



**Australian Government**

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**Department of Health**

**SCHEDULE OF PHARMACEUTICAL BENEFITS**

**SUMMARY OF CHANGES**

**EFFECTIVE 1 May 2015**

## PHARMACEUTICAL BENEFITS

These changes to the Schedule of Pharmaceutical Benefits are effective from 1 May 2015. The Schedule is updated on the first day of each month and is available on the Internet at [www.pbs.gov.au](http://www.pbs.gov.au).

### Fees, Patient Contributions and Safety Net Thresholds

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

Dispensing Fees:	Ready-prepared	\$6.76
	Dangerous drug fee	\$2.71
	Extemporaneously-prepared	\$8.80
	Allowable additional patient charge*	\$4.27
Additional Fees (for safety net prices):	Ready-prepared	\$1.15
	Extemporaneously-prepared	\$1.50
Patient Co-payments:	General	\$37.70
	Concessional	\$6.10
Safety Net Thresholds:	General	\$1453.90
	Concessional	\$366.00
Safety Net Card Issue Fee:		\$9.47

\* 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.

## Prescriber Bag

### Deletions

#### Deletion – Item

10016E **BENZTROPINE**, benzotropine mesylate 2 mg/2 mL injection, 10 x 2 mL vials (*Benzotropine Omega*)

## General Pharmaceutical Benefits

### Additions

#### Addition – Item

10255R **LEUPRORELIN**, leuprorelin acetate 30 mg injection: modified release [1 syringe] (& inert substance diluent [1 syringe]), 1 pack (*Lucrin Depot Paediatric 30 mg PDS*)

10256T **LEUPRORELIN**, leuprorelin acetate 30 mg injection: modified release [1 syringe] (& inert substance diluent [1 syringe]), 1 pack (*Lucrin Depot Paediatric 30 mg PDS*)

10257W **MESALAZINE**, mesalazine 3 g granules, 30 sachets (*Salofalk*)

#### Addition – Brand

8214H *Blooms the Chemist Atorvastatin, IB* – **ATORVASTATIN**, atorvastatin 20 mg tablet, 30

9231W *Blooms the Chemist Atorvastatin, IB* – **ATORVASTATIN**, atorvastatin 20 mg tablet, 30

8215J *Blooms the Chemist Atorvastatin, IB* – **ATORVASTATIN**, atorvastatin 40 mg tablet, 30

9232X *Blooms the Chemist Atorvastatin, IB* – **ATORVASTATIN**, atorvastatin 40 mg tablet, 30

8521L *Blooms the Chemist Atorvastatin, IB* – **ATORVASTATIN**, atorvastatin 80 mg tablet, 30

9233Y *Blooms the Chemist Atorvastatin, IB* – **ATORVASTATIN**, atorvastatin 80 mg tablet, 30

2688L *Azathioprine GH, GQ* – **AZATHIOPRINE**, azathioprine 25 mg tablet, 100

2687K *Azathioprine GH, GQ* – **AZATHIOPRINE**, azathioprine 50 mg tablet, 100

8703C *Citalopram Actavis, VN* – **CITALOPRAM**, citalopram 40 mg tablet, 28

3138E *Clindamycin-Link, LM* – **CLINDAMYCIN**, clindamycin 150 mg capsule, 24

5057E *Clindamycin-Link, LM* – **CLINDAMYCIN**, clindamycin 150 mg capsule, 24 (**Dental**)

9296G *Piax Plus Aspirin, AF* – **CLOPIDOGREL + ASPIRIN**, clopidogrel 75 mg + aspirin 100 mg tablet, 30

5472B *Zilfojim ODT 4, DO* – **ONDANSETRON**, ONDANSETRON Tablet (orally disintegrating) 4 mg, 10

5473C *Zilfojim ODT 8, DO* – **ONDANSETRON**, ONDANSETRON Tablet (orally disintegrating) 8 mg, 10

2242B *Paroxetine Actavis, UA* – **PAROXETINE**, paroxetine 20 mg tablet, 30

9151P *APO-Pramipexole, TX* – **PRAMIPEXOLE**, pramipexole hydrochloride monohydrate 125 microgram tablet, 30

9152Q *APO-Pramipexole, TX* – **PRAMIPEXOLE**, pramipexole hydrochloride monohydrate 250 microgram tablet, 100

9153R *APO-Pramipexole, TX* – **PRAMIPEXOLE**, pramipexole hydrochloride monohydrate 1 mg tablet, 100

2833D *Auro-Pravastatin 10, DO* – **PRAVASTATIN**, pravastatin sodium 10 mg tablet, 30

9237E *Auro-Pravastatin 10, DO* – **PRAVASTATIN**, pravastatin sodium 10 mg tablet, 30

2834E *Auro-Pravastatin 20, DO* – **PRAVASTATIN**, pravastatin sodium 20 mg tablet, 30

9238F *Auro-Pravastatin 20, DO* – **PRAVASTATIN**, pravastatin sodium 20 mg tablet, 30

8197K *Auro-Pravastatin 40, DO* – **PRAVASTATIN**, pravastatin sodium 40 mg tablet, 30

9239G *Auro-Pravastatin 40, DO* – **PRAVASTATIN**, pravastatin sodium 40 mg tablet, 30

8829Q *Auro-Pravastatin 80, DO* – **PRAVASTATIN**, pravastatin sodium 80 mg tablet, 30

9240H *Auro-Pravastatin 80, DO* – **PRAVASTATIN**, pravastatin sodium 80 mg tablet, 30

9120B *Vascalace Caps 1.25, DO* – **RAMIPRIL**, ramipril 1.25 mg capsule, 30

9121C *Vascalace Caps 2.5, DO* – **RAMIPRIL**, ramipril 2.5 mg capsule, 30

9122D *Vascalace Caps 5, DO* – **RAMIPRIL**, ramipril 5 mg capsule, 30

8470T *Vascalace Caps 10, DO* – **RAMIPRIL**, ramipril 10 mg capsule, 30

9368C *Dilart, AF* – **VALSARTAN**, valsartan 40 mg tablet, 28

9369D *Dilart, AF* – **VALSARTAN**, valsartan 80 mg tablet, 28

9370E *Dilart, AF* – **VALSARTAN**, valsartan 160 mg tablet, 28

9371F *Dilart, AF* – **VALSARTAN**, valsartan 320 mg tablet, 28

9372G *Dilart HCT 80/12.5, AF* – **VALSARTAN + HYDROCHLOROTHIAZIDE**, valsartan 80 mg + hydrochlorothiazide 12.5 mg tablet, 28

9373H *Dilart HCT 160/12.5, AF* – **VALSARTAN + HYDROCHLOROTHIAZIDE**, valsartan 160 mg + hydrochlorothiazide 12.5 mg tablet, 28

9374J *Dilart HCT 160/25, AF* – **VALSARTAN + HYDROCHLOROTHIAZIDE**, valsartan 160 mg + hydrochlorothiazide 25 mg tablet, 28

9481B *Dilart HCT 320/12.5, AF* – **VALSARTAN + HYDROCHLOROTHIAZIDE**, valsartan 320 mg + hydrochlorothiazide 12.5 mg tablet, 28

9482C *Dilart HCT 320/25, AF* – **VALSARTAN + HYDROCHLOROTHIAZIDE**, valsartan 320 mg + hydrochlorothiazide 25 mg tablet, 28

#### Addition – Equivalence Indicator

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

9374J *Co-Diovan 160/25, NV* – **VALSARTAN + HYDROCHLOROTHIAZIDE**, valsartan 160 mg + hydrochlorothiazide 25 mg tablet, 28

## Deletions

### Deletion – Item

10013B	<b>BENZTROPINE</b> , benztropine mesylate 2 mg/2 mL injection, 10 x 2 mL vials ( <i>Benztropine Omega</i> )
10027R	<b>BENZTROPINE</b> , benztropine mesylate 2 mg/2 mL injection, 10 x 2 mL vials ( <i>Benztropine Omega</i> ) ( <b>Dental</b> )
2058H	<b>CARBOMER + TRIGLYCERIDE LIPIDS</b> , carbomer 0.2% + triglyceride lipids 1% eye gel, 30 x 600 mg unit doses ( <i>Artelac</i> )
2090B	<b>CARBOMER + TRIGLYCERIDE LIPIDS</b> , carbomer 0.2% + triglyceride lipids 1% eye gel, 30 x 600 mg unit doses ( <i>Artelac</i> ) ( <b>Optometrical</b> )
8652J	<b>MYCOPHENOLATE</b> , mycophenolate 180 mg tablet: enteric, 120 tablets ( <i>Myfortic</i> )
8653K	<b>MYCOPHENOLATE</b> , mycophenolate 360 mg tablet: enteric, 120 tablets ( <i>Myfortic</i> )
1742Q	<b>OESTRADIOL</b> , oestradiol 25 microgram pessary: modified release, 15 ( <i>Vagifem</i> )
9004X	<b>TESTOSTERONE UNDECANOATE</b> , testosterone undecanoate 1 g/4 mL injection, 1 x 4 mL ampoule ( <i>Reandron 1000</i> )

### Deletion – Brand

1007B	<i>Acihexal, SZ</i> – <b>ACICLOVIR</b> , aciclovir 200 mg tablet, 90
1171P	<i>Chloromycetin, PF</i> – <b>CHLORAMPHENICOL</b> , chloramphenicol 1% eye ointment, 4 g
5511C	<i>Chloromycetin, PF</i> – <b>CHLORAMPHENICOL</b> , chloramphenicol 1% eye ointment, 4 g ( <b>Optometrical</b> )
1473M	<i>Fluconazole-Clarix, AE</i> – <b>FLUCONAZOLE</b> , fluconazole 100 mg/50 mL injection, 1 x 50 mL vial
1474N	<i>Fluconazole-Clarix, AE</i> – <b>FLUCONAZOLE</b> , fluconazole 200 mg/100 mL injection, 1 x 100 mL vial
2414C	<i>Frusemide AN, EA</i> – <b>FRUSEMIDE</b> , frusemide 20 mg tablet, 100
2412Y	<i>Frusemide AN, EA</i> – <b>FRUSEMIDE</b> , frusemide 40 mg tablet, 100
8534E	<i>Lercanidipine AN, EA</i> – <b>LERCANIDIPINE</b> , lercanidipine hydrochloride 10 mg tablet, 28
8679T	<i>Lercanidipine AN, EA</i> – <b>LERCANIDIPINE</b> , lercanidipine hydrochloride 20 mg tablet, 28
1627P	<i>Tolvon, MK</i> – <b>MIANSERIN</b> , mianserin hydrochloride 10 mg tablet, 50
8525Q	<i>Lodam SR 200, ZP</i> – <b>TRAMADOL</b> , tramadol hydrochloride 200 mg tablet: modified release, 20 tablets

### Deletion – Equivalence Indicator

1627P	<i>Lumin 10, AF</i> – <b>MIANSERIN</b> , mianserin hydrochloride 10 mg tablet, 50
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## Alterations

