Australian Government

Department of Health and Ageing

SCHEDULE OF PHARMACEUTICAL BENEFITS

This Schedule is also available on the internet at

www.pbs.gov.au

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

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PHARMACEUTICAL BENEFITS

These changes to the Schedule of Pharmaceutical Benefits are effective from 1 March 2009. The Schedule is updated on the first day of each month and is available on the Internet at www.pbs.gov.au.

Fees, Patient Contributions and Safety Net Thresholds

The following fees, patient contributions and safety net thresholds apply as at 1 March 2009 and are included, where applicable, in prices published in the Schedule—

Dispensing Fees:	Ready-prepared	$5.99
	Dangerous drug fee	$2.71
	Extemporaneously-prepared	$8.03
	Allowable additional patient charge*	$3.79
Additional Fees (for safety net prices):	Ready-prepared	$1.03
	Extemporaneously-prepared	$1.39
Patient Co-payments:	General	$32.90
	Concessional	$5.30
Safety Net Thresholds:	General	$1264.90
	Concessional	$318.00
Safety Net Card Issue Fee:		$8.25

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

SUMMARY OF CHANGES

ADDITIONS

Additions — Items

9375K **Amlodipine with valsartan**, Tablet 5 mg (as besylate)-80 mg (*Exforge 5/80*)

9376L **Amlodipine with valsartan**, Tablet 5 mg (as besylate)-160 mg (*Exforge 5/160*)

9377M **Amlodipine with valsartan**, Tablet 10 mg (as besylate)-160 mg (*Exforge 10/160*)

9386B **Amylopectin, modified long chain**, Sachets 60 g, 30 (*Glycosade*)

5543R **Betaxolol hydrochloride**, Eye drops, suspension, 2.5 mg (base) per mL (0.25%), 5 mL (*Betoptic S*) **(Optometrical)**

5544T **Betaxolol hydrochloride**, Eye drops, solution, 5 mg (base) per mL (0.5%), 5 mL (*BetoQuin*, *Betoptic*) **(Optometrical)**

5551E **Bimatoprost**, Eye drops 300 micrograms per mL (0.03%), 3 mL (*Lumigan*) **(Optometrical)**

5534G **Brimonidine tartrate**, Eye drops 2 mg per mL (0.2%), 5 mL (*Enidin*, *Alphagan*) **(Optometrical)**

5535H **Brimonidine tartrate with timolol maleate**, Eye drops 2 mg-5 mg (base) per mL (0.2%-0.5%), 5 mL (*Combigan*) **(Optometrical)**

5540N **Brinzolamide**, Eye drops 10 mg per mL (1%), 5 mL (*BrinzoQuin*, *Azopt*) **(Optometrical)**

5541P **Dorzolamide hydrochloride**, Eye drops 20 mg (base) per mL (2%), 5 mL (*Trusopt*) **(Optometrical)**

5542Q **Dorzolamide hydrochloride with timolol maleate**, Eye drops 20 mg (base)-5 mg (base) per mL (2%-0.5%), 5 mL (*Cosopt*) **(Optometrical)**

9385Y **Essential amino acids formula with vitamins and minerals**, Sachets 12.5 g, 50 (*EAA Supplement*)

5552F **Latanoprost**, Eye drops 50 micrograms per mL (0.005%), 2.5 mL (*Xalatan*) **(Optometrical)**

5553G **Latanoprost with timolol maleate**, Eye drops 50 micrograms-5 mg (base) per mL (0.005%-0.5%), 2.5 mL (*Xalacom*) **(Optometrical)**

9384X **Phenylalanine with carbohydrate**, Sachets 4 g containing 50 mg phenylalanine, 30 (*Phenylalanine Amino Acid Supplement*)

5536J **Pilocarpine hydrochloride**, Eye drops 10 mg per mL (1%), 15 mL (*Isopto Carpine*, *Pilopt*, *P.V. Carpine*) **(Optometrical)**

5537K **Pilocarpine hydrochloride**, Eye drops 20 mg per mL (2%), 15 mL (*Isopto Carpine, Pilopt, P.V. Carpine*) **(Optometrical)**

5538L **Pilocarpine hydrochloride**, Eye drops 40 mg per mL (4%), 15 mL (*Isopto Carpine, Pilopt, P.V. Carpine*) **(Optometrical)**

5539M **Pilocarpine hydrochloride**, Eye drops 60 mg per mL (6%), 15 mL (*Pilopt, P.V. Carpine*) **(Optometrical)**

9381R **Telmisartan with hydrochlorothiazide**, Tablet 80 mg-25 mg (*Micardis Plus 80/25 mg*)

5546X **Timolol maleate**, Eye gel 1 mg (base) per g (0.1%), 5 g (*Nyogel*) **(Optometrical)**

5547Y **Timolol maleate**, Eye drops 2.5 mg (base) per mL (0.25%), 5 mL (*Tenopt, Timoptol*) **(Optometrical)**

5548B **Timolol maleate**, Eye drops 5 mg (base) per mL (0.5%), 5 mL (*Tenopt, Timoptol*) **(Optometrical)**

5549C **Timolol maleate**, Eye drops (gellan gum solution) 2.5 mg (base) per mL (0.25%), 2.5 mL (*Timoptol XE*) **(Optometrical)**

5550D **Timolol maleate**, Eye drops (gellan gum solution) 5 mg (base) per mL (0.5%), 2.5 mL (*Timoptol XE*) **(Optometrical)**

9387C **Trandolapril with verapamil hydrochloride**, Tablet 2 mg-180 mg (sustained release) (*Tarka 2/180*)

5554H **Travoprost**, Eye drops 40 micrograms per mL (0.004%), 2.5 mL (*Travatan*) **(Optometrical)**

5555J **Travoprost with timolol maleate**, Eye drops 40 micrograms-5 mg (base) per mL (0.004%-0.5%), 2.5 mL (*Duotrav*) **(Optometrical)**

9383W **Triglycerides—medium chain, formula**, Sachets 16 g, 25 (*MCT Pro-Cal*)

9368C **Valsartan**, Tablet 40 mg (*Diovan*)

9369D **Valsartan**, Tablet 80 mg (*Diovan*)

9370E **Valsartan**, Tablet 160 mg (*Diovan*)

9371F **Valsartan**, Tablet 320 mg (*Diovan*)

9372G **Valsartan with hydrochlorothiazide**, Tablet 80 mg-12.5 mg (*Co-Diovan 80/12.5*)

9373H **Valsartan with hydrochlorothiazide**, Tablet 160 mg-12.5 mg (*Co-Diovan 160/12.5*)

9374J **Valsartan with hydrochlorothiazide**, Tablet 160 mg-25 mg (*Co-Diovan 160/25*)

9382T **Whey protein formula supplemented with amino acids, long chain polyunsaturated fatty acids, vitamins and minerals, and low in protein, phosphate, potassium and lactose**, Sachets 100 g, 10 (*RenaStart*)

Additions — Brands

1887H *Amoxycillin Sandoz, SZ* — **Amoxycillin**, Powder for syrup 250 mg per 5 mL, 100 mL

3393N *Amoxycillin Sandoz, SZ* — **Amoxycillin**, Powder for syrup 250 mg per 5 mL, 100 mL **(Dental)**

1169M *Cefaclor-GA, GN* — **Cefaclor**, Tablet 375 mg (sustained release)

5045M *Cefaclor-GA, GN* — **Cefaclor**, Tablet 375 mg (sustained release) **(Dental)**

1299J *Diclofenac-GA, GN* — **Diclofenac sodium**, Tablet 25 mg (enteric coated)

5076E *Diclofenac-GA, GN* — **Diclofenac sodium**, Tablet 25 mg (enteric coated) **(Dental)**

5364H *Diclofenac-GA, GN* — **Diclofenac sodium**, Tablet 25 mg (enteric coated) **(Palliative Care)**

5361E *Diclofenac-GA, GN* — **Diclofenac sodium**, Tablet 25 mg (enteric coated) **(Palliative Care) (Diff. Max. Rpts)**

8280T *Vinorelbine 10 Link, LM* — **Vinorelbine tartrate**, Solution for I.V. infusion 10 mg (base) in 1 mL

8281W *Vinorelbine 50 Link, LM* — **Vinorelbine tartrate**, Solution for I.V. infusion 50 mg (base) in 5 mL

DELETIONS

Deletions — Items

2495H **Pancrelipase**, Capsule (containing enteric coated microspheres) providing not less than 10,000 BP units of lipase activity (*Cotazym-S Forte*)

9228Q **Pancrelipase**, Capsule (containing enteric coated microspheres) providing not less than 10,000 BP units of lipase activity (*Cotazym-S Forte*) **(Diff. Max. Rpts)**

Deletions — Brands

1891M *Clamohexal Duo 500 mg/125 mg, HX* — **Amoxycillin with clavulanic acid**, Tablet 500 mg-125 mg

5008N *Clamohexal Duo 500 mg/125 mg, HX* — **Amoxycillin with clavulanic acid**, Tablet 500 mg-125 mg **(Dental)**

8254K *Clamohexal Duo Forte 875 mg/125 mg, HX* — **Amoxycillin with clavulanic acid**, Tablet 875 mg-125 mg

5006L *Clamohexal Duo Forte 875 mg/125 mg, HX* — **Amoxycillin with clavulanic acid**, Tablet 875 mg-125 mg **(Dental)**

1892N *Clamohexal 125 mg/31.25 mg/5 mL, HX* — **Amoxycillin with clavulanic acid**, Powder for syrup 125 mg-31.25 mg per 5 mL, 75 mL

5009P *Clamohexal 125 mg/31.25 mg/5 mL, HX* — **Amoxycillin with clavulanic acid**, Powder for syrup 125 mg-31.25 mg per 5 mL, 75 mL **(Dental)**

8319W *Clamohexal Duo 400 mg/57 mg/5 mL, HX* — **Amoxycillin with clavulanic acid**, Powder for syrup 400 mg-57 mg per 5 mL, 60 mL

5011R *Clamohexal Duo 400 mg/57 mg/5 mL, HX* — **Amoxycillin with clavulanic acid**, Powder for syrup 400 mg-57 mg per 5 mL, 60 mL **(Dental)**

2729P *Baclohexal, HX* — **Baclofen**, Tablet 10 mg

2730Q *Baclohexal, HX* — **Baclofen**, Tablet 25 mg

8415X *Irinotecan-GA, GM* — **Irinotecan hydrochloride trihydrate**, I.V. injection 100 mg in 5 mL

8288F *Epaq, AW* — **Salbutamol sulfate**, Oral pressurised inhalation 100 micrograms (base) per dose (200 doses), CFC-free formulation

3495Y *Epaq, AW* — **Salbutamol sulfate**, Oral pressurised inhalation 100 micrograms (base) per dose (200 doses), CFC-free formulation **(Doctor's Bag)**

ALTERATIONS

Alterations — Restrictions

Restrictions have been amended in respect of the following:

8844L **Bivalirudin trifluoroacetate**, Powder for I.V. injection 250 mg (base) (*Angiomax*)

9282M **Dasatinib**, Tablet 20 mg (*Sprycel*)

9283N **Dasatinib**, Tablet 50 mg (*Sprycel*)

9284P **Dasatinib**, Tablet 70 mg (*Sprycel*)

9285Q **Nilotinib**, Capsule 200 mg (as hydrochloride monohydrate) (*Tasigna*)

8787L **Risperidone**, Tablet 0.5 mg (*Risperidone-GA, Rixadone, APO-Risperidone, Rispa, Risperdal*)

8788M **Risperidone**, Tablet 0.5 mg (orally disintegrating) (*Risperdal Quicklet*)

8789N **Risperidone**, Tablet 1 mg (*APO-Risperidone, Rispa, Risperdal, Risperidone-GA, Risperidone generichealth, Rixadone*)

8790P **Risperidone**, Tablet 1 mg (orally disintegrating) (*Risperdal Quicklet*)

9079W **Risperidone**, Tablet 2 mg (*APO-Risperidone, Rispa, Risperdal, Risperidone-GA, Risperidone generichealth, Rixadone*)

9080X **Risperidone**, Tablet 2 mg (orally disintegrating) (*Risperdal Quicklet*)

9293D **Risperidone**, Oral solution 1 mg per mL, 100 mL (*Risperdal*)

8646C **Tacrolimus**, Capsule 500 micrograms (*Prograf*)

8647D **Tacrolimus**, Capsule 1 mg (*Prograf*)

8648E **Tacrolimus**, Capsule 5 mg (*Prograf*)

2857J **Trandolapril with verapamil hydrochloride**, Tablet 4 mg-240 mg (sustained release) (*Tarka 4/240*)

Alterations — Notes

The note has been deleted in respect of the following:

8844L **Bivalirudin trifluoroacetate**, Powder for I.V. injection 250 mg (base) (*Angiomax*)

The note has been amended in respect of the following:

8712M **Desmopressin acetate**, Nasal spray (pump pack) 10 micrograms per actuation, 60 actuations, 6 mL (*Minirin Nasal Spray*)

Alterations — Maximum Quantity

		From	*To*
2214M	**Mesalazine**, Tablet 500 mg (prolonged release) (*Pentasa*)	100	200
8448P	**Ursodeoxycholic acid**, Capsule 250 mg (*Ursofalk*)	100	200

Alterations — Number of Repeats

		From	*To*
9355J	**Carmellose sodium with glycerin**, Eye drops 5 mg-9 mg per mL (0.5%-0.9%), 15 mL (*Optive*)	2	3
9356K	**Carmellose sodium with glycerin**, Eye drops 5 mg-9 mg per mL (0.5%-0.9%), 15 mL (*Optive*) **(Diff. Max. Rpts)**	5	7
5556K	**Carmellose sodium with glycerin**, Eye drops 5 mg-9 mg per mL (0.5%-0.9%), 15 mL (*Optive*) **(Optometrical)**	2	3

Alterations — Manufacturer's Code

		From	*To*
2502Q	**Calcitriol**, Capsule 0.25 microgram (*Citrihexal*)	HX	SZ
1585K	**Chlorthalidone**, Tablet 25 mg (*Hygroton 25*)	NV	LM
2826R	**Methysergide**, Tablet 1 mg (*Deseril*)	NV	LM

SECTION 100 — HIGHLY SPECIALISED DRUGS PROGRAM

ALTERATIONS

Alterations — Restrictions

6328C **Tacrolimus**, Capsule 500 micrograms (*Prograf*)

6216E **Tacrolimus**, Capsule 1 mg (*Prograf*)

6217F **Tacrolimus**, Capsule 5 mg (*Prograf*)

ADVANCE NOTICES

Advance Notice — Deletion of Item

The following item will be deleted from the Schedule of Pharmaceutical Benefits on 1 June 2009:

Deletion requested by the manufacturer —

8818D **Metoprolol succinate**, Pack containing 15 tablets 23.75 mg (controlled release), 15 tablets 47.5 mg (controlled release) and 15 tablets 95 mg (controlled release) (*Toprol-XL Titration Pack*)

Advance Notice — Deletion of Brands

The following brand will be deleted from the Schedule of Pharmaceutical Benefits on 1 April 2009:

Deletion requested by the manufacturer —

8839F *Attenta, AF* — **Methylphenidate hydrochloride**, Tablet 10 mg

The following brands will be deleted from the Schedule of Pharmaceutical Benefits on 1 June 2009:

Deletions requested by the manufacturer —

2592K *Chem mart Isotretinoin, CH; Terry White Chemists Isotretinoin, TW* — **Isotretinoin**, Capsule 20 mg

Addresses — Medicare Australia

Medicare Australia has responsibility for the operational aspects of the Pharmaceutical Benefits Scheme (PBS). This responsibility covers the processing of pharmaceutical benefit and safety net claims, authority applications and supply of PBS stationery used by medical practitioners, participating dental practitioners and approved pharmacists.
Procedures for ordering prescription forms are set out in Section 1 of this Schedule.

NEW SOUTH WALES and AUSTRALIAN CAPITAL TERRITORY
Pharmaceutical Benefits Branch
130 George Street
Parramatta NSW 2150
General and IME enquiries— Tel: 132 290

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

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

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

SOUTH AUSTRALIA and NORTHERN TERRITORY
Pharmaceutical Services Branch
209 Greenhill Road
Eastwood SA 5063
General and IME enquiries— Tel: 132 290

WESTERN AUSTRALIA
Pharmaceutical Benefits Branch
11th Floor, Bankwest Tower
108 St George's Terrace
Perth WA 6000
General and IME enquiries— Tel: 132 290

TASMANIA
Pharmaceutical Branch
242 Liverpool Street
Hobart TAS 7000
General and IME enquiries— Tel: 132 290

NATIONAL PROGRAM MANAGEMENT
Pharmaceutical Benefits Branch
Medicare Australia
134 Reed Street
Tuggeranong ACT 2900
Telephone— (02) 6124 6333
Website— www.medicareaustralia.gov.au
Email— pbs@medicareaustralia.gov.au

Authority Prescription Applications

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

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

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

Approval is obtained by lodging an application using the REPLY PAID mail service or by using Medicare Australia's FREECALL telephone number:

Mail Applications:	REPLY PAID No. 9857 PBS Authorities Section Medicare Australia GPO Box 9857 In your capital city
Telephone Applications:	Free call 1800 888 333 Australia-wide—24 hour service

For telephone applications please have the following information available:

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

Requests for Drugs via the Special Access Scheme (SAS)

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

Department of Veterans' Affairs

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

Telephone Interpreter Service

A 24-hour, seven days a week telephone service is available by contacting 131 450.
The translating service (TIS) can provide immediate assistance over the telephone or arrange for an interpreter to go to a location specified in either city or country areas. The TIS service has access to 2000 professional interpreters, covering over 100 languages and dialects.

Poisons Information Centres

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

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

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

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

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

TAS
Tel: 131 126

NT
Tel: 131 126

ACT
Tel: 131 126

Drug Information Centres

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

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

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

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

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

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

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

VIC

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

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

SA

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

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

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

National Prescribing Service (NPS)

Therapeutic Advice and
Information Service
(TAIS)
Level 7, 418A Elizabeth
Street
Surry Hills NSW 2010
Tel: 1300 138 677
Fax: (03) 9459 4546
Email: tais@nps.org.au
Web: www.nps.org.au

List of Contact Officers for Recalls of Therapeutic Goods

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

These officers may be contacted—

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

Australian Recall Coordinator

Office of Devices, Blood and Tissues
Therapeutic Goods Administration
Department of Health and Ageing
PO Box 100
Woden ACT 2606
Mr P K Harrison (02) 6232 8636
Mr T Byrne (02) 6232 8637

Australian Capital Territory

ACT Health
GPO Box 825
Canberra ACT 2601
Ms J Strang (02) 6205 0961

New South Wales

Department of Health, NSW
PO Box 103
Gladesville NSW 1675
Mr J E Lumby (02) 9879 3214

Victoria

Department of Human Services
Drugs and Poisons Unit
GPO Box 1670N
Melbourne VIC 3001
Mr K Moyle 1300 364 545
Mr R Bell 1300 364 545

Queensland

Queensland Department of Health
GPO Box 48
Brisbane QLD 4001
Drugs—
Mr A Hawkins (07) 3234 0349
Mr C Healey (07) 3234 0960
Therapeutic Devices—
Mr C Healey (07) 3234 0960
Mr D Jones (07) 3406 8068

South Australia

Drug Policies and Programs
Metropolitan Health Division
South Australian Department of Health
PO Box 287
Rundle Mall SA 5000
Mr W Dollman (08) 8226 7110
Ms E Anear (08) 8226 7387

Western Australia

Health Department of WA
PO Box 8172, Perth Business Centre
Perth WA 6849
Mr M Patterson (08) 9388 4980

Tasmania

Department of Health and Human Services
GPO Box 125B
Hobart TAS 7001
Drugs—
Mr J Galloway (03) 6233 2064
Ms M Sharpe (03) 6233 3766
Therapeutic Devices—
Mr A L Wilkins (03) 6233 3913

Northern Territory

Department of Health and Community Sevices
PO Box 40596
Casuarina NT 0811
Ms H Stone (08) 8922 7035

Index of Manufacturers' Codes

Code	*Manufacturer*
AB	Abbott Australasia Pty Ltd Sir Joseph Banks Corporate Park 32-34 Lord Street Botany NSW 2019 Tel: (02) 9384 9700 Fax: (02) 9384 9800
AC	Alberto Culver Company 14 Loyalty Road North Rocks NSW 2151 Tel: (02) 9630 5099 Fax: (02) 9683 5026
AE	AFT Pharmaceuticals Pty Limited Unit 2, Level 5 255 George Street NSW 2000 Tel: 1800 097 639 Fax: 1800 097 810
AF	Alphapharm Pty Limited Chase Building 2 Wentworth Park Road Glebe NSW 2037 Tel: (02) 9298 3999 Fax: (02) 9566 4686
AG	Allergan Australia Pty Ltd 77 Ridge Street Gordon NSW 2072 Tel: 1800 252 224 Fax: (02) 9498 0290
AL	Alphapharm Medical A Division of Alphapharm Pty Limited Chase Building 2 Wentworth Park Road Glebe NSW 2037 Tel: (02) 9298 3999 Fax: (02) 9566 4686
AN	Amgen Australia Pty Ltd Level 7, 123 Epping Road North Ryde NSW 2113 Tel: (02) 9870 1333 Fax: (02) 9870 1344
AP	AstraZeneca Pty Ltd Alma Road North Ryde NSW 2113 Tel: (02) 9978 3500 Fax: (02) 9978 3700
AQ	Alcon Laboratories (Australia) Pty Ltd Allambie Grove Park 25 Frenchs Forest Road East Frenchs Forest NSW 2086 Tel: 1800 025 004 Fax: (02) 9452 5209
AS	Aspen Pharmacare Australia Pty Ltd First Floor 34-36 Chandos Street St Leonards NSW 2065 Tel: (02) 8436 8300 Fax: (02) 9901 3540
AT	Actelion Pharmaceuticals Australia Pty Ltd Level 2 West, Suites 48-50 7 Narabang Way Belrose NSW 2085 Tel: (02) 9486 4600 Fax: (02) 9986 1344
AV	Aventis Pharma Division of Sanofi-Aventis Australia Pty Limited Building D, Talavera Corporate Centre 12-24 Talavera Road Macquarie Park NSW 2113 Tel: (02) 8666 2000 Fax: (02) 8666 3000
AW	Arrow Pharmaceuticals Pty Ltd A member of Sigma Group of Companies 96 Merrindale Drive Croydon Vic 3136 Tel: (03) 9839 2800 Fax: (03) 9839 2753
AX	Sanofi Pasteur Pty Limited Building D, Talavera Corporate Centre 12-24 Talavera Road Macquarie Park NSW 2113 Tel: 1800 829 468 Fax: 1800 829 329
BB	Blackmores Ltd 23 Roseberry Street Balgowlah NSW 2093 Tel: (02) 9951 0111 Fax: (02) 9949 1954

Code	Manufacturer
BC	Bristol Laboratories A Division of Bristol-Myers Squibb Australia Pty Ltd 556 Princes Highway Noble Park Vic 3174 Tel: (03) 9213 4000 Fax: (03) 9701 1518
BD	Biogen Idec Australia Pty Ltd Suite 2, Level 4 123 Epping Road North Ryde NSW 2113 Tel: (02) 8875 3900 Fax: (02) 9889 1162
BE	BDF Australia Ltd 112-118 Talavera Road North Ryde NSW 2113 Tel: 1800 269 933 Fax: (02) 9887 3487
BF	Bellwether Pharma Limited Suite 2, Level 2 71 Epping Road North Ryde NSW 2113 Tel: (02) 8875 5700 Fax: (02) 9889 2250
BG	Biochemie Australia A Division of Sandoz Pty Ltd Level 4, Suite 7-19 100 Harris Street Pyrmont NSW 2009 Tel: (02) 9566 1500 Fax: (02) 9566 1458
BI	Biotech Pharmaceuticals Pty Ltd 83 Cherry Lane Laverton North Vic 3026 Tel: (03) 9278 7555 Fax: (03) 9369 6730
BK	Becton Dickinson Pty Ltd 80 Rushdale Street Knoxfield Vic 3180 Tel: (03) 9764 2444 Fax: (03) 9764 2550
BN	Bayer Australia Limited 875 Pacific Highway Pymble NSW 2073 Tel: (02) 9391 6000 Fax: (02) 9988 3311
BQ	Bristol-Myers Squibb Pharmaceuticals A Division of Bristol-Myers Squibb Australia Pty Ltd 556 Princes Highway Noble Park Vic 3174 Tel: (03) 9213 4000 Fax: (03) 9701 1518
BR	B. Braun Australia Pty Ltd Norwest Business Park 17 Lexington Drive Bella Vista NSW 2153 Tel: (02) 9629 0200 Fax: (02) 9629 0299
BU	Bausch & Lomb Surgical A Division of Bausch & Lomb (Australia) Pty Ltd Level 4, 113 Wicks Road North Ryde NSW 2113 Tel: (02) 9887 1444 Fax: (02) 9888 9642
BV	B.S.N. 315 Ferntree Gully Road Mount Waverley Vic 3149 Tel: (03) 8540 6777 Fax: 1800 671 000
BX	Baxter Healthcare Pty Limited 1 Baxter Drive Old Toongabbie NSW 2146 Tel: (02) 9848 1111 Fax: (02) 9848 1123
BY	Boehringer Ingelheim Pty Limited 85 Waterloo Road North Ryde NSW 2113 Tel: (02) 8875 8800 Fax: (02) 8875 8801
CC	ConvaTec A Division of Bristol-Myers Squibb Australia Pty Ltd 606 Hawthorn Road East Brighton Vic 3187 Tel: 1800 335 276 Fax: (03) 9525 0920
CF	CNS Pharma Pty Ltd Level 5, Deutsche Bank Place 126 Phillip Street Sydney NSW 2000 Tel: (02) 9629 0638 Fax: (02) 9629 0688

Code	Manufacturer
CH	Chem mart Pty Limited Level 7, 5 Queens Road Melbourne Vic 3004 Tel: (03) 9918 2500 Fax: (03) 9918 2006
CO	Chemists' Own Pty Ltd A member of Sigma Group of Companies 96 Merrindale Drive Croydon Vic 3136 Tel: (03) 9839 2800 Fax: (03) 9839 2753
CR	Pharmacor Limited 5/36 Campbell Avenue Cromer NSW 2099 Tel: (02) 9981 4470 Fax: (02) 9981 4475
CS	CSL Limited 45 Poplar Road Parkville Vic 3052 Tel: (03) 9389 1911 Fax: (03) 9388 2351
CT	Coloplast Pty Ltd 33 Gilby Road Mount Waverley Vic 3149 Tel: 1800 673 317 Fax: (03) 9541 1199
CX	Contact Lens Centre Australia Pty Ltd Unit D6, Hallmark Business Park Cnr Westall and Centre Roads Clayton Vic 3168 Tel: (03) 9543 1811 Fax: (03) 9543 8066
DB	Diabetes Association of Australia 26 Arundel Street Glebe NSW 2037 Tel: 1800 451 737 Fax: (02) 9566 4235
DT	DermaTech Laboratories Pty Ltd Unit 17, 167 Prospect Highway Seven Hills NSW 2147 Tel: (02) 9624 5874 Fax: (02) 9624 8822

Code	Manufacturer
EO	Ego Pharmaceuticals Pty Ltd 21-31 Malcolm Road Braeside Vic 3195 Tel: (03) 9587 1088 Fax: (03) 9580 7647
ES	EBOS Group Pty Ltd Unit 2, 109 Vanessa Street Kingsgrove NSW 2208 Tel: (02) 9502 8410 Fax: (02) 9502 8411
EX	Essex Laboratories Level 4, 66 Waterloo Road North Ryde NSW 2113 Tel: (02) 8988 8000 Fax: (02) 9852 7500
FA	F.H. Faulding & Co. Limited Level 6, 390 St Kilda Road Melbourne Vic 3004 Tel: (03) 9868 0700 Fax: (03) 9868 0111
FB	Pierre Fabre Medicament Australia Pty Limited Unit 26B, Parkview Business Centre 1 Maitland Place Baulkham Hills NSW 2153 Tel: (02) 8858 2800 Fax: (02) 8858 2888
FH	Faulding Healthcare Pty Ltd 87 Yarraman Place Virginia Qld 4014 Tel: (07) 3212 8777 Fax: (07) 3212 8790
FK	PharmaLink Pty Ltd Level 8, 67 Albert Avenue Chatswood NSW 2067 Tel: (02) 9080 7200 Fax: (02) 9080 7201
FL	C. B. Fleet Co. (Aust.) Pty Ltd 25 Macbeth Street Braeside Vic 3195 Tel: (03) 9580 2755 Fax: (03) 9580 2899

Code	*Manufacturer*
FM	Fawns and McAllan Pty Ltd A member of Sigma Group of Companies 96 Merrindale Drive Croydon Vic 3136 Tel: (03) 9839 2800 Fax: (03) 9839 2753
FP	Ferring Pharmaceuticals Pty Ltd Suite 2B, Level 2 802 Pacific Highway Gordon NSW 2072 Tel: (02) 9497 2300 Fax: (02) 9497 2399
FR	Charles E. Frosst Division of Merck Sharp & Dohme (Australia) Pty Ltd 54-68 Ferndell Street South Granville NSW 2142 Tel: (02) 9795 9500 Fax: (02) 9795 9595
GA	Galderma Australia Pty Ltd Suite 4, 13B Narabang Way Belrose NSW 2085 Tel: (02) 9479 0600 Fax: (02) 9986 1699
GC	GlaxoSmithKline Consumer Healthcare 82 Hughes Avenue Ermington NSW 2115 Tel: (02) 9684 0888 Fax: (02) 9684 6958
GH	Goldshield Healthcare (Australia) Pty Ltd Suite 3, Level 1 118-124 Willoughby Road Crows Nest NSW 2059 Tel: (02) 9431 6333 Fax: (02) 9906 7147
GI	Gilead Sciences Pty Ltd Level 1, 128 Jolimont Road East Melbourne Vic 3002 Tel: (03) 9272 4400 Fax: (03) 9272 4435
GK	GlaxoSmithKline Australia Pty Ltd 1061 Mountain Highway Boronia Vic 3155 Tel: (03) 9721 6000 Fax: (03) 9729 5319
GM	Genepharm Pty Ltd 3/10 Inglewood Place Norwest Business Park Baulkham Hills NSW 2153 Tel: 1800 678 302 Fax: (02) 8818 2122
GN	Genepharm Australasia Limited Level 1, 263 City Road Southbank Vic 3006 Tel: 1800 508 168 Fax: (03) 9699 8333
GP	GP Laboratories A Division of Pfizer Pty Limited 38-42 Wharf Road West Ryde NSW 2114 Tel: (02) 9850 3333 Fax: (02) 9858 1347
GQ	Generic Health Pty Ltd Suite 1, Level 1 1175 Toorak Road Camberwell Vic 3124 Tel: (03) 9809 7900 Fax: (03) 9809 7999
GX	GenRx A Division of Apotex Pty Ltd 66 Waterloo Road North Ryde NSW 2113 Tel: (02) 8877 8333 Fax: (02) 8877 8377
GZ	Genzyme Australasia Pty Ltd Level 1, Building C 12-24 Talavera Road North Ryde NSW 2113 Tel: (02) 9978 3900 Fax: (02) 9889 3900
HA	Hamilton Laboratories Pty Ltd 217 Flinders Street Adelaide SA 5000 Tel: (08) 8223 2957 Fax: (08) 8232 1480
HC	Biotech Healthcare A division of Biotech Pharmaceuticals Pty Ltd 83 Cherry Lane Laverton North Vic 3026 Tel: (03) 9278 7555 Fax: (03) 9369 6730

Code	Manufacturer
HH	Hospira Pty Ltd (David Bull Laboratories, Faulding Pharmaceuticals) Level 6, 390 St Kilda Road Melbourne Vic 3004 Tel: (03) 9868 0700 Fax: (03) 9868 0111
HO	Hollister (Distributed in Australia by Liberty Medical Pty Ltd) Unit 6, 345 Ingles Street Port Melbourne Vic 3207 Tel: (03) 9673 4300 Fax: (03) 9646 4018
HR	Paul Hartmann Pty Ltd 27-28/11-21 Underwood Road Homebush NSW 2140 Tel: 1800 805 839 Fax: (02) 8762 7100
HS	healthsense 115 Sherriff Street Underdale SA 5032 Tel: (08) 8408 3200 Fax: (08) 8408 3383
HX	Hexal Australia Pty Ltd Level 4, Suite 7-19 100 Harris Street Pyrmont NSW 2009 Tel: (02) 9566 1500 Fax: (02) 9566 1458
IA	iNova Pharmaceuticals (Australia) Pty Limited 9-15 Chilvers Road Thornleigh NSW 2120 Tel: (02) 9875 6333 Fax: (02) 9875 6416
IQ	Ioquin A Division of Alcon Laboratories (Australia) Pty Ltd Allambie Grove Park 25 Frenchs Forest Road East Frenchs Forest NSW 2086 Tel: 1800 025 004 Fax: (02) 9452 5209
IS	Ipsen Pty Ltd Suite 6, 40 Montclair Avenue Glen Waverley Vic 3150 Tel: (03) 8544 8100 Fax: (03) 9562 5152

Code	Manufacturer
IT	InterPharma Pty Ltd Suite 3, 14 Sydney Road Manly NSW 2095 Tel: (02) 9976 6876 Fax: (02) 9976 6859
IZ	Intensive Care Products Pty Ltd Level 1, APP House 14 Rodborough Road Frenchs Forest NSW 2086 Tel: (02) 9984 2280 Fax: (02) 9984 2222
JC	Janssen-Cilag Pty Ltd 1-5 Khartoum Road North Ryde NSW 2113 Tel: (02) 8875 3333 Fax: (02) 8875 3300
JJ	Johnson & Johnson Medical 1-5 Khartoum Road North Ryde NSW 2113 Tel: (02) 9878 9111 Fax: 1800 808 233
JT	Johnson & Johnson Pacific Pty Limited 45 Jones Street Ultimo NSW 2007 Tel: 13 1565 Fax: (02) 8260 8102
KC	Kimberly-Clark Australia Pty Ltd 52 Alfred Street South Milsons Point NSW 2061 Tel: (02) 9963 8888 Fax: (02) 9957 5687
KE	Kendall Australasia Pty Ltd 22 Giffnock Avenue North Ryde NSW 2113 Tel: 1800 252 467 Fax: (02) 9888 7378
KN	Knoll A Division of Abbott Australasia Pty Ltd Captain Cook Drive Kurnell NSW 2231 Tel: (02) 9668 9711 Fax: (02) 9668 8459

Code	Manufacturer
KR	Kenral Division of Pharmacia Australia Pty Limited 59 Kirby Street Rydalmere NSW 2116 Tel: (02) 9848 3000 Fax: (02) 9848 3333
KY	Key Pharmaceuticals Pty Ltd 12 Lyonpark Road Macquarie Park NSW 2113 Tel: (02) 8113 6200 Fax: (02) 8113 6222
LB	Life Bioscience Pty Ltd 10 Atherton Road Oakleigh Vic 3166 Tel: 1800 114 610 Fax: (03) 8660 2785
LM	Link Medical Products Pty Ltd Level 1, Bridgepoint Centre 3 Brady Street Mosman NSW 2088 Tel: (02) 9960 0150 Fax: (02) 9960 0149
LN	Lennon Healthcare A Division of Aspen Pharmacare Australia Pty Ltd First Floor 34-36 Chandos Street St Leonards NSW 2065 Tel: (02) 8436 8300 Fax: (02) 9901 3540
LU	Lundbeck Australia Pty Ltd Unit 1, 10 Inglewood Place Norwest Business Park Baulkham Hills NSW 2153 Tel: (02) 9836 1655 Fax: (02) 9836 1755
LY	Eli Lilly Australia Pty Limited 112 Wharf Road West Ryde NSW 2114 Tel: (02) 9325 4444 Fax: (02) 9325 4410
MD	Macarthur Research Division of Roche Products Pty Ltd 4-10 Inman Road Dee Why NSW 2099 Tel: (02) 9454 9000 Fax: (02) 9981 3229
MF	Mundipharma Pty Ltd Level 33, 50 Bridge Street Sydney NSW 2000 Tel: (02) 9231 7200 Fax: (02) 9223 0011
MH	Molnlycke Health Care Pty Ltd Building 1, Ground Floor 14 Aquatic Drive Frenchs Forest NSW 2086 Tel: (02) 9453 1144 Fax: (02) 9453 1155
MI	Meditech Int. Pty Ltd Unit 5, 36 Campbell Avenue Cromer NSW 2099 Tel: (02) 9981 4470 Fax: (02) 9981 4475
MK	Merck Sharp & Dohme (Australia) Pty Ltd 54-68 Ferndell Street South Granville NSW 2142 Tel: (02) 9795 9500 Fax: (02) 9795 9595
MM	3M Pharmaceuticals Australia Pty Ltd 9-15 Chilvers Road Thornleigh NSW 2120 Tel: (02) 9875 6333 Fax: (02) 9875 6416
MQ	Alphapharm Pharmaceuticals Chase Building 2 Wentworth Park Road Glebe NSW 2037 Tel: (02) 9298 3999 Fax: (02) 9566 4686
MS	Abbott Diabetes Care (A Division of Abbott Australasia Pty Ltd) 666 Doncaster Road Doncaster Vic 3108 Tel: (03) 9843 7100 Fax: (03) 9855 8020
MT	Mentholatum Australasia Pty Ltd 12-16 Janine Street Scoresby Vic 3179 Tel: (03) 9763 0322 Fax: (03) 9763 2699

Code	*Manufacturer*
MW	McGaw Biomed Australia Pty Ltd c/- B. Braun Australia Pty Ltd Norwest Business Park 17 Lexington Drive Bella Vista NSW 2153 Tel: (02) 9629 0200 Fax: (02) 9629 0299
NA	National Diagnostic Products 22/39 Herbert Street St Leonards NSW 2065 Tel: (02) 9432 8100 Fax: (02) 9432 1151
NC	Novartis Consumer Health Australasia Pty Ltd 327-333 Police Road Mulgrave Vic 3170 Tel: (03) 9701 2711 Fax: (03) 9701 2911
NE	Norgine Pty Limited 3/14 Rodborough Road Frenchs Forest NSW 2086 Tel: (02) 9972 7500 Fax: (02) 9972 7522
NF	FlexPen Products of Novo Nordisk Pharmaceuticals Pty Ltd Level 3, 21 Solent Circuit Baulkham Hills NSW 2153 Tel: (02) 8858 3600 Fax: (02) 8858 3799
NI	InnoLet Products of Novo Nordisk Pharmaceuticals Pty Ltd Level 3, 21 Solent Circuit Baulkham Hills NSW 2153 Tel: (02) 8858 3600 Fax: (02) 8858 3799
NL	NovoLet Products of Novo Nordisk Pharmaceuticals Pty Ltd Level 3, 21 Solent Circuit Baulkham Hills NSW 2153 Tel: (02) 8858 3600 Fax: (02) 8858 3799

Code	*Manufacturer*
NM	Novartis Medicines A Division of Novartis Pharmaceuticals Australia Pty Ltd 54 Waterloo Road North Ryde NSW 2113 Tel: (02) 9805 3555 Fax: (02) 9887 4551
NO	Novo Nordisk Pharmaceuticals Pty Ltd Level 3, 21 Solent Circuit Baulkham Hills NSW 2153 Tel: (02) 8858 3600 Fax: (02) 8858 3799
NQ	Nycomed Pty Ltd 2 Lyonpark Road North Ryde NSW 2113 Tel: (02) 9859 6900 Fax: (02) 9859 6950
NT	Nestlé Australia Ltd 60 Bathurst Street Sydney NSW 2000 Tel: (02) 9931 2345 Fax: (02) 9931 2610
NU	Nutricia Australia Pty Limited Talavera Corporate Centre Level 4, Building D 12-24 Talavera Road North Ryde NSW 2113 Tel: (02) 8875 0300 Fax: (02) 8978 4841
NV	Novartis Pharmaceuticals Australia Pty Ltd 54 Waterloo Road North Ryde NSW 2113 Tel: (02) 9805 3555 Fax: (02) 9887 4551
OA	Orphan Australia Pty Ltd 48 Kangan Drive Berwick Vic 3806 Tel: (03) 9769 5744 Fax: (03) 9769 5944
OB	Oral B Laboratories Pty Ltd Level 3, 90 Mount Street North Sydney NSW 2060 Tel: (02) 9957 6499 Fax: (02) 9957 5383

Code	Manufacturer
OL	Owen Laboratories Division of Galderma Australia Pty Ltd 9 Rodborough Road Frenchs Forest NSW 2086 Tel: 1800 800 765 Fax: (02) 9975 5374
OM	Colgate Oral Care 345 George Street Sydney NSW 2000 Tel: (02) 9229 5600 Fax: (02) 9232 8448
ON	Orion Laboratories Pty Ltd 25-29 Delawney Street Balcatta WA 6021 Tel: (08) 9441 7800 Fax: (08) 9441 7888
OZ	Medical Specialties Australia Pty Ltd 54 Gibbes Street Chatswood NSW 2067 Tel: (02) 9417 7955 Fax: (02) 9417 5779
PC	Pfizer Consumer Healthcare Pty Ltd 32 Cawarra Road Caringbah NSW 2229 Tel: (02) 9710 6500 Fax: (02) 9710 6644
PD	Parke Davis Pty Ltd 32 Cawarra Road Caringbah NSW 2229 Tel: (02) 9710 6500 Fax: (02) 9710 6400
PE	Pacific EyeCare A Division of Allergan Australia Pty Ltd 77 Ridge Street Gordon NSW 2072 Tel: 1800 252 224 Fax: (02) 9498 0290
PF	Pfizer Pty Limited 38-42 Wharf Road West Ryde NSW 2114 Tel: (02) 9850 3333 Fax: (02) 9858 1347
PH	Pharmacia Australia Pty Limited 38-42 Wharf Road West Ryde NSW 2114 Tel: (02) 9850 3333 Fax: (02) 9858 1347
PI	Pharmion Pty Ltd Level 1, 476 St Kilda Road Melbourne Vic 3004 Tel: (03) 9869 8000 Fax: (03) 9869 8099
PK	Pharmatel Fresenius Kabi Pty Ltd Unit 6, 6-18 Bridge Road Hornsby NSW 2077 Tel: (02) 9472 2222 Fax: (02) 9472 2255
PL	Phebra 332 Burns Bay Road Lane Cove NSW 2066 Tel: (02) 9420 9199 Fax: (02) 9420 9177
PM	PMC Pharma A Division of AstraZeneca Pty Ltd Alma Road North Ryde NSW 2113 Tel: (02) 9978 3500 Fax: (02) 9978 3700
PP	Petrus Pharmaceuticals Pty Ltd Level 3, IBM Building 1060 Hay Street West Perth WA 6005 Tel: (08) 9368 5954 Fax: (08) 9368 6692
PU	Pharmacia & Upjohn Pty Limited 38-42 Wharf Road West Ryde NSW 2114 Tel: (02) 9850 3333 Fax: (02) 9858 1347
PX	Point of Care Diagnostics Australia Pty Ltd Unit 14, 76 Reserve Road Artarmon NSW 2064 Tel: (02) 9437 1355 Fax: (02) 9437 1399

Code	Manufacturer
PY	Procter & Gamble Pharmaceuticals Australia Pty Ltd 99 Phillip Street Parramatta NSW 2150 Tel: (02) 9685 4500 Fax: (02) 9685 4777
PZ	Prohealth Asia Pacific Pty Ltd Suite 108A, 20 Lexington Drive Bella Vista NSW 2153 Tel: 1300 024 784 Fax: 1300 008 463
RA	Ranbaxy Australia Pty Limited Suite 4.02, Level 4 Building D 12-24 Talavera Road North Ryde NSW 2113 Tel: (02) 9647 1172 Fax: (02) 9647 1172
RC	Reckitt Benckiser (Australia) Pty Limited 44 Wharf Road West Ryde NSW 2114 Tel: (02) 9857 2000 Fax: (02) 9857 2004
RD	Roche Diagnostics Australia Pty Ltd 31 Victoria Avenue Castle Hill NSW 2154 Tel: (02) 9899 7999 Fax: (02) 9634 4696
RE	Real-RL Division of GlaxoSmithKline Australia Pty Ltd 1061 Mountain Highway Boronia Vic 3155 Tel: (03) 9721 6000 Fax: (03) 9721 5319
RO	Roche Products Pty Ltd 4-10 Inman Road Dee Why NSW 2099 Tel: (02) 9454 9000 Fax: (02) 9971 7401

Code	Manufacturer
SB	Nutricia Australia - Clinical A division of Nutricia Australia Pty Limited Talavera Corporate Centre Level 4, Building D 12-24 Talavera Road North Ryde NSW 2113 Tel: (02) 8875 0300 Fax: (02) 8978 4841
SC	Schering Pty Ltd Australian Subsidiary of Schering AG, Berlin 875 Pacific Highway Pymble NSW 2073 Tel: (02) 9391 6000 Fax: (02) 9988 3311
SE	Servier Laboratories (Aust.) Pty Ltd 8 Cato Street Hawthorn Vic 3122 Tel: (03) 8823 7333 Fax: (03) 9822 9790
SG	Merck Serono Australia Pty Ltd Unit 3-4, 25 Frenchs Forest Road East Frenchs Forest NSW 2086 Tel: (02) 8977 4100 Fax: (02) 9975 1516
SH	Schering-Plough Pty Ltd Level 4, 66 Waterloo Road North Ryde NSW 2113 Tel: (02) 8988 8000 Fax: (02) 9852 7500
SI	Sigma Pharmaceuticals (Australia) Pty Ltd A member of Sigma Group of Companies 96 Merrindale Drive Croydon Vic 3136 Tel: (03) 9839 2800 Fax: (03) 9839 2753
SJ	Sharpe Laboratories Pty Ltd 12 Hope Street Ermington NSW 2115 Tel: (02) 9858 5622 Fax: (02) 9858 5957

Code	Manufacturer
SM	Solvay Pharmaceuticals Division of Solvay Biosciences Pty Ltd Level 1, Building 2 Pymble Corporate Centre 20 Bridge Street Pymble NSW 2073 Tel: (02) 9440 0977 Fax: (02) 9440 0910
SN	Smith & Nephew Healthcare 315 Ferntree Gully Road Mount Waverley Vic 3149 Tel: (03) 8540 6777 Fax: 1800 671 000
SS	SSL Australia Pty Ltd 225 Beach Road Mordialloc Vic 3195 Tel: 1800 999 155 Fax: (03) 9587 6870
SU	Sauter Laboratories (Aust.) Pty Ltd 4-10 Inman Road Dee Why NSW 2099 Tel: (02) 9454 9000 Fax: (02) 9981 3229
SW	Sanofi-Aventis Australia Pty Ltd Building D, Talavera Corporate Centre 12-24 Talavera Road Macquarie Park NSW 2113 Tel: (02) 8666 2000 Fax: (02) 8666 3000
SX	Stiefel Laboratories Pty Limited Unit 14, 5 Salisbury Road Castle Hill NSW 2154 Tel: (02) 9894 5088 Fax: (02) 9894 5016
SY	Schering AG 875 Pacific Highway Pymble NSW 2073 Tel: (02) 9391 6000 Fax: (02) 9988 3311
SZ	Sandoz Pty Ltd Level 4, Suite 7-19 100 Harris Street Pyrmont NSW 2009 Tel: (02) 9566 1500 Fax: (02) 9566 1458

Code	Manufacturer
TA	Actavis Australia Pty Ltd Deacons 225 George Street Sydney NSW 2000 Tel: (08) 8267 6121 Fax: (08) 8267 6121
TM	Technipro Marketing Pty Ltd Unit 10, 13 Berry Street Clyde NSW 2142 Tel: (02) 9897 5899 Fax: (02) 9897 5799
TW	Terry White Chemists Level 7, 5 Queens Road Melbourne Vic 3004 Tel: (03) 9918 2500 Fax: (03) 9918 2006
TX	Apotex Pty Ltd 66 Waterloo Road North Ryde NSW 2113 Tel: (02) 8877 8333 Fax: (02) 8877 8377
UC	UCB Pharma A Division of UCB Australia Pty Ltd Level 1, 1155 Malvern Road Malvern Vic 3144 Tel: (03) 9828 1800 Fax: (03) 9828 1860
UM	Unomedical Pty Ltd 11-17 Wilmette Place Mona Vale NSW 2103 Tel: (02) 9997 8033 Fax: (02) 9997 3760
VF	Vitaflo Australia Pty Ltd 110 Fyans Street South Geelong Vic 3220 Tel: (03) 5229 8222 Fax: (03) 5229 8225
VT	Valeant Pharmaceuticals Australasia Pty Ltd Level 1, 85 St Hilliers Road Auburn NSW 2144 Tel: (02) 9648 4266 Fax: (02) 9648 4655

Code	Manufacturer
WA	Winthrop Pharmaceuticals Division of Sanofi-Aventis Australia Pty Limited Building D, Talavera Corporate Centre 12-24 Talavera Road Macquarie Park NSW 2113 Tel: (02) 8666 2000 Fax: (02) 8666 3000
WF	MedWatchDog Pty Limited 27 Goodwin Street West Ryde NSW 2114 Tel: (02) 9809 0665 Fax: (02) 9989 8469
WT	Wyeth Consumer Healthcare Pty Ltd 17-19 Solent Circuit Norwest Business Park Baulkham Hills NSW 2153 Tel: 1800 555 057 Fax: (02) 9023 0016
WX	Wyeth Australia Pty Limited 17-19 Solent Circuit Norwest Business Park Baulkham Hills NSW 2153 Tel: (02) 9761 8200 Fax: (02) 9023 0000
WY	Wyeth Pharmaceuticals Division of Wyeth Australia Pty Limited 17-19 Solent Circuit Norwest Business Park Baulkham Hills NSW 2153 Tel: (02) 9761 8200 Fax: (02) 9023 0000
XF	Max Pharma Suite 2, 210 Whitehorse Road Balwyn Vic 3103 Tel: (03) 9888 5222 Fax: (03) 9888 5288
XP	Aaxis Pacific Pty Ltd 24-32 Forge Street Blacktown NSW 2148 Tel: (02) 9881 3333 Fax: (02) 9881 3322

Code	Manufacturer
YM	Symbion Pharmacy Services Pty Ltd Level 7, 5 Queens Road Melbourne Vic 3004 Tel: (03) 9918 2000 Fax: (03) 9918 2006
ZP	Spirit Pharmaceuticals Pty Ltd 117 Harrington Street The Rocks Sydney NSW 2000 Tel: (02) 9251 1088 Fax: (02) 9251 1099

Section 1 — Explanatory Notes

Introduction

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

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

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

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

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

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

Queries relating to the PBS can be made to the Pharmaceutical Branches of Medicare Australia (telephone 132 290 Mondays to Saturdays, during business hours). Queries relating to the Repatriation Pharmaceutical Benefits Scheme (RPBS) can be made to the State offices of the Department of Veterans' Affairs (DVA) (telephone 1800 552 580).

1. The Schedule — Where to Find What

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

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

Section 1

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

Please note that except where indicated, the term '**prescriber**' is used in this section to cover doctors, dentists and optometrists who work within the PBS.

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

Section 2

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

Emergency drug (doctor's bag) supplies are also listed at the beginning of this section.

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

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

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

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

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

Section 3

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

Section 4

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

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

Repatriation Schedule of Pharmaceutical Benefits

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

2. Prescribing Medicines — Information for PBS Prescribers

PBS prescribers

Pharmaceutical benefits can only be prescribed by registered doctors, and by dentists and optometrists who are approved to prescribe within the PBS.

PBS Prescription forms

Standard PBS prescription forms are available from Medicare Australia for prescribing pharmaceutical benefits.

For doctors:

- *Personalised forms* – are printed with the doctor's name, qualifications, practice address/es, telephone number and prescriber number (which relates to pharmaceutical benefits). They are only provided to doctors who have a Medicare provider number.

- *Non-personalised (blank) forms* – are distributed as an emergency supply (usually when a doctor has temporarily run out of personalised forms).
- *Locum forms* – have the doctor's name, prescriber number and telephone number (if available) and a space to record the practice where the doctor is working.
- *PBS/RPBS Authority Prescription Forms* – can be in personalised, non-personalised or locum format.
- *Computer PBS prescription forms* – are either continuous or single sheet. On the reverse side they list the name, address and telephone number of the practice, and in the case of a sole doctor practice, the doctor's name.

For dentists:

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

For optometrists:

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

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

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

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

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

Ordering forms

Prescribers are asked not to over order. Getting the right amount of forms helps to reduce the cost to taxpayers and helps to reduce paper wastage. Also, the pads may deteriorate if stored over time.

Order forms for standard and authority PBS prescription forms are available from Medicare Australia stationery officers. Contact details are listed in the front of the Schedule. Order forms for computer PBS prescription form stationery are obtained from Medicare Australia (at the address below). Orders should be sent to:

Prescription Pad Order Clerk
Pharmaceutical Branch
Medicare Australia
GPO Box 9826
Sydney NSW 2001
Telephone (02) 9895 3295

Orders for PBS prescription stationery will only be accepted by application in writing and through the channels mentioned above.

Preparing general PBS prescriptions

Do's and Don't's

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

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

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

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

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

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

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

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

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

Prescribers are issued with individual PBS prescription pads by Medicare Australia for their own use – these pads should not be used by other prescribers, as this can cause confusion through incorrect pharmacy records.

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

The following admixtures are not pharmaceutical benefits:

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

Writing the PBS prescription

The following rules apply for writing PBS prescriptions:

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

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

Restrictions

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

Unrestricted benefits –have no restrictions on their therapeutic uses;

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

Authority required benefits –Authority required benefits fall into two categories:

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

Authority PBS prescriptions

Authority required benefits fall into two categories – A*uthority required* and *Authority required (STREAMLINED)*.

Only doctors and optometrists (not dentists) can write authority PBS prescriptions.

Authority PBS prescriptions cannot have retrospective approval.

Authority required PBS Prescriptions

Approval of authority PBS prescriptions by Medicare Australia may be sought by:

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

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

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

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

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

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

Authority required (STREAMLINED) PBS Prescriptions

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

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

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

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

- the pharmacist/patient copy, which records prescriber, patient, and pharmaceutical benefit item details. The prescription is given directly to the patient to be dispensed at their pharmacy;

- the Medicare Australia/DVA copy which records prescriber, patient, and pharmaceutical benefit item details. After the first dispensing, the Medicare Australia/DVA copy is forwarded to Medicare Australia for processing and payment;
- the prescriber's copy is kept by the prescriber for 12 months. This copy must record the daily dose, details of the disease, clinical justification for using the item, the patient's age (if the patient is a child) and whether the patient has previously received an authority for this pharmaceutical benefit.

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

Writing authority PBS prescriptions

The following rules apply:

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

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

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

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

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

Maximum quantities and repeats

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

Only doctors and optometrists (not dentists) can prescribe repeats.

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

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

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

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

Regulation 24

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

The doctor must first be satisfied all the following conditions apply:

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

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

Urgent cases

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

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

Drugs of addiction

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

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

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

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

Emergency drug (doctor's bag) supplies

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

A doctor must fill out and sign the Emergency Drug (Doctor's Bag) Order Form in triplicate and give the original and duplicate to a pharmacist. Each form is valid for the month indicated on the form.

Doctors can order the maximum quantity of an item provided they do not already have the maximum quantity on hand. Doctors can only get items once a month. They can also ask for a particular brand of a pharmaceutical benefit. If it is unavailable, they must specify another listed brand, and initial the alteration.

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

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

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

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

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

How to prescribe these items?

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

Only doctors (not dentists) can write Authority PBS prescriptions and your patients will be required to pay their normal PBS co-payment.

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

Aboriginal and Torres Strait Islander identification

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

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

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

- Some people may give this information without being asked.

- It is important not to assume that a person is or is not Aboriginal or Torres Strait Islander.

Asking about Aboriginal and/or Torres Strait Islander identification

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

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

Aboriginal and Torres Strait Islander health

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

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

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

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

Communication and cultural issues

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

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

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

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

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

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

You should:

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

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

3. Supplying Medicines — What Pharmacists Need to Know

Eligible suppliers

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

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

Unapproved pharmacists *cannot* supply pharmaceutical benefits.

Approval conditions for pharmacists

A pharmacist approved to supply medicines under the PBS:

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

Before supplying pharmaceutical benefits

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

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

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

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

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

Supplying pharmaceutical benefits

Do's and Don't's

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

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

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

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

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

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

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

Exceptions to this are:

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

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

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

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

What to do if the Schedule changes

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

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

Suspected forgery

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

Regulation 24

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

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

Repeat authorisations

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

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

Preparing Repeat Authorisation Forms

A Repeat Authorisation Form must show:

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

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

Repeat authorisations for injectables and solvents

Where an injectable pharmaceutical benefit requires a solvent, both items should be treated as one pharmaceutical benefit. If repeats are needed, only one repeat authorisation is to be prepared. Details of the injectable and the solvent should appear in the space provided for the 'original prescription transcription'.

Repeat authorisations for deferred supply

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

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

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

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

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

Authority PBS prescriptions

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

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

Urgent cases

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

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

Receipts

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

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

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

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

Emergency drug (doctor's bag) supplies

Pharmacists may supply certain pharmaceutical benefit items free of charge to doctors for emergencies if they receive an Emergency Drug (Doctor's Bag) Order Form in duplicate, signed by the doctor.

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

For more information about emergency supplies see under `2. Prescribing Medicines ... Emergency drug (doctor's bag) supplies'.

4. Patient Charges

Type of patient

There are two types of PBS beneficiaries – general patients and concessional patients. General patients hold a Medicare card. Concessional patients hold a Medicare card and one of the following cards from Centrelink or the DVA:

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

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

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

Establishing entitlement

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

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

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

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

What to charge

Patient contribution

Under the PBS, the maximum cost for a pharmaceutical benefit item at a pharmacy is $32.90 for general patients and $5.30 for concessional patients (except where a special patient contribution, a brand premium, or a therapeutic group premium applies). General patients who have reached the safety net threshold (see details under '5. The Safety Net Scheme') receive pharmaceutical benefit items at the concessional rate of $5.30.

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

The contribution rate for general patients as outpatients at public hospitals throughout Australia is $26.30. The exception is Queensland and hospitals participating in the pharmaceutical reforms where they pay the safety net value of an item when it is listed in the Schedule (see details under '5. The Safety Net Scheme'), or up to $32.90 for items not listed in the Schedule. The public hospital pharmaceutical reforms enable participating public hospitals to prescribe and supply pharmaceutical medication from the Pharmaceutical Benefits Scheme to outpatients and patients upon discharge. A range of chemotherapy drugs will also be available for day-admitted and non-admitted chemotherapy patients.

The contribution rate for concessional patients in all public hospitals is $5.30.

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

It is the patient's responsibility to meet any charge lawfully demanded by an approved pharmacist, otherwise supply may be refused.

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

Patient contributions for early supply of some PBS medicines

Prescriptions for some pharmaceutical benefits are not eligible for Safety Net benefits if resupplied within 20 days of a previous supply of the same pharmaceutical benefit for the same person under the PBS or the RPBS. This is known as the 'Safety Net 20 day rule' which came into effect on 1 January 2006.

Where a prescription is subject to the Safety Net 20 day rule, exclusion from Safety Net benefits has the following effects:

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

For example: The payment for such a prescription for a patient with a Safety Net Entitlement Card would be $5.30 – not free. For a general patient with a Safety Net Concession Card, the usual general patient amount (up to $32.90) would apply – not the Safety Net concessional amount of $5.30.

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

Special patient contributions, brand premiums and therapeutic group premiums

A special patient contribution is payable for a pharmaceutical benefit when there is a disagreement between the manufacturer and the Government over the price for that pharmaceutical benefit. The extra charge for a higher priced product is paid by the patient, together with their usual patient contribution. Other than for bleomycin sulfate, exemptions on medical grounds are available. For RPBS special patient contribution arrangements see the RPBS Explanatory Notes.

Under the brand premium arrangements, Commonwealth reimbursement to pharmacists is based on the lowest-priced brand. Patients pay the difference for higher-priced brands, on top of their usual patient contribution.

Under the therapeutic group premium arrangements, Commonwealth reimbursement to pharmacists is based on the lowest priced benefit items within identified therapeutic groups. Patients pay the difference for higher priced items. Exemptions on medical grounds are available, but must be granted by Medicare Australia.

The Schedule's special patient contributions, brand premiums and therapeutic group premiums apply to maximum quantities. When a quantity is less than, or – on an authority or regulation 24 PBS prescription - more than, the maximum, the contributions or premiums will be a fraction or multiple of the maximum quantity, using standard pricing rules.

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

Solvents

Where a solvent is prescribed as a part of a pharmaceutical benefit, only one patient contribution is charged.

Increased quantities

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

Regulation 24

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

After hours

A pharmacist may charge an extra fee if he/she supplies a PBS item outside his/her pharmacy's normal trading hours. The charge is paid by the patient and does not count towards the safety net.

Delivery

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

5. The Safety Net Scheme

The Safety Net Scheme is designed to protect those patients and their families who require a large number of PBS and RPBS items, and applies to each calendar year.

For the purposes of the scheme, the family includes:

- the spouse or de facto spouse;
- family members under the age of 16 who are in the care and control of the patient; or
- dependent full-time students under the age of 25.

The scheme requires pharmacists, on request by patients, to record the supply of PBS and RPBS items on Prescription Record Forms (PRF's). When patients reach a certain spending level (or Safety Net threshold) within a calendar year, they qualify to receive PBS or RPBS items at a cheaper price or free of charge for the rest of that year. The reductions do not apply to special patient contributions, brand premiums or therapeutic group premiums – these charges must still be met by patients.

The Safety Net threshold may be reached by accumulating eligible patient contributions for PBS prescriptions supplied through community pharmacies and hospitals, or out-patient medications supplied by public hospitals, or a combination of both.

Pharmaceutical benefit items (including authority items) can only be counted towards the safety net threshold when prescribed and supplied according to the Schedule's conditions. A medicine supplied by a pharmacist who is not approved to supply pharmaceutical benefits cannot count towards the Safety Net.

Prescriptions for some pharmaceutical benefits are not eligible for Safety Net benefits if resupplied within 20 days of a previous supply of the same pharmaceutical benefit for the same person under the PBS or RPBS. For such prescriptions, the patient contribution cannot count towards the Safety Net (see also details under '4. Patient Charges' and '7. How Pharmacists Claim Reimbursement'). This does not apply to out-patient medications in public hospitals or to any prescriptions originating from a hospital or day hospital facility.

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

Safety net thresholds

There are two safety net thresholds – one for general patients and the other for concessional patients.

The general patient safety net threshold is currently $1264.90. When patients and/or their families reach this amount, they can apply for a Safety Net Concession Card and pay only $5.30 per PBS prescription for the rest of the calendar year.

The concessional safety net threshold is $318.00 (this also applies to gold, white or orange card holders under the RPBS). Once patients and/or their families reach this amount, they can apply for a Safety Net Entitlement Card and receive items free of charge for the rest of the calendar year.

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

The safety net thresholds are adjusted on 1 January each year in line with inflation. In addition, thresholds increase by an amount equivalent to two co-payments on 1 January of each year from 2006 to 2009.

Safety net cross-over arrangements

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

Concessional patients who were previously general patients can apply for a Safety Net Entitlement Card once they reach the threshold of $318.00. In this case, any pharmaceutical benefits previously supplied at the general rate in that calendar year will need to be converted to the rate of $5.30 per item.

General patients who were previously concessional patients can apply for a Safety Net Concession Card when they reach the general threshold of $1264.90. In this case, any pharmaceutical benefits previously supplied at the concessional rate in that calendar year will be counted at the rate of $5.30 per item.

In the case of families where one parent holds a concession card and other family members are general patients, the family can choose to apply for either a Safety Net Entitlement Card or a Safety Net Concession Card.

To receive a Safety Net Entitlement Card, all pharmaceutical benefits (including general PBS prescriptions) are counted at $5.30 per item until the $318.00 threshold is reached. To receive a Safety Net Concession Card, general pharmaceutical benefits are counted at the general rate of up to $32.90 per item and concessional pharmaceutical benefits at $5.30 per item, until the threshold of $1264.90 is reached.

White DVA card holders can either be general or concessional patients (depending on their Centrelink entitlements). If they are being treated for a specific disability accepted by the DVA, they are also supplied with specific items under the RPBS at the concessional rate of $5.30 per item. Therefore, these patients are encouraged to maintain a concessional PRF, plus a general PRF for those items not covered under the RPBS.

White card holders may choose at any time during the year to count contributions made at the general level towards the concessional safety net threshold. The patient receives a credit of $5.30 for each PBS prescription item purchased. Alternatively, he/she can count contributions at the concessional level towards the general safety net, and receive a credit of $5.30 for each RPBS prescription item purchased.

Those with gold or orange cards receive all of their prescription items under the RPBS, and only pay $5.30 for each item.

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

Recording PBS prescriptions

There are two types of PRF's to record PBS prescription items. One (a blue form) is used by general and concessional patients and veterans who pay for items at community pharmacies. It is available from community pharmacies, Medicare offices and Medicare Australia in each State. The other form (grey) is used by out-patients who pay for items at public hospital pharmacies, and is available through hospital out- patient departments or Medicare Australia State offices.

Patients should record their status (general or concessional) in the appropriate box on the front of the PRF, state their Centrelink, DVA and/or Safety Net Concession/Entitlement Card number, and list family members covered. General patients must also record their Medicare number when applying for a Safety Net Concession Card.

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

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

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

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

Some computer software suppliers provide a special label to record this information on the PRF. Some suppliers also provide a computer printout option that is an acceptable replacement for the PRF.

The patient is responsible for maintenance and storage of the PRF. However, it may be kept in the pharmacy. An individual (or family) may have more than one PRF.

Hospital PRF's

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

Multi-item forms

If a patient submits a multi-item PBS prescription form, which would take the PRF past the safety net expenditure limit, any items in excess are to be treated as entitled items once the Safety Net Entitlement/Concession Card is issued.

These excess items should be treated as 'deferred supply' items.

For example, if a family has $1232.00 recorded on their PRF and they have a new PBS prescription for three items, the first item should be supplied at the general rate. If the second item would take the family over the threshold of $1264.90 the pharmacist should then issue a Safety Net Concession Card and supply the other two items at the concessional rate. This involves the deferral of two items, entry of the Safety Net Concession Card number into the computer, and the subsequent supply of these items.

Qualifying PBS prescriptions

A PBS prescription should be supplied at either the concessional rate or free of charge, as appropriate, when the safety net value or hospital charge for that PBS prescription takes the PRF over the qualifying amount for a Safety Net Entitlement/Concession Card.

Lost PRF's

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

Retrospective entitlement and patient refunds

Responsibility for claiming entitlements rests with the patient. If items accumulated on a PRF have already exceeded the safety net limit, then the cost to the patient of those items in excess of the limit cannot be refunded by a pharmacist.

However, a patient may get a refund in the following circumstances:

- The patient failed to apply for his/her Safety Net Entitlement/Concession Card on reaching the safety net threshold —
  - The patient should write to Medicare Australia and provide copies of pharmacy accounts or a signed statement from the pharmacist giving the date of supply, description and cost of items supplied and paid for. A copy of the relevant PRF's should also be provided. If they are not available, the patient should give the name of the pharmacy where the card was issued and the number on the card, so Medicare Australia can locate the PRF's through its records. Cash refunds are not available in these circumstances cheques are issued. Patients can write to the Medicare Australia office in their State. Contact details are provided in the front of the Schedule.
- The patient cannot satisfy a pharmacist that he/she has a current entitlement and is charged the general patient price —
  - The pharmacist should issue the patient with a receipt and a claim form (provided to the pharmacist by Medicare Australia). The patient can then get a refund from Medicare Australia via Medicare offices or PBS processing centres. RPBS prescription refunds are paid at DVA State offices.

Medicare Australia can only pay refunds for PBS items supplied through approved pharmacies. Refunds for hospital supplied items should be referred to the relevant State/Territory hospital or health department. Refunds cannot be made where the patient was charged the general or concessional amount instead of the Safety Net concessional or Safety Net entitlement amount, respectively, as a result of the Safety Net 20 day rule. Receipts for prescriptions where the Safety Net 20 day rule has applied must include 'SN20DR' to indicate the reason for the amount charged.

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

Applying for a Safety Net Entitlement/Concession Card

Once the safety net threshold has been reached, any adult patient covered by the PRF can complete the application and declaration on the back of the form or the computer-generated application to get a Safety Net Entitlement/Concession Card. Please note that software packages that produce computer generated applications must be approved by Medicare Australia.

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

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

In the case of a concession card, pharmacists should check that the patient's Medicare card number is on the PRF.

Issuing a Safety Net Entitlement/Concession Card

When satisfied that the individual or family is entitled, the pharmacist should issue the next blank Safety Net Entitlement/Concession Card with the following details:

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

The pharmacist should be satisfied that only family members are listed on the card. The unused space on the card should be ruled through to prevent extra names being added. The sticky label from the Safety Net Entitlement/Concession Card, pre-printed with the card number, should be attached to the PRF. The pharmacist should sign and stamp each PRF with the pharmacy's stamp. He/she must then enter the card issue details on a Safety Net – Claim for Payment Form.

Issuing supplementary cards

A pharmacist can give a card holder a supplementary card for a spouse or dependant only at the time the original card is issued. The duplicate card should be recorded in the additional box on the PRF.

Requests for supplementary cards at a later stage should be referred to Medicare Australia State offices, as should requests to add a new family member to the original card (e.g., a new baby or adopted child).

Notification to Medicare Australia and claim for payment

Payment for issuing a Safety Net Entitlement/Concession Card is made after the Safety Net - Claim for Payment Form is sent to Medicare Australia's State office, no later than one month after a card is issued.

Each form must be accompanied by all supporting documentation (PRF's and cancelled or void Safety Net Entitlement/Concession Cards).

Payment will not be made for void cards.

Lost Safety Net Entitlement/Concession Cards

When a card has been lost, damaged, stolen or destroyed, a pharmacist cannot re-issue a patient with a replacement card. The original card holder (or spouse) must apply to Medicare Australia's office in his/her State.

Pharmacy record of issued cards

A record of all cards issued must be kept at the pharmacy from which the pharmacist is approved to supply pharmaceutical benefits. The duplicate ('bookfast') copy in the Safety Net – Claim for Payment book is provided for this purpose.

6. Medicare Australia Entitlement Checks

General Patients

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

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

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

Concessional Patients

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

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

Entitlement checking procedures

General Patients

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

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

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

Concessional Patients

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

Step by step

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

- Re-confirm entitlement with the cardholder/customer;
- Contact Medicare Australia on 132 290, with consent, to confirm the cardholder/customer concession status;
- If Medicare Australia advises that the cardholder/customer is concessionally entitled to receive the PBS medicines on that day, supply the prescription as a concessional entitlement;
- If Medicare Australia advises that the cardholder/customer is not concessionally entitled to receive the PBS medicines on that day, supply as a general prescription. Provide the customer with the information sheet "Your entitlement card" which explains entitlement checking to the customer and the steps they can follow if they are concessionally entitled.

7. How Pharmacists Claim Reimbursement: Information Required

Medicare Australia uses a computerised system for pricing PBS prescriptions, repeat authorisations and emergency drug (doctor's bag) orders, and for calculating claims.

