandage, 1 | 2 | .. | .. | *19.57 | 5.90 | Coban 1584 | MM |
| 4814J | bandage retention cohesive heavy 15 cm x 1.3 m bandage, 1 | 2 | .. | .. | *28.39 | 5.90 | Peg 7425 | MM |
| 4811F | bandage retention cohesive heavy 5 cm x 1.3 m bandage, 1 | 2 | .. | .. | *14.23 | 5.90 | Peg 7420 | MM |
| 4812G | bandage retention cohesive heavy 7.5 cm x 1.3 m bandage, 1 | 2 | .. | .. | *17.51 | 5.90 | Peg 7422 | MM |
| | **BANDAGE RETENTION COHESIVE LIGHT** | | | | | | | |
| 4662J | bandage retention cohesive light 10 cm x 4 m bandage, 1 | 2 | .. | .. | *17.35 | 5.90 | Handygauze Cohesive 8635 | BV |
| 4718H | bandage retention cohesive light 2.5 cm x 4 m bandage, 2 | ‡1 | .. | .. | 12.73 | 5.90 | Handygauze Cohesive 8631 | BV |
| 4719J | bandage retention cohesive light 6 cm x 4 m bandage, 1 | 2 | .. | .. | *14.91 | 5.90 | Handygauze Cohesive 8633 | BV |
| | **BANDAGE RETENTION COTTON CREPE** | | | | | | | |
| 4729X | bandage retention cotton crepe 10 cm x 2.3 m bandage, 1 | 2 | .. | .. | *25.59 | 5.90 | Telfa 8254F | KE |
| | | | | .. | *28.03 | 5.90 | Tensocrepe 36301001 | BV |
| 4727T | bandage retention cotton crepe 5 cm x 2.3 m bandage, 1 | 2 | .. | .. | *17.63 | 5.90 | Telfa 8252F | KE |
| | | | | .. | *18.49 | 5.90 | Tensocrepe 36300501 | BV |
| 4728W | bandage retention cotton crepe 7.5 cm x 2.3 m bandage, 1 | 2 | .. | .. | *22.43 | 5.90 | Telfa 8253F | KE |
| | | | | .. | *22.61 | 5.90 | Tensocrepe 36307501 | BV |
| | **BANDAGE TUBULAR** | | | | | | | |
| | **Note** | | | | | | | |
| | Molnlycke Health Care products are distributed through leading pharmacy distributors. To best ensure product availability at the RPBS agreed prices, special arrangements have been made with API and Independence Australia Health Solutions (IAHS). IAHS orders can be placed on: Tel: 1300 788 855; or Email: customerservice@independenceaustralia.com. Molnlycke Health Care is not able to ensure product availability or pricing on listed products beyond these two suppliers. | | | | | | | |
| 4859R | bandage tubular 10 cm x 1 m bandage, 1 | ‡1 | .. | .. | 15.19 | 5.90 | Tubigrip F 1548 | MH |
| 4855M | bandage tubular 6.25 cm x 1 m bandage, 1 | ‡1 | .. | .. | 15.19 | 5.90 | Tubigrip B 1520 | MH |
| 4856N | bandage tubular 6.75 cm x 1 m bandage, 1 | ‡1 | .. | .. | 15.19 | 5.90 | Tubigrip C 1545 | MH |
| 4857P | bandage tubular 7.5 cm x 1 m bandage, 1 | ‡1 | .. | .. | 15.19 | 5.90 | Tubigrip D 1546 | MH |
| 4858Q | bandage tubular 8.75 cm x 1 m bandage, 1 | ‡1 | .. | .. | 15.19 | 5.90 | Tubigrip E 1547 | MH |
| | **BANDAGE TUBULAR** | | | | | | | |
| 4663K | bandage tubular size C (15 cm to 25 cm) | ‡1 | .. | .. | 15.60 | 5.90 | Elastoplast 2225 | BE |

# VARIOUS

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|---|---|---|---|---|---|---|---|---|
| | bandage: straight, 1 bandage | | | | | | | |
| 4664L | bandage tubular size D (25 cm to 43 cm) bandage: straight, 1 bandage | ‡1 | .. | .. | 15.60 | 5.90 | Elastoplast 2226 | BE |
| 4665M | bandage tubular size E (35 cm to 45 cm) bandage: straight, 1 bandage | ‡1 | .. | .. | 15.60 | 5.90 | Elastoplast 2227 | BE |
| | **BANDAGE TUBULAR FINGER** | | | | | | | |
| 4798M | BANDAGE-TUBULAR (FINGER) Complete pack including applicator, 1 | ‡1 | .. | .. | 17.98 | 5.90 | Tubegauz 0501633 | SS |
| 4726R | bandage tubular finger bandage, 1 | ‡1 | .. | .. | 13.96 | 5.90 | Tubegauz 0501658 | SS |
| | **BANDAGE TUBULAR LIGHT WEIGHT** | | | | | | | |
| | **Note** | | | | | | | |
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| 4673Y | bandage tubular light weight 10 m bandage: large limb size, 1 bandage | ‡1 | .. | .. | 28.34 | 5.90 | Tubifast 2438 | MH |
| 4672X | bandage tubular light weight 10 m bandage: medium limb size, 1 bandage | ‡1 | .. | .. | 26.93 | 5.90 | Tubifast 2436 | MH |
| 4671W | bandage tubular light weight 10 m bandage: small limb size, 1 bandage | ‡1 | .. | .. | 22.97 | 5.90 | Tubifast 2434 | MH |
| | **BANDAGE TUBULAR LONG STOCKING** | | | | | | | |
| | **Note** | | | | | | | |
| | Molnlycke Health Care products are distributed through leading pharmacy distributors. To best ensure product availability at the RPBS agreed prices, special arrangements have been made with API and Independence Australia Health Solutions (IAHS). IAHS orders can be placed on: Tel: 1300 788 855; or Email: customerservice@independenceaustralia.com. Molnlycke Health Care is not able to ensure product availability or pricing on listed products beyond these two suppliers. | | | | | | | |
| 4675C | bandage tubular long stocking bandage: XX/large size, 1 bandage | 2 | .. | .. | *37.35 | 5.90 | Tubigrip 1486 | MH |
| 4799N | bandage tubular long stocking bandage: large size, 1 bandage | 2 | .. | .. | *37.33 | 5.90 | Tubigrip 1484 | MH |
| 4797L | bandage tubular long stocking bandage: medium size, 1 bandage | 2 | .. | .. | *37.33 | 5.90 | Tubigrip 1483 | MH |
| 4674B | bandage tubular long stocking bandage: small size, 1 bandage | 2 | .. | .. | *37.33 | 5.90 | Tubigrip 1482 | MH |
| | **BANDAGE TUBULAR SHORT STOCKING** | | | | | | | |
| | **Note** | | | | | | | |
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| 4816L | bandage tubular short stocking bandage: large D/E size, 1 bandage | 2 | .. | .. | *25.59 | 5.90 | Tubigrip 1481 | MH |
| 4815K | bandage tubular short stocking bandage: medium C/D size, 1 bandage | 2 | .. | .. | *25.59 | 5.90 | Tubigrip 1480 | MH |
| 4661H | bandage tubular short stocking bandage: small B/C size, 1 bandage | 2 | .. | .. | *25.59 | 5.90 | Tubigrip 1479 | MH |
| | **BANDAGE ZINC PASTE** | | | | | | | |
| | **Note** | | | | | | | |
| | Used as an adjunct in the management of leg ulceration and associated eczema and skin conditions. | | | | | | | |
| 4670T | bandage zinc paste 10 cm x 9.1 m bandage, 1 | 2 | 3 | .. | *28.99 | 5.90 | Flexidress 650941 | CC |
| 4668Q | bandage zinc paste 7.5 cm x 6 m bandage, 1 | 2 | .. | .. | *29.41 | 5.90 | Zincaband 3604 | SS |
| | **BANDAGE ZINC PASTE** | | | | | | | |
| | **Note** | | | | | | | |
| | Used as an adjunct in the management of leg ulceration and associated eczema and skin conditions. | | | | | | | |
| | **Note** | | | | | | | |
| | Molnlycke Health Care products are distributed through leading pharmacy distributors. To best ensure product availability at the RPBS agreed prices, special arrangements have been made with API and Independence Australia Health Solutions (IAHS). IAHS orders can be placed on: Tel: 1300 788 855; or Email: customerservice@independenceaustralia.com. Molnlycke Health Care is not able to ensure product availability or pricing on | | | | | | | |

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|---|---|---|---|---|---|---|---|---|
| | listed products beyond these two suppliers. | | | | | | | |
| 4669R | bandage zinc paste 7.5 cm x 6 m bandage, 1 | 2 | 3 | .. | *29.87 | 5.90 | Steripaste 3610 | MH |
| | **BANDAGE ZINC PASTE** | | | | | | | |
| | **Note** Used as an adjunct in the management of leg ulceration and associated eczema and skin conditions. | | | | | | | |
| | **Note** Smith & Nephew products are distributed via the three major wholesalers, API, Sigma & Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS pricing from distributors other than those aforementioned. | | | | | | | |
| 4750B | bandage zinc paste 7.5 cm x 6 m bandage, 1 | 2 | 3 | .. | *74.07 | 5.90 | Viscopaste 4948 | SN |
| 4760M | bandage zinc paste 80 cm (stockings) bandage, 4 | ‡1 | 3 | .. | 85.38 | 5.90 | ZipZoc 66051550 | SN |
| | **BETAINE + POLYAMINOPROPYL BIGUANIDE** | | | | | | | |
| 2525X | betaine 0.1% (40 microgram/40 mL) + polyaminopropyl biguanide 0.1% (40 microgram/40 mL), 6 x 40 mL ampoules | 1 | .. | .. | 26.88 | 5.90 | Prontosan Wound Irrigation Solution | BR |
| | **CADEXOMER-IODINE** | | | | | | | |
| | **Note** Suitable for yellow sloughy infected and malodorous wounds. | | | | | | | |
| | **Note** Smith & Nephew products are distributed via the three major wholesalers, API, Sigma & Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS pricing from distributors other than those aforementioned. | | | | | | | |
| 4937W | DRESSING with CADEXOMER IODINE Sheets 17 g (10 cm x 8 cm), 2, 1 | ‡1 | .. | .. | 156.57 | 5.90 | Iodosorb 66051360 | SN |
| 4935R | DRESSING with CADEXOMER IODINE Sheets 5 g (6 cm x 4 cm), 5, 1 | ‡1 | 2 | .. | 102.83 | 5.90 | Iodosorb 66051330 | SN |
| 4931M | cadexomer-iodine 3 g powder: dusting sterile, 7 x 3 g sachets | ‡1 | 2 | .. | 67.58 | 5.90 | Iodosorb Powder 66051070 | SN |
| 4933P | cadexomer-iodine 50% (500 mg/g) ointment, 2 x 20 g tubes | ‡1 | 2 | .. | 107.76 | 5.90 | Iodosorb Ointment 66051230 | SN |
| 4932N | cadexomer-iodine 50% (500 mg/g) ointment, 4 x 10 g tubes | ‡1 | 2 | .. | 108.79 | 5.90 | Iodosorb Ointment 66051240 | SN |
| 4936T | cadexomer-iodine 8 cm x 6 cm dressing, 3 x 10 g sheets | ‡1 | 2 | .. | 148.56 | 5.90 | Iodosorb 66051340 | SN |
| | **COTTON WOOL** | | | | | | | |
| 4701K | cotton wool roll, 100 g | ‡1 | 2 | .. | 10.72 | 5.90 | JJ 02013 | JJ |
| | **DRESSING ACTIVATED CHARCOAL MALODOROUS WOUND** | | | | | | | |
| 4742N | dressing activated charcoal malodorous wound 10 cm x 10 cm dressing, 10 | ‡1 | .. | .. | 79.19 | 5.90 | CarboFLEX 403202 | CC |
| 4681J | dressing activated charcoal malodorous wound 10.5 cm x 10.5 cm dressing, 1 | 10 | .. | .. | *101.13 | 5.90 | Actisorb Plus MAC031 | JJ |
| 4743P | dressing activated charcoal malodorous wound 15 cm x 20 cm dressing, 5 | ‡1 | .. | .. | 90.08 | 5.90 | CarboFLEX 403204 | CC |
| | **DRESSING ALGINATE CAVITY WOUND** | | | | | | | |
| | **Note** This dressing should be used only on moderately to heavily exuding wounds and should remain in place until saturated or for a maximum of 3 days. | | | | | | | |
| 4832H | DRESSING-ALGINATE (CAVITY WOUND) Rope 2 g, 1 | 10 | .. | .. | *109.33 | 5.90 | Sorbsan 1411 | UM |
| 1905G | DRESSING-ALGINATE (CAVITY WOUND) Rope 2 g, 5 | 2 | .. | .. | *115.47 | 5.90 | Kaltostat 168117 | CC |
| | **DRESSING ALGINATE CAVITY WOUND** | | | | | | | |
| | **Note** This dressing should be used only on moderately to heavily exuding wounds and should remain in place until saturated or for a maximum of 3 days. | | | | | | | |
| | **Note** Coloplast dressings are available via a range of distributors. However, Coloplast's principal agreement to ensure correct RPBS Price to Pharmacy and ready supply has been secured with Independence Australia on 1300 788 855 and BrightSky on 1300 290 400. Please note that Coloplast is unable to guarantee ready supply or rebate for price differences on purchases outside these distributors. | | | | | | | |

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|---|---|---|---|---|---|---|---|---|
| 4682K | dressing alginate cavity wound 2 g (40 cm) rope, 6 x 2 g | 2 | .. | .. | *137.93 | 5.90 | Comfeel SeaSorb Filler 3740 | CT |
| | **DRESSING ALGINATE SUPERFICIAL WOUND** | | | | | | | |
| | **Note** | | | | | | | |
| | This dressing should be used only on moderately to heavily exuding wounds and should remain in place until saturated or for a maximum of 3 days. | | | | | | | |
| | **Note** | | | | | | | |
| | Coloplast dressings are available via a range of distributors. However, Coloplast's principal agreement to ensure correct RPBS Price to Pharmacy and ready supply has been secured with Independence Australia on 1300 788 855 and BrightSky on 1300 290 400. Please note that Coloplast is unable to guarantee ready supply or rebate for price differences on purchases outside these distributors. | | | | | | | |
| 4831G | dressing alginate superficial wound 10 cm x 10 cm dressing, 1 | 10 | 1 | .. | *84.63 | 5.90 | Sorbsan 1410 | UM |
| | | | | .. | *90.33 | 5.90 | Comfeel SeaSorb Dressing 3710 | CT |
| 4684M | dressing alginate superficial wound 5 cm x 5 cm dressing, 1 | 10 | 1 | .. | *47.13 | 5.90 | Comfeel SeaSorb Dressing 3705 | CT |
| | **DRESSING ALGINATE SUPERFICIAL WOUND** | | | | | | | |
| | **Note** | | | | | | | |
| | This dressing should be used only on moderately to heavily exuding wounds and should remain in place until saturated or for a maximum of 3 days. | | | | | | | |
| | **Note** | | | | | | | |
| | Smith & Nephew products are distributed via the three major wholesalers, API, Sigma & Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS pricing from distributors other than those aforementioned. | | | | | | | |
| 4700J | dressing alginate superficial wound 10 cm x 10 cm dressing, 10 | ‡1 | 1 | .. | 98.63 | 5.90 | Algisite M 66000520 | SN |
| 4691X | dressing alginate superficial wound 15 cm x 20 cm dressing, 10 | ‡1 | 1 | .. | 236.28 | 5.90 | Algisite M 66000521 | SN |
| 4699H | dressing alginate superficial wound 5 cm x 5 cm dressing, 10 | ‡1 | 1 | .. | 49.61 | 5.90 | Kaltostat 168210 | CC |
| | | | | .. | 51.49 | 5.90 | Algisite M 66000519 | SN |
| | **DRESSING ALGINATE SUPERFICIAL WOUND** | | | | | | | |
| | **Note** | | | | | | | |
| | This dressing should be used only on moderately to heavily exuding wounds and should remain in place until saturated or for a maximum of 3 days. | | | | | | | |
| 4683L | dressing alginate superficial wound 7.5 cm x 12 cm dressing, 10 | ‡1 | 1 | .. | 91.29 | 5.90 | Kaltostat 168212 | CC |
| | **DRESSING FILM** | | | | | | | |
| | **Note** | | | | | | | |
| | Smith & Nephew products are distributed via the three major wholesalers, API, Sigma & Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS pricing from distributors other than those aforementioned. | | | | | | | |
| 4893M | dressing film 10 cm x 12 cm dressing, 10 | ‡1 | .. | .. | 32.70 | 5.90 | Op-Site Flexigrid 4629 | SN |
| | **DRESSING FILM** | | | | | | | |
| 4687Q | dressing film 10 cm x 12 cm dressing, 4 | ‡1 | .. | .. | 19.86 | 5.90 | Nexcare Tegaderm Transparent H1626 | MM |
| 4688R | dressing film 15 cm x 20 cm dressing, 1 | 6 | .. | .. | *30.87 | 5.90 | Tegaderm Transparent 1628 | MM |
| 4686P | dressing film 6 cm x 7 cm dressing, 8 | ‡1 | .. | .. | 15.85 | 5.90 | Nexcare Tegaderm Transparent H1624 | MM |
| | **DRESSING FILM ISLAND** | | | | | | | |
| 4689T | dressing film island 5 cm x 7 cm dressing, 1 | 10 | .. | .. | *16.43 | 5.90 | Tegaderm Transparent Island 3582 | MM |
| 4690W | dressing film island 9 cm x 10 cm dressing, 1 | 10 | .. | .. | *27.93 | 5.90 | Tegaderm Transparent Island 3586 | MM |
| | **DRESSING FILM ISLAND** | | | | | | | |
| | **Note** | | | | | | | |
| | Smith & Nephew products are distributed via the three major wholesalers, API, Sigma & Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS pricing from distributors other than those aforementioned. | | | | | | | |
| 4898T | dressing film island 5 cm x 7.2 cm dressing, 5 | 2 | .. | .. | *29.13 | 5.90 | Cutifilm Plus 36361370 | SN |
| 4899W | dressing film island 8 cm x 10 cm | 2 | .. | .. | *45.71 | 5.90 | Cutifilm Plus 36361371 | SN |