### Changes to Restrictions

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

8845M	<b>BALSALAZIDE</b> , balsalazide sodium 750 mg capsule, 180 ( <i>Colazide</i> )
1502C	<b>HYDROCORTISONE ACETATE</b> , hydrocortisone acetate 10% (100 mg/g) enema, 21.1 g ( <i>Colifoam</i> )
1611T	<b>MESALAZINE</b> , mesalazine 250 mg tablet: enteric, 100 tablets ( <i>Mesasal</i> )
2214M	<b>MESALAZINE</b> , mesalazine 500 mg tablet: modified release, 100 tablets ( <i>Pentasa</i> )
2234N	<b>MESALAZINE</b> , mesalazine 1 g granules: modified release, 120 x 1 g sachets ( <i>Pentasa</i> )
2287J	<b>MESALAZINE</b> , mesalazine 2 g granules: modified release, 60 x 2 g sachets ( <i>Pentasa</i> )
3413P	<b>MESALAZINE</b> , mesalazine 1 g tablet: modified release, 60 tablets ( <i>Pentasa</i> )
5461K	<b>MESALAZINE</b> , mesalazine 1 g suppository, 30 ( <i>Salofalk</i> )
8598M	<b>MESALAZINE</b> , mesalazine 500 mg granules, 100 x 500 mg sachets ( <i>Salofalk</i> )
8599N	<b>MESALAZINE</b> , mesalazine 1 g granules: modified release, 100 x 1 g sachets ( <i>Salofalk</i> )
8616L	<b>MESALAZINE</b> , mesalazine 2 g/60 mL enema, 7 x 60 mL ( <i>Salofalk</i> )
8617M	<b>MESALAZINE</b> , mesalazine 4 g/60 mL enema, 7 x 60 mL ( <i>Salofalk</i> )
8731M	<b>MESALAZINE</b> , mesalazine 500 mg tablet: enteric, 100 tablets ( <i>Salofalk</i> )
8752P	<b>MESALAZINE</b> , mesalazine 1 g suppository, 30 ( <i>Pentasa</i> )
8753Q	<b>MESALAZINE</b> , mesalazine 1 g/100 mL enema, 7 x 100 mL ( <i>Pentasa</i> )
8768L	<b>MESALAZINE</b> , mesalazine 1 g/application enema, 14 applications ( <i>Salofalk</i> )
9206M	<b>MESALAZINE</b> , mesalazine 1.5 g granules, 60 x 1.5 g sachets ( <i>Salofalk</i> )
9353G	<b>MESALAZINE</b> , mesalazine 1.2 g tablet: modified release, 60 tablets ( <i>Mezavant</i> )
1728Y	<b>OLSALAZINE</b> , olsalazine sodium 250 mg capsule, 100 ( <i>Dipentum</i> )
8086N	<b>OLSALAZINE</b> , olsalazine sodium 500 mg tablet, 100 ( <i>Dipentum</i> )
1920C	<b>PREDNISOLONE SODIUM PHOSPHATE</b> , prednisolone (as sodium phosphate) 20 mg/100 mL enema, 7 x 100 mL ( <i>Predsol</i> )
2554K	<b>PREDNISOLONE SODIUM PHOSPHATE</b> , prednisolone (as sodium phosphate) 5 mg suppository, 10 ( <i>Predsol</i> )
2574L	<b>ROSUVASTATIN</b> , rosuvastatin 20 mg tablet, 30 ( <i>APO-Rosuvastatin, Blooms the Chemist Rosuvastatin, Cavstat, Chem mart Rosuvastatin, Crestor, Crosva 20, Rosuvastatin Actavis 20, Rosuvastatin GH, Rosuvastatin-DRLA, Terry White Chemists Rosuvastatin</i> )
2606E	<b>ROSUVASTATIN</b> , rosuvastatin 5 mg tablet, 30 ( <i>APO-Rosuvastatin, Blooms the Chemist Rosuvastatin, Cavstat, Chem mart Rosuvastatin, Crestor, Crosva 5, Rosuvastatin Actavis 5, Rosuvastatin GH, Rosuvastatin-DRLA, Terry White Chemists Rosuvastatin</i> )
2628H	<b>ROSUVASTATIN</b> , rosuvastatin 10 mg tablet, 30 ( <i>APO-Rosuvastatin, Blooms the Chemist Rosuvastatin, Cavstat, Chem mart Rosuvastatin, Crestor, Crosva 10, Rosuvastatin Actavis 10, Rosuvastatin GH, Rosuvastatin-DRLA, Terry White Chemists Rosuvastatin</i> )
9042X	<b>ROSUVASTATIN</b> , rosuvastatin 5 mg tablet, 30 ( <i>APO-Rosuvastatin, Blooms the Chemist Rosuvastatin, Cavstat, Chem mart Rosuvastatin, Crestor, Crosva 5, Rostor 5, Rosuvastatin AN, Rosuvastatin Actavis 5, Rosuvastatin GH, Rosuvastatin RBX,</i>

9043Y	<i>Rosuvastatin Sandoz, Rosuvastatin-DRLA, Terry White Chemists Rosuvastatin)</i> <b>ROSUVASTATIN</b> , rosuvastatin 10 mg tablet, 30 ( <i>APO-Rosuvastatin, Blooms the Chemist Rosuvastatin, Cavstat, Chem mart Rosuvastatin, Crestor, Crosva 10, Rostor 10, Rosuvastatin AN, Rosuvastatin Actavis 10, Rosuvastatin GH, Rosuvastatin Sandoz, Rosuvastatin-DRLA, Rosuvastatin RBX, Terry White Chemists Rosuvastatin)</i>
9044B	<b>ROSUVASTATIN</b> , rosuvastatin 20 mg tablet, 30 ( <i>APO-Rosuvastatin, Blooms the Chemist Rosuvastatin, Cavstat, Chem mart Rosuvastatin, Crestor, Crosva 20, Rostor 20, Rosuvastatin Actavis 20, Rosuvastatin GH, Rosuvastatin RBX, Rosuvastatin Sandoz, Rosuvastatin-DRLA, Rosuvastatin AN, Terry White Chemists Rosuvastatin)</i>
2093E	<b>SULFASALAZINE</b> , sulfasalazine 500 mg tablet, 100 ( <i>Salazopyrin</i> )
2096H	<b>SULFASALAZINE</b> , SULFASALAZINE Tablet 500 mg (enteric coated), 100 ( <i>Pyralin EN, Salazopyrin-EN</i> )
9208P	<b>SULFASALAZINE</b> , sulfasalazine 500 mg tablet, 100 ( <i>Salazopyrin</i> )
9209Q	<b>SULFASALAZINE</b> , SULFASALAZINE Tablet 500 mg (enteric coated), 100 ( <i>Pyralin EN, Salazopyrin-EN</i> )

### Alteration – Restriction Level

		<i>From</i>	<i>To</i>
8511Y	<b>ALENDRONATE</b> , alendronate 70 mg tablet, 4 ( <i>APO-Alendronate, Alendro Once Weekly, Alendrobell 70mg, Alendronate AN, Alendronate Sandoz, Alendronate-GA, Chem mart Alendronate 70mg, Densate 70, Fonat, Ossmax 70mg, Terry White Chemists Alendronate 70mg</i> )	streamlined	restricted
8657P	<b>CYCLOSPORIN</b> , cyclosporin 10 mg capsule, 60 ( <i>Neoral 10</i> )	authority-required	unrestricted
8658Q	<b>CYCLOSPORIN</b> , cyclosporin 25 mg capsule, 30 ( <i>Cyclosporin Sandoz, Neoral 25</i> )	authority-required	unrestricted
8659R	<b>CYCLOSPORIN</b> , cyclosporin 50 mg capsule, 30 ( <i>Cyclosporin Sandoz, Neoral 50</i> )	authority-required	unrestricted
8660T	<b>CYCLOSPORIN</b> , cyclosporin 100 mg capsule, 30 ( <i>Cyclosporin Sandoz, Neoral 100</i> )	authority-required	unrestricted
8661W	<b>CYCLOSPORIN</b> , cyclosporin 100 mg/mL oral liquid, 50 mL ( <i>Neoral</i> )	authority-required	unrestricted
9184J	<b>FLUDARABINE</b> , fludarabine phosphate 10 mg tablet, 20 ( <i>Fludara</i> )	authority-required	unrestricted
8726G	<b>GLATIRAMER ACETATE</b> , glatiramer acetate 20 mg/mL injection, 28 x 1 mL syringes ( <i>Copaxone</i> )	authority-required	streamlined
1454M	<b>GOSERELIN</b> , goserelin 3.6 mg implant, 1 ( <i>Zoladex Implant</i> )	authority-required	restricted
8093Y	<b>GOSERELIN</b> , goserelin 10.8 mg implant, 1 ( <i>Zoladex 10.8 Implant</i> )	streamlined	restricted
9064C	<b>GOSERELIN (&amp;) BICALUTAMIDE</b> , goserelin 3.6 mg implant [1 implant] (&) bicalutamide 50 mg tablet [28 tablets], 1 pack ( <i>ZolaCos CP 3.6/50</i> )	streamlined	restricted
9065D	<b>GOSERELIN (&amp;) BICALUTAMIDE</b> , goserelin 10.8 mg implant [1 implant] (&) bicalutamide 50 mg tablet [28 tablets], 1 pack ( <i>ZolaCos CP 10.8/50(28)</i> )	streamlined	restricted
9066E	<b>GOSERELIN (&amp;) BICALUTAMIDE</b> , goserelin 10.8 mg implant [1 implant] (&) bicalutamide 50 mg tablet [84 tablets], 1 pack ( <i>ZolaCos CP 10.8/50(84)</i> )	streamlined	restricted
8289G	<b>INTERFERON BETA-1A</b> , 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 ( <i>Avonex</i> )	authority-required	streamlined
8403G	<b>INTERFERON BETA-1A</b> , interferon beta-1a 44 microgram/0.5 mL (12 million international units) injection, 12 x 0.5 mL syringes ( <i>Rebif 44</i> )	authority-required	streamlined
8805K	<b>INTERFERON BETA-1A</b> , interferon beta-1a 30 microgram/0.5 mL (6 million international units) injection, 4 x 0.5 mL syringes ( <i>Avonex</i> )	authority-required	streamlined
8968B	<b>INTERFERON BETA-1A</b> , INTERFERON BETA-1a Injection 44 micrograms (12,000,000 i.u.) in 0.5 mL single dose autoinjector, 12 ( <i>Rebif 44</i> )	authority-required	streamlined
9332E	<b>INTERFERON BETA-1A</b> , interferon beta-1a 44 microgram/0.5 mL (12 million international units) injection, 4 x 1.5 mL cartridges ( <i>Rebif 44</i> )	authority-required	streamlined
8101J	<b>INTERFERON BETA-1B</b> , 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 ( <i>Betaferon</i> )	authority-required	streamlined
1836P	<b>MYCOPHENOLATE</b> , mycophenolate Capsule 250 mg, 50 ( <i>Ceptolate</i> )	authority-required	unrestricted
2150E	<b>MYCOPHENOLATE</b> , mycophenolate 180 mg tablet: enteric, 120 tablets ( <i>Myfortic</i> )	authority-required	unrestricted
2193K	<b>MYCOPHENOLATE</b> , mycophenolate 360 mg tablet: enteric, 120 tablets ( <i>Myfortic</i> )	authority-required	unrestricted
8649F	<b>MYCOPHENOLATE</b> , mycophenolate mofetil 250 mg capsule, 100 ( <i>APO-Mycophenolate, CellCept, Mycophenolate Sandoz, Pharmacor Mycophenolate 250</i> )	authority-required	unrestricted
8650G	<b>MYCOPHENOLATE</b> , mycophenolate mofetil 500 mg tablet, 50 ( <i>APO-Mycophenolate, CellCept, Ceptolate, Pharmacor Mycophenolate 500, Mycophenolate Sandoz</i> )	authority-required	unrestricted
8651H	<b>MYCOPHENOLATE</b> , mycophenolate mofetil 1 g/5 mL oral liquid: powder for, 165 mL ( <i>CellCept</i> )	authority-required	unrestricted
8209C	<b>PAMIDRONATE DISODIUM</b> , pamidronate disodium 30 mg injection [2 x 30 mg vials] (&) inert substance diluent [2 x 10 mL ampoules], 1 pack ( <i>Aredia 30 mg</i> )	streamlined	restricted
8461H	<b>PAMIDRONATE DISODIUM</b> , pamidronate disodium 15 mg/5 mL injection, 1 x 5 mL vial ( <i>Pamisol</i> )	streamlined	restricted