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

PBS Prescription identification

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

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

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

The sticker is not necessary for current repeat authorisation, emergency drug (doctor's bag), or for old style authority PBS prescription and authority to prescribe forms, as they have printed spaces for the necessary details. However, it is required for the new format authority PBS prescription forms.

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

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

Serial numbers

PBS prescription, repeat authorisation, authority PBS prescription, and emergency drug (doctor's bag) forms submitted in each claim must bear consecutive serial numbers starting with:

- 1 – for emergency drug (doctor's bag) supplies;
- 1 – for general benefits;
- C1 – for concessional and Safety Net Concession Card benefits;
- E1 – for Safety Net Entitlement Card benefits; and
- R1 – for RPBS benefits.

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

Each emergency drug (doctor's bag) item should be given a serial number, e.g., if there are five items on the first form in the claim, the first item on the second form in the claim will start with the serial number 6.

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

Repeat authorisations for authority PBS prescriptions

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

Repeat authorisations for deferred supply

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

Injectable item ordered with a solvent

When both an injectable item and a solvent are to be supplied, only one serial number is used. This number should be placed on the left hand side of the prescription, opposite the injectable item.

Dropper containers

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

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

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

PBS prescriptions paid on an average price basis

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

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

Pricing non-pre-priced extemporaneous preparations

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

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

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

Payment to Pharmacists for Dispensing Premium-free Substitutable Medicines

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

A number of conditions and criteria apply to receive this payment. Scripts will be assessed for validity and the Premium Free Dispensing Incentive payment will be paid by Medicare Australia. Further information on this payment can be found on the Medicare Australia website at: http://www.medicareaustralia.gov.au/provider/pbs/pharmacists/reforms.shtml#dispensing

8. How Pharmacists Claim Reimbursement: Documents to be Submitted

A claim for pharmaceutical benefits consists of:

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

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

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

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

Completing the claim form

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

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

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

A total claim amount is not required – this will be calculated by Medicare Australia after the PBS prescriptions have been individually priced.

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

Lodging claims

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

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

Claims for pharmaceutical benefits supplied over 18 months earlier may not be accepted for computer processing. Pharmacists with such claims should contact Medicare Australia.

Reconciliation statements

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

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

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

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

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

9. Pricing PBS Prescriptions

Pricing principles

The same pricing principles apply to all PBS prescriptions.

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

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

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

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

Pricing dates

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

Pricing ready-prepared items

For maximum quantities

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

If the prescription is for an injectable item and solvent, the price of each is added together, but only one dispensing fee is payable.

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

For lesser quantities

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

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

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

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

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

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

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

Wastage table percentage

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

Wastage Factor Table

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

The appropriate wastage table percentage is as follows:

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

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

Pricing extemporaneously-prepared items

General

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

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

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

The amount payable is the sum of:

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

Pricing of ingredients

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

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

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

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

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

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

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

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

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

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

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

Pricing PBS prescriptions where extra ingredients are added to a formula

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

Containers

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

A double size container is allowed for bulk powders.

Special provisions for extemporaneous PBS prescriptions outside the Standard Formulae List

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

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

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

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

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

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

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

10. Miscellaneous

References

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

Standards

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

Legislation

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

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Section 2

Emergency Drug (Doctor's Bag) Supplies

Special Pharmaceutical Benefits

General Pharmaceutical Benefits

Pharmaceutical Benefits for Palliative Care

Pharmaceutical Benefits for Dental Use

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Items Available Under Special Arrangements (s.100)

SYMBOLS USED IN THE SCHEDULE

An arrow (➢) in front of a restriction indicates an additional or amended purpose in this issue.

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

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

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

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

RESTRICTED BENEFITS

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

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

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

CODES FOR INJECTABLE ITEMS WITH ALLOWABLE SOLVENTS

The entry in this schedule of those pharmaceutical benefit injectable items which require a solvent includes the codes of the items with the relevant solvents. For each such item the code is for the injectable with 10mL sodium chloride injection 9 mg per mL (0.9%).

BRAND EQUIVALENCE

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

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

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

BRAND PREMIUM POLICY

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

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

Basically the policy operates by:

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

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

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

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

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

THERAPEUTIC GROUP PREMIUM POLICY

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

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

Basically the policy operates by:

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

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

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

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

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

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

EMERGENCY DRUG (DOCTOR'S BAG) SUPPLIES

Code	Name, Manner of Administration and Form	Max. Qty	Dispensed Price for Max. Qty $	Proprietary Name and Manufacturer	
	ADRENALINE				
3451P	Injection 1 mg in 1 mL (1 in 1,000)	5	19.91	AP	
	ATROPINE SULFATE				
3453R	Injection 600 micrograms in 1 mL	10	20.11	AP	
	BENZTROPINE MESYLATE				
3457Y	Injection 2 mg in 2 mL	5	22.41	Cogentin	FK
	BENZYLPENICILLIN				
3487M	Powder for injection 3 g	1	11.90	BenPen	CS
	BENZYLPENICILLIN				
3486L	Powder for injection 600 mg	10	* 40.39	BenPen	CS
or	*or*				
	PROCAINE PENICILLIN				
3485K	Injection 1.5 g	5	87.97	Cilicaine	SI
	CHLORPROMAZINE HYDROCHLORIDE				
3455W	Injection 50 mg in 2 mL	10	16.39	Largactil	SW
or	*or*				
	HALOPERIDOL				
3456X	Injection 5 mg in 1 mL	10	21.85	Serenace	SI
	CLONAZEPAM				
3478C	Oral liquid 2.5 mg per mL, 10 mL	‡ 1	10.30	Rivotril	RO
	DEXAMETHASONE SODIUM PHOSPHATE				
3472R	Injection equivalent to 4 mg dexamethasone phosphate in 1 mL	5	17.65	HH	
or	*or*				
	HYDROCORTISONE SODIUM SUCCINATE				
3470P	Injection equivalent to 100 mg hydrocortisone with 2 mL solvent	2	* 16.71	Solu-Cortef	PH
or	*or*				
3471Q	Injection equivalent to 250 mg hydrocortisone with 2 mL solvent	1	15.68	Solu-Cortef	PH
	DIAZEPAM				
3458B	Injection 10 mg in 2 mL	5	11.86	HH	
	DIHYDROERGOTAMINE MESYLATE				
3460D	Injection 1 mg in 1 mL	5	16.63	Dihydergot	NV
	DIPHTHERIA and TETANUS VACCINE, ADSORBED, DILUTED FOR ADULT USE				
3463G	Injection 0.5 mL in pre-filled syringe	20	* 274.59	ADT Booster	CS

EMERGENCY DRUG (DOCTOR'S BAG) SUPPLIES

Code	Name, Manner of Administration and Form	Max. Qty	Dispensed Price for Max. Qty $	Proprietary Name and Manufacturer	
	FRUSEMIDE				
3466K	Injection 20 mg in 2 mL	5	10.05	[a] Frusehexal	SZ
				[a] Lasix	SW
	GLUCAGON HYDROCHLORIDE				
3467L	Injection set containing 1 mg (1 i.u.) and 1 mL solvent in disposable syringe	1	42.93	GlucaGen Hypokit	NO
	GLYCERYL TRINITRATE				
3475X	Sublingual spray (pump pack) 400 micrograms per dose (200 doses)	‡ 1	19.70	Nitrolingual Pumpspray	SW
	HYOSCINE BUTYLBROMIDE				
3473T	Injection 20 mg in 1 mL	5	20.95	Buscopan	BY
	LIGNOCAINE HYDROCHLORIDE				
3474W	Injection 100 mg in 5 mL	5	36.90	PF	
	METOCLOPRAMIDE HYDROCHLORIDE				
3476Y	Injection 10 mg in 2 mL	10	12.56	Maxolon	VT
or	*or*				
	PROCHLORPERAZINE				
3477B	Injection containing prochlorperazine mesylate 12.5 mg in 1 mL	10	16.39	Stemetil	SW
	MORPHINE SULFATE				
3479D	Injection 15 mg in 1 mL	5	14.13	HH	
or	*or*				
3480E	Injection 30 mg in 1 mL	5	15.61	HH	
	NALOXONE HYDROCHLORIDE				
3481F	Injection 800 micrograms in 2 mL	5	* 110.69	Naloxone Min-I-Jet	CS
or	*or*				
3482G	Injection 2 mg in 5 mL	2	* 72.95	Naloxone Min-I-Jet	CS

EMERGENCY DRUG (DOCTOR'S BAG) SUPPLIES

Code	Name, Manner of Administration and Form	Max. Qty	Dispensed Price for Max. Qty $	Proprietary Name and Manufacturer	
	PROMETHAZINE HYDROCHLORIDE				
3488N	Injection 50 mg in 2 mL	10	* 21.89	HH	
	SALBUTAMOL SULFATE				
3497C	Nebuliser solution single dose units 5 mg (base) in 2.5 mL, 30	‡ 1	12.60	[a] Asmol 5 uni-dose	AF
				[a] Butamol 5	SI
				[a] GenRx Salbutamol	GX
				[a] Pharmacor Salbutamol 5	CR
				[a] Salbutamol-GA	GM
				[a] Salbutamol Sandoz	SZ
			13.33	[a] Ventolin Nebules	GK
	SALBUTAMOL SULFATE				
3495Y	Oral pressurised inhalation 100 micrograms (base) per dose (200 doses), CFC-free formulation	‡ 1	10.39	[a] Airomir	IA
				[a] Asmol CFC-free	AL
			10.98	[a] Ventolin CFC-free	GK
or	*or*				
3496B	Nebuliser solution single dose units 2.5 mg (base) in 2.5 mL, 30	‡ 1	12.25	[a] Asmol 2.5 uni-dose	AF
				[a] Butamol 2.5	SI
				[a] GenRx Salbutamol	GX
				[a] Pharmacor Salbutamol 2.5	CR
				[a] Salbutamol-GA	GM
				[a] Salbutamol Sandoz	SZ
				[a] PU	
			12.98	[a] Ventolin Nebules	GK
	TERBUTALINE SULFATE				
3491R	Injection 500 micrograms in 1 mL	5	30.16	Bricanyl	AP
	TRAMADOL HYDROCHLORIDE				
3484J	Injection 100 mg in 2 mL	5	13.87	Tramal 100	CS
	VERAPAMIL HYDROCHLORIDE				
3494X	Injection 5 mg in 2 mL	5	11.95	Isoptin	AB

SPECIAL PHARMACEUTICAL BENEFITS

The special patient contribution is payable by all patients in addition to the relevant patient contribution for concessional and general patients. Other than for bleomycin sulfate, exemptions on medical grounds are available. For eligible veterans under RPBS provisions, see RPBS EXPLANATORY NOTES, paragraph 32.

Code	Name, Restriction, Manner of Administration and form	Max. Qty	No. of Rpts	Premium	Reimbursement Price for Max. Qty $	Total Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
	GENERAL PHARMACEUTICAL BENEFITS								
	AMOXYCILLIN								
1888J	Powder for paediatric oral drops 100 mg per mL, 20 mL	‡ 1	1	s0.61	# 12.75	# 13.36	14.14	Amoxil	GK
	Authority Required ***Treatment of infections suspected or proven to be due to a susceptible organism in patients who require a liquid formulation and in whom the syrup formulations are unsuitable.***								
9714G	***Powder for paediatric oral drops 100 mg per mL, 20 mL***	***‡ 1***	***1***	***..***	***# 13.36***	***# 13.36***	***14.75***	***Amoxil***	***GK***
	BLEOMYCIN SULFATE								
	Restricted Benefit ***Germ cell neoplasms;*** ***Lymphoma.***								
2315W	***Powder for injection 15,000 i.u. (solvent required)***	***10***	***..***	***s437.01***	***491.77***	***928.78***	***32.90***	***[a] Blenamax***	***SI***
				s437.00	**** 491.79***	**** 928.79***	***32.90***	***[a] HH***	
	(code 6896Y applies to above item with approved solvent)			***B75.30***	***491.77***	***1004.08***	***32.90***	***[a] Blenoxane***	***BQ***
				s437.01					
	ESCITALOPRAM OXALATE								
	Restricted Benefit ***Major depressive disorders.***								
8849R	***Oral solution 10 mg (base) per mL, 28 mL***	***‡ 1***	***5***	***s4.30***	***37.66***	***41.96***	***32.90***	***Lexapro***	***LU***
	Authority Required ***Major depressive disorders, where:*** ***(a) adverse events have occurred with other suitable PBS-listed drugs; or*** ***(b) drug interactions have occurred with other suitable PBS-listed drugs; or*** ***(c) drug interactions are expected to occur with other suitable PBS-listed drugs; or*** ***(d) transfer to another suitable PBS-listed drug would cause patient confusion resulting in problems with compliance; or*** ***(e) transfer to another suitable PBS-listed drug is likely to result in adverse clinical consequences.***								
9700M	***Oral solution 10 mg (base) per mL, 28 mL***	***‡ 1***	***5***	***..***	***41.96***	***41.96***	***32.90***	***Lexapro***	***LU***

SPECIAL PHARMACEUTICAL BENEFITS

The special patient contribution is payable by all patients in addition to the relevant patient contribution for concessional and general patients. Other than for bleomycin sulfate, exemptions on medical grounds are available. For eligible veterans under RPBS provisions, see RPBS EXPLANATORY NOTES, paragraph 32.

Code	Name, Restriction, Manner of Administration and form	Max. Qty	No. of Rpts	Premium	Reimburse-ment Price for Max. Qty $	Total Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
	LEVETIRACETAM								
	Authority Required ***Treatment of partial epileptic seizures which are not controlled satisfactorily by other anti-epileptic drugs.***								
8654L	***Tablet 250 mg***	***60***	***5***	***s7.13***	***55.99***	***63.12***	***32.90***	***Keppra***	***UC***
8655M	***Tablet 500 mg***	***60***	***5***	***s11.91***	***89.37***	***101.28***	***32.90***	***Keppra***	***UC***
8656N	***Tablet 1 g***	***60***	***5***	***s19.84***	***144.90***	***164.74***	***32.90***	***Keppra***	***UC***
	Authority Required ***Treatment of partial epileptic seizures which are not controlled satisfactorily by other anti-epileptic drugs, and where:*** ***(a) adverse events have occurred with other suitable PBS-listed drugs; or*** ***(b) drug interactions have occurred with other suitable PBS-listed drugs; or*** ***(c) drug interactions are expected to occur with other suitable PBS-listed drugs; or*** ***(d) transfer to another suitable PBS-listed drug would cause patient confusion resulting in problems with compliance; or*** ***(e) transfer to another suitable PBS-listed drug is likely to result in adverse clinical consequences.***								
9708Y	***Tablet 250 mg***	***60***	***5***	***..***	***63.12***	***63.12***	***32.90***	***Keppra***	***UC***
9709B	***Tablet 500 mg***	***60***	***5***	***..***	***101.28***	***101.28***	***32.90***	***Keppra***	***UC***
9710C	***Tablet 1 g***	***60***	***5***	***..***	***164.74***	***164.74***	***32.90***	***Keppra***	***UC***
	NARATRIPTAN HYDROCHLORIDE **CAUTION:** ***Naratriptan is contraindicated in patients with known or suspected coronary artery disease. The drug should not be used within 24 hours of ergotamine or dihydroergotamine use.***								
	Authority Required ***Migraine attacks in patients receiving, or who have failed a reasonable trial of, prophylactic medication and where attacks in the past have usually failed to respond to oral therapy with ergotamine and other appropriate agents, or in whom these agents are contraindicated.*** **NOTE:** ***No applications for increased maximum quantities and/or repeats will be authorised.***								
8298R	***Tablet 2.5 mg (base)***	***4***	***5***	***s2.78***	**** 25.47***	**** 28.25***	***26.50***	***Naramig***	***GK***
	Authority Required ***Migraine attacks in patients receiving, or who have failed a reasonable trial of, prophylactic medication and where attacks in the past have usually failed to respond to oral therapy with ergotamine and other appropriate agents, or in whom these agents are contraindicated, and where:*** ***(a) adverse events have occurred with other suitable PBS-listed drugs; or*** ***(b) drug interactions have occurred with other suitable PBS-listed drugs; or*** ***(c) drug interactions are expected to occur with other suitable PBS-listed drugs; or***								

continued ☞

SPECIAL PHARMACEUTICAL BENEFITS

The special patient contribution is payable by all patients in addition to the relevant patient contribution for concessional and general patients. Other than for bleomycin sulfate, exemptions on medical grounds are available. For eligible veterans under RPBS provisions, see RPBS EXPLANATORY NOTES, paragraph 32.

Code	Name, Restriction, Manner of Administration and form	Max. Qty	No. of Rpts	Premium	Reimburse-ment Price for Max. Qty $	Total Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
	(d) transfer to another suitable PBS-listed drug would cause patient confusion resulting in problems with compliance; or								
	(e) transfer to another suitable PBS-listed drug is likely to result in adverse clinical consequences.								
	NOTE:								
	No applications for increased maximum quantities and/or repeats will be authorised.								
9734H	***Tablet 2.5 mg (base)***	***4***	***5***	***..***	**** 28.25***	**** 28.25***	***29.28***	***Naramig***	***GK***
	ZOLMITRIPTAN								
	CAUTION:								
	Zolmitriptan is contraindicated in patients with known or suspected coronary artery disease. The drug should not be used within 24 hours of ergotamine or dihydroergotamine use.								
	Authority Required								
	Migraine attacks in patients receiving, or who have failed a reasonable trial of, prophylactic medication and where attacks in the past have usually failed to respond to oral therapy with ergotamine and other appropriate agents, or in whom these agents are contraindicated.								
	NOTE:								
	No applications for increased maximum quantities and/or repeats will be authorised.								
8266C	***Tablet 2.5 mg***	***4***	***5***	***s2.76***	**** 25.41***	**** 28.17***	***26.44***	***Zomig***	***AP***
	Authority Required								
	Migraine attacks in patients receiving, or who have failed a reasonable trial of, prophylactic medication and where attacks in the past have usually failed to respond to oral therapy with ergotamine and other appropriate agents, or in whom these agents are contraindicated, and where:								
	(a) adverse events have occurred with other suitable PBS-listed drugs; or								
	(b) drug interactions have occurred with other suitable PBS-listed drugs; or								
	(c) drug interactions are expected to occur with other suitable PBS-listed drugs; or								
	(d) transfer to another suitable PBS-listed drug would cause patient confusion resulting in problems with compliance; or								
	(e) transfer to another suitable PBS-listed drug is likely to result in adverse clinical consequences.								
	NOTE:								
	No applications for increased maximum quantities and/or repeats will be authorised.								
9736K	***Tablet 2.5 mg***	***4***	***5***	***..***	**** 28.17***	**** 28.17***	***29.20***	***Zomig***	***AP***
	PHARMACEUTICAL BENEFITS FOR DENTAL USE								
	AMOXYCILLIN								
3310F	Powder for paediatric oral drops 100 mg per mL, 20 mL	‡ 1	..	s0.61	# 12.75	# 13.36	14.14	Amoxil	GK

ALIMENTARY TRACT AND METABOLISM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
	STOMATOLOGICAL PREPARATIONS							
	Stomatological preparations							
	• ***Antiinfectives and antiseptics for local oral treatment***							
	AMPHOTERICIN							
2931G	Lozenge 10 mg	20	1	..	10.20	11.23	Fungilin	BQ
	NYSTATIN							
3033P	Oral suspension 100,000 units per mL, 24 mL	‡ 1	1	..	10.42	11.45	Mycostatin Nilstat	BQ SI
	• ***Other agents for local oral treatment***							
	BENZYDAMINE HYDROCHLORIDE							
	Restricted Benefit ***Radiation induced mucositis.***							
1121B	***Mouth and throat rinse 22.5 mg per 15 mL, 500 mL***	***‡ 1***	***1***	***..***	***21.09***	***22.12***	***Difflam***	***IA***
	DRUGS FOR ACID RELATED DISORDERS							
	Antacids							
	• ***Combinations and complexes of aluminium, calcium and magnesium compounds***							
	ALUMINIUM HYDROXIDE with MAGNESIUM HYDROXIDE							
2576N	Tablet 200 mg-200 mg	200	5	..	* 15.65	16.68	Mylanta P	JT
2157M	Oral suspension 200 mg-200 mg per 5 mL, 500 mL	2	5	..	* 15.65	16.68	Mylanta P	JT
	ALUMINIUM HYDROXIDE with MAGNESIUM TRISILICATE and MAGNESIUM HYDROXIDE							
2159P	Oral suspension 250 mg-120 mg-120 mg per 5 mL, 500 mL	2	5	..	* 14.01	15.04	Gastrogel	FM

ALIMENTARY TRACT AND METABOLISM—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Proprietary Name and Manufacturer	
	Drugs for peptic ulcer and gastro-oesophageal reflux disease (GORD)								
	• ***H_2-receptor antagonists***								
	NOTE:								
	The base-priced drugs in this therapeutic group are cimetidine, famotidine, nizatidine and ranitidine hydrochloride (except ranitidine hydrochloride effervescent tablet 150 mg (base) and syrup 150 mg (base) per 10 mL, 300 mL).								
	CIMETIDINE								
	NOTE:								
	Helicobacter pylori eradication therapy should be considered prior to commencing initial treatment of peptic ulcer with this drug.								
1157X	Tablet 200 mg	120	5	..	19.54	20.57	a	Magicul 200	AF
				B1.94	21.48	20.57	a	Tagamet	GK
1158Y	Tablet 400 mg	60	5	..	19.54	20.57	a	GenRx Cimetidine	GX
							a	Magicul 400	AF
				B1.94	21.48	20.57	a	Tagamet	GK
1159B	Tablet 800 mg	30	5	..	19.54	20.57	a	GenRx Cimetidine	GX
							a	Magicul 800	AF
	FAMOTIDINE								
	NOTE:								
	Helicobacter pylori eradication therapy should be considered prior to commencing initial treatment of peptic ulcer with this drug.								
2487X	Tablet 20 mg	60	5	..	16.98	18.01	a	Ausfam 20	SI
							a	Chem mart Famotidine	CH
							a	Famohexal	SZ
							a	GenRx Famotidine	GX
							a	Pamacid 20	AF
							a	Pepzan	GM
							a	Terry White Chemists Famotidine	TW
				B4.25	21.23	18.01	a	Pepcidine M	MK
2488Y	Tablet 40 mg	30	5	..	16.98	18.01	a	Ausfam 40	SI
							a	Chem mart Famotidine	CH
							a	Famohexal	SZ
							a	GenRx Famotidine	GX
							a	Pamacid 40	AF
							a	Pepzan	GM
							a	Terry White Chemists Famotidine	TW
				B5.41	22.39	18.01	a	Pepcidine	MK

ALIMENTARY TRACT AND METABOLISM—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Proprietary Name and Manufacturer	
	NIZATIDINE **NOTE:** *Helicobacter pylori* eradication therapy should be considered prior to commencing initial treatment of peptic ulcer with this drug.								
1505F	Capsule 150 mg	60	5	..	18.63	19.66	a	Nizac	LN
							a	Tacidine	AF
				B5.60	24.23	19.66	a	Tazac	AS
1504E	Capsule 300 mg	30	5	..	18.63	19.66	a	Nizac	LN
							a	Tacidine	AF
				B5.60	24.23	19.66	a	Tazac	AS
	RANITIDINE HYDROCHLORIDE **NOTE:** *Helicobacter pylori* eradication therapy should be considered prior to commencing initial treatment of peptic ulcer with this drug.								
1978D	Tablet 150 mg (base)	60	5	..	17.44	18.47	a	Ausran	SI
							a	Chem mart Ranitidine	CH
							a	GenRx Ranitidine	GX
							a	Rani 2	AF
							a	Ranihexal	SZ
							a	Ranoxyl	GM
							a	Terry White Chemists Ranitidine	TW
							a	Ulcaid	RA
				B1.71	19.15	18.47	a	Zantac	GK
1937Y	Effervescent tablet 150 mg (base)	60	5	T3.26	* 20.73	18.50		Zantac	GK
1977C	Tablet 300 mg (base)	30	5	..	17.44	18.47	a	Ausran	SI
							a	Chem mart Ranitidine	CH
							a	GenRx Ranitidine	GX
							a	Rani 2	AF
							a	Ranihexal	SZ
							a	Ranoxyl	GM
							a	Terry White Chemists Ranitidine	TW
							a	Ulcaid	RA
				B1.71	19.15	18.47	a	Zantac	GK
8162N	Syrup 150 mg (base) per 10 mL, 300 mL	2	5	T2.20	* 23.49	22.32		Zantac Syrup	GK

continued ☞

ALIMENTARY TRACT AND METABOLISM—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
	RANITIDINE HYDROCHLORIDE							
	NOTE:							
	Helicobacter pylori eradication therapy should be considered prior to commencing initial treatment of peptic ulcer with this drug.							
	Authority Required							
	Adverse effects occurring with all of the base-priced drugs;							
	Drug interactions occurring with all of the base-priced drugs;							
	Drug interactions expected to occur with all of the base-priced drugs;							
	Transfer to a base-priced drug would cause patient confusion resulting in problems with compliance.							
8903N	***Effervescent tablet 150 mg (base)***	***60***	***5***	***..***	**** 20.73***	***21.76***	***Zantac***	***GK***
8905Q	***Syrup 150 mg (base) per 10 mL, 300 mL***	***2***	***5***	***..***	**** 23.49***	***24.52***	***Zantac Syrup***	***GK***

• *Prostaglandins*

MISOPROSTOL

CAUTION:

Misoprostol is a prostaglandin analogue. It should not be used in pregnant women.

Authority Required (STREAMLINED)

2630

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

2631

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

2632

Gastric ulcer, proven by x-ray, endoscopy or surgery within the previous 2 years. The date and the method by which the ulcer was proven must be documented in the patient's medical records when treatment is initiated.

1648R	***Tablet 200 micrograms***	***120***	***2***	***..***	***51.69***	***32.90***	***Cytotec***	***PH***

• *Proton pump inhibitors*

ESOMEPRAZOLE MAGNESIUM TRIHYDRATE

Restricted Benefit

Initial treatment of gastric ulcer.

NOTE:

Helicobacter pylori eradication therapy should be considered.

8886Q	***Tablet (enteric coated), equivalent to 20 mg esomeprazole***	***30***	***1***	***..***	***38.11***	***32.90***	***Nexium***	***AP***

NOTE:

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

continued ☞

ALIMENTARY TRACT AND METABOLISM—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
	Restriction Benefit ***Healing of gastro-oesophageal reflux disease.*** **NOTE:** ***No applications for increased maximum quantities and/or repeats will be authorised.***							
8601Q	***Tablet (enteric coated), equivalent to 40 mg esomeprazole***	***30***	***1***	***..***	***58.24***	***32.90***	***Nexium***	***AP***
	Restriction Benefit ***Maintenance of healed gastro-oesophageal reflux disease.*** **NOTE:** ***No applications for increased maximum quantities will be authorised.***							
8600P	***Tablet (enteric coated), equivalent to 20 mg esomeprazole***	***30***	***5***	***..***	***38.11***	***32.90***	***Nexium***	***AP***
	LANSOPRAZOLE **Restriction Benefit** ***Initial treatment of peptic ulcer.*** **NOTE:** ***Helicobacter pylori eradication therapy should be considered.***							
2240X	***Capsule 30 mg***	***30***	***1***	***..***	***37.43***	***32.90***	***Zoton***	***WX***
	NOTE: ***No applications for increased repeats will be authorised.***							
8528W	***Sachet containing granules for oral suspension, 30 mg per sachet***	***28***	***1***	***T3.62***	***41.64***	***32.90***	***Zoton***	***WX***
	NOTE: ***No applications for increased repeats will be authorised.***							
	Restriction Benefit ***Gastro-oesophageal reflux disease;*** ***Scleroderma oesophagus.***							
8198L	***Capsule 15 mg***	***30***	***5***	***..***	***23.57***	***24.60***	***Zoton***	***WX***
2241Y	***Capsule 30 mg***	***30***	***5***	***..***	***37.43***	***32.90***	***Zoton***	***WX***
8529X	***Sachet containing granules for oral suspension, 30 mg per sachet***	***28***	***5***	***T3.62***	***41.64***	***32.90***	***Zoton***	***WX***

continued ☞

ALIMENTARY TRACT AND METABOLISM—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
	Authority Required ***Initial treatment of peptic ulcer, in patients unable to take a solid dose form of a proton pump inhibitor.***							
	NOTE: ***Helicobacter pylori eradication therapy should be considered.***							
8949B	***Sachet containing granules for oral suspension, 30 mg per sachet***	***28***	***1***	***..***	***41.64***	***32.90***	***Zoton***	***WX***
	NOTE: ***No applications for increased repeats will be authorised.***							
	Authority Required ***Gastro-oesophageal reflux disease, in patients unable to take a solid dose form of a proton pump inhibitor;*** ***Scleroderma oesophagus, in patients unable to take a solid dose form of a proton pump inhibitor.***							
8950C	***Sachet containing granules for oral suspension, 30 mg per sachet***	***28***	***5***	***..***	***41.64***	***32.90***	***Zoton***	***WX***
	OMEPRAZOLE							
	Restricted Benefit ***Initial treatment of peptic ulcer.***							
	NOTE: ***Helicobacter pylori eradication therapy should be considered.*** ***No applications for increased repeats will be authorised.***							
9109K	***Tablet 20 mg (as magnesium)***	***30***	***1***	***..***	***28.91***	***29.94***	[a] ***Acimax Tablets***	***AL***
							[a] ***Omepral***	***PM***
				B2.75	***31.66***	***29.94***	[a] ***Losec Tablets***	***AP***
8331L	***Tablet 20 mg***	***30***	***1***	***..***	***28.91***	***29.94***	[a] ***Chem mart Omeprazole***	***CH***
							[a] ***GenRx Omeprazole***	***GX***
							[a] ***Meprazol***	***SZ***
							[a] ***Omeprazole-GA***	***GM***
							[a] ***Omeprazole Ranbaxy***	***RA***
							[a] ***Omeprazole Winthrop***	***WA***
							[a] ***Terry White Chemists Omeprazole***	***TW***
	NOTE: ***Bioequivalence has been demonstrated between omeprazole tablet 20 mg and omeprazole tablet 20 mg (as magnesium).***							
1326T	***Capsule 20 mg***	***30***	***1***	***..***	***28.91***	***29.94***	***Probitor***	***SZ***

continued ☞

ALIMENTARY TRACT AND METABOLISM—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Proprietary Name and Manufacturer	
	Restricted Benefit ***Gastro-oesophageal reflux disease;*** ***Scleroderma oesophagus;*** ***Zollinger-Ellison syndrome.***								
8332M	*Tablet 10 mg (as magnesium)*	*30*	*5*	*..*	*22.15*	*23.18*		*Losec Tablets*	*AP*
9110L	*Tablet 20 mg (as magnesium)*	*30*	*5*	*..*	*28.91*	*29.94*	[a]	*Acimax Tablets*	*AL*
							[a]	*Omepral*	*PM*
				B2.75	*31.66*	*29.94*	[a]	*Losec Tablets*	*AP*
8333N	*Tablet 20 mg*	*30*	*5*	*..*	*28.91*	*29.94*	[a]	*Chem mart Omeprazole*	*CH*
							[a]	*GenRx Omeprazole*	*GX*
							[a]	*Meprazol*	*SZ*
							[a]	*Omeprazole-GA*	*GM*
							[a]	*Omeprazole Ranbaxy*	*RA*
							[a]	*Omeprazole Winthrop*	*WA*
							[a]	*Terry White Chemists Omeprazole*	*TW*
	NOTE: ***Bioequivalence has been demonstrated between omeprazole tablet 20 mg and omeprazole tablet 20 mg (as magnesium).***								
1327W	*Capsule 20 mg*	*30*	*5*	*..*	*28.91*	*29.94*		*Probitor*	*SZ*
	PANTOPRAZOLE SODIUM SESQUIHYDRATE								
	Restricted Benefit ***Initial treatment of peptic ulcer.***								
	NOTE: ***Helicobacter pylori eradication therapy should be considered.***								
8007K	*Tablet (enteric coated), equivalent to 40 mg pantoprazole*	*30*	*2*	*..*	*38.71*	*32.90*		*Somac*	*NQ*
	NOTE: ***No applications for increased repeats will be authorised.***								
	Restricted Benefit ***Gastro-oesophageal reflux disease.***								
8399C	*Tablet (enteric coated), equivalent to 20 mg pantoprazole*	*30*	*5*	*..*	*21.94*	*22.97*		*Somac*	*NQ*

continued ☞

ALIMENTARY TRACT AND METABOLISM—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
	Restricted Benefit ***Gastro-oesophageal reflux disease.***							
	Restricted Benefit ***Scleroderma oesophagus;*** ***Zollinger-Ellison syndrome.***							
8008L	***Tablet (enteric coated), equivalent to 40 mg pantoprazole***	*30*	*5*	*..*	*38.71*	*32.90*	***Somac***	***NQ***
	RABEPRAZOLE SODIUM							
	Restricted Benefit ***Initial treatment of peptic ulcer.***							
	NOTE: ***Helicobacter pylori eradication therapy should be considered.***							
8509W	***Tablet 20 mg (enteric coated)***	*30*	*2*	*..*	*37.97*	*32.90*	***Pariet***	***JC***
	NOTE: ***No applications for increased repeats will be authorised.***							
	Restricted Benefit ***Gastro-oesophageal reflux disease;*** ***Scleroderma oesophagus.***							
8507R	***Tablet 10 mg (enteric coated)***	*28*	*5*	*..*	*37.97*	*32.90*	***Pariet***	***JC***
8508T	***Tablet 20 mg (enteric coated)***	*30*	*5*	*..*	*37.97*	*32.90*	***Pariet***	***JC***
	• ***Combinations for eradication of Helicobacter pylori*** ***ESOMEPRAZOLE MAGNESIUM TRIHYDRATE and CLARITHROMYCIN and AMOXYCILLIN***							
	Restricted Benefit ***Eradication of Helicobacter pylori associated with peptic ulcer disease.***							
8738X	***Pack containing 14 tablets (enteric coated) equivalent to 20 mg esomeprazole, 14 tablets clarithromycin 500 mg and 28 capsules amoxycillin 500 mg***	*‡ 1*	*..*	*..*	*80.93*	*32.90*	***Nexium Hp7***	***AP***

ALIMENTARY TRACT AND METABOLISM—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Proprietary Name and Manufacturer	
	OMEPRAZOLE and CLARITHROMYCIN and AMOXYCILLIN								
	Restricted Benefit ***Eradication of Helicobacter pylori associated with peptic ulcer disease.***								
8272J	***Pack containing 14 capsules omeprazole 20 mg, 14 tablets clarithromycin 500 mg and 28 capsules amoxycillin 500 mg***	***‡ 1***	***..***	***..***	***73.75***	***32.90***		***Klacid Hp 7***	***AB***
	• ***Other drugs for peptic ulcer and gastro-oesophageal reflux disease (GORD)***								
	SODIUM ALGINATE with CALCIUM CARBONATE and SODIUM BICARBONATE								
2014B	Oral liquid 1 g-320 mg-534 mg in 20 mL, 500 mL	2	5	..	* 14.25	15.28		Gaviscon P	RC
	SUCRALFATE								
2055E	Tablet equivalent to 1 g anhydrous sucralfate	120	2	.. B2.18	23.98 26.16	25.01 25.01	a a	Ulcyte Carafate	AF AS
	DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS								
	Belladonna and derivatives, plain								
	• ***Belladonna alkaloids, tertiary amines***								
	ATROPINE SULFATE								
1089H	Injection 600 micrograms in 1 mL	10	1	..	20.11	21.14		AP	
	Propulsives								
	• ***Propulsives***								
	DOMPERIDONE								
1347X	Tablet 10 mg	25	..	..	8.46	9.49		Motilium	JC
	METOCLOPRAMIDE HYDROCHLORIDE								
1207M	Tablet 10 mg	25	..	.. B3.01	7.61 10.62	8.64 8.64		Pramin Maxolon	AF VT
1206L	Injection 10 mg in 2 mL	10	..	..	12.56	13.59		Maxolon	VT

ALIMENTARY TRACT AND METABOLISM—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	

ANTIEMETICS AND ANTINAUSEANTS

Antiemetics and antinauseants

• *Serotonin ($5HT_3$) antagonists*

DOLASETRON MESYLATE

Restricted Benefit

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

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

8191D	*Tablet 200 mg*	*2*	*..*	*..*	*50.29*	*32.90*	*Anzemet*	*SW*
8192E	*I.V. injection 100 mg in 5 mL*	*1*	*..*	*..*	*28.86*	*29.89*	*Anzemet*	*SW*

GRANISETRON HYDROCHLORIDE

Restricted Benefit

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

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

8728J	*Tablet 2 mg (base)*	*2*	*..*	*..*	** 58.55*	*32.90*	*Kytril*	*HH*
8729K	*Concentrated injection 3 mg (base) in 3 mL*	*1*	*..*	*..*	*37.42*	*32.90*	*Kytril*	*HH*

Authority Required

Management of nausea and vomiting associated with radiotherapy being used to treat malignancy.

8873B	*Tablet 2 mg (base)*	*5*	*1*	*..*	*137.41*	*32.90*	*Kytril*	*HH*
8730L	*Concentrated injection 3 mg (base) in 3 mL*	*1*	*..*	*..*	*37.42*	*32.90*	*Kytril*	*HH*

ONDANSETRON

Restricted Benefit

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

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

8224W	*Tablet 4 mg*	*4*	*..*	*..*	*40.38*	*32.90*	[a] *Ondansetron-RL*	*RE*
							[a] *Ondaz*	*HX*
							[a] *Onsetron 4*	*SI*
				[B]0.62	*41.00*	*32.90*	[a] *Zofran*	*GK*

continued ☞

ALIMENTARY TRACT AND METABOLISM—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
8225X	*Tablet 8 mg*	*4*	*..*	*..*	*57.50*	*32.90*	[a] *Ondansetron-RL*	*RE*
							[a] *Ondaz*	*HX*
							[a] *Onsetron 8*	*SI*
				B0.69	*58.19*	*32.90*	[a] *Zofran*	*GK*
8410P	*Wafer 4 mg*	*4*	*..*	*..*	*40.38*	*32.90*	[a] *Ondansetron-RL Zydis*	*RE*
							[a] *Ondaz Zydis*	*HX*
				B0.62	*41.00*	*32.90*	[a] *Zofran Zydis*	*GK*
8411Q	*Wafer 8 mg*	*4*	*..*	*..*	*57.50*	*32.90*	[a] *Ondansetron-RL Zydis*	*RE*
							[a] *Ondaz Zydis*	*HX*
				B0.69	*58.19*	*32.90*	[a] *Zofran Zydis*	*GK*
8226Y	*I.V. injection 4 mg in 2 mL*	*1*	*..*	*..*	*25.38*	*26.41*	[a] *Ondansetron-RL*	*RE*
							[a] *Ondaz*	*HX*
							[a] *Onsetron*	*SI*
							[a] *PF*	
				B0.70	*26.08*	*26.41*	[a] *Zofran*	*GK*
8227B	*I.V. injection 8 mg in 4 mL*	*1*	*..*	*..*	*36.79*	*32.90*	[a] *Ondansetron-RL*	*RE*
							[a] *Ondaz*	*HX*
							[a] *Onsetron*	*SI*
							[a] *PF*	
				B0.69	*37.48*	*32.90*	[a] *Zofran*	*GK*

Authority Required

Management of nausea and vomiting associated with radiotherapy being used to treat malignancy.

1594X	*Tablet 4 mg*	*10*	*1*	*..*	*88.19*	*32.90*	[a] *Ondansetron-RL*	*RE*
							[a] *Ondaz*	*HX*
							[a] *Onsetron 4*	*SI*
				B0.69	*88.88*	*32.90*	[a] *Zofran*	*GK*
1595Y	*Tablet 8 mg*	*10*	*1*	*..*	*134.78*	*32.90*	[a] *Ondansetron-RL*	*RE*
							[a] *Ondaz*	*HX*
							[a] *Onsetron 8*	*SI*
				B0.67	*135.45*	*32.90*	[a] *Zofran*	*GK*
8412R	*Wafer 4 mg*	*10*	*1*	*..*	*88.19*	*32.90*	[a] *Ondansetron-RL Zydis*	*RE*
							[a] *Ondaz Zydis*	*HX*
				B0.69	*88.88*	*32.90*	[a] *Zofran Zydis*	*GK*
8413T	*Wafer 8 mg*	*10*	*1*	*..*	*134.78*	*32.90*	[a] *Ondansetron-RL Zydis*	*RE*
							[a] *Ondaz Zydis*	*HX*
				B0.67	*135.45*	*32.90*	[a] *Zofran Zydis*	*GK*
8233H	*Syrup 4 mg per 5 mL, 50 mL*	*‡ 1*	*1*	*..*	*88.19*	*32.90*	*Zofran syrup 50 mL*	*GK*

continued ☞

ALIMENTARY TRACT AND METABOLISM—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Proprietary Name and Manufacturer	
1596B	*I.V. injection 4 mg in 2 mL*	*1*	*..*	*..*	*25.38*	*26.41*	*a*	*Ondansetron-RL*	*RE*
							a	*Ondaz*	*HX*
							a	*Onsetron*	*SI*
							a	*PF*	
				B0.70	*26.08*	*26.41*	*a*	*Zofran*	*GK*
1597C	*I.V. injection 8 mg in 4 mL*	*1*	*..*	*..*	*36.79*	*32.90*	*a*	*Ondansetron-RL*	*RE*
							a	*Ondaz*	*HX*
							a	*Onsetron*	*SI*
							a	*PF*	
				B0.69	*37.48*	*32.90*	*a*	*Zofran*	*GK*

TROPISETRON HYDROCHLORIDE

Restricted Benefit

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

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

2745L	*Capsule 5 mg (base)*	*2*	*..*	*..*	*50.29*	*32.90*	*Navoban*	*NV*
2746M	*I.V. injection 5 mg (base) in 5 mL*	*1*	*..*	*..*	*28.86*	*29.89*	*Navoban*	*NV*

• *Other antiemetics*

APREPITANT

NOTE:

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

Authority Required

Management of nausea and vomiting associated with cytotoxic chemotherapy being used to treat malignancy, in combination with a 5HT3 antagonist and dexamethasone, where any 1 of the following chemotherapy agents are to be administered:
(a) altretamine;
(b) carmustine;
(c) cisplatin when a single dose constitutes a cycle of chemotherapy;
(d) cyclophosphamide at a dose of 1500 mg per square metre per day or greater;
(e) dacarbazine;
(f) procarbazine when a single dose constitutes a cycle of chemotherapy;
(g) streptozocin.
No more than 1 pack containing 1 x 125 mg capsule and 2 x 80 mg capsules will be authorised per cycle of cytotoxic chemotherapy;

Management of nausea and vomiting associated with cytotoxic chemotherapy being used to treat breast cancer, in combination with a 5HT3 antagonist and dexamethasone, where cyclophosphamide and an anthracycline are to be co-administered.
No more than 1 pack containing 1 x 125 mg capsule and 2 x 80 mg capsules will be authorised per cycle of cytotoxic chemotherapy.

NOTE:

No applications for increased maximum quantities will be authorised. Prescribers should advise Medicare Australia of the number of cycles planned when requesting approval for repeats.

continued ☞

ALIMENTARY TRACT AND METABOLISM—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Proprietary Name and Manufacturer	
8808N	***Pack containing 1 capsule 125 mg and 2 capsules 80 mg***	***‡ 1***	***..***	***..***	***147.91***	***32.90***		***Emend***	***MK***
	PROCHLORPERAZINE								
	CAUTION:								
	Prochlorperazine may be associated with parkinsonism and tardive dyskinesia and should be used for short-term treatment only.								
2893G	Tablet containing prochlorperazine maleate 5 mg	25	..	..	9.59	10.62	[a]	Stemzine	AV
				B2.50	12.09	10.62	[a]	Stemetil	SW
2369Q	Injection containing prochlorperazine mesylate 12.5 mg in 1 mL	10	..	..	16.39	17.42		Stemetil	SW
2895J	Suppositories containing prochlorperazine equivalent to 25 mg prochlorperazine maleate, 5	‡ 1	2	..	19.50	20.53		Stemetil	SW
	NOTE:								
	As prochlorperazine may be associated with parkinsonism and tardive dyskinesia it should be used for short-term treatment only. However, authorities for increased maximum quantities and/or repeats of prochlorperazine tablets will be granted for the treatment of emesis associated with malignant disease.								

BILE AND LIVER THERAPY

Bile therapy

• *Bile acid preparations*

URSODEOXYCHOLIC ACID

Authority Required (STREAMLINED)

1700

Primary biliary cirrhosis.

NOTE:

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

8448P	***Capsule 250 mg***	***200***	***2***	***..***	**** 351.23***	***32.90***		***Ursofalk***	***OA***

ALIMENTARY TRACT AND METABOLISM—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Proprietary Name and Manufacturer	
	LAXATIVES								
	Laxatives								
	• ***Contact laxatives***								
	BISACODYL								
	Restricted Benefit ***Paraplegic and quadriplegic patients and others with severe neurogenic impairment of bowel function;*** ***Patients who are receiving long-term nursing care on account of age, infirmity or other condition in hospitals, nursing homes or residential facilities;*** ***For use by a patient who is receiving long-term nursing care and in respect of whom a Carer Allowance is payable as a disabled adult;*** ***Patients receiving palliative care;*** ***Terminal malignant neoplasia;*** ***Anorectal congenital abnormalities;*** ***Megacolon.***								
1259G	*Tablet 5 mg*	*200*	*2*	*..*	*14.17*	*15.20*		*Bisalax* *Lax-Tab*	*AS* *AE*
1260H	*Suppositories 10 mg, 10*	*3*	*5*	*..*	** 21.44*	*22.47*	*a*	*Petrus Bisacodyl Suppositories*	*PP*
				B1.14	** 22.58*	*22.47*	*a*	*Dulcolax*	*BY*
1258F	*Suppositories 10 mg, 12*	*3*	*4*	*..*	** 18.62*	*19.65*		*Fleet Laxative Suppositories* *Petrus Bisacodyl Suppositories*	*FL* *PP*
	• ***Bulk producers***								
	STERCULIA with FRANGULA BARK								
	Restricted Benefit ***Paraplegic and quadriplegic patients and others with severe neurogenic impairment of bowel function;*** ***Patients who are receiving long-term nursing care on account of age, infirmity or other condition in hospitals, nursing homes or residential facilities;*** ***For use by a patient who is receiving long-term nursing care and in respect of whom a Carer Allowance is payable as a disabled adult;*** ***Patients receiving palliative care;*** ***Terminal malignant neoplasia;*** ***Anorectal congenital abnormalities;*** ***Megacolon.***								
1104D	*Granules 620 mg-80 mg per g (62%-8%), 500 g*	*‡ 1*	*1*	*..*	*24.52*	*25.55*		*Normacol Plus*	*NE*

ALIMENTARY TRACT AND METABOLISM—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
	• *Osmotically acting laxatives*							
	LACTULOSE							
	Restricted Benefit							
	Hepatic coma or precoma (chronic porto-systemic encephalopathy);							
	Constipation in patients with malignant neoplasia.							
3064G	*Mixture 3.34 g per 5 mL, 500 mL*	*‡ 1*	*5*	*..*	*13.80*	*14.83*	[a] *Actilax*	*AF*
							[a] *Genlac*	*AW*
							[a] *GenRx Lactulose*	*GX*
							[a] *Lac-Dol*	*GM*
							[a] *Lactocur*	*SZ*
				[B]1.67	*15.47*	*14.83*	[a] *Duphalac*	*SM*
	MACROGOL 3350							
	Restricted Benefit							
	Constipation in patients with malignant neoplasia;							
	Chronic constipation or faecal impaction not adequately controlled with first line interventions such as bulk-forming agents;							
	Paraplegic and quadriplegic patients and others with severe neurogenic impairment of bowel function not responding to other oral therapies;							
	Patients receiving palliative care.							
9146J	*Sachets containing powder for solution 6.563 g with electrolytes, 30*	*‡ 1*	*5*	*..*	*18.10*	*19.13*	*Movicol-Half*	*NE*
8612G	*Sachets containing powder for solution 13.125 g with electrolytes, 30*	*‡ 1*	*5*	*..*	*24.36*	*25.39*	*Movicol*	*NE*
	• *Enemas*							
	BISACODYL							
	Restricted Benefit							
	Paraplegic and quadriplegic patients and others with severe neurogenic impairment of bowel function;							
	Patients who are receiving long-term nursing care on account of age, infirmity or other condition in hospitals, nursing homes or residential facilities;							
	For use by a patient who is receiving long-term nursing care and in respect of whom a Carer Allowance is payable as a disabled adult;							
	Patients receiving palliative care;							
	Terminal malignant neoplasia;							
	Anorectal congenital abnormalities;							
	Megacolon.							
1263L	*Enemas 10 mg in 5 mL, 25*	*‡ 1*	*2*	*..*	*37.97*	*32.90*	*Bisalax*	*AS*

ALIMENTARY TRACT AND METABOLISM—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
	SORBITOL with SODIUM CITRATE and SODIUM LAURYL SULFOACETATE							
	Restricted Benefit ***Paraplegic and quadriplegic patients and others with severe neurogenic impairment of bowel function;*** ***Patients who are receiving long-term nursing care on account of age, infirmity or other condition in hospitals, nursing homes or residential facilities;*** ***For use by a patient who is receiving long-term nursing care and in respect of whom a Carer Allowance is payable as a disabled adult;*** ***Patients receiving palliative care;*** ***Terminal malignant neoplasia;*** ***Anorectal congenital abnormalities;*** ***Megacolon.***							
2091C	***Enemas 3.125 g-450 mg-45 mg in 5 mL, 12***	***2***	***2***	***..***	**** 36.15***	***32.90***	***Microlax***	***JT***

• *Other laxatives*

	GLYCEROL							
	Restricted Benefit ***Paraplegic and quadriplegic patients and others with severe neurogenic impairment of bowel function;*** ***Patients who are receiving long-term nursing care on account of age, infirmity or other condition in hospitals, nursing homes or residential facilities;*** ***For use by a patient who is receiving long-term nursing care and in respect of whom a Carer Allowance is payable as a disabled adult;*** ***Patients receiving palliative care;*** ***Terminal malignant neoplasia;*** ***Anorectal congenital abnormalities;*** ***Megacolon.***							
2555L	***Suppositories 700 mg (for infants), 12***	***3***	***5***	***..***	**** 17.48***	***18.51***	***PP***	
2556M	***Suppositories 1.4 g (for children), 12***	***3***	***5***	***..***	**** 17.87***	***18.90***	***PP***	
2557N	***Suppositories 2.8 g (for adults), 12***	***3***	***5***	***..***	**** 18.32***	***19.35***	***PP***	

ANTIDIARRHEALS, INTESTINAL ANTIINFLAMMATORY/ ANTIINFECTIVE AGENTS

Intestinal antiinfectives

• *Antibiotics*

	NEOMYCIN SULFATE							
2325J	Tablet 500 mg	25	1	..	14.62	15.65	Neosulf	AF
	NYSTATIN							
1696G	Tablet 500,000 units	50	..	..	17.55	18.58	Nilstat	SI
1699K	Capsule 500,000 units	50	..	..	17.55	18.58	Nilstat	SI

ALIMENTARY TRACT AND METABOLISM—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Proprietary Name and Manufacturer	
	VANCOMYCIN								
	Authority Required ***Antibiotic associated pseudomembranous colitis due to Clostridium difficile which is unresponsive to metronidazole;*** ***Antibiotic associated pseudomembranous colitis due to Clostridium difficile where there is intolerance to metronidazole.***								
	NOTE: ***Metronidazole has similar efficacy to vancomycin but may have less selective pressure to vancomycin resistant enterococci and is therefore the preferred treatment.***								
3113W	***Capsule 125 mg (125,000 i.u.) vancomycin activity***	***40***	***..***	***..***	**** 244.81***	***32.90***		***Vancocin***	***AS***
3114X	***Capsule 250 mg (250,000 i.u.) vancomycin activity***	***40***	***..***	***..***	**** 465.61***	***32.90***		***Vancocin***	***AS***
	Electrolytes with carbohydrates								
	• ***Oral rehydration salt formulations***								
	ELECTROLYTE REPLACEMENT (ORAL)								
3196F	Sachets containing powder for oral solution 4.9 g, 10	‡ 1	..	..	12.90	13.93	[a]	O.R.S.	AS
							[a]	Repalyte New Formulation	SW
							[a]	restore O.R.S.	GM
	NOTE: Each sachet contains sodium chloride 470 mg, potassium chloride 300 mg, sodium acid citrate 530 mg and glucose 3.56 g.								
	Antipropulsives								
	• ***Antipropulsives***								
	DIPHENOXYLATE HYDROCHLORIDE with ATROPINE SULFATE								
2501P	Tablet 2.5 mg-25 micrograms	20	..	..	8.19	9.22	[a]	Lofenoxal	HC
				[B]1.83	10.02	9.22	[a]	Lomotil	BI
	LOPERAMIDE HYDROCHLORIDE								
1571Q	Capsule 2 mg	12	..	..	8.16	9.19	[a]	Gastro-Stop Loperamide	AS
				[B]0.94	9.10	9.19	[a]	Imodium	JT

ALIMENTARY TRACT AND METABOLISM—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
	Intestinal antiinflammatory agents							
	• ***Corticosteroids acting locally***							
	HYDROCORTISONE ACETATE							
	Restricted Benefit ***Proctitis;*** ***Ulcerative colitis.***							
1502C	***Rectal foam 90 mg per applicatorful, 14 applications, aerosol 21.1 g***	***2***	***3***	***..***	**** 38.55***	***32.90***	***Colifoam***	***AS***
	[For other listings for this drug see Generic/Proprietary Index]							
	PREDNISOLONE SODIUM PHOSPHATE							
1920C	Retention enema equivalent to 20 mg prednisolone in 100 mL	28	3	..	* 165.79	32.90	Predsol	SI
	PREDNISOLONE SODIUM PHOSPHATE							
	Restricted Benefit ***Proctitis;*** ***Ulcerative colitis.***							
2554K	***Suppositories equivalent to 5 mg prednisolone, 10***	***3***	***3***	***..***	**** 38.39***	***32.90***	***Predsol***	***SI***
	• ***Aminosalicylic acid and similar agents***							
	BALSALAZIDE SODIUM							
	Authority Required (STREAMLINED) **1708** ***Ulcerative colitis where hypersensitivity to sulfonamides exists;*** **1709** ***Ulcerative colitis where intolerance to sulfasalazine exists.***							
	NOTE: ***Not for the treatment of Crohn's disease.***							
8845M	***Capsule 750 mg***	***180***	***5***	***..***	***124.42***	***32.90***	***Colazide***	***PK***
	MESALAZINE							
	Restricted Benefit ***Acute episode of mild to moderate ulcerative proctitis.***							
	NOTE: ***Not for the treatment of Crohn's disease.***							
8752P	***Suppositories 1 g, 28***	***‡ 1***	***..***	***..***	***127.29***	***32.90***	***Pentasa***	***FP***

continued ☞

ALIMENTARY TRACT AND METABOLISM—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
	NOTE: ***No applications for increased maximum quantities and/or repeats will be authorised.***							
	Authority Required (STREAMLINED) **1708** ***Ulcerative colitis where hypersensitivity to sulfonamides exists;*** **1709** ***Ulcerative colitis where intolerance to sulfasalazine exists;*** **2268** ***Crohn's disease where hypersensitivity to sulfonamides exists;*** **2269** ***Crohn's disease where intolerance to sulfasalazine exists.***							
1611T	*Tablet 250 mg (enteric coated)*	*100*	*5*	*..*	*93.00*	*32.90*	*Mesasal*	*GK*
8731M	*Tablet 500 mg (enteric coated)*	*200*	*5*	*..*	** 297.01*	*32.90*	*Salofalk*	*OA*
2214M	*Tablet 500 mg (prolonged release)*	*200*	*5*	*..*	** 297.01*	*32.90*	*Pentasa*	*FP*
2234N	*Sachet containing prolonged release granules, 1 g per sachet*	*100*	*5*	*..*	*279.20*	*32.90*	*Pentasa*	*FP*
2287J	*Sachet containing prolonged release granules, 2 g per sachet*	*60*	*5*	*..*	*311.87*	*32.90*	*Pentasa*	*FP*
	Authority Required (STREAMLINED) **1708** ***Ulcerative colitis where hypersensitivity to sulfonamides exists;*** **1709** ***Ulcerative colitis where intolerance to sulfasalazine exists.*** **NOTE:** ***Not for the treatment of Crohn's disease.***							
8598M	*Sachet containing granules, 500 mg per sachet*	*200*	*5*	*..*	** 297.01*	*32.90*	*Salofalk*	*OA*
8599N	*Sachet containing granules, 1 g per sachet*	*100*	*5*	*..*	*279.20*	*32.90*	*Salofalk*	*OA*
9206M	*Sachet containing granules, 1.5 g per sachet*	*60*	*5*	*..*	*244.49*	*32.90*	*Salofalk*	*OA*

continued ☞

ALIMENTARY TRACT AND METABOLISM—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Proprietary Name and Manufacturer	
	Authority Required (STREAMLINED) **1707** ***Acute episode of mild to moderate ulcerative colitis.***								
	NOTE: ***Not for the treatment of Crohn's disease.***								
8753Q	***Enemas 1 g in 100 mL, 7***	***4***	***..***	***..***	**** 335.79***	***32.90***		***Pentasa***	***FP***
8616L	***Enemas 2 g in 60 mL, 7***	***4***	***..***	***..***	**** 335.79***	***32.90***		***Salofalk***	***OA***
8617M	***Enemas 4 g in 60 mL, 7***	***4***	***..***	***..***	**** 445.47***	***32.90***		***Salofalk***	***OA***
8768L	***Rectal foam 1 g per applicatorful, 14 applications, aerosol 80 g***	***4***	***..***	***..***	**** 335.79***	***32.90***		***Salofalk***	***OA***
	NOTE: ***No applications for increased maximum quantities and/or repeats will be authorised.***								
	OLSALAZINE SODIUM								
	Authority Required (STREAMLINED) **1708** ***Ulcerative colitis where hypersensitivity to sulfonamides exists;***								
	1709 ***Ulcerative colitis where intolerance to sulfasalazine exists.***								
	NOTE: ***Not for the treatment of Crohn's disease.***								
1728Y	***Capsule 250 mg***	***100***	***5***	***..***	***60.98***	***32.90***		***Dipentum***	***UC***
8086N	***Tablet 500 mg***	***100***	***5***	***..***	***102.86***	***32.90***		***Dipentum***	***UC***
	SULFASALAZINE								
2093E	Tablet 500 mg	200	5	..	* 52.31	32.90		Salazopyrin	PH
2096H	Tablet 500 mg (enteric coated)	200	5	..	* 56.61	32.90	a	Pyralin EN	KR
				B1.58	* 58.19	32.90	a	Salazopyrin-EN	PH
	SULFASALAZINE								
	Restricted Benefit ***For use in patients who are receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements.***								
	NOTE: ***No applications for increased maximum quantities and/or repeats will be authorised.***								
9208P	***Tablet 500 mg***	***200***	***11***	***..***	**** 52.31***	***32.90***		***Salazopyrin***	***PH***
9209Q	***Tablet 500 mg (enteric coated)***	***200***	***11***	***..***	**** 56.61***	***32.90***	***a***	***Pyralin EN***	***KR***
				B1.58	**** 58.19***	***32.90***	***a***	***Salazopyrin-EN***	***PH***

ALIMENTARY TRACT AND METABOLISM—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
	DIGESTIVES, INCL. ENZYMES							
	Digestives, incl. enzymes							
	• ***Enzyme preparations***							
	PANCREATIC EXTRACT							
8556H	Capsule (containing enteric coated minimicrospheres) providing not less than 5,000 BP units of lipase activity	500	10	..	* 118.79	32.90	Creon 5000	SM
8020D	Capsule (containing enteric coated minimicrospheres) providing not less than 10,000 BP units of lipase activity	500	10	..	* 170.34	32.90	Creon 10,000	SM
8021E	Capsule (containing enteric coated minimicrospheres) providing not less than 25,000 BP units of lipase activity	200	10	..	* 137.47	32.90	Creon 25,000	SM

PANCREATIC EXTRACT

Restricted Benefit

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

NOTE:

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

9225M	***Capsule (containing enteric coated minimicrospheres) providing not less than 5,000 BP units of lipase activity***	***500***	***21***	***..***	**** 118.79***	***32.90***	***Creon 5000***	***SM***
9226N	***Capsule (containing enteric coated minimicrospheres) providing not less than 10,000 BP units of lipase activity***	***500***	***21***	***..***	**** 170.34***	***32.90***	***Creon 10,000***	***SM***
9227P	***Capsule (containing enteric coated minimicrospheres) providing not less than 25,000 BP units of lipase activity***	***200***	***21***	***..***	**** 137.47***	***32.90***	***Creon 25,000***	***SM***
	PANCRELIPASE							
8366H	Capsule (containing enteric coated microtablets) providing not less than 25,000 BP units of lipase activity	200	10	..	* 137.47	32.90	Panzytrat 25000	TM

continued ☞

ALIMENTARY TRACT AND METABOLISM—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
	PANCRELIPASE							
	Restricted Benefit ***For use in patients with cystic fibrosis, and who are receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements.***							
	NOTE: ***No applications for increased maximum quantities and/or repeats will be authorised.***							
9229R	***Capsule (containing enteric coated microtablets) providing not less than 25,000 BP units of lipase activity***	***200***	***21***	***..***	**** 137.47***	***32.90***	***Panzytrat 25000***	***TM***
	DRUGS USED IN DIABETES							
	Insulins and analogues							
	• Insulins and analogues for injection, fast-acting							
	INSULIN ASPART							
8571D	Injection (human analogue) 100 units per mL, 10 mL	5	2	..	* 158.84	32.90	NovoRapid	NO
8435Y	Injections (human analogue) 100 units per mL, 3 mL, 5	5	1	..	* 263.79	32.90	NovoRapid FlexPen	NF
							NovoRapid Penfill 3 mL	NO
	INSULIN GLULISINE							
9224L	Injection (human analogue) 100 units per mL, 10 mL	5	2	..	* 158.84	32.90	Apidra	SW
1921D	Injections (human analogue) 100 units per mL, 3 mL, 5	5	1	..	* 263.79	32.90	Apidra SoloStar	SW
	INSULIN LISPRO							
8084L	Injection (human analogue) 100 units per mL, 10 mL	5	2	..	* 158.84	32.90	Humalog	LY
8212F	Injections (human analogue) 100 units per mL, 3 mL, 5	5	1	..	* 263.79	32.90	Humalog	LY
	INSULIN NEUTRAL							
1713E	Injection (bovine) 100 units per mL, 10 mL	5	2	..	* 144.59	32.90	Hypurin Neutral	AS
1531N	Injection (human) 100 units per mL, 10 mL	5	2	..	* 133.39	32.90	Actrapid	NO
							Humulin R	LY
1762R	Injections (human) 100 units per mL, 3 mL, 5	5	1	..	* 223.89	32.90	Actrapid Penfill 3 mL	NO
							Humulin R	LY

ALIMENTARY TRACT AND METABOLISM—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
	• *Insulins and analogues for injection, intermediate-acting*							
	INSULIN ISOPHANE (N.P.H.)							
1711C	Injection (bovine) 100 units per mL, 10 mL	5	2	..	* 144.59	32.90	Hypurin Isophane	AS
1533Q	Injection (human) 100 units per mL, 10 mL	5	2	..	* 133.39	32.90	Humulin NPH Protaphane	LY NO
1761Q	Injections (human) 100 units per mL, 3 mL, 5	5	1	..	* 223.89	32.90	Humulin NPH Protaphane InnoLet Protaphane NovoLet 3 mL Protaphane Penfill 3 mL	LY NI NL NO
	• *Insulins and analogues for injection, intermediate-acting combined with fast-acting*							
	INSULIN ASPART—INSULIN ASPART PROTAMINE SUSPENSION							
8609D	Injections (human analogue) 100 units (30 units-70 units) per mL, 3 mL, 5	5	1	..	* 263.79	32.90	NovoMix 30 FlexPen NovoMix 30 Penfill 3 mL	NF NO
	INSULIN LISPRO—INSULIN LISPRO PROTAMINE SUSPENSION							
8390N	Injections (human analogue) 100 units (25 units-75 units) per mL, 3 mL, 5	5	1	..	* 263.79	32.90	Humalog Mix25	LY
8874C	Injections (human analogue) 100 units (50 units-50 units) per mL, 3 mL, 5	5	1	..	* 263.79	32.90	Humalog Mix50	LY
	INSULIN NEUTRAL—INSULIN ISOPHANE (N.P.H.), (MIXED) (Biphasic Isophane)							
1426C	Injection (human) 100 units (30 units-70 units) per mL, 10 mL	5	2	..	* 133.39	32.90	Humulin 30/70	LY
1763T	Injections (human) 100 units (30 units-70 units) per mL, 3 mL, 5	5	1	..	* 223.89	32.90	Humulin 30/70 Mixtard 30/70 InnoLet Mixtard 30/70 Penfill 3 mL	LY NI NO
2062M	Injections (human) 100 units (50 units-50 units) per mL, 3 mL, 5	5	1	..	* 223.89	32.90	Mixtard 50/50 Penfill 3 mL	NO

ALIMENTARY TRACT AND METABOLISM—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Proprietary Name and Manufacturer	
	• *Insulins and analogues for injection, long-acting*								
	INSULIN DETEMIR								
	Restricted Benefit								
	Type 1 diabetes.								
9040T	***Injections (human analogue) 100 units per mL, 3 mL, 5***	***5***	***1***	***..***	**** 432.29***	***32.90***		***Levemir FlexPen***	***NF***
								Levemir Penfill	***NO***
	INSULIN GLARGINE								
9039R	Injections (human analogue) 100 units per mL, 3 mL, 5	5	1	..	* 432.29	32.90		Lantus	SW
								Lantus SoloStar	AV
	Blood glucose lowering drugs, excl. insulins								
	• *Biguanides*								
	METFORMIN HYDROCHLORIDE								
2430X	Tablet 500 mg	100	5	..	12.66	13.69	a	Chem mart Metformin	CH
							a	Diaformin	AF
							a	Formet 500	SI
							a	GenRx Metformin	GX
							a	Glucohexal	SZ
							a	Glucomet 500 mg	GM
							a	Metforbell	BF
							a	Metformin 500	CR
							a	Metformin generichealth	GQ
							a	Metformin Ranbaxy	RA
							a	Terry White Chemists Metformin	TW
							a	GN	
				B1.10	13.76	13.69	a	Glucophage	MQ
				B1.40	14.06	13.69	a	Diabex	AL
8884N	Tablet 500 mg (extended release)	90	5	..	13.99	15.02	a	Diabex XR	AL
							a	Metex XR	SI

continued ☞

ALIMENTARY TRACT AND METABOLISM—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
1801T	Tablet 850 mg	60	5	..	12.66	13.69	[a] Chem mart Metformin	CH
							[a] Diaformin 850	AF
							[a] Formet 850	SI
							[a] GenRx Metformin	GX
							[a] Glucohexal	SZ
							[a] Glucomet 850 mg	GM
							[a] Metforbell	BF
							[a] Metformin 850	CR
							[a] Metformin generichealth	GQ
							[a] Metformin Ranbaxy	RA
							[a] Terry White Chemists Metformin	TW
							[a] GN	
				B1.10	13.76	13.69	[a] Glucophage	MQ
				B1.40	14.06	13.69	[a] Diabex 850	AL
8607B	Tablet 1 g	90	5	..	17.61	18.64	[a] Diaformin 1000	AF
							[a] Formet 1000	SI
							[a] Glucohexal	SZ
				B1.41	19.02	18.64	[a] Diabex 1000	AL
	• ***Sulfonamides, urea derivatives***							
	GLIBENCLAMIDE							
	CAUTION:							
	Sulfonylureas may cause hypoglycaemia, particularly in the elderly.							
2939Q	Tablet 5 mg	100	5	..	11.27	12.30	[a] Glimel	AF
				B1.51	12.78	12.30	[a] Daonil	SW
	GLICLAZIDE							
	CAUTION:							
	Sulfonylureas may cause hypoglycaemia, particularly in the elderly.							
8535F	Tablet 30 mg (modified release)	100	5	..	13.29	14.32	[a] Diamicron MR	SE
							[a] Oziclide MR	RA
2449X	Tablet 80 mg	100	5	..	13.09	14.12	[a] Chem mart Gliclazide	CH
							[a] GenRx Gliclazide	GX
							[a] Glyade	AF
							[a] Mellihexal	SZ
							[a] Nidem	SI
							[a] Terry White Chemists Gliclazide	TW
				B2.03	15.12	14.12	[a] Diamicron	SE

ALIMENTARY TRACT AND METABOLISM—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Proprietary Name and Manufacturer	
	GLIMEPIRIDE **CAUTION:** Sulfonylureas may cause hypoglycaemia, particularly in the elderly.								
8450R	Tablet 1 mg	30	5	..	8.67	9.70	[a]	Aylide 1	AF
							[a]	Diapride 1	SI
							[a]	Dimirel	AV
							[a]	Glimepiride Sandoz	SZ
				B2.81	11.48	9.70	[a]	Amaryl	SW
8451T	Tablet 2 mg	30	5	..	11.12	12.15	[a]	Aylide 2	AF
							[a]	Diapride 2	SI
							[a]	Dimirel	AV
							[a]	Glimepiride Sandoz	SZ
				B2.81	13.93	12.15	[a]	Amaryl	SW
8533D	Tablet 3 mg	30	5	..	12.57	13.60	[a]	Aylide 3	AF
							[a]	Diapride 3	SI
							[a]	Dimirel	AV
							[a]	Glimepiride Sandoz	SZ
				B2.80	15.37	13.60	[a]	Amaryl	SW
8452W	Tablet 4 mg	30	5	..	14.03	15.06	[a]	Aylide 4	AF
							[a]	Diapride 4	SI
							[a]	Dimirel	AV
							[a]	Glimepiride Sandoz	SZ
				B2.80	16.83	15.06	[a]	Amaryl	SW
	GLIPIZIDE **CAUTION:** Sulfonylureas may cause hypoglycaemia, particularly in the elderly.								
2440K	Tablet 5 mg	100	5	..	11.36	12.39	[a]	Melizide	AF
				B4.07	15.43	12.39	[a]	Minidiab	PH
	• ***Combinations of oral blood glucose lowering drugs*** METFORMIN HYDROCHLORIDE with GLIBENCLAMIDE **CAUTION:** Sulfonylureas may cause hypoglycaemia, particularly in the elderly.								
8838E	Tablet 250 mg-1.25 mg	90	5	..	13.18	14.21		Glucovance 250mg/ 1.25mg	AL
8810Q	Tablet 500 mg-2.5 mg	90	5	..	15.56	16.59		Glucovance 500mg/ 2.5mg	AL
8811R	Tablet 500 mg-5 mg	90	5	..	16.74	17.77		Glucovance 500mg/ 5mg	AL

ALIMENTARY TRACT AND METABOLISM—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
	ROSIGLITAZONE MALEATE with METFORMIN HYDROCHLORIDE							
	NOTE:							
	Rosiglitazone with metformin fixed dose combination tablet is not PBS-subsidised when used in combination with insulin.							
	Authority Required (STREAMLINED)							
	2633							
	Type 2 diabetes in a patient whose HbA1c is greater than 7% prior to initiation of a thiazolidinedione (glitazone) despite treatment with metformin and where a sulfonylurea is contraindicated or not tolerated.							
	The date and level of the HbA1c must be documented in the patient's medical records at the time glitazone treatment is initiated. The HbA1c must be no more than 4 months old at the time glitazone treatment is initiated.							
	NOTE:							
	Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances: (a) clinical conditions with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or (b) red cell transfusion within the previous 3 months. A patient in these circumstances will be eligible for treatment where blood glucose monitoring over a 2 week period shows blood glucose levels greater than 10 mmol per L in more than 20% of tests. The results of this blood glucose monitoring, which must be no more than 4 months old at the time of initiation of glitazone therapy, must be documented in the patient's medical records.							
9059T	***Tablet 2 mg (base)-500 mg***	***56***	***5***	***..***	***64.66***	***32.90***	***Avandamet***	***GK***
9060W	***Tablet 2 mg (base)-1 g***	***56***	***5***	***..***	***68.00***	***32.90***	***Avandamet***	***GK***
9061X	***Tablet 4 mg (base)-500 mg***	***56***	***5***	***..***	***94.33***	***32.90***	***Avandamet***	***GK***
9062Y	***Tablet 4 mg (base)-1 g***	***56***	***5***	***..***	***97.66***	***32.90***	***Avandamet***	***GK***
	• ***Alpha glucosidase inhibitors***							
	ACARBOSE							
8188Y	Tablet 50 mg	90	5	..	30.47	31.50	Glucobay 50	BN
8189B	Tablet 100 mg	90	5	..	40.49	32.90	Glucobay 100	BN
	• ***Thiazolidinediones***							
	PIOGLITAZONE HYDROCHLORIDE							
	Authority Required (STREAMLINED)							
	2635							
	Dual oral combination therapy with metformin or a sulfonylurea							
	Type 2 diabetes, in combination with either metformin or a sulfonylurea, in a patient whose HbA1c is greater than 7% prior to initiation of a thiazolidinedione (glitazone) despite treatment with either metformin or a sulfonylurea and where a combination of metformin and a sulfonylurea is contraindicated or not tolerated. .							
	The date and level of the HbA1c must be documented in the patient's medical records at the time glitazone treatment is initiated. The HbA1c must be no more than 4 months old at the time glitazone treatment is initiated.							

continued ☞

ALIMENTARY TRACT AND METABOLISM—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer

NOTE:
Pioglitazone hydrochloride is not PBS-subsidised as monotherapy.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:
(a) clinical conditions with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or
(b) red cell transfusion within the previous 3 months.
A patient in these circumstances will be eligible for treatment where blood glucose monitoring over a 2 week period shows blood glucose levels greater than 10 mmol per L in more than 20% of tests. The results of this blood glucose monitoring, which must be no more than 4 months old at the time of initiation of glitazone therapy, must be documented in the patient's medical records.