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| | dressing, 5 | | | | | | | |
| | **DRESSING FOAM HEAVY EXUDATE**<br>**Note**<br>This dressing should remain in place until saturated or up to a maximum of 7 days. Allow a minimum of 2 cm to 3 cm in excess of the wound size of the dressing around the wound.<br>**Note**<br>Smith & Nephew products are distributed via the three major wholesalers, API, Sigma & Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS pricing from distributors other than those aforementioned. | | | | | | | |
| 4795J | dressing foam heavy exudate 10 cm x 10 cm dressing, 10 | ǂ1 | 1 | .. | 75.27 | 5.90 | Lyofoam Extra 603088 | XP |
| | | | | .. | 126.88 | 5.90 | Allevyn 66007637 | SN |
| | **DRESSING FOAM HEAVY EXUDATE**<br>**Note**<br>This dressing should remain in place until saturated or up to a maximum of 7 days. Allow a minimum of 2 cm to 3 cm in excess of the wound size of the dressing around the wound. | | | | | | | |
| 4880W | dressing foam heavy exudate 20 cm x 15 cm dressing, 10 | ǂ1 | 1 | .. | 189.32 | 5.90 | Lyofoam Extra 603090 | XP |
| | **DRESSING FOAM MODERATE EXUDATE**<br>**Note**<br>This dressing should remain in place until saturated or up to a maximum of 7 days. Allow a minimum of 2 cm to 3 cm in excess of the wound size of the dressing around the wound. | | | | | | | |
| 4891K | dressing foam moderate exudate 10 cm x 10 cm dressing, 10 | ǂ1 | 1 | .. | 49.69 | 5.90 | Lyofoam Flat 603093 | XP |
| 4878R | dressing foam moderate exudate 20 cm x 15 cm dressing, 10 | ǂ1 | 1 | .. | 102.07 | 5.90 | Lyofoam Flat 603095 | XP |
| 4890J | dressing foam moderate exudate 7.5 cm x 7.5 cm dressing, 10 | ǂ1 | 1 | .. | 43.05 | 5.90 | Lyofoam Flat 603092 | XP |
| | **DRESSING FOAM MODERATE EXUDATE**<br>**Note**<br>This dressing should remain in place until saturated or up to a maximum of 7 days. Allow a minimum of 2 cm to 3 cm in excess of the wound size of the dressing around the wound.<br>**Note**<br>Smith & Nephew products are distributed via the three major wholesalers, API, Sigma & Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS pricing from distributors other than those aforementioned. | | | | | | | |
| 4590N | dressing foam moderate exudate 12.5 cm x 12.5 cm dressing, 10 | ǂ1 | .. | .. | 123.44 | 5.90 | Allevyn Adhesive 66000044 | SN |
| | **DRESSING FOAM MODERATE EXUDATE**<br>**Note**<br>Smith & Nephew products are distributed via the three major wholesalers, API, Sigma & Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS pricing from distributors other than those aforementioned. | | | | | | | |
| 4694C | dressing foam moderate exudate cavity conforming foam, 1 x 20 g sachet | 1 | 1 | .. | 88.94 | 5.90 | Cavicare 4563 | SN |
| | **DRESSING FOAM WITH CHARCOAL MALODOROUS WOUND**<br>**Note**<br>This dressing should remain in place on wounds with odour until saturated or up to a maximum of 7 days. Allow a minimum of 2 cm to 3 cm in excess of the wound size of the dressing around the wound. | | | | | | | |
| 4892L | dressing foam with charcoal malodorous wound 10 cm x 10 cm dressing, 10 | 2 | .. | .. | *174.27 | 5.90 | Lyofoam C 603025 | SS |
| | **DRESSING FOAM WITH SILICONE AND SILVER**<br>**Authority required**<br>Wound critical colonisation or chronic wounds that have not responded to conventional dressings<br>**The Clinical criteria is:**<br>Patient must have a wound where there is evidence of critical colonisation; OR<br>Patient must have a well-assessed chronic wound that has not responded to conventional dressings.<br>**Note** | | | | | | | |

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| | Molnlycke Health Care products are distributed through leading pharmacy distributors. To best ensure product availability at the RPBS agreed prices, special arrangements have been made with API and Independence Australia Health Solutions (IAHS). IAHS orders can be placed on: Tel: 1300 788 855; or Email: customerservice@independenceaustralia.com. Molnlycke Health Care is not able to ensure product availability or pricing on listed products beyond these two suppliers. | | | | | | | |
| 2439J | dressing foam with silicone and silver 10 cm x 10 cm dressing, 5 | ǂ1 | .. | .. | 109.51 | 5.90 | Mepilex Ag | MH |
| 2470B | dressing foam with silicone and silver 10 cm x 10 cm dressing, 5 | ǂ1 | .. | .. | 117.27 | 5.90 | Mepilex Border Ag | MH |
| | **DRESSING FOAM WITH SILICONE HEAVY EXUDATE** | | | | | | | |
| | **Note** | | | | | | | |
| | Smith & Nephew products are distributed via the three major wholesalers, API, Sigma & Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS pricing from distributors other than those aforementioned. | | | | | | | |
| 4196W | dressing foam with silicone heavy exudate 10 cm x 10 cm dressing, 10 | ǂ1 | .. | .. | 73.02 | 5.90 | Allevyn Gentle 66800248 | SN |
| 4230P | dressing foam with silicone heavy exudate 10 cm x 10 cm dressing, 10 | ǂ1 | .. | .. | 73.02 | 5.90 | Allevyn Gentle Border 66800270 | SN |
| 4207K | dressing foam with silicone heavy exudate 7.5 cm x 7.5 cm dressing, 10 | ǂ1 | .. | .. | 51.36 | 5.90 | Allevyn Gentle Border 66800269 | SN |
| | **DRESSING FOAM WITH SILICONE HEAVY EXUDATE** | | | | | | | |
| | **Note** | | | | | | | |
| | Molnlycke Healthcare products are distributed through leading pharmacy distributors. To best ensure product availability at RPBS agreed prices, special arrangements have been made with API and Independence Australia Health Solutions (IAHS). IAHS orders can be placed on: Tel: 1300 788 855; or Email customerservice@independenceaustralia.com. Molnlycke Healthcare are not able to ensure product availability or pricing on listed products beyond these two suppliers. | | | | | | | |
| 4643J | dressing foam with silicone heavy exudate 10 cm x 10 cm dressing, 5 | ǂ1 | .. | .. | 42.89 | 5.90 | Mepilex Border 295300 | MH |
| 4642H | dressing foam with silicone heavy exudate 7.5 cm x 7.5 cm dressing, 5 | ǂ1 | .. | .. | 30.98 | 5.90 | Mepilex Border 295200 | MH |
| | **DRESSING FOAM WITH SILICONE LIGHT EXUDATE** | | | | | | | |
| | **Note** | | | | | | | |
| | Molnlycke Healthcare products are distributed through leading pharmacy distributors. To best ensure product availability at RPBS agreed prices, special arrangements have been made with API and Independence Australia Health Solutions (IAHS). IAHS orders can be placed on: Tel: 1300 788 855; or Email customerservice@independenceaustralia.com. Molnlycke Healthcare are not able to ensure product availability or pricing on listed products beyond these two suppliers. | | | | | | | |
| 4645L | dressing foam with silicone light exudate 10 cm x 10 cm dressing, 5 | ǂ1 | .. | .. | 38.42 | 5.90 | Mepilex Lite 284100 | MH |
| 4644K | dressing foam with silicone light exudate 6 cm x 8.5 cm dressing, 5 | ǂ1 | .. | .. | 28.27 | 5.90 | Mepilex Lite 284000 | MH |
| | **DRESSING FOAM WITH SILICONE MODERATE EXUDATE** | | | | | | | |
| | **Note** | | | | | | | |
| | Molnlycke Healthcare products are distributed through leading pharmacy distributors. To best ensure product availability at RPBS agreed prices, special arrangements have been made with API and Independence Australia Health Solutions (IAHS). IAHS orders can be placed on: Tel: 1300 788 855; or Email customerservice@independenceaustralia.com. Molnlycke Healthcare are not able to ensure product availability or pricing on listed products beyond these two suppliers. | | | | | | | |
| 4626L | dressing foam with silicone moderate exudate 10 cm x 10 cm dressing, 5 | ǂ1 | .. | .. | 42.89 | 5.90 | Mepilex 294100 | MH |
| | **DRESSING FOAM WITH SILVER** | | | | | | | |
| | **Authority required** | | | | | | | |
| | For wounds where there is evidence of critical colonisation and for well-assessed chronic wounds that have not responded to conventional dressings | | | | | | | |
| | **Note** | | | | | | | |
| | Smith & Nephew products are distributed via the three major wholesalers, API, Sigma & Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS pricing from distributors other than those aforementioned. | | | | | | | |
| 4255Y | dressing foam with silver 10 cm x 10 cm dressing, 10 | ǂ1 | .. | .. | 200.78 | 5.90 | Allevyn Ag Adhesive 66800075 | SN |
| 4259E | dressing foam with silver 10 cm x 10 cm dressing, 10 | ǂ1 | .. | .. | 204.63 | 5.90 | Allevyn Ag Non-Adhesive 66800086 | SN |
| 4266M | dressing foam with silver 10 cm x 10 cm dressing, 10 | ǂ1 | .. | .. | 200.78 | 5.90 | Allevyn Ag Gentle Border 66800461 | SN |
| 4258D | dressing foam with silver 12.5 cm x 12.5 cm dressing, 10 | ǂ1 | .. | .. | 245.26 | 5.90 | Allevyn Ag Adhesive 66800078 | SN |

# VARIOUS

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|
| 4270R | dressing foam with silver 12.5 cm x 12.5 cm dressing, 10 | ‡1 | .. | .. | 245.26 | 5.90 | Allevyn Ag Gentle Border 66800462 | SN |
| 4252T | dressing foam with silver 7.5 cm x 7.5 cm dressing, 10 | ‡1 | .. | .. | 135.10 | 5.90 | Allevyn Ag Adhesive 66800073 | SN |
| 4263J | dressing foam with silver 7.5 cm x 7.5 cm dressing, 10 | ‡1 | .. | .. | 135.10 | 5.90 | Allevyn Ag Gentle Border 66800460 | SN |
| | **DRESSING GAUZE ABSORBENT** | | | | | | | |
| 4708T | dressing gauze absorbent 10 cm x 10 cm pad, 100 | ‡1 | .. | .. | 27.61 | 5.90 | Handy 71117-06 | BV |
| 4707R | dressing gauze absorbent 5 cm x 5 cm pad, 100 | ‡1 | .. | .. | 14.09 | 5.90 | Handy 71117-05 | BV |
| | **DRESSING GAUZE EYE** | | | | | | | |
| 4768Y | dressing gauze eye pad, 12 | ‡1 | .. | .. | 13.04 | 5.90 | Curity 4112 | KE |
| | **DRESSING GAUZE PARAFFIN** | | | | | | | |
| | **Note** | | | | | | | |
| | Smith & Nephew products are distributed via the three major wholesalers, API, Sigma & Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS pricing from distributors other than those aforementioned. | | | | | | | |
| 4759L | dressing gauze paraffin 10 cm x 10 cm dressing, 10 | ‡1 | .. | .. | 20.14 | 5.90 | Jelonet 7404 | SN |
| | **DRESSING GAUZE PARAFFIN WITH CHLORHEXIDINE ACETATE** | | | | | | | |
| | **Note** | | | | | | | |
| | Smith & Nephew products are distributed via the three major wholesalers, API, Sigma & Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS pricing from distributors other than those aforementioned. | | | | | | | |
| 4845B | dressing gauze paraffin with chlorhexidine acetate 10 cm x 10 cm dressing, 10 | ‡1 | 2 | .. | 27.24 | 5.90 | Bactigras 7457 | SN |
| | **DRESSING HYDROACTIVE CAVITY WOUND** | | | | | | | |
| | **Note** | | | | | | | |
| | Smith & Nephew products are distributed via the three major wholesalers, API, Sigma & Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS pricing from distributors other than those aforementioned. | | | | | | | |
| 4919X | dressing hydroactive cavity wound 10 cm x 10 cm dressing, 5 | 2 | 1 | .. | *187.15 | 5.90 | Allevyn Plus Cavity 66047573 | SN |
| 4918W | dressing hydroactive cavity wound 5 cm x 6 cm dressing, 10 | ‡1 | 1 | .. | 88.71 | 5.90 | Allevyn Plus Cavity 66047571 | SN |
| | **DRESSING HYDROACTIVE DEBRIDEMENT** | | | | | | | |
| | **Note** | | | | | | | |
| | Hartmann wound dressings are available through HARTMANN and Independence Australia only. If you would like to order Hartmann Wound Care products, please call HARTMANN customer service on 1800 805 839 or Independence Australia on 1300 788 855. | | | | | | | |
| 4949L | DRESSING-HYDROACTIVE (DEBRIDEMENT) Dressings 4 cm, 10, 1 | ‡1 | .. | .. | 85.09 | 5.90 | TenderWet 24 Active 609210 | HR |
| 4948K | DRESSING-HYDROACTIVE (DEBRIDEMENT) Dressings 5.5 cm, 10, 1 | ‡1 | .. | .. | 87.14 | 5.90 | TenderWet Active Cavity 609272 | HR |
| 4950M | DRESSING-HYDROACTIVE (DEBRIDEMENT) Dressings 7.5 cm x 7.5 cm, 10, 1 | ‡1 | .. | .. | 115.45 | 5.90 | TenderWet 24 Active 609213 | HR |
| | **DRESSING HYDROACTIVE SUPERFICIAL WOUND HIGH EXUDATE SEMI-PERMEABLE ABSORBENT FOAM** | | | | | | | |
| 4692Y | dressing hydroactive superficial wound high exudate semi-permeable absorbent foam 10 cm x 10 cm (foam alternative) dressing, 10 | ‡1 | .. | .. | 55.11 | 5.90 | CombiDERM 651031 | CC |
| 4695D | dressing hydroactive superficial wound high exudate semi-permeable absorbent foam 11 cm x 11 cm dressing: island, 10 dressings | ‡1 | .. | .. | 111.45 | 5.90 | Tielle MTL101E | JJ |
| 4693B | dressing hydroactive superficial wound high exudate semi-permeable absorbent foam 15 cm x 18 cm (foam alternative) dressing, 5 | ‡1 | .. | .. | 71.93 | 5.90 | CombiDERM 651027 | CC |