8462J	<b>PAMIDRONATE DISODIUM</b> , pamidronate disodium 30 mg/10 mL injection, 1 x 10 mL vial ( <i>Pamisol</i> )	streamlined	restricted
8463K	<b>PAMIDRONATE DISODIUM</b> , pamidronate disodium 60 mg/10 mL injection, 1 x 10 mL vial ( <i>Pamisol</i> )	streamlined	restricted
8481J	<b>RISEDRONATE</b> , risedronate sodium 5 mg tablet, 28 ( <i>Actonel</i> )	streamlined	restricted
8482K	<b>RISEDRONATE</b> , risedronate sodium 30 mg tablet, 28 ( <i>Actonel</i> )	streamlined	restricted
8621R	<b>RISEDRONATE</b> , risedronate sodium 35 mg tablet, 4 ( <i>APO-Risedronate, Acris Once-a-Week, Risedro once a week, Risedronate AN, Risedronate Sandoz, Risedronate-GA</i> )	streamlined	restricted
8972F	<b>RISEDRONATE</b> , RISEDRONATE SODIUM Tablet 35 mg (enteric coated), 4 ( <i>Actonel EC</i> )	streamlined	restricted
9391G	<b>RISEDRONATE</b> , risedronate sodium 150 mg tablet, 1 ( <i>APO-Risedronate, Acris Once-a-Month, Actonel Once-a-Month, Chem mart Risedronate, Terry White Chemists Risedronate</i> )	streamlined	restricted
8724E	<b>SIROLIMUS</b> , sirolimus 1 mg tablet, 100 ( <i>Rapamune</i> )	authority- required	unrestricted
8725F	<b>SIROLIMUS</b> , sirolimus 1 mg/mL oral liquid, 60 mL ( <i>Rapamune</i> )	authority- required	unrestricted
8833X	<b>SIROLIMUS</b> , sirolimus 2 mg tablet, 100 ( <i>Rapamune</i> )	authority- required	unrestricted
8984W	<b>SIROLIMUS</b> , sirolimus 500 microgram tablet, 100 ( <i>Rapamune</i> )	authority- required	unrestricted
5299X	<b>TACROLIMUS</b> , tacrolimus 500 microgram capsule: modified release, 30 capsules ( <i>Prograf XL</i> )	authority- required	unrestricted
5300Y	<b>TACROLIMUS</b> , tacrolimus 1 mg capsule: modified release, 60 capsules ( <i>Prograf XL</i> )	authority- required	unrestricted
5451X	<b>TACROLIMUS</b> , tacrolimus 5 mg capsule: modified release, 30 capsules ( <i>Prograf XL</i> )	authority- required	unrestricted
8646C	<b>TACROLIMUS</b> , tacrolimus 500 microgram capsule, 100 ( <i>Pharmacor Tacrolimus 0.5, Prograf, Tacrolimus Sandoz</i> )	authority- required	unrestricted
8647D	<b>TACROLIMUS</b> , tacrolimus 1 mg capsule, 100 ( <i>Pharmacor Tacrolimus 1, Prograf, Tacrolimus Sandoz</i> )	authority- required	unrestricted
8648E	<b>TACROLIMUS</b> , tacrolimus 5 mg capsule, 50 ( <i>Pharmacor Tacrolimus 5, Prograf, Tacrolimus Sandoz</i> )	authority- required	unrestricted
10062N	<b>TEMOZOLOMIDE</b> , temozolomide 180 mg capsule, 5 ( <i>Astromide, Orion Temozolomide, Temodal</i> )	authority- required	restricted
2438H	<b>TEMOZOLOMIDE</b> , temozolomide 180 mg capsule, 5 ( <i>Astromide, Orion Temozolomide, Temodal</i> )	authority- required	unrestricted
8378Y	<b>TEMOZOLOMIDE</b> , temozolomide 5 mg capsule, 5 ( <i>Astromide, Orion Temozolomide, Temizole 5, Temodal, Temozolomide AN, Temozolomide Alphapharm</i> )	authority- required	unrestricted
8379B	<b>TEMOZOLOMIDE</b> , temozolomide 20 mg capsule, 5 ( <i>Astromide, Orion Temozolomide, Temizole 20, Temodal, Temozolomide Alphapharm, Temozolomide AN</i> )	authority- required	unrestricted
8380C	<b>TEMOZOLOMIDE</b> , temozolomide 100 mg capsule, 5 ( <i>Astromide, Orion Temozolomide, Temizole 100, Temodal, Temozolomide AN, Temozolomide Alphapharm</i> )	authority- required	unrestricted
8381D	<b>TEMOZOLOMIDE</b> , temozolomide 250 mg capsule, 5 ( <i>Astromide, Orion Temozolomide, Temizole 250, Temodal, Temozolomide Alphapharm, Temozolomide AN</i> )	authority- required	unrestricted
8819E	<b>TEMOZOLOMIDE</b> , temozolomide 5 mg capsule, 5 ( <i>Astromide, Orion Temozolomide, Temizole 5, Temodal, Temozolomide Alphapharm, Temozolomide AN</i> )	authority- required	restricted
8820F	<b>TEMOZOLOMIDE</b> , temozolomide 20 mg capsule, 5 ( <i>Astromide, Orion Temozolomide, Temizole 20, Temodal, Temozolomide AN, Temozolomide Alphapharm</i> )	authority- required	restricted
8821G	<b>TEMOZOLOMIDE</b> , temozolomide 100 mg capsule, 5 ( <i>Astromide, Orion Temozolomide, Temizole 100, Temodal, Temozolomide Alphapharm, Temozolomide AN</i> )	authority- required	restricted
9361Q	<b>TEMOZOLOMIDE</b> , temozolomide 140 mg capsule, 5 ( <i>Astromide, Orion Temozolomide, Temizole 140, Temodal, Temozolomide AN, Temozolomide Alphapharm</i> )	authority- required	restricted
9362R	<b>TEMOZOLOMIDE</b> , temozolomide 140 mg capsule, 5 ( <i>Astromide, Orion Temozolomide, Temizole 140, Temodal, Temozolomide Alphapharm, Temozolomide AN</i> )	authority- required	unrestricted
8267D	<b>TILUDRONATE</b> , tiludronate 200 mg tablet, 56 ( <i>Skelid</i> )	streamlined	restricted
9350D	<b>ZOLEDRONIC ACID</b> , zoledronic acid 5 mg/100 mL injection, 1 x 100 mL vial ( <i>Aclasta</i> )	authority- required	streamlined

### Alteration – Manufacturer Code

		<i>From</i>	<i>To</i>
8726G	<i>Copaxone</i> – <b>GLATIRAMER ACETATE</b> , glatiramer acetate 20 mg/mL injection, 28 x 1 mL syringes	CS	TB
9475Q	<i>Sculptra</i> – <b>POLYLACTIC ACID</b> , polylactic acid 150 mg injection, 1 x 150 mg vial	SW	GA
9476R	<i>Sculptra</i> – <b>POLYLACTIC ACID</b> , polylactic acid 150 mg injection, 1 x 150 mg vial	SW	GA

### Alteration – Number of Repeats

		<i>From</i>	<i>To</i>
1836P	<b>MYCOPHENOLATE</b> , mycophenolate Capsule 250 mg, 50 ( <i>Ceptolate</i> )	3	5
8649F	<b>MYCOPHENOLATE</b> , mycophenolate mofetil 250 mg capsule, 100 ( <i>APO-Mycophenolate, CellCept, Mycophenolate</i> )	3	5

	<i>Sandoz, Pharmacor Mycophenolate 250)</i>		
8650G	<b>MYCOPHENOLATE</b> , mycophenolate mofetil 500 mg tablet, 50 ( <i>APO-Mycophenolate, CellCept, Ceptolate, Pharmacor Mycophenolate 500, Mycophenolate Sandoz</i> )	3	5
8651H	<b>MYCOPHENOLATE</b> , mycophenolate mofetil 1 g/5 mL oral liquid: powder for, 165 mL ( <i>CellCept</i> )	3	5

## Advance Notices

### 1 June 2015

#### Deletion – Brand

1172Q	<i>Chloramycetin, PF</i> – <b>CHLORAMPHENICOL</b> , chloramphenicol 0.5% ear drops, 5 mL
1210Q	<i>Ciproxin 750, BN</i> – <b>CIPROFLOXACIN</b> , ciprofloxacin 750 mg tablet, 14

### 1 July 2015

#### Deletion – Brand

1783W	<i>Ceftriaxone ICP, PP</i> – <b>CEFTRIAXONE</b> , ceftriaxone 500 mg injection, 1 x 500 mg vial
9058R	<i>Ceftriaxone ICP, PP</i> – <b>CEFTRIAXONE</b> , ceftriaxone 500 mg injection, 1 x 500 mg vial

### 1 August 2015

#### Deletion – Brand

2873F	<i>Invokana, JC</i> – <b>CANAGLIFLOZIN</b> , canagliflozin 100 mg tablet, 30
2987F	<i>Invokana, JC</i> – <b>CANAGLIFLOZIN</b> , canagliflozin 300 mg tablet, 30
9157Y	<i>Sensipar, AN</i> – <b>CINACALCET</b> , cinacalcet 30 mg tablet, 28
9158B	<i>Sensipar, AN</i> – <b>CINACALCET</b> , cinacalcet 60 mg tablet, 28
9159C	<i>Sensipar, AN</i> – <b>CINACALCET</b> , cinacalcet 90 mg tablet, 28

## Highly Specialised Drugs Program (Public Hospital)

### Alterations

#### Changes to Restrictions

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

10109C	<b>OMALIZUMAB</b> , omalizumab 150 mg/mL injection, 1 x 1 mL syringe ( <i>Xolair</i> )
10118M	<b>OMALIZUMAB</b> , omalizumab 75 mg/0.5 mL injection, 1 x 0.5 mL syringe ( <i>Xolair</i> )

## Advance Notices

### 1 August 2015

#### Deletion – Brand

5621W	<i>Sensipar, AN</i> – <b>CINACALCET</b> , cinacalcet 30 mg tablet, 28
5622X	<i>Sensipar, AN</i> – <b>CINACALCET</b> , cinacalcet 60 mg tablet, 28
5623Y	<i>Sensipar, AN</i> – <b>CINACALCET</b> , cinacalcet 90 mg tablet, 28

## Highly Specialised Drugs Program (Private Hospital)

### Alterations

#### Changes to Restrictions

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

10110D	<b>OMALIZUMAB</b> , omalizumab 75 mg/0.5 mL injection, 1 x 0.5 mL syringe ( <i>Xolair</i> )
10122R	<b>OMALIZUMAB</b> , omalizumab 150 mg/mL injection, 1 x 1 mL syringe ( <i>Xolair</i> )

## Advance Notices

### 1 August 2015

#### Deletion – Brand

9625N	<i>Sensipar, AN</i> – <b>CINACALCET</b> , cinacalcet 30 mg tablet, 28
9626P	<i>Sensipar, AN</i> – <b>CINACALCET</b> , cinacalcet 60 mg tablet, 28
9627Q	<i>Sensipar, AN</i> – <b>CINACALCET</b> , cinacalcet 90 mg tablet, 28

## Repatriation Pharmaceutical Benefits

### Additions

#### Addition – Brand

4806Y *Hydrosorb 900854, HR* – **DRESSING HYDROGEL SHEET**, dressing hydrogel sheet 10 cm x 10 cm dressing, 5

### Deletions

#### Deletion – Brand

4806Y *Aquaclear 900796, HR* – **DRESSING HYDROGEL SHEET**, dressing hydrogel sheet 10 cm x 10 cm dressing, 5

## 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
<b>ALENDRONATE</b>							
<b><u>Restricted benefit</u></b>							
Corticosteroid-induced osteoporosis							
<b>Clinical criteria:</b>							
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,							
<b>AND</b>							
Patient must have a Bone Mineral Density (BMD) T-score of -1.5 or less,							
<b>AND</b>							
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.							
<b><u>Note</u></b>							
Anti-resorptive agents in osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride, strontium ranelate and zoledronic acid.							
<b><u>Restricted benefit</u></b>							
Osteoporosis							
<b>Clinical criteria:</b>							
Patient must have a Bone Mineral Density (BMD) T-score of -2.5 or less,							
<b>AND</b>							
Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.							
<b>Population criteria:</b>							
Patient must be aged 70 years or older.							
The date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.							
<b><u>Note</u></b>							
Anti-resorptive agents in osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride, strontium ranelate and zoledronic acid.							
<b><u>Restricted benefit</u></b>							
Established osteoporosis							
<b>Clinical criteria:</b>							
Patient must have fracture due to minimal trauma,							
<b>AND</b>							
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.							
<b><u>Note</u></b>							
Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride, strontium ranelate and zoledronic acid.							
8511Y NP	alendronate 70 mg tablet, 4	1	5	..	14.01	15.16	<sup>a</sup> APO-Alendronate TX <sup>a</sup> Alendro Once Weekly QA <sup>a</sup> Alendrobell 70mg GQ <sup>a</sup> Alendronate AN EA <sup>a</sup> Alendronate Sandoz SZ <sup>a</sup> Alendronate-GA GN <sup>a</sup> Chem mart CH Alendronate 70mg <sup>a</sup> Densate 70 DO <sup>a</sup> Fonat AL <sup>a</sup> Ossmax 70mg RA

## 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		
							a	Terry White Chemists Alendronate 70mg	TW
<b>BALSALAZIDE</b>									
<b>Authority required (STREAMLINED)</b>									
<b>4824</b>									
Ulcerative colitis									
<b>Clinical criteria:</b>									
Patient must have had a documented hypersensitivity reaction to a sulphonamide; OR									
Patient must be intolerant to sulfasalazine.									
<b>Note</b>									
Not for the treatment of Crohn disease									
<b>Note</b>									
<b>Continuing Therapy Only:</b>									
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing 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	..	125.19	37.70	Colazide		PK
<b>CYCLOSPORIN</b>									
<b>Caution</b>									
Careful monitoring of patients is mandatory.									
8657P	cyclosporin 10 mg capsule, 60	2	3	..	*94.76	37.70	Neoral 10		NV
8658Q	cyclosporin 25 mg capsule, 30	2	3	..	*97.58	37.70	a Cyclosporin Sandoz		SZ
8659R	cyclosporin 50 mg capsule, 30	2	3	..	*195.72	37.70	a Neoral 25 a Cyclosporin Sandoz		NV SZ
8660T	cyclosporin 100 mg capsule, 30	2	3	..	*374.78	37.70	a Neoral 50 a Cyclosporin Sandoz		NV SZ
8661W	cyclosporin 100 mg/mL oral liquid, 50 mL	2	3	..	*713.00	37.70	a Neoral 100 Neoral		NV NV
<b>FLUDARABINE</b>									
9184J	fludarabine phosphate 10 mg tablet, 20	1	5	..	937.04	37.70	Fludara		GZ

### GLATIRAMER ACETATE

#### Authority required (STREAMLINED)

**4881**

Multiple sclerosis

Treatment Phase: Initial treatment

#### Clinical criteria:

The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; OR

The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis, with written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient,

#### AND

Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to the multiple sclerosis, in the preceding 2 years,

#### AND

Patient must be ambulatory (without assistance or support).

Where applicable, the date of the magnetic resonance imaging scan must be recorded in the patient's medical records.