Authority Required (STREAMLINED)

2638

Combination therapy with insulin

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

The date and level of the HbA1c must be documented in the patient's medical records at the time glitazone treatment is initiated. The HbA1c must be no more than 4 months old at the time glitazone treatment is initiated.

NOTE:
Pioglitazone hydrochloride is not PBS-subsidised as monotherapy.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:
(a) clinical conditions with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or
(b) red cell transfusion within the previous 3 months.
A patient in these circumstances will be eligible for treatment where blood glucose monitoring over a 2 week period shows blood glucose levels greater than 10 mmol per L in more than 20% of tests. The results of this blood glucose monitoring, which must be no more than 4 months old at the time of initiation of glitazone therapy, must be documented in the patient's medical records.

Authority Required (STREAMLINED)

2648

Triple oral combination therapy with metformin and a sulfonylurea

Type 2 diabetes, in combination with metformin and a sulfonylurea, in a patient whose HbA1c is greater than 7% prior to initiation of a thiazolidinedione (glitazone) despite treatment with maximally tolerated doses of metformin and a sulfonylurea. .

The date and level of the HbA1c must be documented in the patient's medical records at the time glitazone treatment is initiated. The HbA1c must be no more than 4 months old at the time glitazone treatment is initiated.

continued ☞

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
	NOTE:							
	Pioglitazone hydrochloride is not PBS-subsidised as monotherapy.							
	Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:							
	(a) clinical conditions with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or							
	(b) red cell transfusion within the previous 3 months.							
	A patient in these circumstances will be eligible for treatment where blood glucose monitoring over a 2 week period shows blood glucose levels greater than 10 mmol per L in more than 20% of tests. The results of this blood glucose monitoring, which must be no more than 4 months old at the time of initiation of glitazone therapy, must be documented in the patient's medical records.							
8694N	***Tablet 15 mg (base)***	***28***	***5***	***..***	***61.09***	***32.90***	***Actos***	***LY***
8695P	***Tablet 30 mg (base)***	***28***	***5***	***..***	***90.76***	***32.90***	***Actos***	***LY***
8696Q	***Tablet 45 mg (base)***	***28***	***5***	***..***	***116.21***	***32.90***	***Actos***	***LY***
	ROSIGLITAZONE MALEATE							
	Authority Required (STREAMLINED)							
	2635							
	Dual oral combination therapy with metformin or a sulfonylurea							
	Type 2 diabetes, in combination with either metformin or a sulfonylurea, in a patient whose HbA1c is greater than 7% prior to initiation of a thiazolidinedione (glitazone) despite treatment with either metformin or a sulfonylurea and where a combination of metformin and a sulfonylurea is contraindicated or not tolerated. .							
	The date and level of the HbA1c must be documented in the patient's medical records at the time glitazone treatment is initiated. The HbA1c must be no more than 4 months old at the time glitazone treatment is initiated.							
	NOTE:							
	Rosiglitazone maleate is not PBS-subsidised as monotherapy.							
	Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:							
	(a) clinical conditions with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or							
	(b) red cell transfusion within the previous 3 months.							
	A patient in these circumstances will be eligible for treatment where blood glucose monitoring over a 2 week period shows blood glucose levels greater than 10 mmol per L in more than 20% of tests. The results of this blood glucose monitoring, which must be no more than 4 months old at the time of initiation of glitazone therapy, must be documented in the patient's medical records.							
8689H	***Tablet 4 mg (base)***	***28***	***5***	***..***	***61.09***	***32.90***	***Avandia***	***GK***
8690J	***Tablet 8 mg (base)***	***28***	***5***	***..***	***90.76***	***32.90***	***Avandia***	***GK***

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
	• *Dipeptidyl peptidase 4 (DPP-4) inhibitors*							
	SITAGLIPTIN							
	NOTE:							
	Sitagliptin is not PBS-subsidised for use in combination with metformin and a sulfonylurea (triple oral therapy), as monotherapy or in combination with a thiazolidinedione (glitazone).							
	Authority Required							
	Dual oral combination therapy with metformin or a sulfonylurea							
	Type 2 diabetes, in combination with metformin or a sulfonylurea, in a patient whose HbA1c is greater than 7% prior to initiation of sitagliptin despite treatment with either metformin or a sulfonylurea and where a combination of metformin and a sulfonylurea is contraindicated or not tolerated.							
	The date and level of the qualifying HbA1c must be documented in the patient's medical records. The date of the HbA1c measurement, which must be no more than 4 months old at the time treatment is initiated, must be provided when the first authority application is made.							
	Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:							
	(a) clinical conditions with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or							
	(b) red cell transfusion within the previous 3 months.							
	A patient in these circumstances will be eligible for treatment where blood glucose monitoring over a 2 week period shows blood glucose levels greater than 10 mmol per L in more than 20% of tests. The results of this blood glucose monitoring must be documented in the patient's medical records. The date of measurement of the most recent blood glucose level, which must be no more than 4 months old at the time treatment is initiated, must be provided when the first authority application is made.							
9180E	***Tablet 25 mg (as phosphate monohydrate)***	***28***	***5***	***..***	***90.76***	***32.90***	***Januvia***	***MK***
9181F	***Tablet 50 mg (as phosphate monohydrate)***	***28***	***5***	***..***	***90.76***	***32.90***	***Januvia***	***MK***
9182G	***Tablet 100 mg (as phosphate monohydrate)***	***28***	***5***	***..***	***90.76***	***32.90***	***Januvia***	***MK***

ALIMENTARY TRACT AND METABOLISM—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
	VITAMINS							
	Vitamin A and D, incl. combinations of the two							
	• ***Vitamin D and analogues***							
	CALCITRIOL							
	Authority Required (STREAMLINED)							
	1165 ***Hypocalcaemia due to renal disease;***							
	1166 ***Hypoparathyroidism;***							
	1167 ***Hypophosphataemic rickets;***							
	1467 ***Vitamin D-resistant rickets;***							
	2636 ***Treatment for established osteoporosis in patients with fracture due to minimal trauma. The fracture must have been demonstrated radiologically and the year of plain x-ray or CT-scan or MRI scan must be documented in the patient's medical records when treatment is initiated.*** ***A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.***							
2502Q	*Capsule 0.25 microgram*	*100*	*3*	*..*	*42.82*	*32.90*	[a] *Calcitriol-DP* [a] *Citrihexal* [a] *GenRx Calcitriol* [a] *Kosteo* [a] *Rocaltrol* [a] *Sical*	*GM* *SZ* *GX* *SI* *RO* *AF*
	Vitamin B_1, plain and in combination with vitamin B_6 and vitamin B_{12}							
	• ***Vitamin B_1, plain***							
	THIAMINE HYDROCHLORIDE							
	Authority Required (STREAMLINED)							
	2384 ***Prophylaxis of thiamine deficiency in an Aboriginal or a Torres Strait Islander person.***							
1070H	*Tablet 100 mg*	*100*	*2*	*..*	*10.39*	*11.42*	*Betamin*	*SW*

ALIMENTARY TRACT AND METABOLISM—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Proprietary Name and Manufacturer	
	MINERAL SUPPLEMENTS								
	Calcium								
	• ***Calcium***								
	CALCIUM								
	Authority Required (STREAMLINED)								
	2212								
	Hyperphosphataemia associated with chronic renal failure.								
8560M	***Tablet 250 mg (as citrate)***	***240***	***1***	***..***	**** 21.77***	***22.80***		***Citracal***	***BN***
3116B	***Tablet (chewable) 500 mg (as carbonate)***	***240***	***1***	***..***	**** 25.63***	***26.66***		***Cal-Sup***	***IA***
	Potassium								
	• ***Potassium***								
	POTASSIUM CHLORIDE								
2642C	Tablet 600 mg (sustained release)	200	1	..	* 12.87	13.90	a	Duro-K	NM
				..	12.87	13.90		Span-K	AS
				B2.80	* 15.67	13.90	a	Slow-K	NV
	POTASSIUM CHLORIDE with POTASSIUM BICARBONATE								
3012M	Effervescent tablet 14 mmol potassium and 8 mmol chloride	60	1	..	12.64	13.67	a	K-Sol	LN
				B2.61	15.25	13.67	a	Chlorvescent	AS
	ANABOLIC AGENTS FOR SYSTEMIC USE								
	Anabolic steroids								
	• ***Estren derivatives***								
	NANDROLONE DECANOATE								
	Authority Required								
	Monotherapy for osteoporosis, where other treatment has failed and where specialist advice confirms that this is the only suitable treatment option for the patient. Specialist advice need only be obtained for the first authority approval;								
	Monotherapy for osteoporosis, where other treatment is not tolerated and where specialist advice confirms that this is the only suitable treatment option for the patient. Specialist advice need only be obtained for the first authority approval;								
	Monotherapy for osteoporosis, where other treatment is contraindicated and where specialist advice confirms that this is the only suitable treatment option for the patient. Specialist advice need only be obtained for the first authority approval;								
	Patients receiving PBS-subsidised therapy with this drug for osteoporosis prior to 1 February 2004;								
	Patients on long-term treatment with corticosteroids.								
	NOTE:								
	Monotherapy for the treatment of osteoporosis does not exclude calcium supplementation.								
1671Y	***Injection 50 mg in 1 mL, disposable syringe***	***1***	***7***	***..***	***20.77***	***21.80***		***Deca-Durabolin***	***SH***

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
	ANTITHROMBOTIC AGENTS							
	Antithrombotic agents							
	• ***Vitamin K antagonists***							
	WARFARIN SODIUM							
	CAUTION:							
	The listed brands have NOT been shown to be bioequivalent and should not be interchanged.							
2843P	Tablet 1 mg	50	2	..	11.99	13.02	Coumadin Marevan	SI FM
2209G	Tablet 2 mg	50	2	..	12.34	13.37	Coumadin	SI
2844Q	Tablet 3 mg	50	2	..	12.26	13.29	Marevan	FM
2211J	Tablet 5 mg	50	2	..	13.60	14.63	Coumadin Marevan	SI FM
	• ***Heparin group***							
	DALTEPARIN SODIUM (Low Molecular Weight Heparin Sodium—porcine mucous)							
8603T	Injection 2,500 units (anti-Xa) in 0.2 mL single dose pre-filled syringe	10	1	..	55.18	32.90	Fragmin	PH
2816F	Injection 5,000 units (anti-Xa) in 0.2 mL single dose pre-filled syringe	10	1	..	57.22	32.90	Fragmin	PH
8271H	Injection 7,500 units (anti-Xa) in 0.75 mL single dose pre-filled syringe	10	1	..	83.22	32.90	Fragmin	PH
8269F	Injection 10,000 units (anti-Xa) in 1 mL single dose pre-filled syringe	10	1	..	108.95	32.90	Fragmin	PH
	DALTEPARIN SODIUM (Low Molecular Weight Heparin Sodium—porcine mucous)							
	Restricted Benefit ***Haemodialysis.***							
8641T	***Injection 2,500 units (anti-Xa) in 0.2 mL single dose pre-filled syringe***	***20***	***3***	***..***	**** 104.31***	***32.90***	***Fragmin***	***PH***
8642W	***Injection 5,000 units (anti-Xa) in 0.2 mL single dose pre-filled syringe***	***20***	***3***	***..***	**** 108.45***	***32.90***	***Fragmin***	***PH***
8643X	***Injection 7,500 units (anti-Xa) in 0.75 mL single dose pre-filled syringe***	***20***	***3***	***..***	**** 160.45***	***32.90***	***Fragmin***	***PH***

BLOOD AND BLOOD FORMING ORGANS—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
	ENOXAPARIN SODIUM							
8558K	Injection 20 mg (2,000 i.u. anti-Xa) in 0.2 mL pre-filled syringe	10	1	..	55.18	32.90	Clexane	SW
8510X	Injection 40 mg (4,000 i.u. anti-Xa) in 0.4 mL pre-filled syringe	10	1	..	57.22	32.90	Clexane	SW
9195Y	Solution for injection 40 mg (4,000 i.u. anti-Xa) in 0.4 mL	10	1	..	57.22	32.90	Clexane	SW
8262W	Injection 60 mg (6,000 i.u. anti-Xa) in 0.6 mL pre-filled syringe	10	1	..	79.25	32.90	Clexane	SW
8263X	Injection 80 mg (8,000 i.u. anti-Xa) in 0.8 mL pre-filled syringe	10	1	..	90.27	32.90	Clexane	SW
8264Y	Injection 100 mg (10,000 i.u. anti-Xa) in 1 mL pre-filled syringe	10	1	..	108.65	32.90	Clexane	SW
	ENOXAPARIN SODIUM							
	Restricted Benefit ***Haemodialysis.***							
8716R	***Injection 20 mg (2,000 i.u. anti-Xa) in 0.2 mL pre-filled syringe***	***20***	***3***	***..***	**** 104.31***	***32.90***	***Clexane***	***SW***
8639Q	***Injection 40 mg (4,000 i.u. anti-Xa) in 0.4 mL pre-filled syringe***	***20***	***3***	***..***	**** 108.45***	***32.90***	***Clexane***	***SW***
9196B	***Solution for injection 40 mg (4,000 i.u. anti-Xa) in 0.4 mL***	***20***	***3***	***..***	**** 108.45***	***32.90***	***Clexane***	***SW***
8640R	***Injection 60 mg (6,000 i.u. anti-Xa) in 0.6 mL pre-filled syringe***	***20***	***3***	***..***	**** 152.51***	***32.90***	***Clexane***	***SW***
	HEPARIN SODIUM							
1466E	Injection 5,000 units in 0.2 mL	5	5	..	15.05	16.08	HH	
1463B	Injection (preservative-free) 5,000 units in 5 mL	50	5	..	52.50	32.90	PU	
1076P	Injection 35,000 units in 35 mL	12	5	..	* 278.15	32.90	HH	

BLOOD AND BLOOD FORMING ORGANS—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Proprietary Name and Manufacturer	
	• Platelet aggregation inhibitors excl. heparin								
	ABCIXIMAB								
	Authority Required (STREAMLINED)								
	1716 ***Patients undergoing percutaneous coronary balloon angioplasty;***								
	1717 ***Patients undergoing percutaneous coronary atherectomy;***								
	1718 ***Patients undergoing percutaneous coronary stent placement.***								
8048N	***I.V. injection 10 mg in 5 mL***	***3***	***..***	***..***	**** 1452.68***	***32.90***		***ReoPro***	***LY***
	ASPIRIN								
8202Q	Tablet 100 mg	112	1	..	7.70	8.73	a	DBL Aspirin 100 mg	FA
				B1.36	9.06	8.73	a	Astrix	HH
1010E	Tablet 300 mg (dispersible)	96	1	..	8.21	9.24		Solprin	RC

BLOOD AND BLOOD FORMING ORGANS—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Proprietary Name and Manufacturer	
	CLOPIDOGREL HYDROGEN SULFATE								
	Authority Required (STREAMLINED)								
	1719 ***Prevention of recurrence of ischaemic stroke or transient cerebral ischaemic events in patients with a history of symptomatic cerebrovascular ischaemic episodes while on therapy with low-dose aspirin;***								
	1720 ***Prevention of recurrence of ischaemic stroke or transient cerebral ischaemic events in patients where low-dose aspirin poses an unacceptable risk of gastrointestinal bleeding;***								
	1721 ***Prevention of recurrence of ischaemic stroke or transient cerebral ischaemic events in patients where there is a history of anaphylaxis, urticaria or asthma within 4 hours of ingestion of aspirin, other salicylates, or NSAIDs;***								
	1722 ***Prevention of recurrence of myocardial infarction or unstable angina in patients with a history of symptomatic cardiac ischaemic events while on therapy with low-dose aspirin;***								
	1723 ***Prevention of recurrence of myocardial infarction or unstable angina in patients where low-dose aspirin poses an unacceptable risk of gastrointestinal bleeding;***								
	1724 ***Prevention of recurrence of myocardial infarction or unstable angina in patients where there is a history of anaphylaxis, urticaria or asthma within 4 hours of ingestion of aspirin, other salicylates, or NSAIDs;***								
	3069 ***Treatment of acute coronary syndromes (myocardial infarction or unstable angina) in combination with aspirin to prevent early and long-term atherothrombotic events.***								
	NOTE: ***Not for prophylaxis of DVT or peripheral arterial disease.***								
8358X	***Tablet 75 mg (base)***	***28***	***5***	***..***	***80.49***	***32.90***	***[a]***	***Iscover***	***BQ***
							[a]	***Plavix***	***SW***
	DIPYRIDAMOLE								
	Restricted Benefit ***Prevention of recurrence of ischaemic stroke or transient cerebral ischaemic events:*** ***(a) as adjunctive therapy with low-dose aspirin; or*** ***(b) where low-dose aspirin poses an unacceptable risk of gastrointestinal bleeding; or*** ***(c) where there is a history of anaphylaxis, urticaria or asthma within 4 hours of ingestion of aspirin, other salicylates, or NSAIDs.***								
8335Q	***Capsule 200 mg (sustained release)***	***60***	***5***	***..***	***36.53***	***32.90***		***Persantin SR***	***BY***
	DIPYRIDAMOLE with ASPIRIN								
	Restricted Benefit ***Prevention of recurrence of ischaemic stroke or transient cerebral ischaemic events.***								
8382E	***Capsule 200 mg (sustained release)-25 mg***	***60***	***5***	***..***	***36.76***	***32.90***		***Asasantin SR***	***BY***

BLOOD AND BLOOD FORMING ORGANS—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
	EPTIFIBATIDE ACETATE							
	Authority Required (STREAMLINED) **1884** ***Patients undergoing non-urgent percutaneous intervention with intracoronary stenting.***							
8683B	***Solution for I.V. injection 20 mg (base) in 10 mL***	***2***	***..***	***..***	**** 262.11***	***32.90***	***Integrilin***	***SH***
8684C	***Solution for I.V. infusion 75 mg (base) in 100 mL***	***3***	***..***	***..***	**** 1019.93***	***32.90***	***Integrilin***	***SH***
	TICLOPIDINE HYDROCHLORIDE **CAUTION:** ***Severe neutropenia is common in the early months of therapy. Haematological monitoring should be undertaken at commencement and every two weeks in the first four months of therapy.***							
	Authority Required (STREAMLINED) **1719** ***Prevention of recurrence of ischaemic stroke or transient cerebral ischaemic events in patients with a history of symptomatic cerebrovascular ischaemic episodes while on therapy with low-dose aspirin;*** **1720** ***Prevention of recurrence of ischaemic stroke or transient cerebral ischaemic events in patients where low-dose aspirin poses an unacceptable risk of gastrointestinal bleeding;*** **1721** ***Prevention of recurrence of ischaemic stroke or transient cerebral ischaemic events in patients where there is a history of anaphylaxis, urticaria or asthma within 4 hours of ingestion of aspirin, other salicylates, or NSAIDs;*** **1260** ***Patients established on this drug as a pharmaceutical benefit prior to 1 November 1999.***							
2095G	***Tablet 250 mg***	***60***	***5***	***..***	***146.05***	***32.90***	***Tilodene***	***AF***
	TIROFIBAN HYDROCHLORIDE							
	Authority Required (STREAMLINED) **1729** ***Patients with high risk unstable angina who have new transient or persistent ST-T ischaemic changes and anginal pain lasting longer than 20 minutes;*** **1730** ***Patients with high risk unstable angina who have new transient or persistent ST-T ischaemic changes and repetitive episodes of angina at rest or during minimal exercise in the previous 12 hours;*** **1275** ***Patients with non-Q-wave myocardial infarction.***							
8350L	***Solution concentrate for I.V. infusion 12.5 mg (base) in 50 mL***	***1***	***2***	***..***	***362.68***	***32.90***	***Aggrastat***	***MK***

BLOOD AND BLOOD FORMING ORGANS—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
	• *Enzymes*							
	DROTRECOGIN ALFA (ACTIVATED)							
	Authority Required ***Adult patients with severe sepsis who have a high risk of death as determined by acute dysfunction in at least 2 organs or modified Apache II score of at least 25.*** ***Acute organ dysfunction is defined as follows:*** ***(a) (1) For cardiovascular-system dysfunction, an arterial systolic blood pressure of less than or equal to 90 mmHg or mean arterial pressure of less than or equal to 70 mmHg for at least 1 hour despite adequate fluid resuscitation, adequate intravascular volume status or the use of vasopressors in an attempt to maintain a systolic blood pressure of greater than or equal to 90 mmHg or a mean arterial pressure of greater than or equal to 70 mmHg;*** ***(2) For kidney dysfunction, urine output of less than 0.5 mL per kg of body weight per hour for 1 hour despite adequate fluid resuscitation;*** ***(3) For respiratory-system dysfunction, a ratio of PaO2 to FiO2 of less than or equal to 250;*** ***(4) For haematologic dysfunction, a platelet count of less than 80,000 per cubic millimetre or which has decreased by 50 percent in the previous 3 days;*** ***(5) In the case of unexplained metabolic acidosis, a pH of less than or equal to 7.30 or a base deficit of greater than or equal to 5.0 mmol per L in association with a plasma lactate level of greater than 1.5 times the upper limit of the normal value for the reporting laboratory.*** **NOTE:** ***Medical practitioners should request the appropriate quantity of vials at the time of the authority application, according to the weight of the patient, to achieve a dose of 24 micrograms per kg per hour over a maximum of 96 hours.***							
8614J	***Powder for I.V. infusion 5 mg***	***1***	***..***	***..***	***466.71***	***32.90***	***Xigris***	***LY***
	RETEPLASE (Recombinant plasminogen activator) **Restricted Benefit** ***Treatment of acute myocardial infarction within 6 hours of onset of attack.***							
8253J	***Pack containing 2 vials powder for injection 10 units, 2 single use pre-filled syringes with solvent, 2 reconstitution spikes and 2 needles***	***‡ 1***	***..***	***..***	***2066.53***	***32.90***	***Rapilysin 10 U***	***TA***
	TENECTEPLASE **Restricted Benefit** ***Treatment of acute myocardial infarction within 12 hours of onset of attack.***							
8526R	***Powder for injection 40 mg with solvent***	***1***	***..***	***..***	***1960.33***	***32.90***	***Metalyse***	***BY***
8527T	***Powder for injection 50 mg with solvent***	***1***	***..***	***..***	***2056.63***	***32.90***	***Metalyse***	***BY***

BLOOD AND BLOOD FORMING ORGANS—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
	• *Direct thrombin inhibitors*							
	BIVALIRUDIN TRIFLUOROACETATE							
	Authority Required (STREAMLINED)							
	3075							
➢	***A patient undergoing percutaneous coronary intervention.***							
8844L	***Powder for I.V. injection 250 mg (base)***	***1***	***..***	***..***	***671.32***	***32.90***	***Angiomax***	***CS***
	• *Other antithrombotic agents*							
	FONDAPARINUX SODIUM							
	Authority Required (STREAMLINED)							
	2005							
	Prevention of venous thromboembolic events in patients undergoing major hip surgery;							
	2006							
	Prevention of venous thromboembolic events in patients undergoing total knee replacement.							
	NOTE:							
	No applications for increased maximum quantities and/or repeats will be authorised.							
8775W	***Injection 2.5 mg in 0.5 mL single dose pre-filled syringe***	***7***	***..***	***..***	***140.11***	***32.90***	***Arixtra***	***GK***
	ANTIHEMORRHAGICS							
	Antifibrinolytics							
	• *Amino acids*							
	TRANEXAMIC ACID							
2180R	Tablet 500 mg	100	2	..	51.25	32.90	Cyklokapron	PH
	ANTIANEMIC PREPARATIONS							
	Iron preparations							
	• *Iron bivalent, oral preparations*							
	FERROUS SULFATE							
8815Y	Oral liquid 30 mg per mL, 250 mL	‡ 1	2	..	18.92	19.95	Ferro-Liquid	AE
	• *Iron trivalent, parenteral preparations*							
	IRON POLYMALTOSE COMPLEX							
2593L	Injection 100 mg (iron) in 2 mL	5	..	..	51.55	32.90	[a] Ferrosig	SI
							[a] Ferrum H	AS

BLOOD AND BLOOD FORMING ORGANS—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
	IRON SUCROSE							
	Authority Required (STREAMLINED) **2070** ***Iron deficiency anaemia, in combination with either epoetin alfa or darbepoetin alfa, in patients undergoing chronic haemodialysis who have had a documented hypersensitivity reaction to iron polymaltose and in whom continued intravenous iron therapy is appropriate.***							
8807M	***Concentrate for solution for infusion 2.7 g (equivalent to 100 mg iron (III)) in 5 mL***	***5***	***..***	***..***	***139.05***	***32.90***	***Venofer***	***AS***
	• ***Iron in combination with folic acid*** FERROUS FUMARATE with FOLIC ACID							
9011G	Tablet 310 mg (equivalent to 100 mg iron)-350 micrograms	60	1	..	11.87	12.90	Ferro-f-tab	AE
	Vitamin B_{12} and folic acid							
	• ***Vitamin B_{12} (cyanocobalamin and derivatives)*** ***HYDROXOCOBALAMIN***							
	Restricted Benefit ***Pernicious anaemia;*** ***Other proven vitamin B_{12} deficiencies;*** ***Prophylaxis after gastrectomy.***							
9048F	***Injection 1 mg in 1 mL***	***3***	***..***	***..***	***16.79***	***17.82***	***Neo-B12***	***HH***
	NOTE: ***One injection of hydroxocobalamin 1 mg every three months provides appropriate maintenance therapy in vitamin B_{12} deficiencies.***							
	• ***Folic acid and derivatives*** FOLIC ACID							
2958Q	Tablet 500 micrograms	200	..	..	* 13.35	14.38	Megafol 0.5	AF
1437P	Tablet 5 mg	200	1	..	* 13.59	14.62	Megafol 5	AF
	NOTE: The 5 mg strength tablet should be used in malabsorption states only.							

BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS

Blood and related products

• ***Blood substitutes and plasma protein fractions***

GELATIN - SUCCINYLATED

8444K	I.V. infusion 20 g per 500 mL, 500 mL	3	..	..	* 45.32	32.90	Gelofusine	BR

BLOOD AND BLOOD FORMING ORGANS—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
	POLYGELINE							
2334W	I.V. infusion 17.5 g per 500 mL (3.5%) with electrolytes, 500 mL	3	..	..	* 45.32	32.90	Haemaccel	AE
	I.V. solutions							
	• ***Solutions for parenteral nutrition***							
	GLUCOSE							
2245E	I.V. infusion 278 mmol (anhydrous) per L (5%), 1 L	5	1	..	* 25.49	26.52	BX	
	• ***Solutions affecting the electrolyte balance***							
	ELECTROLYTE REPLACEMENT SOLUTION							
3199J	I.V. infusion 1 L	2	1	..	* 21.53	22.56	Plasma-Lyte 148	BX
	SODIUM CHLORIDE							
2264E	I.V. infusion 154 mmol per L (0.9%), 1 L	5	1	..	* 25.49	26.52	BX	
2260Y	I.V. infusion 513 mmol per L (3%), 1 L	2	1	..	* 17.79	18.82	BX	
	SODIUM CHLORIDE COMPOUND							
2266G	I.V. infusion 1 L	4	1	..	* 29.59	30.62	BX	
	SODIUM CHLORIDE with GLUCOSE							
2281C	I.V. infusion 31 mmol-222 mmol (anhydrous) per L (0.18%-4%), 1 L	5	1	..	* 25.49	26.52	BX	
2279Y	I.V. infusion 19 mmol-104 mmol (anhydrous) per 500 mL (0.225%-3.75%), 500 mL	5	1	..	* 31.59	32.62	BX	
2278X	I.V. infusion 39 mmol-69 mmol (anhydrous) per 500 mL (0.45%-2.5%), 500 mL	5	1	..	* 31.59	32.62	BX	
	SODIUM LACTATE COMPOUND							
2286H	I.V. infusion 1 L	5	1	..	* 25.49	26.52	BX	

CARDIOVASCULAR SYSTEM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Proprietary Name and Manufacturer	
	CARDIAC THERAPY								
	Cardiac glycosides								
	• ***Digitalis glycosides***								
	DIGOXIN								
2605D	Tablet 62.5 micrograms	200	1	..	10.23	11.26	a	Sigmaxin-PG	FM
				B1.79	12.02	11.26	a	Lanoxin-PG	SI
1322N	Tablet 250 micrograms	100	1	..	10.56	11.59	a	Sigmaxin	FM
				B1.80	12.36	11.59	a	Lanoxin	SI
3164M	Oral solution for children 50 micrograms per mL, 60 mL	2	3	..	* 28.25	29.28		Lanoxin	SI
	Antiarrhythmics, class I and III								
	• ***Antiarrhythmics, class IA***								
	DISOPYRAMIDE								
2923W	Capsule 100 mg	100	5	..	26.72	27.75		Rythmodan	SW
2924X	Capsule 150 mg	100	5	..	35.75	32.90		Rythmodan	SW
	• ***Antiarrhythmics, class IB***								
	LIGNOCAINE HYDROCHLORIDE								
2875H	Injection 100 mg in 5 mL	5	..	..	36.90	32.90		PF	
2876J	Infusion 500 mg in 5 mL	10	..	..	29.16	30.19		Xylocard 500	AP
	MEXILETINE HYDROCHLORIDE								
1682M	Capsule 50 mg	100	5	..	32.79	32.90		Mexitil	BY
1683N	Capsule 200 mg	100	5	..	63.36	32.90		Mexitil	BY
	• ***Antiarrhythmics, class IC***								
	FLECAINIDE ACETATE								
	CAUTION:								
	Flecainide acetate should be avoided in patients with poor cardiac function.								
	Restricted Benefit								
	Serious supra-ventricular cardiac arrhythmias;								
	Serious ventricular cardiac arrhythmias where treatment is initiated in a hospital (in-patient or out-patient).								
1088G	***Tablet 50 mg***	***60***	***5***	***..***	***39.28***	***32.90***		***Tambocor***	***IA***
1090J	***Tablet 100 mg***	***60***	***5***	***..***	***46.37***	***32.90***	***a***	***Flecatab***	***AF***
							a	***Tambocor***	***IA***

CARDIOVASCULAR SYSTEM—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Proprietary Name and Manufacturer	
	• *Antiarrhythmics, class III*								
	AMIODARONE HYDROCHLORIDE								
	CAUTION:								
	Amiodarone hydrochloride has been reported to cause frequent and potentially serious toxicity. Regular monitoring of hepatic and thyroid function is recommended.								
	Restricted Benefit								
	Severe cardiac arrhythmias.								
2344J	***Tablet 100 mg***	***30***	***5***	***..***	***14.59***	***15.62***	[a]	***Aratac 100***	***AF***
							[a]	***Cardinorm***	***SZ***
							[a]	***Cordarone X 100***	***SW***
							[a]	***Rithmik 100***	***SI***
2343H	***Tablet 200 mg***	***30***	***5***	***..***	***21.29***	***22.32***	[a]	***Aratac 200***	***AF***
							[a]	***Cardinorm***	***SZ***
							[a]	***Chem mart Amiodarone***	***CH***
							[a]	***Cordarone X 200***	***SW***
							[a]	***GenRx Amiodarone***	***GX***
							[a]	***Rithmik 200***	***SI***
							[a]	***Terry White Chemists Amiodarone***	***TW***
	SOTALOL HYDROCHLORIDE								
	Restricted Benefit								
	Severe cardiac arrhythmias.								
8398B	***Tablet 80 mg***	***60***	***5***	***..***	***15.35***	***16.38***	[a]	***GenRx Sotalol***	***GX***
							[a]	***Solavert***	***SI***
							[a]	***Sotahexal***	***SZ***
				B4.50	***19.85***	***16.38***	[a]	***Sotacor***	***BQ***
2043M	***Tablet 160 mg***	***60***	***5***	***..***	***26.07***	***27.10***	[a]	***Cardol***	***AF***
							[a]	***Chem mart Sotalol***	***CH***
							[a]	***GenRx Sotalol***	***GX***
							[a]	***Solavert***	***SI***
							[a]	***Sotab***	***GM***
							[a]	***Sotahexal***	***SZ***
							[a]	***Terry White Chemists Sotalol***	***TW***
				B4.50	***30.57***	***27.10***	[a]	***Sotacor***	***BQ***
	Cardiac stimulants excl. cardiac glycosides								
	• *Adrenergic and dopaminergic agents*								
	ADRENALINE								
1016L	Injection 1 mg in 1 mL (1 in 1,000)	5	1	..	19.91	20.94		AP	

CARDIOVASCULAR SYSTEM—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	

ADRENALINE

Authority Required

Initial supply for anticipated emergency treatment of acute allergic reactions with anaphylaxis in a patient who:

(a) has been assessed to be at significant risk of anaphylaxis by, or in consultation with, a clinical immunologist, allergist, paediatrician or respiratory physician. The name of the specialist consulted must be provided at the time of application for initial supply; or

(b) has been discharged from hospital or an emergency department after treatment with adrenaline for acute allergic reaction with anaphylaxis;

Continuing supply for anticipated emergency treatment of acute allergic reactions with anaphylaxis, where the patient has previously been issued with an authority prescription for this drug.

NOTE:

The auto-injector should be provided in the framework of a comprehensive anaphylaxis prevention program and an emergency action plan including training in recognition of the symptoms of anaphylaxis and the use of the auto-injector device. (For further information see the Australasian Society of Clinical Immunology and Allergy website at www.allergy.org.au.)

8697R	***I.M. injection 150 micrograms in 0.3 mL single dose syringe auto-injector***	***1***	***..***	***..***	***105.57***	***32.90***	***EpiPen Jr.***	***AL***
8698T	***I.M. injection 300 micrograms in 0.3 mL single dose syringe auto-injector***	***1***	***..***	***..***	***105.57***	***32.90***	***EpiPen***	***AL***

NOTE:

Authorities for increased maximum quantities, up to a maximum of 2, may be authorised for children aged less than 17 years where 2 auto-injectors are necessary to ensure 1 is on hand at all times. No increased maximum quantities will be authorised for patients aged 17 years or older.

No repeats will be issued.

Vasodilators used in cardiac diseases

• *Organic nitrates*

GLYCERYL TRINITRATE

1459T	Tablets 600 micrograms, 100	‡ 1	5	..	11.96	12.99	[a] Lycinate	FM
				B1.64	13.60	12.99	[a] Anginine Stabilised	SI
8171C	Sublingual spray (pump pack) 400 micrograms per dose (200 doses)	‡ 1	5	..	19.70	20.73	Nitrolingual Pumpspray	SW
	NOTE: The spray should not be inhaled.							
8027L	Transdermal patch releasing approximately 5 mg per 24 hours	30	5	..	28.20	29.23	Minitran 5	IA
1515R	Transdermal patch releasing approximately 5 mg per 24 hours	30	5	..	28.20	29.23	Transiderm-Nitro 25	NV
8010N	Transdermal patch releasing approximately 5 mg per 24 hours	30	5	..	28.20	29.23	Nitro-Dur 5	SH

continued ☞

CARDIOVASCULAR SYSTEM—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Proprietary Name and Manufacturer	
8028M	Transdermal patch releasing approximately 10 mg per 24 hours	30	5	..	35.11	32.90		Minitran 10	IA
1516T	Transdermal patch releasing approximately 10 mg per 24 hours	30	5	..	35.11	32.90		Transiderm-Nitro 50	NV
8011P	Transdermal patch releasing approximately 10 mg per 24 hours	30	5	..	35.11	32.90		Nitro-Dur 10	SH
8119H	Transdermal patch releasing approximately 15 mg per 24 hours	30	5	..	35.11	32.90		Minitran 15	IA
8026K	Transdermal patch releasing approximately 15 mg per 24 hours	30	5	..	35.11	32.90		Nitro-Dur 15	SH
	ISOSORBIDE DINITRATE								
2587E	Tablet 10 mg	200	2	..	* 13.71	14.74		Sorbidin	AF
2588F	Sublingual tablet 5 mg	200	2	..	* 14.61	15.64		Isordil Sublingual	SI
	ISOSORBIDE MONONITRATE								
1558B	Tablet 60 mg (sustained release)	30	5	..	12.45	13.48	a	Chem mart Isosorbide Mononitrate	CH
							a	Duride	AF
							a	GenRx Isosorbide Mononitrate	GX
							a	Imtrate 60 mg	GM
							a	Isomonit	SZ
							a	Monodur 60 mg	PM
							a	Terry White Chemists Isosorbide Mononitrate	TW
				B2.84	15.29	13.48	a	Imdur Durule	AP
8273K	Tablet 120 mg (sustained release)	30	5	..	21.31	22.34	a	Monodur 120 mg	PM
				B3.00	24.31	22.34	a	Imdur 120 mg	AP
	• ***Other vasodilators used in cardiac diseases*** NICORANDIL								
8228C	Tablets 10 mg, 60	‡ 1	5	..	23.71	24.74		Ikorel	SW
8229D	Tablets 20 mg, 60	‡ 1	5	..	30.83	31.86		Ikorel	SW

CARDIOVASCULAR SYSTEM—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Proprietary Name and Manufacturer	
	PERHEXILINE MALEATE								
	CAUTION:								
	Regular monitoring of drug serum levels is recommended.								
	Authority Required (STREAMLINED)								
	1023								
	Angina not responding to other therapy.								
1822X	***Tablet 100 mg***	***100***	***5***	***..***	***53.07***	***32.90***		***Pexsig***	***SI***
	ANTIHYPERTENSIVES								
	Antiadrenergic agents, centrally acting								
	• ***Methyldopa***								
	METHYLDOPA								
1629R	Tablet 250 mg	100	5	..	12.19	13.22	a	Hydopa	AF
				B2.24	14.43	13.22	a	Aldomet	AS
	• ***Imidazoline receptor agonists***								
	CLONIDINE								
3145M	Tablet 100 micrograms	100	5	..	28.45	29.48		Catapres 100	BY
3141H	Tablet 150 micrograms	100	5	..	37.01	32.90		Catapres	BY
	MOXONIDINE								
	Restricted Benefit								
	Hypertension in patients receiving concurrent antihypertensive therapy.								
9019Q	***Tablet 200 micrograms***	***30***	***5***	***..***	***19.10***	***20.13***		***Physiotens***	***SM***
9020R	***Tablet 400 micrograms***	***30***	***5***	***..***	***28.35***	***29.38***		***Physiotens***	***SM***
	Antiadrenergic agents, peripherally acting								
	• ***Alpha-adrenoceptor antagonists***								
	PRAZOSIN HYDROCHLORIDE								
1479W	Tablet 1 mg (base)	100	5	..	12.19	13.22	a	Chem mart Prazosin	CH
							a	GenRx Prazosin	GX
							a	Pressin 1	AF
							a	Terry White Chemists Prazosin	TW
				B2.31	14.50	13.22	a	Minipress	PF

continued ☞

CARDIOVASCULAR SYSTEM—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
1480X	Tablet 2 mg (base)	100	5	..	14.50	15.53	[a] Chem mart Prazosin	CH
							[a] GenRx Prazosin	GX
							[a] Pressin 2	AF
							[a] Terry White Chemists Prazosin	TW
				B2.38	16.88	15.53	[a] Minipress	PF
1478T	Tablet 5 mg (base)	100	5	..	20.42	21.45	[a] Chem mart Prazosin	CH
							[a] GenRx Prazosin	GX
							[a] Pressin 5	AF
							[a] Terry White Chemists Prazosin	TW
				B2.58	23.00	21.45	[a] Minipress	PF

Arteriolar smooth muscle, agents acting on

- ***Hydrazinophthalazine derivatives***

HYDRALAZINE HYDROCHLORIDE

1640H	Tablet 25 mg	200	2	..	* 15.07	16.10	Alphapress 25	AF
1639G	Tablet 50 mg	200	2	..	* 16.99	18.02	Alphapress 50	AF

- ***Pyrimidine derivatives***

MINOXIDIL

Authority Required (STREAMLINED)

2759

Severe refractory hypertension. Treatment must be initiated by a consultant physician.

2313R	***Tablet 10 mg***	***100***	***5***	***..***	***52.40***	***32.90***	***Loniten***	***PH***

DIURETICS

Low-ceiling diuretics, thiazides

- ***Thiazides, plain***

HYDROCHLOROTHIAZIDE

1484D	Tablet 25 mg	100	1	..	20.81	21.84	Dithiazide	PL

Low-ceiling diuretics, excl. thiazides

- ***Sulfonamides, plain***

CHLORTHALIDONE

1585K	Tablet 25 mg	100	1	..	* 13.21	14.24	Hygroton 25	LM

CARDIOVASCULAR SYSTEM—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
	INDAPAMIDE HEMIHYDRATE							
8532C	Tablet 1.5 mg (sustained release)	90	1	..	17.85	18.88	Natrilix SR	SE
2436F	Tablet 2.5 mg	90	1	..	17.05	18.08	[a] Chem mart Indapamide	CH
							[a] Dapa-Tabs	AF
							[a] GenRx Indapamide	GX
							[a] Indahexal	SZ
							[a] Insig	SI
							[a] Napamide 2.5 mg	GM
							[a] Terry White Chemists Indapamide	TW
				B2.56	19.61	18.08	[a] Natrilix	SE
	High-ceiling diuretics							
	• ***Sulfonamides, plain***							
	FRUSEMIDE							
2414C	Tablet 20 mg	100	1	..	* 8.59	9.62	Urex-M	FM
				..	8.60	9.63	[a] Chem mart Frusemide	CH
							[a] Frusid	GM
							[a] GenRx Frusemide	GX
							[a] Terry White Chemists Frusemide	TW
				B1.90	* 10.49	9.62	[a] Lasix-M	SW
2412Y	Tablet 40 mg	100	1	..	8.36	9.39	Urex	FM
				..	8.36	9.39	[a] Chem mart Frusemide	CH
							[a] Frusehexal 40 mg	SZ
							[a] Frusid	GM
							[a] GenRx Frusemide	GX
							[a] Terry White Chemists Frusemide	TW
							[a] Uremide	AF
				B2.40	10.76	9.39	[a] Lasix	SW
2415D	Tablet 500 mg	50	3	..	18.31	19.34	Urex-Forte	FM
2411X	Oral solution 10 mg per mL, 30 mL	‡ 1	3	..	16.63	17.66	Lasix	SW
2413B	Injection 20 mg in 2 mL	5	..	..	10.05	11.08	[a] Frusehexal	SZ
							[a] Lasix	SW

CARDIOVASCULAR SYSTEM—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Proprietary Name and Manufacturer	
	• ***Aryloxyacetic acid derivatives***								
	ETHACRYNIC ACID								
	Restricted Benefit								
	Patients hypersensitive to other oral diuretics.								
8748K	***Tablet 25 mg***	***200***	***1***	***..***	**** 57.25***	***32.90***		***Edecrin***	***FK***
	Potassium-sparing agents								
	• ***Aldosterone antagonists***								
	EPLERENONE								
	CAUTION:								
	Serum electrolytes should be checked regularly.								
	Authority Required (STREAMLINED)								
	2637								
	Heart failure with a left ventricular ejection fraction of 40% or less occurring within 3 to 14 days following an acute myocardial infarction. Treatment with eplerenone must be commenced within 14 days of an acute myocardial infarction.								
	The date of the acute myocardial infarction and the date of initiation of eplerenone treatment must be documented in the patient's medical records when PBS-subsidised treatment is initiated.								
8879H	***Tablet 25 mg***	***30***	***5***	***..***	***112.34***	***32.90***		***Inspra***	***PF***
8880J	***Tablet 50 mg***	***30***	***5***	***..***	***112.34***	***32.90***		***Inspra***	***PF***
	SPIRONOLACTONE								
	CAUTION:								
	Serum electrolytes should be checked regularly.								
	CAUTION:								
	Appropriate contraceptive measures should be taken by women of child-bearing age in whom spironolactone therapy has been initiated.								
2339D	Tablet 25 mg	100	5	..	12.06	13.09	a	Spiractin 25	AF
				B1.44	13.50	13.09	a	Aldactone	PH
2340E	Tablet 100 mg	100	5	..	29.89	30.92	a	Spiractin 100	AF
				B1.99	31.88	30.92	a	Aldactone	PH
	• ***Other potassium-sparing agents***								
	AMILORIDE HYDROCHLORIDE								
	CAUTION:								
	Serum electrolytes should be checked regularly.								
3109P	Tablet 5 mg	100	1	..	* 10.55	11.58		Kaluril	AF

CARDIOVASCULAR SYSTEM—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
	Diuretics and potassium-sparing agents in combination							
	• ***Low-ceiling diuretics and potassium-sparing agents***							
	HYDROCHLOROTHIAZIDE with AMILORIDE HYDROCHLORIDE							
	CAUTION:							
	Serum electrolytes should be checked regularly.							
1486F	Tablet 50 mg-5 mg	100	1	..	* 13.45	14.48	Moduretic	MK
	HYDROCHLOROTHIAZIDE with TRIAMTERENE							
	CAUTION:							
	Serum electrolytes should be checked regularly.							
1280J	Tablet 25 mg-50 mg	100	1	..	12.46	13.49	Hydrene 25/50	AF

PERIPHERAL VASODILATORS

Peripheral vasodilators

• ***Other peripheral vasodilators***

PHENOXYBENZAMINE HYDROCHLORIDE

Restricted Benefit

Phaeochromocytoma;

Neurogenic urinary retention.

1862B	***Capsule 10 mg***	***100***	***5***	***..***	***66.93***	***32.90***	***Dibenyline***	***GH***
1166J	***Capsules 10 mg, 30***	***3***	***5***	***..***	**** 204.47***	***32.90***	***Dibenyline***	***GH***
9286R	***Capsules 10 mg, 100***	***‡ 1***	***5***	***..***	***1164.04***	***32.90***	***Dibenzyline***	***GH***

BETA BLOCKING AGENTS

Beta blocking agents

• ***Beta blocking agents, non-selective***

OXPRENOLOL HYDROCHLORIDE

2942W	Tablet 20 mg	100	5	..	9.57	10.60	Corbeton 20	AF
2961W	Tablet 40 mg	100	5	..	11.35	12.38	Corbeton 40	AF
	PINDOLOL							
3062E	Tablet 5 mg	100	5	..	11.05	12.08	[a] Barbloc 5	AF
				B2.71	13.76	12.08	[a] Visken 5	NV
3065H	Tablet 15 mg	50	5	..	13.28	14.31	[a] Barbloc 15	AF
				B2.69	15.97	14.31	[a] Visken 15	NV

CARDIOVASCULAR SYSTEM—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
	PROPRANOLOL HYDROCHLORIDE							
2565B	Tablet 10 mg	100	5	..	9.76	10.79	Deralin 10	AF
				B3.14	12.90	10.79	Inderal	AP
2566C	Tablet 40 mg	100	5	..	10.13	11.16	Deralin 40	AF
				B3.14	13.27	11.16	Inderal	AP
2899N	Tablet 160 mg	50	5	..	10.58	11.61	Deralin 160	AF
	SOTALOL HYDROCHLORIDE							
	For listings see Generic/Proprietary Index							
	• ***Beta blocking agents, selective***							
	ATENOLOL							
1081X	Tablet 50 mg	30	5	..	9.84	10.87	[a] Atehexal	SZ
							[a] Atenolol-GA	GN
							[a] Chem mart Atenolol	CH
							[a] GenRx Atenolol	GX
							[a] Noten	AF
							[a] Tensig	SI
							[a] Terry White Chemists Atenolol	TW
				B3.54	13.38	10.87	[a] Tenormin	AP
	BISOPROLOL FUMARATE							
	Authority Required (STREAMLINED)							
	1734							
	Moderate to severe heart failure in patients stabilised on conventional therapy which must include an ACE-inhibitor if tolerated.							
8604W	***Tablet 2.5 mg***	***28***	***5***	***..***	***55.08***	***32.90***	***Bicor***	***AL***
8605X	***Tablet 5 mg***	***28***	***5***	***..***	***67.32***	***32.90***	***Bicor***	***AL***
8606Y	***Tablet 10 mg***	***28***	***5***	***..***	***82.63***	***32.90***	***Bicor***	***AL***
	METOPROLOL SUCCINATE							
	Authority Required (STREAMLINED)							
	1734							
	Moderate to severe heart failure in patients stabilised on conventional therapy which must include an ACE-inhibitor if tolerated.							
8818D	***Pack containing 15 tablets 23.75 mg (controlled release), 15 tablets 47.5 mg (controlled release) and 15 tablets 95 mg (controlled release)***	***‡ 1***	***..***	***..***	***94.25***	***32.90***	***Toprol-XL Titration Pack***	***AP***

continued ☞

CARDIOVASCULAR SYSTEM—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Proprietary Name and Manufacturer	
8732N	***Tablet 23.75 mg (controlled release)***	***15***	***..***	***..***	***20.61***	***21.64***		***Toprol-XL 23.75***	***AP***
8733P	***Tablet 47.5 mg (controlled release)***	***30***	***5***	***..***	***72.03***	***32.90***		***Toprol-XL 47.5***	***AP***
8734Q	***Tablet 95 mg (controlled release)***	***30***	***5***	***..***	***88.53***	***32.90***		***Toprol-XL 95***	***AP***
8735R	***Tablet 190 mg (controlled release)***	***30***	***5***	***..***	***109.17***	***32.90***		***Toprol-XL 190***	***AP***
	METOPROLOL TARTRATE								
1324Q	Tablet 50 mg	100	5	..	10.41	11.44	a	Chem mart Metoprolol	CH
							a	GenRx Metoprolol	GX
							a	Metohexal	SZ
							a	Metolol	GM
							a	Metrol 50	SI
							a	Minax 50	AF
							a	Terry White Chemists Metoprolol	TW
				B2.35	12.76	11.44		Lopresor 50	NV
				B3.25	13.66	11.44	a	Betaloc	AP
1325R	Tablet 100 mg	60	5	..	11.60	12.63	a	Chem mart Metoprolol	CH
							a	GenRx Metoprolol	GX
							a	Metohexal	SZ
							a	Metolol	GM
							a	Metrol 100	SI
							a	Minax 100	AF
							a	Terry White Chemists Metoprolol	TW
				B2.35	13.95	12.63		Lopresor 100	NV
				B3.25	14.85	12.63	a	Betaloc	AP

CARDIOVASCULAR SYSTEM—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Proprietary Name and Manufacturer	
	• ***Alpha and beta blocking agents***								
	CARVEDILOL								
	Authority Required (STREAMLINED)								
	1734								
	Moderate to severe heart failure in patients stabilised on conventional therapy which must include an ACE-inhibitor if tolerated;								
	1735								
	Patients receiving this drug as a pharmaceutical benefit prior to 1 August 2002.								
8255L	***Tablet 3.125 mg***	***30***	***..***	***..***	***18.53***	***19.56***	[a]	***Chem mart Carvedilol 3.125 mg***	***CH***
							[a]	***Dilasig 3.125***	***SI***
							[a]	***Dilatrend 3.125***	***RO***
							[a]	***GenRx Carvedilol***	***GX***
							[a]	***GN-Carvedilol***	***GM***
							[a]	***Kredex***	***MD***
							[a]	***Terry White Chemists Carvedilol 3.125 mg***	***TW***
							[a]	***Vedilol 3.125***	***ZP***
8256M	***Tablet 6.25 mg***	***60***	***5***	***..***	***62.71***	***32.90***	[a]	***Chem mart Carvedilol 6.25 mg***	***CH***
							[a]	***Dilasig 6.25***	***SI***
							[a]	***Dilatrend 6.25***	***RO***
							[a]	***GenRx Carvedilol***	***GX***
							[a]	***GN-Carvedilol***	***GM***
							[a]	***Kredex***	***MD***
							[a]	***Terry White Chemists Carvedilol 6.25 mg***	***TW***
							[a]	***Vedilol 6.25***	***ZP***

continued ☞

CARDIOVASCULAR SYSTEM—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Proprietary Name and Manufacturer	
8257N	***Tablet 12.5 mg***	***60***	***5***	***..***	***76.87***	***32.90***	[a]	***Chem mart Carvedilol 12.5 mg***	***CH***
							[a]	***Dilasig 12.5***	***SI***
							[a]	***Dilatrend 12.5***	***RO***
							[a]	***GenRx Carvedilol***	***GX***
							[a]	***GN-Carvedilol***	***GM***
							[a]	***Kredex***	***MD***
							[a]	***Terry White Chemists Carvedilol 12.5 mg***	***TW***
							[a]	***Vedilol 12.5***	***ZP***
8258P	***Tablet 25 mg***	***60***	***5***	***..***	***94.60***	***32.90***	[a]	***Chem mart Carvedilol 25 mg***	***CH***
							[a]	***Dilasig 25***	***SI***
							[a]	***Dilatrend 25***	***RO***
							[a]	***GenRx Carvedilol***	***GX***
							[a]	***GN-Carvedilol***	***GM***
							[a]	***Kredex***	***MD***
							[a]	***Terry White Chemists Carvedilol 25 mg***	***TW***
							[a]	***Vedilol 25***	***ZP***
	LABETALOL HYDROCHLORIDE								
1566K	Tablet 100 mg	100	5	..	15.40	16.43	[a]	Presolol 100	AF
				B2.99	18.39	16.43	[a]	Trandate	SI
1567L	Tablet 200 mg	100	5	..	21.48	22.51	[a]	Presolol 200	AF
				B2.97	24.45	22.51	[a]	Trandate	SI

CARDIOVASCULAR SYSTEM—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
	CALCIUM CHANNEL BLOCKERS							
	Selective calcium channel blockers with mainly vascular effects							
	• ***Dihydropyridine derivatives***							
	NOTE: The base-priced drugs in this therapeutic group are amlodipine, felodipine and nifedipine (except nifedipine controlled release tablet 20 mg).							
	AMLODIPINE							
2751T	Tablet 5 mg (as besylate)	30	5	..	16.46	17.49	[a] Amlodipine-GA	GM
							[a] Amlodipine generichealth	GQ
							[a] Amlodipine Sandoz	SZ
							[a] APO-Amlodipine	TX
							[a] Chem mart Amlodipine	CH
							[a] Ozlodip	RA
							[a] Perivasc	AF
							[a] Pharmacor Amlodipine 5	CR
							[a] Terry White Chemists Amlodipine	TW
				B3.05	19.51	17.49	[a] Norvasc	PF
1343Q	Tablet 5 mg (as maleate)	30	5	..	16.46	17.49	[a] Amlo 5	ZP
	NOTE: Bioequivalence has been demonstrated between the tablet containing 5 mg amlodipine (as besylate) and the tablet containing 5 mg amlodipine (as maleate).							
2752W	Tablet 10 mg (as besylate)	30	5	..	24.40	25.43	[a] Amlodipine-GA	GM
							[a] Amlodipine generichealth	GQ
							[a] Amlodipine Sandoz	SZ
							[a] APO-Amlodipine	TX
							[a] Chem mart Amlodipine	CH
							[a] Ozlodip	RA
							[a] Perivasc	AF
							[a] Pharmacor Amlodipine 10	CR
							[a] Terry White Chemists Amlodipine	TW
				B4.45	28.85	25.43	[a] Norvasc	PF
1345T	Tablet 10 mg (as maleate)	30	5	..	24.40	25.43	[a] Amlo 10	ZP
	NOTE: Bioequivalence has been demonstrated between the tablet containing 10 mg amlodipine (as besylate) and the tablet containing 10 mg amlodipine (as maleate).							

CARDIOVASCULAR SYSTEM—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Proprietary Name and Manufacturer	
	FELODIPINE								
2361G	Tablet 2.5 mg (extended release)	30	5	..	13.05	14.08	a	Felodur ER 2.5 mg	AL
				B5.00	18.05	14.08	a	Plendil ER	AP
2366M	Tablet 5 mg (extended release)	30	5	..	15.71	16.74	a	Felodil XR 5	SI
							a	Felodur ER 5 mg	AL
				B5.00	20.71	16.74	a	Plendil ER	AP
2367N	Tablet 10 mg (extended release)	30	5	..	23.38	24.41	a	Felodil XR 10	SI
							a	Felodur ER 10 mg	AL
				B5.00	28.38	24.41	a	Plendil ER	AP
	LERCANIDIPINE HYDROCHLORIDE								
8534E	Tablet 10 mg	30	5	T2.01	22.04	21.06		Zanidip	SM
8679T	Tablet 20 mg	30	5	T4.02	33.04	30.05		Zanidip	SM

LERCANIDIPINE HYDROCHLORIDE

Authority Required

Adverse effects occurring with all of the base-priced drugs;

Drug interactions occurring with all of the base-priced drugs;

Drug interactions expected to occur with all of the base-priced drugs;

Transfer to a base-priced drug would cause patient confusion resulting in problems with compliance.

8939L	***Tablet 10 mg***	***30***	***5***	***..***	***22.04***	***23.07***		***Zanidip***	***SM***
8940M	***Tablet 20 mg***	***30***	***5***	***..***	***33.04***	***32.90***		***Zanidip***	***SM***
	NIFEDIPINE								
1694E	Tablet 10 mg	60	5	..	15.43	16.46	a	Adefin 10	AF
							a	Nypine 10	AW
				B1.17	16.60	16.46	a	Adalat 10	BN
1695F	Tablet 20 mg	60	5	..	17.74	18.77	a	Adefin 20	AF
							a	GenRx Nifedipine	GX
							a	Nifehexal	SZ
							a	Nyefax 20 mg	GM
							a	Nypine 20	AW
				B2.21	19.95	18.77	a	Adalat 20	BN
8610E	Tablet 20 mg (controlled release)	30	5	T2.26	19.97	18.74		Adalat Oros 20mg	BN
1906H	Tablet 30 mg (controlled release)	30	5	..	18.64	19.67	a	Addos XR 30	SI
							a	Adefin XL 30	AF
				B2.54	21.18	19.67	a	Adalat Oros 30	BN

continued ☞

CARDIOVASCULAR SYSTEM—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Proprietary Name and Manufacturer	
1907J	Tablet 60 mg (controlled release)	30	5	..	21.88	22.91	a	Addos XR 60	SI
							a	Adefin XL 60	AF
				B2.81	24.69	22.91	a	Adalat Oros 60	BN

NIFEDIPINE

Authority Required

Adverse effects occurring with all of the base-priced drugs;

Drug interactions occurring with all of the base-priced drugs;

Drug interactions expected to occur with all of the base-priced drugs;

Transfer to a base-priced drug would cause patient confusion resulting in problems with compliance.

8938K	***Tablet 20 mg (controlled release)***	***30***	***5***	***..***	***19.97***	***21.00***		***Adalat Oros 20mg***	***BN***

Selective calcium channel blockers with direct cardiac effects

• *Phenylalkylamine derivatives*

VERAPAMIL HYDROCHLORIDE

CAUTION:

The myocardial depressant effects of this drug and of beta-blocking drugs are additive.