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|---|---|---|---|---|---|---|---|---|
| 4696E | dressing hydroactive superficial wound high exudate semi-permeable absorbent foam 18 cm x 18 cm dressing: island, 5 dressings | ‡1 | .. | .. | 136.05 | 5.90 | Tielle MT2442 | JJ |
| | **DRESSING HYDROACTIVE SUPERFICIAL WOUND HIGH EXUDATE SEMI-PERMEABLE ABSORBENT FOAM** | | | | | | | |
| | **Note** | | | | | | | |
| | Coloplast dressings are available via a range of distributors. However, Coloplast's principal agreement to ensure correct RPBS Price to Pharmacy and ready supply has been secured with Independence Australia on 1300 788 855 and BrightSky on 1300 290 400. Please note that Coloplast is unable to guarantee ready supply or rebate for price differences on purchases outside these distributors. | | | | | | | |
| 4927H | dressing hydroactive superficial wound high exudate semi-permeable absorbent foam 10 cm x 10 cm pad: waterproof, 10 pads | ‡1 | 1 | .. | 88.14 | 5.90 | Biatain Non-adhesive 3410 | CT |
| 4929K | dressing hydroactive superficial wound high exudate semi-permeable absorbent foam 12 cm x 12 cm pad: waterproof, 10 pads | ‡1 | 1 | .. | 97.16 | 5.90 | Biatain Adhesive 3420 | CT |
| 4928J | dressing hydroactive superficial wound high exudate semi-permeable absorbent foam 15 cm x 15 cm pad: waterproof, 5 pads | ‡1 | 2 | .. | 86.66 | 5.90 | Biatain Non-adhesive 3413 | CT |
| 4930L | dressing hydroactive superficial wound high exudate semi-permeable absorbent foam 18 cm x 18 cm pad: waterproof, 5 pads | ‡1 | 2 | .. | 94.03 | 5.90 | Biatain Adhesive 3423 | CT |
| | **DRESSING HYDROACTIVE SUPERFICIAL WOUND LIGHT EXUDATE** | | | | | | | |
| | **Note** | | | | | | | |
| | Smith & Nephew products are distributed via the three major wholesalers, API, Sigma & Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS pricing from distributors other than those aforementioned. | | | | | | | |
| 4906F | dressing hydroactive superficial wound light exudate 10 cm x 10 cm dressing, 5 | 2 | 1 | .. | *108.53 | 5.90 | Allevyn Thin 66047578 | SN |
| 4905E | dressing hydroactive superficial wound light exudate 5 cm x 6 cm dressing, 10 | ‡1 | 1 | .. | 59.39 | 5.90 | Allevyn Thin 66047576 | SN |
| | **DRESSING HYDROACTIVE SUPERFICIAL WOUND MODERATE EXUDATE** | | | | | | | |
| | **Note** | | | | | | | |
| | Smith & Nephew products are distributed via the three major wholesalers, API, Sigma & Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS pricing from distributors other than those aforementioned. | | | | | | | |
| 4886E | dressing hydroactive superficial wound moderate exudate 10 cm x 10 cm dressing, 5 | 2 | 1 | .. | *79.65 | 5.90 | Cutinova Hydro 66047443 | SN |
| 4885D | dressing hydroactive superficial wound moderate exudate 5 cm x 6 cm dressing, 10 | ‡1 | 1 | .. | 48.10 | 5.90 | Cutinova Hydro 66047441 | SN |
| | **DRESSING HYDROCOLLOID CAVITY WOUND** | | | | | | | |
| | **Note** | | | | | | | |
| | This dressing should remain in place until saturated or strike through occurs for a maximum of 7 days. | | | | | | | |
| 4896Q | dressing hydrocolloid cavity wound paste, 30 g | 10 | .. | .. | *145.33 | 5.90 | DuoDERM Paste H7930 | CC |
| | **DRESSING HYDROCOLLOID CAVITY WOUND** | | | | | | | |
| | **Note** | | | | | | | |
| | This dressing should remain in place until saturated or strike through occurs for a maximum of 7 days. | | | | | | | |
| | **Note** | | | | | | | |
| | Coloplast dressings are available via a range of distributors. However, Coloplast's principal agreement to ensure correct RPBS Price to Pharmacy and ready supply has been secured with Independence Australia on 1300 788 855 and BrightSky on 1300 290 400. Please note that Coloplast is unable to guarantee ready supply or rebate for price differences on purchases outside these distributors. | | | | | | | |
| 4895P | dressing hydrocolloid cavity wound paste, 50 g | 2 | 3 | .. | *43.43 | 5.90 | Comfeel Paste 4701 | CT |
| | **DRESSING HYDROCOLLOID SUPERFICIAL WOUND LIGHT EXUDATE** | | | | | | | |
| | **Note** | | | | | | | |

# VARIOUS

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|---|---|---|---|---|---|---|---|---|
| | This dressing should be applied to a thickness of 3 mm to 5 mm. It should be covered with a hydrocolloid dressing and may be left in place for up to 7 days. | | | | | | | |
| 4907G | dressing hydrocolloid superficial wound light exudate 10 cm x 10 cm dressing, 10 | ‡1 | 1 | .. | 71.93 | 5.90 | DuoDERM Extra Thin H7955 | CC |

**DRESSING HYDROCOLLOID SUPERFICIAL WOUND LIGHT EXUDATE**

**Note**

This dressing should be applied to a thickness of 3 mm to 5 mm. It should be covered with a hydrocolloid dressing and may be left in place for up to 7 days.

**Note**

Coloplast dressings are available via a range of distributors. However, Coloplast's principal agreement to ensure correct RPBS Price to Pharmacy and ready supply has been secured with Independence Australia on 1300 788 855 and BrightSky on 1300 290 400. Please note that Coloplast is unable to guarantee ready supply or rebate for price differences on purchases outside these distributors.

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 4924E | dressing hydrocolloid superficial wound light exudate 10 cm x 10 cm dressing, 10 | ‡1 | 1 | .. | 69.99 | 5.90 | Comfeel Plus Transparent 3533 | CT |
| 4888G | dressing hydrocolloid superficial wound light exudate 5 cm x 7 cm dressing, 10 | ‡1 | 1 | .. | 41.93 | 5.90 | Comfeel Plus Transparent 3530 | CT |
| 4889H | dressing hydrocolloid superficial wound light exudate 9 cm x 14 cm dressing, 10 | ‡1 | 1 | .. | 84.73 | 5.90 | Comfeel Plus Transparent 3536 | CT |

**DRESSING HYDROCOLLOID SUPERFICIAL WOUND LIGHT EXUDATE**

**Note**

This dressing should be applied to a thickness of 3 mm to 5 mm. It should be covered with a hydrocolloid dressing and may be left in place for up to 7 days.

**Note**

Hartmann wound dressings are available through HARTMANN and Independence Australia only. If you would like to order Hartmann Wound Care products, please call HARTMANN customer service on 1800 805 839 or Independence Australia on 1300 788 855.

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 4947J | dressing hydrocolloid superficial wound light exudate 10 cm x 10 cm dressing, 10 | ‡1 | 1 | .. | 48.36 | 5.90 | Hydrocoll Thin 900758 | HR |

**DRESSING HYDROCOLLOID SUPERFICIAL WOUND MODERATE EXUDATE**

**Note**

This dressing should remain in place until saturated or strike through occurs for a maximum of 7 days.

**Note**

Coloplast dressings are available via a range of distributors. However, Coloplast's principal agreement to ensure correct RPBS Price to Pharmacy and ready supply has been secured with Independence Australia on 1300 788 855 and BrightSky on 1300 290 400. Please note that Coloplast is unable to guarantee ready supply or rebate for price differences on purchases outside these distributors.

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 4923D | DRESSING-HYDROCOLLOID (SUPERFICIAL WOUND-MODERATE EXUDATE) Dressings with alginate 10 cm x 10 cm, 10, 1 | ‡1 | 1 | .. | 82.21 | 5.90 | Comfeel Plus Ulcer Dressing 3110 | CT |
| 4679G | dressing hydrocolloid superficial wound moderate exudate 10 cm (round) dressing, 1 | 5 | .. | .. | *59.83 | 5.90 | Comfeel Plus Pressure Relieving 3353 | CT |
| 4678F | dressing hydrocolloid superficial wound moderate exudate 7 cm (butterfly shape) dressing, 1 | 5 | .. | .. | *55.38 | 5.90 | Comfeel Plus Pressure Relieving 3350 | CT |

**DRESSING HYDROCOLLOID SUPERFICIAL WOUND MODERATE EXUDATE**

**Note**

This dressing should remain in place until saturated or strike through occurs for a maximum of 7 days.

**Note**

Smith & Nephew products are distributed via the three major wholesalers, API, Sigma & Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS pricing from distributors other than those aforementioned.

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 4921B | dressing hydrocolloid superficial wound moderate exudate 10 cm x 10 cm dressing, 10 | ‡1 | 1 | .. | 80.51 | 5.90 | Replicare Ultra 66000434 | SN |

**DRESSING HYDROCOLLOID SUPERFICIAL WOUND MODERATE EXUDATE**

**Note**

This dressing should remain in place until saturated or strike through occurs for a maximum of 7 days.

# VARIOUS

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|---|---|---|---|---|---|---|---|---|
| | **Note** | | | | | | | |
| | Hartmann wound dressings are available through HARTMANN and Independence Australia only. If you would like to order Hartmann Wound Care products, please call HARTMANN customer service on 1800 805 839 or Independence Australia on 1300 788 855. | | | | | | | |
| 4945G | dressing hydrocolloid superficial wound moderate exudate 10 cm x 10 cm dressing, 10 | ‡1 | 1 | .. | 48.36 | 5.90 | Hydrocoll 900744 | HR |
| 4946H | dressing hydrocolloid superficial wound moderate exudate 15 cm x 15 cm dressing, 10 | ‡1 | 1 | .. | 90.12 | 5.90 | Hydrocoll 900936 | HR |
| | **DRESSING HYDROCOLLOID SUPERFICIAL WOUND MODERATE EXUDATE** | | | | | | | |
| | **Note** | | | | | | | |
| | This dressing should remain in place until saturated or strike through occurs for a maximum of 7 days. | | | | | | | |
| 4897R | dressing hydrocolloid superficial wound moderate exudate 10 cm x 10 cm dressing, 5 | 2 | 1 | .. | *81.61 | 5.90 | DuoDERM CGF H7660 | CC |
| 4920Y | dressing hydrocolloid superficial wound moderate exudate 20 cm x 20 cm dressing, 5 | 2 | 1 | .. | *222.53 | 5.90 | DuoDERM CGF H7662 | CC |
| | **DRESSING HYDROFIBRE ALTERNATE TO ALGINATES** | | | | | | | |
| 4649Q | dressing hydrofibre alternate to alginates 10 cm x 10 cm dressing, 10 | ‡1 | 1 | .. | 101.19 | 5.90 | Aquacel 177902 | CC |
| 4922C | dressing hydrofibre alternate to alginates 15 cm x 15 cm dressing, 5 | 2 | 1 | .. | *208.91 | 5.90 | Aquacel 177903 | CC |
| 4698G | dressing hydrofibre alternate to alginates 2 g (30 cm) rope, 5 x 2 g | ‡1 | 1 | .. | 83.92 | 5.90 | Aquacel 177904 | CC |
| | **DRESSING HYDROFIBRE GELLING FIBRE** | | | | | | | |
| | **Note** | | | | | | | |
| | Smith & Nephew products are distributed via the three major wholesalers, API, Sigma and Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS agreed pricing from distributors other than those aforementioned. | | | | | | | |
| 2486W | dressing hydrofibre gelling fibre 10 cm x 10 cm dressing, 10 | ‡1 | 1 | .. | 95.69 | 5.90 | Durafiber 66800560 | SN |
| 2445Q | dressing hydrofibre gelling fibre 15 cm x 15 cm dressing, 5 | ‡2 | 1 | .. | *199.03 | 5.90 | Durafiber 66800561 | SN |
| 2462N | dressing hydrofibre gelling fibre 2 cm x 45 cm rope, 5 | ‡1 | 1 | .. | 79.91 | 5.90 | Durafiber 66800563 | SN |
| | **DRESSING HYDROGEL** | | | | | | | |
| 2471C | dressing hydrogel 10 cm x 10 cm dressing, 20 | 1 | .. | .. | 114.25 | 5.90 | Sorbact Absorption Dressing S98222 | QL |
| | **DRESSING HYDROGEL AMORPHOUS** | | | | | | | |
| | **Note** | | | | | | | |
| | This dressing should be applied to a thickness of 3 mm to 5 mm and remain in situ in infected wounds for 24 hours and in clean wounds for up to 3 days. It should be covered with a secondary dressing such as foam or film. It should not be covered with gauze or combine. | | | | | | | |
| | **Note** | | | | | | | |
| | Coloplast dressings are available via a range of distributors. However, Coloplast's principal agreement to ensure correct RPBS Price to Pharmacy and ready supply has been secured with Independence Australia on 1300 788 855 and BrightSky on 1300 290 400. Please note that Coloplast is unable to guarantee ready supply or rebate for price differences on purchases outside these distributors. | | | | | | | |
| 4912M | dressing hydrogel amorphous gel, 10 x 15 g tubes | ‡1 | 1 | .. | 64.69 | 5.90 | DuoDERM Gel H7990 | CC |
| | | | | .. | 72.30 | 5.90 | Comfeel Purilon Gel 3900 | CT |
| | **DRESSING HYDROGEL AMORPHOUS** | | | | | | | |
| | **Note** | | | | | | | |
| | This dressing should be applied to a thickness of 3 mm to 5 mm and remain in situ in infected wounds for 24 hours and in clean wounds for up to 3 days. It should be covered with a secondary dressing such as foam or film. It should not be covered with gauze or combine. | | | | | | | |
| | **Note** | | | | | | | |
| | Smith & Nephew products are distributed via the three major wholesalers, API, Sigma & Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS pricing from distributors other than those aforementioned. | | | | | | | |
| 4894N | dressing hydrogel amorphous gel, 25 g | 4 | 3 | .. | *62.39 | 5.90 | Intrasite Gel 7313 | SN |
| 4599C | dressing hydrogel amorphous gel, 50 g | 3 | 3 | .. | *30.72 | 5.90 | SoloSite Gel 36361338 | SN |

# VARIOUS

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|---|---|---|---|---|---|---|---|---|
| | **DRESSING HYDROGEL AMORPHOUS** | | | | | | | |
| | **Note**<br>This dressing should be applied to a thickness of 3 mm to 5 mm and remain in situ in infected wounds for 24 hours and in clean wounds for up to 3 days. It should be covered with a secondary dressing such as foam or film. It should not be covered with gauze or combine. | | | | | | | |
| 4913N | dressing hydrogel amorphous gel, 3 x 30 g tubes | 3 | 1 | .. | *97.32 | 5.90 | DuoDERM Gel H7987 | CC |
| 4914P | dressing hydrogel amorphous gel, 50 g | 3 | 3 | .. | *33.33 | 5.90 | Solugel 10336 | JJ |
| | **DRESSING HYDROGEL FOAM** | | | | | | | |
| 2533H | dressing hydrogel foam 10 cm x 10 cm dressing, 10 | 1 | .. | .. | 79.66 | 5.90 | Sorbact Foam Dressing S98310 | QL |
| | **DRESSING HYDROGEL RIBBON** | | | | | | | |
| 2512F | dressing hydrogel ribbon 1 cm x 50 cm dressing, 20 | 1 | .. | .. | 118.10 | 5.90 | Sorbact Ribbon Gauze S98118 | QL |
| 2529D | dressing hydrogel ribbon 5 cm x 200 cm dressing, 10 | 1 | .. | .. | 114.25 | 5.90 | Sorbact Ribbon Gauze S98120 | QL |
| | **DRESSING HYDROGEL SHEET** | | | | | | | |
| | **Note**<br>This dressing should be applied to a thickness of 3 mm to 5 mm and remain in situ in infected wounds for 24 hours and in clean wounds for up to 3 days. It should be covered with a secondary dressing such as foam or film. It should not be covered with gauze or combine. | | | | | | | |
| | **Note**<br>Hartmann wound dressings are available through HARTMANN and Independence Australia only. If you would like to order Hartmann Wound Care products, please call HARTMANN customer service on 1800 805 839 or Independence Australia on 1300 788 855. | | | | | | | |
| 4806Y | dressing hydrogel sheet 10 cm x 10 cm dressing, 5 | 2 | .. | .. | *53.49 | 5.90 | Aquaclear 900796 | HR |
| | **DRESSING HYDROGEL SHEET** | | | | | | | |
| | **Note**<br>This dressing should be applied to a thickness of 3 mm to 5 mm and remain in situ in infected wounds for 24 hours and in clean wounds for up to 3 days. It should be covered with a secondary dressing such as foam or film. It should not be covered with gauze or combine. | | | | | | | |
| 4911L | dressing hydrogel sheet 9.5 cm x 10.2 cm dressing, 5 | 2 | .. | .. | *83.41 | 5.90 | Nu-Gel 2497 | JJ |
| | **DRESSING NON ADHERENT** | | | | | | | |
| | **Note**<br>Molnlycke Healthcare products are distributed through leading pharmacy distributors. To best ensure product availability at RPBS agreed prices, special arrangements have been made with API and Independence Australia Health Solutions (IAHS). IAHS orders can be placed on: Tel: 1300 788 855; or Email customerservice@independenceaustralia.com. Molnlycke Healthcare are not able to ensure product availability or pricing on listed products beyond these two suppliers. | | | | | | | |
| 4243H | DRESSING SELF ADHESIVE NON-ADHERENT DRY ABSORBENT Dressings, non-woven, with silicone 5 cm x 7.5 cm, 10, 1 | ‡1 | .. | .. | 63.83 | 5.90 | Mepitel 290510 | MH |
| 4244J | DRESSING SELF ADHESIVE NON-ADHERENT DRY ABSORBENT Dressings, non-woven, with silicone 7.5 cm x 10 cm, 10, 1 | ‡1 | .. | .. | 107.83 | 5.90 | Mepitel 290710 | MH |
| | **DRESSING NON ADHERENT** | | | | | | | |
| | **Note**<br>Smith & Nephew products are distributed via the three major wholesalers, API, Sigma & Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS pricing from distributors other than those aforementioned. | | | | | | | |
| 4861W | dressing non adherent 10 cm x 10 cm dressing, 10 | ‡1 | .. | .. | 33.91 | 5.90 | Melolin 66974933 | SN |
| 4862X | dressing non adherent 10 cm x 10 cm dressing, 5 | 2 | .. | .. | *25.61 | 5.90 | Cutilin Non-Stick Wound Pad 36361375 | SN |
| 4819P | dressing non adherent 5 cm x 5 cm dressing, 5 | 2 | .. | .. | *16.01 | 5.90 | Cutilin Non-Stick Wound Pad 36361374 | SN |
| 4860T | dressing non adherent 5 cm x 5 cm dressing, 5 | 2 | .. | .. | *16.69 | 5.90 | Melolin 36361357 | SN |
| | **DRESSING NON ADHERENT** | | | | | | | |