#### Note

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

#### Note

## 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
	No increase in the maximum number of repeats may be authorised.						
	<b>Authority required (STREAMLINED)</b>						
	<b>4887</b>						
	Multiple sclerosis						
	Treatment Phase: Continuing treatment						
	<b>Clinical criteria:</b>						
	The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis,						
	<b>AND</b>						
	Patient must have previously been issued with an authority prescription for this drug,						
	<b>AND</b>						
	Patient must not show continuing progression of disability while on treatment with this drug,						
	<b>AND</b>						
	Patient must have demonstrated compliance with, and an ability to tolerate this therapy.						
	<b>Note</b>						
	No increase in the maximum quantity or number of units may be authorised.						
	<b>Note</b>						
	No increase in the maximum number of repeats may be authorised.						
8726G	glatiramer acetate 20 mg/mL injection, 28 x 1 mL syringes	1	5	..	1092.99	37.70	Copaxone TB
	<b>GOSERELIN</b>						
	<b>Restricted benefit</b>						
	Carcinoma of the prostate						
	<b>Clinical criteria:</b>						
	The condition must be locally advanced (stage C); OR						
	The condition must be metastatic (stage D).						
	<b>Restricted benefit</b>						
	Breast cancer						
	<b>Clinical criteria:</b>						
	The condition must be locally advanced (stage III); OR						
	The condition must be metastatic (stage IV),						
	<b>AND</b>						
	The condition must be hormone receptor positive.						
	<b>Restricted benefit</b>						
	Endometriosis						
	<b>Clinical criteria:</b>						
	The condition must be visually proven,						
	<b>AND</b>						
	The treatment must be for the short-term (up to 6 months).						
	<b>Note</b>						
	Only 1 course of not more than 6 months' therapy will be authorised.						
	<b>Restricted benefit</b>						
	Breast cancer						
	<b>Clinical criteria:</b>						
	The condition must be hormone receptor positive,						
	<b>AND</b>						
	The treatment must be an alternative to adjuvant chemotherapy.						
1454M	goserelin 3.6 mg implant, 1	1	5	..	333.34	37.70	Zoladex Implant AP

### GOSERELIN

#### **Restricted benefit**

## 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	
	Carcinoma of the prostate							
	<b>Clinical criteria:</b>							
	The condition must be locally advanced (stage C); OR							
	The condition must be metastatic (stage D).							
8093Y	goserelin 10.8 mg implant, 1	1	1	..	1109.10	37.70	Zoladex 10.8 Implant	AP
	<b>GOSERELIN (&amp;) BICALUTAMIDE</b>							
	<b>Restricted benefit</b>							
	Carcinoma of the prostate							
	<b>Clinical criteria:</b>							
	The condition must be metastatic (stage D),							
	<b>AND</b>							
	Patient must require a combination of an antiandrogen and a GnRH (LH-RH) agonist.							
	<b>Note</b>							
	No increase in the maximum quantity or number of units may be authorised.							
	<b>Note</b>							
	No increase in the maximum number of repeats may be authorised.							
9064C	goserelin 3.6 mg implant [1 implant] (& bicalutamide 50 mg tablet [28 tablets], 1 pack	#1	5	..	477.71	37.70	ZolaCos CP 3.6/50	AP
9065D	goserelin 10.8 mg implant [1 implant] (& bicalutamide 50 mg tablet [28 tablets], 1 pack	#1	..	..	1248.63	37.70	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	..	1527.71	37.70	ZolaCos CP 10.8/50(84)	AP
	<b>HYDROCORTISONE ACETATE</b>							
	<b>Restricted benefit</b>							
	Proctitis							
	<b>Note</b>							
	<b>Continuing Therapy Only:</b>							
	For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.							
	<b>Restricted benefit</b>							
	Ulcerative colitis							
	<b>Note</b>							
	<b>Continuing Therapy Only:</b>							
	For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing 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	..	*40.78	37.70	Colifoam	HM
	<b>INTERFERON BETA-1A</b>							
	<b>Authority required (STREAMLINED)</b>							
	<b>4881</b>							
	Multiple sclerosis							
	Treatment Phase: Initial treatment							
	<b>Clinical criteria:</b>							
	The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; OR							
	The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis, with written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient,							
	<b>AND</b>							
	Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to the multiple sclerosis, in the preceding 2 years,							
	<b>AND</b>							
	Patient must be ambulatory (without assistance or support).							

## 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	
Where applicable, the date of the magnetic resonance imaging scan must be recorded in the patient's medical records.								
<b>Note</b>								
No increase in the maximum quantity or number of units may be authorised.								
<b>Note</b>								
No increase in the maximum number of repeats may be authorised.								
<b>Authority required (STREAMLINED)</b>								
<b>4887</b>								
Multiple sclerosis								
Treatment Phase: Continuing treatment								
<b>Clinical criteria:</b>								
The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis,								
<b>AND</b>								
Patient must have previously been issued with an authority prescription for this drug,								
<b>AND</b>								
Patient must not show continuing progression of disability while on treatment with this drug,								
<b>AND</b>								
Patient must have demonstrated compliance with, and an ability to tolerate this therapy.								
<b>Note</b>								
No increase in the maximum quantity or number of units may be authorised.								
<b>Note</b>								
No increase in the maximum number of repeats may be authorised.								
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	..	1057.11	37.70	Avonex	BD
8403G	interferon beta-1a 44 microgram/0.5 mL (12 million international units) injection, 12 x 0.5 mL syringes	1	5	..	1057.11	37.70	Rebif 44	SG
8805K	interferon beta-1a 30 microgram/0.5 mL (6 million international units) injection, 4 x 0.5 mL syringes	1	5	..	1057.11	37.70	Avonex	BD
8968B	INTERFERON BETA-1a Injection 44 micrograms (12,000,000 i.u.) in 0.5 mL single dose autoinjector, 12	1	5	..	1057.11	37.70	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	..	1057.11	37.70	Rebif 44	SG

### INTERFERON BETA-1B

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

**4881**

Multiple sclerosis

Treatment Phase: Initial treatment

#### **Clinical criteria:**

The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; OR

The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis, with written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient,

**AND**

Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to the multiple sclerosis, in the preceding 2 years,

**AND**

Patient must be ambulatory (without assistance or support).

Where applicable, the date of the magnetic resonance imaging scan must be recorded in the patient's medical records.

#### **Note**

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

#### **Note**

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

## 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	
<b>Authority required (STREAMLINED)</b>								
<b>4887</b>								
Multiple sclerosis								
Treatment Phase: Continuing treatment								
<b>Clinical criteria:</b>								
The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis,								
<b>AND</b>								
Patient must have previously been issued with an authority prescription for this drug,								
<b>AND</b>								
Patient must not show continuing progression of disability while on treatment with this drug,								
<b>AND</b>								
Patient must have demonstrated compliance with, and an ability to tolerate this therapy.								
<b>Note</b>								
No increase in the maximum quantity or number of units may be authorised.								
<b>Note</b>								
No increase in the maximum number of repeats may be authorised.								
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	..	1001.15	37.70	Betaferon	BN
<b>LEUPRORELIN</b>								
<b>Authority required (STREAMLINED)</b>								
<b>4871</b>								
Central precocious puberty								
Treatment Phase: Continuing treatment								
<b>Clinical criteria:</b>								
Patient must have previously been issued with an authority prescription for this drug for this condition.								
<b>Treatment criteria:</b>								
Must be treated by a medical practitioner in consultation with a paediatric endocrinologist; OR								
Must be treated by a medical practitioner in consultation with an endocrinologist specialising in paediatrics.								
10255R	leuprorelin acetate 30 mg injection: modified release [1 syringe] (&) inert substance diluent [1 syringe], 1 pack	#1	1	..	1451.67	37.70	Lucrin Depot Paediatric 30 mg PDS	VE
<b>LEUPRORELIN</b>								
<b>Authority required</b>								
Central precocious puberty								
Treatment Phase: Initial treatment								
<b>Population criteria:</b>								
Patient must be under 8 years of age (girls) or 9 years of age (boys); OR								
Patient must have received treatment with a gonadotropin releasing hormone analogue (GnRHa) for this condition prior to 1 May 2015.								
<b>Treatment criteria:</b>								
Must be treated by a paediatric endocrinologist; OR								
Must be treated by an endocrinologist specialising in paediatrics.								
10256T	leuprorelin acetate 30 mg injection: modified release [1 syringe] (&) inert substance diluent [1 syringe], 1 pack	#1	1	..	1451.67	37.70	Lucrin Depot Paediatric 30 mg PDS	VE
<b>MESALAZINE</b>								
<b>Authority required (STREAMLINED)</b>								
<b>4824</b>								
Ulcerative colitis								
<b>Clinical criteria:</b>								
Patient must have had a documented hypersensitivity reaction to a sulphonamide; OR								

## 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	
	Patient must be intolerant to sulfasalazine.							
	<b>Note</b>							
	Not for the treatment of Crohn disease							
	<b>Note</b>							
	<b>Continuing Therapy Only:</b>							
	For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.							
10257W NP	mesalazine 3 g granules, 30 sachets	1	5	..	245.26	37.70	Salofalk	OA
8598M NP	mesalazine 500 mg granules, 100 x 500 mg sachets	2	5	..	*297.78	37.70	Salofalk	OA
8599N NP	mesalazine 1 g granules: modified release, 100 x 1 g sachets	1	5	..	279.97	37.70	Salofalk	OA
9206M NP	mesalazine 1.5 g granules, 60 x 1.5 g sachets	1	5	..	245.26	37.70	Salofalk	OA
9353G NP	mesalazine 1.2 g tablet: modified release, 60 tablets	1	5	..	221.33	37.70	Mezavant	ZI

### MESALAZINE

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

**4873**

Ulcerative colitis

#### **Clinical criteria:**

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

Patient must be intolerant to sulfasalazine.

#### **Note**

##### **Continuing Therapy Only:**

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

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

**4896**

Crohn disease

#### **Clinical criteria:**

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

Patient must be intolerant to sulfasalazine.

#### **Note**

##### **Continuing Therapy Only:**

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

1611T NP	mesalazine 250 mg tablet: enteric, 100 tablets	1	5	..	93.77	37.70	Mesasal	AS
2214M NP	mesalazine 500 mg tablet: modified release, 100 tablets	2	5	..	*297.78	37.70	Pentasa	FP
2234N NP	mesalazine 1 g granules: modified release, 120 x 1 g sachets	1	5	..	331.01	37.70	Pentasa	FP
2287J NP	mesalazine 2 g granules: modified release, 60 x 2 g sachets	1	5	..	312.64	37.70	Pentasa	FP
3413P NP	mesalazine 1 g tablet: modified release, 60 tablets	2	5	..	*331.02	37.70	Pentasa	FP
8731M NP	mesalazine 500 mg tablet: enteric, 100 tablets	2	5	..	*297.78	37.70	Salofalk	OA

### MESALAZINE

#### **Restricted benefit**

Acute episode of mild to moderate ulcerative proctitis

#### **Note**

Not for the treatment of Crohn disease

#### **Note**

## 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	
No increase in the maximum quantity or number of units may be authorised.								
<b>Note</b>								
No increase in the maximum number of repeats may be authorised.								
<b>Note</b>								
<b>Continuing Therapy Only:</b>								
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing 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	..	136.73	37.70	Salofalk	OA
8752P NP	mesalazine 1 g suppository, 30	1	1	..	136.73	37.70	Pentasa	FP
<hr/>								
<b>MESALAZINE</b>								
<b>Authority required (STREAMLINED)</b>								
<b>4888</b>								
Acute episode of mild to moderate ulcerative colitis								
<b>Note</b>								
Not for the treatment of Crohn disease								
<b>Note</b>								
No increase in the maximum quantity or number of units may be authorised.								
<b>Note</b>								
No increase in the maximum number of repeats may be authorised.								
<b>Note</b>								
<b>Continuing Therapy Only:</b>								
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.								
8616L NP	mesalazine 2 g/60 mL enema, 7 x 60 mL	4	1	..	*336.56	37.70	Salofalk	OA
8617M NP	mesalazine 4 g/60 mL enema, 7 x 60 mL	4	1	..	*446.24	37.70	Salofalk	OA
8753Q NP	mesalazine 1 g/100 mL enema, 7 x 100 mL	4	1	..	*336.56	37.70	Pentasa	FP
8768L NP	mesalazine 1 g/application enema, 14 applications	4	1	..	*336.56	37.70	Salofalk	OA
<hr/>								
<b>MYCOPHENOLATE</b>								
<b>Caution</b>								
Careful monitoring of patients is mandatory.								
<b>Note</b>								
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	5	..	*317.26	37.70	<sup>a</sup> Ceptolate	AF
8649F	mycophenolate mofetil 250 mg capsule, 100	3	5	..	*317.26	37.70	<sup>a</sup> APO-Mycophenolate	TX
							<sup>a</sup> CellCept	RO
							<sup>a</sup> Mycophenolate Sandoz	SZ
							<sup>a</sup> Pharmacor Mycophenolate 250	CR
<hr/>								
<b>MYCOPHENOLATE</b>								
<b>Caution</b>								
Careful monitoring of patients is mandatory.								
2150E	mycophenolate 180 mg tablet: enteric, 120 tablets	1	5	..	135.45	37.70	Myfortic	NV
2193K	mycophenolate 360 mg tablet: enteric, 120 tablets	1	5	..	258.73	37.70	Myfortic	NV
8650G	mycophenolate mofetil 500 mg tablet, 50	3	5	..	*317.23	37.70	<sup>a</sup> APO-Mycophenolate	TX