1248Q	Tablet 40 mg	100	5	..	11.08	12.11	a	Anpec 40	AF
				B0.76	11.84	12.11	a	Isoptin	AB
1250T	Tablet 80 mg	100	5	..	15.03	16.06	a	Anpec 80	AF
				B0.76	15.79	16.06	a	Isoptin	AB
1254B	Tablet 120 mg	100	5	..	19.09	20.12		Isoptin	AB
1253Y	Tablet 160 mg	60	5	..	18.01	19.04		Isoptin	AB
2208F	Tablet 180 mg (sustained release)	30	5	..	13.29	14.32	a	Cordilox 180 SR	KN
				B2.27	15.56	14.32	a	Isoptin 180 SR	AB
1241H	Tablet 240 mg (sustained release)	30	5	..	15.72	16.75	a	Anpec SR	AF
							a	Cordilox SR	KN
				B2.26	17.98	16.75	a	Isoptin SR	AB
2206D	Capsule 160 mg (sustained release)	30	5	..	12.02	13.05		Veracaps SR	SI
2207E	Capsule 240 mg (sustained release)	30	5	..	15.81	16.84		Veracaps SR	SI
1060T	Injection 5 mg in 2 mL	5	..	..	11.95	12.98		Isoptin	AB

CARDIOVASCULAR SYSTEM—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
	• *Benzothiazepine derivatives*							
	DILTIAZEM HYDROCHLORIDE							
	CAUTION:							
	The myocardial depressant effects of this drug and of beta-blocking drugs are additive.							
1335G	Tablet 60 mg	90	5	..	15.77	16.80	[a] Cardizem	SW
							[a] Chem mart Diltiazem	CH
							[a] Coras	AF
							[a] Diltahexal	SZ
							[a] Dilzem 60 mg	GM
							[a] GenRx Diltiazem	GX
							[a] Terry White Chemists Diltiazem	TW
							[a] Vasocardol	AV
1312C	Capsule 180 mg (controlled delivery)	30	5	..	16.83	17.86	[a] Cardizem CD	SW
							[a] Chem mart Diltiazem CD	CH
							[a] Diltahexal CD	SZ
							[a] Dilzem CD	GM
							[a] GenRx Diltiazem CD	GX
							[a] Terry White Chemists Diltiazem CD	TW
							[a] Vasocardol CD	AV
1313D	Capsule 240 mg (controlled delivery)	30	5	..	20.64	21.67	[a] Cardizem CD	SW
							[a] Chem mart Diltiazem CD	CH
							[a] Diltahexal CD	SZ
							[a] Dilzem CD	GM
							[a] GenRx Diltiazem CD	GX
							[a] Terry White Chemists Diltiazem CD	TW
							[a] Vasocardol CD	AV
8480H	Capsule 360 mg (controlled delivery)	30	5	..	25.21	26.24	[a] Cardizem CD	SW
							[a] Diltahexal CD	SZ
							[a] Vasocardol CD	AV

CARDIOVASCULAR SYSTEM—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Proprietary Name and Manufacturer	
	AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM								
	ACE inhibitors, plain								
	• ***ACE inhibitors, plain***								
	CAUTION:								
	Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.								
	CAPTOPRIL								
1147J	Tablet 12.5 mg	90	5	..	16.25	17.28	a	Acenorm 12.5 mg	AF
							a	Captohexal	SZ
							a	GenRx Captopril	GX
							a	GM	
1148K	Tablet 25 mg	90	5	..	20.84	21.87	a	Acenorm 25 mg	AF
							a	Captohexal	SZ
							a	GenRx Captopril	GX
							a	GM	
				B3.67	24.51	21.87	a	Capoten	BQ
1149L	Tablet 50 mg	90	5	..	35.27	32.90	a	Acenorm 50 mg	AF
							a	Captohexal	SZ
							a	GenRx Captopril	GX
							a	GM	
				B3.66	38.93	32.90	a	Capoten	BQ
	CAPTOPRIL								
	Restricted Benefit								
	For patients unable to take a solid dose form of an ACE inhibitor.								
8760C	***Oral solution 5 mg per mL, 95 mL***	***‡ 1***	***5***	***..***	***111.39***	***32.90***		***Capoten***	***BQ***
	ENALAPRIL MALEATE								
1370D	Tablet 5 mg	30	5	..	12.71	13.74	a	Alphapril	AF
							a	Auspril	SI
							a	Chem mart Enalapril	CH
							a	Enahexal	SZ
							a	Enalabell	BF
							a	Enalapril-DP 5mg	GM
							a	Enalapril Winthrop	WA
							a	GenRx Enalapril	GX
							a	Terry White Chemists Enalapril	TW
				B2.46	15.17	13.74	a	Renitec M	MK

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CARDIOVASCULAR SYSTEM—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
1368B	Tablet 10 mg	30	5	..	17.02	18.05	[a] Alphapril	AF
							[a] Auspril	SI
							[a] Chem mart Enalapril	CH
							[a] Enahexal	SZ
							[a] Enalabell	BF
							[a] Enalapril-DP 10mg	GM
							[a] Enalapril Winthrop	WA
							[a] GenRx Enalapril	GX
							[a] Terry White Chemists Enalapril	TW
				B2.46	19.48	18.05	[a] Amprace 10	FR
							[a] Renitec	MK
1369C	Tablet 20 mg	30	5	..	20.03	21.06	[a] Alphapril	AF
							[a] Auspril	SI
							[a] Chem mart Enalapril	CH
							[a] Enahexal	SZ
							[a] Enalabell	BF
							[a] Enalapril-DP 20mg	GM
							[a] Enalapril Winthrop	WA
							[a] GenRx Enalapril	GX
							[a] Terry White Chemists Enalapril	TW
				B2.47	22.50	21.06	[a] Amprace 20	FR
							[a] Renitec 20	MK
	FOSINOPRIL SODIUM							
1182F	Tablet 10 mg	30	5	..	15.22	16.25	[a] Fosinopril Sandoz	SZ
							[a] Fosinopril Winthrop	WA
							[a] Fosipril 10	SI
							[a] GenRx Fosinopril	GX
							[a] Monace 10	AF
							[a] Monopril	BQ
1183G	Tablet 20 mg	30	5	..	19.82	20.85	[a] Fosinopril Sandoz	SZ
							[a] Fosinopril Winthrop	WA
							[a] Fosipril 20	SI
							[a] GenRx Fosinopril	GX
							[a] Monace 20	AF
							[a] Monopril	BQ

CARDIOVASCULAR SYSTEM—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
	LISINOPRIL							
2456G	Tablet 5 mg	30	5	..	13.70	14.73	[a] APO-Lisinopril	TX
							[a] Chem mart Lisinopril	CH
							[a] Fibsol 5	SI
							[a] GenRx Lisinopril	GX
							[a] Liprace	GM
							[a] Lisinobell	BF
							[a] Lisinopril 5	CR
							[a] Lisinopril generichealth	GQ
							[a] Lisinopril Hexal	HX
							[a] Lisinopril Winthrop	WA
							[a] Lisodur	AF
							[a] Terry White Chemists Lisinopril	TW
				[B]1.52	15.22	14.73	[a] Prinivil 5	MK
				[B]2.08	15.78	14.73	[a] Zestril	AP
2457H	Tablet 10 mg	30	5	..	17.56	18.59	[a] Chem mart Lisinopril	CH
							[a] Fibsol 10	SI
							[a] GenRx Lisinopril	GX
							[a] Liprace	GM
							[a] Lisinobell	BF
							[a] Lisinopril 10	CR
							[a] Lisinopril generichealth	GQ
							[a] Lisinopril Hexal	HX
							[a] Lisinopril Winthrop	WA
							[a] Lisodur	AF
							[a] Terry White Chemists Lisinopril	TW
				[B]1.53	19.09	18.59	[a] Prinivil 10	MK
				[B]2.08	19.64	18.59	[a] Zestril	AP

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CARDIOVASCULAR SYSTEM—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
2458J	Tablet 20 mg	30	5	..	20.56	21.59	[a] APO-Lisinopril	TX
							[a] Chem mart Lisinopril	CH
							[a] Fibsol 20	SI
							[a] GenRx Lisinopril	GX
							[a] Liprace	GM
							[a] Lisinobell	BF
							[a] Lisinopril 20	CR
							[a] Lisinopril generichealth	GQ
							[a] Lisinopril Hexal	HX
							[a] Lisinopril Winthrop	WA
							[a] Lisodur	AF
							[a] Terry White Chemists Lisinopril	TW
				[B]1.53	22.09	21.59	[a] Prinivil 20	MK
				[B]2.08	22.64	21.59	[a] Zestril	AP
	PERINDOPRIL							
3050M	Tablet containing 2 mg perindopril erbumine	30	5	..	12.96	13.99	[a] Chem mart Perindopril	CH
							[a] GenRx Perindopril	GX
							[a] Indopril 2	SI
							[a] Perindo	AF
							[a] Perindopril 2	CR
							[a] Perindopril-DP	GM
							[a] Terry White Chemists Perindopril	TW
9006B	Tablet containing 2.5 mg perindopril arginine	30	5	..	12.96	13.99	[a] Coversyl 2.5mg	SE
	NOTE: Bioequivalence has been demonstrated between perindopril erbumine 2 mg and perindopril arginine 2.5 mg.							
3051N	Tablet containing 4 mg perindopril erbumine	30	5	..	18.64	19.67	[a] Chem mart Perindopril	CH
							[a] GenRx Perindopril	GX
							[a] Indopril 4	SI
							[a] Perindo	AF
							[a] Perindopril 4	CR
							[a] Perindopril-DP	GM
							[a] Terry White Chemists Perindopril	TW
9007C	Tablet containing 5 mg perindopril arginine	30	5	..	18.64	19.67	[a] Coversyl 5mg	SE

continued ☞

CARDIOVASCULAR SYSTEM—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
	NOTE: Bioequivalence has been demonstrated between perindopril erbumine 4 mg and perindopril arginine 5 mg.							
8704D	Tablet containing 8 mg perindopril erbumine	30	5	..	25.16	26.19	[a] Chem mart Perindopril	CH
							[a] GenRx Perindopril	GX
							[a] Indopril 8	SI
							[a] Perindo	AF
							[a] Perindopril 8	CR
							[a] Perindopril-DP	GM
							[a] Terry White Chemists Perindopril	TW
9008D	Tablet containing 10 mg perindopril arginine	30	5	..	25.16	26.19	[a] Coversyl 10mg	SE
	NOTE: Bioequivalence has been demonstrated between perindopril erbumine 8 mg and perindopril arginine 10 mg.							
	QUINAPRIL HYDROCHLORIDE							
1968N	Tablet 5 mg (base)	30	5	..	13.75	14.78	[a] Acquin 5	SI
							[a] APO-Quinapril	TX
							[a] Filpril	AF
							[a] Pharmacor Quinapril 5	CR
							[a] Quinapril-DP	GM
							[a] Quinapril generichealth	GQ
							[a] Quinapril Sandoz	SZ
				[B]0.38	14.13	14.78	[a] Accupril	PF
1969P	Tablet 10 mg (base)	30	5	..	17.00	18.03	[a] Acquin 10	SI
							[a] APO-Quinapril	TX
							[a] Filpril	AF
							[a] Pharmacor Quinapril 10	CR
							[a] Quinapril-DP	GM
							[a] Quinapril generichealth	GQ
				[B]0.52	17.52	18.03	[a] Accupril	PF
1970Q	Tablet 20 mg (base)	30	5	..	19.61	20.64	[a] Acquin 20	SI
							[a] APO-Quinapril	TX
							[a] Filpril	AF
							[a] Pharmacor Quinapril 20	CR
							[a] Quinapril-DP	GM
							[a] Quinapril generichealth	GQ
							[a] Quinapril Sandoz	SZ
				[B]0.77	20.38	20.64	[a] Accupril	PF

CARDIOVASCULAR SYSTEM—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
	RAMIPRIL							
1944H	Tablet 1.25 mg	30	5	..	11.17	12.20	[a] Prilace 1.25	SI
							[a] Ramace 1.25 mg	AV
							[a] Ramipril Sandoz	SZ
							[a] Ramipril Winthrop	WA
							[a] Tritace 1.25 mg	SW
							[a] Tryzan Tabs 1.25	AF
9120B	Capsule 1.25 mg	30	5	..	11.17	12.20	[a] Pharmacor Ramipril 1.25	CR
							[a] Ramipril-DP	GM
							[a] Ramipril generichealth	GQ
							[a] Tryzan Caps 1.25	AF
	NOTE: Ramipril 1.25 mg tablets and capsules are bioequivalent.							
1945J	Tablet 2.5 mg	30	5	..	13.57	14.60	[a] Prilace 2.5	SI
							[a] Ramace 2.5 mg	AV
							[a] Ramipril Sandoz	SZ
							[a] Ramipril Winthrop	WA
							[a] Tritace 2.5 mg	SW
							[a] Tryzan Tabs 2.5	AF
9121C	Capsule 2.5 mg	30	5	..	13.57	14.60	[a] Pharmacor Ramipril 2.5	CR
							[a] Ramipril-DP	GM
							[a] Ramipril generichealth	GQ
							[a] Tryzan Caps 2.5	AF
	NOTE: Ramipril 2.5 mg tablets and capsules are bioequivalent.							
1946K	Tablet 5 mg	30	5	..	15.50	16.53	[a] Prilace 5	SI
							[a] Ramace 5 mg	AV
							[a] Ramipril Sandoz	SZ
							[a] Ramipril Winthrop	WA
							[a] Tritace 5 mg	SW
							[a] Tryzan Tabs 5	AF
9122D	Capsule 5 mg	30	5	..	15.50	16.53	[a] Pharmacor Ramipril 5	CR
							[a] Ramipril-DP	GM
							[a] Ramipril generichealth	GQ
							[a] Tryzan Caps 5	AF
	NOTE: Ramipril 5 mg tablets and capsules are bioequivalent.							

continued ☞

CARDIOVASCULAR SYSTEM—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
1316G	Tablet 10 mg	30	5	..	22.80	23.83	[a] Ramipril Sandoz	SZ
							[a] Tritace	SW
							[a] Tryzan Tabs 10	AF
8470T	Capsule 10 mg	30	5	..	22.80	23.83	[a] GenRx Ramipril	GX
							[a] Pharmacor Ramipril 10	CR
							[a] Prilace 10	SI
							[a] Ramace 10 mg	AV
							[a] Ramipril-DP	GM
							[a] Ramipril generichealth	GQ
							[a] Ramipril Sandoz	SZ
							[a] Ramipril Winthrop	WA
							[a] Tritace 10 mg	SW
							[a] Tryzan Caps 10	AF
	NOTE: Ramipril 10 mg tablets and capsules are bioequivalent.							
8668F	Pack containing 7 tablets 2.5 mg, 21 tablets 5 mg and 10 capsules 10 mg	‡ 1	..	..	21.60	22.63	Tritace Titration Pack	SW
	TRANDOLAPRIL							
2791X	Capsule 500 micrograms	28	5	..	9.87	10.90	[a] APO-Trandolapril	TX
							[a] Dolapril 0.5	SI
							[a] Tranalpha	AF
							[a] Trandolapril-DP	GM
				B1.57	11.44	10.90	[a] Gopten	AB
2792Y	Capsule 1 mg	28	5	..	14.64	15.67	[a] APO-Trandolapril	TX
							[a] Dolapril 1	SI
							[a] Tranalpha	AF
							[a] Trandolapril-DP	GM
				B1.57	16.21	15.67	[a] Gopten	AB
2793B	Capsule 2 mg	28	5	..	15.80	16.83	[a] APO-Trandolapril	TX
							[a] Dolapril 2	SI
							[a] Tranalpha	AF
							[a] Trandolapril-DP	GM
				B1.58	17.38	16.83	[a] Gopten	AB
8758Y	Capsule 4 mg	28	5	..	24.23	25.26	[a] APO-Trandolapril	TX
							[a] Dolapril 4	SI
							[a] Tranalpha	AF
							[a] Trandolapril-DP	GM
				B1.57	25.80	25.26	[a] Gopten	AB

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
	ACE inhibitors, combinations							
	CAUTION: Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.							
	• ***ACE inhibitors and diuretics***							
	ENALAPRIL MALEATE with HYDROCHLOROTHIAZIDE							
	Restricted Benefit ***Hypertension in patients who are not adequately controlled with 20 mg enalapril maleate.***							
8477E	***Tablet 20 mg-6 mg***	***30***	***5***	***..***	***28.50***	***29.53***	[a] ***Enalapril/HCT Sandoz***	***SZ***
							[a] ***Renitec Plus 20/6***	***MK***
	FOSINOPRIL SODIUM with HYDROCHLOROTHIAZIDE							
	Restricted Benefit ***Hypertension in patients who are not adequately controlled with either hydrochlorothiazide or fosinopril sodium monotherapy.***							
8400D	***Tablet 10 mg-12.5 mg***	***30***	***5***	***..***	***21.83***	***22.86***	[a] ***APO-Fosinopril HCTZ 10/12.5***	***TX***
							[a] ***Fosinopril/HCT Sandoz 10mg/ 12.5mg***	***SZ***
							[a] ***Fosinopril/HCT Winthrop 10mg/ 12.5mg***	***WA***
							[a] ***Hyforil***	***RA***
							[a] ***Monoplus 10/12.5***	***BQ***
8401E	***Tablet 20 mg-12.5 mg***	***30***	***5***	***..***	***29.24***	***30.27***	[a] ***APO-Fosinopril HCTZ 20/12.5***	***TX***
							[a] ***Fosetic 20/12.5***	***ZP***
							[a] ***Fosinopril/HCT Sandoz 20mg/ 12.5mg***	***SZ***
							[a] ***Fosinopril/HCT Winthrop 20mg/ 12.5mg***	***WA***
							[a] ***Hyforil***	***RA***
							[a] ***Monoplus 20/12.5***	***BQ***
	PERINDOPRIL with INDAPAMIDE HEMIHYDRATE							
2190G	Tablet containing 2.5 mg perindopril arginine-0.625 mg indapamide hemihydrate	30	5	..	16.31	17.34	Coversyl Plus LD 2.5mg/0.625mg	SE

continued ☞

CARDIOVASCULAR SYSTEM—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
	PERINDOPRIL with INDAPAMIDE HEMIHYDRATE							
	Restricted Benefit ***Hypertension in patients who are not adequately controlled with indapamide and/or perindopril.***							
8449Q	***Tablet containing 4 mg perindopril erbumine-1.25 mg indapamide hemihydrate***	***30***	***5***	***..***	***29.15***	***30.18***	[a] ***Chem mart Perindopril/ Indapamide 4/ 1.25***	***CH***
							[a] ***GenRx Perindopril/ Indapamide 4/ 1.25***	***GX***
							[a] ***Perindo Combi 4/ 1.25***	***AF***
							[a] ***Terry White Chemists Perindopril/ Indapamide 4/ 1.25***	***TW***
2845R	***Tablet containing 5 mg perindopril arginine-1.25 mg indapamide hemihydrate***	***30***	***5***	***..***	***29.15***	***30.18***	[a] ***Coversyl Plus 5mg/ 1.25mg***	***SE***
	NOTE: ***Bioequivalence has been demonstrated between perindopril erbumine/indapamide hemihydrate tablet 4 mg-1.25 mg and perindopril arginine/indapamide hemihydrate tablet 5 mg-1.25 mg.***							
	QUINAPRIL HYDROCHLORIDE with HYDROCHLOROTHIAZIDE							
	Restricted Benefit ***Hypertension in patients who are not adequately controlled with either hydrochlorothiazide or quinapril hydrochloride monotherapy.***							
8589C	***Tablet 10 mg (base)-12.5 mg***	***30***	***5***	***..***	***19.22***	***20.25***	***Accuretic 10/ 12.5mg***	***PF***
8590D	***Tablet 20 mg (base)-12.5 mg***	***30***	***5***	***..***	***21.83***	***22.86***	***Accuretic 20/ 12.5mg***	***PF***
	• ***ACE inhibitors and calcium channel blockers*** ***LERCANIDIPINE HYDROCHLORIDE with ENALAPRIL MALEATE***							
	Restricted Benefit ***Hypertension in a patient who is not adequately controlled with either lercanidipine hydrochloride or enalapril maleate monotherapy.***							
9144G	***Tablet 10 mg-10 mg***	***30***	***5***	***..***	***31.06***	***32.09***	***Zan-Extra 10/10***	***SM***
9145H	***Tablet 10 mg-20 mg***	***30***	***5***	***..***	***34.07***	***32.90***	***Zan-Extra 10/20***	***SM***

CARDIOVASCULAR SYSTEM—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
	RAMIPRIL with FELODIPINE							
	Restricted Benefit							
	Hypertension in a patient not adequately controlled with either ramipril or felodipine monotherapy.							
2626F	***Tablet 2.5 mg-2.5 mg (modified release)***	***30***	***5***	***..***	***20.63***	***21.66***	***Triasyn 2.5/2.5***	***SW***
2629J	***Tablet 5 mg-5 mg (modified release)***	***30***	***5***	***..***	***25.22***	***26.25***	***Triasyn 5.0/5.0***	***SW***
	TRANDOLAPRIL with VERAPAMIL HYDROCHLORIDE							
	CAUTION:							
	The myocardial depressant effects of verapamil hydrochloride and of beta-blocking drugs are additive.							
	Restricted Benefit							
➢	***Hypertension in a patient who is not adequately controlled with either trandolapril or verapamil hydrochloride sustained release monotherapy.***							
9387C	***Tablet 2 mg-180 mg (sustained release)***	***28***	***5***	***..***	***22.95***	***23.98***	***Tarka 2/180***	***AB***
2857J	***Tablet 4 mg-240 mg (sustained release)***	***28***	***5***	***..***	***33.31***	***32.90***	***Tarka 4/240***	***AB***
	Angiotensin II antagonists, plain							
	• ***Angiotensin II antagonists, plain***							
	CANDESARTAN CILEXETIL							
8295N	Tablet 4 mg	30	5	..	20.49	21.52	Atacand	AP
8296P	Tablet 8 mg	30	5	..	24.30	25.33	Atacand	AP
8297Q	Tablet 16 mg	30	5	..	30.13	31.16	Atacand	AP
8889W	Tablet 32 mg	30	5	..	46.19	32.90	Atacand	AP
	EPROSARTAN MESYLATE							
8397Y	Tablet 400 mg (base)	56	5	T1.52	* 32.17	31.68	Teveten	SM
8447N	Tablet 600 mg (base)	28	5	..	30.60	31.63	Teveten	SM
	EPROSARTAN MESYLATE							
	Authority Required							
	Adverse effects occurring with all of the base-priced drugs;							
	Drug interactions occurring with all of the base-priced drugs;							
	Drug interactions expected to occur with all of the base-priced drugs;							
	Transfer to a base-priced drug would cause patient confusion resulting in problems with compliance.							
8951D	***Tablet 400 mg (base)***	***56***	***5***	***..***	**** 32.17***	***32.90***	***Teveten***	***SM***

CARDIOVASCULAR SYSTEM—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
	IRBESARTAN							
8246B	Tablet 75 mg	30	5	..	20.68	21.71	[a] Avapro [a] Karvea	BQ SW
8247C	Tablet 150 mg	30	5	..	24.72	25.75	[a] Avapro [a] Karvea	BQ SW
8248D	Tablet 300 mg	30	5	..	29.81	30.84	[a] Avapro [a] Karvea	BQ SW
	OLMESARTAN MEDOXOMIL							
2147B	Tablet 20 mg	30	5	..	24.72	25.75	Olmetec	SH
2148C	Tablet 40 mg	30	5	..	29.81	30.84	Olmetec	SH
	TELMISARTAN							
8355R	Tablet 40 mg	28	5	..	21.23	22.26	Micardis	BY
8356T	Tablet 80 mg	28	5	..	28.48	29.51	Micardis	BY
	VALSARTAN							
9368C	Tablet 40 mg	28	..	..	15.58	16.61	Diovan	NV
9369D	Tablet 80 mg	28	5	..	19.70	20.73	Diovan	NV
9370E	Tablet 160 mg	28	5	..	23.47	24.50	Diovan	NV
9371F	Tablet 320 mg	28	5	..	28.22	29.25	Diovan	NV

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

Angiotensin II antagonists, combinations

• *Angiotensin II antagonists and diuretics*

CANDESARTAN CILEXETIL with HYDROCHLOROTHIAZIDE

Restricted Benefit
Hypertension in patients who are not adequately controlled with 16 mg candesartan cilexetil.

8504N	***Tablet 16 mg-12.5 mg***	***30***	***5***	***..***	***32.36***	***32.90***	***Atacand Plus 16/ 12.5***	***AP***

EPROSARTAN MESYLATE with HYDROCHLOROTHIAZIDE

Restricted Benefit
Hypertension in patients who are not adequately controlled with either hydrochlorothiazide or eprosartan mesylate monotherapy.

8624X	***Tablet 600 mg (base)-12.5 mg***	***28***	***5***	***..***	***32.69***	***32.90***	***Teveten Plus 600/ 12.5***	***SM***

CARDIOVASCULAR SYSTEM—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
	IRBESARTAN with HYDROCHLOROTHIAZIDE							
	Restricted Benefit ***Hypertension in patients who are not adequately controlled with either hydrochlorothiazide or irbesartan monotherapy.***							
8404H	***Tablet 150 mg-12.5 mg***	***30***	***5***	***..***	***26.94***	***27.97***	[a] ***Avapro HCT 150/12.5***	***BQ***
							[a] ***Karvezide 150/12.5***	***SW***
8405J	***Tablet 300 mg-12.5 mg***	***30***	***5***	***..***	***32.03***	***32.90***	[a] ***Avapro HCT 300/12.5***	***BQ***
							[a] ***Karvezide 300/12.5***	***SW***
2136K	***Tablet 300 mg-25 mg***	***30***	***5***	***..***	***34.26***	***32.90***	[a] ***Avapro HCT 300/25***	***BQ***
							[a] ***Karvezide 300/25***	***SW***
	OLMESARTAN MEDOXOMIL with HYDROCHLOROTHIAZIDE							
	Restricted Benefit ***Hypertension in patients who are not adequately controlled with either hydrochlorothiazide or olmesartan medoxomil monotherapy.***							
2161R	***Tablet 20 mg-12.5 mg***	***30***	***5***	***..***	***26.93***	***27.96***	***Olmetec Plus***	***SH***
2166B	***Tablet 40 mg-12.5 mg***	***30***	***5***	***..***	***32.01***	***32.90***	***Olmetec Plus***	***SH***
2170F	***Tablet 40 mg-25 mg***	***30***	***5***	***..***	***34.26***	***32.90***	***Olmetec Plus***	***SH***
	TELMISARTAN with HYDROCHLOROTHIAZIDE							
	Restricted Benefit ***Hypertension in patients who are not adequately controlled with either hydrochlorothiazide or telmisartan monotherapy.***							
8622T	***Tablet 40 mg-12.5 mg***	***28***	***5***	***..***	***23.30***	***24.33***	***Micardis Plus 40/12.5 mg***	***BY***
8623W	***Tablet 80 mg-12.5 mg***	***28***	***5***	***..***	***30.55***	***31.58***	***Micardis Plus 80/12.5 mg***	***BY***
9381R	***Tablet 80 mg-25 mg***	***28***	***5***	***..***	***32.64***	***32.90***	***Micardis Plus 80/25 mg***	***BY***
	VALSARTAN with HYDROCHLOROTHIAZIDE							
	Restricted Benefit ***Hypertension in patients who are not adequately controlled with either hydrochlorothiazide or valsartan monotherapy.***							
9372G	***Tablet 80 mg-12.5 mg***	***28***	***5***	***..***	***21.78***	***22.81***	***Co-Diovan 80/12.5***	***NV***
9373H	***Tablet 160 mg-12.5 mg***	***28***	***5***	***..***	***25.55***	***26.58***	***Co-Diovan 160/12.5***	***NV***

continued ☞

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
9374J	***Tablet 160 mg-25 mg***	***28***	***5***	***..***	***27.63***	***28.66***	***Co-Diovan 160/25***	***NV***

- ***Angiotensin II antagonists and calcium channel blockers***

AMLODIPINE with VALSARTAN

Restricted Benefit

Hypertension in patients who are not adequately controlled with either amlodipine or valsartan monotherapy.

9375K	***Tablet 5 mg (as besylate)-80 mg***	***28***	***5***	***..***	***29.47***	***30.50***	***Exforge 5/80***	***NV***
9376L	***Tablet 5 mg (as besylate)-160 mg***	***28***	***5***	***..***	***33.25***	***32.90***	***Exforge 5/160***	***NV***
9377M	***Tablet 10 mg (as besylate)-160 mg***	***28***	***5***	***..***	***40.64***	***32.90***	***Exforge 10/160***	***NV***

LIPID MODIFYING AGENTS

GENERAL STATEMENT FOR LIPID-LOWERING DRUGS PRESCRIBED AS PHARMACEUTICAL BENEFITS

Use the following criteria to determine patient eligibility for subsidisation under the PBS for the following drugs:

- atorvastatin calcium
- fluvastatin sodium
- pravastatin sodium
- rosuvastatin calcium
- simvastatin
- fenofibrate
- gemfibrozil

By writing a PBS prescription, the prescriber is certifying the patient satisfies the qualifying criteria set out below and the use is in accordance with the registered indications which differ between agents in this class - refer to the current Product Information for details. Note also that patients already established on a particular lipid-lowering drug, where use satisfies the PBS qualifying criteria, but is outside the registered indications for that drug, are not required to switch to another drug in the class to retain PBS eligibility.

Patients in very high risk categories (see below) may commence drug therapy with statins or fibrates immediately (ie simultaneously with an appropriate diet). For all other patients, dietary therapy should be trialled prior to initiation of drug therapy.

continued ☞

CARDIOVASCULAR SYSTEM—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer

Dietary therapy should be continued concurrently with pharmacological therapy and should be reviewed on at least an annual basis.

Patients identified as being in one of the following very high risk categories may commence drug therapy with statins or fibrates at any cholesterol level:

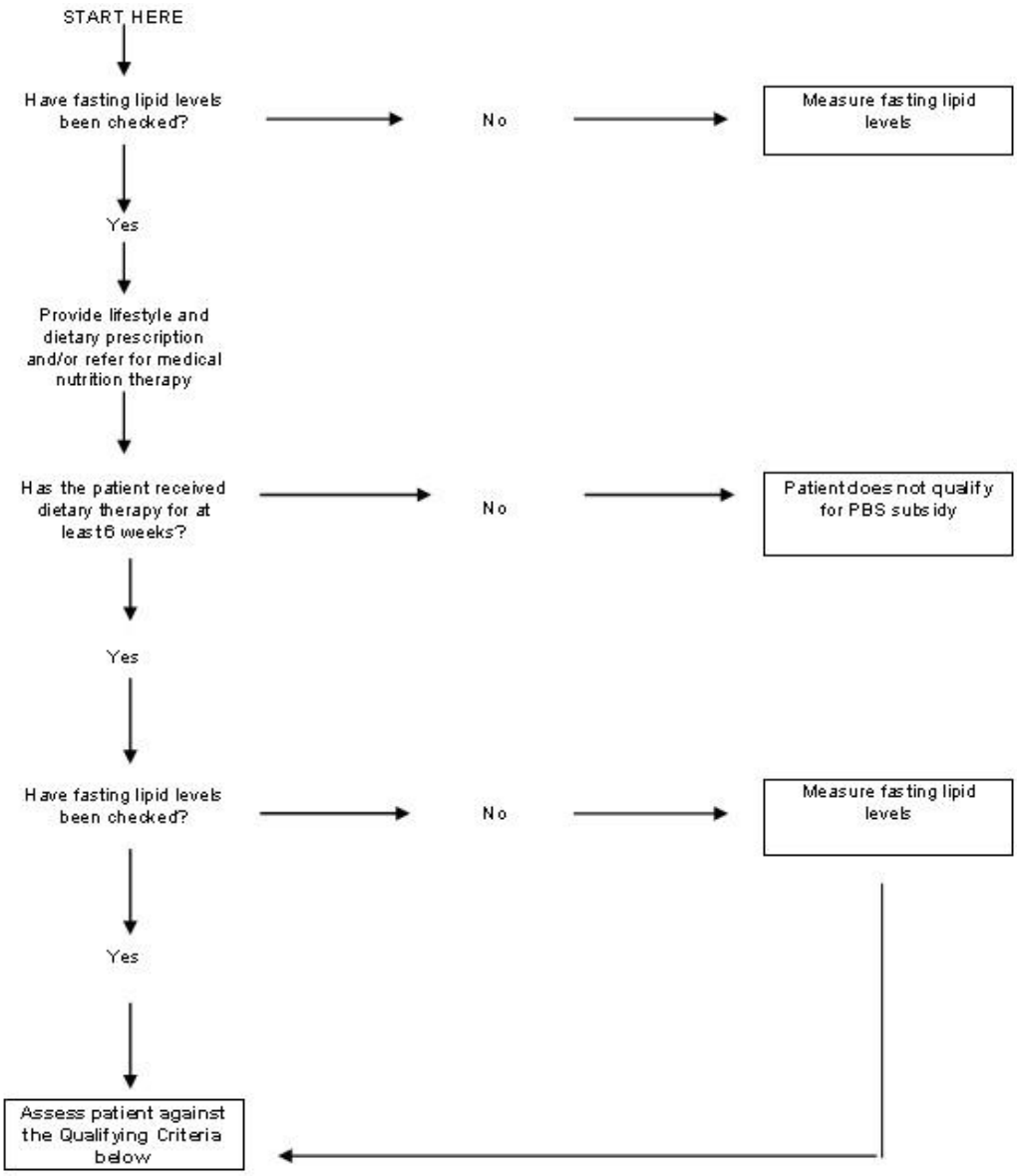
- coronary heart disease which has become symptomatic
- cerebrovascular disease which has become symptomatic
- peripheral vascular disease which has become symptomatic
- diabetes mellitus with microalbuminuria (defined as urinary albumin excretion rate of >20mcg/min or urinary albumin to creatinine ratio of > 2.5 for males, > 3.5 for females)
- diabetes mellitus in Aboriginal or Torres Strait Islander patients
- diabetes mellitus in patients aged 60 years or more
- family history of coronary heart disease which has become symptomatic before the age of 55 years in two or more first degree relatives
- family history of coronary heart disease which has become symptomatic before the age of 45 years in one or more first degree relatives

If your patient is not identified as being in any of the above very high risk categories, then use the flow-chart and table below to determine whether your patient satisfies the following criteria for subsidisation under the PBS. Document how the patient meets each of these steps in the patient record. Lipid levels must be measured at an accredited laboratory.

continued ☞

CARDIOVASCULAR SYSTEM—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer



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Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer

POST-DIETARY QUALIFYING CRITERIA

Dietary therapy should be continued concurrently with pharmacological therapy and should be reviewed on at least an annual basis.

PATIENT CATEGORY	LIPID LEVELS FOR PBS SUBSIDY
Patients with diabetes mellitus not otherwise included	total cholesterol > 5.5 mmol/L
Aboriginal or Torres Strait Islander patients Patients with hypertension	total cholesterol > 6.5 mmol/L or total cholesterol > 5.5 mmol/L and HDL cholesterol < 1 mmol/L
Patients with HDL cholesterol < 1 mmol/L	total cholesterol > 6.5 mmol/L
Patients with familial hypercholesterolaemia identified by: • DNA mutation; or • tendon xanthomas in the patient or their first or second degree relative Patients with: • family history of coronary heart disease which has become symptomatic before the age of 60 years in one or more first degree relatives; or • family history of coronary heart disease which has become symptomatic before the age of 50 years in one or more second degree relatives	If aged 18 years or less at treatment initiation: LDL cholesterol > 4 mmol/L If aged more than 18 years at treatment initiation: LDL cholesterol > 5 mmol/L or total cholesterol > 6.5 mmol/L or total cholesterol > 5.5 mmol/L and HDL cholesterol < 1 mmol/L

continued ☞

CARDIOVASCULAR SYSTEM—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	

Patients not eligible under the above:

- men aged 35 to 75 years
- post-menopausal women aged up to 75 years

total cholesterol > 7.5 mmol/L
or
triglyceride > 4 mmol/L

Patients not otherwise included

total cholesterol > 9 mmol/L
or
triglyceride > 8 mmol/L

Lipid modifying agents, plain

- ***HMG CoA reductase inhibitors***

ATORVASTATIN CALCIUM

Restricted Benefit

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

8213G	***Tablet 10 mg (atorvastatin)***	***30***	***5***	***..***	***42.27***	***32.90***	***Lipitor***	***PF***
8214H	***Tablet 20 mg (atorvastatin)***	***30***	***5***	***..***	***57.57***	***32.90***	***Lipitor***	***PF***
8215J	***Tablet 40 mg (atorvastatin)***	***30***	***5***	***..***	***78.62***	***32.90***	***Lipitor***	***PF***
8521L	***Tablet 80 mg (atorvastatin)***	***30***	***5***	***..***	***109.82***	***32.90***	***Lipitor***	***PF***

Restricted Benefit

For use in patients who meet the criteria set out in the General Statement for Lipid-Lowering Drugs, and who are receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements.

NOTE:

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

9230T	***Tablet 10 mg (atorvastatin)***	***30***	***11***	***..***	***42.27***	***32.90***	***Lipitor***	***PF***
9231W	***Tablet 20 mg (atorvastatin)***	***30***	***11***	***..***	***57.57***	***32.90***	***Lipitor***	***PF***
9232X	***Tablet 40 mg (atorvastatin)***	***30***	***11***	***..***	***78.62***	***32.90***	***Lipitor***	***PF***
9233Y	***Tablet 80 mg (atorvastatin)***	***30***	***11***	***..***	***109.82***	***32.90***	***Lipitor***	***PF***

CARDIOVASCULAR SYSTEM—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Proprietary Name and Manufacturer	
	FLUVASTATIN SODIUM								
	Restricted Benefit ***For use in patients that meet the criteria set out in the General Statement for Lipid-Lowering Drugs.***								
8023G	***Capsule 20 mg (fluvastatin)***	***28***	***5***	***..***	***26.22***	***27.25***	***a***	***Lescol***	***NV***
				B3.28	***29.50***	***27.25***	***a***	***Vastin***	***NM***
8024H	***Capsule 40 mg (fluvastatin)***	***28***	***5***	***..***	***30.78***	***31.81***	***a***	***Lescol***	***NV***
				B3.58	***34.36***	***31.81***	***a***	***Vastin***	***NM***
2863Q	***Tablet 80 mg (fluvastatin) (prolonged release)***	***28***	***5***	***..***	***47.14***	***32.90***		***Lescol XL***	***NV***
	Restricted Benefit ***For use in patients who meet the criteria set out in the General Statement for Lipid-Lowering Drugs, and who are receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements.*** **NOTE:** ***No applications for increased maximum quantities and/or repeats will be authorised.***								
9234B	***Capsule 20 mg (fluvastatin)***	***28***	***11***	***..***	***26.22***	***27.25***	***a***	***Lescol***	***NV***
				B3.28	***29.50***	***27.25***	***a***	***Vastin***	***NM***
9235C	***Capsule 40 mg (fluvastatin)***	***28***	***11***	***..***	***30.78***	***31.81***	***a***	***Lescol***	***NV***
				B3.58	***34.36***	***31.81***	***a***	***Vastin***	***NM***
9236D	***Tablet 80 mg (fluvastatin) (prolonged release)***	***28***	***11***	***..***	***47.14***	***32.90***		***Lescol XL***	***NV***

CARDIOVASCULAR SYSTEM—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Proprietary Name and Manufacturer	
	PRAVASTATIN SODIUM								
	Restricted Benefit								
	For use in patients that meet the criteria set out in the General Statement for Lipid-Lowering Drugs.								
2833D	***Tablet 10 mg***	***30***	***5***	***..***	***21.23***	***22.26***	[a]	***Chem mart Pravastatin***	***CH***
							[a]	***Cholstat 10***	***AF***
							[a]	***GenRx Pravastatin***	***GX***
							[a]	***Lipostat 10***	***SI***
							[a]	***Liprachol***	***SZ***
							[a]	***Pravastatin 10***	***CR***
							[a]	***Pravastatin-DP***	***GM***
							[a]	***Pravastatin-GA 10***	***GN***
							[a]	***Pravastatin generichealth***	***GQ***
							[a]	***Pravastatin Winthrop***	***WA***
							[a]	***Terry White Chemists Pravastatin***	***TW***
				B3.52	***24.75***	***22.26***	[a]	***Pravachol***	***BQ***
2834E	***Tablet 20 mg***	***30***	***5***	***..***	***30.20***	***31.23***	[a]	***Chem mart Pravastatin***	***CH***
							[a]	***Cholstat 20***	***AF***
							[a]	***GenRx Pravastatin***	***GX***
							[a]	***Lipostat 20***	***SI***
							[a]	***Liprachol***	***SZ***
							[a]	***Pravastatin 20***	***CR***
							[a]	***Pravastatin-DP***	***GM***
							[a]	***Pravastatin-GA 20***	***GN***
							[a]	***Pravastatin generichealth***	***GQ***
							[a]	***Pravastatin Winthrop***	***WA***
							[a]	***Terry White Chemists Pravastatin***	***TW***
							[a]	***Vastoran***	***RA***
				B3.52	***33.72***	***31.23***	[a]	***Pravachol***	***BQ***

continued ☞

CARDIOVASCULAR SYSTEM—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Proprietary Name and Manufacturer	
8197K	***Tablet 40 mg***	***30***	***5***	***..***	***43.27***	***32.90***	[a]	***Chem mart Pravastatin***	***CH***
							[a]	***Cholstat 40***	***AF***
							[a]	***GenRx Pravastatin***	***GX***
							[a]	***Lipostat 40***	***SI***
							[a]	***Liprachol***	***SZ***
							[a]	***Pravastatin 40***	***CR***
							[a]	***Pravastatin-DP***	***GM***
							[a]	***Pravastatin-GA 40***	***GN***
							[a]	***Pravastatin generichealth***	***GQ***
							[a]	***Pravastatin Winthrop***	***WA***
							[a]	***Terry White Chemists Pravastatin***	***TW***
							[a]	***Vastoran***	***RA***
				B3.07	***46.34***	***32.90***	[a]	***Pravachol***	***BQ***
8829Q	***Tablet 80 mg***	***30***	***5***	***..***	***61.28***	***32.90***	[a]	***APO-Pravastatin***	***TX***
							[a]	***Chem mart Pravastatin***	***CH***
							[a]	***Lipostat 80***	***SI***
							[a]	***Pravastatin-GA 80***	***GN***
							[a]	***Pravastatin generichealth***	***GQ***
							[a]	***Terry White Chemists Pravastatin***	***TW***
				B3.37	***64.65***	***32.90***	[a]	***Pravachol***	***BQ***

continued ☞

CARDIOVASCULAR SYSTEM—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Proprietary Name and Manufacturer	
	Restricted Benefit ***For use in patients who meet the criteria set out in the General Statement for Lipid-Lowering Drugs, and who are receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements.*** **NOTE:** ***No applications for increased maximum quantities and/or repeats will be authorised.***								
9237E	***Tablet 10 mg***	***30***	***11***	***..***	***21.23***	***22.26***	***a***	***Chem mart Pravastatin***	***CH***
							a	***Cholstat 10***	***AF***
							a	***GenRx Pravastatin***	***GX***
							a	***Lipostat 10***	***SI***
							a	***Liprachol***	***SZ***
							a	***Pravastatin 10***	***CR***
							a	***Pravastatin-DP***	***GM***
							a	***Pravastatin-GA 10***	***GN***
							a	***Pravastatin generichealth***	***GQ***
							a	***Pravastatin Winthrop***	***WA***
							a	***Terry White Chemists Pravastatin***	***TW***
				B3.52	***24.75***	***22.26***	***a***	***Pravachol***	***BQ***
9238F	***Tablet 20 mg***	***30***	***11***	***..***	***30.20***	***31.23***	***a***	***Chem mart Pravastatin***	***CH***
							a	***Cholstat 20***	***AF***
							a	***GenRx Pravastatin***	***GX***
							a	***Lipostat 20***	***SI***
							a	***Liprachol***	***SZ***
							a	***Pravastatin 20***	***CR***
							a	***Pravastatin-DP***	***GM***
							a	***Pravastatin-GA 20***	***GN***
							a	***Pravastatin generichealth***	***GQ***
							a	***Pravastatin Winthrop***	***WA***
							a	***Terry White Chemists Pravastatin***	***TW***
							a	***Vastoran***	***RA***
				B3.52	***33.72***	***31.23***	***a***	***Pravachol***	***BQ***

continued ☞

CARDIOVASCULAR SYSTEM—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
9239G	*Tablet 40 mg*	*30*	*11*	*..*	*43.27*	*32.90*	[a] *Chem mart Pravastatin*	*CH*
							[a] *Cholstat 40*	*AF*
							[a] *GenRx Pravastatin*	*GX*
							[a] *Lipostat 40*	*SI*
							[a] *Liprachol*	*SZ*
							[a] *Pravastatin 40*	*CR*
							[a] *Pravastatin-DP*	*GM*
							[a] *Pravastatin-GA 40*	*GN*
							[a] *Pravastatin generichealth*	*GQ*
							[a] *Pravastatin Winthrop*	*WA*
							[a] *Terry White Chemists Pravastatin*	*TW*
							[a] *Vastoran*	*RA*
				B3.07	*46.34*	*32.90*	[a] *Pravachol*	*BQ*
9240H	*Tablet 80 mg*	*30*	*11*	*..*	*61.28*	*32.90*	[a] *APO-Pravastatin*	*TX*
							[a] *Chem mart Pravastatin*	*CH*
							[a] *Lipostat 80*	*SI*
							[a] *Pravastatin-GA 80*	*GN*
							[a] *Pravastatin generichealth*	*GQ*
							[a] *Terry White Chemists Pravastatin*	*TW*
				B3.37	*64.65*	*32.90*	[a] *Pravachol*	*BQ*
	ROSUVASTATIN CALCIUM							
	Restricted Benefit							
	For use in patients that meet the criteria set out in the General Statement for Lipid-Lowering Drugs.							
9042X	*Tablet 5 mg (rosuvastatin)*	*30*	*5*	*..*	*50.75*	*32.90*	*Crestor*	*AP*
9043Y	*Tablet 10 mg (rosuvastatin)*	*30*	*5*	*..*	*69.48*	*32.90*	*Crestor*	*AP*
9044B	*Tablet 20 mg (rosuvastatin)*	*30*	*5*	*..*	*96.00*	*32.90*	*Crestor*	*AP*
9045C	*Tablet 40 mg (rosuvastatin)*	*30*	*5*	*..*	*134.01*	*32.90*	*Crestor*	*AP*

CARDIOVASCULAR SYSTEM—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Proprietary Name and Manufacturer	
	SIMVASTATIN								
	Restricted Benefit								
	For use in patients that meet the criteria set out in the General Statement for Lipid-Lowering Drugs.								
2013Y	*Tablet 5 mg*	*30*	*5*	*..*	*19.46*	*20.49*	[a]	*Simvabell*	*BF*
							[a]	*Simvahexal*	*SZ*
							[a]	*Simvasyn*	*CR*
							[a]	*Zimstat*	*AF*
				B1.08	*20.54*	*20.49*	[a]	*Zocor*	*MK*
2011W	*Tablet 10 mg*	*30*	*5*	*..*	*24.61*	*25.64*	[a]	*Chem mart Simvastatin*	*CH*
							[a]	*GenRx Simvastatin*	*GX*
							[a]	*Ransim*	*RA*
							[a]	*Simvabell*	*BF*
							[a]	*Simvahexal*	*SZ*
							[a]	*Simvar 10*	*AW*
							[a]	*Simvastatin-DP*	*GM*
							[a]	*Simvastatin generichealth*	*GQ*
							[a]	*Simvastatin-Spirit 10*	*ZP*
							[a]	*Simvastatin Winthrop*	*WA*
							[a]	*Simvasyn*	*CR*
							[a]	*Terry White Chemists Simvastatin*	*TW*
							[a]	*Zimstat*	*AF*
							[a]	*GN*	
				B1.08	*25.69*	*25.64*	[a]	*Lipex 10*	*FR*
							[a]	*Zocor*	*MK*

continued ☞

CARDIOVASCULAR SYSTEM—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Proprietary Name and Manufacturer	
2012X	*Tablet 20 mg*	*30*	*5*	*..*	*32.77*	*32.90*	*a*	*Chem mart Simvastatin*	*CH*
							a	*GenRx Simvastatin*	*GX*
							a	*Ransim*	*RA*
							a	*Simvabell*	*BF*
							a	*Simvahexal*	*SZ*
							a	*Simvar 20*	*AW*
							a	*Simvastatin-DP*	*GM*
							a	*Simvastatin generichealth*	*GQ*
							a	*Simvastatin-Spirit 20*	*ZP*
							a	*Simvastatin Winthrop*	*WA*
							a	*Simvasyn*	*CR*
							a	*Terry White Chemists Simvastatin*	*TW*
							a	*Zimstat*	*AF*
							a	*GN*	
				B1.08	*33.85*	*32.90*	*a*	*Lipex 20*	*FR*
							a	*Zocor*	*MK*
8173E	*Tablet 40 mg*	*30*	*5*	*..*	*44.02*	*32.90*	*a*	*Chem mart Simvastatin*	*CH*
							a	*GenRx Simvastatin*	*GX*
							a	*Ransim*	*RA*
							a	*Simvabell*	*BF*
							a	*Simvahexal*	*SZ*
							a	*Simvar 40*	*AW*
							a	*Simvastatin-DP*	*GM*
							a	*Simvastatin generichealth*	*GQ*
							a	*Simvastatin-Spirit 40*	*ZP*
							a	*Simvastatin Winthrop*	*WA*
							a	*Simvasyn*	*CR*
							a	*Terry White Chemists Simvastatin*	*TW*
							a	*Zimstat*	*AF*
							a	*GN*	
				B0.93	*44.95*	*32.90*	*a*	*Lipex 40*	*FR*
							a	*Zocor*	*MK*

continued ☞

CARDIOVASCULAR SYSTEM—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Proprietary Name and Manufacturer	
8313M	***Tablet 80 mg***	***30***	***5***	***..***	***58.99***	***32.90***	[a]	***Chem mart Simvastatin***	***CH***
							[a]	***GenRx Simvastatin***	***GX***
							[a]	***Ransim***	***RA***
							[a]	***Simvabell***	***BF***
							[a]	***Simvahexal***	***SZ***
							[a]	***Simvar 80***	***AW***
							[a]	***Simvastatin-DP***	***GM***
							[a]	***Simvastatin generichealth***	***GQ***
							[a]	***Simvastatin-Spirit 80***	***ZP***
							[a]	***Simvastatin Winthrop***	***WA***
							[a]	***Simvasyn***	***CR***
							[a]	***Terry White Chemists Simvastatin***	***TW***
							[a]	***Zimstat***	***AF***
							[a]	***GN***	
				B1.04	***60.03***	***32.90***	[a]	***Lipex 80***	***FR***
							[a]	***Zocor***	***MK***

Restricted Benefit

For use in patients who meet the criteria set out in the General Statement for Lipid-Lowering Drugs, and who are receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements.

NOTE:

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

9241J	***Tablet 5 mg***	***30***	***11***	***..***	***19.46***	***20.49***	[a]	***Simvabell***	***BF***
							[a]	***Simvahexal***	***SZ***
							[a]	***Simvasyn***	***CR***
							[a]	***Zimstat***	***AF***
				B1.08	***20.54***	***20.49***	[a]	***Zocor***	***MK***

continued ☞

CARDIOVASCULAR SYSTEM—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Proprietary Name and Manufacturer	
9242K	***Tablet 10 mg***	***30***	***11***	***..***	***24.61***	***25.64***	***a***	***Chem mart Simvastatin***	***CH***
							a	***GenRx Simvastatin***	***GX***
							a	***Ransim***	***RA***
							a	***Simvabell***	***BF***
							a	***Simvahexal***	***SZ***
							a	***Simvar 10***	***AW***
							a	***Simvastatin-DP***	***GM***
							a	***Simvastatin generichealth***	***GQ***
							a	***Simvastatin-Spirit 10***	***ZP***
							a	***Simvastatin Winthrop***	***WA***
							a	***Simvasyn***	***CR***
							a	***Terry White Chemists Simvastatin***	***TW***
							a	***Zimstat***	***AF***
							a	***GN***	
				B1.08	***25.69***	***25.64***	***a***	***Lipex 10***	***FR***
							a	***Zocor***	***MK***
9243L	***Tablet 20 mg***	***30***	***11***	***..***	***32.77***	***32.90***	***a***	***Chem mart Simvastatin***	***CH***
							a	***GenRx Simvastatin***	***GX***
							a	***Ransim***	***RA***
							a	***Simvabell***	***BF***
							a	***Simvahexal***	***SZ***
							a	***Simvar 20***	***AW***
							a	***Simvastatin-DP***	***GM***
							a	***Simvastatin generichealth***	***GQ***
							a	***Simvastatin-Spirit 20***	***ZP***
							a	***Simvastatin Winthrop***	***WA***
							a	***Simvasyn***	***CR***
							a	***Terry White Chemists Simvastatin***	***TW***
							a	***Zimstat***	***AF***
							a	***GN***	
				B1.08	***33.85***	***32.90***	***a***	***Lipex 20***	***FR***
							a	***Zocor***	***MK***

continued ☞

CARDIOVASCULAR SYSTEM—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Proprietary Name and Manufacturer	
9244M	***Tablet 40 mg***	***30***	***11***	***..***	***44.02***	***32.90***	***a***	***Chem mart Simvastatin***	***CH***
							a	***GenRx Simvastatin***	***GX***
							a	***Ransim***	***RA***
							a	***Simvabell***	***BF***
							a	***Simvahexal***	***SZ***
							a	***Simvar 40***	***AW***
							a	***Simvastatin-DP***	***GM***
							a	***Simvastatin generichealth***	***GQ***
							a	***Simvastatin-Spirit 40***	***ZP***
							a	***Simvastatin Winthrop***	***WA***
							a	***Simvasyn***	***CR***
							a	***Terry White Chemists Simvastatin***	***TW***
							a	***Zimstat***	***AF***
							a	***GN***	
				B0.93	***44.95***	***32.90***	***a***	***Lipex 40***	***FR***
							a	***Zocor***	***MK***
9245N	***Tablet 80 mg***	***30***	***11***	***..***	***58.99***	***32.90***	***a***	***Chem mart Simvastatin***	***CH***
							a	***GenRx Simvastatin***	***GX***
							a	***Ransim***	***RA***
							a	***Simvabell***	***BF***
							a	***Simvahexal***	***SZ***
							a	***Simvar 80***	***AW***
							a	***Simvastatin-DP***	***GM***
							a	***Simvastatin generichealth***	***GQ***
							a	***Simvastatin-Spirit 80***	***ZP***
							a	***Simvastatin Winthrop***	***WA***
							a	***Simvasyn***	***CR***
							a	***Terry White Chemists Simvastatin***	***TW***
							a	***Zimstat***	***AF***
							a	***GN***	
				B1.04	***60.03***	***32.90***	***a***	***Lipex 80***	***FR***
							a	***Zocor***	***MK***

CARDIOVASCULAR SYSTEM—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	

• *Fibrates*

FENOFIBRATE

NOTE:

The risk of serious muscle toxicity is increased if fenofibrate is used concomitantly with HMG CoA reductase inhibitors or other fibrates. Such combination therapy should be used with caution in patients with severe combined dyslipidaemia and high cardiovascular risk without any history of muscular disease and patients monitored closely for chronic signs of muscle toxicity.

Restricted Benefit

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

9022W	*Tablet 48 mg*	*60*	*5*	*..*	*29.62*	*30.65*	*Lipidil*	*SM*
9023X	*Tablet 145 mg*	*30*	*5*	*..*	*41.32*	*32.90*	*Lipidil*	*SM*

Restricted Benefit

For use in patients who meet the criteria set out in the General Statement for Lipid-Lowering Drugs, and who are receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements.

NOTE:

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

9246P	*Tablet 48 mg*	*60*	*11*	*..*	*29.62*	*30.65*	*Lipidil*	*SM*
9247Q	*Tablet 145 mg*	*30*	*11*	*..*	*41.32*	*32.90*	*Lipidil*	*SM*

CARDIOVASCULAR SYSTEM—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Proprietary Name and Manufacturer	
	GEMFIBROZIL								
	NOTE:								
	The risk of serious muscle toxicity is increased if gemfibrozil is used concomitantly with HMG CoA reductase inhibitors or other fibrates. Such combination therapy should be used with caution in patients with severe combined dyslipidaemia and high cardiovascular risk without any history of muscular disease and patients monitored closely for chronic signs of muscle toxicity.								
	Restricted Benefit								
	For use in patients that meet the criteria set out in the General Statement for Lipid-Lowering Drugs.								
1453L	***Tablet 600 mg***	***60***	***5***	***..***	***29.27***	***30.30***	[a]	***Ausgem***	***SI***
							[a]	***Chem mart Gemfibrozil***	***CH***
							[a]	***Gemhexal***	***SZ***
							[a]	***GenRx Gemfibrozil***	***GX***
							[a]	***Jezil***	***AF***
							[a]	***Lipazil 600 mg***	***GM***
							[a]	***Pharmacor Gemfibrozil 600***	***CR***
							[a]	***Terry White Chemists Gemfibrozil***	***TW***
				B2.31	***31.58***	***30.30***	[a]	***Lopid***	***PF***
	Restricted Benefit								
	For use in patients who meet the criteria set out in the General Statement for Lipid-Lowering Drugs, and who are receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements.								
	NOTE:								
	No applications for increased maximum quantities and/or repeats will be authorised.								
9248R	***Tablet 600 mg***	***60***	***11***	***..***	***29.27***	***30.30***	[a]	***Ausgem***	***SI***
							[a]	***Chem mart Gemfibrozil***	***CH***
							[a]	***Gemhexal***	***SZ***
							[a]	***GenRx Gemfibrozil***	***GX***
							[a]	***Jezil***	***AF***
							[a]	***Lipazil 600 mg***	***GM***
							[a]	***Pharmacor Gemfibrozil 600***	***CR***
							[a]	***Terry White Chemists Gemfibrozil***	***TW***
				B2.31	***31.58***	***30.30***	[a]	***Lopid***	***PF***
	• *Bile acid sequestrants*								
	CHOLESTYRAMINE								
2967E	Sachets 4.7 g (equivalent to 4 g cholestyramine), 50	2	5	..	* 57.03	32.90		Questran Lite	BQ

CARDIOVASCULAR SYSTEM—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
	CHOLESTYRAMINE							
	Restricted Benefit ***For use in patients who are receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements.***							
	NOTE: ***No applications for increased maximum quantities and/or repeats will be authorised.***							
9249T	***Sachets 4.7 g (equivalent to 4 g cholestyramine), 50***	***2***	***11***	***..***	**** 57.03***	***32.90***	***Questran Lite***	***BQ***
	COLESTIPOL HYDROCHLORIDE							
1224K	Sachets 5 g, 120	‡ 1	5	..	67.26	32.90	Colestid	PH
	COLESTIPOL HYDROCHLORIDE							
	Restricted Benefit ***For use in patients who are receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements.***							
	NOTE: ***No applications for increased maximum quantities and/or repeats will be authorised.***							
9250W	***Sachets 5 g, 120***	***‡ 1***	***11***	***..***	***67.26***	***32.90***	***Colestid***	***PH***

• *Other lipid modifying agents*

EZETIMIBE

Authority Required (STREAMLINED)

Treatment, in conjunction with dietary therapy and exercise, for co-administration with an HMG CoA reductase inhibitor (statin) in patients whose cholesterol levels are inadequately controlled with a statin and who have:

2649
(a) coronary heart disease; or

2650
(b) diabetes mellitus; or

2651
(c) peripheral vascular disease; or

2652
(d) heterozygous familial hypercholesterolaemia; or

2653
(e) symptomatic cerebrovascular disease; or

2667
(f) family history of coronary heart disease; or

continued ☞

CARDIOVASCULAR SYSTEM—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
	2668 ***(g) hypertension.*** ***Inadequate control with a statin is defined as follows:*** ***(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy, a cholesterol level in excess of that threshold after at least 3 months of treatment at a daily dose of 40 mg or greater of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or*** ***(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level, a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a daily dose of 40 mg or greater of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.*** **Authority Required (STREAMLINED)** **1989** ***Patients eligible for PBS-subsidised lipid-lowering medication (according to the criteria set out in the General Statement for Lipid-Lowering Drugs) where treatment with an HMG CoA reductase inhibitor (statin) is contraindicated;*** **2669** ***Patients eligible for PBS-subsidised lipid-lowering medication (according to the criteria set out in the General Statement for Lipid-Lowering Drugs) where treatment with an HMG CoA reductase inhibitor (statin) must be discontinued or reduced to a dose of 20 mg or less per day, because the patient developed a clinically important product-related adverse event during treatment with a statin.*** ***A clinically important product-related adverse event is defined as follows:*** ***(i) Severe myalgia (muscle symptoms without CK elevation) which is proven to be temporally associated with statin treatment; or*** ***(ii) Myositis (clinically important CK elevation, with or without muscle symptoms) demonstrated by results twice the upper limit of normal on a single reading or a rising pattern on consecutive measurements and which is unexplained by other causes; or*** ***(iii) Unexplained, persistent elevations of serum transaminases (greater than 3 times the upper limit of normal) during treatment with a statin.*** **Authority Required (STREAMLINED)** **1991** ***Homozygous sitosterolaemia;*** **2438** ***Patients with homozygous familial hypercholesterolaemia who are eligible for PBS-subsidised lipid-lowering medication (according to the criteria set out in the General Statement for Lipid-Lowering Drugs), in combination with an HMG CoA reductase inhibitor (statin).***							
8757X	***Tablet 10 mg***	***30***	***5***	***..***	***70.54***	***32.90***	***Ezetrol***	***MK***

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	

Lipid modifying agents, combinations

• *HMG CoA reductase inhibitors in combination with other lipid modifying agents*

EZETIMIBE with SIMVASTATIN

Authority Required (STREAMLINED)

Treatment, in conjunction with dietary therapy and exercise, in patients whose cholesterol levels are inadequately controlled with an HMG CoA reductase inhibitor (statin) and who have:

2654

(a) coronary heart disease; or

2655

(b) diabetes mellitus; or

2656

(c) peripheral vascular disease; or

2657

(d) heterozygous familial hypercholesterolaemia; or

2658

(e) cerebrovascular disease which has become symptomatic; or

2678

(f) family history of coronary heart disease; or

2679

(g) hypertension;

Inadequate control with a statin is defined as follows:
(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy, a cholesterol level in excess of that threshold after at least 3 months of treatment at a daily dose of 40 mg or greater of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when the ezetimibe component is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when the ezetimibe component is initiated; or
(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level, a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a daily dose of 40 mg or greater of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when the ezetimibe component is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when the ezetimibe component is initiated;

2431

Patients with homozygous familial hypercholesterolaemia who are eligible for PBS-subsidised lipid-lowering medication (according to the criteria set out in the General Statement for Lipid-Lowering Drugs).

8881K	*Tablet 10 mg-40 mg*	*30*	*5*	*..*	*107.42*	*32.90*	*Vytorin*	*MK*
8882L	*Tablet 10 mg-80 mg*	*30*	*5*	*..*	*123.54*	*32.90*	*Vytorin*	*MK*

CARDIOVASCULAR SYSTEM—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
	• *HMG CoA reductase inhibitors, other combinations*							
	AMLODIPINE BESYLATE with ATORVASTATIN CALCIUM							
	Restricted Benefit							
	For use in patients who have hypertension and/or angina and who meet the criteria set out in the General Statement for Lipid-Lowering Drugs, and:							
	(a) who are currently receiving treatment with a dihydropyridine calcium channel blocker; or							
	(b) whose blood pressure and/or angina is inadequately controlled with other classes of antihypertensive and/or anti-anginal agent, and in whom adjunctive therapy with a dihydropyridine calcium channel blocker would be appropriate; or							
	(c) who are intolerant of the side effects of other classes of antihypertensive and/or anti-anginal agent, and in whom replacement therapy with a dihydropyridine calcium channel blocker would be appropriate.							
9049G	***Tablet 5 mg (base)-10 mg (base)***	***30***	***5***	***..***	***51.37***	***32.90***	***Caduet 5/10***	***PF***
9050H	***Tablet 5 mg (base)-20 mg (base)***	***30***	***5***	***..***	***67.58***	***32.90***	***Caduet 5/20***	***PF***
9051J	***Tablet 5 mg (base)-40 mg (base)***	***30***	***5***	***..***	***88.63***	***32.90***	***Caduet 5/40***	***PF***
9052K	***Tablet 5 mg (base)-80 mg (base)***	***30***	***5***	***..***	***119.83***	***32.90***	***Caduet 5/80***	***PF***
9053L	***Tablet 10 mg (base)-10 mg (base)***	***30***	***5***	***..***	***58.56***	***32.90***	***Caduet 10/10***	***PF***
9054M	***Tablet 10 mg (base)-20 mg (base)***	***30***	***5***	***..***	***75.18***	***32.90***	***Caduet 10/20***	***PF***
9055N	***Tablet 10 mg (base)-40 mg (base)***	***30***	***5***	***..***	***96.23***	***32.90***	***Caduet 10/40***	***PF***
9056P	***Tablet 10 mg (base)-80 mg (base)***	***30***	***5***	***..***	***127.43***	***32.90***	***Caduet 10/80***	***PF***

DERMATOLOGICALS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
	ANTIFUNGALS FOR DERMATOLOGICAL USE							
	Antifungals for topical use							
	• ***Antibiotics***							
	NYSTATIN							
	Authority Required (STREAMLINED) **2354** ***Treatment of a fungal or a yeast infection in an Aboriginal or a Torres Strait Islander person.***							
1698J	***Cream 100,000 units per g, 15 g***	***2***	***3***	***..***	**** 18.13***	***19.16***	***Mycostatin***	***BQ***
	• ***Imidazole and triazole derivatives***							
	BIFONAZOLE							
	Authority Required (STREAMLINED) **2354** ***Treatment of a fungal or a yeast infection in an Aboriginal or a Torres Strait Islander person.***							
8066M	***Cream 10 mg per g (1%), 15 g***	***2***	***3***	***..***	**** 25.37***	***26.40***	***Mycospor***	***BN***
	CLOTRIMAZOLE							
	Authority Required (STREAMLINED) **2354** ***Treatment of a fungal or a yeast infection in an Aboriginal or a Torres Strait Islander person.***							
1027C	***Lotion 10 mg per mL (1%), 20 mL***	***2***	***3***	***..***	**** 17.93***	***18.96***	***Canesten***	***BN***
	KETOCONAZOLE							
	Authority Required (STREAMLINED) **2354** ***Treatment of a fungal or a yeast infection in an Aboriginal or a Torres Strait Islander person.***							
9024Y	***Cream 20 mg per g (2%), 30 g***	***‡ 1***	***2***	***..***	***22.69***	***23.72***	***Nizoral 2% Cream***	***JT***
9025B	***Shampoo 10 mg per g (1%), 100 mL***	***‡ 1***	***1***	***..***	***17.17***	***18.20***	***Nizoral 1%***	***JT***
1574W	***Shampoo 20 mg per g (2%), 60 mL***	***‡ 1***	***1***	***..***	***17.88***	***18.91***	***Nizoral 2%***	***JT***
	MICONAZOLE							
	Authority Required (STREAMLINED) **2354** ***Treatment of a fungal or a yeast infection in an Aboriginal or a Torres Strait Islander person.***							
9031H	***Tincture 20 mg per mL (2%), 30 mL***	***‡ 1***	***2***	***..***	***19.04***	***20.07***	***Daktarin***	***JT***

DERMATOLOGICALS—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Proprietary Name and Manufacturer	
	MICONAZOLE NITRATE								
	Authority Required (STREAMLINED) **2354** ***Treatment of a fungal or a yeast infection in an Aboriginal or a Torres Strait Islander person.***								
9026C	***Cream 20 mg per g (2%), 15 g***	***2***	***3***	***..***	**** 15.47***	***16.50***		***Daktarin***	***JT***
9027D	***Cream 20 mg per g (2%), 30 g***	***‡ 1***	***2***	***..***	***14.36***	***15.39***		***Daktarin***	***JT***
9028E	***Cream 20 mg per g (2%), 70 g***	***‡ 1***	***1***	***..***	***16.36***	***17.39***		***Daktarin***	***JT***
9029F	***Powder 20 mg per g (2%), 30 g***	***‡ 1***	***2***	***..***	***15.13***	***16.16***		***Daktarin***	***JT***
9030G	***Lotion 20 mg per mL (2%), 30 g***	***‡ 1***	***2***	***..***	***16.29***	***17.32***		***Daktarin***	***JT***
	• Other antifungals for topical use ***TERBINAFINE HYDROCHLORIDE***								
	Authority Required (STREAMLINED) **2354** ***Treatment of a fungal or a yeast infection in an Aboriginal or a Torres Strait Islander person.***								
9160D	***Cream 10 mg per g (1%), 15 g***	***2***	***3***	***..***	**** 36.93***	***32.90***		***Lamisil***	***NC***
	Antifungals for systemic use								
	• Antifungals for systemic use GRISEOFULVIN								
1460W	Tablet 125 mg	100	2	..	25.44	26.47		Grisovin	SI
2982Y	Tablet 500 mg	28	2	..	26.56	27.59		Grisovin 500	SI
	TERBINAFINE HYDROCHLORIDE								
	Authority Required ***Treatment of a dermatophyte infection in an Aboriginal or a Torres Strait Islander person where topical treatment has failed.***								
2285G	***Tablet 250 mg (base)***	***42***	***..***	***..***	***102.39***	***32.90***	***a***	***GenRx Terbinafine***	***GX***
							a	***Tamsil***	***SI***
							a	***Terbihexal***	***SZ***
							a	***Terbinafine 250***	***CR***
							a	***Terbinafine-DP***	***GM***
							a	***Zabel***	***AF***
				B1.46	***103.85***	***32.90***	***a***	***Lamisil***	***NV***

continued ☞

DERMATOLOGICALS—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Proprietary Name and Manufacturer	
	Authority Required ***Proximal or extensive (greater than 80% nail involvement) onychomycosis due to dermatophyte infection where topical treatment has failed. This infection must be proven by microscopy or culture and confirmed by an Approved Pathology Authority. The date of the pathology report must be provided at the time of application and must not be more than 12 months old.***								
	NOTE: ***No applications for increased maximum quantities and/or repeats will be authorised.***								
2804N	***Tablet 250 mg (base)***	***42***	***1***	***..***	***102.39***	***32.90***	***a***	***GenRx Terbinafine***	***GX***
							a	***Tamsil***	***SI***
							a	***Terbihexal***	***SZ***
							a	***Terbinafine 250***	***CR***
							a	***Terbinafine-DP***	***GM***
							a	***Zabel***	***AF***
				B1.46	***103.85***	***32.90***	***a***	***Lamisil***	***NV***
	ANTIPSORIATICS								
	Antipsoriatics for topical use								
	• ***Tars***								
	COAL TAR - PREPARED								
8864M	Gel 10 mg per g (1%), 100 mL	‡ 1	2	..	32.65	32.90		Exorex	GM
	• ***Other antipsoriatics for topical use***								
	CALCIPOTRIOL								
	Restricted Benefit ***Chronic stable plaque type psoriasis vulgaris.***								
8291J	***Ointment 50 micrograms per g (0.005%), 30 g***	***‡ 1***	***1***	***..***	***27.63***	***28.66***		***Daivonex***	***CS***
2080L	***Cream 50 micrograms per g (0.005%), 30 g***	***‡ 1***	***1***	***..***	***27.63***	***28.66***		***Daivonex***	***CS***
	Restricted Benefit ***Chronic stable plaque type psoriasis vulgaris of the scalp.***								
9163G	***Scalp solution 50 micrograms per mL (0.005%), 30 mL***	***‡ 1***	***1***	***..***	***27.63***	***28.66***		***Daivonex***	***CS***

DERMATOLOGICALS—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
	Antipsoriatics for systemic use							
	• ***Retinoids for treatment of psoriasis***							
	ACITRETIN							
	CAUTION:							
	This drug is a potent teratogen—pregnancy should be avoided for at least two years after cessation of therapy.							
	NOTE:							
	Care must be taken to comply with the provisions of State/Territory law when prescribing acitretin.							
	Authority Required (STREAMLINED)							
	1366							
	Severe intractable psoriasis;							
	1363							
	Severe forms of disorders of keratinisation.							
2019G	***Capsule 10 mg***	*100*	*2*	*..*	*205.34*	*32.90*	***Neotigason***	***TA***
2020H	***Capsule 25 mg***	*100*	*2*	*..*	*392.78*	*32.90*	***Neotigason***	***TA***
	ANTIBIOTICS AND CHEMOTHERAPEUTICS FOR DERMATOLOGICAL USE							
	Chemotherapeutics for topical use							
	• ***Sulfonamides***							
	SILVER SULFADIAZINE with CHLORHEXIDINE GLUCONATE							
	Restricted Benefit							
	Prevention and treatment of infection in partial or full skin thickness loss due to burns;							
	Prevention and treatment of infection in partial or full skin thickness loss due to epidermolysis bullosa;							
	Stasis ulcers.							
1996C	***Cream 10 mg-2 mg per g (1%-0.2%), 50 g***	*‡ 1*	*..*	*..*	*18.38*	*19.41*	***Silvazine***	***SN***
1997D	***Cream 10 mg-2 mg per g (1%-0.2%), 100 g***	*‡ 1*	*..*	*..*	*21.17*	*22.20*	***Silvazine***	***SN***
	CORTICOSTEROIDS, DERMATOLOGICAL PREPARATIONS							
	Corticosteroids, plain							
	• ***Corticosteroids, weak (group I)***							
	HYDROCORTISONE							
	Restricted Benefit							
	Treatment of corticosteroid-responsive dermatoses.							
1495Q	***Cream 10 mg per g (1%), 50 g***	*‡ 1*	*1*	*..*	*8.27*	*9.30*	***Egocort Cream 1%***	***EO***

DERMATOLOGICALS—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Proprietary Name and Manufacturer	
	HYDROCORTISONE ACETATE								
	Restricted Benefit ***Treatment of corticosteroid-responsive dermatoses.***								
2887Y	*Cream 10 mg per g (1%), 30 g*	*‡ 1*	*1*	*..*	*8.61*	*9.64*	*a*	*Cortic-DS 1%*	*FM*
				B1.90	*10.51*	*9.64*	*a*	*Sigmacort*	*SI*
2881P	*Cream 10 mg per g (1%), 50 g*	*‡ 1*	*1*	*..*	*8.27*	*9.30*	*a*	*Cortic-DS 1%*	*FM*
				B0.08	*8.35*	*9.30*		*Cortef*	*DT*
				B1.91	*10.18*	*9.30*	*a*	*Sigmacort*	*SI*
2888B	*Topical ointment 10 mg per g (1%), 30 g*	*‡ 1*	*1*	*..*	*8.61*	*9.64*	*a*	*Cortic-DS 1%*	*FM*
				B1.90	*10.51*	*9.64*	*a*	*Sigmacort*	*SI*
2882Q	*Topical ointment 10 mg per g (1%), 50 g*	*‡ 1*	*1*	*..*	*8.27*	*9.30*	*a*	*Cortic-DS 1%*	*FM*
				B1.91	*10.18*	*9.30*	*a*	*Sigmacort*	*SI*
	[For other listings for this drug see Generic/Proprietary Index]								
	• ***Corticosteroids, moderately potent (group II)*** ***TRIAMCINOLONE ACETONIDE***								
	Restricted Benefit ***Treatment of corticosteroid-responsive dermatoses.***								
2117K	*Cream 200 micrograms per g (0.02%), 100 g*	*2*	*..*	*..*	** 14.45*	*15.48*	*a*	*Tricortone*	*FM*
				B3.30	** 17.75*	*15.48*	*a*	*Aristocort 0.02%*	*SI*
2118L	*Ointment 200 micrograms per g (0.02%), 100 g*	*2*	*..*	*..*	** 14.45*	*15.48*	*a*	*Tricortone*	*FM*
				B3.30	** 17.75*	*15.48*	*a*	*Aristocort 0.02%*	*SI*
	• ***Corticosteroids, potent (group III)*** ***BETAMETHASONE DIPROPIONATE***								
	Restricted Benefit ***Treatment of corticosteroid-responsive dermatoses.***								
1115Q	*Cream 500 micrograms (base) per g (0.05%), 15 g*	*‡ 1*	*1*	*..*	*13.12*	*14.15*	*a*	*Diprosone*	*SH*
							a	*Eleuphrat*	*EX*
1119X	*Ointment 500 micrograms (base) per g (0.05%), 15 g*	*‡ 1*	*1*	*..*	*13.12*	*14.15*	*a*	*Diprosone*	*SH*
							a	*Eleuphrat*	*EX*
	BETAMETHASONE VALERATE								
	Restricted Benefit ***Treatment of corticosteroid-responsive dermatoses.***								
2812B	*Cream 200 micrograms (base) per g (0.02%), 100 g*	*2*	*..*	*..*	** 24.89*	*25.92*	*a*	*Antroquoril*	*EX*
							a	*Celestone-M*	*SH*
							b	*Cortival 1/5*	*FM*
				B6.18	** 31.07*	*25.92*	*b*	*Betnovate 1/5*	*SI*

continued ☞

DERMATOLOGICALS—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Proprietary Name and Manufacturer	
2813C	***Cream 500 micrograms (base) per g (0.05%), 15 g***	***‡ 1***	***1***	***..***	***8.12***	***9.15***	***b***	***Cortival 1/2***	***FM***
				B1.91	***10.03***	***9.15***	***b***	***Betnovate 1/2***	***SI***
2820K	***Ointment 200 micrograms (base) per g (0.02%), 100 g***	***2***	***..***	***..***	**** 24.89***	***25.92***	***a***	***Antroquoril***	***EX***
							a	***Celestone-M***	***SH***
2815E	***Ointment 500 micrograms (base) per g (0.05%), 15 g***	***‡ 1***	***1***	***..***	***8.12***	***9.15***	***b***	***Cortival 1/2***	***FM***
				B1.91	***10.03***	***9.15***	***b***	***Betnovate 1/2***	***SI***
	METHYLPREDNISOLONE ACEPONATE								
	Restricted Benefit ***Treatment of corticosteroid-responsive dermatoses.***								
8054X	***Cream 1 mg per g (0.1%), 15 g***	***‡ 1***	***..***	***..***	***14.02***	***15.05***		***Advantan***	***CS***
8055Y	***Ointment 1 mg per g (0.1%), 15 g***	***‡ 1***	***..***	***..***	***14.02***	***15.05***		***Advantan***	***CS***
8128T	***Fatty ointment 1 mg per g (0.1%), 15 g***	***‡ 1***	***..***	***..***	***14.02***	***15.05***		***Advantan***	***CS***
	Restricted Benefit ***Eczema.***								
8618N	***Lotion 1 mg per g (0.1%), 20 g***	***‡ 1***	***..***	***..***	***14.74***	***15.77***		***Advantan***	***CS***
	MOMETASONE FUROATE								
	Restricted Benefit ***Treatment of corticosteroid-responsive dermatoses.***								
1913Q	***Cream 1 mg per g (0.1%), 15 g***	***‡ 1***	***..***	***..***	***13.96***	***14.99***	***a***	***Elocon***	***SH***
							a	***Novasone***	***EX***
1915T	***Ointment 1 mg per g (0.1%), 15 g***	***‡ 1***	***..***	***..***	***13.96***	***14.99***	***a***	***Elocon***	***SH***
							a	***Novasone***	***EX***
8043H	***Lotion 1 mg per g (0.1% w/w), 30 mL***	***‡ 1***	***..***	***..***	***18.54***	***19.57***	***a***	***Elocon***	***SH***
							a	***Novasone***	***EX***

DERMATOLOGICALS—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Proprietary Name and Manufacturer	
	ANTI-ACNE PREPARATIONS								
	Anti-acne preparations for systemic use								
	• ***Retinoids for treatment of acne***								
	ISOTRETINOIN								
	CAUTION:								
	This drug causes birth defects. Isotretinoin has been reported to cause other frequent and potentially serious toxicity.								
	NOTE:								
	Care must be taken to comply with the provisions of State/Territory law when prescribing isotretinoin.								
	Authority Required (STREAMLINED)								
	1354								
	Severe cystic acne not responsive to other therapy.								
2591J	***Capsule 10 mg***	***60***	***3***	***..***	***94.12***	***32.90***	***a***	***Oratane***	***GM***
							a	***Roaccutane***	***RO***
2592K	***Capsule 20 mg***	***60***	***3***	***..***	***143.36***	***32.90***	***a***	***Chem mart Isotretinoin***	***CH***
							a	***GenRx Isotretinoin***	***GX***
							a	***Oratane***	***GM***
							a	***Terry White Chemists Isotretinoin***	***TW***
				B2.37	***145.73***	***32.90***	***a***	***Roaccutane***	***RO***
2549E	***Capsule 40 mg***	***30***	***3***	***..***	***129.96***	***32.90***		***Oratane***	***GM***
	OTHER DERMATOLOGICAL PREPARATIONS								
	Other dermatological preparations								
	• ***Other dermatologicals***								
	DAPSONE								
8801F	Tablet 25 mg	100	1	..	100.15	32.90		LM	
1272Y	Tablet 100 mg	100	1	..	113.41	32.90		LM	
	IMIQUIMOD								
	Authority Required								
	Treatment of biopsy confirmed primary (previously untreated) superficial basal cell carcinoma (sBCC) in patients with normal immune function for whom surgical excision, cryotherapy, or curettage with diathermy are inappropriate and topical drug therapy is required.								
	The date of the pathology report and name of the Approved Pathology Authority must be provided at the time of application.								
	NOTE:								
	The patient or carer must be able to understand and administer the imiquimod dosing regimen.								
	No applications for increased maximum quantities and/or repeats will be authorised.								
	Treatment of recurrent (previously treated) lesions will not be authorised.								

continued ☞

DERMATOLOGICALS—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
2546B	***Cream 50 mg per g (5%), 250 mg single use sachets, 12***	***1***	***1***	***..***	***159.52***	***32.90***	***Aldara***	***IA***

PIMECROLIMUS

Authority Required

Treatment of facial or eyelid atopic dermatitis in patients aged at least 3 months with 1 or more of the following contraindications to topical corticosteroids:
(i) perioral dermatitis;
(ii) periorbital dermatitis;
(iii) rosacea;
(iv) epidermal atrophy;
(v) dermal atrophy;
(vi) allergy to topical corticosteroids;
(vii) cataracts;
(viii) glaucoma;
(ix) raised intraocular pressure.