# VARIOUS

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|
| 4755G | dressing non adherent 5 cm x 7.5 cm dressing, 10 | ǂ1 | .. | .. | 11.23 | 5.90 | Telfa 1970C | KE |
| 4758K | dressing non adherent 7.5 cm x 10 cm self adhesive dressing, 6 | ǂ1 | .. | .. | 11.44 | 5.90 | Telfa 2140C | KE |
| 4844Y | dressing non adherent 7.5 cm x 10 cm self adhesive dressing, 6 | ǂ1 | 2 | .. | 12.23 | 5.90 | Telfa 7650C | KE |
| | **DRESSING NON ADHERENT** | | | | | | | |
| | **Note** | | | | | | | |
| | Hartmann wound dressings are available through HARTMANN and Independence Australia only. If you would like to order Hartmann Wound Care products, please call HARTMANN customer service on 1800 805 839 or Independence Australia on 1300 788 855. | | | | | | | |
| 4944F | dressing non adherent 7.5 cm x 10 cm dressing, 10 | ǂ1 | .. | .. | 15.45 | 5.90 | Atrauman 499513 | HR |
| | **DRESSING TULLE NON GAUZE PARAFFIN** | | | | | | | |
| 4909J | dressing tulle non gauze paraffin 7.6 cm x 7.6 cm dressing, 1 | 10 | 1 | .. | *15.93 | 5.90 | Adaptic 2012 | JJ |
| | **DRESSING WITH SILVER** | | | | | | | |
| | **Authority required** | | | | | | | |
| | For wounds where there is evidence of critical colonisation and for well-assessed chronic wounds that have not responded to conventional dressings | | | | | | | |
| | **Note** | | | | | | | |
| | Coloplast dressings are available via a range of distributors. However, Coloplast's principal agreement to ensure correct RPBS Price to Pharmacy and ready supply has been secured with Independence Australia on 1300 788 855 and BrightSky on 1300 290 400. Please note that Coloplast is unable to guarantee ready supply or rebate for price differences on purchases outside these distributors. | | | | | | | |
| 4646M | dressing with silver 10 cm x 10 cm dressing: hydroactive, 5 dressings | ǂ1 | .. | .. | 176.09 | 5.90 | Biatain Ag 9622 | CT |
| 4647N | dressing with silver 12.5 cm x 12.5 cm dressing: hydroactive, 5 dressings | ǂ1 | .. | .. | 191.50 | 5.90 | Biatain Ag 9632 | CT |
| | **DRESSING WITH SILVER** | | | | | | | |
| | **Authority required** | | | | | | | |
| | For wounds where there is evidence of critical colonisation and for well-assessed chronic wounds that have not responded to conventional dressings | | | | | | | |
| | **Note** | | | | | | | |
| | Hartmann wound dressings are available through HARTMANN and Independence Australia only. If you would like to order Hartmann Wound Care products, please call HARTMANN customer service on 1800 805 839 or Independence Australia on 1300 788 855. | | | | | | | |
| 4648P | dressing with silver 10 cm x 10 cm dressing: tulle, 3 dressings | ǂ1 | .. | .. | 43.99 | 5.90 | Atrauman Ag 499572 | HR |
| | **GAUZE AND COTTON TISSUE COMBINE ROLL** | | | | | | | |
| 4761N | gauze and cotton tissue combine roll 10 cm x 10 m roll: wrapped pack, 1 pack | ǂ1 | .. | .. | 17.42 | 5.90 | JJ 12010 | JJ |
| 4767X | gauze and cotton tissue combine roll 9 cm x 10 m roll: wrapped pack, 1 pack | ǂ1 | .. | .. | 15.60 | 5.90 | BSN 2902165 | BV |
| | **TAPE NON WOVEN RETENTION POLYACRYLATE** | | | | | | | |
| | **Note** | | | | | | | |
| | Molnlycke Healthcare products are distributed through leading pharmacy distributors. To best ensure product availability at RPBS agreed prices, special arrangements have been made with API and Independence Australia Health Solutions (IAHS). IAHS orders can be placed on: Tel: 1300 788 855; or Email customerservice@independenceaustralia.com. Molnlycke Healthcare are not able to ensure product availability or pricing on listed products beyond these two suppliers. | | | | | | | |
| 4917T | tape non woven retention polyacrylate 2.5 cm x 10 m tape, 1 roll | ǂ1 | .. | .. | 11.25 | 5.90 | Mefix 310250 | MH |
| | **TAPE NON WOVEN RETENTION POLYACRYLATE** | | | | | | | |
| 4915Q | tape non woven retention polyacrylate 2.5 cm x 9.1 m tape, 1 roll | ǂ1 | .. | .. | 13.08 | 5.90 | Medipore 2961 | MM |
| | **TAPE PLASTER ADHESIVE ELASTIC** | | | | | | | |
| 4780N | tape plaster adhesive elastic 2.5 cm x 2.5 m tape, 1 roll | ǂ1 | .. | .. | 12.97 | 5.90 | Leukoplast 01071-00 | BV |
| 4781P | tape plaster adhesive elastic 5 cm x 2.5 m tape, 1 roll | ǂ1 | .. | .. | 18.77 | 5.90 | Leukoplast 01072-00 | BV |
| 4782Q | tape plaster adhesive elastic 7.5 cm x 2.5 m tape, 1 roll | ǂ1 | .. | .. | 22.34 | 5.90 | Leukoplast 01073-00 | BV |
| | **TAPE PLASTER ADHESIVE HYPOALLERGENIC** | | | | | | | |
| 4783R | tape plaster adhesive hypoallergenic | ǂ1 | .. | .. | 10.55 | 5.90 | Leukopor 2471 | BV |

# VARIOUS

| Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | Brand Name and Manufacturer | |
|---|---|---|---|---|---|---|---|---|
| | 1.25 cm x 5 m tape, 1 roll | | | | | | | |
| 4785W | tape plaster adhesive hypoallergenic 1.25 cm x 5 m tape, 1 roll | ǂ1 | .. | .. | 10.82 | 5.90 | Leukosilk 1021 | BV |
| 4848E | tape plaster adhesive hypoallergenic 1.9 cm x 5.4 m dispenser tape, 1 roll | ǂ1 | .. | .. | 11.26 | 5.90 | Nexcare Durable Cloth First Aid Tape 799 | MM |
| 4849F | tape plaster adhesive hypoallergenic 1.9 cm x 7.3 m dispenser tape, 1 roll | ǂ1 | .. | .. | 11.26 | 5.90 | Nexcare Gentle Paper First Aid Tape 789 | MM |
| 4787Y | tape plaster adhesive hypoallergenic 2.5 cm x 5 m tape, 1 roll | ǂ1 | .. | .. | 13.46 | 5.90 | Leukosilk 1022 | BV |
| 4794H | tape plaster adhesive hypoallergenic 2.5 cm x 5 m tape, 1 roll | ǂ1 | .. | .. | 12.94 | 5.90 | Leukopor 2472 | BV |
| 4788B | tape plaster adhesive hypoallergenic 5 cm x 5 m stretch tape, 1 roll | ǂ1 | .. | .. | 17.42 | 5.90 | Leukoflex 1124 | BV |
| 4789C | tape plaster adhesive hypoallergenic 5 cm x 5 m stretch tape, 1 roll | ǂ1 | .. | .. | 17.26 | 5.90 | Leukosilk 1024 | BV |
| 4790D | tape plaster adhesive hypoallergenic 5 cm x 5 m stretch tape, 1 roll | ǂ1 | .. | .. | 16.41 | 5.90 | Leukopor 2474 | BV |

**TAPE PLASTER ADHESIVE WITH SILICONE**

**Note**

Molnlycke Healthcare products are distributed through leading pharmacy distributors. To best ensure product availability at RPBS agreed prices, special arrangements have been made with API and Independence Australia Health Solutions (IAHS). IAHS orders can be placed on: Tel: 1300 788 855; or Email customerservice@independenceaustralia.com. Molnlycke Healthcare are not able to ensure product availability or pricing on listed products beyond these two suppliers.

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 4239D | tape plaster adhesive with silicone 2 cm x 3 m tape, 1 roll | ǂ1 | .. | .. | 21.58 | 5.90 | Mepitac 298300 | MH |
| 4240E | tape plaster adhesive with silicone 4 cm x 1.5 m tape, 1 roll | ǂ1 | .. | .. | 21.58 | 5.90 | Mepitac 298400 | MH |

# Section 2

## Standard Packs and Prices

**NOTE—**

*Standard packs and prices (including mark-up, but without dispensing fee and dangerous drug fee) are for items against the price of which an asterisk (*) is shown in Section 1 of the Schedule.*

# (APPLY WASTAGE FACTOR IN CALCULATING BROKEN QUANTITY PRICES)

| Code | Name, Form/Strength | Pack and | Price | Manufacturer |
|---|---|---|---|---|
| 4579B | **alprostadil 10 microgram injection [2 x 10 microgram syringes] (&) inert substance diluent [2 x 0.6 mL syringes], 1 pack** | 2@ | 33.02 | PF |
| 4580C | **alprostadil 20 microgram injection [2 x 20 microgram syringes] (&) inert substance diluent [2 x 0.6 mL syringes], 1 pack** | 2@ | 42.13 | PF |
| 4118R | **ALUMINIUM HYDROXIDE with MAGNESIUM HYDROXIDE and SIMETHICONE Oral suspension 400 mg-400 mg-30 mg per 5 mL, 500 mL, 1** | 1@ | 8.11 | JT |
| 4453J | **ALUMINIUM HYDROXIDE with MAGNESIUM HYDROXIDE and SIMETHICONE Tablet 400 mg-400 mg-40 mg, 100** | 100@ | 19.85 | JT |
| 4657D | **bandage compression 10 cm x 3.5 m bandage: high stretch, 1 bandage** | 1@ | 14.43 | MH |
| 4748X | **bandage compression 10 cm x 3 m bandage: high stretch, 1 bandage** | 1@ | 13.30 | CC |
| 4748X | **bandage compression 10 cm x 3 m bandage: high stretch, 1 bandage** | 1@ | 24.04 | BV |
| 4656C | **bandage compression 7.5 cm x 3.5 m bandage: high stretch, 1 bandage** | 1@ | 12.39 | SS |
| 4736G | **bandage compression 7.5 cm x 3 m bandage: high stretch, 1 bandage** | 1@ | 17.58 | BV |
| 4654Y | **BANDAGE-COMPRESSION Bandage, short stretch, 8 cm x 2.6 m, 1** | 1@ | 14.27 | BV |
| 4598B | **bandage compression bandage: four layer, 1 bandage** | 1@ | 29.24 | SN |
| 4658E | | 1@ | 43.60 | SN |
| 4813H | **bandage retention cohesive heavy 10 cm x 1.3 m bandage, 1** | 1@ | 7.33 | MM |
| 4660G | **bandage retention cohesive heavy 10 cm x 2 m bandage, 1** | 1@ | 6.47 | MM |
| 4814J | **bandage retention cohesive heavy 15 cm x 1.3 m bandage, 1** | 1@ | 10.88 | MM |
| 4811F | **bandage retention cohesive heavy 5 cm x 1.3 m bandage, 1** | 1@ | 3.80 | MM |
| 4812G | **bandage retention cohesive heavy 7.5 cm x 1.3 m bandage, 1** | 1@ | 5.44 | MM |
| 4662J | **bandage retention cohesive light 10 cm x 4 m bandage, 1** | 1@ | 5.36 | BV |
| 4719J | **bandage retention cohesive light 6 cm x 4 m bandage, 1** | 1@ | 4.14 | BV |
| 4729X | **bandage retention cotton crepe 10 cm x 2.3 m bandage, 1** | 1@ | 10.70 | BV |
| 4729X | **bandage retention cotton crepe 10 cm x 2.3 m bandage, 1** | 1@ | 9.48 | KE |
| 4727T | **bandage retention cotton crepe 5 cm x 2.3 m bandage, 1** | 1@ | 5.50 | KE |
| 4727T | **bandage retention cotton crepe 5 cm x 2.3 m bandage, 1** | 1@ | 5.93 | BV |
| 4728W | **bandage retention cotton crepe 7.5 cm x 2.3 m bandage, 1** | 1@ | 7.90 | KE |
| 4728W | **bandage retention cotton crepe 7.5 cm x 2.3 m bandage, 1** | 1@ | 7.99 | BV |
| 4799N | **bandage tubular long stocking bandage: large size, 1 bandage** | 1@ | 15.35 | MH |
| 4797L | **bandage tubular long stocking bandage: medium size, 1 bandage** | 1@ | 15.35 | MH |
| 4674B | **bandage tubular long stocking bandage: small size, 1 bandage** | 1@ | 15.35 | MH |
| 4675C | **bandage tubular long stocking bandage: XX/large size, 1 bandage** | 1@ | 15.36 | MH |
| 4816L | **bandage tubular short stocking bandage: large D/E size, 1 bandage** | 1@ | 9.48 | MH |
| 4815K | **bandage tubular short stocking bandage: medium C/D size, 1 bandage** | 1@ | 9.48 | MH |
| 4661H | **bandage tubular short stocking bandage: small B/C size, 1 bandage** | 1@ | 9.48 | MH |
| 4670T | **bandage zinc paste 10 cm x 9.1 m bandage, 1** | 1@ | 11.18 | CC |
| 4668Q | **bandage zinc paste 7.5 cm x 6 m bandage, 1** | 1@ | 11.39 | SS |
| 4669R | | 1@ | 11.62 | MH |
| 4750B | | 1@ | 33.72 | SN |
| 4150K | **bromazepam 3 mg tablet, 30** | 30@ | 11.53 | RO |
| 4151L | **bromazepam 6 mg tablet, 30** | 30@ | 14.84 | RO |
| 4055K | **calcium carbonate 420 mg + glycine 180 mg tablet: chewable, 100** | 100@ | 8.38 | MM |
| 4094L | **CALCIUM Tablet (chewable) 500 mg (as carbonate), 60** | 60@ | 6.70 | IA |
| 4333C | | 60@ | 6.70 | IA |
| 4142B | **CALCIUM Tablet 600 mg (as carbonate), 120** | 120@ | 7.89 | PP |
| 4681J | **dressing activated charcoal malodorous wound 10.5 cm x 10.5 cm dressing, 1** | 1@ | 9.45 | JJ |
| 4832H | **DRESSING-ALGINATE (CAVITY WOUND) Rope 2 g, 1** | 1@ | 10.27 | UM |
| 1905G | **DRESSING-ALGINATE (CAVITY WOUND) Rope 2 g, 5** | 5@ | 54.42 | CC |
| 4682K | **dressing alginate cavity wound 2 g (40 cm) rope, 6 x 2 g** | 1@ | 65.65 | CT |
| 4831G | **dressing alginate superficial wound 10 cm x 10 cm dressing, 1** | 1@ | 8.37 | CT |
| 4831G | **dressing alginate superficial wound 10 cm x 10 cm dressing, 1** | 1@ | 7.80 | UM |
| 4684M | **dressing alginate superficial wound 5 cm x 5 cm dressing, 1** | 1@ | 4.05 | CT |
| 4688R | **dressing film 15 cm x 20 cm dressing, 1** | 1@ | 4.04 | MM |
| 4898T | **dressing film island 5 cm x 7.2 cm dressing, 5** | 1@ | 11.25 | SN |
| 4689T | **dressing film island 5 cm x 7 cm dressing, 1** | 1@ | 0.98 | MM |
| 4899W | **dressing film island 8 cm x 10 cm dressing, 5** | 1@ | 19.54 | SN |
| 4690W | **dressing film island 9 cm x 10 cm dressing, 1** | 1@ | 2.13 | MM |
| 4892L | **dressing foam with charcoal malodorous wound 10 cm x 10 cm dressing, 10** | 1@ | 83.82 | SS |
| 4919X | **dressing hydroactive cavity wound 10 cm x 10 cm dressing, 5** | 1@ | 90.26 | SN |
| 4906F | **dressing hydroactive superficial wound light exudate 10 cm x 10 cm dressing, 5** | 1@ | 50.95 | SN |
| 4886E | **dressing hydroactive superficial wound moderate exudate 10 cm x 10 cm** | 1@ | 36.51 | SN |