## 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	
							<sup>a</sup> CellCept	RO
							<sup>a</sup> Ceptolate	AF
							<sup>a</sup> Mycophenolate Sandoz	SZ
							<sup>a</sup> Pharmacor Mycophenolate 500	CR
8651H	mycophenolate mofetil 1 g/5 mL oral liquid: powder for, 165 mL	#1	5	..	290.29	37.70	CellCept	RO
<b>OLSALAZINE</b>								
<b>Authority required (STREAMLINED)</b>								
<b>4824</b>								
Ulcerative colitis								
<b>Clinical criteria:</b>								
Patient must have had a documented hypersensitivity reaction to a sulphonamide; OR								
Patient must be intolerant to sulfasalazine.								
<b>Note</b>								
Not for the treatment of Crohn disease								
<b>Note</b>								
<b>Continuing Therapy Only:</b>								
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing 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 NP	olsalazine sodium 250 mg capsule, 100	1	5	..	61.75	37.70	Dipentum	IX
8086N NP	olsalazine sodium 500 mg tablet, 100	1	5	..	103.63	37.70	Dipentum	IX
<b>PAMIDRONATE DISODIUM</b>								
<b>Restricted benefit</b>								
Symptomatic Paget disease of bone								
<b>Note</b>								
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.								
<b>Note</b>								
<b>Continuing Therapy Only:</b>								
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing 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 NP	pamidronate disodium 30 mg injection [2 x 30 mg vials] (&) inert substance diluent [2 x 10 mL ampoules], 1 pack	1	..	..	87.96	37.70	<sup>a</sup> Aredia 30 mg	NV
8462J NP	pamidronate disodium 30 mg/10 mL injection, 1 x 10 mL vial	2	..	..	*87.96	37.70	<sup>a</sup> Pamisol	HH
<b>PAMIDRONATE DISODIUM</b>								
<b>Restricted benefit</b>								
Symptomatic Paget disease of bone								
<b>Note</b>								
<b>Continuing Therapy Only:</b>								
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.								
8461H NP	pamidronate disodium 15 mg/5 mL injection, 1 x 5 mL vial	4	..	..	*87.96	37.70	Pamisol	HH
8463K NP	pamidronate disodium 60 mg/10 mL injection, 1 x 10 mL vial	1	..	..	87.95	37.70	Pamisol	HH
<b>PREDNISOLONE SODIUM PHOSPHATE</b>								

## 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	
<b>Note</b>								
<b>Continuing Therapy Only:</b>								
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing 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	..	*211.68	37.70	Predsol	QA
<b>PREDNISOLONE SODIUM PHOSPHATE</b>								
<b>Restricted benefit</b>								
Proctitis								
<b>Note</b>								
<b>Continuing Therapy Only:</b>								
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.								
<b>Restricted benefit</b>								
Ulcerative colitis								
<b>Note</b>								
<b>Continuing Therapy Only:</b>								
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing 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	..	*42.04	37.70	Predsol	QA
<b>RISEDRONATE</b>								
<b>Restricted benefit</b>								
Corticosteroid-induced osteoporosis								
<b>Clinical criteria:</b>								
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,								
<b>AND</b>								
Patient must have a Bone Mineral Density (BMD) T-score of -1.5 or less,								
<b>AND</b>								
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.								
<b>Note</b>								
Anti-resorptive agents in osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride, strontium ranelate and zoledronic acid.								
<b>Restricted benefit</b>								
Osteoporosis								
<b>Clinical criteria:</b>								
Patient must have a Bone Mineral Density (BMD) T-score of -2.5 or less,								
<b>AND</b>								
Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.								
<b>Population criteria:</b>								
Patient must be aged 70 years or older.								
The date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.								
<b>Note</b>								
Anti-resorptive agents in osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride, strontium ranelate and zoledronic acid.								
<b>Restricted benefit</b>								
Established osteoporosis								
<b>Clinical criteria:</b>								
Patient must have fracture due to minimal trauma,								
<b>AND</b>								

## 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	
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.								
<b>Note</b>								
Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride, strontium ranelate and zoledronic acid.								
8481J NP	risedronate sodium 5 mg tablet, 28	1	5	..	42.11	37.70	Actonel	UA
8621R NP	risedronate sodium 35 mg tablet, 4	1	5	..	42.11	37.70	<sup>a</sup> APO-Risedronate	TX
							<sup>a</sup> Acris Once-a-Week	AF
							<sup>a</sup> Risedro once a week	QA
							<sup>a</sup> Risedronate AN	EA
							<sup>a</sup> Risedronate Sandoz	SZ
							<sup>a</sup> Risedronate-GA	GN
8972F NP	RISEDRONATE SODIUM Tablet 35 mg (enteric coated), 4	1	5	..	42.11	37.70	Actonel EC	UA
9391G NP	risedronate sodium 150 mg tablet, 1	1	5	..	44.69	37.70	<sup>a</sup> APO-Risedronate	TX
							<sup>a</sup> Acris Once-a-Month	AF
							<sup>a</sup> Actonel Once-a-Month	UA
							<sup>a</sup> Chem mart	CH
							<sup>a</sup> Risedronate	
							<sup>a</sup> Terry White Chemists	TW
							Risedronate	
<hr/>								
<b>RISEDRONATE</b>								
<b>Restricted benefit</b>								
Symptomatic Paget disease of bone								
<b>Note</b>								
<b>Continuing Therapy Only:</b>								
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing 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	..	235.41	37.70	Actonel	UA
<hr/>								
<b>ROSUVASTATIN</b>								
<b>Restricted benefit</b>								
For use in patients who meet the criteria set out in the General Statement for Lipid-Lowering Drugs								
2574L NP	rosuvastatin 20 mg tablet, 30	1	5	..	35.11	36.26	<sup>a</sup> APO-Rosuvastatin	TX
							<sup>a</sup> Blooms the Chemist	IB
							Rosuvastatin	
							<sup>a</sup> Cavstat	AF
							<sup>a</sup> Chem mart	CH
							Rosuvastatin	
							<sup>a</sup> Crestor	AP
							<sup>a</sup> Crosuva 20	ZP
							<sup>a</sup> Rosuvastatin Actavis	GN
							20	
							<sup>a</sup> Rosuvastatin GH	GQ
							<sup>a</sup> Rosuvastatin-DRLA	RI
							<sup>a</sup> Terry White Chemists	TW
							Rosuvastatin	
2606E NP	rosuvastatin 5 mg tablet, 30	1	5	..	20.32	21.47	<sup>a</sup> APO-Rosuvastatin	TX

## 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
							<sup>a</sup> Blooms the Chemist Rosuvastatin IB
							<sup>a</sup> Cavstat AF
							<sup>a</sup> Chem mart Rosuvastatin CH
							<sup>a</sup> Crestor AP
							<sup>a</sup> Crosva 5 ZP
							<sup>a</sup> Rosuvastatin Actavis 5 GN
							<sup>a</sup> Rosuvastatin GH GQ
							<sup>a</sup> Rosuvastatin-DRLA RI
							<sup>a</sup> Terry White Chemists Rosuvastatin TW
2628H NP	rosuvastatin 10 mg tablet, 30	1	5	..	26.68	27.83	<sup>a</sup> APO-Rosuvastatin TX
							<sup>a</sup> Blooms the Chemist Rosuvastatin IB
							<sup>a</sup> Cavstat AF
							<sup>a</sup> Chem mart Rosuvastatin CH
							<sup>a</sup> Crestor AP
							<sup>a</sup> Crosva 10 ZP
							<sup>a</sup> Rosuvastatin Actavis 10 GN
							<sup>a</sup> Rosuvastatin GH GQ
							<sup>a</sup> Rosuvastatin-DRLA RI
							<sup>a</sup> Terry White Chemists Rosuvastatin TW

### ROSUVASTATIN

#### **Restricted benefit**

For use in patients who meet the criteria set out in the General Statement for Lipid-Lowering Drugs

#### **Clinical criteria:**

The treatment must not be prescribed for hypercholesterolaemia if the patient has heterozygous familial hypercholesterolaemia.

9042X NP	rosuvastatin 5 mg tablet, 30	1	5	..	20.32	21.47	<sup>a</sup> APO-Rosuvastatin TX
							<sup>a</sup> Blooms the Chemist Rosuvastatin IB
							<sup>a</sup> Cavstat AF
							<sup>a</sup> Chem mart Rosuvastatin CH
							<sup>a</sup> Crestor AP
							<sup>a</sup> Crosva 5 ZP
							<sup>a</sup> Rostor 5 DO
							<sup>a</sup> Rosuvastatin AN EA
							<sup>a</sup> Rosuvastatin Actavis 5 GN
							<sup>a</sup> Rosuvastatin GH GQ
							<sup>a</sup> Rosuvastatin RBX RA
							<sup>a</sup> Rosuvastatin Sandoz SZ
							<sup>a</sup> Rosuvastatin-DRLA RI
							<sup>a</sup> Terry White Chemists Rosuvastatin TW
9043Y NP	rosuvastatin 10 mg tablet, 30	1	5	..	26.68	27.83	<sup>a</sup> APO-Rosuvastatin TX
							<sup>a</sup> Blooms the Chemist Rosuvastatin IB
							<sup>a</sup> Cavstat AF
							<sup>a</sup> Chem mart Rosuvastatin CH
							<sup>a</sup> Crestor AP
							<sup>a</sup> Crosva 10 ZP
							<sup>a</sup> Rostor 10 DO
							<sup>a</sup> Rosuvastatin AN EA

## 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	
							<sup>a</sup> Rosuvastatin Actavis 10	GN
							<sup>a</sup> Rosuvastatin GH	GQ
							<sup>a</sup> Rosuvastatin RBX	RA
							<sup>a</sup> Rosuvastatin Sandoz	SZ
							<sup>a</sup> Rosuvastatin-DRLA	RI
							<sup>a</sup> Terry White Chemists Rosuvastatin	TW
9044B NP	rosuvastatin 20 mg tablet, 30	1	5	..	35.11	36.26	<sup>a</sup> APO-Rosuvastatin	TX
							<sup>a</sup> Blooms the Chemist Rosuvastatin	IB
							<sup>a</sup> Cavstat	AF
							<sup>a</sup> Chem mart Rosuvastatin	CH
							<sup>a</sup> Crestor	AP
							<sup>a</sup> Crosuva 20	ZP
							<sup>a</sup> Rostor 20	DO
							<sup>a</sup> Rosuvastatin AN	EA
							<sup>a</sup> Rosuvastatin Actavis 20	GN
							<sup>a</sup> Rosuvastatin GH	GQ
							<sup>a</sup> Rosuvastatin RBX	RA
							<sup>a</sup> Rosuvastatin Sandoz	SZ
							<sup>a</sup> Rosuvastatin-DRLA	RI
							<sup>a</sup> Terry White Chemists Rosuvastatin	TW

### SIROLIMUS

#### Caution

Careful monitoring of patients is mandatory.