Authority Required

Short-term (up to 3 weeks) intermittent treatment of atopic dermatitis of the face or eyelids in patients aged at least 3 months who fail to achieve satisfactory disease control with intermittent topical corticosteroid therapy, and where more than 3 months have passed since the initial diagnosis of atopic dermatitis.

Failure to achieve satisfactory disease control with intermittent topical corticosteroid therapy is manifest by:
(i) failure of the facial skin to clear despite at least 2 weeks of topical hydrocortisone 1% applied every day; or
(ii) failure of the facial skin to clear despite at least 1 week of a moderate or potent topical corticosteroid applied every day; or
(iii) clearing of the facial skin with at least 2 weeks of topical hydrocortisone 1% applied every day, but almost immediate and significant flare in facial disease (within 48 hours) upon stopping topical corticosteroids, occurring on at least 2 consecutive occasions; or
(iv) clearing of the facial skin with at least 1 week of a moderate or potent topical corticosteroid applied every day, but almost immediate and significant flare in facial disease (within 48 hours) upon stopping topical corticosteroids, occurring on at least 2 consecutive occasions.

8802G	***Cream 10 mg per g (1%), 15 g***	***‡ 1***	***1***	***..***	***33.36***	***32.90***	***Elidel***	***NV***

NOTE:
No applications for increased maximum quantities and/or repeats will be authorised. Only 1 authority application per 6 months, per patient, will be authorised.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Proprietary Name and Manufacturer	
	OTHER GYNECOLOGICALS								
	Contraceptives for topical use								
	• ***Intrauterine contraceptives***								
	LEVONORGESTREL								
	Restricted Benefit ***Contraception;*** ***Idiopathic menorrhagia where oral treatments are ineffective;*** ***Idiopathic menorrhagia where oral treatments are contraindicated.***								
8633J	*Intrauterine drug delivery system 52 mg (releasing approximately 20 micrograms per 24 hours)*	*1*	*..*	*..*	*245.98*	*32.90*		*Mirena*	*SC*
	Other gynecologicals								
	• ***Prolactine inhibitors***								
	BROMOCRIPTINE MESYLATE								
	Restricted Benefit ***Prevention of the onset of lactation in the puerperium for medical reasons.***								
1444B	*Tablet 2.5 mg (base)*	*30*	*..*	*..*	*19.15*	*20.18*	*a*	*Kripton 2.5*	*AF*
				B2.84	*21.99*	*20.18*	*a*	*Parlodel*	*NV*
	Restricted Benefit ***Acromegaly;*** ***Parkinson's disease;*** ***Pathological hyperprolactinaemia where surgery is not indicated;*** ***Pathological hyperprolactinaemia where surgery has already been used with incomplete resolution;*** ***Pathological hyperprolactinaemia where radiotherapy is not indicated;*** ***Pathological hyperprolactinaemia where radiotherapy has already been used with incomplete resolution.***								
1443Y	*Tablet 2.5 mg (base)*	*60*	*5*	*..*	*32.30*	*32.90*	*a*	*Kripton 2.5*	*AF*
				B2.92	*35.22*	*32.90*	*a*	*Parlodel*	*NV*
1446D	*Capsule 5 mg (base)*	*60*	*5*	*..*	*49.82*	*32.90*	*a*	*Kripton 5*	*AF*
				B2.91	*52.73*	*32.90*	*a*	*Parlodel*	*NV*
1445C	*Capsule 10 mg (base)*	*100*	*5*	*..*	*155.51*	*32.90*	*a*	*Kripton 10*	*AF*
				B3.08	*158.59*	*32.90*	*a*	*Parlodel*	*NV*
	CABERGOLINE								
	Restricted Benefit ***Prevention of the onset of lactation in the puerperium for medical reasons.***								
8115D	*Tablet 500 micrograms*	*2*	*..*	*..*	*26.58*	*27.61*		*Dostinex*	*PH*

continued ☞

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Proprietary Name and Manufacturer	
	Authority Required (STREAMLINED) **2659** ***Pathological hyperprolactinaemia where surgery is not indicated;*** **2660** ***Pathological hyperprolactinaemia where surgery has already been used with incomplete resolution;*** **2661** ***Pathological hyperprolactinaemia where radiotherapy is not indicated;*** **2662** ***Pathological hyperprolactinaemia where radiotherapy has already been used with incomplete resolution.***								
8114C	***Tablet 500 micrograms***	***8***	***5***	***..***	***75.79***	***32.90***		***Dostinex***	***PH***
	QUINAGOLIDE HYDROCHLORIDE **Authority Required (STREAMLINED)** **2659** ***Pathological hyperprolactinaemia where surgery is not indicated;*** **2660** ***Pathological hyperprolactinaemia where surgery has already been used with incomplete resolution;*** **2661** ***Pathological hyperprolactinaemia where radiotherapy is not indicated;*** **2662** ***Pathological hyperprolactinaemia where radiotherapy has already been used with incomplete resolution.***								
8860H	***Pack containing 3 tablets 25 micrograms (base) and 3 tablets 50 micrograms (base)***	***‡ 1***	***..***	***..***	***11.04***	***12.07***		***Norprolac***	***FP***
8822H	***Tablet 75 micrograms (base)***	***30***	***5***	***..***	***54.36***	***32.90***		***Norprolac***	***FP***
	SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM								
	Hormonal contraceptives for systemic use								
	• ***Progestogens and estrogens, fixed combinations***								
	LEVONORGESTREL with ETHINYLOESTRADIOL								
1456P	Pack containing 21 tablets 125 micrograms-50 micrograms and 7 inert tablets	4	2	..	17.23	18.26		Microgynon 50 ED	SC
1393H	Tablets 150 micrograms-30 micrograms, 21	4	2	B11.45	28.68	18.26	a	Microgynon 30	SC
	NOTE: This product may be interchanged with products with "a" flagging in item 1394J.								

continued ☞

GENITO URINARY SYSTEM AND SEX HORMONES—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Proprietary Name and Manufacturer	
1394J	Pack containing 21 tablets	4	2	..	17.23	18.26	a	Levlen ED	SY
	150 micrograms-30 micrograms and 7						b	Monofeme 28	WX
	inert tablets			B11.45	28.68	18.26	a	Microgynon 30 ED	SC
				B11.78	29.01	18.26	b	Nordette 28	WY
	NOTE: The products with "a" flagging may also be interchanged with item 1393H.								
	NORETHISTERONE with ETHINYLOESTRADIOL								
2772X	Tablets 500 micrograms-35 micrograms, 21	4	2	B7.92	* 24.59	17.70	a	Brevinor	PH
	NOTE: This product may be interchanged with the products in item 2774B.								
2774B	Pack containing 21 tablets	4	2	..	* 16.67	17.70	a	Norimin 28 Day	KR
	500 micrograms-35 micrograms and 7 inert tablets			B7.92	* 24.59	17.70	a	Brevinor	PH
	NOTE: These products may also be interchanged with item 2772X.								
2773Y	Tablets 1 mg-35 micrograms, 21	4	2	B7.92	* 24.59	17.70	a	Brevinor-1	PH
	NOTE: This product may be interchanged with the products in item 2775C.								
2775C	Pack containing 21 tablets	4	2	..	* 16.67	17.70	a	Norimin-1 28 Day	KR
	1 mg-35 micrograms and 7 inert tablets			B7.92	* 24.59	17.70	a	Brevinor-1	PH
	NOTE: These products may also be interchanged with item 2773Y.								
	NORETHISTERONE with MESTRANOL								
3176E	Tablets 1 mg-50 micrograms, 21	4	2	..	* 16.67	17.70		Norinyl-1	PH
3179H	Pack containing 21 tablets	4	2	..	* 16.67	17.70		Norinyl-1/28	PH
	1 mg-50 micrograms and 7 inert tablets								
	• Progestogens and estrogens, sequential preparations								
	LEVONORGESTREL with ETHINYLOESTRADIOL								
1392G	Pack containing 6 tablets	4	2	..	17.23	18.26	a	Logynon ED	SY
	50 micrograms-30 micrograms, 5						b	Trifeme 28	WX
	tablets 75 micrograms-40 micrograms,			B11.45	28.68	18.26	a	Triquilar ED	SC
	10 tablets			B11.78	29.01	18.26	b	Triphasil 28	WY
	125 micrograms-30 micrograms and 7 inert tablets								

GENITO URINARY SYSTEM AND SEX HORMONES—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Proprietary Name and Manufacturer	
	NORETHISTERONE with ETHINYLOESTRADIOL								
2776D	Pack containing 12 tablets	4	2	..	* 16.67	17.70	a	Improvil 28 Day	KR
	500 micrograms-35 micrograms, 9 tablets 1 mg-35 micrograms and 7 inert tablets			B7.92	* 24.59	17.70	a	Synphasic	PH
	• *Progestogens*								
	ETONOGESTREL								
8487Q	Subcutaneous implant 68 mg	1	..	..	215.49	32.90		Implanon	SH
	LEVONORGESTREL								
2913H	Tablets 30 micrograms, 28	4	2	..	16.89	17.92		Microlut 28	SC
	MEDROXYPROGESTERONE ACETATE								
3118D	Injection 150 mg in 1 mL	1	1	..	14.21	15.24	a	Depo-Ralovera	KR
				B3.34	17.55	15.24	a	Depo-Provera	PH
	[For other listings for this drug see Generic/Proprietary Index]								
	NORETHISTERONE								
1967M	Tablets 350 micrograms, 28	4	2	..	* 16.67	17.70		Micronor	JC
				..	* 16.67	17.70	a	Locilan 28 Day	KR
				B4.00	* 20.67	17.70	a	Noriday 28 Day	PH
	Androgens								
	• *3-oxoandrosten (4) derivatives*								
	TESTOSTERONE								
	Authority Required								
	Androgen deficiency in males with established pituitary or testicular disorders;								
	Androgen deficiency in males 40 years and older who do not have established pituitary or testicular disorders other than aging, confirmed by at least 2 morning blood samples taken on different mornings. Androgen deficiency is confirmed by testosterone less than 8 nmol per L, or 8-15 nmol per L with high LH (greater than 1.5 times the upper limit of the eugonadal reference range for young men);								
	Micropenis, pubertal induction, or constitutional delay of growth or puberty, in males under 18 years of age.								
8098F	***Subcutaneous implant 100 mg***	***6***	***..***	***..***	**** 209.15***	***32.90***		***SH***	
8099G	***Subcutaneous implant 200 mg***	***3***	***..***	***..***	**** 209.12***	***32.90***		***SH***	
8830R	***Transdermal gel 50 mg in 5 g sachet, 30***	***‡ 1***	***5***	***..***	***94.69***	***32.90***		***Testogel***	***SC***
8460G	***Transdermal patches 12.2 mg (releasing approximately 2.5 mg per 24 hours), 60***	***‡ 1***	***5***	***..***	***95.41***	***32.90***		***Androderm***	***HH***
8619P	***Transdermal patches 24.3 mg (releasing approximately 5 mg per 24 hours), 30***	***‡ 1***	***5***	***..***	***95.41***	***32.90***		***Androderm***	***HH***

GENITO URINARY SYSTEM AND SEX HORMONES—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
	TESTOSTERONE ENANTHATE							
	Authority Required ***Androgen deficiency in males with established pituitary or testicular disorders;*** ***Androgen deficiency in males 40 years and older who do not have established pituitary or testicular disorders other than aging, confirmed by at least 2 morning blood samples taken on different mornings. Androgen deficiency is confirmed by testosterone less than 8 nmol per L, or 8-15 nmol per L with high LH (greater than 1.5 times the upper limit of the eugonadal reference range for young men);*** ***Micropenis, pubertal induction, or constitutional delay of growth or puberty, in males under 18 years of age.***							
2114G	***Injection 250 mg in 1 mL***	***3***	***3***	***..***	***33.05***	***32.90***	***Primoteston Depot***	***SC***
	TESTOSTERONE ESTERS							
	Authority Required ***Androgen deficiency in males with established pituitary or testicular disorders;*** ***Androgen deficiency in males 40 years and older who do not have established pituitary or testicular disorders other than aging, confirmed by at least 2 morning blood samples taken on different mornings. Androgen deficiency is confirmed by testosterone less than 8 nmol per L, or 8-15 nmol per L with high LH (greater than 1.5 times the upper limit of the eugonadal reference range for young men);*** ***Micropenis, pubertal induction, or constitutional delay of growth or puberty, in males under 18 years of age.***							
2670M	***Injection 100 mg***	***3***	***3***	***..***	**** 20.24***	***21.27***	***Sustanon 100***	***SH***
2101N	***Injection 250 mg***	***3***	***3***	***..***	**** 33.05***	***32.90***	***Sustanon 250***	***SH***
	TESTOSTERONE UNDECANOATE							
	Authority Required ***Androgen deficiency in males with established pituitary or testicular disorders;*** ***Androgen deficiency in males 40 years and older who do not have established pituitary or testicular disorders other than aging, confirmed by at least 2 morning blood samples taken on different mornings. Androgen deficiency is confirmed by testosterone less than 8 nmol per L, or 8-15 nmol per L with high LH (greater than 1.5 times the upper limit of the eugonadal reference range for young men);*** ***Micropenis, pubertal induction, or constitutional delay of growth or puberty, in males under 18 years of age.***							
2115H	***Capsule 40 mg***	***60***	***5***	***..***	***37.10***	***32.90***	***Andriol Testocaps***	***SH***
9004X	***I.M. injection 1,000 mg in 4 mL***	***1***	***1***	***..***	***146.98***	***32.90***	***Reandron 1000***	***SC***
	Estrogens							
	• ***Natural and semisynthetic estrogens, plain***							
	OESTRADIOL							
8274L	Tablet 2 mg	56	2	..	13.57	14.60	Zumenon	SM
1742Q	Vaginal tablets 25 micrograms, 15	‡ 1	2	..	22.81	23.84	Vagifem	NO

continued ☞

GENITO URINARY SYSTEM AND SEX HORMONES—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
	OESTRADIOL							
	Restricted Benefit ***For use for post-menopausal symptoms where a trial of peri- or post-menopausal low-dose oestrogen therapy has demonstrated intolerance to oral oestrogens.***							
	NOTE: ***Oestradiol should be used in conjunction with an oral progestogen in women with an intact uterus.***							
8286D	***Transdermal gel 1 mg in 1 g sachet, 28***	***‡ 1***	***5***	***..***	***17.33***	***18.36***	***Sandrena***	***SH***
8761D	***Transdermal patches 390 micrograms (releasing approximately 25 micrograms per 24 hours), 8***	***‡ 1***	***5***	***..***	***17.33***	***18.36***	***Estradot 25***	***NV***
8311K	***Transdermal patches 750 micrograms (releasing approximately 25 micrograms per 24 hours), 8***	***‡ 1***	***5***	***..***	***17.33***	***18.36***	***Estraderm MX 25***	***NV***
8485N	***Transdermal patches 2 mg (releasing approximately 25 micrograms per 24 hours), 4***	***‡ 1***	***5***	***..***	***17.33***	***18.36***	***Climara 25***	***SC***
1743R	***Transdermal patches 2 mg (releasing approximately 25 micrograms per 24 hours), 8***	***‡ 1***	***5***	***..***	***17.33***	***18.36***	***Estraderm 25***	***NV***
8762E	***Transdermal patches 585 micrograms (releasing approximately 37.5 micrograms per 24 hours), 8***	***‡ 1***	***5***	***..***	***17.33***	***18.36***	***Estradot 37.5***	***NV***
8140K	***Transdermal patches 1.5 mg (releasing approximately 50 micrograms per 24 hours), 8***	***‡ 1***	***5***	***..***	***17.33***	***18.36***	***Estraderm MX 50***	***NV***
8125P	***Transdermal patches 3.8 mg (releasing approximately 50 micrograms per 24 hours), 4***	***‡ 1***	***5***	***..***	***17.33***	***18.36***	***Climara 50***	***SC***
1744T	***Transdermal patches 4 mg (releasing approximately 50 micrograms per 24 hours), 8***	***‡ 1***	***5***	***..***	***17.33***	***18.36***	***Estraderm 50***	***NV***
8763F	***Transdermal patches 780 micrograms (releasing approximately 50 micrograms per 24 hours), 8***	***‡ 1***	***5***	***..***	***17.33***	***18.36***	***Estradot 50***	***NV***
8486P	***Transdermal patches 5.7 mg (releasing approximately 75 micrograms per 24 hours), 4***	***‡ 1***	***5***	***..***	***19.49***	***20.52***	***Climara 75***	***SC***
8764G	***Transdermal patches 1.17 mg (releasing approximately 75 micrograms per 24 hours), 8***	***‡ 1***	***5***	***..***	***19.49***	***20.52***	***Estradot 75***	***NV***

continued ☞

GENITO URINARY SYSTEM AND SEX HORMONES—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
8312L	***Transdermal patches 3 mg (releasing approximately 100 micrograms per 24 hours), 8***	***‡ 1***	***5***	***..***	***19.49***	***20.52***	***Estraderm MX 100***	***NV***
8126Q	***Transdermal patches 7.6 mg (releasing approximately 100 micrograms per 24 hours), 4***	***‡ 1***	***5***	***..***	***19.49***	***20.52***	***Climara 100***	***SC***
1745W	***Transdermal patches 8 mg (releasing approximately 100 micrograms per 24 hours), 8***	***‡ 1***	***5***	***..***	***19.49***	***20.52***	***Estraderm 100***	***NV***
8765H	***Transdermal patches 1.56 mg (releasing approximately 100 micrograms per 24 hours), 8***	***‡ 1***	***5***	***..***	***19.49***	***20.52***	***Estradot 100***	***NV***
	OESTRADIOL VALERATE							
1663M	Tablet 1 mg	56	2	..	11.57	12.60	Progynova	SC
1664N	Tablet 2 mg	56	2	..	13.94	14.97	Progynova	SC
	OESTRIOL							
1771F	Pessaries 500 micrograms, 15	‡ 1	2	..	20.83	21.86	Ovestin Ovula	SH
1781R	Vaginal cream 1 mg per g (0.1%), 15 g	‡ 1	1	..	18.66	19.69	Ovestin	SH
	OESTROGENS—CONJUGATED							
1733F	Tablet 300 micrograms	56	2	..	* 15.15	16.18	Premarin	WX
1734G	Tablet 625 micrograms	56	2	..	* 15.67	16.70	Premarin	WX
	Progestogens							
	• ***Pregnen (4) derivatives***							
	MEDROXYPROGESTERONE ACETATE							
2323G	Tablet 5 mg	56	2	..	14.78	15.81	[a] Ralovera	KR
				B1.74	16.52	15.81	[a] Provera	PH
2321E	Tablet 10 mg	30	2	..	15.42	16.45	[a] Medroxyhexal	SZ
							[a] Ralovera	KR
				B1.75	17.17	16.45	[a] Provera	PH
2319C	Injection 50 mg in 1 mL	1	1	..	11.48	12.51	Depo-Provera	PH

continued ☞

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Proprietary Name and Manufacturer	
	MEDROXYPROGESTERONE ACETATE								
	Restricted Benefit ***Endometriosis.***								
2722G	***Tablet 10 mg***	***100***	***2***	***..***	***31.78***	***32.81***	***a***	***Ralovera***	***KR***
				B1.64	***33.42***	***32.81***	***a***	***Provera***	***PH***
	[For other listings for this drug see Generic/Proprietary Index]								
	• ***Pregnadien derivatives*** DYDROGESTERONE								
1350C	Tablet 10 mg	28	2	..	14.96	15.99		Duphaston	SM
	• ***Estren derivatives*** NORETHISTERONE								
2993M	Tablet 5 mg	30	2	..	33.12	32.90		Primolut N	SC
	Progestogens and estrogens in combination								
	• ***Progestogens and estrogens, combinations*** OESTRADIOL with NORETHISTERONE ACETATE								
8353P	Tablets 1 mg-500 micrograms, 28	‡ 1	5	..	17.26	18.29		Kliovance	NO
8081H	Tablets 2 mg-1 mg, 28	‡ 1	5	..	17.26	18.29		Kliogest	NO
	OESTRADIOL with NORETHISTERONE ACETATE								
	Restricted Benefit ***For use for post-menopausal symptoms where a trial of peri- or post-menopausal low-dose oestrogen therapy has demonstrated intolerance to oral oestrogens.***								
8427M	***Transdermal patches 620 micrograms-2.7 mg (releasing approximately 50 micrograms-140 micrograms per 24 hours), 8***	***‡ 1***	***5***	***..***	***19.49***	***20.52***		***Estalis continuous 50/140***	***NV***
8428N	***Transdermal patches 510 micrograms-4.8 mg (releasing approximately 50 micrograms-250 micrograms per 24 hours), 8***	***‡ 1***	***5***	***..***	***19.49***	***20.52***		***Estalis continuous 50/250***	***NV***
	OESTROGENS—CONJUGATED with MEDROXYPROGESTERONE ACETATE								
8168X	Tablets 625 micrograms-2.5 mg, 28	‡ 1	5	..	17.38	18.41		Premia 2.5 Continuous	WX
8169Y	Tablets 625 micrograms-5 mg, 28	‡ 1	5	..	17.38	18.41		Premia 5 Continuous	WX

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
	• *Progestogens and estrogens, sequential preparations*							
	OESTRADIOL and OESTRADIOL with DYDROGESTERONE							
8244X	Pack containing 14 tablets oestradiol 2 mg and 14 tablets oestradiol 2 mg with dydrogesterone 10 mg	‡ 1	5	..	17.34	18.37	Femoston 2/10	SM
	OESTRADIOL and OESTRADIOL with NORETHISTERONE ACETATE							
1764W	Pack containing 12 tablets oestradiol 2 mg, 10 tablets oestradiol 2 mg with norethisterone acetate 1 mg and 6 tablets oestradiol 1 mg	‡ 1	5	..	17.26	18.29	Trisequens	NO
	OESTRADIOL and OESTRADIOL with NORETHISTERONE ACETATE							
	Restricted Benefit							
	For use for post-menopausal symptoms where a trial of peri- or post-menopausal low-dose oestrogen therapy has demonstrated intolerance to oral oestrogens.							
8425K	***Pack containing 4 transdermal patches oestradiol 780 micrograms (releasing approximately 50 micrograms per 24 hours) and 4 transdermal patches oestradiol with norethisterone acetate 620 micrograms-2.7 mg (releasing approximately 50 micrograms-140 micrograms per 24 hours)***	***‡ 1***	***5***	***..***	***19.49***	***20.52***	***Estalis sequi 50/ 140***	***NV***
8426L	***Pack containing 4 transdermal patches oestradiol 780 micrograms (releasing approximately 50 micrograms per 24 hours) and 4 transdermal patches oestradiol with norethisterone acetate 510 micrograms-4.8 mg (releasing approximately 50 micrograms-250 micrograms per 24 hours)***	***‡ 1***	***5***	***..***	***19.49***	***20.52***	***Estalis sequi 50/ 250***	***NV***
8029N	***Pack containing 4 transdermal patches oestradiol 4 mg (releasing approximately 50 micrograms per 24 hours) and 4 transdermal patches oestradiol with norethisterone acetate 10 mg-30 mg (releasing approximately 50 micrograms- 250 micrograms per 24 hours)***	***‡ 1***	***5***	***..***	***19.49***	***20.52***	***Estracombi***	***NV***

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
	Gonadotropins and other ovulation stimulants							
	• ***Gonadotropins***							
	FOLLITROPIN ALFA							
	Restricted Benefit ***Anovulatory infertility.*** **NOTE:** ***Except in cases of hypopituitarism or primary amenorrhoea, the patient should have been adequately treated with clomiphene citrate and/or gonadorelin and failed to have conceived.*** ***Women who have had apparent ovulation induced by other agents and have failed to conceive should have laparoscopic evidence that there is no other impediment to conception.*** ***Oligomenorrhoea should have been present for at least twelve months or amenorrhoea for at least six months prior to treatment.*** ***Patients with hyperprolactinaemia should have had appropriate surgical or medical treatment prior to treatment.***							
8672K	***Injection set containing 1 vial powder for injection 75 i.u. and 1 pre-filled syringe solvent 1 mL***	*5*	*5*	*..*	** 247.14*	*32.90*	***Gonal-f 75***	***SG***
8674M	***Injection set containing 1 vial powder for injection 1,050 i.u. and 1 pre-filled syringe solvent 2 mL***	*1*	*5*	*..*	*655.76*	*32.90*	***Gonal-f***	***SG***
	Restricted Benefit ***Anovulatory infertility.*** **NOTE:** ***Except in cases of hypopituitarism or primary amenorrhoea, the patient should have been adequately treated with clomiphene citrate and/or gonadorelin and failed to have conceived.*** ***Women who have had apparent ovulation induced by other agents and have failed to conceive should have laparoscopic evidence that there is no other impediment to conception.*** ***Oligomenorrhoea should have been present for at least twelve months or amenorrhoea for at least six months prior to treatment.*** ***Patients with hyperprolactinaemia should have had appropriate surgical or medical treatment prior to treatment.***							
	Restricted Benefit ***For the treatment of infertility in males due to hypogonadotrophic hypogonadism, following failure of 6 months' treatment with human chorionic gonadotrophin to achieve adequate spermatogenesis. Combined treatment with HCG must be given.***							
8673L	***Injection set containing 10 vials powder for injection 75 i.u. and 10 pre-filled syringes solvent 1 mL***	*1*	*5*	*..*	*470.25*	*32.90*	***Gonal-f 75***	***SG***
8713N	***Injection 300 i.u. in 0.5 mL multi-dose cartridge***	*3*	*5*	*..*	** 563.00*	*32.90*	***Gonal-f Pen***	***SG***

continued ☞

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
8675N	***Injection set containing 1 vial powder for injection 450 i.u. and 1 pre-filled syringe solvent 1 mL***	*3*	*5*	*..*	** 841.46*	*32.90*	***Gonal-f***	***SG***
8714P	***Injection 450 i.u. in 0.75 mL multi-dose cartridge***	*3*	*5*	*..*	** 841.49*	*32.90*	***Gonal-f Pen***	***SG***
8715Q	***Injection 900 i.u. in 1.5 mL multi-dose cartridge***	*2*	*5*	*..*	** 1114.81*	*32.90*	***Gonal-f Pen***	***SG***

FOLLITROPIN BETA

Restricted Benefit
Anovulatory infertility.

NOTE:
Except in cases of hypopituitarism or primary amenorrhoea, the patient should have been adequately treated with clomiphene citrate and/or gonadorelin and failed to have conceived.

Women who have had apparent ovulation induced by other agents and have failed to conceive should have laparoscopic evidence that there is no other impediment to conception.

Oligomenorrhoea should have been present for at least twelve months or amenorrhoea for at least six months prior to treatment.

Patients with hyperprolactinaemia should have had appropriate surgical or medical treatment prior to treatment.

Restricted Benefit
For the treatment of infertility in males due to hypogonadotrophic hypogonadism, following failure of 6 months' treatment with human chorionic gonadotrophin to achieve adequate spermatogenesis. Combined treatment with HCG must be given.

8565T	***Solution for injection 300 i.u. in 0.36 mL multi-dose cartridge***	*3*	*5*	*..*	** 563.00*	*32.90*	***Puregon 300 IU/ 0.36 mL***	***SH***
8566W	***Solution for injection 600 i.u. in 0.72 mL multi-dose cartridge***	*2*	*5*	*..*	** 748.65*	*32.90*	***Puregon 600 IU/ 0.72 mL***	***SH***
8871X	***Solution for injection 900 i.u. in 1.08 mL multi-dose cartridge***	*2*	*5*	*..*	** 1114.79*	*32.90*	***Puregon 900 IU/ 1.08 mL***	***SH***

HUMAN CHORIONIC GONADOTROPHIN

Restricted Benefit
Anovulatory infertility.

NOTE:
Except in cases of hypopituitarism or primary amenorrhoea, the patient should have been adequately treated with clomiphene citrate and/or gonadorelin and failed to have conceived.

Women who have had apparent ovulation induced by other agents and have failed to conceive should have laparoscopic evidence that there is no other impediment to conception.

Oligomenorrhoea should have been present for at least twelve months or amenorrhoea for at least six months prior to treatment.

Patients with hyperprolactinaemia should have had appropriate surgical or medical treatment prior to treatment.

continued ☞

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Proprietary Name and Manufacturer	
	Restricted Benefit ***For the treatment of infertility in males due to hypogonadotrophic hypogonadism;*** ***For the treatment of infertility in males associated with isolated luteinising hormone deficiency;*** ***For the treatment of males who have combined deficiency of human growth hormone and gonadotrophins and in whom the absence of secondary sexual characteristics indicates a lag in maturation.***								
	Restricted Benefit ***For the treatment of boys over the age of 16 years who show clinical evidence of hypogonadism or delayed puberty. Treatment must not extend beyond 6 months.***								
1579D	*Injection set containing 3 ampoules powder for injection 500 units and 3 ampoules solvent 1 mL*	*1*	*5*	*..*	*30.44*	*31.47*		*Pregnyl*	*SH*
1581F	*Injection set containing 3 ampoules powder for injection 1,500 units and 3 ampoules solvent 1 mL*	*1*	*5*	*..*	*40.66*	*32.90*		*Pregnyl*	*SH*
	Restricted Benefit ***Cryptorchism not due to organic obstruction in boys over 12 months of age.***								
1583H	*Injection set containing 3 ampoules powder for injection 500 units and 3 ampoules solvent 1 mL*	*2*	*1*	*..*	** 53.01*	*32.90*		*Pregnyl*	*SH*
	• ***Ovulation stimulants, synthetic*** ***CLOMIPHENE CITRATE*** **NOTE:** ***Care must be taken to comply with the provisions of State/Territory law when prescribing clomiphene citrate.***								
	Restricted Benefit ***Anovulatory infertility;*** ***Patients undergoing in-vitro fertilisation.***								
1211R	*Tablet 50 mg*	*10*	*5*	*..*	** 32.67*	*32.90*	*a*	*Clomhexal*	*HX*
							a	*Fermil*	*SI*
							a	*GenRx Clomiphene*	*GX*
				B 0.14	*32.81*	*32.90*	*a*	*Serophene*	*SG*
				B 3.90	*36.57*	*32.90*	*a*	*Clomid*	*SW*

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
	Antiandrogens							
	• ***Antiandrogens, plain preparations***							
	CYPROTERONE ACETATE							
	Authority Required (STREAMLINED)							
	1230							
	Moderate to severe androgenisation in non-pregnant women (acne alone is not a sufficient indication of androgenisation).							
	CAUTION:							
	This drug should not be used during pregnancy as it may result in feminisation of the male foetus.							
1269T	*Tablet 50 mg*	*20*	*5*	*..*	*52.31*	*32.90*	[a] *Cyprohexal*	*SZ*
							[a] *Cyprone*	*AF*
							[a] *Cyprostat*	*SY*
							[a] *GenRx Cyproterone Acetate*	*GX*
							[a] *Procur*	*GM*
				B3.13	*55.44*	*32.90*	[a] *Androcur*	*SC*
	Authority Required (STREAMLINED)							
	1014							
	Advanced carcinoma of the prostate;							
	1404							
	To reduce drive in sexual deviations in males.							
1270W	*Tablet 50 mg*	*100*	*5*	*..*	** 207.29*	*32.90*	[a] *Cyprohexal*	*SZ*
							[a] *Cyprone*	*AF*
							[a] *Cyprostat*	*SY*
							[a] *GenRx Cyproterone Acetate*	*GX*
							[a] *Procur*	*GM*
				B3.00	** 210.29*	*32.90*	[a] *Androcur*	*SC*
8019C	*Tablet 100 mg*	*50*	*5*	*..*	*169.33*	*32.90*	[a] *Cyprohexal*	*SZ*
							[a] *Cyprostat-100*	*SY*
							[a] *GenRx Cyproterone Acetate*	*GX*
							[a] *Procur 100*	*GM*
				B1.65	*170.98*	*32.90*	[a] *Androcur-100*	*SC*

GENITO URINARY SYSTEM AND SEX HORMONES—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
	Other sex hormones and modulators of the genital system							
	• ***Antigonadotropins and similar agents***							
	DANAZOL							
	CAUTION:							
	Pregnancy must be excluded prior to administration of this drug.							
	Authority Required (STREAMLINED)							
	1090							
	Endometriosis, visually proven;							
	1151							
	Hereditary angio-oedema;							
	2639							
	Short-term treatment (up to 6 months) of intractable primary menorrhagia (Treatment of this indication is limited to 6 months. See Australian Product Information);							
	2640							
	Short-term treatment (up to 6 months) of severe benign (fibrocystic) breast disease or mastalgia associated with severe symptomatic benign breast disease in patients refractory to other treatments (Treatment of this indication is limited to 6 months. See Australian Product Information).							
1285P	*Capsule 100 mg*	*100*	*5*	*..*	*58.15*	*32.90*	*Azol 100*	*AF*
1287R	*Capsule 200 mg*	*100*	*5*	*..*	*86.54*	*32.90*	*Azol 200*	*AF*
	GESTRINONE							
	Authority Required							
	Short-term treatment (up to 6 months) of visually proven endometriosis (only 1 course of not more than 6 months' therapy will be authorised).							
8015W	*Capsule 2.5 mg*	*8*	*5*	*..*	*77.52*	*32.90*	*Dimetriose*	*SW*
	• ***Selective estrogen receptor modulators***							
	RALOXIFENE HYDROCHLORIDE							
	For listings see Generic/Proprietary Index							

UROLOGICALS

Other urologicals, incl. antispasmodics

• ***Urinary antispasmodics***

OXYBUTYNIN HYDROCHLORIDE

Restricted Benefit

Detrusor overactivity.

8039D	*Tablet 5 mg*	*100*	*5*	*..*	*15.54*	*16.57*	[a] *Ditropan*	*SW*
							[a] *Oxybutynin Sandoz*	*SZ*
							[a] *Oxybutynin Winthrop*	*WA*

GENITO URINARY SYSTEM AND SEX HORMONES—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
	PROPANTHELINE BROMIDE							
	Restricted Benefit ***Detrusor overactivity.***							
1953T	***Tablet 15 mg***	***200***	***5***	***..***	**** 26.03***	***27.06***	***Pro-Banthine***	***SI***
	• ***Other urologicals*** ***PHENOXYBENZAMINE HYDROCHLORIDE***							
	Restricted Benefit ***Phaeochromocytoma;*** ***Neurogenic urinary retention.***							
1862B	***Capsule 10 mg***	***100***	***5***	***..***	***66.93***	***32.90***	***Dibenyline***	***GH***
1166J	***Capsules 10 mg, 30***	***3***	***5***	***..***	**** 204.47***	***32.90***	***Dibenyline***	***GH***
9286R	***Capsules 10 mg, 100***	***‡ 1***	***5***	***..***	***1164.04***	***32.90***	***Dibenzyline***	***GH***

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
	PITUITARY AND HYPOTHALAMIC HORMONES AND ANALOGUES							
	Anterior pituitary lobe hormones and analogues							
	• ***ACTH***							
	TETRACOSACTRIN							
2832C	Injection 1 mg in 1 mL	5	5	..	* 70.84	32.90	Synacthen Depot 1 mg/1 mL	NV
	• ***Thyrotropin***							
	THYROTROPIN ALFA							
	Authority Required							
	Ablation of thyroid remnant tissue, in combination with radioactive iodine, in a post thyroidectomy patient without known metastatic disease.							
2700D	***Powder for injection 0.9 mg, 2***	***1***	***..***	***..***	***1900.99***	***32.90***	***Thyrogen***	***GZ***
	Posterior pituitary lobe hormones							
	• ***Vasopressin and analogues***							
	DESMOPRESSIN ACETATE							
	Authority Required (STREAMLINED)							
	1678							
	Cranial diabetes insipidus.							
8662X	***Tablet 200 micrograms***	***90***	***5***	***..***	**** 179.48***	***32.90***	***Minirin***	***FP***
2129C	***Intranasal solution 100 micrograms per mL, 2.5 mL***	***5***	***5***	***..***	**** 160.74***	***32.90***	***Minirin***	***FP***
8711L	***Nasal spray (pump pack) 10 micrograms per actuation, 60 actuations, 6 mL***	***2***	***5***	***..***	**** 160.61***	***32.90***	***Minirin Nasal Spray***	***FP***
	Authority Required (STREAMLINED)							
	2641							
	Primary nocturnal enuresis in patients aged 6 years or older who are refractory to an enuresis alarm;							
	2642							
	Primary nocturnal enuresis in patients aged 6 years or older for whom an enuresis alarm is contraindicated. The reason that an alarm is contraindicated must be documented in the patient's medical records when treatment is initiated.							
	NOTE:							
	Not to be used in preference to enuresis alarms.							
8663Y	***Tablet 200 micrograms***	***30***	***5***	***..***	***63.82***	***32.90***	***Minirin***	***FP***
	NOTE:							
	Only one application per six months with no more than twice the maximum quantity will be authorised for the tablets.							

continued ☞

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
	Authority Required (STREAMLINED) **2641** ***Primary nocturnal enuresis in patients aged 6 years or older who are refractory to an enuresis alarm;*** **2642** ***Primary nocturnal enuresis in patients aged 6 years or older for whom an enuresis alarm is contraindicated. The reason that an alarm is contraindicated must be documented in the patient's medical records when treatment is initiated.*** **NOTE:** ***Not to be used in preference to enuresis alarms.*** ***Desmopressin nasal spray may be associated with an increased risk of hyponatraemia compared to the tablet formulation.***							
8712M	*Nasal spray (pump pack) 10 micrograms per actuation, 60 actuations, 6 mL*	*‡ 1*	*5*	*..*	*83.30*	*32.90*	*Minirin Nasal Spray*	*FP*
	Hypothalamic hormones • ***Gonadotropin-releasing hormones*** ***NAFARELIN ACETATE*** **Authority Required** ***Initial treatment (up to 6 months) of visually proven endometriosis;*** ***Subsequent treatment (up to 6 months) of visually proven endometriosis, where 2 years or more have elapsed since the end of the previous course and where a recent bone density assessment has been made. The date of the assessment must be provided.***							
2962X	*Nasal spray (pump pack) 200 micrograms (base) per dose (60 doses)*	*‡ 1*	*5*	*..*	*95.08*	*32.90*	*Synarel*	*PH*
	CORTICOSTEROIDS FOR SYSTEMIC USE							
	Corticosteroids for systemic use, plain • ***Mineralocorticoids*** FLUDROCORTISONE ACETATE							
1433K	Tablet 100 micrograms	200	1	..	* 22.07	23.10	Florinef	BQ

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
	• *Glucocorticoids*							
	BETAMETHASONE ACETATE with BETAMETHASONE SODIUM PHOSPHATE							
	Restricted Benefit							
	Alopecia areata;							
	For local intra-articular or peri-articular infiltration;							
	Granulomata, dermal;							
	Keloid;							
	Lichen planus hypertrophic;							
	Lichen simplex chronicus;							
	Lupus erythematosus, chronic discoid;							
	Necrobiosis lipoidica;							
	Uveitis.							
2694T	***Injection 3 mg-3.9 mg (equivalent to 5.7 mg betamethasone) in 1 mL***	***5***	***..***	***..***	***25.74***	***26.77***	***Celestone Chronodose***	***SH***
	CORTISONE ACETATE							
1246N	Tablet 5 mg	50	4	..	14.87	15.90	Cortate	AS
1247P	Tablet 25 mg	60	4	..	16.81	17.84	Cortate	AS
	DEXAMETHASONE							
1292B	Tablet 500 micrograms	30	4	..	8.41	9.44	Dexmethsone	AS
2507Y	Tablet 4 mg	30	4	..	11.97	13.00	Dexmethsone	AS
	DEXAMETHASONE SODIUM PHOSPHATE							
2509C	Injection equivalent to 4 mg dexamethasone phosphate in 1 mL	5	..	..	17.65	18.68	HH	
1291Y	Injection equivalent to 8 mg dexamethasone phosphate in 2 mL	5	1	..	27.15	28.18	HH	
	HYDROCORTISONE							
1499X	Tablet 4 mg	50	4	..	10.76	11.79	Hysone 4	AF
1500Y	Tablet 20 mg	60	4	..	14.40	15.43	Hysone 20	AF
	HYDROCORTISONE SODIUM SUCCINATE							
1501B	Injection equivalent to 100 mg hydrocortisone with 2 mL solvent	2	..	..	* 16.71	17.74	Solu-Cortef	PH
3096Y	Injection equivalent to 250 mg hydrocortisone with 2 mL solvent	1	..	..	15.68	16.71	Solu-Cortef	PH

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Proprietary Name and Manufacturer	
	HYDROCORTISONE SODIUM SUCCINATE								
	Restricted Benefit ***For use in a hospital.***								
1510L	***Injection equivalent to 100 mg hydrocortisone with 2 mL solvent***	***6***	***..***	***..***	**** 38.15***	***32.90***		***Solu-Cortef***	***PH***
1511M	***Injection equivalent to 250 mg hydrocortisone with 2 mL solvent***	***6***	***..***	***..***	**** 61.61***	***32.90***		***Solu-Cortef***	***PH***
	METHYLPREDNISOLONE ACETATE								
	Restricted Benefit ***For local intra-articular or peri-articular infiltration.***								
1928L	***Injection 40 mg in 1 mL***	***5***	***..***	***..***	***24.38***	***25.41***	***a***	***Depo-Nisolone***	***KR***
				B0.76	***25.14***	***25.41***	***a***	***Depo-Medrol***	***PH***
	METHYLPREDNISOLONE SODIUM SUCCINATE								
2981X	Powder for injection equivalent to 40 mg methylprednisolone with diluent	5	..	..	33.15	32.90		Solu-Medrol	PF
8834Y	Powder for injection equivalent to 1 g methylprednisolone with diluent	1	..	..	98.67	32.90		Solu-Medrol	PF
	PREDNISOLONE								
3152X	Tablet 1 mg	100	4	..	8.00	9.03	a	Predsolone	LN
				B0.46	8.46	9.03	a	Panafcortelone	AS
1917X	Tablet 5 mg	60	4	..	8.15	9.18		Panafcortelone Solone	AS FM
1916W	Tablet 25 mg	30	4	..	9.90	10.93		Panafcortelone Solone	AS FM
	PREDNISOLONE SODIUM PHOSPHATE								
8285C	Oral solution equivalent to 5 mg prednisolone per mL, 30 mL	‡ 1	5	..	14.71	15.74	a	PredMix	LN
				B1.86	16.57	15.74	a	Redipred	AS
	PREDNISONE								
1934T	Tablet 1 mg	100	4	..	8.57	9.60	a	Predsone	LN
				B0.65	9.22	9.60	a	Panafcort	AS
1935W	Tablet 5 mg	60	4	..	8.92	9.95		Panafcort Sone	AS FM
1936X	Tablet 25 mg	30	4	..	11.29	12.32		Panafcort Sone	AS FM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Proprietary Name and Manufacturer	
	TRIAMCINOLONE ACETONIDE								
	Restricted Benefit								
	Alopecia areata;								
	For local intra-articular or peri-articular infiltration;								
	Granulomata, dermal;								
	Keloid;								
	Lichen planus hypertrophic;								
	Lichen simplex chronicus;								
	Lupus erythematosus, chronic discoid;								
	Necrobiosis lipoidica;								
	Psoriasis.								
2990J	***Injection 10 mg in 1 mL***	***5***	***..***	***..***	***25.74***	***26.77***		***Kenacort-A10***	***BQ***

THYROID THERAPY

Thyroid preparations

- ***Thyroid hormones***

LIOTHYRONINE SODIUM

Authority Required (STREAMLINED)

1219
Management of patients with thyroid cancer;

1858
Replacement therapy for hypothyroid patients who have documented intolerance to thyroxine sodium;

1859
Replacement therapy for hypothyroid patients who have documented resistance to thyroxine sodium;

1182
Initiation of thyroid therapy in severely hypothyroid patients.

2318B	***Tablet 20 micrograms***	***100***	***2***	***..***	***83.10***	***32.90***		***Tertroxin***	***SI***
	THYROXINE SODIUM								
2174K	Tablet equivalent to 50 micrograms	200	1	..	24.00	25.03	a	Eutroxsig	FM
	anhydrous thyroxine sodium			B1.30	25.30	25.03	a	Oroxine	SI
9287T	Tablet equivalent to 75 micrograms	200	1	..	24.69	25.72	a	Eutroxsig	FM
	anhydrous thyroxine sodium			B1.46	26.15	25.72	a	Oroxine	SI
2175L	Tablet equivalent to 100 micrograms	200	1	..	24.64	25.67	a	Eutroxsig	FM
	anhydrous thyroxine sodium			B1.31	25.95	25.67	a	Oroxine	SI
2173J	Tablet equivalent to 200 micrograms	200	1	..	27.86	28.89	a	Eutroxsig	FM
	anhydrous thyroxine sodium			B1.29	29.15	28.89	a	Oroxine	SI

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
	Antithyroid preparations							
	• ***Thiouracils***							
	PROPYLTHIOURACIL							
1955X	Tablet 50 mg	200	2	..	* 47.21	32.90	PL	
	• ***Sulfur-containing imidazole derivatives***							
	CARBIMAZOLE							
1153Q	Tablet 5 mg	200	2	..	* 30.61	31.64	Neo-Mercazole	LM
	PANCREATIC HORMONES							
	Glycogenolytic hormones							
	• ***Glycogenolytic hormones***							
	GLUCAGON HYDROCHLORIDE							
1449G	Injection set containing 1 mg (1 i.u.) and 1 mL solvent in disposable syringe	1	1	..	42.93	32.90	GlucaGen Hypokit	NO
	CALCIUM HOMEOSTASIS							
	Anti-parathyroid agents							
	• ***Calcitonin preparations***							
	SALCATONIN							
	NOTE:							
	The maximum quantities for salcatonin shown represent the number of individual ampoules and NOT multiples of the manufacturer's packs. The pack size for both strengths is five ampoules.							
	Authority Required (STREAMLINED)							
	1392							
	Symptomatic Paget's disease of bone;							
	1412							
	Treatment initiated in a hospital (in-patient or out-patient) of hypercalcaemia.							
2995P	***Injection 50 i.u. in 1 mL***	***30***	***5***	***..***	**** 207.23***	***32.90***	***Miacalcic 50***	***NV***
2997R	***Injection 100 i.u. in 1 mL***	***15***	***5***	***..***	**** 160.70***	***32.90***	***Miacalcic 100***	***NV***
	• ***Other anti-parathyroid agents***							
	CINACALCET HYDROCHLORIDE							
	Authority Required							
	Maintenance therapy, following initiation and stabilisation of treatment with cinacalcet, of a patient with chronic kidney disease on dialysis who has after 6 months treatment:							
	(a) a decrease of at least 30% in iPTH concentrations; or							
	(b) iPTH greater than 15 pmol per L and an (adjusted) serum calcium concentration of less than 2.6 mmol per L.							

continued ☞

SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
	NOTE: ***During the titration phase, intact PTH should be monitored 4 weekly (measured at least 12 hours post dose) and dose titrated until an appropriate iPTH concentration is achieved. During the titration phase, approval will be limited to sufficient supply for 4 weeks treatment at a time, with doses between 30 and 180 mg per day according to the patient's response and tolerability.*** ***During the maintenance phase, approval will be limited to provide sufficient quantity for 4 weeks treatment up to a maximum of 6 months supply for doses between 30 and 180 mg per day according to the patient's response and tolerability. Intact PTH should be monitored quarterly (measured at least 12 hours post dose) and dose adjusted as necessary to maintain an appropriate iPTH concentration.***							
9157Y	***Tablet 30 mg (base)***	***28***	***5***	***..***	***343.17***	***32.90***	***Sensipar***	***AN***
9158B	***Tablet 60 mg (base)***	***28***	***5***	***..***	***669.89***	***32.90***	***Sensipar***	***AN***
9159C	***Tablet 90 mg (base)***	***28***	***5***	***..***	***1001.84***	***32.90***	***Sensipar***	***AN***

ANTIINFECTIVES FOR SYSTEMIC USE

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Proprietary Name and Manufacturer	
	ANTIBACTERIALS FOR SYSTEMIC USE								
	Tetracyclines								
	• ***Tetracyclines***								
	DOXYCYCLINE								
9105F	Tablet 100 mg (as monohydrate)	7	1	..	8.04	9.07	a	Chem mart Doxycycline	CH
							a	Doxyhexal	SZ
							a	GenRx Doxycycline	GX
							a	Terry White Chemists Doxycycline	TW
2709N	Tablet 100 mg (as hydrochloride)	7	1	..	8.04	9.07	a	Doxsig	SI
							a	Doxy-100	GM
							a	Doxylin 100	AF
				B1.19	9.23	9.07	a	Vibramycin	PF
	NOTE: Bioequivalence has been demonstrated between doxycycline tablet 100 mg (as hydrochloride) and doxycycline tablet 100 mg (as monohydrate).								
2708M	Capsule 100 mg (as hydrochloride)	7	1	..	8.04	9.07	a	DBL Doxycycline	FA
				B1.15	9.19	9.07	a	Doryx	HH
	DOXYCYCLINE								
	Restricted Benefit ***Bronchiectasis in patients aged 8 years or older; Chronic bronchitis in patients aged 8 years or older; Severe acne.***								
9106G	***Tablet 50 mg (as monohydrate)***	***25***	***5***	..	***9.64***	***10.67***	a	***Chem mart Doxycycline***	***CH***
							a	***Doxyhexal***	***SZ***
							a	***Frakas***	***SI***
							a	***GenRx Doxycycline***	***GX***
							a	***Terry White Chemists Doxycycline***	***TW***
2711Q	***Tablet 50 mg (as hydrochloride)***	***25***	***5***	..	***9.64***	***10.67***	a	***Doxy-50***	***GM***
							a	***Doxylin 50***	***AF***
				B1.25	***10.89***	***10.67***	a	***Vibra-Tabs***	***PF***
	NOTE: ***Bioequivalence has been demonstrated between doxycycline tablet 50 mg (as hydrochloride) and doxycycline tablet 50 mg (as monohydrate).***								

continued ☞

ANTIINFECTIVES FOR SYSTEMIC USE—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Proprietary Name and Manufacturer	
2707L	***Capsule 50 mg (as hydrochloride)***	***25***	***5***	***..***	***9.64***	***10.67***	***a***	***DBL Doxycycline***	***FA***
				B1.31	***10.95***	***10.67***	***a***	***Doryx***	***HH***
	Restricted Benefit ***Pelvic inflammatory disease.***								
9107H	***Tablet 100 mg (as monohydrate)***	***28***	***..***	***..***	**** 14.19***	***15.22***	***a***	***Chem mart Doxycycline***	***CH***
							a	***Doxyhexal***	***SZ***
							a	***GenRx Doxycycline***	***GX***
							a	***Terry White Chemists Doxycycline***	***TW***
2702F	***Tablet 100 mg (as hydrochloride)***	***28***	***..***	***..***	**** 14.19***	***15.22***	***a***	***Doxsig***	***SI***
							a	***Doxy-100***	***GM***
							a	***Doxylin 100***	***AF***
				B4.76	**** 18.95***	***15.22***	***a***	***Vibramycin***	***PF***
	NOTE: ***Bioequivalence has been demonstrated between doxycycline tablet 100 mg (as hydrochloride) and doxycycline tablet 100 mg (as monohydrate).***								
2703G	***Capsule 100 mg (as hydrochloride)***	***28***	***..***	***..***	**** 14.19***	***15.22***	***a***	***DBL Doxycycline***	***FA***
				B4.60	**** 18.79***	***15.22***	***a***	***Doryx***	***HH***
	Restricted Benefit ***Urethritis.***								
9108J	***Tablet 100 mg (as monohydrate)***	***21***	***..***	***..***	***12.13***	***13.16***	***a***	***GenRx Doxycycline***	***GX***
				..	**** 12.14***	***13.17***	***a***	***Chem mart Doxycycline***	***CH***
							a	***Doxyhexal***	***SZ***
							a	***Terry White Chemists Doxycycline***	***TW***
2714W	***Tablet 100 mg (as hydrochloride)***	***21***	***..***	***..***	**** 12.14***	***13.17***	***a***	***Doxsig***	***SI***
							a	***Doxy-100***	***GM***
							a	***Doxylin 100***	***AF***
				B3.57	**** 15.71***	***13.17***	***a***	***Vibramycin***	***PF***
	NOTE: ***Bioequivalence has been demonstrated between doxycycline tablet 100 mg (as hydrochloride) and doxycycline tablet 100 mg (as monohydrate).***								
2715X	***Capsule 100 mg (as hydrochloride)***	***21***	***..***	***..***	***12.09***	***13.12***	***a***	***DBL Doxycycline***	***FA***
				B2.09	***14.18***	***13.12***	***a***	***Doryx***	***HH***

ANTIINFECTIVES FOR SYSTEMIC USE—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Proprietary Name and Manufacturer	
	MINOCYCLINE **CAUTION:** There are concerns about the incidence of benign intracranial hypertension associated with this drug.								
3037W	Capsule 100 mg	11	..	..	9.22	10.25		Akamin 100	AF
	NOTE: No applications for increased maximum quantities and/or repeats will be authorised.								
	_____								
	MINOCYCLINE **CAUTION:** ***There are concerns about the incidence of benign intracranial hypertension associated with this drug.***								
	Restricted Benefit ***Severe acne not responding to other tetracyclines.***								
	NOTE: ***No applications for increased maximum quantities and/or repeats will be authorised.***								
1616C	***Tablet 50 mg***	***60***	***5***	***..***	***15.06***	***16.09***	[a]	***Akamin 50***	***AF***
				B0.85	***15.91***	***16.09***	[a]	***Minomycin-50***	***SI***
	Beta-lactam antibacterials, penicillins								
	• ***Penicillins with extended spectrum***								
	AMOXYCILLIN								
1884E	Capsule 250 mg	20	1	..	8.12	9.15	[a]	Alphamox 250	AF
							[a]	Amohexal	HX
							[a]	Amoxycillin-DP	GM
							[a]	APO-Amoxycillin	TX
							[a]	Chem mart Amoxycillin	CH
							[a]	Cilamox	SI
							[a]	GenRx Amoxycillin	GX
							[a]	Terry White Chemists Amoxycillin	TW
				B0.79	8.91	9.15	[a]	Amoxil	GK

continued ☞

ANTIINFECTIVES FOR SYSTEMIC USE—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
1889K	Capsule 500 mg	20	1	..	10.22	11.25	[a] Alphamox 500	AF
							[a] Amohexal	HX
							[a] Amoxycillin-DP	GM
							[a] Amoxycillin Sandoz	SZ
							[a] APO-Amoxycillin	TX
							[a] Chem mart Amoxycillin	CH
							[a] Cilamox	SI
							[a] GenRx Amoxycillin	GX
							[a] Moxacin	AS
							[a] Terry White Chemists Amoxycillin	TW
				B0.80	11.02	11.25	[a] Amoxil	GK
1878W	Sachet containing oral powder 3 g	1	..	..	8.68	9.71	Amoxil	GK
1886G	Powder for syrup 125 mg per 5 mL, 100 mL	‡ 1	1	..	# 10.42	11.81	[a] Alphamox 125	AF
							[a] Amoxycillin Sandoz	SZ
							[a] Bgramin	GM
							[a] Chem mart Amoxycillin	CH
							[a] GenRx Amoxycillin	GX
							[a] Ranmoxy	RA
							[a] Terry White Chemists Amoxycillin	TW
				B0.95	# 11.37	11.81	[a] Amoxil	GK
1887H	Powder for syrup 250 mg per 5 mL, 100 mL	‡ 1	1	..	# 11.26	12.65	[a] Alphamox 250	AF
							[a] Amohexal	HX
							[a] Amoxycillin Sandoz	SZ
							[a] Bgramin	GM
							[a] Chem mart Amoxycillin	CH
							[a] Cilamox	SI
							[a] GenRx Amoxycillin	GX
							[a] Ranmoxy	RA
							[a] Terry White Chemists Amoxycillin	TW
				B0.79	# 12.05	12.65	[a] Amoxil Forte	GK
8705E	Powder for oral suspension 500 mg per 5 mL, 100 mL	‡ 1	1	..	# 14.27	15.66	Maxamox	SZ

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Proprietary Name and Manufacturer	
	AMOXYCILLIN								
	Restricted Benefit ***Acute exacerbations of chronic bronchitis.***								
8581P	***Tablet 1 g***	***14***	***1***	***..***	***10.36***	***11.39***	[a]	***Amoxycillin Sandoz***	***BG***
				B1.17	***11.53***	***11.39***	[a]	***Maxamox***	***SZ***
	AMPICILLIN								
2390T	Powder for injection 500 mg	5	1	..	10.65	11.68	[a]	Austrapen	LN
							[a]	Ibimicyn	GM
2977Q	Powder for injection 1 g	5	1	..	13.64	14.67	[a]	Aspen Ampicyn	AS
							[a]	Austrapen	LN
							[a]	Ibimicyn	GM
	• ***Beta-lactamase sensitive penicillins*** BENZATHINE BENZYLPENICILLIN								
2267H	Injection 900 mg in 2.3 mL single use pre-filled syringe	10	..	..	292.68	32.90		Bicillin L-A	AS
	BENZYLPENICILLIN								
1775K	Powder for injection 600 mg	10	1	..	* 40.39	32.90		BenPen	CS
2647H	Powder for injection 3 g	10	..	..	* 62.49	32.90		BenPen	CS
	PHENOXYMETHYLPENICILLIN								
1787C	Tablet 250 mg	50	..	..	* 11.15	12.18		Abbocillin-VK Filmtab	SI
3028J	Tablet 500 mg	50	..	..	* 13.63	14.66		Abbocillin-VK Filmtab	SI
1789E	Capsule 250 mg	50	..	..	10.98	12.01		LPV	AS
				..	10.98	12.01	[a]	Cilicaine VK	FM
							[a]	Cilopen VK	GM
							[a]	Penhexal VK	HX
2965C	Capsule 500 mg	50	..	..	13.41	14.44		LPV	AS
				..	13.41	14.44	[a]	Cilicaine VK	FM
							[a]	Cilopen VK	GM
							[a]	Penhexal VK	HX
9143F	Oral suspension 150 mg (as benzathine) per 5 mL, 100 mL	2	1	..	* 21.97	23.00		Abbocillin-V	SI
								Cilicaine V	FM

ANTIINFECTIVES FOR SYSTEMIC USE—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Proprietary Name and Manufacturer	
	PHENOXYMETHYLPENICILLIN								
	Restricted Benefit ***Prophylaxis of recurrent streptococcal infections (including rheumatic fever).***								
1703P	***Tablet 250 mg***	***50***	***5***	***..***	**** 11.15***	***12.18***		***Abbocillin-VK Filmtab***	***SI***
1705R	***Capsule 250 mg***	***50***	***5***	***..***	***10.98***	***12.01***		***LPV***	***AS***
				..	***10.98***	***12.01***	***a***	***Cilicaine VK***	***FM***
							a	***Cilopen VK***	***GM***
							a	***Penhexal VK***	***HX***
	PROCAINE PENICILLIN								
1794K	Injection 1.5 g	5	..	..	87.97	32.90		Cilicaine	SI
	• ***Beta-lactamase resistant penicillins***								
	DICLOXACILLIN								
	Restricted Benefit ***Serious staphylococcal infections.***								
8121K	***Capsule 250 mg***	***24***	***..***	***..***	***11.02***	***12.05***	***a***	***Diclocil***	***BQ***
							a	***Dicloxsig***	***SI***
							a	***Distaph 250***	***AF***
8122L	***Capsule 500 mg***	***24***	***..***	***..***	***16.51***	***17.54***	***a***	***Diclocil***	***BQ***
							a	***Dicloxsig***	***SI***
							a	***Distaph 500***	***AF***
	FLUCLOXACILLIN **CAUTION:** Severe cholestatic hepatitis has been reported with this drug. Significant risk factors are age, particularly greater than 55 years, and duration of treatment longer than 14 days.								
1524F	Powder for injection 500 mg	5	..	..	15.06	16.09	a	Flubiclox	GM
							a	Flucil	AS
1525G	Powder for injection 1 g	5	1	..	20.23	21.26	a	Flubiclox	GM
							a	Flucil	AS
							a	HH	

continued ☞

ANTIINFECTIVES FOR SYSTEMIC USE—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
	FLUCLOXACILLIN							
	CAUTION:							
	Severe cholestatic hepatitis has been reported with this drug. Significant risk factors are age, particularly greater than 55 years, and duration of treatment longer than 14 days.							
	Restricted Benefit							
	Serious staphylococcal infections.							
1526H	*Capsule 250 mg (as sodium)*	*24*	*..*	*..*	*11.02*	*12.05*	[a] *Flopen*	*AS*
							[a] *Staphylex 250*	*AF*
1527J	*Capsule 500 mg (as sodium)*	*24*	*..*	*..*	*16.51*	*17.54*	[a] *Flopen*	*AS*
							[a] *Staphylex 500*	*AF*
9149M	*Powder for oral liquid 125 mg (as sodium) per 5 mL, 100 mL*	*‡ 1*	*..*	*..*	*# 15.94*	*17.33*	*LN*	
9150N	*Powder for oral liquid 250 mg (as sodium) per 5 mL, 100 mL*	*‡ 1*	*..*	*..*	*# 19.65*	*21.04*	*LN*	
	• ***Combinations of penicillins, incl. beta-lactamase inhibitors***							
	AMOXYCILLIN with CLAVULANIC ACID							
	CAUTION:							
	Hepatotoxicity has been reported with this drug.							
	Restricted Benefit							
	Infections where resistance to amoxycillin is suspected;							
	Infections where resistance to amoxycillin is proven.							
1891M	*Tablet 500 mg-125 mg*	*10*	*1*	*..*	*11.73*	*12.76*	[a] *Clamoxyl Duo*	*AL*
							[a] *Curam 500/125*	*SZ*
							[a] *GA-Amclav 500/125*	*GM*
							[a] *Moxiclav Duo 500/125*	*AW*
				B1.55	*13.28*	*12.76*	[a] *Augmentin Duo*	*GK*

continued ☞

ANTIINFECTIVES FOR SYSTEMIC USE—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Proprietary Name and Manufacturer	
8254K	***Tablet 875 mg-125 mg***	***10***	***1***	***..***	***14.17***	***15.20***	[a]	***Chem mart Amoxycillin and Clavulanic Acid***	***CH***
							[a]	***Clamoxyl Duo forte***	***AL***
							[a]	***Clavycillin 875/125***	***CR***
							[a]	***Curam 875/125***	***SZ***
							[a]	***GA-Amclav Forte 875/125***	***GM***
							[a]	***GenRx Amoxycillin and Clavulanic Acid***	***GX***
							[a]	***Moxiclav Duo Forte 875/125***	***AW***
							[a]	***Terry White Chemists Amoxycillin and Clavulanic Acid***	***TW***
				B2.04	***16.21***	***15.20***	[a]	***Augmentin Duo forte***	***GK***
1892N	***Powder for syrup 125 mg-31.25 mg per 5 mL, 75 mL***	***‡ 1***	***1***	***..***	***# 12.05***	***13.44***	[a]	***Clamoxyl***	***AL***
				B1.51	***# 13.56***	***13.44***	[a]	***Augmentin***	***GK***
8319W	***Powder for syrup 400 mg-57 mg per 5 mL, 60 mL***	***‡ 1***	***1***	***..***	***# 13.56***	***14.95***	[a]	***Clamoxyl Duo 400***	***AL***
				B1.54	***# 15.10***	***14.95***	[a]	***Augmentin Duo 400***	***GK***
	TICARCILLIN with CLAVULANIC ACID								
	Restricted Benefit ***Infections where positive bacteriological evidence confirms that this antibiotic is an appropriate therapeutic agent; Septicaemia, suspected; Septicaemia, proven.***								
2179Q	***Powder for injection 3 g-100 mg (solvent required)*** ***(code 6884H applies to above item with approved solvent)***	***10***	***..***	***..***	***162.89***	***32.90***		***Timentin***	***GK***
	Other beta-lactam antibacterials								
	• ***First-generation cephalosporins***								
	CEFALOTIN								
2964B	Powder for injection 1 g	10	1	..	40.35	32.90	[a]	Cefalotin Sandoz	SZ
							[a]	Keflin Neutral	AS
							[a]	HH	

ANTIINFECTIVES FOR SYSTEMIC USE—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
	CEPHALEXIN							
3058Y	Capsule 250 mg	20	1	..	8.42	9.45	[a] Cefalexin Sandoz	SZ
							[a] Cephabell	BF
							[a] Cephalexin Max	XF
							[a] Cephatrust 250	MI
							[a] Chem mart Cephalexin	CH
							[a] Cilex	GM
							[a] GenRx Cephalexin	GX
							[a] Ialex	LN
							[a] Ibilex 250	AF
							[a] Rancef	RA
							[a] Sporahexal	HX
							[a] Terry White Chemists Cephalexin	TW
				B3.30	11.72	9.45	[a] Keflex	AS
3119E	Capsule 500 mg	20	1	..	10.34	11.37	[a] Cefalexin Sandoz	SZ
							[a] Cephabell	BF
							[a] Cephalexin Max	XF
							[a] Cephatrust 500	MI
							[a] Chem mart Cephalexin	CH
							[a] Cilex	GM
							[a] GenRx Cephalexin	GX
							[a] Ialex	LN
							[a] Ibilex 500	AF
							[a] Rancef	RA
							[a] Sporahexal	HX
							[a] Terry White Chemists Cephalexin	TW
				B4.41	14.75	11.37	[a] Keflex	AS
3094W	Granules for syrup 125 mg per 5 mL, 100 mL	‡ 1	1	..	# 11.41	12.80	[a] Cefalexin Sandoz	SZ
							[a] Chem mart Cephalexin	CH
							[a] Cilex	GM
							[a] GenRx Cephalexin	GX
							[a] Ialex	LN
							[a] Ibilex 125	AF
							[a] Terry White Chemists Cephalexin	TW
				B3.55	# 14.96	12.80	[a] Keflex	AS

continued ☞

ANTIINFECTIVES FOR SYSTEMIC USE—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
3095X	Granules for syrup 250 mg per 5 mL, 100 mL	‡ 1	1	..	# 12.81	14.20	[a] Cefalexin Sandoz	SZ
							[a] Chem mart Cephalexin	CH
							[a] Cilex	GM
							[a] GenRx Cephalexin	GX
							[a] Ialex	LN
							[a] Ibilex 250	AF
							[a] Terry White Chemists Cephalexin	TW
				B4.38	# 17.19	14.20	[a] Keflex	AS
	CEPHAZOLIN							
	Restricted Benefit							
	Infections where positive bacteriological evidence confirms that this antibiotic is an appropriate therapeutic agent;							
	Septicaemia, suspected;							
	Septicaemia, proven.							
1256D	***Powder for injection 500 mg***	***10***	***..***	***..***	**** 45.13***	***32.90***	***HH***	
1257E	***Powder for injection 1 g***	***10***	***..***	***..***	***66.09***	***32.90***	***[a] Cefazolin Sandoz***	***SZ***
							[a] Kefzol	***AS***
				..	**** 66.09***	***32.90***	***[a] HH***	
	• ***Second-generation cephalosporins***							
	CEFACLOR							
	CAUTION:							
	Serum sickness-like reactions have been reported with this drug, especially in children.							
1169M	Tablet 375 mg (sustained release)	10	1	..	12.46	13.49	[a] Cefaclor-GA	GN
							[a] Chem mart Cefaclor CD	CH
							[a] Douglas Cefaclor-CD	GM
							[a] GenRx Cefaclor CD	GX
							[a] Karlor CD	LN
							[a] Keflor CD	AF
							[a] Ozcef	RA
							[a] Terry White Chemists Cefaclor CD	TW
				B5.20	17.66	13.49	[a] Ceclor CD	AS

continued ☞

ANTIINFECTIVES FOR SYSTEMIC USE—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
2460L	Powder for oral suspension 125 mg per 5 mL, 100 mL	‡ 1	1	..	# 13.07	14.46	[a] Aclor 125	AW
							[a] Cefaclor Sandoz	SZ
							[a] Chem mart Cefaclor	CH
							[a] GenRx Cefaclor	GX
							[a] Keflor	AF
							[a] Ozcef	RA
							[a] Terry White Chemists Cefaclor	TW
				B4.18	# 17.25	14.46	[a] Ceclor	AS
2461M	Powder for oral suspension 250 mg per 5 mL, 75 mL	‡ 1	1	..	# 13.40	14.79	[a] Aclor 250	AW
							[a] Cefaclor Sandoz	SZ
							[a] Chem mart Cefaclor	CH
							[a] GenRx Cefaclor	GX
							[a] Keflor	AF
							[a] Ozcef	RA
							[a] Terry White Chemists Cefaclor	TW
				B4.37	# 17.77	14.79	[a] Ceclor	AS
	CEFUROXIME AXETIL							
8292K	Tablet 250 mg (base)	14	1	..	18.19	19.22	Zinnat	GK

• *Third-generation cephalosporins*

CEFOTAXIME

Restricted Benefit

Infections where positive bacteriological evidence confirms that this antibiotic is an appropriate therapeutic agent;

Septicaemia, suspected;

Septicaemia, proven.

1085D	***Powder for injection 1 g***	***10***	***..***	***..***	***27.27***	***28.30***	[a] ***HH***	
				B25.10	**** 52.39***	***28.32***	[a] ***Cefotaxime Sandoz***	***SZ***
1086E	***Powder for injection 2 g***	***10***	***..***	***..***	***44.60***	***32.90***	[a] ***HH***	
				B46.50	**** 91.09***	***32.90***	[a] ***Cefotaxime Sandoz***	***SZ***

CEFTRIAXONE

Restricted Benefit

Gonorrhoea.