# (APPLY WASTAGE FACTOR IN CALCULATING BROKEN QUANTITY PRICES)

| Code | Name, Form/Strength | Pack and Price | | Manufacturer |
|---|---|---|---|---|
| | **dressing, 5** | | | |
| 4896Q | **dressing hydrocolloid cavity wound paste, 30 g** | 1@ | 13.87 | CC |
| 4895P | **dressing hydrocolloid cavity wound paste, 50 g** | 1@ | 18.40 | CT |
| 4679G | **dressing hydrocolloid superficial wound moderate exudate 10 cm (round) dressing, 1** | 1@ | 10.64 | CT |
| 4897R | **dressing hydrocolloid superficial wound moderate exudate 10 cm x 10 cm dressing, 5** | 1@ | 37.49 | CC |
| 4920Y | **dressing hydrocolloid superficial wound moderate exudate 20 cm x 20 cm dressing, 5** | 1@ | 107.95 | CC |
| 4678F | **dressing hydrocolloid superficial wound moderate exudate 7 cm (butterfly shape) dressing, 1** | 1@ | 9.75 | CT |
| 4922C | **dressing hydrofibre alternate to alginates 15 cm x 15 cm dressing, 5** | 1@ | 101.14 | CC |
| 2445Q | **dressing hydrofibre gelling fibre 15 cm x 15 cm dressing, 5** | 1@ | 96.20 | SN |
| 4894N | **dressing hydrogel amorphous gel, 25 g** | 1@ | 13.94 | SN |
| 4913N | **dressing hydrogel amorphous gel, 3 x 30 g tubes** | 1@ | 30.23 | CC |
| 4599C | **dressing hydrogel amorphous gel, 50 g** | 1@ | 8.03 | SN |
| 4914P | | 1@ | 8.90 | JJ |
| 4806Y | **dressing hydrogel sheet 10 cm x 10 cm dressing, 5** | 1@ | 23.43 | HR |
| 4911L | **dressing hydrogel sheet 9.5 cm x 10.2 cm dressing, 5** | 1@ | 38.39 | JJ |
| 4862X | **dressing non adherent 10 cm x 10 cm dressing, 5** | 1@ | 9.49 | SN |
| 4819P | **dressing non adherent 5 cm x 5 cm dressing, 5** | 1@ | 4.69 | SN |
| 4860T | | 1@ | 5.03 | SN |
| 4909J | **dressing tulle non gauze paraffin 7.6 cm x 7.6 cm dressing, 1** | 1@ | 0.93 | JJ |
| 4237B | **fexofenadine hydrochloride 60 mg tablet, 20** | 20@ | 16.19 | SW |
| 4246L | **glycerol 2.8 g suppository, 12** | 1@ | 4.66 | PP |
| 4577X | **nicotine 10 mg/16 hours patch, 7** | 1@ | 24.18 | JT |
| 4572P | **nicotine 14 mg/24 hours patch, 7** | 1@ | 31.16 | GC |
| 4572P | **nicotine 14 mg/24 hours patch, 7** | 1@ | 24.07 | AF |
| 4578Y | **nicotine 15 mg/16 hours patch, 7** | 1@ | 26.77 | JT |
| 4573Q | **nicotine 21 mg/24 hours patch, 7** | 1@ | 31.16 | GC |
| 4573Q | **nicotine 21 mg/24 hours patch, 7** | 1@ | 25.63 | AF |
| 4576W | **nicotine 5 mg/16 hours patch, 7** | 1@ | 22.19 | JT |
| 4571N | **nicotine 7 mg/24 hours patch, 7** | 1@ | 22.49 | AF |

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# GENERIC/PROPRIETARY INDEX

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# THERAPEUTIC GROUP PREMIUM POLICY

**PHARMACEUTICAL BENEFIT ITEMS WHICH HAVE A THERAPEUTIC GROUP PREMIUM WITH EFFECT FROM 1 August 2013**

The Schedule of Pharmaceutical Benefits shows differences in price in some therapeutic groups where alternative drugs may have a therapeutic group premium.

The Therapeutic Group Premium Policy applies within narrowly defined therapeutic sub-groups where the drugs concerned are of similar safety and health outcomes.

The Australian Government, through the PBS, subsidises up to the price of the lowest priced drug in the group. This means that consumers may have to pay for more expensive drugs (those with a therapeutic group premium). This extra amount does not count towards their PBS safety net threshold.

Therapeutic group premiums apply where a prescriber has prescribed a drug within a therapeutic group that attracts a therapeutic group premium and has not sought an exemption from Department of Human Services on clinical grounds.

The exemption provisions are:

- adverse effects occurring with all of the base-priced drugs; or
- drug interactions occurring with all of the base-priced drugs; or
- drug interactions expected to occur with all of the base-priced drugs; or
- transfer to a base-priced drug would cause patient confusion resulting in problems with compliance.

The premiums are not a Government charge but reflect the fact that the supplier(s) of the drug charge a price higher than the Government is willing to subsidise.

Under the Therapeutic Group Premium Policy drug substitution by pharmacists is not permitted.

For ease of prescribing and dispensing, and in the interests of your patients, the following list shows those PBS drugs that attract a therapeutic group premium.

| Premium Priced Brand | Form and Strength | Therapeutic Group Premium $ |
|---|---|---|
| ***ANGIOTENSIN II ANTAGONISTS*** | | |
| Teveten | eprosartan 400 mg tablet, 28 | 2.96 |
| Teveten | eprosartan 600 mg tablet, 28 | 1.69 |
| Olmetec | olmesartan medoxomil 20 mg tablet, 30 | 2.51 |
| Olmetec | olmesartan medoxomil 40 mg tablet, 30 | 2.51 |
| Micardis | telmisartan 40 mg tablet, 28 | 2.50 |
| Micardis | telmisartan 80 mg tablet, 28 | 2.50 |

The base-priced drugs in this therapeutic group are candesartan cilexetil, irbesartan, losartan and valsartan.

# BRAND PREMIUM POLICY

**BRANDS OF PHARMACEUTICAL BENEFIT ITEMS WHICH HAVE A BRAND PREMIUM AND THAT MAY BE SUBSTITUTED WITH EFFECT FROM 1 August 2013**

The Schedule of Pharmaceutical Benefits shows differences in price between some alternative brands of the same drug product.

Manufacturers can develop generic equivalents and apply to have them listed on the PBS. In doing this, manufacturers need to ensure that they comply with the relevant legislation applicable to patents. These brands are clinically equivalent and must undergo the same strict quality controls. Although these brands are designed to act on the body in exactly the same way, they are usually cheaper than the originator brands.

The Australian Government, through the PBS, subsidises up to the price of the lowest priced brand (except in those instances where the lowest priced brand has, as part of its price, a therapeutic group premium). This means that consumers may have to pay extra for more expensive brands (those with a brand premium). This extra amount does not count towards their PBS safety net threshold.

Brand substitution by pharmacists without reference to the prescriber is permitted for PBS prescriptions where:

- the patient agrees to the substitution;
- the brands are identified in the Schedule of Pharmaceutical Benefits as being interchangeable;
- the prescriber has not indicated on the prescription form that substitution is not to occur; and
- substitution is permitted under the relevant State or Territory legislation.

Prescription forms supplied by Department of Human Services contain a box to be ticked where brand substitution is not to take place.

Prescribers not using these prescription forms should endorse the prescription if brand substitution is not permitted. Where a stamp is used for this purpose, the prescriber will be required to initial the stamped statement.

For ease of prescribing and dispensing, and in the interests of your patients, the following list shows those PBS drugs that attract a brand premium and that can be substituted where permitted. They are listed alphabetically, by brand name, with the brand premium and benchmark brand(s) cited in the last column.

# Brand Premium

| Premium Priced Brand | Form and Strength | Max. Qty | Brand Premium $ | Benchmark Priced Brands |
|---|---|---|---|---|
| Abbocillin-V | phenoxymethylpenicillin 150 mg/5 mL oral liquid, 100 mL | 2 | 1.90 | Cilicaine V |
| Accupril | quinapril 10 mg tablet, 30 | 30 | 1.64 | Acquin 10; Acquin Aspen 10; APO-Quinapril; Aquinafil; Qpril 10; Quinapril generichealth; Quinapril Pfizer |
| | quinapril 20 mg tablet, 30 | 30 | 1.64 | Acquin 20; Acquin Aspen 20; APO-Quinapril; Aquinafil; Qpril 20; Quinapril-GA; Quinapril generichealth; Quinapril Pfizer; Quinapril Sandoz |
| | quinapril 5 mg tablet, 30 | 30 | 1.62 | Acquin 5; Acquin Aspen 5; APO-Quinapril; Aquinafil; Qpril 5; Quinapril generichealth; Quinapril Pfizer; Quinapril Sandoz |
| Adalat 10 | nifedipine 10 mg tablet, 60 | 60 | 0.95 | Adefin 10 |
| Adalat 20 | nifedipine 20 mg tablet, 60 | 60 | 1.76 | Adefin 20; GenRx Nifedipine; Nifehexal |
| Adalat Oros 30 | nifedipine 30 mg tablet: modified release, 30 tablets | 30 | 2.03 | Addos XR 30; Adefin XL 30; APO-Nifedipine XR |
| Adalat Oros 60 | nifedipine 60 mg tablet: modified release, 30 tablets | 30 | 2.24 | Addos XR 60; Adefin XL 60; APO-Nifedipine XR |
| Aldactone | spironolactone 100 mg tablet, 100 | 100 | 2.40 | Spiractin 100 |
| | spironolactone 25 mg tablet, 100 | 100 | 1.75 | Spiractin 25 |
| Aldomet | methyldopa 250 mg tablet, 100 | 100 | 3.54 | Hydopa |
| Alphagan | brimonidine tartrate 0.2% eye drops, 5 mL | 1 | 1.63 | Enidin |
| Amaryl | glimepiride 1 mg tablet, 30 | 30 | 2.80 | APO-Glimepiride; Aylide 1; Diapride 1; Dimirel; Glimepiride GA 1; Glimepiride Sandoz |
| | glimepiride 2 mg tablet, 30 | 30 | 2.80 | APO-Glimepiride; Aylide 2; Diapride 2; Dimirel; Glimepiride GA 2; Glimepiride Sandoz |
| | glimepiride 3 mg tablet, 30 | 30 | 2.81 | APO-Glimepiride; Aylide 3; Diapride 3; Dimirel; Glimepiride GA 3; Glimepiride Sandoz |
| | glimepiride 4 mg tablet, 30 | 30 | 2.81 | APO-Glimepiride; Aylide 4; Diapride 4; Dimirel; Glimepiride GA 4; Glimepiride Sandoz |
| Amoxil | amoxycillin 125 mg/5 mL oral liquid: powder for, 100 mL | 1 | 0.72 | Alphamox 125; Amoxycillin Sandoz; Bgramin; Chem mart Amoxycillin; GenRx Amoxycillin; Ranmoxy; Terry White Chemists Amoxycillin |
| | amoxycillin 250 mg capsule, 20 | 20 | 0.71 | Alphamox 250; Amoxycillin-GA; Amoxycillin Ranbaxy; Amoxycillin Sandoz; APO-Amoxycillin; Chem mart Amoxycillin; Cilamox; Terry White Chemists Amoxycillin; Yomax 250 |
| | amoxycillin 500 mg capsule, 20 | 20 | 0.72 | Alphamox 500; Amoxycillin-GA; Amoxycillin generichealth 500; Amoxycillin Ranbaxy; Amoxycillin Sandoz; APO-Amoxycillin; Chem mart Amoxycillin; Cilamox; Terry White Chemists Amoxycillin; Yomax 500 |
| Amoxil Forte | amoxycillin 250 mg/5 mL oral liquid: powder for, 100 mL | 1 | 0.70 | Alphamox 250; Amoxycillin Sandoz; Bgramin; Chem mart Amoxycillin; Cilamox; GenRx Amoxycillin; Ranmoxy; Terry White Chemists Amoxycillin |
| Anafranil 25 | clomipramine hydrochloride 25 mg tablet, 50 | 50 | 3.06 | Chem mart Clomipramine; GenRx Clomipramine; Placil; Terry White Chemists Clomipramine |
| Anaprox 550 | naproxen sodium 550 mg tablet, 50 | 50 | 2.17 | Crysanal |
| Androcur | cyproterone acetate 50 mg tablet, 20 | 20 | 2.86 | Cyprocur 50; Cyprohexal; Cyprone; Cyprostat; Cyproterone Sandoz; GenRx Cyproterone Acetate; Procur |
| | cyproterone acetate 50 mg tablet, 50 | 100 | 2.64 | Cyprocur 50; Cyprohexal; Cyprone; Cyprostat; Cyproterone Sandoz; GenRx Cyproterone Acetate; Procur |
| Androcur-100 | cyproterone acetate 100 mg tablet, 50 | 50 | 1.11 | Cyprocur 100; Cyprohexal; Cyprostat-100; Cyproterone Sandoz; GenRx Cyproterone Acetate; Procur 100 |
| Anginine Stabilised | glyceryl trinitrate 600 microgram tablet: sublingual, 100 tablets | 1 | 2.94 | Lycinate |
| Aristocort 0.02% | triamcinolone acetonide 0.02% (200 microgram/g) cream, 100 g | 2 | 3.78 | Tricortone |
| | triamcinolone acetonide 0.02% (200 microgram/g) ointment, 100 g | 2 | 3.78 | Tricortone |
| Aropax | paroxetine 20 mg tablet, 30 | 30 | 0.58 | Chem mart Paroxetine; Extine 20; GenRx Paroxetine; Paroxetine-GA; Paroxetine Sandoz; Paxtine; Roxet 20; Terry White Chemists Paroxetine |
| Astrix | aspirin 100 mg tablet, 112 | 112 | 2.32 | Mayne Pharma Aspirin; Spren 100 |
| Atrovent | ipratropium bromide 250 microgram/mL inhalation: solution, 30 x 1 mL ampoules | 2 | 0.54 | Aeron 250; APO-Ipratropium; Ipratrin; Ipravent |
| Atrovent Adult | ipratropium bromide 500 microgram/mL inhalation: solution, 30 x 1 mL ampoules | 2 | 0.54 | Aeron 500; APO-Ipratropium; Ipratrin Adult; Ipravent |
| Augmentin | amoxycillin 125 mg/5 mL + clavulanic acid 31.25 mg/5 mL oral liquid: powder for, 75 mL | 1 | 3.00 | Clamoxyl; Curam; GA-Amclav 125/31.25 |
| Augmentin Duo | amoxycillin 500 mg + clavulanic acid 125 mg tablet, 10 | 10 | 4.14 | Amoxycillin/ Clavulanic Acid 500/125 generichealth; APO-Amoxycillin/ Clavulanic Acid 500/125; Clamoxyl Duo; Curam Duo 500/125; GA-Amclav 500/125; Moxiclav Duo 500/125; Pharmacor AmoxyClav 500/125 |
| Augmentin Duo 400 | amoxycillin 400 mg/5 mL + clavulanic acid 57 mg/5 mL oral liquid: powder for, 60 mL | 1 | 4.21 | Clamoxyl Duo 400; Curam Duo; GA-Amclav Forte 400/57 |
| Augmentin Duo | amoxycillin 875 mg + clavulanic acid 125 mg tablet, 10 | 10 | 5.21 | Amoxycillin/ Clavulanic Acid 875/125 generichealth; APO- |