8724E	sirolimus 1 mg tablet, 100	1	3	..	815.59	37.70	Rapamune	PF
8725F	sirolimus 1 mg/mL oral liquid, 60 mL	1	3	..	530.08	37.70	Rapamune	PF
8833X	sirolimus 2 mg tablet, 100	1	3	..	1584.03	37.70	Rapamune	PF
8984W	sirolimus 500 microgram tablet, 100	1	3	..	413.63	37.70	Rapamune	PF

### 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.

2093E NP	sulfasalazine 500 mg tablet, 100	2	5	..	*50.62	37.70	Salazopyrin	PF
2096H NP	SULFASALAZINE Tablet 500 mg (enteric coated), 100	2	5	<sup>B</sup> 2.48	*57.08	37.70	<sup>a</sup> Salazopyrin-EN	PF
				..	*54.60	37.70	<sup>a</sup> Pyralin EN	FZ

### SULFASALAZINE

#### Restricted benefit

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

#### Note

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

#### Note

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

9208P	sulfasalazine 500 mg tablet, 100	2	11	..	*50.62	37.70	Salazopyrin	PF
9209Q	SULFASALAZINE Tablet 500 mg (enteric coated),	2	11	..	*54.60	37.70	<sup>a</sup> Pyralin EN	FZ

## 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	
	100			<sup>B</sup> 2.48	*57.08	37.70	<sup>a</sup> Salazopyrin-EN	PF
<b>TACROLIMUS</b>								
<b>Caution</b>								
Careful monitoring of patients is mandatory.								
5299X	tacrolimus 500 microgram capsule: modified release, 30 capsules	1	3	..	58.88	37.70	Prograf XL	LL
5300Y	tacrolimus 1 mg capsule: modified release, 60 capsules	1	3	..	214.27	37.70	Prograf XL	LL
5451X	tacrolimus 5 mg capsule: modified release, 30 capsules	1	3	..	499.53	37.70	Prograf XL	LL
8646C	tacrolimus 500 microgram capsule, 100	1	3	..	180.49	37.70	<sup>a</sup> Pharmacor Tacrolimus 0.5	CR
							<sup>a</sup> Prograf	LL
8647D	tacrolimus 1 mg capsule, 100	1	3	..	340.63	37.70	<sup>a</sup> Tacrolimus Sandoz <sup>a</sup> Pharmacor	SZ CR
							Tacrolimus 1	
							<sup>a</sup> Prograf	LL
8648E	tacrolimus 5 mg capsule, 50	1	3	..	827.61	37.70	<sup>a</sup> Tacrolimus Sandoz <sup>a</sup> Pharmacor	SZ CR
							Tacrolimus 5	
							<sup>a</sup> Prograf	LL
							<sup>a</sup> Tacrolimus Sandoz	SZ
<b>TEMOZOLOMIDE</b>								
<b>Restricted benefit</b>								
Glioblastoma multiforme								
<b>Treatment criteria:</b>								
Patient must be undergoing concomitant radiotherapy.								
<b>Note</b>								
Temozolomide is not PBS-subsidised for use in conjunction with PBS-subsidised carmustine.								
<b>Note</b>								
No increase in the maximum number of repeats may be authorised.								
10062N	temozolomide 180 mg capsule, 5	3	2	..	*1766.53	37.70	<sup>a</sup> Astromide	GN
							<sup>a</sup> Orion Temozolomide	ON
							<sup>a</sup> Temodal	MK
8819E	temozolomide 5 mg capsule, 5	3	2	..	*93.94	37.70	<sup>a</sup> Astromide	GN
							<sup>a</sup> Orion Temozolomide	ON
							<sup>a</sup> Temizole 5	QA
							<sup>a</sup> Temodal	MK
							<sup>a</sup> Temozolomide AN	EA
							<sup>a</sup> Temozolomide	AF
8820F	temozolomide 20 mg capsule, 5	3	2	..	*257.77	37.70	<sup>a</sup> Alphapharm Astromide	GN
							<sup>a</sup> Orion Temozolomide	ON
							<sup>a</sup> Temizole 20	QA
							<sup>a</sup> Temodal	MK
							<sup>a</sup> Temozolomide AN	EA
							<sup>a</sup> Temozolomide	AF
8821G	temozolomide 100 mg capsule, 5	3	2	..	*1044.91	37.70	<sup>a</sup> Alphapharm Astromide	GN
							<sup>a</sup> Orion Temozolomide	ON
							<sup>a</sup> Temizole 100	QA
							<sup>a</sup> Temodal	MK
							<sup>a</sup> Temozolomide AN	EA
							<sup>a</sup> Temozolomide	AF

## 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	
9361Q	temozolomide 140 mg capsule, 5	3	2	..	*1411.06	37.70	Alphapharm Astromide	GN
							<sup>a</sup> Orion Temozolomide	ON
							<sup>a</sup> Temizole 140	QA
							<sup>a</sup> Temodal	MK
							<sup>a</sup> Temozolomide AN	EA
							<sup>a</sup> Temozolomide Alphapharm	AF
<hr/>								
	<b>TEMOZOLOMIDE</b>							
2438H	temozolomide 180 mg capsule, 5	1	5	..	593.35	37.70	Astromide	GN
							<sup>a</sup> Orion Temozolomide	ON
							<sup>a</sup> Temodal	MK
8378Y	temozolomide 5 mg capsule, 5	1	5	..	37.14	37.70	Astromide	GN
							<sup>a</sup> Orion Temozolomide	ON
							<sup>a</sup> Temizole 5	QA
							<sup>a</sup> Temodal	MK
							<sup>a</sup> Temozolomide AN	EA
							<sup>a</sup> Temozolomide Alphapharm	AF
8379B	temozolomide 20 mg capsule, 5	1	5	..	92.20	37.70	Astromide	GN
							<sup>a</sup> Orion Temozolomide	ON
							<sup>a</sup> Temizole 20	QA
							<sup>a</sup> Temodal	MK
							<sup>a</sup> Temozolomide AN	EA
							<sup>a</sup> Temozolomide Alphapharm	AF
8380C	temozolomide 100 mg capsule, 5	1	5	..	357.50	37.70	Astromide	GN
							<sup>a</sup> Orion Temozolomide	ON
							<sup>a</sup> Temizole 100	QA
							<sup>a</sup> Temodal	MK
							<sup>a</sup> Temozolomide AN	EA
							<sup>a</sup> Temozolomide Alphapharm	AF
8381D	temozolomide 250 mg capsule, 5	1	5	..	828.94	37.70	Astromide	GN
							<sup>a</sup> Orion Temozolomide	ON
							<sup>a</sup> Temizole 250	QA
							<sup>a</sup> Temodal	MK
							<sup>a</sup> Temozolomide AN	EA
							<sup>a</sup> Temozolomide Alphapharm	AF
9362R	temozolomide 140 mg capsule, 5	1	5	..	474.86	37.70	Astromide	GN
							<sup>a</sup> Orion Temozolomide	ON
							<sup>a</sup> Temizole 140	QA
							<sup>a</sup> Temodal	MK
							<sup>a</sup> Temozolomide AN	EA
							<sup>a</sup> Temozolomide Alphapharm	AF

### TILUDRONATE

#### **Restricted benefit**

Symptomatic Paget disease of bone

#### **Note**

#### **Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been

## 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	
initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.								
8267D NP	tiludronate 200 mg tablet, 56	1	2	..	304.96	37.70	Skelid	SW
<b>ZOLEDRONIC ACID</b>								
<b><u>Authority required (STREAMLINED)</u></b>								
<b>4876</b>								
Symptomatic Paget disease of bone								
Only 1 treatment each year per patient will be PBS-subsidised								
9350D	zoledronic acid 5 mg/100 mL injection, 1 x 100 mL vial	1	..	..	589.51	37.70	Aclasta	NV

## 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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### OMALIZUMAB

#### Authority required

Uncontrolled severe allergic asthma

Treatment Phase: Initial treatment

#### Clinical criteria:

Patient must be under the care of the same physician for at least 12 months,

#### AND

Patient must have a diagnosis of asthma confirmed and documented by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma, defined by the following standard clinical features: (i) forced expiratory volume (FEV1) reversibility greater than or equal to 12% and greater than or equal to 200 mL at baseline within 30 minutes after administration of salbutamol (200 to 400 micrograms), or (ii) airway hyperresponsiveness defined as a greater than 20% decline in FEV1 during a direct bronchial provocation test or greater than 15% decline during an indirect bronchial provocation test, or (iii) peak expiratory flow (PEF) variability of greater than 15% between the two highest and two lowest peak expiratory flow rates during 14 days,

#### AND

Patient must have a duration of asthma of at least 1 year,

#### AND

Patient must have forced expiratory volume (FEV1) less than or equal to 80% predicted, documented on 3 or more occasions in the previous 12 months,

#### AND

Patient must have past or current evidence of atopy, documented by skin prick testing or RAST,

#### AND

Patient must have total serum human immunoglobulin E greater than or equal to 76 IU/mL,

#### AND

Patient must have signed a patient acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criteria for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment,

#### AND

Patient must have failed to achieve adequate control with optimised asthma therapy, despite formal assessment of and adherence to correct inhaler technique, which has been documented,

#### AND

Patient must not receive more than 28 weeks of treatment under this restriction.

#### Population criteria:

Patient must be aged 12 years or older.

#### Treatment criteria:

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

Optimised asthma therapy includes:

(i) adherence to maximal inhaled therapy, including high dose inhaled corticosteroid (budesonide 1600 micrograms per day or fluticasone propionate 1000 micrograms per day or equivalent), plus long-acting beta-2 agonist therapy (at least salmeterol 50 micrograms bd or eformoterol 12 micrograms bd) for at least 12 months, unless contraindicated or not tolerated, AND

(ii) treatment with oral corticosteroids, either daily oral corticosteroids for at least 6 weeks, OR a cumulative dose of oral corticosteroids of at least 500 mg prednisolone equivalent in the previous 12 months, unless contraindicated or not tolerated.

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

The initial IgE assessment must be no more than 12 months old at the time of application.

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

(a) an Asthma Control Questionnaire (ACQ-5) score of at least 2.0, as assessed in the previous month, AND

(b) while receiving optimised asthma therapy in the past 12 months, experienced at least 1 admission to hospital for a severe asthma exacerbation, OR 1 severe asthma exacerbation, requiring documented use of systemic corticosteroids (oral corticosteroids initiated or increased for at least 3 days, or parenteral corticosteroids) prescribed/supervised by a physician.

The Asthma Control Questionnaire (5 item version) assessment of the patient's response to this initial course of treatment, and the assessment of oral corticosteroid dose, must be made at around 22 to 26 weeks after the first dose so that there is adequate time for a response to be demonstrated and for the application for continuing therapy to be processed.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted within 4 weeks of the date of assessment, and no later than 2 weeks prior to the patient completing their current treatment course, to avoid an interruption to supply. Where a response

## 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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assessment is not undertaken and submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with omalizumab.

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

At the time of the authority application, medical practitioners should request the appropriate maximum quantity and number of repeats to provide for an initial course of omalizumab consisting of the recommended number of doses for the baseline IgE level and body weight of the patient (refer to the TGA-approved Product Information) to be administered every 2 or 4 weeks.

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

- (a) a completed authority prescription form; and
- (b) a completed Severe Allergic Asthma PBS Authority Application - Supporting Information Form, which includes the following:
  - (i) details of prior optimised asthma drug therapy (dosage, date of commencement and duration of therapy); and
  - (ii) details of severe exacerbation/s experienced in the past 12 months while receiving optimised asthma therapy (date and treatment); and
  - (iii) the signed patient acknowledgement; and
  - (c) the IgE pathology report; and
  - (d) a completed Asthma Control Questionnaire (ACQ-5) calculation sheet including the date of assessment of the patient's symptoms.

### **Note**

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

### **Note**

For copies of the ACQ please contact Novartis Medical Information on 1800 671 203 or [medinfo.phauno@novartis.com](mailto:medinfo.phauno@novartis.com)

### **Note**

It is recommended that an application for continuing treatment is submitted at the time of the 22 to 26 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised omalizumab treatment.

### **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](http://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**

#### **TREATMENT OF ADULT AND ADOLESCENT PATIENTS WITH UNCONTROLLED SEVERE ALLERGIC ASTHMA**

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

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

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

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

(a) Initial treatment:

Applications for initial treatment should be made where a patient has received no prior PBS-subsidised omalizumab treatment in this treatment cycle and wishes to commence such therapy.

(b) Continuing treatment:

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

(2) Baseline measurements to determine response:

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

## HIGHLY SPECIALISED DRUGS PROGRAM (PUBLIC HOSPITAL)

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the Department of Human Services will assess response according to these revised baseline measurements.

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

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

(4) Monitoring of patients:

Anaphylaxis and anaphylactoid reactions have been reported following first or subsequent administration of omalizumab (see Product Information). Patients should be monitored post-injection, and medications for the treatment of anaphylactic reactions should be available for immediate use following administration of omalizumab. Patients should be informed that such reactions are possible and prompt medical attention should be sought if allergic reactions occur.

### **Note**

Formal assessment and correction of inhaler technique should be performed in accordance with the National Asthma Council (NAC) Information Paper for Health Professionals on Inhaler Technique (available at [www.humanservices.gov.au](http://www.humanservices.gov.au) or [www.nationalasthma.org.au](http://www.nationalasthma.org.au)); the assessment and adherence to correct technique should be documented in the patient's medical records. Patients can obtain support with inhaler technique through their local Asthma Foundation (1800 645 130).

### **Note**

Special Pricing Arrangements apply.

### **Authority required**

Uncontrolled severe allergic asthma

Treatment Phase: Continuing treatment

### **Clinical criteria:**

Patient must have a documented history of severe allergic asthma,

### **AND**

Patient must have demonstrated or sustained an adequate response to treatment with this drug,

### **AND**

Patient must not receive more than 24 weeks of treatment under this restriction.

### **Treatment criteria:**

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

An adequate response to omalizumab treatment is defined as:

- (a) a reduction in the Asthma Control Questionnaire (ACQ-5) score of at least 0.5 from baseline, OR
- (b) maintenance oral corticosteroid dose reduced by at least 25% from baseline, and no deterioration in ACQ-5 score from baseline.

All applications for continuing treatment with omalizumab must include a measurement of response to the prior course of therapy. The Asthma Control Questionnaire (5 item version) assessment of the patient's response to the prior course of treatment, and the assessment of oral corticosteroid dose, must be made at around 18 to 22 weeks after the first dose so that there is adequate time for a response to be demonstrated and for the application for continuing therapy to be processed.