9058R	***Powder for injection 500 mg***	***1***	***..***	***..***	***10.06***	***11.09***	***Ceftriaxone ICP***	***IZ***

continued ☞

ANTIINFECTIVES FOR SYSTEMIC USE—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Proprietary Name and Manufacturer	
	Restricted Benefit ***Infections where positive bacteriological evidence confirms that this antibiotic is an appropriate therapeutic agent;*** ***Septicaemia, suspected;*** ***Septicaemia, proven.***								
1783W	***Powder for injection 500 mg***	***5***	***..***	***..***	**** 26.34***	***27.37***		***Ceftriaxone ICP***	***IZ***
1784X	***Powder for injection 1 g***	***5***	***..***	***..***	**** 37.79***	***32.90***	***a***	***Ceftriaxone ICP***	***IZ***
							a	***Ceftriaxone Sandoz***	***SZ***
							a	***DBL Ceftriaxone***	***HH***
							a	***Rocephin***	***RO***
				..	***37.79***	***32.90***	***a***	***XF***	
1785Y	***Powder for injection 2 g***	***5***	***..***	***..***	**** 62.39***	***32.90***	***a***	***Ceftriaxone ICP***	***IZ***
							a	***Ceftriaxone Sandoz***	***SZ***
							a	***DBL Ceftriaxone***	***HH***
							a	***Rocephin***	***RO***
	• ***Fourth-generation cephalosporins*** ***CEFEPIME***								
	Authority Required ***Treatment of febrile neutropenia.***								
8315P	***Powder for injection 1 g (solvent required)*** ***(code 7079N applies to above item with approved solvent)***	***10***	***..***	***..***	**** 183.39***	***32.90***		***Maxipime***	***BQ***
8316Q	***Powder for injection 2 g (solvent required)*** ***(code 7085X applies to above item with approved solvent)***	***10***	***..***	***..***	**** 331.19***	***32.90***		***Maxipime***	***BQ***
	Sulfonamides and trimethoprim								
	• ***Trimethoprim and derivatives*** TRIMETHOPRIM								
2922T	Tablet 300 mg	7	1	..	8.05	9.08	a	Alprim	AF
				B1.03	9.08	9.08	a	Triprim	SI
	• ***Combinations of sulfonamides and trimethoprim, incl. derivatives*** TRIMETHOPRIM with SULFAMETHOXAZOLE **CAUTION:** There is an increased risk of severe adverse reactions with this combination in the elderly.								
2949F	Tablet 80 mg-400 mg	10	1	..	8.24	9.27		Resprim	AF

continued ☞

ANTIINFECTIVES FOR SYSTEMIC USE—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Proprietary Name and Manufacturer	
2951H	Tablet 160 mg-800 mg	10	1	..	8.96	9.99	a	Bactrim DS	RO
							a	Resprim Forte	AF
				B1.10	10.06	9.99	a	Septrin Forte	SI
3103H	Oral suspension 40 mg-200 mg per 5 mL, 100 mL	‡ 1	1	..	8.62	9.65		Bactrim	RO
				B1.46	10.08	9.65		Septrin	SI

Macrolides, lincosamides and streptogramins

• *Macrolides*

AZITHROMYCIN

Restricted Benefit

Uncomplicated urethritis due to Chlamydia trachomatis;

Uncomplicated cervicitis due to Chlamydia trachomatis.

NOTE:

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

8200N	***Tablet 500 mg***	***2***	***..***	***..***	***23.46***	***24.49***		***Zithromax***	***PF***

Restricted Benefit

Trachoma.

NOTE:

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

8336R	***Tablet 500 mg***	***2***	***2***	***..***	***23.46***	***24.49***		***Zithromax***	***PF***
8201P	***Powder for oral suspension 200 mg per 5 mL, 15 mL***	***‡ 1***	***..***	***..***	***# 22.98***	***24.37***		***Zithromax***	***PF***

CLARITHROMYCIN

8318T	Tablet 250 mg	14	1	..	12.25	13.28	a	APO-Clarithromycin	TX
							a	Chem mart Clarithromycin	CH
							a	Clarac	GM
							a	Clarihexal	SZ
							a	Clarithro 250	SI
							a	GenRx Clarithromycin	GX
							a	Kalixocin	AF
							a	Terry White Chemists Clarithromycin	TW
				B1.96	14.21	13.28	a	Klacid	AB

continued ☞

ANTIINFECTIVES FOR SYSTEMIC USE—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Proprietary Name and Manufacturer	
	CLARITHROMYCIN								
	Restricted Benefit ***Bordetella pertussis;*** ***Atypical mycobacterial infections.***								
9192T	***Powder for oral liquid 250 mg per 5 mL, 50 mL***	***‡ 1***	***..***	***..***	***# 36.80***	***32.90***		***Klacid***	***AB***
	ERYTHROMYCIN								
1404X	Capsule 250 mg	25	1	..	9.00	10.03	a	DBL Erythromycin	FA
				B1.35	10.35	10.03	a	Eryc	HH
	ERYTHROMYCIN ETHYL SUCCINATE								
2750R	Tablet 400 mg (base)	25	1	..	8.93	9.96	a	E-Mycin	AF
				B2.36	11.29	9.96	a	E.E.S. 400 Filmtab	LM
2424N	Powder for oral liquid 200 mg (base) per 5 mL, 100 mL	‡ 1	1	..	# 11.00	12.39	a	E-Mycin 200	AF
				B1.67	# 12.67	12.39	a	E.E.S. 200	LM
2428T	Powder for oral liquid 400 mg (base) per 5 mL, 100 mL	‡ 1	1	..	# 12.23	13.62	a	E-Mycin 400	AF
				B1.35	# 13.58	13.62	a	E.E.S. Granules	LM
	ERYTHROMYCIN LACTOBIONATE								
1397M	Powder for I.V. infusion 1 g (base)	5	..	..	* 50.94	32.90		Erythrocin-I.V.	LM
	ROXITHROMYCIN								
8129W	Tablet for oral suspension 50 mg	10	1	..	12.46	13.49		Rulide D	SW
1760P	Tablet 150 mg	10	1	..	11.33	12.36	a	Biaxsig	AV
							a	Roxar 150	SI
							a	Roxide	SZ
							a	Roximycin	AF
				B2.60	13.93	12.36	a	Rulide	SW
8016X	Tablet 300 mg	5	1	..	11.33	12.36	a	Biaxsig	AV
							a	Roxar 300	SI
							a	Roxide	SZ
							a	Roximycin	AF
				B2.60	13.93	12.36	a	Rulide	SW

• *Lincosamides*

CLINDAMYCIN

Restricted Benefit

Gram-positive coccal infections where these cannot be safely and effectively treated with a penicillin.

3138E	***Capsule 150 mg***	***24***	***..***	***..***	***19.33***	***20.36***	***a***	***Cleocin***	***KR***
				B1.45	***20.78***	***20.36***	***a***	***Dalacin C***	***PH***

ANTIINFECTIVES FOR SYSTEMIC USE—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
	LINCOMYCIN							
2530E	Injection 600 mg in 2 mL	5	..	..	30.65	31.68	Lincocin	PH
	Aminoglycoside antibacterials							
	• ***Other aminoglycosides***							
	GENTAMICIN SULFATE							
2824P	Injection 80 mg (base) in 2 mL	10	1	..	* 20.07	21.10	[a] HH	
				..	20.07	21.10	[a] PU	
	TOBRAMYCIN SULFATE							
	Restricted Benefit							
	Infections where positive bacteriological evidence confirms that this antibiotic is an appropriate therapeutic agent;							
	Septicaemia, suspected;							
	Septicaemia, proven.							
1356J	***Injection 80 mg (base) in 2 mL***	***10***	***1***	***..***	**** 64.59***	***32.90***	***HH***	
8872Y	***Injection 80 mg (base) in 2 mL (without preservative)***	***10***	***1***	***..***	**** 64.59***	***32.90***	***PU***	
	Quinolone antibacterials							
	• ***Fluoroquinolones***							
	CIPROFLOXACIN							
	Restricted Benefit							
	Gonorrhoea.							
	NOTE:							
	No applications for increased maximum quantities and/or repeats will be authorised.							
1311B	***Tablet 250 mg***	***2***	***..***	***..***	***11.67***	***12.70***	***Ciproxin 250***	***BN***

continued ☞

ANTIINFECTIVES FOR SYSTEMIC USE—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Proprietary Name and Manufacturer	
	Authority Required								
	Respiratory tract infection proven or suspected to be caused by Pseudomonas aeruginosa in severely immunocompromised patients;								
	Bacterial gastroenteritis in severely immunocompromised patients;								
	Treatment of infections proven to be due to Pseudomonas aeruginosa or other gram-negative bacteria resistant to all other oral antimicrobials;								
	Treatment of joint and bone infections, epididymo-orchitis, prostatitis or perichondritis of the pinna, suspected or proven to be caused by gram-negative bacteria or gram-positive bacteria resistant to all other appropriate antimicrobials.								
1208N	*Tablet 250 mg*	*14*	*..*	*..*	*25.90*	*26.93*	*a*	*C-Flox 250*	*AL*
							a	*Cifran*	*RA*
							a	*Ciprol 250*	*SI*
							a	*GenRx Ciprofloxacin*	*GX*
							a	*Profloxin*	*SZ*
				B1.45	*27.35*	*26.93*	*a*	*Ciproxin 250*	*BN*
1209P	*Tablet 500 mg*	*14*	*..*	*..*	*44.32*	*32.90*	*a*	*C-Flox 500*	*AL*
							a	*Cifran*	*RA*
							a	*Ciprofloxacin 500*	*CR*
							a	*Ciprofloxacin-BW*	*BF*
							a	*Ciprol 500*	*SI*
							a	*GenRx Ciprofloxacin*	*GX*
							a	*Profloxin*	*SZ*
							a	*Proquin*	*GM*
							a	*GN*	
				B1.26	*45.58*	*32.90*	*a*	*Ciproxin 500*	*BN*
1210Q	*Tablet 750 mg*	*14*	*..*	*..*	*62.07*	*32.90*	*a*	*C-Flox 750*	*AL*
							a	*Cifran*	*RA*
							a	*Ciprofloxacin 750*	*CR*
							a	*Ciprofloxacin-BW*	*BF*
							a	*Ciprol 750*	*SI*
							a	*GenRx Ciprofloxacin*	*GX*
							a	*Profloxin*	*SZ*
							a	*Proquin*	*GM*
							a	*GN*	
				B1.37	*63.44*	*32.90*	*a*	*Ciproxin 750*	*BN*

ANTIINFECTIVES FOR SYSTEMIC USE—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
	NORFLOXACIN							
	Authority Required ***Acute bacterial enterocolitis;*** ***Complicated urinary tract infection.***							
3010K	***Tablet 400 mg***	***14***	***1***	***..***	***17.29***	***18.32***	[a] ***Chem mart Norfloxacin***	***CH***
							[a] ***GenRx Norfloxacin***	***GX***
							[a] ***Norflohexal***	***SZ***
							[a] ***Nufloxib***	***AF***
							[a] ***Roxin***	***SI***
							[a] ***Terry White Chemists Norfloxacin***	***TW***
							[a] ***GM***	
				B3.62	***20.91***	***18.32***	[a] ***Noroxin***	***MK***
	Other antibacterials							
	• ***Glycopeptide antibacterials***							
	VANCOMYCIN							
	Restricted Benefit ***Prophylaxis of endocarditis in patients hypersensitive to penicillin.***							
3130R	***Powder for injection 500 mg (500,000 i.u.) vancomycin activity***	***2***	***..***	***..***	**** 46.09***	***32.90***	[a] ***Vancocin CP***	***AS***
							[a] ***Vancomycin Sandoz***	***SZ***
							[a] ***HH***	
2269K	***Powder for injection 1 g (1,000,000 i.u.) vancomycin activity***	***1***	***..***	***..***	***46.07***	***32.90***	[a] ***Vancomycin Sandoz***	***SZ***
							[a] ***HH***	
	Restricted Benefit ***Endophthalmitis;*** ***Use initiated in a hospital for infections where vancomycin is an appropriate antibiotic.***							
3131T	***Powder for injection 500 mg (500,000 i.u.) vancomycin activity***	***5***	***..***	***..***	**** 103.89***	***32.90***	[a] ***Vancocin CP***	***AS***
							[a] ***Vancomycin Sandoz***	***SZ***
							[a] ***HH***	
2270L	***Powder for injection 1 g (1,000,000 i.u.) vancomycin activity***	***3***	***..***	***..***	**** 123.41***	***32.90***	[a] ***Vancomycin Sandoz***	***SZ***
							[a] ***HH***	

ANTIINFECTIVES FOR SYSTEMIC USE—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Proprietary Name and Manufacturer	
	• *Steroid antibacterials*								
	FUSIDIC ACID								
	Restricted Benefit								
	For use in combination with another antibiotic in the treatment of proven serious staphylococcal infections.								
2312Q	***Tablet (sodium salt) 250 mg***	***36***	***1***	***..***	***84.93***	***32.90***		***Fucidin***	***CS***
	• *Imidazole derivatives*								
	METRONIDAZOLE								
1636D	Tablet 200 mg	21	1	..	7.53	8.56	[a]	Metrogyl 200	AF
							[a]	Metronide 200	AV
				B2.30	9.83	8.56	[a]	Flagyl	SW
1626N	Tablet 400 mg	5	2	..	7.45	8.48		Metrogyl 400	AF
1642K	Suppositories 500 mg, 10	‡ 1	..	..	22.73	23.76		Flagyl	SW
	METRONIDAZOLE								
	Restricted Benefit								
	Treatment of anaerobic infections.								
1621H	***Tablet 400 mg***	***21***	***1***	***..***	***9.60***	***10.63***	***[a]***	***Metrogyl 400***	***AF***
							[a]	***Metronide 400***	***AV***
				B2.30	***11.90***	***10.63***	***[a]***	***Flagyl***	***SW***
	Restricted Benefit								
	Prophylaxis in large bowel surgery;								
	Treatment, in a hospital, of acute anaerobic sepsis.								
1638F	***I.V. infusion 500 mg in 100 mL***	***5***	***1***	***..***	**** 31.54***	***32.57***	***[a]***	***BX***	
				..	**** 31.54***	***32.57***	***[a]***	***DBL Metronidazole Intravenous Infusion***	***HH***
							[a]	***Metronidazole Sandoz***	***SZ***
	METRONIDAZOLE BENZOATE								
1630T	Oral suspension 320 mg per 5 mL (equivalent to 200 mg metronidazole in 5 mL), 100 mL	‡ 1	..	..	16.74	17.77		Flagyl S	SW

ANTIINFECTIVES FOR SYSTEMIC USE—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Proprietary Name and Manufacturer	
	TINIDAZOLE								
1465D	Tablet 500 mg	4	..	..	8.77	9.80	a	Simplotan	GP
				B2.51	11.28	9.80	a	Fasigyn	PF
	• ***Nitrofuran derivatives***								
	NITROFURANTOIN								
	CAUTION:								
	Nitrofurantoin may cause peripheral neuritis and severe pulmonary reactions.								
1692C	Capsule 50 mg	30	1	..	16.01	17.04		Macrodantin	PU
1693D	Capsule 100 mg	30	1	..	23.75	24.78		Macrodantin	PU
	• ***Other antibacterials***								
	HEXAMINE HIPPURATE								
3124K	Tablet 1 g	100	5	..	40.49	32.90		Hiprex	IA
	ANTIMYCOTICS FOR SYSTEMIC USE								
	Antimycotics for systemic use								
	• ***Antibiotics***								
	AMPHOTERICIN								
1047D	Powder for injection 50 mg	1	..	..	34.22	32.90		Fungizone	BQ
	• ***Imidazole derivatives***								
	KETOCONAZOLE								
	Authority Required								
	Symptomatic genital candidiasis recurring after treatment of at least 2 episodes with topical therapy.								
	CAUTION:								
	Hepatotoxicity has been reported with ketoconazole.								
1573T	***Tablet 200 mg***	***10***	..	..	***19.11***	***20.14***		***Nizoral***	***JC***
	Authority Required								
	Oral candidiasis in severely immunocompromised persons where topical therapy has failed;								
	Systemic or deep mycoses where other forms of therapy have failed.								
	CAUTION:								
	Hepatotoxicity has been reported with ketoconazole.								
1572R	***Tablet 200 mg***	***30***	***5***	..	***41.16***	***32.90***		***Nizoral***	***JC***

ANTIINFECTIVES FOR SYSTEMIC USE—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
	• *Triazole derivatives*							
	FLUCONAZOLE							
	Authority Required							
	Treatment of cryptococcal meningitis in patients unable to take or tolerate amphotericin;							
	Maintenance therapy in patients with cryptococcal meningitis and immunosuppression;							
	Treatment of oropharyngeal candidiasis in immunosuppressed patients;							
	Treatment of oesophageal candidiasis in immunosuppressed patients;							
	Secondary prophylaxis of oropharyngeal candidiasis in immunosuppressed patients;							
	Treatment of serious and life-threatening candida infections in patients unable to tolerate amphotericin.							
1471K	*Capsule 50 mg*	*28*	*5*	*..*	*149.34*	*32.90*	[a] *DBL Fluconazole*	*HH*
							[a] *Diflucan*	*PF*
							[a] *Dizole 50*	*AF*
							[a] *Fluconazole Hexal*	*SZ*
							[a] *Fluzole 50*	*SI*
							[a] *Ozole*	*RA*
1472L	*Capsule 100 mg*	*28*	*5*	*..*	*277.87*	*32.90*	[a] *DBL Fluconazole*	*HH*
							[a] *Diflucan*	*PF*
							[a] *Dizole 100*	*AF*
							[a] *Fluconazole Hexal*	*SZ*
							[a] *Fluconazole Winthrop*	*WA*
							[a] *Ozole*	*RA*
1475P	*Capsule 200 mg*	*28*	*5*	*..*	*520.33*	*32.90*	[a] *DBL Fluconazole*	*HH*
							[a] *Diflucan*	*PF*
							[a] *Dizole 200*	*AF*
							[a] *Fluconazole Hexal*	*SZ*
							[a] *Fluconazole Winthrop*	*WA*
							[a] *Fluzole 200*	*SI*
							[a] *Ozole*	*RA*
1473M	*Solution for I.V. infusion 100 mg in 50 mL*	*7*	*..*	*..*	** 165.24*	*32.90*	[a] *Diflucan*	*PF*
							[a] *Fluconazole Hexal*	*SZ*
1474N	*Solution for I.V. infusion 200 mg in 100 mL*	*7*	*..*	*..*	** 296.28*	*32.90*	[a] *Diflucan*	*PF*
							[a] *Fluconazole Hexal*	*SZ*
							[a] *BX*	
1757L	*Solution for I.V. infusion 400 mg in 200 mL*	*1*	*..*	*..*	*73.32*	*32.90*	*BX*	

ANTIINFECTIVES FOR SYSTEMIC USE—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
	ITRACONAZOLE							
	Authority Required ***Systemic aspergillosis;*** ***Systemic sporotrichosis;*** ***Systemic histoplasmosis;*** ***Treatment and maintenance therapy in patients with AIDS who have disseminated pulmonary histoplasmosis infection;*** ***Treatment and maintenance therapy in patients with AIDS who have chronic pulmonary histoplasmosis infection;*** ***Treatment of oropharyngeal candidiasis in immunosuppressed patients;*** ***Treatment of oesophageal candidiasis in immunosuppressed patients.***							
8196J	***Capsule 100 mg***	***60***	***5***	***..***	***242.19***	***32.90***	***Sporanox***	***JC***
	POSACONAZOLE							
	Authority Required ***Treatment of invasive aspergillosis in patients intolerant to, or with disease refractory to, alternative therapy;*** ***Treatment of fusariosis, zygomycosis, coccidioidomycosis, chromoblastomycosis and mycetoma in patients intolerant to, or with disease refractory to, alternative therapy.***							
	Authority Required ***Prophylaxis of invasive fungal infections, including both yeasts and moulds, in a patient who is at high risk of developing these infections, defined as follows:.*** ***(1) Neutropenia*** ***Patients with anticipated neutropenia (an absolute neutrophil count of less than 500 cells per cubic millimetre) for at least 10 days, who are receiving chemotherapy for acute myelogenous leukaemia or myelodysplastic syndrome. Treatment should continue until recovery of the neutrophil count to at least 500 cells per cubic millimetre. Patients who have had a previous invasive fungal infection should have secondary prophylaxis during subsequent episodes of neutropenia.*** ***(2) Graft versus host disease (GVHD)*** ***Patients with acute GVHD grades II to IV or extensive chronic GVHD, who are receiving intensive immunosuppressive therapy after allogeneic haematopoietic stem cell transplant. No more than 6 months therapy per episode will be PBS-subsidised.***							
9360P	***Oral suspension 40 mg per mL, 105 mL***	***‡ 1***	***5***	***..***	***732.83***	***32.90***	***Noxafil***	***SH***
	VORICONAZOLE							
	Authority Required ***For the treatment and maintenance therapy of definite or probable invasive aspergillosis in immunocompromised patients;*** ***For the treatment and maintenance therapy of serious fungal infections caused by Scedosporium species or Fusarium species;*** ***For the treatment and maintenance therapy of serious Candida infections where:*** ***(a) treatment with amphotericin has failed; or*** ***(b) treatment with amphotericin is not tolerated and the causative species is not susceptible to fluconazole; or*** ***(c) treatment with fluconazole has failed; or*** ***(d) treatment with fluconazole is not tolerated;***							

continued ☞

ANTIINFECTIVES FOR SYSTEMIC USE—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
	For the treatment and maintenance therapy of other serious invasive mycosis where:							
	(a) treatment with amphotericin has failed; or							
	(b) treatment with amphotericin is not tolerated.							
9363T	***Tablet 50 mg***	***56***	***..***	***..***	***700.44***	***32.90***	***Vfend***	***PF***
9364W	***Tablet 200 mg***	***56***	***..***	***..***	***2630.65***	***32.90***	***Vfend***	***PF***
	ANTIMYCOBACTERIALS							
	Drugs for treatment of tuberculosis							
	• ***Hydrazides***							
	ISONIAZID							
1554T	Tablet 100 mg	100	2	..	11.20	12.23	FM	
	Drugs for treatment of lepra							
	• ***Drugs for treatment of lepra***							
	DAPSONE							
8801F	Tablet 25 mg	100	1	..	100.15	32.90	LM	
1272Y	Tablet 100 mg	100	1	..	113.41	32.90	LM	
	RIFAMPICIN							
	Restricted Benefit							
	Prophylaxis of meningococcal disease in close contacts and carriers;							
	Prophylactic treatment of contacts of patients with Haemophilus influenzae type B.							
1981G	***Capsule 150 mg***	***10***	***..***	***..***	***10.07***	***11.10***	***Rimycin 150***	***AF***
1984K	***Capsule 300 mg***	***10***	***..***	***..***	***13.12***	***14.15***	***Rimycin 300***	***AF***
8025J	***Syrup 100 mg per 5 mL, 60 mL***	***‡ 1***	***..***	***..***	***28.14***	***29.17***	***Rifadin***	***SW***
	Authority Required							
	Leprosy in adults.							
1982H	***Capsule 150 mg***	***100***	***..***	***..***	***36.58***	***32.90***	***Rimycin 150***	***AF***
1983J	***Capsule 300 mg***	***100***	***..***	***..***	***64.51***	***32.90***	***Rimycin 300***	***AF***

ANTIINFECTIVES FOR SYSTEMIC USE—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Proprietary Name and Manufacturer	

ANTIVIRALS FOR SYSTEMIC USE

Direct acting antivirals

• *Nucleosides and nucleotides excl. reverse transcriptase inhibitors*

ACICLOVIR

Authority Required

Moderate to severe initial genital herpes. Microbiological confirmation of diagnosis (viral culture, antigen detection or nucleic acid amplification by PCR) is desirable but need not delay treatment.

NOTE:

Aciclovir 200 mg is not PBS-subsidised for chickenpox, herpes zoster or herpes simplex infections other than genital herpes.

1003T	*Tablet 200 mg*	*50*	*..*	*..*	** 69.11*	*32.90*	*a*	*Acihexal*	*SZ*
							a	*Acyclo-V 200*	*AF*
							a	*Lovir*	*GM*
				..	*69.11*	*32.90*	*a*	*GenRx Aciclovir*	*GX*
				B4.34	** 73.45*	*32.90*	*a*	*Zovirax 200 mg*	*GK*

NOTE:

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

Authority Required

Episodic treatment or suppressive therapy of moderate to severe recurrent genital herpes. Microbiological confirmation of diagnosis (viral culture, antigen detection or nucleic acid amplification by PCR) is required but need not delay treatment.

NOTE:

Aciclovir 200 mg is not PBS-subsidised for chickenpox, herpes zoster or herpes simplex infections other than genital herpes.

1007B	*Tablet 200 mg*	*90*	*5*	*..*	*121.47*	*32.90*	*a*	*Aciclovir 200*	*CR*
							a	*Acihexal*	*SZ*
							a	*Acyclo-V 200*	*AF*
							a	*Chem mart Aciclovir*	*CH*
							a	*GenRx Aciclovir*	*GX*
							a	*Lovir*	*GM*
							a	*Ozvir*	*RA*
							a	*Terry White Chemists Aciclovir*	*TW*
				B3.21	*124.68*	*32.90*	*a*	*Zovirax 200 mg*	*GK*

Authority Required

Treatment of patients with herpes zoster within 72 hours of the onset of the rash;

Herpes zoster ophthalmicus.

continued ☞

ANTIINFECTIVES FOR SYSTEMIC USE—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Proprietary Name and Manufacturer	
	NOTE:								
	Aciclovir is effective only if commenced within 72 hours of onset of rash.								
	Aciclovir 800 mg is not PBS-subsidised for herpes simplex or chickenpox.								
1052J	***Tablet 800 mg***	***35***	***..***	***..***	***145.89***	***32.90***	***a***	***Aciclovir 800***	***CR***
							a	***Acihexal***	***SZ***
							a	***Acyclo-V 800***	***AF***
							a	***GenRx Aciclovir***	***GX***
							a	***Lovir***	***GM***
				B1.56	***147.45***	***32.90***	***a***	***Zovirax 800 mg***	***GK***
	NOTE:								
	No applications for repeats will be authorised.								
	Authority Required								
	Patients with advanced HIV disease (CD4 cell counts of less than 150 million per litre).								
8234J	***Tablet 800 mg***	***120***	***5***	***..***	***445.90***	***32.90***	***a***	***Acihexal***	***SZ***
							a	***Acyclo-V 800***	***AF***
							a	***Lovir***	***GM***
				B5.19	***451.09***	***32.90***	***a***	***Zovirax 800 mg***	***GK***
	FAMCICLOVIR								
	Authority Required								
	Episodic treatment of moderate to severe recurrent genital herpes. Microbiological confirmation of diagnosis (viral culture, antigen detection or nucleic acid amplification by PCR) is required but need not delay treatment.								
	NOTE:								
	Famciclovir 125 mg is not PBS-subsidised for chickenpox, herpes zoster or herpes simplex infections other than genital herpes.								
8092X	***Tablet 125 mg***	***40***	***1***	***..***	***136.63***	***32.90***		***Famvir***	***NV***
	Authority Required								
	Episodic treatment of moderate to severe recurrent genital herpes. Microbiological confirmation of diagnosis (viral culture, antigen detection or nucleic acid amplification by PCR) is required but need not delay treatment.								
	NOTE:								
	Famciclovir 250 mg is not PBS-subsidised for chickenpox or herpes simplex infections other than genital herpes.								
2274Q	***Tablet 250 mg***	***20***	***1***	***..***	***136.63***	***32.90***		***Famvir***	***NV***
	Authority Required								
	Treatment of patients with herpes zoster within 72 hours of the onset of the rash.								
	NOTE:								
	Famciclovir is effective only if commenced within 72 hours of onset of rash.								
	Famciclovir 250 mg is not PBS-subsidised for chickenpox or herpes simplex infections other than genital herpes.								

continued ☞

ANTIINFECTIVES FOR SYSTEMIC USE—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
8002E	***Tablet 250 mg***	***21***	***..***	***..***	***143.15***	***32.90***	***Famvir***	***NV***

NOTE:
No applications for repeats will be authorised.

Authority Required
Suppressive therapy of moderate to severe recurrent genital herpes. Microbiological confirmation of diagnosis (viral culture, antigen detection or nucleic acid amplification by PCR) is required but need not delay treatment.

NOTE:
Famciclovir 250 mg is not PBS-subsidised for chickenpox or herpes simplex infections other than genital herpes.

8217L	***Tablet 250 mg***	***56***	***5***	***..***	***356.50***	***32.90***	***Famvir***	***NV***

Authority Required
Treatment of immunocompromised patients with herpes zoster within 72 hours of the onset of the rash.

NOTE:
Famciclovir is effective only if commenced within 72 hours of onset of rash.

Famciclovir 500 mg is not PBS-subsidised for chickenpox.
Famciclovir 500 mg is not PBS-subsidised for herpes zoster, genital herpes or other herpes simplex infections in immunocompetent patients.

8897G	***Tablet 500 mg***	***30***	***..***	***..***	***201.92***	***32.90***	***Famvir***	***NV***

NOTE:
No applications for repeats will be authorised.

Authority Required
Episodic treatment or suppressive therapy of moderate to severe recurrent genital herpes in immunocompromised patients. Microbiological confirmation of diagnosis (viral culture, antigen detection or nucleic acid amplification by PCR) is required but need not delay treatment.

Authority Required
Episodic treatment of moderate to severe recurrent oral or labial herpes in a patient with HIV infection and a CD4 cell count of less than 500 million per litre. Microbiological confirmation of diagnosis (viral culture, antigen detection or nucleic acid amplification by PCR) is required but need not delay treatment.

Authority Required
Suppressive therapy of moderate to severe recurrent oral or labial herpes in a patient with HIV infection and:
(a) a CD4 cell count of less than 150 million per litre; or
(b) other opportunistic infections or AIDS defining tumours.
Microbiological confirmation of diagnosis (viral culture, antigen detection or nucleic acid amplification by PCR) is required but need not delay treatment.

8896F	***Tablet 500 mg***	***56***	***5***	***..***	***356.50***	***32.90***	***Famvir***	***NV***

continued ☞

ANTIINFECTIVES FOR SYSTEMIC USE—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
	NOTE:							
	Famciclovir 500 mg is not PBS-subsidised for chickenpox.							
	Famciclovir 500 mg is not PBS-subsidised for herpes zoster, genital herpes or other herpes simplex infections in immunocompetent patients.							
	VALACICLOVIR HYDROCHLORIDE							
	Authority Required							
	Moderate to severe initial genital herpes. Microbiological confirmation of diagnosis (viral culture, antigen detection or nucleic acid amplification by PCR) is desirable but need not delay treatment.							
	NOTE:							
	Valaciclovir 500 mg is not PBS-subsidised for chickenpox or herpes simplex infections other than genital herpes.							
8133C	***Tablet 500 mg (base)***	***20***	***..***	***..***	**** 105.35***	***32.90***	***Valtrex***	***GK***
	NOTE:							
	No applications for increased maximum quantities and/or repeats will be authorised.							
	Authority Required							
	Episodic treatment or suppressive therapy of moderate to severe recurrent genital herpes. Microbiological confirmation of diagnosis (viral culture, antigen detection or nucleic acid amplification by PCR) is required but need not delay treatment.							
	NOTE:							
	Valaciclovir 500 mg is not PBS-subsidised for chickenpox or herpes simplex infections other than genital herpes.							
8134D	***Tablet 500 mg (base)***	***30***	***5***	***..***	***155.00***	***32.90***	***Valtrex***	***GK***
	Authority Required							
	Treatment of patients with herpes zoster within 72 hours of the onset of the rash;							
	Herpes zoster ophthalmicus.							
	NOTE:							
	Valaciclovir is effective only if commenced within 72 hours of onset of rash.							
	Valaciclovir 500 mg is not PBS-subsidised for chickenpox or herpes simplex infections other than genital herpes.							
8064K	***Tablet 500 mg (base)***	***42***	***..***	***..***	***213.63***	***32.90***	***Valtrex***	***GK***
	NOTE:							
	No applications for repeats will be authorised.							

ANTIINFECTIVES FOR SYSTEMIC USE—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
	VACCINES							
	Bacterial vaccines							
	• ***Pneumococcal vaccines***							
	PNEUMOCOCCAL VACCINE, POLYVALENT							
	Restricted Benefit							
	Splenectomised persons over 2 years of age;							
	Persons with Hodgkin's disease;							
	Persons at high risk of pneumococcal infections.							
1903E	***Injection 0.5 mL (23 valent)***	***1***	***..***	***..***	***45.70***	***32.90***	***Pneumovax 23***	***CS***
	• ***Tetanus vaccines***							
	DIPHTHERIA and TETANUS VACCINE, ADSORBED, DILUTED FOR ADULT USE							
	NOTE:							
	For immunisation of adults and children aged greater than or equal to 8 years.							
8783G	Injection 0.5 mL in pre-filled syringe	5	..	..	74.91	32.90	ADT Booster	CS
	Viral vaccines							
	• ***Influenza vaccines***							
	INFLUENZA VACCINE							
	Restricted Benefit							
	Children up to 35 months of age at increased risk of adverse consequences from infections of the lower respiratory tract.							
2265F	***Injection (trivalent) 0.25 mL (containing A/Brisbane/59/2007, A/Brisbane/10/2007 and B/Florida/4/2006 like strains)***	***1***	***..***	***..***	***16.56***	***17.59***	***Fluvax Junior*** ***Vaxigrip Junior***	***CS*** ***AX***
	Restricted Benefit							
	Persons at special risk of adverse consequences from infections of the lower respiratory tract.							
2852D	***Injection (trivalent) 0.5 mL (containing A/Brisbane/59/2007, A/Brisbane/10/2007 and B/Florida/4/2006 like strains)***	***1***	***..***	***..***	***19.20***	***20.23***	***Fluvax*** ***Influvac*** ***Vaxigrip***	***CS*** ***SM*** ***AX***

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
	ANTINEOPLASTIC AGENTS							
	Alkylating agents							
	• ***Nitrogen mustard analogues***							
	CHLORAMBUCIL							
1163F	Tablet 2 mg	100	2	..	* 137.55	32.90	Leukeran	GK
	CYCLOPHOSPHAMIDE							
1266P	Tablet 50 mg	50	2	..	30.86	31.89	Cycloblastin	PH
1079T	Powder for injection 500 mg (solvent required) (code 6704W applies to above item with approved solvent)	2	..	..	* 29.33	30.36	Endoxan	BX
1080W	Powder for injection 1 g (solvent required) (code 6710E applies to above item with approved solvent)	1	..	..	26.59	27.62	Endoxan	BX
1031G	Powder for injection 2 g (solvent required) (code 7055H applies to above item with approved solvent)	1	..	..	42.39	32.90	Endoxan	BX
	IFOSFAMIDE							
	Restricted Benefit ***Relapsed or refractory germ cell tumours following first-line chemotherapy;*** ***Relapsed or refractory sarcomas following first-line chemotherapy.***							
8076C	***Powder for I.V. injection 1 g***	***5***	***5***	***..***	**** 261.14***	***32.90***	***Holoxan***	***BX***
8077D	***Powder for I.V. injection 2 g***	***5***	***5***	***..***	**** 476.74***	***32.90***	***Holoxan***	***BX***
	MELPHALAN							
2547C	Tablet 2 mg	25	1	..	50.45	32.90	Alkeran	GK
	• ***Alkyl sulphonates***							
	BUSULFAN							
1128J	Tablet 2 mg	100	..	..	85.83	32.90	Myleran	GK
	• ***Ethylene imines***							
	THIOTEPA							
2345K	Powder for injection 15 mg	2	1	..	* 155.23	32.90	SI	

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
	• *Nitrosoureas*							
	CARMUSTINE							
	Restricted Benefit							
	Glioblastoma multiforme, suspected or confirmed, at the time of initial surgery.							
	NOTE:							
	Carmustine is not PBS-subsidised for use in conjunction with PBS-subsidised temozolomide.							
8898H	*Implants 7.7 mg, 8*	*‡ 1*	*..*	*..*	*16044.43*	*32.90*	*Gliadel*	*OA*
	FOTEMUSTINE							
	Authority Required							
	Metastatic malignant melanoma.							
8786K	*Powder for injection 208 mg with solvent*	*1*	*4*	*..*	*1100.15*	*32.90*	*Muphoran*	*SE*
	• *Other alkylating agents*							
	TEMOZOLOMIDE							
	Authority Required							
	Glioblastoma multiforme concomitantly with radiotherapy.							
	NOTE:							
	Temozolomide is not PBS-subsidised for use in conjunction with PBS-subsidised carmustine.							
8819E	*Capsule 5 mg*	*15*	*2*	*..*	** 207.62*	*32.90*	*Temodal*	*SH*
8820F	*Capsule 20 mg*	*15*	*2*	*..*	** 567.50*	*32.90*	*Temodal*	*SH*
8821G	*Capsule 100 mg*	*15*	*2*	*..*	** 2388.86*	*32.90*	*Temodal*	*SH*
9361Q	*Capsule 140 mg*	*15*	*2*	*..*	** 3265.67*	*32.90*	*Temodal*	*SH*
	NOTE:							
	Applications for doses above 150 mg per day will not be authorised. No applications for increased repeats will be authorised.							
	Authority Required							
	Recurrence of anaplastic astrocytoma following standard therapy;							
	Recurrence of glioblastoma multiforme following standard therapy;							
	Glioblastoma multiforme following radiotherapy.							
8378Y	*Capsule 5 mg*	*5*	*5*	*..*	*73.32*	*32.90*	*Temodal*	*SH*
8379B	*Capsule 20 mg*	*5*	*5*	*..*	*203.96*	*32.90*	*Temodal*	*SH*
8380C	*Capsule 100 mg*	*5*	*5*	*..*	*807.79*	*32.90*	*Temodal*	*SH*
9362R	*Capsule 140 mg*	*5*	*5*	*..*	*1111.75*	*32.90*	*Temodal*	*SH*
8381D	*Capsule 250 mg*	*5*	*5*	*..*	*1862.88*	*32.90*	*Temodal*	*SH*

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
	Antimetabolites							
	• ***Folic acid analogues***							
	METHOTREXATE							
1622J	Tablet 2.5 mg	30	5	..	13.11	14.14	[a] Methoblastin [a] HH	PH
2272N	Tablet 10 mg	15	1	..	22.37	23.40	Methoblastin	PH
2396D	Injection 5 mg in 2 mL	5	..	..	37.64	32.90	HH	
2395C	Injection 50 mg in 2 mL	5	..	..	36.93	32.90	HH PU	
8863L	Solution concentrate for I.V. infusion 500 mg in 20 mL	1	..	..	65.18	32.90	HH	
8851W	Solution concentrate for I.V. infusion 1000 mg in 10 mL	1	..	..	124.37	32.90	[a] Methotrexate Ebewe [a] HH	IT
8852X	Solution concentrate for I.V. infusion 5000 mg in 50 mL	1	..	..	565.63	32.90	Methotrexate Ebewe	IT

METHOTREXATE

Restricted Benefit

For patients requiring doses greater than 20 mg per week.

1623K	***Tablet 10 mg***	***50***	***2***	***..***	***47.00***	***32.90***	***Methoblastin***	***PH***

PEMETREXED DISODIUM

Authority Required

Locally advanced or metastatic non-small cell lung cancer, after prior platinum-based chemotherapy.

Doses greater than 500 mg per metre squared body surface area (BSA) will not be approved for PBS subsidy. The patient's BSA must be provided at the time of the authority approval.

Authority Required

Mesothelioma in combination with cisplatin.

Doses greater than 500 mg per metre squared body surface area (BSA) will not be approved for PBS subsidy. The patient's BSA must be provided at the time of the authority approval.

NOTE:

No applications for increased maximum quantities for the 500 mg vial will be authorised.

9131N	***Powder for I.V. infusion 100 mg (base)***	***1***	***3***	***..***	***359.42***	***32.90***	***Alimta***	***LY***
9130M	***Powder for I.V. infusion 500 mg (base)***	***1***	***3***	***..***	***1700.98***	***32.90***	***Alimta***	***LY***

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Proprietary Name and Manufacturer	
	RALTITREXED								
	Authority Required								
	For use as a single agent in the treatment of advanced colorectal cancer.								
8284B	***Powder for I.V. infusion 2 mg***	***3***	***2***	***..***	**** 855.86***	***32.90***		***Tomudex***	***HH***
	• ***Purine analogues***								
	CLADRIBINE								
	Authority Required								
	Hairy cell leukaemia.								
8800E	***Injection 10 mg in 5 mL***	***7***	***..***	***..***	**** 4629.14***	***32.90***		***Litak***	***OA***
1811H	***Solution for I.V. infusion 10 mg in 10 mL***	***7***	***..***	***..***	***4629.16***	***32.90***		***Leustatin***	***JC***
	FLUDARABINE PHOSPHATE								
	Authority Required								
	B-cell chronic lymphocytic leukaemia in combination with cyclophosphamide where the patient has advanced disease (Binet Stage B or C) or evidence of progressive Stage A disease.								
	Stage A progressive disease is defined by at least one of the following: persistent rise in lymphocyte count with doubling time less than 12 months; a downward trend in haemoglobin or platelets, or both; more than 50% increase in the size of liver, spleen, or lymph nodes, or appearance of these signs if not previously present; constitutional symptoms attributable to disease.								
	The diagnosis of chronic lymphocytic leukaemia (CLL) must have been established based on: (a) a lymphocytosis, with more than 5,000 million lymphocytes per L in the peripheral blood; and (b) a clonal population of B-cells (CD5/CD19) documented by flow cytometry.								
9184J	***Tablet 10 mg***	***20***	***5***	***..***	***974.64***	***32.90***		***Fludara***	***BN***
9185K	***Powder for I.V. injection 50 mg***	***5***	***3***	***..***	***1598.44***	***32.90***	***a***	***Fludara***	***BN***
9207N	***Solution for I.V. injection 50 mg in 2 mL***	***5***	***3***	***..***	***1598.44***	***32.90***	***a***	***Fludarabine Ebewe***	***IT***
	NOTE: The solution for I.V. injection and powder for I.V. injection (after reconstitution) are bioequivalent.								
	MERCAPTOPURINE								
1598D	Tablet 50 mg	100	2	..	* 231.87	32.90		Purinethol	GK
	THIOGUANINE								
1233X	Tablet 40 mg	25	1	..	198.23	32.90		Lanvis	GK

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Proprietary Name and Manufacturer	
	• *Pyrimidine analogues*								
	CAPECITABINE								
	Authority Required								
	Advanced breast cancer after failure of prior therapy which includes a taxane and an anthracycline;								
	Advanced breast cancer where therapy with a taxane and/or an anthracycline is contraindicated;								
	Advanced breast cancer in combination with docetaxel after failure of prior anthracycline-containing chemotherapy;								
	Treatment of advanced or metastatic colorectal cancer;								
	Adjuvant treatment of stage III (Dukes C) colon cancer, following complete resection of the primary tumour.								
	NOTE:								
	In the adjuvant setting, the recommended treatment duration is 24 weeks.								
	Capecitabine is not PBS-subsidised for the treatment of patients with stage II (Dukes B) colon cancer.								
	Capecitabine is not PBS-subsidised for the adjuvant treatment of patients with rectal cancer.								
8361C	***Tablet 150 mg***	***60***	***2***	***..***	***123.50***	***32.90***		***Xeloda***	***RO***
8362D	***Tablet 500 mg***	***120***	***2***	***..***	***694.74***	***32.90***		***Xeloda***	***RO***
	CYTARABINE								
2884T	Injection 100 mg in 5 mL	10	1	..	* 95.09	32.90		PU	
	FLUOROURACIL								
2528C	Injection 500 mg in 10 mL	10	..	..	* 57.29	32.90	[a]	HH	
				..	* 57.29	32.90	[a]	Fluorouracil Ebewe	IT
9005Y	Injection 1000 mg in 20 mL	5	..	..	* 50.14	32.90		Fluorouracil Ebewe	IT
	GEMCITABINE HYDROCHLORIDE								
	Authority Required								
	Advanced breast cancer in combination with paclitaxel after failure of prior therapy which includes an anthracycline;								
	Advanced epithelial ovarian cancer, in combination with carboplatin, in patients who relapse more than 6 months after platinum-based therapy;								
	Locally advanced or metastatic non-small cell lung cancer;								
	Locally advanced or metastatic adenocarcinoma of the pancreas;								
	Locally advanced or metastatic bladder cancer, in combination with cisplatin.								
8049P	***Powder for I.V. infusion 200 mg (base)***	***4***	***2***	***..***	**** 235.51***	***32.90***		***Gemzar***	***LY***
8050Q	***Powder for I.V. infusion 1 g (base)***	***2***	***2***	***..***	**** 549.11***	***32.90***		***Gemzar***	***LY***
	Plant alkaloids and other natural products								
	• *Vinca alkaloids and analogues*								
	VINBLASTINE SULFATE								
2199R	Solution for I.V. injection 10 mg in 10 mL	5	..	..	105.41	32.90		HH	

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Proprietary Name and Manufacturer	
	VINCRISTINE SULFATE								
2374Y	I.V. injection 1 mg in 1 mL	10	..	..	* 160.91	32.90	a	HH	
							a	PU	
	VINORELBINE TARTRATE								
	Authority Required								
	Locally advanced or metastatic non-small cell lung cancer.								
9009E	***Capsule 20 mg (base)***	***20***	***2***	***..***	**** 2091.19***	***32.90***		***Navelbine***	***FB***
9010F	***Capsule 30 mg (base)***	***16***	***2***	***..***	**** 2481.19***	***32.90***		***Navelbine***	***FB***
	Authority Required								
	Advanced breast cancer after failure of prior therapy which includes an anthracycline;								
	Locally advanced or metastatic non-small cell lung cancer.								
8280T	***Solution for I.V. infusion 10 mg (base) in 1 mL***	***16***	***2***	***..***	**** 1183.27***	***32.90***	***a***	***Navelbine***	***FB***
							a	***Vinorelbine 10 Link***	***LM***
							a	***Vinorelbine Ebewe***	***IT***
							a	***HH***	
8281W	***Solution for I.V. infusion 50 mg (base) in 5 mL***	***4***	***2***	***..***	**** 1234.23***	***32.90***	***a***	***Navelbine***	***FB***
							a	***Vinorelbine 50 Link***	***LM***
							a	***Vinorelbine Ebewe***	***IT***
							a	***HH***	
	• Podophyllotoxin derivatives								
	ETOPOSIDE								
1396L	Capsule 50 mg	20	..	..	470.79	32.90		Vepesid	BQ
1389D	Capsule 100 mg	10	..	..	413.19	32.90		Vepesid	BQ
1390E	Solution for I.V. infusion 100 mg in 5 mL	5	..	..	* 172.84	32.90	a	HH	
				..	172.86	32.90	a	Etoposide Ebewe	IT
	ETOPOSIDE PHOSPHATE								
8120J	Powder for I.V. infusion 113.6 mg (equivalent to 100 mg etoposide)	5	..	..	* 172.84	32.90		Etopophos	BQ
8515E	Powder for I.V. infusion 1136 mg (equivalent to 1 g etoposide)	1	..	..	327.35	32.90		Etopophos	BQ

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
	• *Taxanes*							
	DOCETAXEL							
	Authority Required ***Neoadjuvant treatment of a patient with a WHO performance status of 1 or less, with inoperable Stage III, IVa or IVb squamous cell carcinoma of the oral cavity, larynx, oropharynx or hypopharynx, in combination with cisplatin and fluorouracil.*** **NOTE:** ***The carcinoma can be considered inoperable for technical or organ preservation reasons.***							
9291B	***Injection set containing 1 single use vial concentrate for I.V. infusion 20 mg (anhydrous) in 0.5 mL and 1 single use vial solvent 1.5 mL***	***1***	***..***	***..***	***338.73***	***32.90***	***Taxotere***	***SW***
	Authority Required ***Adjuvant treatment of node-positive breast cancer in combination with an anthracycline and cyclophosphamide;*** ***Advanced breast cancer after failure of prior therapy which includes an anthracycline;*** ***Advanced metastatic ovarian cancer after failure of prior therapy which includes a platinum compound;*** ***Locally advanced or metastatic non-small cell lung cancer;*** ***Treatment of HER2 positive early breast cancer in combination with trastuzumab.***							
	Authority Required ***Treatment of androgen independent (hormone refractory) metastatic carcinoma of the prostate in a patient with a Karnofsky performance-status score of at least 60%. Docetaxel must be used as first-line chemotherapy and administered in three weekly cycles.*** **NOTE:** ***A maximum of 10 cycles of treatment with docetaxel will be authorised under this restriction.***							
8071T	***Injection set containing 1 single use vial concentrate for I.V. infusion 20 mg (anhydrous) in 0.5 mL and 1 single use vial solvent 1.5 mL***	***2***	***..***	***..***	**** 660.65***	***32.90***	***Taxotere***	***SW***

continued ☞

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
	Authority Required ***Neoadjuvant treatment of a patient with a WHO performance status of 1 or less, with inoperable Stage III, IVa or IVb squamous cell carcinoma of the oral cavity, larynx, oropharynx or hypopharynx, in combination with cisplatin and fluorouracil.*** **NOTE:** ***The carcinoma can be considered inoperable for technical or organ preservation reasons.*** **Authority Required** ***Adjuvant treatment of node-positive breast cancer in combination with an anthracycline and cyclophosphamide;*** ***Advanced breast cancer after failure of prior therapy which includes an anthracycline;*** ***Advanced metastatic ovarian cancer after failure of prior therapy which includes a platinum compound;*** ***Locally advanced or metastatic non-small cell lung cancer;*** ***Treatment of HER2 positive early breast cancer in combination with trastuzumab.*** **Authority Required** ***Treatment of androgen independent (hormone refractory) metastatic carcinoma of the prostate in a patient with a Karnofsky performance-status score of at least 60%. Docetaxel must be used as first-line chemotherapy and administered in three weekly cycles.*** **NOTE:** ***A maximum of 10 cycles of treatment with docetaxel will be authorised under this restriction.***							
8074Y	***Injection set containing 1 single use vial concentrate for I.V. infusion 80 mg (anhydrous) in 2 mL and 1 single use vial solvent 6 mL***	***1***	***..***	***..***	***1299.91***	***32.90***	***Taxotere***	***SW***
	PACLITAXEL **Authority Required** ***Adjuvant treatment of node-positive breast cancer administered sequentially to an anthracycline and cyclophosphamide;*** ***Advanced breast cancer after failure of prior therapy which includes an anthracycline;*** ***Advanced metastatic ovarian cancer after failure of prior therapy which includes a platinum compound;*** ***Primary treatment of ovarian cancer in combination with a platinum compound;*** ***Locally advanced or metastatic non-small cell lung cancer;*** ***Treatment of HER2 positive early breast cancer in combination with trastuzumab.***							
3026G	***Solution concentrate for I.V. infusion 30 mg in 5 mL***	***5***	***..***	***..***	**** 969.64***	***32.90***	[a] ***Anzatax*** [a] ***Baxter Paclitaxel*** [a] ***Taxol***	***HH*** ***BX*** ***BQ***
				..	***969.65***	***32.90***	[a] ***Paclitaxel Ebewe***	***IT***
8018B	***Solution concentrate for I.V. infusion 100 mg in 16.7 mL***	***2***	***..***	***..***	**** 1284.57***	***32.90***	[a] ***Anzatax*** [a] ***Baxter Paclitaxel*** [a] ***Paclitaxel Ebewe*** [a] ***Taxol***	***HH*** ***BX*** ***IT*** ***BQ***

continued ☞

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
3017T	***Solution concentrate for I.V. infusion 150 mg in 25 mL***	***2***	***..***	***..***	**** 1868.01***	***32.90***	***[a] Anzatax***	***HH***
							[a] Paclitaxel Ebewe	***IT***
							[a] Taxol	***BQ***
8360B	***Solution concentrate for I.V. infusion 300 mg in 50 mL***	***1***	***..***	***..***	***1885.41***	***32.90***	***[a] Anzatax***	***HH***
							[a] Baxter Paclitaxel	***BX***
							[a] Paclitaxel Ebewe	***IT***
							[a] Taxol	***BQ***
	Cytotoxic antibiotics and related substances							
	• *Anthracyclines and related substances*							
	DOXORUBICIN HYDROCHLORIDE							
1336H	Solution for I.V. injection or intravesical administration 10 mg in 5 mL	4	..	..	* 142.43	32.90	[a] Adriamycin Solution	PH
							[a] Doxorubicin Ebewe	IT
							[a] HH	
1340M	Solution for I.V. injection or intravesical administration 20 mg in 10 mL	4	..	..	* 245.83	32.90	Adriamycin Solution	PH
1342P	Solution for I.V. injection or intravesical administration 50 mg in 25 mL	3	..	..	* 417.32	32.90	[a] Adriamycin Solution	PH
							[a] Doxorubicin Ebewe	IT
							[a] HH	
8827N	Solution for I.V. injection or intravesical administration 100 mg in 50 mL	1	..	..	286.20	32.90	Doxorubicin Ebewe	IT
8828P	Solution for I.V. injection or intravesical administration 200 mg in 100 mL	1	..	..	551.40	32.90	[a] Adriamycin	PF
							[a] Doxorubicin Ebewe	IT
	DOXORUBICIN HYDROCHLORIDE, PEGYLATED LIPOSOMAL							
	Authority Required							
	Advanced epithelial ovarian cancer in women who have failed a first-line platinum-based chemotherapy regimen;							
	Metastatic breast cancer, as monotherapy, after failure of prior therapy which includes capecitabine and a taxane;							
	Metastatic breast cancer, as monotherapy, where therapy with capecitabine and/or a taxane is contraindicated.							
8569B	***Suspension for I.V. infusion 20 mg in 10 mL***	***1***	***..***	***..***	***702.62***	***32.90***	***Caelyx***	***SH***
8570C	***Suspension for I.V. infusion 50 mg in 25 mL***	***1***	***..***	***..***	***1621.36***	***32.90***	***Caelyx***	***SH***
	EPIRUBICIN HYDROCHLORIDE							
1375J	Solution for injection 10 mg in 5 mL	4	..	..	* 219.35	32.90	[a] Epirubicin Ebewe	IT
							[a] Pharmorubicin Solution	PH

continued ☞

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
1376K	Solution for injection 20 mg in 10 mL	4	..	..	* 401.07	32.90	Pharmorubicin Solution	PH
1377L	Solution for injection 50 mg in 25 mL	4	..	..	* 975.67	32.90	[a] Epirubicin Ebewe [a] Pharmorubicin Solution [a] HH	IT PH
8817C	Solution for injection 100 mg in 50 mL	2	..	..	* 962.65	32.90	[a] Epirubicin Ebewe [a] HH	IT
8858F	Solution for injection 200 mg in 100 mL	1	..	..	948.32	32.90	Epirubicin Ebewe	IT
	IDARUBICIN HYDROCHLORIDE							
	Restricted Benefit ***Acute myelogenous leukaemia.***							
2446R	***Capsule 5 mg***	***3***	..	..	**** 246.68***	***32.90***	***Zavedos***	***PH***
2448W	***Capsule 10 mg***	***3***	..	..	**** 451.19***	***32.90***	***Zavedos***	***PH***
8530Y	***Solution for I.V. injection 5 mg in 5 mL***	***3***	..	..	***568.45***	***32.90***	***Zavedos Solution***	***PH***
8531B	***Solution for I.V. injection 10 mg in 10 mL***	***6***	..	..	***2104.37***	***32.90***	***Zavedos Solution***	***PH***
	MITOZANTRONE HYDROCHLORIDE							
1932Q	Injection 10 mg (base) in 5 mL	1	..	..	157.90	32.90	[a] Mitozantrone Ebewe [a] PU	IT
1929M	Injection 20 mg (base) in 10 mL	1	..	..	300.18	32.90	[a] Mitozantrone Ebewe [a] Onkotrone [a] HH [a] PU	IT BX
1930N	Injection 25 mg (base) in 12.5 mL	1	..	..	369.02	32.90	[a] Onkotrone [a] PU	BX
	Other antineoplastic agents							
	• ***Platinum compounds***							
	CARBOPLATIN							
1160C	Solution for I.V. injection 50 mg in 5 mL	2	..	..	* 67.87	32.90	[a] Carboplatin Ebewe [a] HH [a] PU	IT
1161D	Solution for I.V. injection 150 mg in 15 mL	6	..	..	* 431.51	32.90	[a] Carboplatin Ebewe [a] HH [a] PU	IT

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ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
1162E	Solution for I.V. injection 450 mg in 45 mL	2	..	..	* 279.95	32.90	[a] Baxter Carboplatin	BX
							[a] Carboplatin Ebewe	IT
							[a] HH	
							[a] PU	
	CISPLATIN							
2578Q	I.V. injection 10 mg in 10 mL	1	..	..	14.42	15.45	PU	
2579R	I.V. injection 50 mg in 50 mL	1	..	..	28.60	29.63	[a] HH	
							[a] PU	
2580T	I.V. injection 100 mg in 100 mL	1	..	..	60.48	32.90	[a] Cisplatin Ebewe	IT
							[a] HH	
							[a] PU	
	OXALIPLATIN							
	Authority Required ***Metastatic colorectal cancer in patients with a WHO performance status of 2 or less, to be used in combination with 5-fluorouracil and folinic acid;*** ***Adjuvant treatment of stage III (Dukes C) colon cancer, in combination with 5-fluorouracil and folinic acid, following complete resection of the primary tumour.*** **NOTE:** ***Oxaliplatin is not PBS-subsidised for the treatment of patients with stage II (Dukes B) colon cancer.*** ***Oxaliplatin is not PBS-subsidised for the adjuvant treatment of patients with rectal cancer.***							
8847P	***Solution concentrate for I.V. infusion 50 mg in 10 mL***	***1***	***2***	***..***	***370.25***	***32.90***	[a] ***Eloxatin***	***SW***
8539K	***Powder for I.V. infusion 50 mg***	***1***	***2***	***..***	***370.25***	***32.90***	[a] ***Oxalatin***	***ZP***
							[a] ***Oxaliplatin Ebewe***	***IT***
							[a] ***Winthrop Oxaliplatin***	***WA***
							[a] ***HH***	
	NOTE: ***The solution concentrate for I.V. infusion 50 mg and powder for I.V. infusion 50 mg (after reconstitution) are bioequivalent.***							
8848Q	***Solution concentrate for I.V. infusion 100 mg in 20 mL***	***1***	***2***	***..***	***701.59***	***32.90***	[a] ***Eloxatin***	***SW***
8540L	***Powder for I.V. infusion 100 mg***	***1***	***2***	***..***	***701.59***	***32.90***	[a] ***Oxalatin***	***ZP***
							[a] ***Oxaliplatin Ebewe***	***IT***
							[a] ***Winthrop Oxaliplatin***	***WA***
							[a] ***HH***	
	NOTE: ***The solution concentrate for I.V. infusion 100 mg and powder for I.V. infusion 100 mg (after reconstitution) are bioequivalent.***							
2310N	***Solution concentrate for I.V. infusion 200 mg in 40 mL***	***1***	***2***	***..***	***1371.19***	***32.90***	***Eloxatin***	***SW***

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
	• *Monoclonal antibodies*							
	CETUXIMAB							
	Authority Required ***Initial treatment of stage III, IVa or IVb squamous cell cancer of the larynx, oropharynx or hypopharynx for the week prior to radiotherapy, where cisplatin is contraindicated according to the TGA-approved Product Information;*** ***Initial treatment of stage III, IVa or IVb squamous cell cancer of the larynx, oropharynx or hypopharynx, in combination with radiotherapy, where cisplatin is not tolerated.*** **NOTE:** ***No applications for repeats will be authorised.***							
9136W	***Solution for I.V. infusion 100 mg in 20 mL***	***1***	***..***	***..***	***390.63***	***32.90***	***Erbitux***	***SG***
9097T	***Solution for I.V. infusion 100 mg in 50 mL***	***1***	***..***	***..***	***390.63***	***32.90***	***Erbitux***	***SG***
9137X	***Solution for I.V. infusion 500 mg in 100 mL***	***1***	***..***	***..***	***1850.93***	***32.90***	***Erbitux***	***SG***
	Authority Required ***Continuing treatment of stage III, IVa or IVb squamous cell cancer of the larynx, oropharynx or hypopharynx, in combination with radiotherapy, where cisplatin is either contraindicated or not tolerated.*** **NOTE:** ***A maximum lifetime supply for this indication is limited to a maximum of 8 treatments per site and to 10 treatments per site for patients in whom radiotherapy is interrupted.***							
9138Y	***Solution for I.V. infusion 100 mg in 20 mL***	***1***	***6***	***..***	***390.63***	***32.90***	***Erbitux***	***SG***
9098W	***Solution for I.V. infusion 100 mg in 50 mL***	***1***	***6***	***..***	***390.63***	***32.90***	***Erbitux***	***SG***
9139B	***Solution for I.V. infusion 500 mg in 100 mL***	***1***	***6***	***..***	***1850.93***	***32.90***	***Erbitux***	***SG***
	RITUXIMAB							
	Authority Required ***Relapsed or refractory low-grade B-cell non-Hodgkin's lymphoma;*** ***Relapsed or refractory follicular B-cell non-Hodgkin's lymphoma.***							
8293L	***Solution for I.V. infusion 100 mg in 10 mL***	***2***	***3***	***..***	***947.64***	***32.90***	***Mabthera***	***RO***
8294M	***Solution for I.V. infusion 500 mg in 50 mL***	***1***	***3***	***..***	***2339.56***	***32.90***	***Mabthera***	***RO***

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ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
	Authority Required ***Treatment of previously untreated, CD20 positive, diffuse large B-cell non-Hodgkin's lymphoma, in combination with chemotherapy;*** ***Treatment of symptomatic patients with previously untreated, CD20 positive, Stage III or IV, follicular, B-cell non-Hodgkin's lymphoma, in combination with chemotherapy.***							
8665C	***Solution for I.V. infusion 100 mg in 10 mL***	***2***	***7***	***..***	***947.64***	***32.90***	***Mabthera***	***RO***
8666D	***Solution for I.V. infusion 500 mg in 50 mL***	***1***	***7***	***..***	***2339.56***	***32.90***	***Mabthera***	***RO***

• *Protein kinase inhibitors*

DASATINIB

NOTE:

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

Prescribing information (including Authority Application forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Any queries concerning patients who are enrolled on the Dasatinib Compassionate Program may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written applications for authority to prescribe dasatinib should be forwarded to:

Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

Authority Required

➢ ***Initial treatment, as the sole PBS-subsidised therapy, of a patient with chronic myeloid leukaemia in any disease phase bearing the Philadelphia chromosome or expressing the transcript, BCR-ABL, who has active leukaemia (as defined by presence on current pathology assessments of either the Philadelphia chromosome on cytogenetic or FISH analysis, or the presence of the transcript BCR-ABL greater than 1% on the international scale) and who has failed an adequate trial of imatinib.***

Failure of an adequate trial of imatinib is defined as:

(i) Lack of response to initial imatinib therapy, defined as either:
— failure to achieve a haematological response after a minimum of 3 months therapy with imatinib for patients initially treated in chronic phase; or
— failure to achieve any cytogenetic response after a minimum of 6 months therapy with imatinib for patients initially treated in chronic phase as demonstrated on bone marrow biopsy by presence of greater than 95% Philadelphia chromosome positive cells; or
— failure to achieve a major cytogenetic response or a peripheral blood BCR-ABL level of less than 1% after a minimum of 12 months therapy with imatinib; OR

(ii) Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph positive cells on bone marrow biopsy), during ongoing imatinib therapy;
OR

continued ☞

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	

(iii) Loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing in value by at least 5 fold to a level of greater than 1% confirmed on a subsequent test), during ongoing imatinib therapy;
OR

(iv) Development of accelerated phase or blast crisis in a patient previously prescribed imatinib for any phase of chronic myeloid leukaemia.

Accelerated phase is defined by the presence of 1 or more of the following:
(1) Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 15% but less than 30%; or
(2) Percentage of blasts plus promyelocytes in the peripheral blood or bone marrow greater than or equal to 30%; or
(3) Peripheral basophils greater than or equal to 20%; or
(4) Progressive splenomegaly to a size greater than or equal to 10 cm below the left costal margin to be confirmed on 2 occasions at least 4 weeks apart, or a greater than or equal to 50% increase in size below the left costal margin over 4 weeks; or
(5) Karyotypic evolution (chromosomal abnormalities in addition to a single Philadelphia chromosome).

Blast crisis is defined as either:
(1) Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 30%; or
(2) Extramedullary involvement other than spleen and liver; OR

(v) Disease progression (defined as a greater than or equal to 50% increase in peripheral white blood cell count, blast count, basophils or platelets) during first-line imatinib therapy in patients with accelerated phase or blast crisis chronic myeloid leukaemia;
OR

(vi) Grade 3 or 4 non-haematological toxicity that is imatinib related and necessitates permanent cessation of imatinib. For patients with imatinib related toxicities, leukaemia activity does not need to be demonstrated.

Applications for authorisation must be in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Chronic Myeloid Leukaemia Dasatinib/Nilotinib PBS Authority Application - Supporting Information Form; and
(c) a signed patient acknowledgement; and
(d) a bone marrow biopsy pathology report demonstrating the patient has active chronic myeloid leukaemia, either manifest as cytogenetic evidence of the Philadelphia chromosome, or RT-PCR level of BCR-ABL transcript greater than 1% on the international scale. (The date of the relevant pathology report needs to be provided); and
(e) where there has been a loss of response to imatinib, a copy of the current confirming pathology report(s) from an Approved Pathology Authority or details of the dates of assessment in the case of progressive splenomegaly or extramedullary involvement; or
(f) details of Grade 3 or 4 non-haematological toxicity.

NOTE:

Dasatinib will only be subsidised for patients with chronic myeloid leukaemia who are not receiving concomitant PBS-subsidised imatinib mesylate, nilotinib or interferon alfa therapy.

Patients should be commenced on a dose of dasatinib of at least 100 mg (base) daily. Continuing therapy is dependent on patients demonstrating a major cytogenetic response to dasatinib therapy or a peripheral blood BCR-ABL level of less than 1% at 18 months and thereafter at 12 monthly intervals, irrespective of the daily dasatinib dose received.

From 1 November 2008, under the PBS, a patient will be able to trial either dasatinib and/or nilotinib within the initial 18 month treatment period, providing the patient's CML is not resistant to the first second-line agent.

Dasatinib is not PBS-subsidised for patients with CML that is resistant to nilotinib.

9282M	***Tablet 20 mg***	***60***	***2***	***..***	***3245.93***	***32.90***	***Sprycel***	***BQ***

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ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
9283N	*Tablet 50 mg*	*60*	*2*	*..*	*5250.25*	*32.90*	*Sprycel*	*BQ*
9284P	*Tablet 70 mg*	*60*	*2*	*..*	*6464.58*	*32.90*	*Sprycel*	*BQ*

Authority Required

Continuing treatment, as the sole PBS-subsidised therapy, of a patient who has received initial treatment with dasatinib as a pharmaceutical benefit for chronic myeloid leukaemia, and who has demonstrated either a major cytogenetic response, or less than 1% BCR-ABL level in the blood, to dasatinib in the preceding 18 months and thereafter at 12 monthly intervals.

Applications for authorisation must be in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Chronic Myeloid Leukaemia Dasatinib/Nilotinib Authority Application Form for continuing treatment; and
(3) demonstration of continued response to treatment as evidenced by either:
(a) major cytogenetic response [see Note explaining definitions of response]. Where this has been supplied within the previous 12 months (or 18 months for the initial supply), only the date of the relevant pathology report needs to be provided; or
(b) a peripheral blood level of BCR-ABL of less than 1% on the international scale [see Note explaining definitions of response]. Where this has been supplied within the previous 12 months (or 18 months for the initial supply), only the date of the relevant pathology report needs to be provided.

NOTE:

Definitions of response.
A major cytogenetic response is defined as less than 35% Philadelphia positive bone marrow cells.
A bone marrow or peripheral blood BCR-ABL level of less than 1% on the international scale (Blood 108: 28-37, 2006) also indicates a response, at least the biological equivalent of a major cytogenetic response.

Authority approval requirements.
For the purposes of assessing response to PBS-subsidised treatment with dasatinib, either cytogenetic analysis indicating the number of Philadelphia positive [t (9;22)] cells in the bone marrow measured by standard karyotyping, or quantitative PCR indicating the relative level of BCR-ABL transcript in the peripheral blood using the international scale, must be submitted. For bone marrow analyses, where the standard karyotyping is not informative for technical reasons, a cytogenetic analysis performed on the bone marrow by the use of fluorescence in situ hybridisation (FISH) with BCR-ABL specific probe must be submitted. The cytogenetic or peripheral blood quantitative PCR analyses must be submitted as follows:
(i) between 10 and 18 months of the commencement of treatment with dasatinib, at which time patients in whom a major cytogenetic response or peripheral blood BCR-ABL level of less than 1% has been demonstrated may receive authorisation for a further 12 months of treatment; and
(ii) at no greater than 12 month intervals thereafter, to demonstrate that the major cytogenetic response or peripheral blood BCR-ABL level of less than 1% has been sustained.
For each authority application where eligibility for continuing PBS-subsidised treatment is to be demonstrated, a copy of the cytogenetic analysis indicating the number of Philadelphia positive [t (9;22)] cells in the bone marrow measured by standard karyotyping, or a copy of the quantitative PCR indicating the relative level of BCR-ABL transcript in the peripheral blood using the international scale, must be submitted as described in (i) and (ii) above. For bone marrow analyses, where the standard karyotyping conducted at the time of application is not informative, a copy of a cytogenetic analysis conducted on the bone marrow using FISH with BCR-ABL specific probe must be submitted with the authority application. A copy of the non-informative standard karyotype analysis must be included with the authority application.
Where a patient has previously received PBS-subsidised treatment with dasatinib, no approval will be granted for PBS-subsidised re-treatment where that patient has at any time failed to meet the criteria for continuing treatment.

continued ☞

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
2478K	***Tablet 20 mg***	***60***	***5***	***..***	***3245.93***	***32.90***	***Sprycel***	***BQ***
2482P	***Tablet 50 mg***	***60***	***5***	***..***	***5250.25***	***32.90***	***Sprycel***	***BQ***
2485T	***Tablet 70 mg***	***60***	***5***	***..***	***6464.58***	***32.90***	***Sprycel***	***BQ***

Authority Required

Initial treatment, as monotherapy, of a patient with acute lymphoblastic leukaemia (ALL) bearing the Philadelphia chromosome or expressing the transcript, BCR-ABL, who has failed treatment with chemotherapy AND imatinib and where appropriate, allogeneic haemopoietic stem cell transplantation.

Failure of treatment is defined as either:
(i) Failure to achieve a complete morphological and cytogenetic remission after a minimum of 2 months treatment with intensive chemotherapy and imatinib;
(ii) Morphological or cytogenetic relapse of leukaemia after achieving a complete remission induced by chemotherapy and imatinib;
(iii) Morphological or cytogenetic relapse or persistence of leukaemia after allogeneic haemopoietic stem cell transplantation.