# Brand Premium

| Premium Priced Brand | Form and Strength | Max. Qty | Brand Premium $ | Benchmark Priced Brands |
|---|---|---|---|---|
| forte | | | | Amoxycillin and Clavulanic Acid; Chem mart Amoxycillin and Clavulanic Acid; Clamoxyl Duo forte; Curam Duo Forte 875/125; GA-Amclav Forte 875/125; GenRx Amoxycillin and Clavulanic Acid; Moxiclav Duo Forte 875/125; Pharmacor AmoxyClav 875/125; Terry White Chemists Amoxycillin and Clavulanic Acid |
| Aurorix | moclobemide 150 mg tablet, 60 | 60 | 0.48 | Amira 150; Chem mart Moclobemide; Clobemix; GenRx Moclobemide; Moclobemide Sandoz; Mohexal; Terry White Chemists Moclobemide |
| Aurorix 300 mg | moclobemide 300 mg tablet, 60 | 60 | 0.95 | Amira 300; Chem mart Moclobemide; Clobemix; GenRx Moclobemide; Moclobemide Sandoz; Terry White Chemists Moclobemide |
| Avanza | mirtazapine 30 mg tablet, 30 | 30 | 3.50 | Aurozapine 30; Axit 30; Chem mart Mirtazapine; GenRx Mirtazapine; Mirtazapine-DP; Mirtazapine-GA; Mirtazapine GH; Mirtazapine Sandoz; Mirtazon; Terry White Chemists Mirtazapine |
| | mirtazapine 45 mg tablet, 30 | 30 | 3.51 | APO-Mirtazapine; Aurozapine 45; Axit 45; Chem mart Mirtazapine; Mirtazapine-GA; Mirtazapine GH; Mirtazapine Sandoz; Mirtazon; Terry White Chemists Mirtazapine |
| Avanza SolTab | MIRTAZAPINE Tablet 15 mg (orally disintegrating), 30 | 30 | 1.20 | Milivin OD 15; Remeron SolTab |
| | MIRTAZAPINE Tablet 30 mg (orally disintegrating), 30 | 30 | 1.20 | Milivin OD 30; Remeron SolTab |
| | MIRTAZAPINE Tablet 45 mg (orally disintegrating), 30 | 30 | 1.20 | Milivin OD 45; Remeron SolTab |
| Azopt | brinzolamide 1% (10 mg/mL) eye drops, 5 mL | 1 | 1.18 | BrinzoQuin |
| Betaloc | METOPROLOL TARTRATE Tablet 100 mg, 60 | 60 | 3.76 | Chem mart Metoprolol; GenRx Metoprolol; Metohexal; Metrol 100; Minax 100; Terry White Chemists Metoprolol |
| | METOPROLOL TARTRATE Tablet 50 mg, 100 | 100 | 3.77 | Chem mart Metoprolol; GenRx Metoprolol; Metohexal; Metrol 50; Minax 50; Terry White Chemists Metoprolol |
| Betnovate 1/2 | betamethasone (as valerate) 0.05% (500 microgram/g) cream, 15 g | 1 | 2.94 | Cortival 1/2 |
| Betnovate 1/5 | betamethasone (as valerate) 0.02% (200 microgram/g) cream, 100 g | 2 | 6.88 | Cortival 1/5 |
| Betoptic | betaxolol 0.5% eye drops, 5 mL | 1 | 2.08 | BetoQuin |
| Brevinor | ethinyloestradiol 35 microgram + norethisterone 500 microgram tablet [84] (&) inert substance tablet [28], 112 [4 x 28] | 4 | 7.67 | Norimin 28 Day |
| Brevinor-1 | ethinyloestradiol 35 microgram + norethisterone 1 mg tablet [84] (&) inert substance tablet [28], 112 [4 x 28] | 4 | 7.67 | Norimin-1 28 Day |
| Capoten | captopril 25 mg tablet, 90 | 90 | 5.20 | Captopril Sandoz; GenRx Captopril; Zedace |
| | captopril 50 mg tablet, 90 | 90 | 4.04 | Captopril Sandoz; GenRx Captopril; Zedace |
| Carafate | sucralfate 1 g tablet, 120 | 120 | 2.07 | Ulcyte |
| Ceclor | cefaclor 125 mg/5 mL oral liquid: powder for, 100 mL | 1 | 4.26 | Aclor 125; Chem mart Cefaclor; GenRx Cefaclor; Keflor; Terry White Chemists Cefaclor |
| | cefaclor 250 mg/5 mL oral liquid: powder for, 75 mL | 1 | 4.48 | Aclor 250; Chem mart Cefaclor; GenRx Cefaclor; Keflor; Terry White Chemists Cefaclor |
| Ceclor CD | cefaclor 375 mg tablet: modified release, 10 tablets | 10 | 5.46 | Cefaclor-GA; Cefaclor GH; Chem mart Cefaclor CD; GenRx Cefaclor CD; Karlor CD; Keflor CD; Ozcef; Terry White Chemists Cefaclor CD |
| Celestone-M | betamethasone (as valerate) 0.02% (200 microgram/g) cream, 100 g | 2 | 2.46 | Antroquoril |
| Ciloxan | ciprofloxacin 0.3% eye drops, 5 mL | 2 | 2.06 | CiloQuin |
| Cipramil | citalopram 20 mg tablet, 28 | 28 | 2.79 | APO-Citalopram; Auro-Citalopram 20; Celapram; Celica; Chem mart Citalopram; Ciazil; Citalopram-GA; Citalopram generichealth; Citalopram Sandoz; Pharmacor Citalo 20; Talam; Terry White Chemists Citalopram |
| Ciproxin 250 | ciprofloxacin 250 mg tablet, 14 | 14 | 0.60 | C-Flox 250; Cifran; Ciprofloxacin-DRLA; Ciprofloxacin Sandoz; Ciprol 250; GenRx Ciprofloxacin |
| Ciproxin 500 | ciprofloxacin 500 mg tablet, 14 | 14 | 0.61 | C-Flox 500; Cifran; Ciprofloxacin 500; Ciprofloxacin-BW; Ciprofloxacin-DRLA; Ciprofloxacin-GA; Ciprofloxacin Sandoz; Ciprol 500; GenRx Ciprofloxacin; Loxip 500 |
| Ciproxin 750 | ciprofloxacin 750 mg tablet, 14 | 14 | 0.60 | C-Flox 750; Cifran; Ciprofloxacin 750; Ciprofloxacin-BW; Ciprofloxacin-DRLA; Ciprofloxacin-GA; Ciprofloxacin Sandoz; Ciprol 750; GenRx Ciprofloxacin; Loxip 750 |
| Colgout | colchicine 500 microgram tablet, 30 | 30 | 0.85 | Lengout |
| Dalacin C | clindamycin 150 mg capsule, 24 | 24 | 1.37 | Cleocin |
| Daonil | glibenclamide 5 mg tablet, 100 | 100 | 1.44 | Glimel |
| Depo-Medrol | methylprednisolone acetate 40 mg/mL injection, 5 x 1 mL vials | 5 | 0.96 | Depo-Nisolone |
| Depo-Provera | medroxyprogesterone acetate 150 mg/mL injection, 1 x 1 mL vial | 1 | 3.20 | Depo-Ralovera |
| Diabex | metformin hydrochloride 500 mg tablet, 100 | 100 | 1.20 | APO-Metformin 500; Chem mart Metformin; Diaformin; Formet 500; Formet Aspen 500; GenRx Metformin; |

# Brand Premium

| Premium Priced Brand | Form and Strength | Max. Qty | Brand Premium $ | Benchmark Priced Brands |
|---|---|---|---|---|
| | | | | Glucobete 500; Metformin 500; Metformin-GA; Metformin generichealth; Metformin Ranbaxy; Metformin Sandoz; Terry White Chemists Metformin |
| Diabex 1000 | metformin hydrochloride 1 g tablet, 90 | 90 | 1.23 | APO-Metformin 1000; Chem mart Metformin 1000; Diaformin 1000; Formet 1000; Glucobete 1000; Metformin-GA; Metformin generichealth 1000; Metformin Ranbaxy 1000; Metformin Sandoz; Pharmacor Metformin 1000; Terry White Chemists Metformin 1000 |
| Diabex 850 | metformin hydrochloride 850 mg tablet, 60 | 60 | 1.20 | APO-Metformin 850; Chem mart Metformin; Diaformin 850; Formet 850; Formet Aspen 850; GenRx Metformin; Glucobete 850; Glucophage; Metformin 850; Metformin-GA; Metformin generichealth; Metformin Ranbaxy; Metformin Sandoz; Terry White Chemists Metformin |
| Diprosone | betamethasone (as dipropionate) 0.05% (500 microgram/g) cream, 15 g | 1 | 2.45 | Eleuphrat |
| | betamethasone (as dipropionate) 0.05% (500 microgram/g) ointment, 15 g | 1 | 2.45 | Eleuphrat |
| Doryx | doxycycline 100 mg capsule: modified release, 21 capsules | 21 | 6.56 | Mayne Pharma Doxycycline |
| | doxycycline 100 mg capsule: modified release, 7 capsules | 7 | 2.80 | Mayne Pharma Doxycycline |
| | doxycycline 100 mg capsule: modified release, 7 capsules | 28 | 11.20 | Mayne Pharma Doxycycline |
| | doxycycline 50 mg capsule: modified release, 25 capsules | 25 | 4.72 | Mayne Pharma Doxycycline |
| Dulcolax | bisacodyl 10 mg suppository, 10 | 3 | 1.50 | Petrus Bisacodyl Suppositories |
| Duphalac | LACTULOSE Mixture 3.34 g per 5 mL, 500 mL, 1 | 1 | 1.01 | Actilax; Genlac; GenRx Lactulose; Lac-Dol; Lactocur |
| | LACTULOSE Mixture 3.34 g per 5 mL, 500 mL, 1 | 3 | 3.03 | Actilax; Genlac; GenRx Lactulose; Lac-Dol; Lactocur |
| Duratears | paraffin 1 g/g eye ointment, 3.5 g | 2 | 2.54 | Poly Visc |
| E.E.S. 200 | erythromycin (as ethylsuccinate) 200 mg/5 mL oral liquid: powder for, 100 mL | 1 | 2.71 | E-Mycin 200 |
| E.E.S. 400 Filmtab | erythromycin (as ethylsuccinate) 400 mg tablet, 25 | 25 | 2.67 | E-Mycin |
| E.E.S. Granules | erythromycin (as ethylsuccinate) 400 mg/5 mL oral liquid: powder for, 100 mL | 1 | 2.73 | E-Mycin 400 |
| Elocon | mometasone furoate 0.1% (1 mg/g) cream, 15 g | 1 | 2.90 | Novasone |
| | mometasone furoate 0.1% (1 mg/g) lotion, 30 mL | 1 | 2.91 | Novasone; Zatamil |
| | mometasone furoate 0.1% (1 mg/g) ointment, 15 g | 1 | 2.90 | Novasone; Zatamil |
| Epilim EC | valproate sodium 200 mg tablet: enteric, 100 | 200 | 1.98 | Sodium Valproate Sandoz; Valprease 200; Valpro 200; Valproate Winthrop EC 200 |
| | valproate sodium 500 mg tablet: enteric, 100 | 200 | 2.00 | Sodium Valproate Sandoz; Valprease 500; Valpro 500; Valproate Winthrop EC 500 |
| Eryc | erythromycin 250 mg capsule: enteric, 25 | 25 | 2.91 | Mayne Pharma Erythromycin |
| Fasigyn | tinidazole 500 mg tablet, 4 | 4 | 2.42 | Simplotan |
| Feldene | piroxicam 10 mg capsule, 50 | 50 | 2.53 | Chem mart Piroxicam; GenRx Piroxicam; Mobilis 10; Terry White Chemists Piroxicam |
| | piroxicam 20 mg capsule, 25 | 25 | 2.49 | Chem mart Piroxicam; GenRx Piroxicam; Mobilis 20; Terry White Chemists Piroxicam |
| Feldene-D | piroxicam 20 mg tablet: dispersible, 25 | 25 | 2.95 | Mobilis D-20 |
| Flagyl | metronidazole 200 mg tablet, 21 | 21 | 2.30 | Metrogyl 200; Metronide 200 |
| | metronidazole 400 mg tablet, 21 | 21 | 2.30 | Metrogyl 400; Metronide 400 |
| Fosamax Plus 70 mg/140 mcg | alendronate 70 mg + colecalciferol 140 microgram tablet, 4 | 4 | 2.49 | Dronalen Plus |
| Genteal | HYPROMELLOSE Eye drops 3 mg per mL (0.3%), 15 mL (contains sodium perborate as preservative), 1 | 1 | 1.95 | In a Wink Moisturising |
| Genteal gel | carbomer-980 0.2% (2 mg/g) + hypromellose 0.3% (3 mg/g) eye gel, 10 g | 1 | 1.95 | HPMC PAA |
| Glucophage | metformin hydrochloride 850 mg tablet, 60 | 60 | 0.74 | APO-Metformin 850; Chem mart Metformin; Diabex 850; Diaformin 850; Formet 850; Formet Aspen 850; GenRx Metformin; Glucobete 850; Metformin 850; Metformin-GA; Metformin generichealth; Metformin Ranbaxy; Metformin Sandoz; Terry White Chemists Metformin |
| Gopten | trandolapril 1 mg capsule, 28 | 28 | 1.28 | APO-Trandolapril; Dolapril 1; Tranalpha; Trandolapril-DP; Trandolapril generichealth |
| | trandolapril 2 mg capsule, 28 | 28 | 2.69 | APO-Trandolapril; Dolapril 2; Tranalpha; Trandolapril-DP; Trandolapril generichealth |
| | trandolapril 4 mg capsule, 28 | 28 | 2.69 | APO-Trandolapril; Dolapril 4; Tranalpha; Trandolapril-DP; Trandolapril generichealth |
| | trandolapril 500 microgram capsule, 28 | 28 | 1.23 | APO-Trandolapril; Dolapril 0.5; Tranalpha; Trandolapril-DP; Trandolapril generichealth |
| Imdur 120 mg | isosorbide mononitrate 120 mg tablet: modified release, 30 tablets | 30 | 3.75 | Monodur 120 mg |

# Brand Premium

| Premium Priced Brand | Form and Strength | Max. Qty | Brand Premium $ | Benchmark Priced Brands |
|---|---|---|---|---|
| Imdur Durule | isosorbide mononitrate 60 mg tablet: modified release, 30 tablets | 30 | 3.75 | Chem mart Isosorbide Mononitrate; Duride; GenRx Isosorbide Mononitrate; Imtrate 60 mg; Isomonit; Monodur 60 mg; Terry White Chemists Isosorbide Mononitrate |
| Imigran | SUMATRIPTAN Tablet 50 mg (as succinate), 2 | 4 | 1.56 | APO-Sumatriptan; Chem mart Sumatriptan; Sumagran 50; Sumagran Aspen 50; Sumatab; Terry White Chemists Sumatriptan |
| Imodium | loperamide hydrochloride 2 mg capsule, 12 | 12 | 0.75 | Gastrex; Gastro-Stop Loperamide |
| Indocid | indomethacin 25 mg capsule, 50 | 100 | 2.48 | Arthrexin |
| Isoptin | verapamil hydrochloride 40 mg tablet, 100 | 100 | 0.73 | Anpec 40 |
| | verapamil hydrochloride 80 mg tablet, 100 | 100 | 0.71 | Anpec 80 |
| Isoptin 180 SR | verapamil hydrochloride 180 mg tablet: modified release, 30 tablets | 30 | 3.50 | Cordilox 180 SR |
| Isoptin SR | verapamil hydrochloride 240 mg tablet: modified release, 30 tablets | 30 | 3.50 | Cordilox SR |
| Keflex | cephalexin 125 mg/5 mL oral liquid: powder for, 100 mL | 1 | 3.74 | APO-Cephalexin; Cefalexin Sandoz; Chem mart Cephalexin; Cilex; Ialex; Ibilex 125; Terry White Chemists Cephalexin |
| | cephalexin 250 mg capsule, 20 | 20 | 3.38 | Cefalexin Sandoz; Cephalexin generichealth; Chem mart Cephalexin; Cilex; GenRx Cephalexin; Ialex; Ibilex 250; Pharmacor Cephalexin 250; Rancef; Terry White Chemists Cephalexin |
| | cephalexin 250 mg capsule, 20 | 40 | 6.76 | Cefalexin Sandoz; Cephalexin generichealth; Chem mart Cephalexin; Cilex; GenRx Cephalexin; Ialex; Ibilex 250; Pharmacor Cephalexin 250; Rancef; Terry White Chemists Cephalexin |
| | cephalexin 250 mg/5 mL oral liquid: powder for, 100 mL | 1 | 4.80 | APO-Cephalexin; Cefalexin Sandoz; Chem mart Cephalexin; Cilex; Ialex; Ibilex 250; Terry White Chemists Cephalexin |
| | cephalexin 500 mg capsule, 20 | 20 | 4.83 | Cefalexin Sandoz; Cephalexin generichealth; Chem mart Cephalexin; Cilex; GenRx Cephalexin; Ialex; Ibilex 500; Pharmacor Cephalexin 500; Rancef; Terry White Chemists Cephalexin |
| Kenacomb Otic | triamcinolone acetonide 0.1% (1 mg/g) + neomycin sulfate 0.25% (2.5 mg/g) + gramicidin 0.025% (250 microgram/g) + nystatin 100 000 international units/g ointment, 5 g | 1 | 1.95 | Otocomb Otic |
| | triamcinolone acetonide 0.1% (1 mg/mL) + neomycin sulfate 0.25% (2.5 mg/mL) + gramicidin 0.025% (250 microgram/mL) + nystatin 100 000 international units/mL ear drops, 7.5 mL | 1 | 1.95 | Otocomb Otic |
| Klacid | clarithromycin 250 mg tablet, 14 | 14 | 1.28 | APO-Clarithromycin; Chem mart Clarithromycin; Clarac; Clarihexal; Clarithro 250; Kalixocin; Terry White Chemists Clarithromycin |
| Lacri-Lube | paraffin 1 g/g eye ointment, 2 x 3.5 g tubes | 1 | 2.12 | Ircal |
| Lamictal | lamotrigine 100 mg tablet, 56 | 56 | 1.34 | APO-Lamotrigine; GenRx Lamotrigine; Lamidus; Lamogine; Lamotrigine Aspen 100; Lamotrigine-GA; Lamotrigine generichealth; Lamotrigine Sandoz; Lamotrust 100; Reedos 100; Seaze 100; Torlemo DT 100 |
| | lamotrigine 200 mg tablet, 56 | 56 | 1.45 | APO-Lamotrigine; GenRx Lamotrigine; Lamidus; Lamogine; Lamotrigine Aspen 200; Lamotrigine-GA; Lamotrigine generichealth; Lamotrigine Sandoz; Lamotrust 200; Reedos 200; Seaze 200; Torlemo DT 200 |
| | lamotrigine 25 mg tablet, 56 | 56 | 1.47 | APO-Lamotrigine; GenRx Lamotrigine; Lamidus; Lamogine; Lamotrigine Aspen 25; Lamotrigine-GA; Lamotrigine generichealth; Lamotrigine Sandoz; Lamotrust 25; Reedos 25; Seaze 25; Torlemo DT 25 |
| | lamotrigine 5 mg tablet, 56 | 56 | 1.46 | Lamogine; Seaze 5 |
| | lamotrigine 50 mg tablet, 56 | 56 | 1.68 | APO-Lamotrigine; GenRx Lamotrigine; Lamidus; Lamogine; Lamotrigine-GA; Lamotrigine generichealth; Lamotrigine Sandoz; Lamotrust 50; Reedos 50; Seaze 50; Torlemo DT 50 |
| Lanoxin | digoxin 250 microgram tablet, 100 | 100 | 2.94 | Sigmaxin |
| Lanoxin-PG | digoxin 62.5 microgram tablet, 200 | 200 | 2.95 | Sigmaxin-PG |
| Lasix | frusemide 40 mg tablet, 100 | 100 | 2.40 | APO-Frusemide; Chem mart Frusemide; Frusax; Frusemide Sandoz; Frusid; GenRx Frusemide; Terry White Chemists Frusemide; Uremide |
| Lasix-M | frusemide 20 mg tablet, 50 | 100 | 1.92 | Urex-M |
| Lexapro | escitalopram 10 mg tablet, 28 | 28 | 4.70 | APO-Escitalopram; Chem mart Escitalopram; Escicor 10; Escitalopram-DRLA; Escitalopram GA; Escitalopram generichealth; Esipram; Esitalo; Lexam 10; LoxaLate; Pharmacor Escitalopram 10; Terry White Chemists Escitalopram |
| | escitalopram 20 mg tablet, 28 | 28 | 6.85 | APO-Escitalopram; Chem mart Escitalopram; Escicor 20; |