The first assessment should, where possible, be completed by the same physician who initiated treatment with omalizumab. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted within 4 weeks of the date of assessment, and no later than 2 weeks prior to the patient completing their current treatment course, to avoid an interruption to supply. Where a response assessment is not undertaken and submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with omalizumab.

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

At the time of the authority application, medical practitioners should request the appropriate maximum quantity and number of repeats to provide for a continuing course of omalizumab consisting of the recommended number of doses for the baseline IgE level and body weight of the patient (refer to the TGA-approved Product Information), sufficient for 24 weeks of therapy.

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

- (a) a completed authority prescription form; and
- (b) a completed Severe Allergic Asthma PBS Authority Application - Supporting Information Form which includes details of maintenance oral corticosteroid dose; and
- (c) a completed Asthma Control Questionnaire (ACQ-5) calculation sheet including the date of assessment of the patient's symptoms.

### **Note**

If the same physician cannot assess the patient please call the Department of Human Services on 1800 700 270.

### **Note**

For copies of the ACQ please contact Novartis Medical Information on 1800 671 203 or [medinfo.phauno@novartis.com](mailto:medinfo.phauno@novartis.com)

### **Note**

It is recommended that an application for continuing treatment is submitted at the time of the 18 to 22 week assessment, to ensure continuity of

## 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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treatment for those patients who meet the continuation criterion for PBS-subsidised omalizumab 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](http://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**

#### **TREATMENT OF ADULT AND ADOLESCENT PATIENTS WITH UNCONTROLLED SEVERE ALLERGIC ASTHMA**

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

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

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

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

(a) Initial treatment:

Applications for initial treatment should be made where a patient has received no prior PBS-subsidised omalizumab treatment in this treatment cycle and wishes to commence such therapy.

(b) Continuing treatment:

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

(2) Baseline measurements to determine response:

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

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

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

(4) Monitoring of patients:

Anaphylaxis and anaphylactoid reactions have been reported following first or subsequent administration of omalizumab (see Product Information). Patients should be monitored post-injection, and medications for the treatment of anaphylactic reactions should be available for immediate use following administration of omalizumab. Patients should be informed that such reactions are possible and prompt medical attention should be sought if allergic reactions occur.

### **Note**

Formal assessment and correction of inhaler technique should be performed in accordance with the National Asthma Council (NAC) Information Paper for Health Professionals on Inhaler Technique (available at [www.humanservices.gov.au](http://www.humanservices.gov.au) or [www.nationalasthma.org.au](http://www.nationalasthma.org.au)); the assessment and adherence to correct technique should be documented in the patient's medical records. Patients can obtain support with inhaler technique through their local Asthma Foundation (1800 645 130).

### **Note**

Special Pricing Arrangements apply.

### **Authority required**

Uncontrolled severe allergic asthma

Treatment Phase: Initial treatment - balance of supply

### **Clinical criteria:**

Patient must have received insufficient therapy with this drug under the Initial treatment restriction to complete 28 weeks treatment,

**AND**

## 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
	The treatment must provide no more than the balance of up to 28 weeks treatment available under the above restriction.					
	<b>Treatment criteria:</b>					
	Must be treated by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma.					
	<b>Note</b>					
	Authority approval for sufficient therapy to complete a maximum of 28 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).					
	Written application for authority approval for sufficient therapy to complete a maximum of 28 weeks of treatment should be forwarded to:					
	Department of Human Services					
	Prior Written Approval of Complex Drugs					
	Reply Paid 9826					
	GPO Box 9826					
	HOBART TAS 7001					
	<b>Note</b>					
	Special Pricing Arrangements apply.					
	<b>Authority required</b>					
	Uncontrolled severe allergic asthma					
	Treatment Phase: Continuing treatment - balance of supply					
	<b>Clinical criteria:</b>					
	Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment,					
	<b>AND</b>					
	The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.					
	<b>Treatment criteria:</b>					
	Must be treated by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma.					
	<b>Note</b>					
	Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).					
	Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:					
	Department of Human Services					
	Prior Written Approval of Complex Drugs					
	Reply Paid 9826					
	GPO Box 9826					
	HOBART TAS 7001					
	<b>Note</b>					
	Special Pricing Arrangements apply.					
10109C	omalizumab 150 mg/mL injection, 1 x 1 mL syringe	1	..	..	410.00	Xolair NV

### **OMALIZUMAB**

#### **Authority required**

Uncontrolled severe allergic asthma

Treatment Phase: Initial treatment

#### **Clinical criteria:**

Patient must be under the care of the same physician for at least 12 months,

#### **AND**

Patient must have a diagnosis of asthma confirmed and documented by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma, defined by the following standard clinical features: (i) forced expiratory volume (FEV1) reversibility greater than or equal to 12% and greater than or equal to 200 mL at baseline within 30 minutes after administration of salbutamol (200 to 400 micrograms), or (ii) airway hyperresponsiveness defined as a greater than 20% decline in FEV1 during a direct bronchial provocation test or greater than 15% decline during an indirect bronchial provocation test, or (iii) peak expiratory flow (PEF) variability of greater than 15% between the two highest and two lowest peak expiratory flow rates during 14 days,

#### **AND**

Patient must have a duration of asthma of at least 1 year,

## 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
	<b>AND</b>					
	Patient must have forced expiratory volume (FEV1) less than or equal to 80% predicted, documented on 3 or more occasions in the previous 12 months,					
	<b>AND</b>					
	Patient must have past or current evidence of atopy, documented by skin prick testing or RAST,					
	<b>AND</b>					
	Patient must have total serum human immunoglobulin E greater than or equal to 76 IU/mL,					
	<b>AND</b>					
	Patient must have signed a patient acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criteria for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment,					
	<b>AND</b>					
	Patient must have failed to achieve adequate control with optimised asthma therapy, despite formal assessment of and adherence to correct inhaler technique, which has been documented,					
	<b>AND</b>					
	Patient must not receive more than 28 weeks of treatment under this restriction.					
	<b>Population criteria:</b>					
	Patient must be aged 12 years or older.					
	<b>Treatment criteria:</b>					
	Must be treated by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma.					
	Optimised asthma therapy includes:					
	(i) adherence to maximal inhaled therapy, including high dose inhaled corticosteroid (budesonide 1600 micrograms per day or fluticasone propionate 1000 micrograms per day or equivalent), plus long-acting beta-2 agonist therapy (at least salmeterol 50 micrograms bd or eformoterol 12 micrograms bd) for at least 12 months, unless contraindicated or not tolerated, AND					
	(ii) treatment with oral corticosteroids, either daily oral corticosteroids for at least 6 weeks, OR a cumulative dose of oral corticosteroids of at least 500 mg prednisolone equivalent in the previous 12 months, unless contraindicated or not tolerated.					
	If the requirement for treatment with optimised asthma therapy cannot be met because of contraindications according to the relevant TGA-approved Product Information and/or intolerances of a severity necessitating permanent treatment withdrawal, details of the contraindication and/or intolerance must be provided in the authority application.					
	The initial IgE assessment must be no more than 12 months old at the time of application.					
	The following initiation criteria indicate failure to achieve adequate control and must be demonstrated in all patients at the time of the application:					
	(a) an Asthma Control Questionnaire (ACQ-5) score of at least 2.0, as assessed in the previous month, AND					
	(b) while receiving optimised asthma therapy in the past 12 months, experienced at least 1 admission to hospital for a severe asthma exacerbation, OR 1 severe asthma exacerbation, requiring documented use of systemic corticosteroids (oral corticosteroids initiated or increased for at least 3 days, or parenteral corticosteroids) prescribed/supervised by a physician.					
	The Asthma Control Questionnaire (5 item version) assessment of the patient's response to this initial course of treatment, and the assessment of oral corticosteroid dose, must be made at around 22 to 26 weeks after the first dose so that there is adequate time for a response to be demonstrated and for the application for continuing therapy to be processed.					
	This assessment, which will be used to determine eligibility for continuing treatment, must be submitted within 4 weeks of the date of assessment, and no later than 2 weeks prior to the patient completing their current treatment course, to avoid an interruption to supply. Where a response assessment is not undertaken and submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with omalizumab.					
	A patient who fails to respond to a course of PBS-subsidised omalizumab for the treatment of uncontrolled severe allergic asthma will not be eligible to receive further PBS-subsidised treatment with omalizumab for this condition within 6 months of the date on which treatment was ceased.					
	At the time of the authority application, medical practitioners should request the appropriate maximum quantity and number of repeats to provide for an initial course of omalizumab consisting of the recommended number of doses for the baseline IgE level and body weight of the patient (refer to the TGA-approved Product Information) to be administered every 2 or 4 weeks.					
	The authority application must be made in writing and must include:					
	(a) a completed authority prescription form; and					
	(b) a completed Severe Allergic Asthma PBS Authority Application - Supporting Information Form, which includes the following:					
	(i) details of prior optimised asthma drug therapy (dosage, date of commencement and duration of therapy); and					
	(ii) details of severe exacerbation/s experienced in the past 12 months while receiving optimised asthma therapy (date and treatment); and					
	(iii) the signed patient acknowledgement; and					
	(c) the IgE pathology report; and					

## 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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(d) a completed Asthma Control Questionnaire (ACQ-5) calculation sheet including the date of assessment of the patient's symptoms.

### **Note**

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

### **Note**

For copies of the ACQ please contact Novartis Medical Information on 1800 671 203 or [medinfo.phauno@novartis.com](mailto:medinfo.phauno@novartis.com)

### **Note**

It is recommended that an application for continuing treatment is submitted at the time of the 22 to 26 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised omalizumab treatment.

### **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](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

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### **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.

(b) Continuing treatment:

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

(2) Baseline measurements to determine response:

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

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

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

(4) Monitoring of patients:

Anaphylaxis and anaphylactoid reactions have been reported following first or subsequent administration of omalizumab (see Product Information). Patients should be monitored post-injection, and medications for the treatment of anaphylactic reactions should be available for immediate use following administration of omalizumab. Patients should be informed that such reactions are possible and prompt medical attention should be sought if allergic reactions occur.

### **Note**

Formal assessment and correction of inhaler technique should be performed in accordance with the National Asthma Council (NAC) Information Paper for Health Professionals on Inhaler Technique (available at [www.humanservices.gov.au](http://www.humanservices.gov.au) or [www.nationalasthma.org.au](http://www.nationalasthma.org.au)); the assessment and adherence to correct technique should be documented in the patient's medical records. Patients can obtain support with inhaler technique through their local Asthma Foundation (1800 645 130).

### **Note**

## 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
	Special Pricing Arrangements apply.					
	<b><u>Authority required</u></b> Uncontrolled severe allergic asthma Treatment Phase: Initial treatment - balance of supply					
	<b>Clinical criteria:</b> Patient must have received insufficient therapy with this drug under the Initial treatment restriction to complete 28 weeks treatment, <b>AND</b> The treatment must provide no more than the balance of up to 28 weeks treatment available under the above restriction.					
	<b>Treatment criteria:</b> Must be treated by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma.					
	<b><u>Note</u></b> Authority approval for sufficient therapy to complete a maximum of 28 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Written application for authority approval for sufficient therapy to complete a maximum of 28 weeks of treatment should be forwarded to: Department of Human Services Prior Written Approval of Complex Drugs Reply Paid 9826 GPO Box 9826 HOBART TAS 7001					
	<b><u>Note</u></b> Special Pricing Arrangements apply.					
	<b><u>Authority required</u></b> Uncontrolled severe allergic asthma Treatment Phase: Continuing treatment					
	<b>Clinical criteria:</b> Patient must have a documented history of severe allergic asthma, <b>AND</b> Patient must have demonstrated or sustained an adequate response to treatment with this drug, <b>AND</b> Patient must not receive more than 24 weeks of treatment under this restriction.					
	<b>Treatment criteria:</b> Must be treated by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma. An adequate response to omalizumab treatment is defined as: (a) a reduction in the Asthma Control Questionnaire (ACQ-5) score of at least 0.5 from baseline, OR (b) maintenance oral corticosteroid dose reduced by at least 25% from baseline, and no deterioration in ACQ-5 score from baseline. All applications for continuing treatment with omalizumab must include a measurement of response to the prior course of therapy. The Asthma Control Questionnaire (5 item version) assessment of the patient's response to the prior course of treatment, and the assessment of oral corticosteroid dose, must be made at around 18 to 22 weeks after the first dose so that there is adequate time for a response to be demonstrated and for the application for continuing therapy to be processed. The first assessment should, where possible, be completed by the same physician who initiated treatment with omalizumab. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted within 4 weeks of the date of assessment, and no later than 2 weeks prior to the patient completing their current treatment course, to avoid an interruption to supply. Where a response assessment is not undertaken and submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with omalizumab. A patient who fails to respond to a course of PBS-subsidised omalizumab for the treatment of uncontrolled severe allergic asthma will not be eligible to receive further PBS-subsidised treatment with omalizumab for this condition within 6 months of the date on which treatment was ceased. At the time of the authority application, medical practitioners should request the appropriate maximum quantity and number of repeats to provide for a continuing course of omalizumab consisting of the recommended number of doses for the baseline IgE level and body weight of the patient (refer to the TGA-approved Product Information), sufficient for 24 weeks of therapy. The authority application must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Severe Allergic Asthma PBS Authority Application - Supporting Information Form which includes details of maintenance oral corticosteroid dose; and					

## 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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(c) a completed Asthma Control Questionnaire (ACQ-5) calculation sheet including the date of assessment of the patient's symptoms.