> ***Patients must have active leukaemia, as defined by presence on current pathology assessments of either morphological infiltration of the bone marrow (greater than 5% lymphoblasts) or cerebrospinal fluid or other sites; OR***
> ***the presence of cells bearing the Philadelphia chromosome on cytogenetic or FISH analysis in the bone marrow of patients in morphological remission.***

The first authority application must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Acute Lymphoblastic Leukaemia Dasatinib PBS Authority Application - Supporting Information Form; and
(c) a signed patient acknowledgement; and
(d) a pathology report demonstrating that the patient has active acute lymphoblastic leukaemia, either manifest as cytogenetic evidence of the Philadelphia chromosome, or morphological evidence of acute lymphoblastic leukaemia plus qualitative RT-PCR evidence of BCR-ABL transcript. The date of the relevant pathology report(s) need(s) to be provided.

Authority Required

Initial treatment, as monotherapy, of a patient with acute lymphoblastic leukaemia bearing the Philadelphia chromosome or expressing the transcript, BCR-ABL, who has been treated prior to 1 December 2007 and has failed treatment with chemotherapy and where appropriate, allogeneic haemopoietic stem cell transplantation.

> ***Patients must have active leukaemia, as defined by presence on current pathology assessments of either morphological infiltration of the bone marrow (greater than 5% lymphoblasts) or cerebrospinal fluid or other sites; OR***
> ***the presence of cells bearing the Philadelphia chromosome on cytogenetic or FISH analysis in the bone marrow of patients in morphological remission.***

continued ☞

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	

The first authority application must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Acute Lymphoblastic Leukaemia Dasatinib PBS Authority Application - Supporting Information Form; and
(c) a signed patient acknowledgement; and
(d) a pathology report demonstrating that the patient has active acute lymphoblastic leukaemia, either manifest as cytogenetic evidence of the Philadelphia chromosome, or morphological evidence of acute lymphoblastic leukaemia plus qualitative RT-PCR evidence of BCR-ABL transcript. The date of the relevant pathology report(s) need(s) to be provided.

Authority Required

Continuing treatment, as monotherapy, of a patient with acute lymphoblastic leukaemia bearing the Philadelphia chromosome or expressing the transcript, BCR-ABL, where the patient has previously been issued with an authority prescription for dasatinib and does not have progressive disease.

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

NOTE:
Dasatinib will only be subsidised for patients with acute lymphoblastic leukaemia who are not receiving concomitant PBS-subsidised imatinib mesylate and who are not appropriate for an allogeneic haemopoietic stem cell transplant.

9125G	*Tablet 20 mg*	*60*	*2*	*..*	*3245.93*	*32.90*	*Sprycel*	*BQ*
9126H	*Tablet 50 mg*	*60*	*2*	*..*	*5250.25*	*32.90*	*Sprycel*	*BQ*
9127J	*Tablet 70 mg*	*60*	*2*	*..*	*6464.58*	*32.90*	*Sprycel*	*BQ*

NOTE:
No applications for increased repeats will be authorised.

ERLOTINIB

Authority Required

Initial PBS-subsidised treatment, as monotherapy, in a patient with locally advanced or metastatic (stage IIIB or IV) non-small cell lung cancer with a WHO performance status of 3 or less, after prior treatment with platinum-based chemotherapy, where:
(1) (a) disease progression has occurred following treatment with docetaxel or pemetrexed; or
(b) treatment with docetaxel and pemetrexed is either contraindicated or cannot be tolerated; and
(2) further cytotoxic chemotherapy is not appropriate.

Authority Required

Continuing PBS-subsidised treatment, as monotherapy, in a patient with locally advanced or metastatic (stage IIIB or IV) non-small cell lung cancer who has previously been issued with an authority prescription for this drug and who does not have progressive disease.

Authority Required

Initial PBS-subsidised treatment, as monotherapy, in a patient with locally advanced or metastatic (stage IIIB or IV) non-small cell lung cancer, after prior treatment with platinum-based chemotherapy:
(1) where:
(a) disease progression occurred following treatment with docetaxel or pemetrexed; or
(b) treatment with docetaxel and pemetrexed was either contraindicated or could not be tolerated; and
(2) who has received treatment with erlotinib under the Erlotinib Access Programme prior to 1 August 2008; and
(3) who does not have progressive disease.

continued ☞

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
9166K	*Tablet 25 mg (as hydrochloride)*	*30*	*3*	*..*	*793.76*	*32.90*	*Tarceva*	*RO*
9167L	*Tablet 100 mg (as hydrochloride)*	*30*	*3*	*..*	*2702.91*	*32.90*	*Tarceva*	*RO*
9168M	*Tablet 150 mg (as hydrochloride)*	*30*	*3*	*..*	*3309.23*	*32.90*	*Tarceva*	*RO*

GEFITINIB

NOTE:

Any queries concerning the arrangements to prescribe gefitinib may be directed to Medicare Australia on 1800 700 270.

Written applications for authority to prescribe gefitinib should be forwarded to:

Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

Authority Required

Initial PBS-subsidised treatment, as monotherapy, of locally advanced or metastatic non-small cell lung cancer in patients with a WHO performance status of 2 or less, where:
(1) disease progression has occurred following treatment with at least 1 chemotherapy agent; and
(2) there is evidence that the patient has an activating mutation(s) of the epidermal growth factor receptor (EGFR) gene in tumour material. The mutation(s) must be demonstrated by analysis of the DNA sequence of the EGFR gene.

The authority application must be made in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Gefitinib (Iressa) PBS Authority Application for Use in the Treatment of Locally Advanced or Metastatic Non-Small Cell Lung Cancer - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and
(3) details of the prior chemotherapy including the name(s) of drug(s) and date of the most recent treatment cycle; and
(4) details of the patient's WHO performance status; and
(5) a copy of the pathology report providing evidence of the presence of activating mutation(s) of the EGFR gene from an Approved Pathology Authority.

Authority Required

Continuing PBS-subsidised treatment, as monotherapy, of locally advanced or metastatic non-small cell lung cancer in patients with a WHO performance status of 2 or less, where the patient has previously been issued with an authority prescription for gefitinib.

Applications for continuing treatment may be made in writing or on the telephone by contacting Medicare Australia on 1800 700 270.

8769M	*Tablet 250 mg*	*30*	*1*	*..*	*3850.93*	*32.90*	*Iressa*	*AP*

NOTE:

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

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer

IMATINIB

NOTE:

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

Prescribing information (including Authority Application forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe imatinib mesylate should be forwarded to:

Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

For the following diseases, written authority is required at initiation and for continuation:
Chronic myeloid leukaemia (chronic phase);
Dermatofibrosarcoma protuberans;
Hypereosinophilic syndrome;
Chronic eosinophilic leukaemia;
Myelodysplastic or myeloproliferative disorder;
Aggressive systemic mastocytosis with eosinophilia.

NOTE:

Imatinib mesylate is not PBS-subsidised for the treatment of patients with resectable malignant gastrointestinal stromal tumours.

Authority Required

Initial PBS-subsidised treatment, for up to 3 months, of adult patients with a metastatic or unresectable malignant gastrointestinal stromal tumour which has been histologically confirmed by the detection of CD117 on immunohistochemical staining.

Patients who have not previously been treated with imatinib mesylate for a metastatic or unresectable malignant gastrointestinal stromal tumour must commence treatment at a dose not exceeding 400 mg per day for at least 3 months. Authority prescriptions for a higher dose will not be approved during this initial 3 month treatment period.

Patients who have previously been treated with non-PBS-subsidised imatinib mesylate for a metastatic or unresectable malignant gastrointestinal stromal tumour are eligible to receive up to 3 months treatment at a dose of up to 600 mg per day.

Applications for authorisation must be in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Imatinib Mesylate (Glivec) PBS Authority Application for Use in the Treatment of Gastrointestinal Stromal Tumour - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
(i) a copy of a pathology report from an Approved Pathology Authority supporting the diagnosis of a gastrointestinal stromal tumour and confirming the presence of CD117 on immunohistochemical staining; and
(ii) a copy of the most recent (within 2 months of the application) computed tomography (CT) scan, magnetic resonance imaging (MRI) or ultrasound assessment of the tumour(s), including whether or not there is evidence of metastatic disease; and
(iii) where the application for authority to prescribe is being sought on the basis of an unresectable tumour, written evidence in support of that claim must be provided; and
(iv) for patients who commenced treatment with imatinib mesylate for a metastatic or unresectable malignant gastrointestinal stromal tumour prior to 1 December 2004, the date on which therapy with imatinib mesylate was commenced.

continued ☞

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
	Authority Required ***Continuing PBS-subsidised treatment, at a dose of up to 600 mg per day, of adult patients with a metastatic or unresectable malignant gastrointestinal stromal tumour who have previously been issued with an authority prescription for this drug.*** ***Applications for continuing treatment may be made by telephone (1800 700 270, hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).*** **NOTE:** ***Patients who achieve a response to treatment at an imatinib dose of 400 mg per day should be continued at this dose and assessed for response at regular intervals. Patients who fail to achieve a response to 400 mg per day may have their dose increased to 600 mg per day. Authority applications for doses higher than 600 mg per day will not be approved.*** ***A response to treatment is defined as a decrease from baseline in the sum of the products of the perpendicular diameters of all measurable lesions of 50% or greater. (Response definition based on the Southwest Oncology Group standard criteria, see Demetri et al. N Engl J Med 2002; 347: 472-80.)***							
9111M	*Tablet 100 mg (as mesylate)*	*60*	*2*	*..*	*2032.10*	*32.90*	*Glivec*	*NV*
9112N	*Tablet 400 mg (as mesylate)*	*30*	*2*	*..*	*3918.26*	*32.90*	*Glivec*	*NV*
	NOTE: ***No applications for increased repeats will be authorised.***							
	Authority Required ***Initial treatment of patients in the chronic phase of chronic myeloid leukaemia expressing the Philadelphia chromosome or the transcript, bcr-abl tyrosine kinase, and who have a primary diagnosis of chronic myeloid leukaemia.*** ***Applications under this restriction will be limited to provide patients with a maximum of 18 months of therapy from the date the first application for initial treatment was approved.*** ***Applications for authorisation must be in writing and must include:*** ***(1) a completed authority prescription form; and*** ***(2) a completed Imatinib Mesylate (Glivec) PBS Authority Application for Use in the Treatment of Chronic Myeloid Leukaemia - Supporting Information form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and*** ***(3) a pathology cytogenetic report conducted on peripheral blood or bone marrow supporting the diagnosis of chronic myeloid leukaemia to confirm eligibility for treatment, or a qualitative PCR report documenting the presence of the bcr-abl transcript in either peripheral blood or bone marrow; and*** ***(4) a copy of a signed patient acknowledgement form indicating that the patient understands and acknowledges that PBS-subsidised treatment with imatinib mesylate for the chronic phase of chronic myeloid leukaemia will cease if subsequent testing demonstrates that:*** ***(i) the patient has failed to achieve a major cytogenetic response within the initial 18 months of treatment [see Note defining major cytogenetic response]; or*** ***(ii) the patient has failed to sustain a major cytogenetic response for 12 months from the date of the last pathology report that indicated that a major cytogenetic response had been achieved [see Note defining major cytogenetic response].***							

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ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer

NOTE:

Imatinib mesylate in the chronic phase of chronic myeloid leukaemia will only be subsidised for patients who are not receiving concomitant PBS-subsidised interferon alfa therapy.

Patients should be commenced on a dose of imatinib mesylate of 400 mg (base) daily and maintained on a minimum dose of imatinib mesylate of 400 mg (base) daily. Prescribing of lower doses should be carefully considered. Continuing therapy is dependent on patients demonstrating a response to imatinib mesylate therapy following the initial 18 months of treatment and at 12 monthly intervals thereafter, irrespective of the daily imatinib mesylate dose received.

Authority Required

Continuing treatment of patients who have received initial treatment with imatinib mesylate as a pharmaceutical benefit for the chronic phase of chronic myeloid leukaemia and who have demonstrated either a major cytogenetic response or less than 1% bcr-abl level in the blood in the preceding 12 months.

Applications for authorisation must be in writing and must include:
(1) a completed authority prescription form; and
(2) demonstration of continued response to treatment as evidenced by either:
(a) major cytogenetic response [see Note explaining requirements]. Where this has been supplied within the previous 12 months, only the date of the relevant pathology report need be provided; or
(b) a peripheral blood level of bcr-abl of less than 1% on the international scale [see Note explaining requirements]. Where this has been supplied within the previous 12 months, only the date of the relevant pathology report need be provided.

NOTE:

Definitions of response.
A major cytogenetic response is defined as less than 35% Philadelphia positive bone marrow cells.
A peripheral blood bcr-abl level of less than 1% on the international scale (Blood 108: 28-37, 2006) also indicates a response, at least the biological equivalent of a major cytogenetic response.

Authority approval requirements.
For the purposes of assessing response to PBS-subsidised treatment with imatinib mesylate, either cytogenetic analysis indicating the number of Philadelphia positive [t (9;22)] cells in the bone marrow measured by standard karyotyping, or quantitative PCR indicating the relative level of bcr-abl transcript in the peripheral blood using the international scale, must be submitted. For bone marrow analyses, where the standard karyotyping is not informative for technical reasons, a cytogenetic analysis performed on the bone marrow by the use of fluorescence in situ hybridisation (FISH) with bcr-abl specific probe must be submitted. The cytogenetic or peripheral blood quantitative PCR analyses must be submitted as follows:
(i) between 10 and 12 months of the commencement of treatment with imatinib mesylate, at which time patients in whom a major cytogenetic response or peripheral blood bcr-abl level of less than 1% has been demonstrated may receive authorisation for a further 12 months of treatment; and
(ii) within 18 months of the commencement of treatment with imatinib mesylate, in patients who have failed to demonstrate a major cytogenetic response or peripheral blood bcr-abl level of less than 1% at between 10 and 12 months (patients in whom a major cytogenetic response or peripheral blood bcr-abl level of less than 1% is demonstrable by 18 months may also receive authorisation for a further 12 months of treatment); and
(iii) at no greater than 12 month intervals thereafter, to demonstrate that the major cytogenetic response or peripheral blood bcr-abl level of less than 1% has been sustained.

For each authority application where eligibility for continuing PBS-subsidised treatment is to be demonstrated, a copy of the cytogenetic analysis indicating the number of Philadelphia positive [t (9;

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ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
	22)] cells in the bone marrow measured by standard karyotyping, or a copy of the quantitative PCR indicating the relative level of bcr-abl transcript in the peripheral blood using the international scale, must be submitted as described in (i) to (iii) above. For bone marrow analyses, where the standard karyotyping conducted at the time of application is not informative, a copy of a cytogenetic analysis conducted on the bone marrow using FISH with bcr-abl specific probe must be submitted with the authority application. A copy of the non-informative standard karyotype analysis must be included with the authority application.							
	Where a patient has previously received PBS-subsidised treatment with imatinib mesylate, no approval will be granted for PBS-subsidised re-treatment in the chronic phase of chronic myeloid leukaemia, where that patient has at any time failed to meet the criteria for continuing treatment.							
9113P	***Tablet 100 mg (as mesylate)***	***60***	***5***	***..***	***2032.10***	***32.90***	***Glivec***	***NV***
9114Q	***Tablet 400 mg (as mesylate)***	***30***	***5***	***..***	***3918.26***	***32.90***	***Glivec***	***NV***
	NOTE:							
	No applications for increased repeats will be authorised.							

Authority Required

Treatment of patients in the accelerated phase of chronic myeloid leukaemia expressing the Philadelphia chromosome or the transcript, bcr-abl tyrosine kinase, and who have a primary diagnosis of chronic myeloid leukaemia. Progress to the accelerated phase is defined by the presence of 1 or more of the following:
(1) Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 15% but less than 30%; or
(2) Percentage of blasts plus promyelocytes in the peripheral blood or bone marrow greater than or equal to 30%; or

(3) Peripheral basophils greater than or equal to 20%; or
(4) Progressive splenomegaly to a size greater than or equal to 10 cm below the left costal margin to be confirmed on 2 occasions at least 4 weeks apart, or a greater than or equal to 50% increase in size below the left costal margin over 4 weeks; or
(5) Karyotypic evolution (chromosomal abnormalities in addition to a single Philadelphia chromosome).

Applications for authorisation must be in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Imatinib Mesylate (Glivec) PBS Authority Application for Use in the Treatment of Chronic Myeloid Leukaemia - Supporting Information form, stating which of the above criteria are satisfied by the patient; and
(c) a copy of the confirming pathology report from an Approved Pathology Authority in the case of criteria (1), (2), (3) and (5) above, or details of the dates of assessments in the case of progressive splenomegaly.

Authority Required

Treatment of patients in the blast phase of chronic myeloid leukaemia expressing the Philadelphia chromosome or the transcript, bcr-abl tyrosine kinase, and who have a primary diagnosis of chronic myeloid leukaemia. Progress to myeloid blast crisis is defined as either:
(1) Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 30%; or
(2) Extramedullary involvement other than spleen and liver.

Applications for authorisation must be in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Imatinib Mesylate (Glivec) PBS Authority Application for Use in the Treatment of Chronic Myeloid Leukaemia - Supporting Information form, stating which of the above criteria are satisfied by the patient; and
(c) a copy of the confirming pathology report from an Approved Pathology Authority in the case of criterion (1) above, or details of the date of assessment in the case of extramedullary involvement.

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ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
	Authority Required ***Continuing treatment of patients with chronic myeloid leukaemia expressing the Philadelphia chromosome or the transcript, bcr-abl tyrosine kinase, where the patient has previously received PBS-subsidised treatment with imatinib mesylate of:*** ***(a) the accelerated phase of chronic myeloid leukaemia; or*** ***(b) the blast phase of chronic myeloid leukaemia.***							
9115R	***Tablet 100 mg (as mesylate)***	***60***	***2***	***..***	***2032.10***	***32.90***	***Glivec***	***NV***
9116T	***Tablet 400 mg (as mesylate)***	***30***	***2***	***..***	***3918.26***	***32.90***	***Glivec***	***NV***
	NOTE: ***No applications for increased repeats will be authorised.***							
	Authority Required ***Initial treatment in combination with chemotherapy as induction or consolidation of a newly diagnosed patient with acute lymphoblastic leukaemia (ALL) bearing the Philadelphia chromosome or expressing the transcript, BCR-ABL.*** ***The first authority application must be made in writing and must include:*** ***(a) a completed authority prescription form; and*** ***(b) a completed Acute Lymphoblastic Leukaemia Imatinib PBS Authority Application - Supporting Information Form; and*** ***(c) a pathology cytogenetic report conducted on peripheral blood or bone marrow supporting the diagnosis of acute lymphoblastic leukaemia to confirm eligibility for treatment, with either cytogenetic evidence of the Philadelphia chromosome, or a qualitative PCR report documenting the presence of the BCR-ABL transcript in either peripheral blood or bone marrow. (The date of the relevant pathology report needs to be provided); and*** ***(d) a signed patient acknowledgement.***							
	Authority Required ***Initial treatment of a patient with acute lymphoblastic leukaemia bearing the Philadelphia chromosome or expressing the transcript BCR-ABL who was previously treated with imatinib mesylate under the Imatinib Compassionate Program and who meets all the PBS criteria.*** ***The first authority application must be made in writing and must include:*** ***(a) a completed authority prescription form; and*** ***(b) a completed Acute Lymphoblastic Leukaemia Imatinib PBS Authority Application - Supporting Information Form; and*** ***(c) a pathology cytogenetic report conducted on peripheral blood or bone marrow supporting the diagnosis of acute lymphoblastic leukaemia to confirm eligibility for treatment, with either cytogenetic evidence of the Philadelphia chromosome, or a qualitative PCR report documenting the presence of the BCR-ABL transcript in either peripheral blood or bone marrow. (The date of the relevant pathology report needs to be provided); and*** ***(d) a signed patient acknowledgement.***							
	Authority Required ***Continuing treatment in combination with chemotherapy as maintenance of first complete remission of patients with acute lymphoblastic leukaemia bearing the Philadelphia chromosome or expressing the transcript, BCR-ABL.*** ***Authority applications for continuing treatment may be made by telephone to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).*** ***Imatinib mesylate is available with a lifetime maximum of 24 months imatinib mesylate therapy for patients with acute lymphoblastic leukaemia reimbursed through the PBS.***							

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ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
	Any queries concerning the arrangements to prescribe imatinib mesylate beyond 24 months may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).							
	NOTE: ***Allogeneic stem cell transplantation is the preferred therapy for eligible patients achieving a complete remission of Philadelphia positive acute lymphoblastic leukaemia.***							
9123E	***Tablet 100 mg (as mesylate)***	***60***	***2***	***..***	***2032.10***	***32.90***	***Glivec***	***NV***
9124F	***Tablet 400 mg (as mesylate)***	***30***	***2***	***..***	***3918.26***	***32.90***	***Glivec***	***NV***
	NOTE: ***No applications for increased repeats will be authorised.***							
	Authority Required ***Initial PBS-subsidised treatment of a patient with unresectable, locally recurrent or metastatic dermatofibrosarcoma protuberans.*** ***Maximum dose: 800 mg per day.*** ***(1) Where the application for authority to prescribe is being sought on the basis of unresectable tumour, written evidence in support of that claim must be provided; and*** ***(2) Where the application for authority to prescribe is being sought on the basis of locally recurrent disease, the site of the local recurrence must be specified; and*** ***(3) Where the application for authority to prescribe is being sought on the basis of metastatic disease, the site(s) of metastatic disease must be provided.*** ***Applications for authorisation for initial treatment must be made in writing and must include:*** ***(a) a completed authority prescription form; and*** ***(b) a completed Rare Diseases Imatinib PBS Authority Application - Supporting Information Form; and*** ***(c) a signed patient acknowledgement.***							
	Authority Required ***Continuing PBS-subsidised treatment of a patient with unresectable, locally recurrent or metastatic dermatofibrosarcoma protuberans who has previously been issued with an authority prescription for imatinib and who has demonstrated a response, but whose disease remains unresectable.*** ***Maximum dose: 800 mg per day.*** ***Applications for authorisation must be made in writing and must include:*** ***(a) a completed authority prescription form; and*** ***(b) a completed Rare Diseases Imatinib PBS Authority Application - Supporting Information Form; and*** ***(c) a statement that the disease has not progressed on imatinib therapy.***							
9172R	***Tablet 100 mg (as mesylate)***	***60***	***2***	***..***	***2032.10***	***32.90***	***Glivec***	***NV***
9173T	***Tablet 400 mg (as mesylate)***	***30***	***2***	***..***	***3918.26***	***32.90***	***Glivec***	***NV***
	NOTE: ***No applications for increased repeats will be authorised.***							

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ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	

Authority Required

Initial PBS-subsidised treatment of a patient with hypereosinophilic syndrome or chronic eosinophilic leukaemia requiring treatment and confirmed to carry the FIP1L1-PDGFRA fusion gene.

Maximum dose: 400 mg per day.

Applications for authorisation for initial treatment must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Rare Diseases Imatinib PBS Authority Application - Supporting Information Form; and
(c) a copy of the pathology report confirming the presence of the FIP1L1-PDGFRA fusion gene; and
(d) a copy of the full blood examination report confirming the presence of hypereosinophilic syndrome or chronic eosinophilic leukaemia; and
(e) details of organ involvement requiring treatment, including a copy of the radiology, nuclear medicine, respiratory function or anatomical pathology reports as appropriate; and
(f) a signed patient acknowledgement.

Authority Required

Continuing PBS-subsidised treatment of a patient with hypereosinophilic syndrome or chronic eosinophilic leukaemia who has previously been issued with an authority prescription for imatinib and who has achieved and maintained a complete haematological response.

Maximum dose: 400 mg per day.

Applications for authorisation must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Rare Diseases Imatinib PBS Authority Application - Supporting Information Form; and
(c) a copy of the full blood examination report which demonstrates a complete haematological response, with a normal eosinophil count; and
(d) a statement that the disease has not progressed on imatinib therapy.

9174W	*Tablet 100 mg (as mesylate)*	*60*	*2*	*..*	*2032.10*	*32.90*	*Glivec*	*NV*
9175X	*Tablet 400 mg (as mesylate)*	*30*	*2*	*..*	*3918.26*	*32.90*	*Glivec*	*NV*

NOTE:
No applications for increased repeats will be authorised.

Authority Required

Initial PBS-subsidised treatment of a patient with a myelodysplastic or myeloproliferative disorder where:
(1) there is confirmed evidence of a platelet-derived growth factor receptor (PDGFR) gene re-arrangement either by standard karyotyping, or FISH or PDGFRB fusion gene transcript; and
(2) the patient has previously failed an adequate trial of one or more of the following conventional therapies:
— cytarabine;
— etoposide;
— hydroxyurea.

Maximum dose: 400 mg per day.

continued ☞

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
	Applications for authorisation for initial treatment must be made in writing and must include:							
	(a) a completed authority prescription form; and							
	(b) a completed Rare Diseases Imatinib PBS Authority Application - Supporting Information Form; and							
	(c) a copy of the pathology report confirming the platelet-derived growth factor receptor (PDGFR) gene re-arrangement; and							
	(d) a copy of the bone marrow biopsy report which demonstrates the presence of a myelodysplastic or myeloproliferative disorder; and							
	(e) details of the prior therapy trialled and the response; and							
	(f) a signed patient acknowledgement.							
	Authority Required							
	Continuing PBS-subsidised treatment of a patient with a PDGFRB fusion gene-positive myelodysplastic or myeloproliferative disorder who has previously been issued with an authority prescription for imatinib and who has demonstrated a complete haematological response.							
	Maximum dose: 400 mg per day.							
	Applications for authorisation must be made in writing and must include:							
	(a) a completed authority prescription form; and							
	(b) a completed Rare Diseases Imatinib PBS Authority Application - Supporting Information Form; and							
	(c) a copy of the full blood examination report which demonstrates a complete haematological response; and							
	(d) a statement that the disease has not progressed on imatinib therapy.							
9176Y	***Tablet 100 mg (as mesylate)***	***60***	***2***	***..***	***2032.10***	***32.90***	***Glivec***	***NV***
9177B	***Tablet 400 mg (as mesylate)***	***30***	***2***	***..***	***3918.26***	***32.90***	***Glivec***	***NV***
	NOTE:							
	No applications for increased repeats will be authorised.							
	Authority Required							
	Initial PBS-subsidised treatment of a patient with aggressive systemic mastocytosis with eosinophilia where:							
	(1) there is confirmed evidence of the FIP1L1-PDGFRA fusion gene; and							
	(2) the patient has previously failed an adequate trial of one or more of the following conventional therapies:							
	— corticosteroids;							
	— hydroxyurea.							
	Maximum dose: 400 mg per day.							
	Applications for authorisation for initial treatment must be made in writing and must include:							
	(a) a completed authority prescription form; and							
	(b) a completed Rare Diseases Imatinib PBS Authority Application - Supporting Information Form; and							
	(c) a copy of the pathology report confirming the presence of the FIP1L1-PDGFRA fusion gene; and							
	(d) a copy of the bone marrow biopsy report and/or other tissue biopsy report confirming the diagnosis of aggressive systemic mastocytosis and a copy of the full blood examination report demonstrating eosinophilia; and							
	(e) details of symptomatic organ involvement requiring treatment, including a copy of the radiology, nuclear medicine, respiratory function or anatomical pathology reports as appropriate; and							
	(f) details of prior treatment trialled and the response; and							
	(g) a signed patient acknowledgement.							

continued ☞

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	

Authority Required

Continuing PBS-subsidised treatment of a patient with aggressive systemic mastocytosis confirmed to carry the FIP1L1-PDGFRA fusion gene, who has previously been issued with an authority prescription for imatinib and who has demonstrated a complete haematological response.

Maximum dose: 400 mg per day.

Applications for authorisation must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Rare Diseases Imatinib PBS Authority Application - Supporting Information Form; and
(c) a copy of the full blood examination report which demonstrates a complete haematological response; and
(d) a statement that the disease has not progressed on imatinib therapy.

9178C	*Tablet 100 mg (as mesylate)*	*60*	*2*	*..*	*2032.10*	*32.90*	*Glivec*	*NV*
9179D	*Tablet 400 mg (as mesylate)*	*30*	*2*	*..*	*3918.26*	*32.90*	*Glivec*	*NV*

NOTE:
No applications for increased repeats will be authorised.

LAPATINIB
NOTE:
Any queries concerning the arrangements to prescribe lapatinib may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Lapatinib should not be used in patients with a left ventricular ejection fraction (LVEF) of less than 45% or with symptomatic heart failure. Cardiac function must be tested by a suitable method including, for example, ECHO or MUGA, prior to seeking the initial authority approval and then at 3 monthly intervals during treatment.

Lapatinib is not PBS-subsidised when used in combination with Commonwealth-subsidised trastuzumab. Once PBS-subsidised lapatinib has been commenced, a patient cannot subsequently receive Commonwealth-subsidised trastuzumab.

If disease progression occurs, the prescribing doctor must contact Medicare Australia within one week on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) and lapatinib treatment must be ceased immediately.

Authority Required

Initial treatment, in combination with capecitabine, of a patient with HER2 positive metastatic breast cancer (equivalent to Stage IIIC or Stage IV) who has received prior therapy with an anthracycline and a taxane, each for at least 3 cycles, and whose disease has progressed despite treatment with trastuzumab for metastatic disease.

Authority applications for initial treatment must be made in writing and must include:
(a) a completed authority prescription form;
(b) a pathology report demonstrating HER2 positivity has been demonstrated by in situ hybridisation (ISH);
(c) date of last treatment with a taxane and total number of cycles;
(d) date of last treatment with an anthracycline and total number of cycles;
(e) a signed patient acknowledgment;
(f) dates of treatment with trastuzumab; and
(g) date of demonstration of progression whilst on treatment with trastuzumab.

NOTE:
Treatment with trastuzumab for metastatic disease is defined as trastuzumab administered alone or in combination with chemotherapy for at least 6 weeks at standard doses.

continued ☞

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
	Authority Required ***Initial treatment, in combination with capecitabine, of a patient with HER2 positive metastatic breast cancer who was receiving treatment with lapatinib prior to 1 May 2008.*** ***Authority applications for initial PBS-subsidised treatment must be made in writing and must include:*** ***(a) a completed authority prescription form;*** ***(b) a pathology report demonstrating that HER2 positivity has been demonstrated by in situ hybridisation (ISH);*** ***(c) a signed patient acknowledgment; and*** ***(d) the date the patient commenced non-PBS-subsidised treatment with lapatinib.***							
	Authority Required ***Continuing treatment, in combination with capecitabine, of a patient with HER2 positive metastatic breast cancer who has previously received treatment with PBS-subsidised lapatinib and who does not have progressive disease.*** ***Authority applications must be made in writing and must include:*** ***(a) a completed authority prescription form; and*** ***(b) a statement from the prescribing doctor that the disease has not progressed.***							
9148L	***Tablet 250 mg (as ditosylate monohydrate)***	***140***	***2***	***..***	**** 3387.03***	***32.90***	***Tykerb***	***GK***
	NOTE: ***No applications for increased maximum quantities and/or repeats will be authorised.***							
	NILOTINIB **NOTE:** ***Any queries concerning the arrangements to prescribe nilotinib may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).*** ***Prescribing information (including Authority Application forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.*** ***Any queries concerning patients who are enrolled on the Nilotinib Compassionate Program may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).*** ***Applications for authority to prescribe nilotinib should be forwarded to:*** ***Medicare Australia*** ***Prior Written Approval of Specialised Drugs*** ***Reply Paid 9826*** ***GPO Box 9826*** ***HOBART TAS 7001***							
➢	**Authority Required** ***Initial treatment, as the sole PBS-subsidised therapy, of a patient with chronic myeloid leukaemia in chronic or accelerated phase bearing the Philadelphia chromosome or expressing the transcript, BCR-ABL, who has active leukaemia (as defined by presence on current pathology assessments of either the Philadelphia chromosome on cytogenetic or FISH analysis, or the presence of the transcript BCR-ABL greater than 1% on the international scale) and who has failed an adequate trial of imatinib.*** ***Failure of an adequate trial of imatinib is defined as:*** ***(i) Lack of response to initial imatinib therapy, defined as either:*** ***— failure to achieve a haematological response after a minimum of 3 months therapy with imatinib for patients initially treated in chronic phase; or***							

continued ☞

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer

— failure to achieve any cytogenetic response after a minimum of 6 months therapy with imatinib for patients initially treated in chronic phase as demonstrated on bone marrow biopsy by presence of greater than 95% Philadelphia chromosome positive cells; or
— failure to achieve a major cytogenetic response or a peripheral blood BCR-ABL level of less than 1% after a minimum of 12 months therapy with imatinib; OR

(ii) Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph positive cells on bone marrow biopsy), during ongoing imatinib therapy;
OR

(iii) Loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing in value by at least 5 fold to a level of greater than 1% confirmed on a subsequent test), during ongoing imatinib therapy;
OR

(iv) Development of accelerated phase in a patient previously prescribed imatinib for the chronic phase of chronic myeloid leukaemia.

Accelerated phase is defined by the presence of 1 or more of the following:
(1) Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 15% but less than 30%; or
(2) Percentage of blasts plus promyelocytes in the peripheral blood or bone marrow greater than or equal to 30%, provided that blast count is less than 30%; or
(3) Peripheral basophils greater than or equal to 20%; or
(4) Progressive splenomegaly to a size greater than or equal to 10 cm below the left costal margin to be confirmed on 2 occasions at least 4 weeks apart, or a greater than or equal to 50% increase in size below the left costal margin over 4 weeks; or
(5) Karyotypic evolution (chromosomal abnormalities in addition to a single Philadelphia chromosome); OR

(v) Disease progression (defined as a greater than or equal to 50% increase in peripheral white blood cell count, blast count, basophils or platelets) during first-line imatinib therapy in patients with accelerated phase chronic myeloid leukaemia, provided that blast crisis has been excluded on bone marrow biopsy;
OR

(vi) Grade 3 or 4 non-haematological toxicity that is imatinib related and necessitates permanent cessation of imatinib. For patients with imatinib related toxicities, leukaemia activity does not need to be demonstrated.

Applications for authorisation must be in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Chronic Myeloid Leukaemia Dasatinib/Nilotinib PBS Authority Application - Supporting Information Form; and
(c) a signed patient acknowledgement; and
(d) a bone marrow biopsy pathology report demonstrating the patient has active chronic myeloid leukaemia, either manifest as cytogenetic evidence of the Philadelphia chromosome, or RT-PCR level of BCR-ABL transcript greater than 1% on the international scale. (The date of the relevant pathology report needs to be provided); and
(e) where there has been a loss of response to imatinib, a copy of the current confirming pathology report(s) from an Approved Pathology Authority; or
(f) details of Grade 3 or 4 non-haematological imatinib related toxicity.

NOTE:
Nilotinib will only be subsidised for patients with chronic myeloid leukaemia who are not receiving concomitant PBS-subsidised imatinib mesylate, dasatinib or interferon alfa therapy.

Patients should be commenced on a dose of nilotinib of 400 mg twice daily. Continuing therapy is dependent on patients demonstrating a major cytogenetic response to nilotinib therapy or a peripheral blood BCR-ABL level of less than 1% at 18 months and thereafter at 12 monthly intervals, irrespective of the daily nilotinib dose received.

continued ☞

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
	Nilotinib is not PBS-subsidised for patients with CML that is resistant to dasatinib. ***Nilotinib is not TGA-registered and not PBS-subsidised for patients with CML in blast crisis.*** ***Requests for doses of greater than nilotinib 400 mg twice daily will not be approved.*** ***From 1 November 2008, under the PBS, a patient will be able to trial either dasatinib and/or nilotinib within the initial 18 month treatment period, providing the patient's CML is not resistant to the first second-line agent.***							
9285Q	***Capsule 200 mg (as hydrochloride monohydrate)***	***112***	***2***	***..***	**** 5489.99***	***32.90***	***Tasigna***	***NV***

Authority Required

Continuing treatment, as the sole PBS-subsidised therapy, of a patient who has received initial treatment with nilotinib as a pharmaceutical benefit for chronic myeloid leukaemia, and who has demonstrated either a major cytogenetic response, or less than 1% BCR-ABL level in the blood, to nilotinib in the preceding 18 months and thereafter at 12 monthly intervals.

Applications for authorisation must be in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Chronic Myeloid Leukaemia Dasatinib/Nilotinib Authority Application Form for continuing treatment; and
(3) demonstration of continued response to treatment as evidenced by either:
(a) major cytogenetic response [see Note explaining definitions of response]. Where this has been supplied within the previous 12 months (or 18 months for the initial supply), only the date of the relevant pathology report needs to be provided; or
(b) a peripheral blood level of BCR-ABL of less than 1% on the international scale [see Note explaining definitions of response]. Where this has been supplied within the previous 12 months (or 18 months for the initial supply), only the date of the relevant pathology report needs to be provided.

NOTE:

Definitions of response.
A major cytogenetic response is defined as less than 35% Philadelphia positive bone marrow cells.
A bone marrow or peripheral blood BCR-ABL level of less than 1% on the international scale (Blood 108: 28-37, 2006) also indicates a response, at least the biological equivalent of a major cytogenetic response.

Authority approval requirements.
For the purposes of assessing response to PBS-subsidised treatment with nilotinib, either cytogenetic analysis indicating the number of Philadelphia positive [t (9;22)] cells in the bone marrow measured by standard karyotyping, or quantitative PCR indicating the relative level of BCR-ABL transcript in the peripheral blood using the international scale, must be submitted. For bone marrow analyses, where the standard karyotyping is not informative for technical reasons, a cytogenetic analysis performed on the bone marrow by the use of fluorescence in situ hybridisation (FISH) with BCR-ABL specific probe must be submitted. The cytogenetic or peripheral blood quantitative PCR analyses must be submitted as follows:
(i) between 10 and 18 months of the commencement of treatment with nilotinib, at which time patients in whom a major cytogenetic response or peripheral blood BCR-ABL level of less than 1% has been demonstrated may receive authorisation for a further 12 months of treatment; and
(ii) at no greater than 12 month intervals thereafter, to demonstrate that the major cytogenetic response or peripheral blood BCR-ABL level of less than 1% has been sustained.

continued ☞

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
	For each authority application where eligibility for continuing PBS-subsidised treatment is to be demonstrated, a copy of the cytogenetic analysis indicating the number of Philadelphia positive [t (9;22)] cells in the bone marrow measured by standard karyotyping, or a copy of the quantitative PCR indicating the relative level of BCR-ABL transcript in the peripheral blood using the international scale, must be submitted as described in (i) and (ii) above. For bone marrow analyses, where the standard karyotyping conducted at the time of application is not informative, a copy of a cytogenetic analysis conducted on the bone marrow using FISH with BCR-ABL specific probe must be submitted with the authority application. A copy of the non-informative standard karyotype analysis must be included with the authority application.							
	Where a patient has previously received PBS-subsidised treatment with nilotinib, no approval will be granted for PBS-subsidised re-treatment where that patient has at any time failed to meet the criteria for continuing treatment.							
9171Q	***Capsule 200 mg (as hydrochloride monohydrate)***	***112***	***5***	***..***	**** 5489.99***	***32.90***	***Tasigna***	***NV***
	SORAFENIB							
	Authority Required ***Initial treatment, as the sole PBS-subsidised agent, of advanced (BCLC Stage C) hepatocellular carcinoma in a patient with a WHO performance status of 2 or less and Child Pugh class A;*** ***Continuing treatment, as the sole PBS-subsidised agent, of advanced hepatocellular carcinoma in a patient who has previously been treated with PBS-subsidised sorafenib and who does not have progressive disease.***							
	NOTE: ***Sorafenib is not PBS-subsidised for adjunctive treatment after resection, ablation or chemoembolization.*** ***Sorafenib is not PBS-subsidised for maintenance therapy after disease progression.***							
	No applications for increased maximum quantities and/or repeats will be authorised.							
9380Q	***Tablet 200 mg (as tosylate)***	***120***	***2***	***..***	**** 6456.65***	***32.90***	***Nexavar***	***BN***

• *Other antineoplastic agents*

BORTEZOMIB

NOTE:

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

Prescribing information (including Authority Application forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Applications for authority to prescribe bortezomib should be forwarded to:

Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

continued ☞

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer

Authority Required

Initial PBS-subsidised treatment, as monotherapy or in combination with a corticosteroid and/or cyclophosphamide, of multiple myeloma in a patient with a WHO performance status of 2 or less, who has progressive disease, who has received at least 1 prior therapy (other than thalidomide), who has undergone or is ineligible for a primary stem cell transplant and who has experienced treatment failure after a trial of at least four (4) weeks of thalidomide at a dose of at least 100 mg daily.

If the dosing requirement for thalidomide cannot be met, the application must state the reasons why this criterion cannot be satisfied.

Thalidomide treatment failure is defined as:
(1) confirmed disease progression during or within 6 months of discontinuing thalidomide treatment; or
(2) severe intolerance or toxicity unresponsive to clinically appropriate dose adjustment.

Progressive disease is defined as at least 1 of the following:
(a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or
(b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or
(c) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or
(d) an increase in the size or number of lytic bone lesions (not including compression fractures); or
(e) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or
(f) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Severe intolerance due to thalidomide is defined as unacceptable somnolence or sedation interfering with activities of daily living.

Toxicity from thalidomide is defined as peripheral neuropathy (Grade 2 or greater, interfering with function), drug-related seizures, serious Grade 3 or Grade 4 drug-related dermatological reactions, such as Stevens-Johnson Syndrome, or other Grade 3 or 4 toxicity.

The authority application must be made in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Multiple Myeloma Authority Application - Supporting Information Form,
which includes details of prior treatments including name(s) of drug(s) and date of most recent treatment cycle and record of prior stem cell transplant or ineligibility for prior stem cell transplant; the patient's WHO performance status; details of thalidomide treatment failure; details of the basis of the diagnosis of progressive disease; and nomination of which disease activity parameters will be used to assess response.

To enable confirmation by Medicare Australia of response, current diagnostic reports of the following are required:
(a) the level of serum monoclonal protein; and
(b) if Bence-Jones proteinuria is present, the results of 24-hour urinary light chain M protein excretion.

If neither serum M protein or urine Bence-Jones protein are present in measurable quantities, additional diagnostic reports are required, including:
(c) bone marrow aspirate and trephine; and
(d) if present, the size and location of lytic bone lesions (not including compression fractures); or
(e) if present, the size and location of all soft tissue plasmacytomas by clinical or radiographic examination i.e. MRI or CT-scan; or
(f) if present, the level of hypercalcaemia, corrected for albumin concentration; or
(g) if present, the serum free light chain levels.

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ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer

As these parameters will be used to determine response, results for (a) and (b) should be provided for all patients. Where the patient has oligo-secretory or non-secretory multiple myeloma, (c) must be provided and if relevant (d), (e) or (f). Where the prescriber plans to assess response in patients with oligo-secretory or non-secretory multiple myeloma with free light chain assays, (g) must be provided. Where 1 or more results cannot be provided, the application must state the reason(s) these cannot be provided; and
(3) duration of thalidomide and daily dose prescribed; and
(4) a signed patient acknowledgment.

Authority Required

Continuing PBS-subsidised treatment, as monotherapy or in combination with a corticosteroid and/or cyclophosphamide, of multiple myeloma in a patient who has previously received 4 treatment cycles of bortezomib and who, at the time of application, has demonstrated at least a partial response to bortezomib.

If serum M protein and urine Bence-Jones protein levels are measurable, partial response (PR) compared with baseline (prior to treatment with bortezomib) is defined as:
(a) at least a 50% reduction in the level of serum M protein (monoclonal protein); or
(b) at least a 90% reduction in 24-hour urinary light chain M protein excretion or to less than 200 mg per 24 hours.

If serum M protein and urine Bence-Jones protein levels are unmeasurable as in non-secretory/oligo-secretory multiple myeloma, partial response compared with baseline is defined as:
(c) at least a 50% reduction in the difference between involved and uninvolved serum free light chain (FLC) levels.

If serum M protein and urine Bence-Jones protein and serum FLC are unmeasurable/unavailable, partial response compared with baseline is defined as:
(d) at least a 50% reduction in bone marrow plasma cells; or
(e) normalisation of corrected serum calcium to less than or equal to 2.65 mmol per L; or
(f) no increase in size or number of lytic bone lesions (development of compression fracture does not exclude response); or
(g) at least a 50% reduction in the size of soft tissue plasmacytoma (by clinical or applicable radiographic examination, i.e. MRI or CT-Scan).

For the purpose of assessing eligibility for continuing PBS-subsidised bortezomib treatment beyond 4 cycles, the patient must have achieved at least a partial response at the completion of cycle 4. The results of the response assessment must be included in a written application to Medicare Australia for further treatment. Where a response assessment is not submitted to Medicare Australia prior to cycle 5, patients will be deemed to have failed to respond to treatment with bortezomib. Continuing PBS-subsidised supply will not be approved if there is a gap of more than 6 months between the initial application and subsequent applications.

The same parameters provided for the diagnosis of progressive disease are to be used to demonstrate at least a partial response to treatment.

The authority application must be made in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Multiple Myeloma Authority Application - Supporting Information Form; and
(3) diagnostic reports demonstrating the patient has achieved at least a partial response.

Diagnostic reports must be no more than 1 month old at the time of application.

Patients who fail to demonstrate at least a partial response after 8 cycles will not be eligible to receive further PBS-subsidised treatment with bortezomib.

No more than 2 cycles of treatment beyond the cycle at which a confirmed complete response was first achieved will be authorised. Confirmation requires 2 determinations a minimum of 6 weeks apart.

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ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
9117W	***Powder for injection 3.5 mg (solvent required)*** ***(code 7086Y applies to above item with approved solvent)***	*4*	*3*	*..*	** 7001.95*	*32.90*	*Velcade*	*JC*

Authority Required

Continuing PBS-subsidised treatment, as monotherapy or in combination with a corticosteroid and/or cyclophosphamide, of multiple myeloma in a patient who has previously received 8 treatment cycles with bortezomib and who, at the time of application, has demonstrated at least a partial response to bortezomib but who has not received 2 treatment cycles after first achieving a confirmed complete response.

If serum M protein and urine Bence-Jones protein levels are measurable, partial response (PR) compared with baseline (prior to treatment with bortezomib) is defined as:
(a) at least a 50% reduction in the level of serum M protein (monoclonal protein); or
(b) at least a 90% reduction in 24-hour urinary light chain M protein excretion or to less than 200 mg per 24 hours.

If serum M protein and urine Bence-Jones protein levels are unmeasurable as in non-secretory/oligo-secretory multiple myeloma, partial response compared with baseline is defined as:
(c) the difference between involved and uninvolved serum free light chain (FLC) levels, with at least a 50% reduction in this value.

If serum M protein and urine Bence-Jones protein levels and serum FLC are unmeasurable/unavailable, partial response compared with baseline is defined as:
(d) at least a 50% reduction in bone marrow plasma cells; or
(e) normalisation of corrected serum calcium to less than or equal to 2.65 mmol per L; or
(f) no increase in size or number of lytic bone lesions (development of compression fracture does not exclude response); or
(g) at least a 50% reduction in the size of soft tissue plasmacytoma (by clinical or applicable radiographic examination, i.e. MRI or CT-Scan).

The same parameters provided for the diagnosis of progressive disease are to be used to demonstrate at least a partial response to treatment.

Diagnostic reports must be within 1 month of the date of application.

For the purpose of assessing eligibility for continuing PBS-subsidised bortezomib treatment beyond 8 cycles, the patient must have achieved at least a partial response at the completion of cycle 8. The results of the response assessment must be included in a written application to Medicare Australia for further treatment. Where a response assessment is not submitted to Medicare Australia prior to cycle 9, patients will be deemed to have failed to respond to treatment with bortezomib. Continuing PBS-subsidised supply will not be approved if there is a gap of more than 10 months between the initial application and an application following completion of 8 treatment cycles.

The authority application must be made in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Multiple Myeloma Authority Application - Supporting Information Form; and
(3) diagnostic reports demonstrating the patient has achieved at least a partial response.

No more than 2 cycles of treatment beyond the cycle at which the complete response was first achieved will be authorised. Confirmation requires 2 determinations a minimum of 6 weeks apart.

Applications for PBS-subsidised treatment with bortezomib that extends beyond 11 cycles will not be approved.

continued ☞

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
	Authority Required ***Initial PBS-subsidised treatment of multiple myeloma in patients receiving treatment with bortezomib prior to 1 November 2007.*** ***Patients who fail to demonstrate at least a partial response after 4 cycles will not be eligible to receive further PBS-subsidised treatment with bortezomib.*** ***Diagnostic reports demonstrating at least a partial response must be within 1 month of the date of application.*** ***Patients may qualify for PBS-subsidised treatment under this restriction for a maximum of 3 cycles. To receive further treatment the patient must qualify under the continuing treatment criteria.*** ***The authority application must be made in writing and must include:*** ***(1) a completed authority prescription form; and*** ***(2) a completed Multiple Myeloma Authority Application - Supporting Information Form; and*** ***(3) a signed patient acknowledgment; and*** ***(4) details including relevant reports of the basis of the diagnosis of progressive disease and nomination of which disease activity parameters will be used to assess response; and*** ***(5) if relevant, details including relevant reports for patients who have demonstrated a partial response and who have received 4 or more cycles.***							
9118X	***Powder for injection 3.5 mg (solvent required)*** ***(code 7087B applies to above item with approved solvent)***	***4***	***2***	***..***	**** 7001.95***	***32.90***	***Velcade***	***JC***
	HYDROXYUREA							
3093T	Capsule 500 mg	100	..	..	76.03	32.90	Hydrea	BQ
	IRINOTECAN HYDROCHLORIDE TRIHYDRATE **Authority Required** ***Metastatic colorectal cancer in patients with a WHO performance status of 2 or less.*** **NOTE:** ***In first-line usage, effectiveness and tolerance may be improved when irinotecan is combined with an infusional 5-fluorouracil regimen.***							
8414W	***I.V. injection 40 mg in 2 mL***	***1***	***3***	***..***	***142.91***	***32.90***	***[a] Camptosar*** ***[a] Irinotecan Sandoz*** ***[a] HH***	***PU*** ***SZ***
8415X	***I.V. injection 100 mg in 5 mL***	***2***	***3***	***..***	**** 653.23***	***32.90***	***[a] Camptosar*** ***[a] Irinotecan Sandoz*** ***[a] HH***	***PU*** ***SZ***
9119Y	***I.V. injection 500 mg in 25 mL***	***1***	***3***	***..***	***1623.97***	***32.90***	***HH***	
	TOPOTECAN HYDROCHLORIDE **Authority Required** ***Advanced metastatic ovarian cancer after failure of prior therapy which includes a platinum compound.***							
8199M	***Powder for I.V. infusion 4 mg (base)***	***5***	***1***	***..***	***2125.93***	***32.90***	***Hycamtin***	***GK***

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
	ENDOCRINE THERAPY							
	Hormones and related agents							
	• ***Progestogens***							
	MEDROXYPROGESTERONE ACETATE							
	Restricted Benefit ***Hormone-dependent advanced breast cancer.***							
2728N	*Tablet 500 mg*	*30*	*2*	*..*	*132.91*	*32.90*	*Provera*	*PH*
	Restricted Benefit ***Hormone-dependent breast cancer;*** ***Endometrial cancer.***							
2725K	*Tablet 100 mg*	*100*	*2*	*..*	*95.20*	*32.90*	*Provera*	*PH*
2316X	*Tablet 200 mg*	*60*	*2*	*..*	*107.32*	*32.90*	*Provera*	*PH*
2727M	*Tablet 250 mg*	*60*	*2*	*..*	*132.67*	*32.90*	*Provera*	*PH*
	[For other listings for this drug see Generic/Proprietary Index]							
	MEGESTROL ACETATE							
	Restricted Benefit ***Hormone-dependent advanced breast cancer.***							
2734X	*Tablet 160 mg*	*30*	*2*	*..*	*72.52*	*32.90*	*Megace*	*BQ*
	• ***Gonadotropin releasing hormone analogues***							
	GOSERELIN ACETATE							
	Authority Required ***Locally advanced (equivalent to stage C) or metastatic (equivalent to stage D) carcinoma of the prostate;*** ***Hormone-dependent locally advanced (equivalent to stage III) or metastatic (equivalent to stage IV) breast cancer in pre-menopausal women;*** ***Short-term treatment (up to 6 months) of visually proven endometriosis (only 1 course of not more than 6 months' therapy will be authorised).***							
1454M	*Subcutaneous implant 3.6 mg (base) in pre-filled injection syringe*	*1*	*5*	*..*	*332.57*	*32.90*	*Zoladex Implant*	*AP*
	Authority Required ***Locally advanced (equivalent to stage C) or metastatic (equivalent to stage D) carcinoma of the prostate.***							
8093Y	*Subcutaneous implant (long acting) 10.8 mg (base) in pre-filled injection syringe*	*1*	*1*	*..*	*1108.33*	*32.90*	*Zoladex 10.8 Implant*	*AP*

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
	GOSERELIN ACETATE and BICALUTAMIDE							
	Authority Required ***Metastatic (equivalent to stage D) prostatic carcinoma in patients for whom a combination of an antiandrogen and a GnRH (LH-RH) agonist is required.***							
	NOTE: ***No applications for increased maximum quantities and/or repeats will be authorised.***							
9064C	***Pack containing 1 subcutaneous implant goserelin 3.6 mg in pre-filled injection syringe and 28 tablets bicalutamide 50 mg***	***‡ 1***	***5***	***..***	***505.61***	***32.90***	***ZolaCos CP 3.6/50***	***AP***
9065D	***Pack containing 1 subcutaneous implant goserelin 10.8 mg in pre-filled injection syringe and 28 tablets bicalutamide 50 mg***	***‡ 1***	***..***	***..***	***1274.52***	***32.90***	***ZolaCos CP 10.8/ 50(28)***	***AP***
9066E	***Pack containing 1 subcutaneous implant goserelin 10.8 mg in pre-filled injection syringe and 84 tablets bicalutamide 50 mg***	***‡ 1***	***1***	***..***	***1606.90***	***32.90***	***ZolaCos CP 10.8/ 50(84)***	***AP***
	LEUPRORELIN ACETATE							
	Authority Required ***Locally advanced (equivalent to stage C) or metastatic (equivalent to stage D) carcinoma of the prostate.***							
8875D	***I.M. injection (modified release), powder for injection 7.5 mg with diluent in pre-filled dual-chamber syringe***	***1***	***5***	***..***	***419.77***	***32.90***	***Lucrin Depot 7.5mg PDS***	***AB***
8707G	***Suspension for subcutaneous injection (modified release), 7.5 mg injection set***	***1***	***5***	***..***	***419.77***	***32.90***	***Eligard 1 month***	***HH***
8876E	***I.M. injection (modified release), powder for injection 22.5 mg with diluent in pre-filled dual-chamber syringe***	***1***	***1***	***..***	***1108.33***	***32.90***	***Lucrin Depot 3 Month PDS***	***AB***
8708H	***Suspension for subcutaneous injection (modified release), 22.5 mg injection set***	***1***	***1***	***..***	***1108.33***	***32.90***	***Eligard 3 month***	***HH***
8877F	***I.M. injection (modified release), powder for injection 30 mg with diluent in pre-filled dual-chamber syringe***	***1***	***1***	***..***	***1450.90***	***32.90***	***Lucrin Depot 4 Month PDS***	***AB***
8709J	***Suspension for subcutaneous injection (modified release), 30 mg injection set***	***1***	***1***	***..***	***1450.90***	***32.90***	***Eligard 4 month***	***HH***
8859G	***Suspension for subcutaneous injection (modified release), 45 mg injection set***	***1***	***..***	***..***	***2123.55***	***32.90***	***Eligard 6 month***	***HH***

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Proprietary Name and Manufacturer	
	TRIPTORELIN EMBONATE								
	Authority Required ***Locally advanced (equivalent to stage C) or metastatic (equivalent to stage D) carcinoma of the prostate.***								
9378N	***Powder for I.M. injection (prolonged release) 3.75 mg (base) with solvent, syringe and needles***	***1***	***5***	***..***	***419.77***	***32.90***		***Diphereline***	***IS***
9379P	***Powder for I.M. injection (prolonged release) 11.25 mg (base) with solvent, syringe and needles***	***1***	***1***	***..***	***1108.33***	***32.90***		***Diphereline***	***IS***

Hormone antagonists and related agents

• *Anti-estrogens*

TAMOXIFEN CITRATE

Restricted Benefit
Treatment of hormone-dependent breast cancer.

NOTE:
This drug is not PBS-subsidised for primary prevention of breast cancer.

2109B	***Tablet 10 mg (base)***	***60***	***5***	***..***	***38.45***	***32.90***	[a]	***Genox 10***	***AF***
							[a]	***Tamoxen 10 mg***	***GM***
2110C	***Tablet 20 mg (base)***	***60***	***5***	***..***	***59.81***	***32.90***	[a]	***Chem mart Tamoxifen***	***CH***
							[a]	***Genox 20***	***AF***
							[a]	***GenRx Tamoxifen***	***GX***
							[a]	***Tamosin***	***SI***
							[a]	***Tamoxen 20 mg***	***GM***
							[a]	***Tamoxifen Sandoz***	***SZ***
							[a]	***Terry White Chemists Tamoxifen***	***TW***
				B3.82	**** 63.65***	***32.90***	[a]	***Nolvadex-D***	***AP***

TOREMIFENE CITRATE

Restricted Benefit
Treatment of hormone-dependent metastatic breast cancer in post-menopausal patients.

NOTE:
This drug is not PBS-subsidised for primary prevention of breast cancer.

8216K	***Tablet 60 mg (base)***	***30***	***5***	***..***	***68.68***	***32.90***		***Fareston***	***SH***

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
	• *Anti-androgens*							
	BICALUTAMIDE							
	Authority Required							
	Metastatic (equivalent to stage D) prostatic carcinoma in combination with GnRH (LH-RH) agonist therapy.							
	NOTE:							
	No applications for increased maximum quantities and/or repeats will be authorised.							
8094B	*Tablet 50 mg*	*28*	*5*	*..*	*194.99*	*32.90*	[a] *APO-Bicalutamide*	*TX*
							[a] *Bicalutamide-GA*	*GM*
							[a] *Bicalutamide Ranbaxy*	*RA*
							[a] *Calutex*	*SI*
							[a] *Cosamide*	*AF*
							[a] *Cosudex*	*AP*
	CYPROTERONE ACETATE							
	Authority Required (STREAMLINED)							
	1014							
	Advanced carcinoma of the prostate;							
	1404							
	To reduce drive in sexual deviations in males.							
1270W	*Tablet 50 mg*	*100*	*5*	*..*	** 207.29*	*32.90*	[a] *Cyprohexal*	*SZ*
							[a] *Cyprone*	*AF*
							[a] *Cyprostat*	*SY*
							[a] *GenRx Cyproterone Acetate*	*GX*
							[a] *Procur*	*GM*
				[B]3.00	** 210.29*	*32.90*	[a] *Androcur*	*SC*
8019C	*Tablet 100 mg*	*50*	*5*	*..*	*169.33*	*32.90*	[a] *Cyprohexal*	*SZ*
							[a] *Cyprostat-100*	*SY*
							[a] *GenRx Cyproterone Acetate*	*GX*
							[a] *Procur 100*	*GM*
				[B]1.65	*170.98*	*32.90*	[a] *Androcur-100*	*SC*
	[For other listings for this drug see Generic/Proprietary Index]							
	FLUTAMIDE							
	Authority Required							
	Metastatic (equivalent to stage D) prostatic carcinoma in combination with GnRH (LH-RH) agonist therapy.							
	NOTE:							
	No applications for increased maximum quantities and/or repeats will be authorised.							
1417N	*Tablet 250 mg*	*100*	*5*	*..*	*212.60*	*32.90*	[a] *Eulexin*	*SH*
							[a] *Flutamin*	*AF*

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
	NILUTAMIDE							
	Authority Required ***Locally advanced (equivalent to stage C) or metastatic (equivalent to stage D) prostatic carcinoma, in combination with GnRH (LH-RH) agonist therapy;*** ***Locally advanced (equivalent to stage C) or metastatic (equivalent to stage D) prostatic carcinoma, in conjunction with surgical orchidectomy.***							
8131Y	***Tablet 150 mg***	***30***	***5***	***..***	***236.13***	***32.90***	***Anandron***	***SW***
	• *Enzyme inhibitors*							
	ANASTROZOLE							
	Restricted Benefit ***Treatment of hormone-dependent breast cancer in post-menopausal women.*** **NOTE:** ***This drug is not PBS-subsidised for primary prevention of breast cancer.*** ***This drug is not PBS-subsidised for adjuvant hormonal treatment of early breast cancer extended beyond 5 years.***							
8179L	***Tablet 1 mg***	***30***	***5***	***..***	***179.75***	***32.90***	***Arimidex***	***AP***
	EXEMESTANE							
	Restricted Benefit ***Treatment of hormone-dependent advanced breast cancer in post-menopausal women with disease progression following treatment with tamoxifen citrate;*** ***Treatment of hormone-dependent early breast cancer in post-menopausal women following a minimum of 2 years' treatment with tamoxifen citrate.*** **NOTE:** ***This drug is not PBS-subsidised for primary prevention of breast cancer.*** ***This drug is not PBS-subsidised for adjuvant hormonal treatment of early breast cancer extended beyond 5 years, i.e. a patient who has received 2 years of tamoxifen therapy may only receive 3 years of PBS-subsidised treatment with exemestane.***							
8506Q	***Tablet 25 mg***	***30***	***5***	***..***	***179.75***	***32.90***	***Aromasin***	***PH***
	LETROZOLE							
	Restricted Benefit ***Treatment of hormone-dependent advanced breast cancer in post-menopausal women;*** ***Treatment of hormone-dependent early breast cancer in post-menopausal women;*** ***Extended adjuvant treatment of hormone-dependent early breast cancer in post-menopausal women commencing within 6 months of ceasing treatment with tamoxifen citrate.*** **NOTE:** ***This drug is not PBS-subsidised for primary prevention of breast cancer.*** ***This drug is not PBS-subsidised for adjuvant hormonal treatment of early breast cancer extended beyond 5 years.*** ***This drug is not PBS-subsidised for extended adjuvant early breast cancer treatment where the total duration of letrozole (or any other aromatase inhibitor) treatment extends beyond 5 years.***							
8245Y	***Tablet 2.5 mg***	***30***	***5***	***..***	***179.75***	***32.90***	***Femara 2.5 mg***	***NV***

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
	IMMUNOSTIMULANTS							
	Immunostimulants							
	• ***Interferons***							
	INTERFERON ALFA-2a							
	CAUTION:							
	Treatment with interferon alfa has been associated with depression and suicide in some patients. Patients with a history of suicidal ideation or depressive illness should be warned of the risks. Psychiatric status during therapy should be monitored.							
	Authority Required							
	Hairy cell leukaemia;							
	Myeloproliferative disease with excessive thrombocytosis.							
8180M	***Injection 3,000,000 i.u. in 0.5 mL single dose pre-filled syringe***	*15*	*4*	*..*	* *505.79*	*32.90*	***Roferon-A***	***RO***
	Authority Required							
	Myeloproliferative disease with excessive thrombocytosis.							
8551C	***Injection 4,500,000 i.u. in 0.5 mL single dose pre-filled syringe***	*5*	*4*	*..*	* *264.29*	*32.90*	***Roferon-A***	***RO***
8552D	***Injection 6,000,000 i.u. in 0.5 mL single dose pre-filled syringe***	*5*	*4*	*..*	* *344.29*	*32.90*	***Roferon-A***	***RO***
8553E	***Injection 9,000,000 i.u. in 0.5 mL single dose pre-filled syringe***	*5*	*4*	*..*	* *505.69*	*32.90*	***Roferon-A***	***RO***
	Authority Required							
	Low grade non-Hodgkin's lymphoma with clinical features suggestive of a poor prognosis, in combination with anthracycline-based chemotherapy.							
8181N	***Injection 3,000,000 i.u. in 0.5 mL single dose pre-filled syringe***	*15*	*5*	*..*	* *505.79*	*32.90*	***Roferon-A***	***RO***
8182P	***Injection 4,500,000 i.u. in 0.5 mL single dose pre-filled syringe***	*5*	*5*	*..*	* *264.29*	*32.90*	***Roferon-A***	***RO***
8183Q	***Injection 6,000,000 i.u. in 0.5 mL single dose pre-filled syringe***	*5*	*5*	*..*	* *344.29*	*32.90*	***Roferon-A***	***RO***
8184R	***Injection 9,000,000 i.u. in 0.5 mL single dose pre-filled syringe***	*5*	*5*	*..*	* *505.69*	*32.90*	***Roferon-A***	***RO***

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
	INTERFERON ALFA-2b							
	CAUTION:							
	Treatment with interferon alfa has been associated with depression and suicide in some patients. Patients with a history of suicidal ideation or depressive illness should be warned of the risks. Psychiatric status during therapy should be monitored.							
	Authority Required							
	Hairy cell leukaemia.							
8572E	***Solution for injection 18,000,000 i.u. in 1.2 mL multi-dose injection pen***	***3***	***4***	***..***	**** 605.60***	***32.90***	***Intron A Redipen***	***SH***
	Authority Required							
	Maintenance treatment of multiple myeloma once remission has been achieved with chemotherapy;							
	Low grade non-Hodgkin's lymphoma with clinical features suggestive of a poor prognosis, in combination with anthracycline-based chemotherapy.							
8348J	***Solution for injection 18,000,000 i.u. in 1.2 mL multi-dose injection pen***	***3***	***5***	***..***	**** 605.60***	***32.90***	***Intron A Redipen***	***SH***
8476D	***Solution for injection 30,000,000 i.u. in 1.2 mL multi-dose injection pen***	***3***	***5***	***..***	**** 1005.32***	***32.90***	***Intron A Redipen***	***SH***
	INTERFERON BETA-1a							
	Authority Required							
	Initial treatment of clinically definite relapsing-remitting multiple sclerosis in ambulatory (without assistance or support) patients who have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to the multiple sclerosis, in the preceding 2 years. The diagnosis must be confirmed by magnetic resonance imaging of the brain and/or spinal cord and the date of the scan included in the authority application, unless the authority application is accompanied by written certification provided by a radiologist that an MRI scan is contraindicated because of the risk of physical (not psychological) injury to the patient. The authority will be limited to the maximum quantity and number of repeats indicated in the schedule;							
	Continuing treatment of clinically definite relapsing-remitting multiple sclerosis in patients previously issued with an authority prescription for this drug who do not show continuing progression of disability while on treatment with this drug and who have demonstrated compliance with, and an ability to tolerate, this therapy. Authorities will be limited to the maximum quantity and number of repeats indicated in the schedule.							
8289G	***Injection set comprising 1 vial powder for injection 30 micrograms (6,000,000 i.u.) with diluent***	***4***	***5***	***..***	***1056.34***	***32.90***	***Avonex***	***BD***
8805K	***Injection 30 micrograms (6,000,000 i.u.) in 0.5 mL single dose pre-filled syringe***	***4***	***5***	***..***	***1056.34***	***32.90***	***Avonex***	***BD***
8403G	***Injection 44 micrograms (12,000,000 i.u.) in 0.5 mL single dose pre-filled syringe***	***12***	***5***	***..***	***1056.34***	***32.90***	***Rebif 44***	***SG***

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
	INTERFERON BETA-1b							
	Authority Required ***Initial treatment of clinically definite relapsing-remitting multiple sclerosis in ambulatory (without assistance or support) patients who have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to the multiple sclerosis, in the preceding 2 years. The diagnosis must be confirmed by magnetic resonance imaging of the brain and/or spinal cord and the date of the scan included in the authority application, unless the authority application is accompanied by written certification provided by a radiologist that an MRI scan is contraindicated because of the risk of physical (not psychological) injury to the patient. The authority will be limited to the maximum quantity and number of repeats indicated in the schedule;*** ***Continuing treatment of clinically definite relapsing-remitting multiple sclerosis in patients previously issued with an authority prescription for this drug who do not show continuing progression of disability while on treatment with this drug and who have demonstrated compliance with, and an ability to tolerate, this therapy. Authorities will be limited to the maximum quantity and number of repeats indicated in the schedule.***							
8101J	***Injection set comprising 1 vial powder for injection 8,000,000 i.u. (250 micrograms) and solvent***	***15***	***5***	***..***	***1179.73***	***32.90***	***Betaferon***	***SC***
	• Other immunostimulants							
	BCG IMMUNOTHERAPEUTIC (Bacillus Calmette-Guérin/ Connaught strain)							
	Restricted Benefit ***Treatment of carcinoma in situ of the urinary bladder.***							
1140B	***Single dose set comprising 1 vial powder for intravesical administration containing 6.6 to 19.2 x 10^8 CFU and 1 vial diluent 3 mL***	***3***	***1***	***..***	**** 459.44***	***32.90***	***ImmuCyst***	***SW***
	BCG-TICE (Bacillus Calmette-Guérin/ Tice strain)							
	Restricted Benefit ***Primary and relapsing superficial urothelial carcinoma of the bladder.***							
1131M	***Vial containing powder for intravesical administration approximately 5 x 10^8 CFU***	***3***	***1***	***..***	***555.96***	***32.90***	***OncoTICE***	***SH***

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
	GLATIRAMER ACETATE							
	Authority Required ***Initial treatment of clinically definite relapsing-remitting multiple sclerosis in ambulatory (without assistance or support) patients who have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to the multiple sclerosis, in the preceding 2 years. The diagnosis must be confirmed by magnetic resonance imaging of the brain and/or spinal cord and the date of the scan included in the authority application, unless the authority application is accompanied by written certification provided by a radiologist that an MRI scan is contraindicated because of the risk of physical (not psychological) injury to the patient. The authority will be limited to the maximum quantity and number of repeats indicated in the schedule;*** ***Continuing treatment of clinically definite relapsing-remitting multiple sclerosis in patients previously issued with an authority prescription for this drug who do not show continuing progression of disability while on treatment with this drug and who have demonstrated compliance with, and an ability to tolerate, this therapy. Authorities will be limited to the maximum quantity and number of repeats indicated in the schedule.***							
8726G	***Injection 20 mg in 1 mL single dose pre-filled syringe***	***28***	***5***	***..***	***1092.22***	***32.90***	***Copaxone***	***SW***

IMMUNOSUPPRESSANTS

Immunosuppressants

- ***Selective immunosuppressants***

EFALIZUMAB

NOTE:

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

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Applications for authority to prescribe efalizumab should be forwarded to:

Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

NOTE:

TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents efalizumab, etanercept and infliximab, for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological agents' appears in the following NOTES and restrictions, it only refers to efalizumab, etanercept and infliximab.

From 1 December 2007, all patients will be able to commence a 'Biological Treatment Cycle' (Cycle), where they may trial efalizumab, etanercept or infliximab without having to meet the initial treatment criteria, that is they will not need to experience a disease flare when swapping to an alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

A patient who received PBS-subsidised biological agent treatment for chronic plaque psoriasis prior to 1 December 2007 is considered to be in their first Cycle as of 1 December 2007.

Patients are eligible for PBS-subsidised treatment with only 1 biological agent at any 1 time.

continued ☞

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer

Within the same Treatment Cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for a PBS-subsidised biological agent, they must change to an alternate agent if they wish to continue PBS-subsidised biological treatment. A patient who, prior to 1 December 2007, was authorised to receive PBS-subsidised initial treatment for chronic plaque psoriasis with the same agent twice, is exempt from this condition in respect of applications approved prior to 1 December 2007.