# Brand Premium

| Premium Priced Brand | Form and Strength | Max. Qty | Brand Premium $ | Benchmark Priced Brands |
|---|---|---|---|---|
| | | | | Escitalopram-DRLA; Escitalopram GA; Escitalopram generichealth; Esipram; Esitalo; Lexam 20; LoxaLate; Pharmacor Escitalopram 20; Terry White Chemists Escitalopram |
| Lioresal 10 | baclofen 10 mg tablet, 100 | 100 | 1.33 | Chem mart Baclofen; Clofen 10; GenRx Baclofen; Stelax 10; Terry White Chemists Baclofen |
| Lioresal 25 | baclofen 25 mg tablet, 100 | 100 | 1.33 | Chem mart Baclofen; Clofen 25; GenRx Baclofen; Stelax 25; Terry White Chemists Baclofen |
| Lipex 10 | simvastatin 10 mg tablet, 30 | 30 | 1.85 | APO-Simvastatin; Auro-Simvastatin 10; Chem mart Simvastatin; GenRx Simvastatin; Ransim; Simvacor 10; Simvar 10; Simvastatin-DP; Simvastatin-DRLA; Simvastatin-GA 10; Simvastatin generichealth; Simvastatin Sandoz; Simvastatin-Spirit 10; Terry White Chemists Simvastatin; Zimstat; Zocor |
| Lipex 20 | simvastatin 20 mg tablet, 30 | 30 | 1.82 | APO-Simvastatin; Auro-Simvastatin 20; Chem mart Simvastatin; Ransim; Simvacor 20; Simvar 20; Simvastatin-DP; Simvastatin-DRLA; Simvastatin-GA 20; Simvastatin generichealth; Simvastatin Sandoz; Simvastatin-Spirit 20; Terry White Chemists Simvastatin; Zimstat; Zocor |
| Lipex 40 | simvastatin 40 mg tablet, 30 | 30 | 1.84 | APO-Simvastatin; Auro-Simvastatin 40; Chem mart Simvastatin; Ransim; Simvacor 40; Simvar 40; Simvastatin-DP; Simvastatin-DRLA; Simvastatin-GA 40; Simvastatin generichealth; Simvastatin Sandoz; Simvastatin-Spirit 40; Terry White Chemists Simvastatin; Zimstat; Zocor |
| Lipex 80 | simvastatin 80 mg tablet, 30 | 30 | 1.84 | APO-Simvastatin; Auro-Simvastatin 80; Chem mart Simvastatin; Ransim; Simvacor 80; Simvar 80; Simvastatin-DP; Simvastatin-DRLA; Simvastatin-GA 80; Simvastatin generichealth; Simvastatin Sandoz; Simvastatin-Spirit 80; Terry White Chemists Simvastatin; Zimstat; Zocor |
| Liquifilm Forte | polyvinyl alcohol 3% eye drops, 15 mL | 1 | 5.59 | PVA Forte |
| Liquifilm Tears | polyvinyl alcohol 1.4% eye drops, 15 mL | 1 | 1.60 | PVA Tears |
| Lomotil | diphenoxylate hydrochloride 2.5 mg + atropine sulfate 25 microgram tablet, 20 | 20 | 1.73 | Lofenoxal |
| Lopid | gemfibrozil 600 mg tablet, 60 | 60 | 1.62 | Ausgem; Chem mart Gemfibrozil; Gemfibrozil-GA; Gemhexal; GenRx Gemfibrozil; Jezil; Lipigem; Terry White Chemists Gemfibrozil |
| Lopresor 100 | METOPROLOL TARTRATE Tablet 100 mg, 60 | 60 | 2.22 | APO-Metoprolol |
| Lopresor 50 | METOPROLOL TARTRATE Tablet 50 mg, 100 | 100 | 2.26 | APO-Metoprolol |
| Losec Tablets | omeprazole 20 mg tablet: enteric, 30 tablets | 30 | 3.03 | Acimax Tablets; Omepral; Omeprazole Sandoz |
| Luvox | fluvoxamine maleate 100 mg tablet, 30 | 30 | 2.01 | APO-Fluvoxamine; Faverin 100; Fluvoxamine GA; Movox 100; Voxam |
| | fluvoxamine maleate 50 mg tablet, 30 | 30 | 1.99 | APO-Fluvoxamine; Faverin 50; Fluvoxamine GA; Movox 50; Voxam |
| Maxamox | amoxycillin 1 g tablet, 14 | 14 | 0.58 | Amoxycillin Sandoz |
| Microgynon 30 ED | levonorgestrel 150 microgram + ethinyloestradiol 30 microgram tablet [84 tablets] (&) inert substance tablet [28 tablets], 112 [4 x 28 tablets] | 4 | 11.41 | Femme-Tab ED 30/150; Levlen ED |
| Minidiab | glipizide 5 mg tablet, 100 | 100 | 3.83 | Melizide |
| Minomycin-50 | minocycline 50 mg tablet, 60 | 60 | 1.89 | Akamin 50 |
| Mobic | meloxicam 15 mg capsule, 30 | 30 | 1.75 | APO-Meloxicam; Chem mart Meloxicam; Melox 15; Movalis 15; Terry White Chemists Meloxicam |
| | meloxicam 15 mg tablet, 30 | 30 | 1.75 | APO-Meloxicam; Chem mart Meloxicam 15 mg; GenRx Meloxicam; Meloxiauro 15; Meloxibell; Meloxicam-GA; Meloxicam Ranbaxy; Meloxicam Sandoz; Movalis 15; Moxicam 15; Pharmacor Meloxicam 15; Terry White Chemists Meloxicam 15 mg |
| | meloxicam 7.5 mg capsule, 30 | 30 | 1.76 | APO-Meloxicam; Chem mart Meloxicam; Melox 7.5; Movalis 7.5; Terry White Chemists Meloxicam |
| | meloxicam 7.5 mg tablet, 30 | 30 | 1.76 | APO-Meloxicam; Chem mart Meloxicam 7.5 mg; GenRx Meloxicam; Meloxiauro 7.5; Meloxibell; Meloxicam-GA; Meloxicam Ranbaxy; Meloxicam Sandoz; Movalis 7.5; Moxicam 7.5; Pharmacor Meloxicam 7.5; Terry White Chemists Meloxicam 7.5 mg |
| Mogadon | nitrazepam 5 mg tablet, 25 | 25 | 1.46 | Alodorm |
| | nitrazepam 5 mg tablet, 25 | 50 | 2.92 | Alodorm |
| Monodur 60 mg | isosorbide mononitrate 60 mg tablet: modified release, 30 tablets | 30 | 2.75 | Chem mart Isosorbide Mononitrate; Duride; GenRx Isosorbide Mononitrate; Imdur Durule; Imtrate 60 mg; Isomonit; Terry White Chemists Isosorbide Mononitrate |
| Naprosyn | naproxen 250 mg tablet, 50 | 100 | 2.24 | Inza 250 |

# Brand Premium

| Premium Priced Brand | Form and Strength | Max. Qty | Brand Premium $ | Benchmark Priced Brands |
|---|---|---|---|---|
| | naproxen 500 mg tablet, 50 | 50 | 1.28 | Inza 500 |
| Naprosyn SR1000 | naproxen 1 g tablet: modified release, 28 tablets | 28 | 1.29 | Proxen SR 1000 |
| Naprosyn SR750 | naproxen 750 mg tablet: modified release, 28 tablets | 28 | 1.22 | Proxen SR 750 |
| Natrilix | indapamide hemihydrate 2.5 mg tablet, 90 | 90 | 4.11 | Chem mart Indapamide; Dapa-Tabs; GenRx Indapamide; Indapamide-GA; Indapamide Sandoz; Insig; Terry White Chemists Indapamide |
| Nilstat | nystatin 100 000 international units/mL oral liquid, 24 mL | 1 | 2.01 | Mycostatin |
| Nordette 28 | levonorgestrel 150 microgram + ethinyloestradiol 30 microgram tablet [84 tablets] (&) inert substance tablet [28 tablets], 112 [4 x 28 tablets] | 4 | 11.37 | Monofeme 28 |
| Noriday 28 Day | norethisterone 350 microgram tablet, 112 [4 x 28] | 4 | 3.90 | Locilan 28 Day |
| Normison | temazepam 10 mg tablet, 25 | 25 | 2.05 | APO-Temazepam; Temaze; Temtabs |
| | temazepam 10 mg tablet, 25 | 50 | 4.10 | APO-Temazepam; Temaze; Temtabs |
| Noroxin | norfloxacin 400 mg tablet, 14 | 14 | 3.27 | GenRx Norfloxacin; Norfloxacin-GA; Norfloxacin Sandoz; Nufloxib; Roxin |
| Norvasc | amlodipine 10 mg tablet, 30 | 30 | 5.50 | Amlo 10; Amlodipine-DRLA; Amlodipine-GA; Amlodipine generichealth; Amlodipine Pfizer; Amlodipine Sandoz; APO-Amlodipine; Auro-Amlodipine 10; Chem mart Amlodipine; Nordip; Norvapine; Ozlodip; Terry White Chemists Amlodipine |
| | amlodipine 5 mg tablet, 30 | 30 | 3.75 | Amlo 5; Amlodipine-DRLA; Amlodipine-GA; Amlodipine generichealth; Amlodipine Pfizer; Amlodipine Sandoz; APO-Amlodipine; Auro-Amlodipine 5; Chem mart Amlodipine; Nordip; Norvapine; Ozlodip; Terry White Chemists Amlodipine |
| Oroxine | thyroxine sodium 100 microgram tablet, 200 | 200 | 2.21 | Eutroxsig |
| | thyroxine sodium 200 microgram tablet, 200 | 200 | 2.21 | Eutroxsig |
| | thyroxine sodium 50 microgram tablet, 200 | 200 | 2.20 | Eutroxsig |
| | thyroxine sodium 75 microgram tablet, 200 | 200 | 2.27 | Eutroxsig |
| Orudis SR 200 | ketoprofen 200 mg capsule: modified release, 28 capsules | 28 | 2.21 | Oruvail SR |
| Panadeine Forte | CODEINE PHOSPHATE with PARACETAMOL Tablet 30 mg-500 mg, 20 | 20 | 2.40 | APO- Paracetamol/Codeine 500/30; Codalgin Forte; Codapane Forte; Comfarol Forte; Prodeine Forte |
| | CODEINE PHOSPHATE with PARACETAMOL Tablet 30 mg-500 mg, 20 | 60 | 7.20 | APO- Paracetamol/Codeine 500/30; Codalgin Forte; Codapane Forte; Comfarol Forte; Prodeine Forte |
| Panafcort | prednisone 1 mg tablet, 100 | 100 | 0.60 | Predsone |
| Panafcortelone | prednisolone 1 mg tablet, 100 | 100 | 0.44 | Predsolone |
| Plendil ER | felodipine 10 mg tablet: modified release, 30 tablets | 30 | 4.08 | Felodil XR 10; Felodur ER 10 mg; Fendex ER |
| | felodipine 2.5 mg tablet: modified release, 30 tablets | 30 | 4.06 | Felodur ER 2.5 mg; Fendex ER |
| | felodipine 5 mg tablet: modified release, 30 tablets | 30 | 4.07 | Felodil XR 5; Felodur ER 5 mg; Fendex ER |
| Pravachol | pravastatin sodium 10 mg tablet, 30 | 30 | 2.64 | APO-Pravastatin; Chem mart Pravastatin; Cholstat 10; Lipostat 10; Pharmacor Pravastat 10; Pravastatin Actavis 10; Pravastatin-GA 10; Pravastatin generichealth; Pravastatin Sandoz; Terry White Chemists Pravastatin |
| | pravastatin sodium 20 mg tablet, 30 | 30 | 2.64 | APO-Pravastatin; Chem mart Pravastatin; Cholstat 20; Cholvastin; Lipostat 20; Pharmacor Pravastat 20; Pravastatin Actavis 20; Pravastatin-GA 20; Pravastatin generichealth; Pravastatin Sandoz; Terry White Chemists Pravastatin |
| | pravastatin sodium 40 mg tablet, 30 | 30 | 2.82 | APO-Pravastatin; Chem mart Pravastatin; Cholstat 40; Cholvastin; Lipostat 40; Pharmacor Pravastat 40; Pravastatin Actavis 40; Pravastatin-GA 40; Pravastatin generichealth; Pravastatin Sandoz; Terry White Chemists Pravastatin |
| | pravastatin sodium 80 mg tablet, 30 | 30 | 2.80 | APO-Pravastatin; Chem mart Pravastatin; Lipostat 80; Pravastatin-GA 80; Pravastatin generichealth; Pravastatin Sandoz; Terry White Chemists Pravastatin |
| Prinivil 10 | lisinopril 10 mg tablet, 30 | 30 | 2.97 | APO-Lisinopril; Chem mart Lisinopril; Fibsol 10; Lisinopril-DRLA; Lisinopril-GA; Lisinopril generichealth; Lisinopril Sandoz; Terry White Chemists Lisinopril; Zestril; Zinopril 10 |
| Prinivil 20 | lisinopril 20 mg tablet, 30 | 30 | 2.96 | APO-Lisinopril; Chem mart Lisinopril; Fibsol 20; Lisinopril-DRLA; Lisinopril-GA; Lisinopril generichealth; Lisinopril Sandoz; Terry White Chemists Lisinopril; Zestril; Zinopril 20 |
| Provera | medroxyprogesterone acetate 10 mg tablet, 100 | 100 | 1.95 | Ralovera |
| | medroxyprogesterone acetate 10 mg tablet, 30 | 30 | 1.96 | Medroxyprogesterone Sandoz; Ralovera |
| | medroxyprogesterone acetate 5 mg tablet, 56 | 56 | 1.95 | Ralovera |
| Prozac 20 | fluoxetine 20 mg capsule, 28 | 28 | 2.90 | Auscap Aspen; Chem mart Fluoxetine; Fluoxetine 20; Fluoxetine-GA; Fluoxetine generichealth; Fluoxetine RBX; |