**Note**

If the same physician cannot assess the patient please call the Department of Human Services on 1800 700 270.

**Note**

For copies of the ACQ please contact Novartis Medical Information on 1800 671 203 or [medinfo.phauno@novartis.com](mailto:medinfo.phauno@novartis.com)

**Note**

It is recommended that an application for continuing treatment is submitted at the time of the 18 to 22 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised omalizumab treatment.

**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](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

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**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.

(b) Continuing treatment:

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

(2) Baseline measurements to determine response:

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

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

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

(4) Monitoring of patients:

Anaphylaxis and anaphylactoid reactions have been reported following first or subsequent administration of omalizumab (see Product Information). Patients should be monitored post-injection, and medications for the treatment of anaphylactic reactions should be available for immediate use following administration of omalizumab. Patients should be informed that such reactions are possible and prompt medical attention should be sought if allergic reactions occur.

**Note**

Formal assessment and correction of inhaler technique should be performed in accordance with the National Asthma Council (NAC) Information Paper for Health Professionals on Inhaler Technique (available at [www.humanservices.gov.au](http://www.humanservices.gov.au) or [www.nationalasthma.org.au](http://www.nationalasthma.org.au)); the assessment and adherence to correct technique should be documented in the patient's medical records. Patients can obtain support with inhaler technique through their local Asthma Foundation (1800 645 130).

**Note**

## 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
	Special Pricing Arrangements apply.					
	<b>Authority required</b>					
	Uncontrolled severe allergic asthma					
	Treatment Phase: Continuing treatment - balance of supply					
	<b>Clinical criteria:</b>					
	Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment,					
	<b>AND</b>					
	The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.					
	<b>Treatment criteria:</b>					
	Must be treated by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma.					
	<b>Note</b>					
	Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).					
	Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:					
	Department of Human Services					
	Prior Written Approval of Complex Drugs					
	Reply Paid 9826					
	GPO Box 9826					
	HOBART TAS 7001					
	<b>Note</b>					
	Special Pricing Arrangements apply.					
10118M	omalizumab 75 mg/0.5 mL injection, 1 x 0.5 mL syringe	1	..	..	205.00	Xolair 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
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### OMALIZUMAB

#### **Authority required**

Uncontrolled severe allergic asthma

Treatment Phase: Initial treatment

#### **Clinical criteria:**

Patient must be under the care of the same physician for at least 12 months,

#### **AND**

Patient must have a diagnosis of asthma confirmed and documented by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma, defined by the following standard clinical features: (i) forced expiratory volume (FEV1) reversibility greater than or equal to 12% and greater than or equal to 200 mL at baseline within 30 minutes after administration of salbutamol (200 to 400 micrograms), or (ii) airway hyperresponsiveness defined as a greater than 20% decline in FEV1 during a direct bronchial provocation test or greater than 15% decline during an indirect bronchial provocation test, or (iii) peak expiratory flow (PEF) variability of greater than 15% between the two highest and two lowest peak expiratory flow rates during 14 days,

#### **AND**

Patient must have a duration of asthma of at least 1 year,

#### **AND**

Patient must have forced expiratory volume (FEV1) less than or equal to 80% predicted, documented on 3 or more occasions in the previous 12 months,

#### **AND**

Patient must have past or current evidence of atopy, documented by skin prick testing or RAST,

#### **AND**

Patient must have total serum human immunoglobulin E greater than or equal to 76 IU/mL,

#### **AND**

Patient must have signed a patient acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criteria for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment,

#### **AND**

Patient must have failed to achieve adequate control with optimised asthma therapy, despite formal assessment of and adherence to correct inhaler technique, which has been documented,

#### **AND**

Patient must not receive more than 28 weeks of treatment under this restriction.

#### **Population criteria:**

Patient must be aged 12 years or older.

#### **Treatment criteria:**

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

Optimised asthma therapy includes:

(i) adherence to maximal inhaled therapy, including high dose inhaled corticosteroid (budesonide 1600 micrograms per day or fluticasone propionate 1000 micrograms per day or equivalent), plus long-acting beta-2 agonist therapy (at least salmeterol 50 micrograms bd or formoterol 12 micrograms bd) for at least 12 months, unless contraindicated or not tolerated, AND

(ii) treatment with oral corticosteroids, either daily oral corticosteroids for at least 6 weeks, OR a cumulative dose of oral corticosteroids of at least 500 mg prednisolone equivalent in the previous 12 months, unless contraindicated or not tolerated.

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

The initial IgE assessment must be no more than 12 months old at the time of application.

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

(a) an Asthma Control Questionnaire (ACQ-5) score of at least 2.0, as assessed in the previous month, AND

(b) while receiving optimised asthma therapy in the past 12 months, experienced at least 1 admission to hospital for a severe asthma exacerbation, OR 1 severe asthma exacerbation, requiring documented use of systemic corticosteroids (oral corticosteroids initiated or increased for at least 3 days, or parenteral corticosteroids) prescribed/supervised by a physician.

The Asthma Control Questionnaire (5 item version) assessment of the patient's response to this initial course of treatment, and the assessment of oral corticosteroid dose, must be made at around 22 to 26 weeks after the first dose so that there is adequate time for a response to be demonstrated and for the application for continuing therapy to be processed.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted within 4 weeks of the date of assessment, and no later than 2 weeks prior to the patient completing their current treatment course, to avoid an interruption to supply. Where a response assessment is not undertaken and submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with

## HIGHLY SPECIALISED DRUGS PROGRAM (PRIVATE HOSPITAL)

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omalizumab.

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

At the time of the authority application, medical practitioners should request the appropriate maximum quantity and number of repeats to provide for an initial course of omalizumab consisting of the recommended number of doses for the baseline IgE level and body weight of the patient (refer to the TGA-approved Product Information) to be administered every 2 or 4 weeks.

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

- (a) a completed authority prescription form; and
- (b) a completed Severe Allergic Asthma PBS Authority Application - Supporting Information Form, which includes the following:
  - (i) details of prior optimised asthma drug therapy (dosage, date of commencement and duration of therapy); and
  - (ii) details of severe exacerbation/s experienced in the past 12 months while receiving optimised asthma therapy (date and treatment); and
  - (iii) the signed patient acknowledgement; and
- (c) the IgE pathology report; and
- (d) a completed Asthma Control Questionnaire (ACQ-5) calculation sheet including the date of assessment of the patient's symptoms.

### **Note**

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

### **Note**

For copies of the ACQ please contact Novartis Medical Information on 1800 671 203 or [medinfo.phauno@novartis.com](mailto:medinfo.phauno@novartis.com)

### **Note**

It is recommended that an application for continuing treatment is submitted at the time of the 22 to 26 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised omalizumab treatment.

### **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](http://www.humanservices.gov.au)

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### **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.

(b) Continuing treatment:

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

(2) Baseline measurements to determine response:

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

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

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

(4) Monitoring of patients:

Anaphylaxis and anaphylactoid reactions have been reported following first or subsequent administration of omalizumab (see Product Information). Patients should be monitored post-injection, and medications for the treatment of anaphylactic reactions should be available for immediate use following administration of omalizumab. Patients should be informed that such reactions are possible and prompt medical attention should be sought if allergic reactions occur.

**Note**

Formal assessment and correction of inhaler technique should be performed in accordance with the National Asthma Council (NAC) Information Paper for Health Professionals on Inhaler Technique (available at [www.humanservices.gov.au](http://www.humanservices.gov.au) or [www.nationalasthma.org.au](http://www.nationalasthma.org.au)); the assessment and adherence to correct technique should be documented in the patient's medical records. Patients can obtain support with inhaler technique through their local Asthma Foundation (1800 645 130).

**Note**

Special Pricing Arrangements apply.

**Authority required**

Uncontrolled severe allergic asthma

Treatment Phase: Initial treatment - balance of supply

**Clinical criteria:**

Patient must have received insufficient therapy with this drug under the Initial treatment restriction to complete 28 weeks treatment,

**AND**

The treatment must provide no more than the balance of up to 28 weeks treatment available under the above restriction.

**Treatment criteria:**

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

**Note**

Authority approval for sufficient therapy to complete a maximum of 28 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 28 weeks of treatment should be forwarded to:

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HOBART TAS 7001

**Note**

Special Pricing Arrangements apply.

**Authority required**

Uncontrolled severe allergic asthma

Treatment Phase: Continuing treatment

**Clinical criteria:**

Patient must have a documented history of severe allergic asthma,

**AND**

Patient must have demonstrated or sustained an adequate response to treatment with this drug,

**AND**

Patient must not receive more than 24 weeks of treatment under this restriction.

**Treatment criteria:**

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

An adequate response to omalizumab treatment is defined as:

(a) a reduction in the Asthma Control Questionnaire (ACQ-5) score of at least 0.5 from baseline, OR

(b) maintenance oral corticosteroid dose reduced by at least 25% from baseline, and no deterioration in ACQ-5 score from baseline.

All applications for continuing treatment with omalizumab must include a measurement of response to the prior course of therapy. The Asthma Control Questionnaire (5 item version) assessment of the patient's response to the prior course of treatment, and the assessment of oral corticosteroid dose, must be made at around 18 to 22 weeks after the first dose so that there is adequate time for a response to be demonstrated

## 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 for the application for continuing therapy to be processed.

The first assessment should, where possible, be completed by the same physician who initiated treatment with omalizumab. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted within 4 weeks of the date of assessment, and no later than 2 weeks prior to the patient completing their current treatment course, to avoid an interruption to supply. Where a response assessment is not undertaken and submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with omalizumab.

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

At the time of the authority application, medical practitioners should request the appropriate maximum quantity and number of repeats to provide for a continuing course of omalizumab consisting of the recommended number of doses for the baseline IgE level and body weight of the patient (refer to the TGA-approved Product Information), sufficient for 24 weeks of therapy.

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

- (a) a completed authority prescription form; and
- (b) a completed Severe Allergic Asthma PBS Authority Application - Supporting Information Form which includes details of maintenance oral corticosteroid dose; and
- (c) a completed Asthma Control Questionnaire (ACQ-5) calculation sheet including the date of assessment of the patient's symptoms.

**Note**

If the same physician cannot assess the patient please call the Department of Human Services on 1800 700 270.

**Note**

For copies of the ACQ please contact Novartis Medical Information on 1800 671 203 or [medinfo.phauno@novartis.com](mailto:medinfo.phauno@novartis.com)

**Note**

It is recommended that an application for continuing treatment is submitted at the time of the 18 to 22 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised omalizumab treatment.

**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](http://www.humanservices.gov.au)

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**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.

(b) Continuing treatment:

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

(2) Baseline measurements to determine response:

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

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

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised omalizumab therapy of at least 6 months, must re-qualify for initial treatment with respect to the indices of disease severity (oral corticosteroid dose, Asthma Control Questionnaire (ACQ-5)

## 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	
	score, and relevant exacerbation history). Patients must have received optimised standard therapy, at adequate doses and for the minimum period specified, immediately prior to the time the new baseline assessments are performed.						
	(4) Monitoring of patients:						
	Anaphylaxis and anaphylactoid reactions have been reported following first or subsequent administration of omalizumab (see Product Information). Patients should be monitored post-injection, and medications for the treatment of anaphylactic reactions should be available for immediate use following administration of omalizumab. Patients should be informed that such reactions are possible and prompt medical attention should be sought if allergic reactions occur.						
	<b>Note</b>						
	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 <a href="http://www.humanservices.gov.au">www.humanservices.gov.au</a> or <a href="http://www.nationalasthma.org.au">www.nationalasthma.org.au</a> ); 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).						
	<b>Note</b>						
	Special Pricing Arrangements apply.						
	<b>Authority required</b>						
	Uncontrolled severe allergic asthma						
	Treatment Phase: Continuing treatment - balance of supply						
	<b>Clinical criteria:</b>						
	Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment,						
	<b>AND</b>						
	The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.						
	<b>Treatment criteria:</b>						
	Must be treated by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma.						
	<b>Note</b>						
	Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).						
	Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:						
	Department of Human Services						
	Prior Written Approval of Complex Drugs						
	Reply Paid 9826						
	GPO Box 9826						
	HOBART TAS 7001						
	<b>Note</b>						
	Special Pricing Arrangements apply.						
10110D	omalizumab 75 mg/0.5 mL injection, 1 x 0.5 mL syringe	1	..	..	219.96	Xolair	NV
10122R	omalizumab 150 mg/mL injection, 1 x 1 mL syringe	1	..	..	433.16	Xolair	NV