# Brand Premium

| Premium Priced Brand | Form and Strength | Max. Qty | Brand Premium $ | Benchmark Priced Brands |
|---|---|---|---|---|
| | | | | Fluoxetine Sandoz; GenRx Fluoxetine; Lovan; Terry White Chemists Fluoxetine; Zactin |
| Prozac Tab | fluoxetine 20 mg tablet: dispersible, 28 | 28 | 2.90 | Lovan 20 Tab; Zactin Tablet |
| Redipred | prednisolone (as sodium phosphate) 5 mg/mL oral liquid, 30 mL | 1 | 2.36 | PredMix |
| Renitec | enalapril maleate 10 mg tablet, 30 | 30 | 3.78 | Acetec; Auspril; Chem mart Enalapril; Enalapril-GA; Enalapril generichealth; Enalapril Sandoz; GenRx Enalapril; Terry White Chemists Enalapril |
| Renitec 20 | enalapril maleate 20 mg tablet, 30 | 30 | 3.78 | Acetec; Auspril; Chem mart Enalapril; Enalapril-GA; Enalapril generichealth; Enalapril Sandoz; GenRx Enalapril; Terry White Chemists Enalapril |
| Renitec M | enalapril maleate 5 mg tablet, 30 | 30 | 3.77 | Acetec; Auspril; Chem mart Enalapril; Enalapril-GA; Enalapril generichealth; Enalapril Sandoz; GenRx Enalapril; Terry White Chemists Enalapril |
| Rivotril | clonazepam 2 mg tablet, 100 | 100 | 1.93 | Paxam 2 |
| | clonazepam 2 mg tablet, 100 | 200 | 3.86 | Paxam 2 |
| | clonazepam 500 microgram tablet, 100 | 100 | 1.71 | Paxam 0.5 |
| | clonazepam 500 microgram tablet, 100 | 200 | 3.42 | Paxam 0.5 |
| Rulide | roxithromycin 150 mg tablet, 10 | 10 | 2.09 | APO-Roxithromycin; Biaxsig; Chem mart Roxithromycin; Roxar 150; Roximycin; Roxithromycin-GA; Roxithromycin Sandoz; Terry White Chemists Roxithromycin |
| | roxithromycin 300 mg tablet, 5 | 5 | 2.09 | APO-Roxithromycin; Biaxsig; Chem mart Roxithromycin; Roxar 300; Roximycin; Roxithromycin-GA; Roxithromycin Sandoz; Terry White Chemists Roxithromycin |
| Salazopyrin-EN | SULFASALAZINE Tablet 500 mg (enteric coated), 100 | 200 | 1.96 | Pyralin EN |
| Septrin Forte | trimethoprim 160 mg + sulfamethoxazole 800 mg tablet, 10 | 10 | 1.46 | Bactrim DS; Resprim Forte |
| Serepax | oxazepam 15 mg tablet, 25 | 25 | 2.68 | Alepam 15 |
| | oxazepam 15 mg tablet, 25 | 50 | 5.36 | Alepam 15 |
| | oxazepam 30 mg tablet, 25 | 25 | 2.68 | Alepam 30; APO-Oxazepam; Murelax |
| | oxazepam 30 mg tablet, 25 | 50 | 5.36 | Alepam 30; APO-Oxazepam; Murelax |
| Sigmacort | hydrocortisone acetate 1% (10 mg/g) cream, 30 g | 1 | 2.69 | Cortic-DS 1% |
| | hydrocortisone acetate 1% (10 mg/g) cream, 50 g | 1 | 2.70 | Cortic-DS 1% |
| | hydrocortisone acetate 1% (10 mg/g) ointment, 30 g | 1 | 2.69 | Cortic-DS 1% |
| | hydrocortisone acetate 1% (10 mg/g) ointment, 50 g | 1 | 2.70 | Cortic-DS 1% |
| Sinemet | levodopa 250 mg + carbidopa anhydrous 25 mg tablet, 100 | 100 | 2.92 | Levo/Carbidopa Sandoz |
| Sinemet 100/25 | levodopa 100 mg + carbidopa anhydrous 25 mg tablet, 100 | 100 | 5.19 | Kinson |
| Slow-K | potassium chloride 600 mg (8 mmol potassium) tablet: modified release, 100 tablets | 200 | 2.94 | Duro-K |
| Sofradex | dexamethasone 0.05% (500 microgram/mL) + framycetin sulfate 0.5% (5 mg/mL) + gramicidin 0.005% (50 microgram/mL) ear drops, 8 mL | 1 | 1.91 | Otodex |
| Sotacor | sotalol hydrochloride 160 mg tablet, 60 | 60 | 4.26 | Cardol; Chem mart Sotalol; GenRx Sotalol; Solavert; Sotalol Sandoz; Terry White Chemists Sotalol |
| | sotalol hydrochloride 80 mg tablet, 60 | 60 | 4.26 | GenRx Sotalol; Solavert; Sotalol Sandoz |
| Stemetil | prochlorperazine maleate 5 mg tablet, 25 | 25 | 3.45 | APO-Prochlorperazine; Pharmacor Prozine 5; ProCalm; Prochlorperazine-GA; Prochlorperazine GH; Stemzine |
| Tazac | nizatidine 150 mg capsule, 60 | 60 | 5.32 | Nizac; Tacidine |
| | nizatidine 300 mg capsule, 30 | 30 | 5.32 | Nizac; Tacidine |
| Tears Naturale | dextran-70 0.1% (1 mg/mL) + hypromellose 0.3% (3 mg/mL) eye drops, 15 mL | 1 | 2.04 | Poly-Tears |
| Tenormin | atenolol 50 mg tablet, 30 | 30 | 2.85 | APO-Atenolol; Atenolol-GA; Atenolol GH; Atenolol Sandoz; Chem mart Atenolol; Noten; Tenolten 50; Tensig; Terry White Chemists Atenolol |
| Timoptol | timolol 0.5% (5 mg/mL) eye drops, 5 mL | 1 | 3.03 | Tenopt |
| Tofranil 10 | imipramine hydrochloride 10 mg tablet, 50 | 50 | 2.79 | Tolerade 10 |
| Tofranil 25 | imipramine hydrochloride 25 mg tablet, 50 | 50 | 2.78 | Tolerade 25 |
| Tolvon | mianserin hydrochloride 10 mg tablet, 50 | 50 | 3.29 | Lumin 10 |
| | mianserin hydrochloride 20 mg tablet, 50 | 50 | 3.30 | Lumin 20 |
| Tramal | tramadol hydrochloride 50 mg capsule, 20 | 20 | 2.41 | APO-Tramadol; Chem mart Tramadol; GA Tramadol 50mg; Lodam 50; Terry White Chemists Tramadol; Tramadol Sandoz; Tramedo; Zydol |
| Tramal SR 100 | tramadol hydrochloride 100 mg tablet: modified release, 20 tablets | 20 | 4.49 | APO-Tramadol SR; Chem mart Tramadol SR; GA Tramadol SR 100mg; Lodam SR 100; Terry White Chemists Tramadol SR; Tramadol Sandoz SR; Tramadol SR generichealth; Tramedo SR 100; Zydol SR 100 |
| Tramal SR 150 | tramadol hydrochloride 150 mg tablet: modified release, 20 tablets | 20 | 5.37 | APO-Tramadol SR; Chem mart Tramadol SR; GA Tramadol SR 150mg; Lodam SR 150; Terry White Chemists Tramadol SR; Tramadol Sandoz SR; Tramadol SR generichealth; Tramedo SR 150; Zydol SR 150 |

# Brand Premium

| Premium Priced Brand | Form and Strength | Max. Qty | Brand Premium $ | Benchmark Priced Brands |
|---|---|---|---|---|
| Tramal SR 200 | tramadol hydrochloride 200 mg tablet: modified release, 20 tablets | 20 | 6.08 | APO-Tramadol SR; Chem mart Tramadol SR; GA Tramadol SR 200mg; Lodam SR 200; Terry White Chemists Tramadol SR; Tramadol Sandoz SR; Tramadol SR generichealth; Tramedo SR 200; Zydol SR 200 |
| Trandate | labetalol hydrochloride 100 mg tablet, 100 | 100 | 3.13 | Presolol 100 |
| | labetalol hydrochloride 200 mg tablet, 100 | 100 | 3.14 | Presolol 200 |
| Triphasil 28 | levonorgestrel 50 microgram + ethinyloestradiol 30 microgram tablet [24 tablets] (&) levonorgestrel 75 microgram + ethinyloestradiol 40 microgram tablet [20 tablets] (&) levonorgestrel 125 microgram + ethinyloestradiol 30 microgram tablet [40 tablets] (&) inert substance tablet [28 tablets], 112 [4 x 28 tablets] | 4 | 11.37 | Trifeme 28 |
| Triprim | trimethoprim 300 mg tablet, 7 | 7 | 1.89 | Alprim |
| | trimethoprim 300 mg tablet, 7 | 14 | 3.78 | Alprim |
| Triquilar ED | levonorgestrel 50 microgram + ethinyloestradiol 30 microgram tablet [24 tablets] (&) levonorgestrel 75 microgram + ethinyloestradiol 40 microgram tablet [20 tablets] (&) levonorgestrel 125 microgram + ethinyloestradiol 30 microgram tablet [40 tablets] (&) inert substance tablet [28 tablets], 112 [4 x 28 tablets] | 4 | 11.41 | Logynon ED |
| Valium | diazepam 2 mg tablet, 50 | 50 | 0.82 | Antenex 2; APO-Diazepam; Ranzepam; Valpam 2 |
| | diazepam 5 mg tablet, 50 | 50 | 0.85 | Antenex 5; APO-Diazepam; Diazepam-GA; Ranzepam; Valpam 5 |
| Vastin | fluvastatin 20 mg capsule, 28 | 28 | 3.09 | Lescol |
| | fluvastatin 40 mg capsule, 28 | 28 | 3.38 | Lescol |
| Ventolin CFC-free | salbutamol 100 microgram/actuation inhalation: pressurised, 200 actuations | 2 | 2.34 | Airomir; APO-Salbutamol Inhaler; Asmol CFC-free |
| Ventolin Nebules | salbutamol 2.5 mg/2.5 mL inhalation: solution, 30 x 2.5 mL ampoules | 2 | 1.18 | Asmol 2.5 uni-dose; Butamol 2.5; GenRx Salbutamol; Pharmacor Salbutamol 2.5; Salbutamol-GA; Salbutamol Sandoz |
| | salbutamol 5 mg/2.5 mL inhalation: solution, 30 x 2.5 mL ampoules | 2 | 1.14 | Asmol 5 uni-dose; Butamol 5; GenRx Salbutamol; Pharmacor Salbutamol 5; Salbutamol-GA; Salbutamol Sandoz |
| Vibra-Tabs | doxycycline 50 mg tablet, 25 | 25 | 1.95 | Doxy-50; Doxylin 50 |
| Viscotears | carbomer-980 0.2% (2 mg/g) eye gel, 10 g | 1 | 1.49 | PAA |
| Visken 15 | pindolol 15 mg tablet, 50 | 50 | 1.70 | Barbloc 15 |
| Voltaren 25 | diclofenac sodium 25 mg tablet: enteric, 50 tablets | 100 | 1.86 | APO-Diclofenac; Chem mart Diclofenac; Clonac 25; Diclofenac-GA; Diclofenac Sandoz; Fenac 25; Terry White Chemists Diclofenac |
| Voltaren 50 | diclofenac sodium 50 mg tablet: enteric, 50 tablets | 50 | 1.86 | APO-Diclofenac; Chem mart Diclofenac; Clonac 50; Diclofenac-GA; Diclofenac Sandoz; Fenac; Terry White Chemists Diclofenac |
| Xanax | alprazolam 1 mg tablet, 50 | 50 | 1.95 | Alprax 1; Alprazolam Sandoz; Chem mart Alprazolam; GenRx Alprazolam; Kalma 1; Ralozam; Terry White Chemists Alprazolam |
| | alprazolam 250 microgram tablet, 50 | 50 | 1.96 | Alprax 0.25; Alprazolam Sandoz; Kalma 0.25 |
| | alprazolam 500 microgram tablet, 50 | 50 | 1.95 | Alprax 0.5; Alprazolam Sandoz; Kalma 0.5 |
| Xanax Tri-Score | alprazolam 2 mg tablet, 50 | 50 | 1.96 | Alprax 2; Alprazolam Sandoz; Chem mart Alprazolam; GenRx Alprazolam; Kalma 2; Ralozam; Terry White Chemists Alprazolam |
| Zanidip | lercanidipine hydrochloride 10 mg tablet, 28 | 28 | 2.66 | APO-Lercanidipine; Chem mart Lercanidipine; Ledip; Lercadip; Lercan; Lercanidipine GH; Lercanidipine Sandoz; Terry White Chemists Lercanidipine; Zircol |
| | lercanidipine hydrochloride 20 mg tablet, 28 | 28 | 2.65 | APO-Lercanidipine; Chem mart Lercanidipine; Ledip; Lercadip; Lercan; Lercanidipine GH; Lercanidipine Sandoz; Terry White Chemists Lercanidipine; Zircol |
| Zantac | ranitidine 150 mg tablet, 60 | 60 | 1.72 | Ausran; Chem mart Ranitidine; GenRx Ranitidine; Rani 2; Ranitidine Sandoz; Ranoxyl; Terry White Chemists Ranitidine; Ulcaid |
| | ranitidine 300 mg tablet, 30 | 30 | 1.72 | Ausran; Chem mart Ranitidine; GenRx Ranitidine; Rani 2; Ranitidine Sandoz; Ranoxyl; Terry White Chemists Ranitidine |
| Zestril | lisinopril 10 mg tablet, 30 | 30 | 2.96 | APO-Lisinopril; Chem mart Lisinopril; Fibsol 10; Lisinopril-DRLA; Lisinopril-GA; Lisinopril generichealth; Lisinopril Sandoz; Prinivil 10; Terry White Chemists Lisinopril; Zinopril 10 |
| | lisinopril 20 mg tablet, 30 | 30 | 2.96 | APO-Lisinopril; Chem mart Lisinopril; Fibsol 20; Lisinopril-DRLA; Lisinopril-GA; Lisinopril generichealth; Lisinopril Sandoz; Prinivil 20; Terry White Chemists Lisinopril; Zinopril 20 |
| | lisinopril 5 mg tablet, 30 | 30 | 2.96 | APO-Lisinopril; Chem mart Lisinopril; Fibsol 5; Lisinopril-DRLA; Lisinopril-GA; Lisinopril generichealth; Lisinopril Sandoz; Terry White Chemists Lisinopril; Zinopril 5 |

# Brand Premium

| Premium Priced Brand | Form and Strength | Max. Qty | Brand Premium $ | Benchmark Priced Brands |
|---|---|---|---|---|
| Zocor | simvastatin 10 mg tablet, 30 | 30 | 1.85 | APO-Simvastatin; Auro-Simvastatin 10; Chem mart Simvastatin; GenRx Simvastatin; Lipex 10; Ransim; Simvacor 10; Simvar 10; Simvastatin-DP; Simvastatin-DRLA; Simvastatin-GA 10; Simvastatin generichealth; Simvastatin Sandoz; Simvastatin-Spirit 10; Terry White Chemists Simvastatin; Zimstat |
| | simvastatin 20 mg tablet, 30 | 30 | 1.82 | APO-Simvastatin; Auro-Simvastatin 20; Chem mart Simvastatin; Lipex 20; Ransim; Simvacor 20; Simvar 20; Simvastatin-DP; Simvastatin-DRLA; Simvastatin-GA 20; Simvastatin generichealth; Simvastatin Sandoz; Simvastatin-Spirit 20; Terry White Chemists Simvastatin; Zimstat |
| | simvastatin 40 mg tablet, 30 | 30 | 1.84 | APO-Simvastatin; Auro-Simvastatin 40; Chem mart Simvastatin; Lipex 40; Ransim; Simvacor 40; Simvar 40; Simvastatin-DP; Simvastatin-DRLA; Simvastatin-GA 40; Simvastatin generichealth; Simvastatin Sandoz; Simvastatin-Spirit 40; Terry White Chemists Simvastatin; Zimstat |
| | simvastatin 5 mg tablet, 30 | 30 | 1.84 | Simvastatin Sandoz; Zimstat |
| | simvastatin 80 mg tablet, 30 | 30 | 1.84 | APO-Simvastatin; Auro-Simvastatin 80; Chem mart Simvastatin; Lipex 80; Ransim; Simvacor 80; Simvar 80; Simvastatin-DP; Simvastatin-DRLA; Simvastatin-GA 80; Simvastatin generichealth; Simvastatin Sandoz; Simvastatin-Spirit 80; Terry White Chemists Simvastatin; Zimstat |
| Zoloft | sertraline 100 mg tablet, 30 | 30 | 1.20 | Auro-Sertraline 100; Chem mart Sertraline; Eleva 100; GenRx Sertraline; Sertra 100; Sertracor 100; Sertraline-DRLA; Sertraline-GA; Sertraline generichealth; Sertraline Pfizer; Sertraline Sandoz; Setrona; Terry White Chemists Sertraline; Xydep 100 |
| | sertraline 50 mg tablet, 30 | 30 | 1.20 | Auro-Sertraline 50; Chem mart Sertraline; Eleva 50; GenRx Sertraline; Sertra 50; Sertracor 50; Sertraline-DRLA; Sertraline-GA; Sertraline generichealth; Sertraline Pfizer; Sertraline Sandoz; Setrona; Terry White Chemists Sertraline; Xydep 50 |
| Zoton FasTabs | lansoprazole 30 mg tablet: orally disintegrating, 28 tablets | 28 | 0.96 | Zopral ODT |
| Zovirax 200 mg | aciclovir 200 mg tablet, 25 | 50 | 2.36 | Acihexal; Acyclo-V 200; Lovir |
| | aciclovir 200 mg tablet, 90 | 90 | 1.91 | Aciclovir 200; Aciclovir GH; Acihexal; Acyclo-V 200; Chem mart Aciclovir; GenRx Aciclovir; Lovir; Ozvir; Terry White Chemists Aciclovir |
| Zovirax 800 mg | aciclovir 800 mg tablet, 35 | 35 | 0.93 | Aciclovir 800; Acihexal; Acyclo-V 800; GenRx Aciclovir |
| Zyban | bupropion hydrochloride 150 mg tablet: modified release, 30 tablets | 30 | 0.80 | Prexaton |
| | bupropion hydrochloride 150 mg tablet: modified release, 90 tablets | 90 | 0.96 | Prexaton |
| Zyloprim | allopurinol 100 mg tablet, 200 | 200 | 2.54 | Allopurinol Sandoz; Allosig; Chem mart Allopurinol; GenRx Allopurinol; Terry White Chemists Allopurinol |
| | allopurinol 300 mg tablet, 60 | 60 | 2.33 | Allopurinol Sandoz; Allosig; Chem mart Allopurinol; GenRx Allopurinol; Progout 300; Terry White Chemists Allopurinol |