Initial treatment with efalizumab consists of 16 weeks of therapy, with infliximab consists of 22 weeks of therapy, and with etanercept consists of 12 weeks of active therapy followed by a biological treatment-free period of at least 12 weeks. Response to treatment for all 3 agents must be assessed after 12 weeks of treatment.

Following demonstration of response to initial treatment, these biological agents are available as continuing therapy. Ongoing access to continuing treatment is available for as long as the response to therapy is sustained. In the case of efalizumab and infliximab, continuing treatment consists of 24 weeks of continuous active treatment. In the case of etanercept, continuing treatment consists of 12 weeks of active therapy followed by a biological treatment-free period of at least 12 weeks.

Patients must be assessed for response to each course of continuing treatment according to the criteria included in the relevant continuing treatment restriction.

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

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

Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle.

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

How to prescribe biological agents for the treatment of severe chronic plaque psoriasis after 1 December 2007.

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Application for approval for initial treatment.

Applications for a course of initial treatment should be made in the following situations:
(i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); and
(ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under '(4) Swapping therapy' below]; and
(iii) patients who wish to re-commence treatment following a break in PBS-subsidised therapy with that agent (Initial 2).

All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 16 weeks of therapy in the case of efalizumab, 12 weeks of therapy in the case of etanercept, and 22 weeks of treatment in the case of infliximab. Approval will be based on the criteria included in the relevant initial treatment restriction.

Grandfather patients (Infliximab only).

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ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer

Applications for patients who commenced treatment with infliximab prior to 7 March 2007, may apply for initial PBS-subsidised treatment as continuing therapy under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with a biological agent prior to PBS listing of that agent.

Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment. Approval will be based on the criteria included in the relevant restriction.

(2) Assessment of response to initial treatment.

When prescribing efalizumab or infliximab, where the initial treatment course is for 16 or 22 weeks respectively, a PASI assessment must be conducted after at least 12 weeks of treatment. This assessment must be submitted to Medicare Australia within 1 month of the completion of this initial treatment course. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with efalizumab or infliximab. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

Applications for continuing treatment with efalizumab or infliximab must also be submitted to Medicare Australia prior to the completion of this initial course of therapy to ensure continuity of treatment for those patients who meet the continuation criterion and wish to continue on treatment with either efalizumab or infliximab.

When prescribing etanercept, a PASI assessment must be conducted at the completion of the 12 week initial treatment course. This assessment, which will be used to determine eligibility for future treatment according to the criterion included in the relevant continuing treatment restriction, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with etanercept. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

(3) Application for continuing treatment.

As stated above, following the completion of an initial treatment course of efalizumab or infliximab to which an adequate response has been demonstrated, patients may qualify to receive up to 24 weeks of continuing treatment with efalizumab or infliximab. Patients are eligible to continue to receive continuous treatment with efalizumab or infliximab in 24 week courses providing they continue to sustain a response.

For second and subsequent courses of PBS-subsidised treatment with efalizumab or infliximab it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

At the completion of an initial 12 week treatment course of etanercept to which an adequate response has been demonstrated, followed by a biological treatment-free period of at least 12 weeks, patients may qualify to receive continuing treatment with etanercept. Continuing treatment is available in the form of 12 weeks of active etanercept treatment followed by a biological treatment-free period of at least 12 weeks. Patients are eligible to receive continuing treatment with etanercept on this cyclical basis, for as long as they continue to sustain a response. Continuing applications must be submitted at least 12 weeks after cessation of the most recent course of etanercept treatment.

A PASI assessment must be conducted for each course of continuing treatment for each biological agent, according to the requirements set out in the relevant restriction. Assessment of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia no later than 1 month from the date that course was completed or treatment was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to sustain a response to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

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ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer

NOTE:

(4) Swapping therapy.

Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate agent within the same Treatment Cycle without having to requalify with respect to disease severity (i.e. a PASI score of greater than 15), or prior treatment requirements.

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

Patients may trial an alternate biological agent at any time, regardless of whether they are receiving therapy with a biological agent at the time of the application or not. However, they cannot swap to a particular agent if they have failed to respond to treatment with that particular agent in the same Cycle.

Patients who commenced treatment with infliximab prior to 7 March 2007 access these interchangeability arrangements in the same way as patients who have not.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required 12 week biological treatment-free period applying to patients who have demonstrated a response to their most recent course of etanercept. This means that patients who have demonstrated a response to a 12 week course of etanercept must have a PBS-subsidised biological therapy treatment-free period of at least 12 weeks, immediately following this course of treatment, before swapping to efalizumab or infliximab. Patients who fail to respond to etanercept and who qualify and wish to try a course of efalizumab or infliximab, may do so without having to have any treatment-free period.

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

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

(5) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated, based on the baseline PASI assessment submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment authority is submitted within a Treatment Cycle and subsequent response will be assessed according to this revised PASI score.

For new patients and patients commencing a new Cycle, the first baseline PASI assessment must be conducted, preferably while the patient is still receiving their most recent prior therapy, but no later than 1 month following cessation of such therapy, as outlined in the relevant restriction. This is not required for any subsequent PASI scores provided for these patients within the same Cycle, nor for patients who received initial PBS-subsidised therapy under a 'grandfather' restriction.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatment applications.

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

Patients who wish to trial a second or subsequent Biological Treatment Cycle, following a break in PBS-subsidised biological therapy of at least 5 years, must requalify for initial treatment according to the criteria of the relevant restriction and index of disease severity. Patients must have had at least 1 prior treatment, as listed in the criteria, for a minimum of 6 weeks, and must have a PASI assessment conducted preferably whilst still on treatment, but no later than 1 month following cessation of treatment. The PASI assessment must be no older than 1 month at the time of application.

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ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer

Authority Required

Initial treatment [Initial 1, Whole body (New patients — No prior biological agent)]
Initial treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over who:
(a) have severe chronic plaque psoriasis where lesions have been present for at least 6 months from the time of initial diagnosis; and
(b) have not received any prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle; and
(c) have signed a patient acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment (whole body); and
(d) have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 3 of the following 4 treatments:
(i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; and/or
(ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; and/or
(iii) cyclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; and/or
(iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks.

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity to necessitate permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of acceptable toxicities including severity, associated with phototherapy, methotrexate, cyclosporin and acitretin, can be found on the Medicare Australia website (www.medicareaustralia.gov.au).

The following initiation criterion indicates failure to achieve an adequate response and must be demonstrated in all patients at the time of the application:
(a) A current Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.
(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 1 month following cessation of each course of treatment.
(c) The most recent PASI assessment must be no more than 1 month old at the time of application.

Applications for authorisation must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and
(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy]; and
(iii) the signed patient acknowledgement.

A maximum of 16 weeks of treatment with efalizumab will be authorised under this restriction.

Where fewer than 3 repeats are requested at the time of the authority application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period beyond 16 weeks.

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ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer

A PASI assessment of the patient's response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with efalizumab. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

It is recommended that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised efalizumab treatment.

Authority Required

Initial or re-Treatment [Initial 2, Whole body (Received prior biological agent under PBS)]
Treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over who:
(a) have a documented history of severe chronic plaque psoriasis; and
(b) have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle; and
(c) have not failed PBS-subsidised therapy with efalizumab for the treatment of this condition in the current Treatment Cycle.

Applications for authorisation must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and
(ii) details of prior biological treatment, including dosage, date and duration of treatment.

Applications for patients who have demonstrated a response to PBS-subsidised efalizumab treatment within this Treatment Cycle and who wish to re-commence efalizumab treatment within the same Cycle following a break in therapy, will only be approved where evidence of the patient's response to their most recent course of PBS-subsidised efalizumab treatment has been submitted to Medicare Australia within 1 month of cessation of treatment.

A maximum of 16 weeks of treatment with efalizumab will be authorised under this restriction.

Where fewer than 3 repeats are requested at the time of the authority application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period beyond 16 weeks.

A PASI assessment of the patient's response to this course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with efalizumab. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

It is recommended that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised efalizumab treatment.

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ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer

Patients who fail to demonstrate a response to treatment with each of the biological agents, efalizumab, etanercept and infliximab, are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may re-commence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

Authority Required

Initial treatment [Initial 1, Face, hand, foot (New patients — No prior biological agent)]
Initial treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over who:
(a) have severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis; and
(b) have not received any prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle; and
(c) have signed a patient acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment (face, hand, foot); and
(d) have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 3 of the following 4 treatments:
(i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; and/or
(ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; and/or
(iii) cyclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; and/or
(iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks.

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity to necessitate permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of acceptable toxicities including severity, associated with phototherapy, methotrexate, cyclosporin and acitretin, can be found on the Medicare Australia website (www.medicareaustralia.gov.au).

The following initiation criterion indicates failure to achieve an adequate response and must be demonstrated in all patients at the time of the application:
(a) Chronic plaque psoriasis classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where:
(i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment; or
(ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.
(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 1 month following cessation of each course of treatment.
(c) The most recent PASI assessment must be no more than 1 month old at the time of application.

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ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer

Applications for authorisation must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and
(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy]; and
(iii) the signed patient acknowledgement.

A maximum of 16 weeks of treatment with efalizumab will be authorised under this restriction.

Where fewer than 3 repeats are requested at the time of the authority application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period beyond 16 weeks.

A PASI assessment of the patient's response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with efalizumab. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

It is recommended that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised efalizumab treatment.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

Authority Required

Initial or re-Treatment [Initial 2, Face, hand, foot (Received prior biological agent under PBS)]
Treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over who:
(a) have a documented history of severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot; and

(b) have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle; and
(c) have not failed PBS-subsidised therapy with efalizumab for the treatment of this condition in the current Treatment Cycle.

Applications for authorisation must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and
(ii) details of prior biological treatment, including dosage, date and duration of treatment.

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Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
	Applications for patients who have demonstrated a response to PBS-subsidised efalizumab treatment within this Treatment Cycle and who wish to re-commence efalizumab treatment within the same Cycle following a break in therapy, will only be approved where evidence of the patient's response to their most recent course of PBS-subsidised efalizumab treatment has been submitted to Medicare Australia within 1 month of cessation of treatment.							
	A maximum of 16 weeks of treatment with efalizumab will be authorised under this restriction.							
	Where fewer than 3 repeats are requested at the time of the authority application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period beyond 16 weeks.							
	A PASI assessment of the patient's response to this course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with efalizumab. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.							
	It is recommended that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised efalizumab treatment.							
	The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.							
	Patients who fail to demonstrate a response to treatment with each of the biological agents, efalizumab, etanercept and infliximab, are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may re-commence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.							
9000Q	***Injection set containing 4 vials powder for injection 125 mg and 4 pre-filled syringes diluent 1.3 mL***	***1***	***3***	***..***	***1029.14***	***32.90***	***Raptiva***	***SG***
	NOTE: ***No applications for increased repeats will be authorised.***							
	Authority Required ***Continuing treatment (Whole body)*** ***Continuing PBS-subsidised treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over:*** ***(a) who have a documented history of severe chronic plaque psoriasis; and*** ***(b) whose most recent course of PBS-subsidised biological treatment for this condition in this Treatment Cycle was with efalizumab; and*** ***(c) who have demonstrated an adequate response to their most recent course of treatment with efalizumab.***							
	An adequate response to treatment is defined as: ***A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the pre-biological treatment baseline value for this Treatment Cycle.***							

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Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer

This assessment must be provided to Medicare Australia no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with efalizumab, the assessment of response must be after a minimum of 12 weeks of treatment with an initial course.

Applications for authorisation must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
(i) the completed Psoriasis Area and Severity Index (PASI) calculation sheet along with the date of the assessment of the patient's condition.

Approval will be based on the PASI assessment of response to the most recent course of treatment with efalizumab.

A maximum of 24 weeks of treatment with efalizumab will be authorised under this restriction.

Where fewer than 5 repeats are requested at the time of the authority application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for continuing authority applications, or for treatment that would otherwise extend the treatment period beyond 24 weeks.

A PASI assessment of the patient's response must be conducted within 4 weeks prior to completion of this course of treatment. This assessment, which will be used to determine eligibility for further continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with efalizumab. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

It is recommended that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised efalizumab treatment.

Patients who fail to demonstrate a response to treatment with each of the biological agents, efalizumab, etanercept and infliximab, are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may re-commence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

Authority Required

Continuing treatment (Face, hand, foot)
Continuing PBS-subsidised treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over:
(a) who have a documented history of severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot; and
(b) whose most recent course of PBS-subsidised biological treatment for this condition in this Treatment Cycle was with efalizumab; and
(c) who have demonstrated an adequate response to treatment with efalizumab.

An adequate response to efalizumab treatment is defined as the plaque or plaques assessed prior to biological treatment showing:
(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the pre-biological treatment baseline values; or
(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the pre-biological treatment baseline value.

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ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	

This assessment must be provided to Medicare Australia no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with efalizumab, the assessment of response must be after a minimum of 12 weeks of treatment with an initial course.

Applications for authorisation must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
(i) the completed Psoriasis Area and Severity Index (PASI) calculation sheet and face, hand, foot area diagrams along with the date of the assessment of the patient's condition [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].

A maximum of 24 weeks of treatment with efalizumab will be authorised under this restriction.

Where fewer than 5 repeats are requested at the time of the authority application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for continuing authority applications, or for treatment that would otherwise extend the treatment period beyond 24 weeks.

A PASI assessment of the patient's response must be conducted within 4 weeks prior to completion of this course of treatment. This assessment, which will be used to determine eligibility for further continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with efalizumab. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

It is recommended that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised efalizumab treatment.

The PASI assessment for continuing treatment must be performed on the same affected area assessed at baseline.

Patients who fail to demonstrate a response to treatment with each of the biological agents, efalizumab, etanercept and infliximab, are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may re-commence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

9001R	***Injection set containing 4 vials powder for injection 125 mg and 4 pre-filled syringes diluent 1.3 mL***	***1***	***5***	***..***	***1029.14***	***32.90***	***Raptiva***	***SG***

NOTE:
No applications for increased repeats will be authorised.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
	EVEROLIMUS							
	CAUTION:							
	Careful monitoring of patients is mandatory.							
	Authority Required							
	Maintenance therapy, following initiation and stabilisation of treatment with everolimus and where therapy remains under the supervision and direction of the transplant unit reviewing that patient, of patients with:							
	(a) renal transplants. The name of the specialised transplant unit reviewing treatment and the date of the latest review at the specialised transplant unit must be included in the authority application; or							
	(b) cardiac transplants. The name of the specialised transplant unit reviewing treatment and the date of the latest review at the specialised transplant unit must be included in the authority application.							
8840G	***Tablet 0.25 mg***	***60***	***3***	***..***	***282.36***	***32.90***	***Certican***	***NV***
8841H	***Tablet 0.5 mg***	***60***	***3***	***..***	***543.40***	***32.90***	***Certican***	***NV***
8842J	***Tablet 0.75 mg***	***120***	***3***	***..***	**** 1578.19***	***32.90***	***Certican***	***NV***
	LEFLUNOMIDE							
	CAUTION:							
	Leflunomide is a category X drug and must not be given to pregnant women. Pregnancy should be avoided for two years after cessation of therapy, unless special wash-out procedures are carried out.							
	Authority Required (STREAMLINED)							
	2643							
	Initial treatment of severe active rheumatoid arthritis where other disease modifying anti-rheumatic drugs (including methotrexate) are ineffective and/or inappropriate. Treatment must be initiated by a physician;							
	2681							
	Initial treatment of severe active psoriatic arthritis where other disease modifying anti-rheumatic drugs (including methotrexate) are ineffective and/or inappropriate. Treatment must be initiated by a physician.							
	NOTE:							
	No applications for increased maximum quantities and/or repeats will be authorised.							
8373Q	***Pack containing 3 tablets leflunomide 100 mg and 30 tablets leflunomide 20 mg***	***‡ 1***	***..***	***..***	***218.58***	***32.90***	***Arava***	***SW***
	Authority Required (STREAMLINED)							
	2644							
	Treatment of severe active rheumatoid arthritis where other disease modifying anti-rheumatic drugs (including methotrexate) are ineffective and/or inappropriate. Treatment must be initiated by a physician;							
	2682							
	Treatment of severe active psoriatic arthritis where other disease modifying anti-rheumatic drugs (including methotrexate) are ineffective and/or inappropriate. Treatment must be initiated by a physician.							
8374R	***Tablet 10 mg***	***30***	***5***	***..***	***95.01***	***32.90***	***[a] Arabloc***	***AV***
							[a] Arava	***SW***
8375T	***Tablet 20 mg***	***30***	***5***	***..***	***141.53***	***32.90***	***[a] Arabloc***	***AV***
							[a] Arava	***SW***

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
	MYCOPHENOLATE MOFETIL							
	CAUTION:							
	Careful monitoring of patients is mandatory.							
	Authority Required							
	Maintenance therapy, following initiation and stabilisation of treatment with mycophenolate mofetil and where therapy remains under the supervision and direction of the transplant unit reviewing that patient, of patients with:							
	(a) renal transplants. The name of the specialised transplant unit reviewing treatment and the date of the latest review at the specialised transplant unit must be included in the authority application; or							
	(b) cardiac transplants. The name of the specialised transplant unit reviewing treatment and the date of the latest review at the specialised transplant unit must be included in the authority application.							
8649F	***Capsule 250 mg***	***300***	***3***	***..***	***627.38***	***32.90***	***CellCept***	***RO***
8650G	***Tablet 500 mg***	***150***	***3***	***..***	***627.38***	***32.90***	***CellCept***	***RO***
8651H	***Powder for oral suspension 1 g per 5 mL, 165 mL***	***‡ 1***	***3***	***..***	***# 289.42***	***32.90***	***CellCept***	***RO***
	MYCOPHENOLATE SODIUM							
	CAUTION:							
	Careful monitoring of patients is mandatory.							
	Authority Required							
	Maintenance therapy, following initiation and stabilisation of treatment with mycophenolate sodium and where therapy remains under the supervision and direction of the transplant unit reviewing that patient, of patients with renal transplants. The name of the specialised transplant unit reviewing treatment and the date of the latest review at the specialised transplant unit must be included in the authority application.							
8652J	***Tablet (enteric coated) 180 mg (mycophenolic acid)***	***120***	***3***	***..***	***262.99***	***32.90***	***Myfortic***	***NV***
8653K	***Tablet (enteric coated) 360 mg (mycophenolic acid)***	***120***	***3***	***..***	***503.10***	***32.90***	***Myfortic***	***NV***
	SIROLIMUS							
	CAUTION:							
	Careful monitoring of patients is mandatory.							
	Authority Required							
	Maintenance therapy, following initiation and stabilisation of treatment with sirolimus and where therapy remains under the supervision and direction of the transplant unit reviewing that patient, of patients with renal transplants. The name of the specialised transplant unit reviewing treatment and the date of the latest review at the specialised transplant unit must be included in the authority application.							
8724E	***Tablet 1 mg***	***100***	***3***	***..***	***814.82***	***32.90***	***Rapamune***	***WX***
8833X	***Tablet 2 mg***	***100***	***3***	***..***	***1583.26***	***32.90***	***Rapamune***	***WX***
8725F	***Oral solution 1 mg per mL, 60 mL***	***‡ 1***	***3***	***..***	***529.31***	***32.90***	***Rapamune***	***WX***

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer

• *Tumor necrosis factor alpha (TNF-alpha) inhibitors*

ADALIMUMAB

NOTE:

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

Written applications for authority to prescribe adalimumab should be forwarded to:

Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

Further prescribing information is on the Medicare Australia website at www.medicareaustralia.gov.au.

NOTE:

TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying anti-rheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, etanercept, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-1 inhibitor (anakinra) and the T-cell co-stimulation modulator (abatacept).

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

PBS-subsidised infliximab, anakinra, rituximab and abatacept must be used in combination with methotrexate at a dose of at least 7.5 mg weekly. Where a patient cannot tolerate 7.5 mg of methotrexate weekly, they are only eligible to receive PBS-subsidised etanercept and adalimumab.

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

From 1 March 2008, under the PBS, all patients will be able to commence a Treatment Cycle where they may trial PBS-subsidised bDMARD agents without having to experience a disease flare when swapping to an alternate agent. Under these interchangeability arrangements, within a single Treatment Cycle, a patient may continue to receive long-term treatment with a bDMARD while they continue to show a response to therapy.

A patient who received PBS-subsidised bDMARD treatment prior to 1 March 2008 is considered to be in their first Cycle as of 1 March 2008.

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

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a Treatment Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised bDMARD therapy before they are eligible to commence the next Cycle.

For patients who have failed PBS-subsidised treatment with 3 bDMARDs prior to 1 March 2008 please contact Medicare Australia on 1800 700 270.

The 5-year break is measured from the date of the last approval for PBS-subsidised bDMARD treatment in the most recent Cycle to the date of the first application for initial treatment with a bDMARD under the new Treatment Cycle.

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

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

continued ☞

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer

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

If patients fail to respond to a particular bDMARD within a single Treatment Cycle, they are not eligible to receive further PBS-subsidised treatment with that drug until they commence the next Cycle.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 March 2008.

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

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for etanercept, adalimumab, anakinra and abatacept, 22 weeks of therapy for infliximab and 2 infusions of rituximab.

From 1 March 2008, a patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to Medicare Australia within 4 weeks.

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

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

Rituximab patients:
A further application may be submitted to Medicare Australia 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

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

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

Assessments of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Rituximab patients:
A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.

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

(2) Swapping therapy.

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ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer

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

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

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

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

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

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

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

NOTE:

(3) Baseline measurements to determine response.

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

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

The baseline joint and blood counts should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment.

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

A patient who wishes to trial a second or subsequent Treatment Cycle following a break in PBS-subsidised bDMARD therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have received treatment with at least 1 non-biological DMARD, at an adequate dose, for a minimum of 3 months at the time the ESR and/or CRP levels and the active joint count are measured.

(5) Patients 'grandfathered' onto PBS-subsidised treatment with rituximab or abatacept.

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ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer

From 1 March 2008, a patient who commenced treatment with rituximab for severe rheumatoid arthritis prior to 7 March 2007 or abatacept for severe rheumatoid arthritis prior to 1 November 2007 and who was 'grandfathered' on to PBS-subsidised therapy, and who continues to receive treatment in the same Treatment Cycle, will have further applications for treatment with rituximab or abatacept assessed under the continuing treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment with abatacept will be authorised under this criterion.

'Grandfather' arrangements will only apply for the first Treatment Cycle. For the second and subsequent Cycles, a 'grandfather' patient must requalify for initial treatment under the criteria that applies to a new patient. See 'Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' above for further details.

Authority Required

Initial 1 (new patients)
Application for initial PBS-subsidised treatment with adalimumab, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of adults who:
(a) have severe active rheumatoid arthritis; and
(b) have received no prior PBS-subsidised treatment with a bDMARD for this condition in this treatment cycle; and
(c) have failed to achieve an adequate response to the following treatments:
(i) methotrexate at a dose of at least 20 mg weekly; and
(ii) methotrexate (at a minimum dose of 7.5 mg weekly), in combination with 2 other non-biological disease modifying anti-rheumatic drugs (DMARDs), for a minimum of 3 months; and
(iii) a minimum of 3 months' treatment with:
— leflunomide alone; or
— leflunomide in combination with methotrexate; or
— cyclosporin.

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of the accepted toxicities, including severity, can be found on the Medicare Australia website [www.medicareaustralia.gov.au].

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

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.

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

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ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer

The authority application must be made in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes details of the patient's ESR and CRP measurements and the patient's active joint count which must have been assessed no earlier than 1 month prior to the date of application; and
(3) a signed patient acknowledgement.

A maximum of 16 weeks of treatment will be authorised under this restriction.

Where fewer than 3 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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

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

Authority Required

Initial 2 (change or re-commencement)
Application for an initial course of PBS-subsidised treatment with adalimumab, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of adults who:
(a) have a documented history of severe active rheumatoid arthritis; and
(b) have received prior PBS-subsidised bDMARD treatment for this condition in this treatment cycle and are eligible to receive further bDMARD therapy.

The authority application must be made in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].

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

A maximum of 16 weeks of treatment will be authorised under this restriction.

Where fewer than 3 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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

continued ☞

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	

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

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

8737W	*Injection 40 mg in 0.8 mL pre-filled syringe*	*2*	*3*	*..*	*1773.93*	*32.90*	*Humira*	*AB*
9099X	*Injection 40 mg in 0.8 mL pre-filled pen*	*2*	*3*	*..*	*1773.93*	*32.90*	*Humira*	*AB*

NOTE:
No applications for increased maximum quantities and/or repeats will be authorised.
Applications for treatment with adalimumab where the dosing frequency exceeds 40 mg per fortnight will not be approved.

Authority Required

Continuing treatment
Continuing PBS-subsidised treatment with adalimumab, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of adults:
(a) who have a documented history of severe active rheumatoid arthritis; and
(b) who have demonstrated an adequate response to treatment with adalimumab; and
(c) whose most recent course of PBS-subsidised bDMARD treatment in this treatment cycle was with adalimumab.

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

The authority application must be made in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].

A maximum of 24 weeks of treatment will be approved under this restriction.

Where fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
	All applications for continuing treatment with adalimumab must include a measurement of response to the prior course of therapy. This assessment must be provided to Medicare Australia no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with adalimumab, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.							
	Patients who fail to demonstrate a response to treatment with adalimumab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug, in this treatment cycle. Patients may re-trial adalimumab after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised bDMARD was approved in this cycle and the date of the first application under the new cycle.							
8741C	***Injection 40 mg in 0.8 mL pre-filled syringe***	***2***	***5***	***..***	***1773.93***	***32.90***	***Humira***	***AB***
9100Y	***Injection 40 mg in 0.8 mL pre-filled pen***	***2***	***5***	***..***	***1773.93***	***32.90***	***Humira***	***AB***
	NOTE:							
	No applications for increased maximum quantities and/or repeats will be authorised.							
	Applications for treatment with adalimumab where the dosing frequency exceeds 40 mg per fortnight will not be approved.							
	NOTE:							
	TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS							
	The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents (adalimumab, etanercept and infliximab) for adult patients with severe active psoriatic arthritis.							
	Patients are eligible for PBS-subsidised treatment with only 1 of the above biological agents at any 1 time. Where the term 'biological agents' appears in the following NOTES and restrictions, it only refers to adalimumab, etanercept and infliximab.							
	From 1 August 2006, all patients will be able to commence a 'Biological Treatment Cycle' (Cycle), where they may trial adalimumab, etanercept or infliximab without having to meet the initial treatment criteria, that is they will not need to experience a disease flare, when swapping to the alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.							
	Following demonstration of response to initial treatment, these biological agents are available under the PBS for continuing treatment as set out in the continuing treatment restriction for each agent.							
	Once patients have either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological therapy before they are eligible to commence another Cycle [further details are under '(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' below].							
	The 5-year break in therapy will be measured from the date the last approval for PBS-subsidised treatment was granted in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Cycle.							
	Within the same Cycle, patients are not allowed to fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for any biological agent, they must change to an alternate agent which they have not previously failed, if they wish to continue PBS-subsidised biological treatment.							
	Patients for whom a break in PBS-subsidised therapy of less than 5 years has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.							

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Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer

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

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

How to prescribe biological agents for the treatment of severe active psoriatic arthritis after 1 August 2006.

(1) Initial treatment.

Applications for initial treatment should be made where:
(i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); and
(ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; and
(iii) patients wish to re-commence treatment with a specific biological agent following a break in PBS-subsidised therapy with that specific agent (Initial 2).

All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 16 weeks of therapy for all agents except for infliximab, for which a maximum of 22 weeks will be authorised. It is recommended that patients be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological agent supply.

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

Grandfather patients.

Applications for patients who commenced treatment with etanercept prior to 17 March 2005 or adalimumab and infliximab prior to 16 March 2006, may apply for initial PBS-subsidised treatment as continuing therapy under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with any biological agent prior to PBS listing of that agent.

Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment for all agents. Approval will be based on the criteria included in the relevant restriction.

(2) Continuing treatment.

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

Patients must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.

(3) Swapping therapy.

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

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

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ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer

Patients may alternate between therapy with any biological agent of their choice (1 at a time) providing:
(i) they have not received PBS-subsidised treatment with that particular biological agent previously; or
(ii) they have demonstrated an adequate response to that particular biological agent if they have previously trialled it on the PBS.

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

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

(4) Baseline measurements to determine response.

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

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.

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

Patients who wish to trial a second or subsequent treatment Cycle following a break in PBS-subsidised biological therapy of at least 5 years, must re-qualify for initial treatment with respect to both the indices of disease severity. Patients must have received treatment with methotrexate or sulfasalazine or leflunomide, at an adequate dose, for a minimum of 3 months at the time the ESR or CRP levels and the active joint counts are measured.

Authority Required

Initial 1

Initial PBS-subsidised treatment with adalimumab, by a rheumatologist or clinical immunologist with expertise in the management of psoriatic arthritis, of adults who:
(1) have severe active psoriatic arthritis; and
(2) have received no prior PBS-subsidised biological treatment for this condition in this Treatment Cycle; and
(3) have failed to achieve an adequate response to:
(a) methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months; and
(b) sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months; or
(c) leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months.

Patients must have had the psoriatic component of their disease confirmed by a dermatologist or by biopsy at any time.

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity to necessitate permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of acceptable toxicities, including severity, can be found on the Medicare Australia website (www.medicareaustralia.gov.au).

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ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer

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

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

The authority application must be made in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes details of the patient's ESR and CRP measurements and the patient's active joint count which must have been assessed no earlier than 1 month prior to the date of application; and
(3) a copy of the signed patient acknowledgement form which is included in the Supporting Information Form. Completion of this form declares that the patient understands and acknowledges that PBS-subsidised treatment will cease if they do not demonstrate the response to treatment required to support continuation of PBS-subsidised treatment at any assessment where a response must be demonstrated.

Where fewer than 3 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Patients who fail to demonstrate a response to treatment with adalimumab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug, in this Treatment Cycle.

Authority Required

Initial 2
Initial PBS-subsidised treatment with adalimumab, by a rheumatologist or clinical immunologist with expertise in the management of psoriatic arthritis, of adults who:
(1) have a documented history of severe active psoriatic arthritis; and
(2) have received prior PBS-subsidised biological treatment for this condition in this Treatment Cycle and are eligible to receive further biological therapy; and
(3) have not failed treatment with adalimumab during the current Treatment Cycle.

Applications for patients who have demonstrated a response to PBS-subsidised adalimumab treatment within this Treatment Cycle and who wish to re-commence adalimumab treatment within the same Cycle following a break in therapy, will only be approved where evidence of a response to the patient's most recent course of PBS-subsidised adalimumab treatment has been submitted to Medicare Australia within 1 month of cessation of treatment.

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

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

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ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	

The authority application must be made in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].

Where fewer than 3 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Patients who fail to demonstrate a response to treatment with adalimumab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug, in this Treatment Cycle.

Once patients fail to respond to treatment with 3 biological agents, they are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may re-commence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

9033K	*Injection 40 mg in 0.8 mL pre-filled syringe*	*2*	*3*	*..*	*1773.93*	*32.90*	*Humira*	*AB*
9101B	*Injection 40 mg in 0.8 mL pre-filled pen*	*2*	*3*	*..*	*1773.93*	*32.90*	*Humira*	*AB*

NOTE:
No applications for increased maximum quantities and/or repeats will be authorised.
Applications for treatment with adalimumab where the dosing frequency exceeds 40 mg per fortnight will not be approved.

Authority Required

Initial 3
Initial PBS-subsidised supply for continuing treatment with adalimumab, by a rheumatologist or clinical immunologist with expertise in the management of psoriatic arthritis, of adults who:
(1) have a documented history of severe active psoriatic arthritis; and
(2) were receiving treatment with adalimumab prior to 16 March 2006; and
(3) have demonstrated a response as specified in the criteria for continuing PBS-subsidised treatment with adalimumab.

The authority application must be made in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and
(3) a copy of the signed patient acknowledgement form which is included in the Supporting Information Form. Completion of this form declares that the patient understands and acknowledges that PBS-subsidised treatment will cease if they do not demonstrate the response to treatment required to support continuation of PBS-subsidised treatment at any assessment where a response must be demonstrated.

A maximum of 24 weeks of treatment with adalimumab will be authorised under this restriction.

Where fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Patients who fail to demonstrate a response to treatment with adalimumab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug, in this Treatment Cycle.

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

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ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
	Authority Required ***Continuing treatment*** ***Continuing PBS-subsidised treatment with adalimumab, by a rheumatologist or clinical immunologist with expertise in the management of psoriatic arthritis, of adults:*** ***(1) who have a documented history of severe active psoriatic arthritis; and*** ***(2) whose most recent course of PBS-subsidised biological agent for this condition in the current Treatment Cycle was with adalimumab; and*** ***(3) who, at the time of application, demonstrate an adequate response to treatment with adalimumab.*** ***An adequate response to treatment with adalimumab is defined as:*** ***an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following:*** ***(i) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or*** ***(ii) a reduction in the number of the following major active joints, from at least 4, by at least 50%:*** ***— elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or*** ***— shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).*** ***The authority application must be made in writing and must include:*** ***(1) a completed authority prescription form; and*** ***(2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].*** ***All applications for continuing treatment with adalimumab must include a measurement of response to the prior course of therapy. This assessment must be provided to Medicare Australia no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with adalimumab, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with the initial treatment course.*** ***Where fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).*** ***Patients who fail to demonstrate a response to treatment with adalimumab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug, in this Treatment Cycle.*** ***Once patients fail to respond to treatment with 3 biological agents, they are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may re-commence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.***							
9034L	***Injection 40 mg in 0.8 mL pre-filled syringe***	***2***	***5***	***..***	***1773.93***	***32.90***	***Humira***	***AB***
9102C	***Injection 40 mg in 0.8 mL pre-filled pen***	***2***	***5***	***..***	***1773.93***	***32.90***	***Humira***	***AB***

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ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer

NOTE:

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

Applications for treatment with adalimumab where the dosing frequency exceeds 40 mg per fortnight will not be approved.

NOTE:

TREATMENT OF ADULT PATIENTS WITH ACTIVE ANKYLOSING SPONDYLITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and infliximab for adult patients with active ankylosing spondylitis. Where the term 'tumour necrosis factor (TNF) alfa antagonist' appears in the following NOTES and restrictions, it refers to adalimumab, etanercept and infliximab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 TNF-alfa antagonists at any 1 time.

From 1 March 2007, under the PBS, all patients will be able to commence a treatment cycle where they may trial each PBS-subsidised TNF-alfa antagonist without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a TNF-alfa antagonist while they continue to show a response to therapy.

A patient who received PBS-subsidised TNF-alfa antagonist treatment prior to 1 March 2007 is considered to be in their first cycle as of 1 March 2007.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised TNF-alfa antagonist more than once. A patient who, prior to 1 March 2007, was authorised to receive PBS-subsidised initial treatment for ankylosing spondylitis with the same agent twice, is exempt from this condition in respect of applications approved prior to 1 March 2007.

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

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

A patient who has failed fewer than 3 TNF-alfa antagonists in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

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

(1) How to prescribe PBS-subsidised TNF-alfa antagonist therapy after 1 March 2007.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised TNF-alfa antagonist treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or

(ii) a patient has received prior PBS-subsidised (initial or continuing) TNF-alfa antagonist therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to re-commence treatment with a specific TNF-alfa antagonist following a break in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for etanercept and adalimumab and 18 weeks of treatment for infliximab.

From 1 March 2007, a patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

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ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.

For second and subsequent courses of PBS-subsidised TNF-alfa antagonist treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

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

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

Assessments of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.

(2) Swapping therapy.

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

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

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

To avoid confusion, an application for a patient who wishes to swap to an alternate TNF-alfa antagonist should be accompanied by the approved authority prescription or remaining repeats for the TNF-alfa antagonist the patient is ceasing.

(3) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a TNF-alfa antagonist. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and Medicare Australia will assess response according to these revised baseline measurements.

For a new patient, the BASDAI used to determine the baseline must be measured while the patient is receiving NSAID therapy and completing their exercise program. However, this is not required for any subsequent BASDAI results for these patients, nor for patients who were 'grandfathered' on to TNF-alfa antagonist treatment.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response.

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

continued ☞

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer

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

(5) Patients 'grandfathered' onto PBS-subsidised treatment with adalimumab.

A patient who commenced treatment with adalimumab for active ankylosing spondylitis prior to 1 November 2006 and who continues to receive treatment at the time of application, may qualify for treatment under the initial 'grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment with adalimumab will be authorised under this criterion.

Following completion of the initial PBS-subsidised course, further applications for treatment with adalimumab will be assessed under the continuing treatment restriction.

Where pre-TNF-alfa antagonist treatment baselines cannot be provided, the following criteria must be met to demonstrate a response to treatment:
The BASDAI score must be either:
(i) no more than 20% greater than the score included in the initial application for PBS-subsidised treatment; or
(ii) no greater than 2.
AND
One of the following:
(a) an ESR measurement no greater than 25 mm per hour; or
(b) a CRP measurement no greater than 10 mg per L.

'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must requalify for initial treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' above for further details.

Authority Required

Initial 1 (new patients)
First course of PBS-subsidised treatment with adalimumab, by a rheumatologist, of an adult with active ankylosing spondylitis who has radiographically (plain X-ray) confirmed Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis and who has not received any PBS-subsidised treatment with either adalimumab, etanercept or infliximab in this treatment cycle; AND
(a) who has at least 2 of the following:
(i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; or
(ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI) [for further information on the BASMI please refer to the Medicare Australia website at www.medicareaustralia.gov.au]; or
(iii) limitation of chest expansion relative to normal values for age and gender [for chest expansion normal values please refer to the Medicare Australia website at www.medicareaustralia.gov.au]; AND
(b) who has failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months.

The application must include details of the NSAIDs trialled, their doses and duration of treatment. If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used.

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ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer

If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication.

If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance. Details of the toxicities, including severity, which will be accepted for the purposes of administering this restriction can be found on the Medicare Australia website [www.medicareaustralia.gov.au].

For details on the appropriate minimum exercise program that will be accepted for the purposes of administering this restriction, please refer to the Medicare Australia website at www.medicareaustralia.gov.au.

The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of the initial application:
(a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale; AND
(b) an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 10 mg per L.

The BASDAI must be determined at the completion of the 3 month NSAID and exercise trial, but prior to ceasing NSAID treatment. The BASDAI must be no more than 1 month old at the time of initial application.

Both ESR and CRP measures should be provided with the initial treatment application and both must be no more than 1 month old. If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reason this criterion cannot be satisfied.

Authority applications must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form [www.medicareaustralia.gov.au] which must include the following:
(i) a copy of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and
(ii) a completed BASDAI Assessment Form [www.medicareaustralia.gov.au]; and
(iii) a completed Exercise Program Self Certification Form included in the supporting information form; and
(iv) a signed patient acknowledgment form. Completion of this form declares that the patient understands and acknowledges that PBS-subsidised treatment with the TNF-alfa antagonists (adalimumab, etanercept or infliximab) for ankylosing spondylitis will cease if they do not demonstrate the response to treatment required to support continuation of PBS-subsidised treatment at any assessment where a response must be demonstrated.

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

A maximum of 16 weeks of treatment with adalimumab will be approved under this criterion.

Where fewer than 3 repeats are initially requested with the authority prescription, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone.

Authority Required

Initial 2 (change or re-commencement for all patients)
Initial course of PBS-subsidised treatment with adalimumab, by a rheumatologist, of an adult with a documented history of active ankylosing spondylitis who, in this treatment cycle, has received prior PBS-subsidised treatment with either adalimumab, etanercept or infliximab for this condition and has not failed PBS-subsidised therapy with adalimumab.

To demonstrate a response to treatment the application must be accompanied by the results of the most recent course of TNF-alfa antagonist therapy within the timeframes specified in the relevant restriction.

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ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
	Where the most recent course of PBS-subsidised TNF-alfa antagonist treatment was approved under an initial treatment restriction after 1 March 2007, the patient must have been assessed for response to that course following a minimum of 12 weeks of treatment. Where the most recent course of PBS-subsidised TNF-alfa antagonist treatment was approved under an initial treatment restriction prior to 1 March 2007, the patient must have been assessed for response to that course following at least 4 weeks of treatment. These assessments must be provided to Medicare Australia no later than 4 weeks from the date the course was ceased.							
	If the response assessment to the previous course of TNF-alfa antagonist treatment is not submitted as detailed above, the patient will be deemed to have failed therapy with that particular course of TNF-alfa antagonist.							
	Authority applications must be made in writing and must include: ***(a) a completed authority prescription form; and*** ***(b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form [www.medicareaustralia.gov.au] which includes a completed BASDAI Assessment Form with certification by the prescriber and the patient that the patient did not have access to their baseline BASDAI at the time of their assessment.***							
	A maximum of 16 weeks of treatment with adalimumab will be approved under this criterion.							
	Where fewer than 3 repeats are initially requested with the authority prescription, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone.							
9077R	***Injection 40 mg in 0.8 mL pre-filled syringe***	***2***	***3***	***..***	***1773.93***	***32.90***	***Humira***	***AB***
9103D	***Injection 40 mg in 0.8 mL pre-filled pen***	***2***	***3***	***..***	***1773.93***	***32.90***	***Humira***	***AB***
	NOTE: ***No applications for increased maximum quantities and/or repeats will be authorised.*** ***Applications for treatment with adalimumab where the dosing frequency exceeds 40 mg per fortnight will not be approved.***							
	Authority Required ***Initial ('grandfather' patients)*** ***Initial PBS-subsidised course of adalimumab treatment, by a rheumatologist, of an adult with a documented history of active ankylosing spondylitis who has radiographically (plain X-ray) confirmed Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis and who was receiving treatment with adalimumab prior to 1 November 2006; AND*** ***(a) is receiving treatment with adalimumab at the time of application; AND*** ***(b) has not received prior PBS-subsidised treatment with infliximab or etanercept; AND*** ***(c) whose current Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score is either:*** ***(i) less than or equal to 5 on a 0-10 scale; OR*** ***(ii) improved by at least 2 from baseline; AND*** ***(d) who has:*** ***(i) an ESR measurement no greater than 25 mm per hour; or*** ***(ii) a CRP measurement no greater than 10 mg per L; or*** ***(iii) an ESR or CRP measurement reduced by at least 20% from pre-treatment baseline.***							
	The BASDAI assessment and ESR and/or CRP measurements provided must be no more than 1 month old at the time of application. Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and supplied in all subsequent continuing treatment applications.							

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ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer

Authority applications must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form [www.medicareaustralia.gov.au] which includes the following:
(i) a copy of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and
(ii) a completed BASDAI Assessment Form [www.medicareaustralia.gov.au]; and
(iii) a signed patient acknowledgment form included in the supporting information form. Completion of this form declares that the patient understands and acknowledges that PBS-subsidised treatment with the TNF-alfa antagonists (adalimumab, etanercept or infliximab) for ankylosing spondylitis will cease if they do not demonstrate the response to treatment required to support continuation of PBS-subsidised treatment at any assessment where a response must be demonstrated.

The assessment of the patient's response to this initial course of therapy must be made within the 4 weeks prior to completion of the course in order to ensure continuity of treatment.

A patient ceasing treatment or swapping to an alternate agent and wishing to demonstrate a response to treatment, must be assessed no earlier than 12 weeks from the commencement of PBS-subsidised treatment. This assessment must be provided to Medicare Australia no later than 4 weeks from the date that course was ceased.

If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

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

Where fewer than 5 repeats are initially requested with the authority prescription, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone.

Patients may only qualify for PBS-subsidised treatment under this criterion once.

Authority Required

Continuing treatment for all patients
Continuing PBS-subsidised treatment, by a rheumatologist, of an adult with a documented history of active ankylosing spondylitis who:
(a) has demonstrated a response to treatment with adalimumab; and
(b) whose most recent course of PBS-subsidised therapy in this treatment cycle was with adalimumab.

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

For a 'grandfather' patient who does not have baselines prior to commencing treatment with a TNF-alfa antagonist, see Note 5 for a definition of response to treatment.

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

The first application for continuing treatment following an initial treatment course must be made following a minimum of 12 weeks of treatment with adalimumab.

Applications for continuing treatment must be made in writing and should be posted to Medicare Australia no less than 2 weeks prior to the completion of the current treatment course.

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ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
	Written applications for authorisation must include: ***(a) a completed authority prescription form; and*** ***(b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form [www.medicareaustralia.gov.au] which includes a completed BASDAI Assessment Form with certification by the prescriber and the patient that the patient did not have access to their baseline BASDAI at the time of their continuing treatment assessment.*** ***All measurements provided must be no more than 1 month old at the time of application.*** ***A maximum of 24 weeks of treatment with adalimumab will be authorised under this criterion.*** ***Where fewer than 5 repeats are initially requested with the authority prescription, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone.***							
9078T	***Injection 40 mg in 0.8 mL pre-filled syringe***	***2***	***5***	***..***	***1773.93***	***32.90***	***Humira***	***AB***
9104E	***Injection 40 mg in 0.8 mL pre-filled pen***	***2***	***5***	***..***	***1773.93***	***32.90***	***Humira***	***AB***
	NOTE: ***No applications for increased maximum quantities and/or repeats will be authorised.*** ***Applications for treatment with adalimumab where the dosing frequency exceeds 40 mg per fortnight will not be approved.*** **NOTE:** ***TREATMENT OF ADULT PATIENTS WITH SEVERE REFRACTORY CROHN DISEASE*** ***The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab and infliximab for adult patients with severe refractory Crohn disease. Where the term 'tumour necrosis factor (TNF) alfa antagonist' appears in the following NOTES and restrictions, it refers to adalimumab and infliximab only.*** ***A patient is eligible for PBS-subsidised treatment with only 1 of the 2 TNF-alfa antagonists at any 1 time.*** ***From 1 August 2008, under the PBS, all patients will be able to commence a treatment cycle where they may trial each PBS-subsidised TNF-alfa antagonist without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a TNF-alfa antagonist while they continue to show a response to therapy.*** ***A patient who received PBS-subsidised TNF-alfa antagonist treatment prior to 1 August 2008 is considered to be in their first cycle as of 1 August 2008.*** ***Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised TNF-alfa antagonist more than twice.*** ***Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised TNF-alfa antagonist therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised TNF-alfa antagonist treatment in the most recent cycle to the date of the first application for initial treatment with a TNF-alfa antagonist under the new treatment cycle.*** ***A patient who has failed fewer than 3 trials of TNF-alfa antagonists in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.*** ***A patient who has failed fewer than 3 trials of TNF-alfa antagonists in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.*** ***There is no limit to the number of treatment cycles a patient may undertake in their lifetime.*** ***(1) How to prescribe PBS-subsidised TNF-alfa antagonist therapy after 1 August 2008.***							

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ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised TNF-alfa antagonist treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or

(ii) a patient has received prior PBS-subsidised (initial or continuing) TNF-alfa antagonist therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to re-commence treatment with a specific TNF-alfa antagonist following a break in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and 14 weeks of therapy for infliximab.

From 1 August 2008, a patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.

For second and subsequent courses of PBS-subsidised TNF-alfa antagonist treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

Adalimumab only: Two completed authority prescriptions must be submitted with every initial application for adalimumab. One prescription must be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats. The second prescription must be written for 2 doses of 40 mg and 2 repeats.

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

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

Assessments of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised TNF-alfa antagonist is approved, a patient may swap if eligible to the alternate TNF-alfa antagonist within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Crohn Disease Activity Index (CDAI) Score, evidence of intestinal inflammation), or the prior corticosteroid therapy and immunosuppressive therapy.

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

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

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ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer

To avoid confusion, an application for a patient who wishes to swap to the alternate TNF-alfa antagonist should be accompanied by the approved authority prescription or remaining repeats for the TNF-alfa antagonist the patient is ceasing.

(3) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements of the CDAI or evidence of intestinal inflammation submitted with the first authority application for a TNF-alfa antagonist. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and Medicare Australia will assess response according to these revised baseline measurements.

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

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

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised TNF-alfa antagonist therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have received treatment with a corticosteroid and at least 1 immunosuppressive agent, at an adequate dose, for a minimum of 3 consecutive months immediately prior to the time the CDAI score or the indices of intestinal inflammation are measured.

(5) Patients 'grandfathered' onto PBS-subsidised treatment with adalimumab or infliximab.

A patient who commenced treatment with adalimumab for severe refractory Crohn disease prior to 9 November 2007 or infliximab prior to 7 March 2007 and who continues to receive treatment at the time of application, may qualify for treatment under the initial 'grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment with adalimumab or infliximab will be authorised under this criterion.

Following completion of the initial PBS-subsidised course, further applications for treatment with adalimumab or infliximab will be assessed under the continuing treatment restriction.

'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must requalify for initial treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' above for further details.

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ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer

Authority Required

Initial 1 (new patients)
Initial treatment of Crohn disease in a patient assessed by CDAI.

Initial PBS-subsidised treatment with adalimumab by a gastroenterologist or a consultant physician as specified in the NOTE below, of a patient with severe refractory Crohn disease who satisfies the following criteria:
(a) has confirmed Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician as specified in the NOTE below; and
(b) has signed a patient acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and
(c) has failed to achieve an adequate response to prior systemic therapy including:
(i) a tapered course of steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period; and
(ii) immunosuppressive therapy including:
— azathioprine at a dose of at least 2 mg per kg daily for 3 or more months; or
— 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months; or
— methotrexate at a dose of at least 15 mg weekly for 3 or more months.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application. .

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of the accepted toxicities including severity can be found on the Medicare Australia website (www.medicareaustralia.gov.au). .

The following initiation criterion indicates failure to achieve an adequate response and must be demonstrated in all patients at the time of the application:
(a) have a severity of disease activity which results in a Crohn Disease Activity Index (CDAI) Score greater than or equal to 300 as assessed.

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.

The most recent CDAI assessment must be no more than 1 month old at the time of application.

Applications for authorisation must be made in writing and must include:
(a) two completed authority prescription forms; and
(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
(i) the completed current Crohn Disease Activity Index (CDAI) calculation sheet including the date of assessment of the patient's condition; and
(ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and
(iii) the signed patient acknowledgement.

A maximum of 16 weeks treatment will be authorised under this criterion.

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Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer

Two completed authority prescriptions must be submitted with every initial application for adalimumab. One prescription must be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats. The second prescription must be written for 2 doses of 40 mg and 2 repeats. Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment with adalimumab may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

A CDAI assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks therapy so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with adalimumab.

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised adalimumab treatment.

Authority Required

Initial 2
Change or re-commencement of treatment of Crohn disease in a patient assessed by CDAI.

Initial PBS-subsidised treatment with adalimumab by a gastroenterologist or a consultant physician as specified in the NOTE below of a patient who:
(a) has a documented history of severe refractory Crohn disease; and
(b) in this treatment cycle, has received prior PBS-subsidised treatment with infliximab or adalimumab for this condition; and
(c) has not failed PBS-subsidised therapy with adalimumab for this condition more than once in the current treatment cycle.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

To demonstrate a response to treatment the application must be accompanied by the results of the most recent course of TNF-alfa antagonist therapy within the timeframes specified in the relevant restriction.

Where the most recent course of PBS-subsidised TNF-alfa antagonist treatment was approved under an initial treatment restriction, the patient must have been assessed for response to that course following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

If the response assessment to the previous course of TNF-alfa antagonist treatment is not submitted as detailed above, the patient will be deemed to have failed therapy with that particular course of TNF-alfa antagonist.

Authority applications must be made in writing and must include:
(a) two completed authority prescription forms; and
(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
(i) the completed current Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient's condition; and
(ii) details of prior TNF alfa antagonist treatment including details of date and duration of treatment.

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ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer

Two completed authority prescriptions must be submitted with every initial application for adalimumab. One prescription must be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats. The second prescription must be written for 2 doses of 40 mg and 2 repeats. Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment with adalimumab may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

A CDAI assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks therapy so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with adalimumab.

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised adalimumab treatment.

Authority Required

Initial 1

Initial treatment of Crohn disease in a patient with short gut syndrome or an ostomy patient.

Initial PBS-subsidised treatment with adalimumab by a gastroenterologist, or consultant physician as specified in the NOTE below of a patient who satisfies the following criteria:
(a) has confirmed Crohn disease defined by standard clinical, endoscopic and/or imaging features, including histological evidence with the diagnosis confirmed by a gastroenterologist or consultant physician as specified in the NOTE below; and
(b) has diagnostic imaging or surgical evidence of short gut syndrome or has an ileostomy or colostomy; and
(c) has evidence of intestinal inflammation; and
(d) has signed a patient acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and
(e) has failed to achieve an adequate response to prior systemic drug therapy including:
(i) a tapered course of steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period; and
(ii) immunosuppressive therapy including:
— azathioprine at a dose of at least 2 mg per kg daily for 3 or more months; or
— 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months; or
— methotrexate at a dose of at least 15 mg weekly for 3 or more months.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of the accepted toxicities including severity can be found on the Medicare Australia website (www.medicareaustralia.gov.au).

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ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer

The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the application:
(a) have evidence of intestinal inflammation, including:
(i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; AND/OR
(ii) faeces: higher than normal lactoferrin or calprotectin level; AND/OR
(iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery;
AND/OR
(b) be assessed clinically as being in a high faecal output state;
AND/OR
(c) be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of adalimumab.

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.

Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the continuing treatment restriction. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy.

Applications for authorisation must be made in writing and must include:
(a) two completed authority prescription forms; and
(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
(i) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and
(ii) reports and dates of the pathology or diagnostic imaging test(s) nominated as the response criterion, if relevant; and
(iii) date of the most recent clinical assessment; and
(iv) the signed patient acknowledgement.

All assessments, pathology tests and diagnostic imaging studies must be made within 1 month of the date of application.

A maximum of 16 weeks treatment will be authorised under this criterion.

Two completed authority prescriptions must be submitted with every initial application for adalimumab. One prescription must be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats. The second prescription must be written for 2 doses of 40 mg and 2 repeats. Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment with adalimumab may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

The assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks therapy so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with adalimumab.

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised adalimumab treatment.

continued ☞

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer

Authority Required

Initial 2

Change or re-commencement of treatment of Crohn disease in a patient with short gut syndrome, an ostomy patient or a patient with extensive small intestine disease.

Initial PBS-subsidised treatment with adalimumab by a gastroenterologist or a consultant physician as specified in the NOTE below of a patient who:
(a) has a documented history of severe refractory Crohn disease; and
(b) in this treatment cycle, has received prior PBS-subsidised treatment with infliximab or adalimumab for this condition; and
(c) has not failed PBS-subsidised therapy with adalimumab for this condition more than once in the current treatment cycle.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

To demonstrate a response to treatment the application must be accompanied by the results of the most recent course of TNF-alfa antagonist therapy within the timeframes specified in the relevant restriction.

Where the most recent course of PBS-subsidised TNF-alfa antagonist treatment was approved under an initial treatment restriction, the patient must have been assessed for response to that course following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.
If the response assessment to the previous course of TNF-alfa antagonist treatment is not submitted as detailed above, the patient will be deemed to have failed therapy with that particular course of TNF-alfa antagonist.

Authority applications must be made in writing and must include:
(a) two completed authority prescription forms; and
(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
(i) reports and dates of the pathology or diagnostic imaging test(s) nominated as the response criteria, if relevant; and
(ii) details of prior TNF alfa antagonist treatment including details of date and duration of treatment.

A maximum of 16 weeks of treatment will be approved under this criterion.

Two completed authority prescriptions must be submitted with every initial application for adalimumab. One prescription must be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats. The second prescription must be written for 2 doses of 40 mg and 2 repeats. Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment with adalimumab may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

The assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of therapy so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with adalimumab.

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised adalimumab treatment.

continued ☞

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer

Authority Required

Initial 1

Initial treatment of Crohn disease in a patient with extensive small intestine disease.

Initial PBS-subsidised treatment with adalimumab by a gastroenterologist or a consultant physician as specified in the NOTE below, of a patient with severe refractory Crohn disease who satisfies the following criteria:
(a) has confirmed Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or consultant physician as specified in the NOTE below; and
(b) has extensive small intestinal disease with radiological evidence of intestinal inflammation affecting more than 50 cm of the small intestine; and
(c) has signed a patient acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and
(d) has failed to achieve an adequate response to prior systemic therapy including:
(i) a tapered course of steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period; and
(ii) immunosuppressive therapy including:
— azathioprine at a dose of at least 2 mg per kg daily for 3 or more months; or
— 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months; or
— methotrexate at a dose of at least 15 mg weekly for 3 or more months.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of the accepted toxicities including severity can be found on the Medicare Australia website (www.medicareaustralia.gov.au).

The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the application:
(a) have severity of disease activity which results in a Crohn Disease Activity Index (CDAI) Score greater than or equal to 220;
AND/OR
(b) have evidence of active intestinal inflammation, including:
(i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; AND/OR
(ii) faeces: higher than normal lactoferrin or calprotectin level; AND/OR
(iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery;
AND/OR
(c) be assessed clinically as being in a high faecal output state;
AND/OR
(d) be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of adalimumab.

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.

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ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
	Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the continuing treatment restriction. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy.							
	Applications for authorisation must be made in writing and must include: ***(a) two completed authority prescription forms; and*** ***(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:*** ***(i) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and*** ***(ii) (1) reports and dates of the pathology or diagnostic imaging test(s) nominated as the response criterion, if relevant; or*** ***(2) the completed current Crohn Disease Activity Index (CDAI) calculation sheet including the dates of assessment of the patient's condition, if relevant; and*** ***(iii) date of the most recent clinical assessment; and*** ***(iv) the signed patient acknowledgement.***							
	All assessments, pathology tests and diagnostic imaging studies must be made within 1 month of the date of application.							
	A maximum of 16 weeks treatment of adalimumab will be authorised under his criterion.							
	Two completed authority prescriptions must be submitted with every initial application for adalimumab. One prescription must be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats. The second prescription must be written for 2 doses of 40 mg and 2 repeats. Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment with adalimumab may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.							
	The assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of therapy after the first dose so that there is adequate time for a response to be demonstrated.							
	This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with adalimumab.							
	It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised adalimumab treatment.							
9186L	***Injection 40 mg in 0.8 mL pre-filled syringe, 6***	***1***	***..***	***..***	***5035.93***	***32.90***	***Humira***	***AB***
9187M	***Injection 40 mg in 0.8 mL pre-filled pen, 6***	***1***	***..***	***..***	***5035.93***	***32.90***	***Humira***	***AB***
	<u>NOTE:</u> ***No applications for increased maximum quantities and/or repeats will be authorised.***							
9188N	***Injection 40 mg in 0.8 mL pre-filled syringe***	***2***	***2***	***..***	***1773.93***	***32.90***	***Humira***	***AB***
9190Q	***Injection 40 mg in 0.8 mL pre-filled pen***	***2***	***2***	***..***	***1773.93***	***32.90***	***Humira***	***AB***

continued ☞

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer

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

Authority Required

Initial 3 (grandfather)
Initial PBS-subsidised treatment of Crohn disease in a patient assessed by CDAI who has previously received non-PBS-subsidised therapy with adalimumab.

Initial PBS-subsidised supply for continuing treatment with adalimumab by a gastroenterologist, a consultant physician as specified in the NOTE below, or other consultant physician in consultation with a gastroenterologist of a patient who:
(a) has a documented history of severe refractory Crohn disease and was receiving treatment with adalimumab prior to 9 November 2007; and
(b) had a Crohn Disease Activity Index (CDAI) Score of greater than or equal to 300 prior to commencing treatment with adalimumab. Where a baseline CDAI assessment is not available, please call Medicare Australia on 1800 700 270 to discuss; and
(c) has signed a patient acknowledgement indicating that they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and
(d) has demonstrated or sustained an adequate response to treatment with adalimumab. For advice please contact Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

An adequate response to adalimumab treatment is defined as a reduction in Crohn Disease Activity Index (CDAI) Score to no greater than 150.

Applications for authorisation must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
(i) the completed current and baseline Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient's condition; and
(ii) the signed patient acknowledgement.

The current CDAI assessment must be no more than 1 month old at the time of application. The baseline CDAI assessment must be from immediately prior to commencing treatment with adalimumab.

The assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion.

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with adalimumab.

A maximum of 24 weeks treatment will be approved under this criterion.
Where fewer than 5 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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

continued ☞

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer

Authority Required

Continuing treatment of Crohn disease in a patient assessed by CDAI.

Continuing PBS-subsidised treatment with adalimumab by a gastroenterologist, a consultant physician as specified in the NOTE below or other consultant physician in consultation with a gastroenterologist, of a patient who:
(a) has a documented history of severe refractory Crohn disease; and
(b) has demonstrated or sustained an adequate response to treatment with adalimumab.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

An adequate response to adalimumab treatment is defined as a reduction in Crohn Disease Activity Index (CDAI) Score to a level no greater than 150.

Applications for authorisation must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
(i) the completed Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient's condition.

The CDAI assessment must be no more than 1 month old at the time of application.

If the application is the first application for continuing treatment with adalimumab, a CDAI assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of therapy so that there is adequate time for a response to be demonstrated.

The assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion.

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with adalimumab.

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

A maximum of 24 weeks treatment will be authorised under this criterion.
Where fewer than 5 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority Required

Continuing treatment of Crohn disease in a patient with short gut syndrome or an ostomy patient.

Continuing PBS-subsidised treatment with adalimumab by a gastroenterologist, a consultant physician as specified in the NOTE below or other consultant physician in consultation with a gastroenterologist, of a patient who:
(a) has a documented history of severe refractory Crohn disease with intestinal inflammation and with short gut syndrome or with an ileostomy or colostomy; and
(b) has demonstrated or sustained an adequate response to treatment with adalimumab.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

continued ☞

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer

An adequate response to adalimumab treatment is defined as:
(a) improvement of intestinal inflammation as demonstrated by:
(i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; AND/OR
(ii) faeces: normalisation of lactoferrin or calprotectin level; AND/OR
(iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or
(b) reversal of high faecal output state; or
(c) avoidance of the need for surgery or total parenteral nutrition (TPN).

Applications for authorisation must be made in writing and must include:
(a) a completed authority prescription; and
(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
(i) the reports and dates of the pathology or diagnostic imaging test(s) used to assess response to therapy or the date of clinical assessment.

The patient's assessment must be no more than 1 month old at the time of application.

If the application is the first application for continuing treatment with adalimumab, an assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of therapy after the first dose so that there is adequate time for a response to be demonstrated.

The assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion.

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with adalimumab.

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

A maximum of 24 weeks of treatment will be authorised under this criterion.
Where fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority Required

Continuing treatment of Crohn disease in a patient with extensive small intestine disease.

Continuing PBS-subsidised treatment with adalimumab by a gastroenterologist, or consultant physician as specified in the NOTE below or other consultant physician in consultation with a gastroenterologist, of a patient who:
(a) has a documented history of severe refractory Crohn disease with extensive intestinal inflammation affecting more than 50 cm of the small intestine; and
(b) has demonstrated or sustained an adequate response to treatment with adalimumab.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

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ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer

An adequate response to adalimumab treatment is defined as:
(a) a reduction in Crohn Disease Activity Index (CDAI) Score to no greater than 150; or
(b) improvement of intestinal inflammation as demonstrated by:
(i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; AND/OR
(ii) faeces: normalisation of lactoferrin or calprotectin level; AND/OR
(iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or
(c) reversal of high faecal output state; or
(d) avoidance of the need for surgery or total parenteral nutrition (TPN).

Applications for authorisation must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
(i) the completed Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient's condition; or
(ii) the reports and dates of the pathology test or diagnostic imaging test(s) used to assess response to therapy; or
(iii) the date of clinical assessment.

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

If the application is the first application for continuing treatment with adalimumab, an assessment of the patient's response must be made following a minimum of 12 weeks of therapy so that there is adequate time for a response to be demonstrated.

The assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion.

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with adalimumab.

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

A maximum of 24 weeks treatment will be authorised under this criterion.
Where fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer

Authority Required

Initial 3

Initial PBS-subsidised treatment of Crohn disease in a patient with short gut syndrome, an ostomy patient, or a patient with extensive small intestine disease, who has previously received non-PBS-subsidised therapy with adalimumab.

Initial PBS-subsidised supply for continuing treatment with adalimumab by a gastroenterologist, a consultant physician as specified in the NOTE below, or other consultant physician in consultation with a gastroenterologist, of a patient who:
(a) has a documented history of severe refractory Crohn disease and was receiving treatment with adalimumab prior to 9 November 2007; and
(b) (1) has a history of extensive small intestinal disease with radiological evidence of intestinal inflammation affecting more than 50 cm of the small intestine; or
(2) has diagnostic imaging or surgical evidence of short gut syndrome or has an ileostomy or colostomy with a documented history of intestinal inflammation; and
(c) has signed a patient acknowledgement indicating that they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and
(d) has demonstrated or sustained an adequate response to treatment with adalimumab according to the criteria included in the relevant continuation restriction. For advice please contact Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

The same criteria used to determine an inadequate response to prior treatment at baseline must be used to determine response to treatment and eligibility for continuing therapy, according to the criteria included in the continuing treatment restriction.

An adequate response to adalimumab treatment is defined as:
(a) a reduction in Crohn Disease Activity Index (CDAI) Score to no greater than 150; or
(b) improvement of intestinal inflammation as demonstrated by:
(i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; AND/OR
(ii) faeces: normalisation of lactoferrin or calprotectin level; AND/OR
(iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or
(c) reversal of high faecal output state; or
(d) avoidance of the need for surgery or total parenteral nutrition (TPN).

Applications for authorisation must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
(i) (1) the completed current and baseline Crohn Disease Activity Index (CDAI) Score calculation sheet, where relevant, including the date of the assessment of the patient's condition; or
(2) the reports and dates of the current and baseline pathology or diagnostic imaging test(s) in order to assess response to therapy; or
(3) the date of clinical assessment(s); and
(ii) the signed patient acknowledgement.

The patient's assessment must be no more than 1 month old at the time of application. The baseline CDAI assessments must be from immediately prior to commencing treatment with adalimumab. Where a baseline assessment is not available, please call Medicare Australia on 1800 700 270 to discuss.

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Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	

The assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion.

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with adalimumab.

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

Patients who fail to demonstrate or sustain a response to treatment with adalimumab for Crohn disease as specified in the criteria for continuing treatment with adalimumab, will not be eligible to recommence PBS-subsidised treatment with this drug within 12 months of the date on which treatment was ceased.

A maximum of 24 weeks treatment will be authorised under this criterion.
Where fewer than 5 repeats are requested at the time of this application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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

9189P	***Injection 40 mg in 0.8 mL pre-filled syringe***	***2***	***5***	***..***	***1773.93***	***32.90***	***Humira***	***AB***
9191R	***Injection 40 mg in 0.8 mL pre-filled pen***	***2***	***5***	***..***	***1773.93***	***32.90***	***Humira***	***AB***

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

ETANERCEPT
NOTE:
Any queries concerning the arrangements to prescribe etanercept may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written applications for authority to prescribe etanercept should be forwarded to:

Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

Further prescribing information is on the Medicare Australia website at www.medicareaustralia.gov.au.

NOTE:
TREATMENT OF ADULT PATIENTS WITH ACTIVE ANKYLOSING SPONDYLITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and infliximab for adult patients with active ankylosing spondylitis. Where the term 'tumour necrosis factor (TNF) alfa antagonist' appears in the following NOTES and restrictions, it refers to adalimumab, etanercept and infliximab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 TNF-alfa antagonists at any 1 time.

From 1 March 2007, under the PBS, all patients will be able to commence a treatment cycle where they may trial each PBS-subsidised TNF-alfa antagonist without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a TNF-alfa antagonist while they continue to show a response to therapy.

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ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer

A patient who received PBS-subsidised TNF-alfa antagonist treatment prior to 1 March 2007 is considered to be in their first cycle as of 1 March 2007.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised TNF-alfa antagonist more than once. A patient who, prior to 1 March 2007, was authorised to receive PBS-subsidised initial treatment for ankylosing spondylitis with the same agent twice, is exempt from this condition in respect of applications approved prior to 1 March 2007.

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

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

A patient who has failed fewer than 3 TNF-alfa antagonists in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

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

(1) How to prescribe PBS-subsidised TNF-alfa antagonist therapy after 1 March 2007.

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

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for etanercept and adalimumab and 18 weeks of treatment for infliximab.

From 1 March 2007, a patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.

For second and subsequent courses of PBS-subsidised TNF-alfa antagonist treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

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

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

Assessments of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

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ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.

(2) Swapping therapy.

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

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

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

To avoid confusion, an application for a patient who wishes to swap to an alternate TNF-alfa antagonist should be accompanied by the approved authority prescription or remaining repeats for the TNF-alfa antagonist the patient is ceasing.

(3) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a TNF-alfa antagonist. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and Medicare Australia will assess response according to these revised baseline measurements.

For a new patient, the BASDAI used to determine the baseline must be measured while the patient is receiving NSAID therapy and completing their exercise program. However, this is not required for any subsequent BASDAI results for these patients, nor for patients who were 'grandfathered' on to TNF-alfa antagonist treatment.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response.

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

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

(5) Patients 'grandfathered' onto PBS-subsidised treatment with etanercept.

From 1 March 2007, a patient who commenced treatment with etanercept for active ankylosing spondylitis prior to 1 July 2004 and who was 'grandfathered' onto PBS-subsidised therapy, and who continues to receive treatment in the same treatment cycle, will have further applications for treatment with etanercept assessed under the continuing treatment restriction.

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ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer

Where pre-TNF-alfa antagonist treatment baselines were not provided, the following criteria must be met to demonstrate a response to treatment:
The BASDAI score must be either:
(i) no more than 20% greater than the score included in the initial application for PBS-subsidised treatment; or
(ii) no greater than 2.
AND
One of the following:
(a) an ESR measurement no greater than 25 mm per hour; or
(b) a CRP measurement no greater than 10 mg per L.

'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather" patient must requalify for initial treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' above for further details.

Authority Required

Initial 1 (new patients)
First course of PBS-subsidised treatment with etanercept, by a rheumatologist, of an adult with active ankylosing spondylitis who has radiographically (plain X-ray) confirmed Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis and who has not received any PBS-subsidised treatment with either adalimumab, etanercept or infliximab in this treatment cycle; AND
(a) who has at least 2 of the following:
(i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; or
(ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI) [for further information on the BASMI please refer to the Medicare Australia website at www.medicareaustralia.gov.au]; or
(iii) limitation of chest expansion relative to normal values for age and gender [for chest expansion normal values please refer to the Medicare Australia website at www.medicareaustralia.gov.au]; AND
(b) who has failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months.

The application must include details of the NSAIDs trialled, their doses and duration of treatment. If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used.

If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication.

If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance. Details of the toxicities, including severity, which will be accepted for the purposes of administering this restriction can be found on the Medicare Australia website [www.medicareaustralia.gov.au].

For details on the appropriate minimum exercise program that will be accepted for the purposes of administering this restriction, please refer to the Medicare Australia website at www.medicareaustralia.gov.au.

The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of the initial application:
(a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale; AND
(b) an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 10 mg per L.

The BASDAI must be determined at the completion of the 3 month NSAID and exercise trial, but prior to ceasing NSAID treatment. The BASDAI must be no more than 1 month old at the time of initial application.

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ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer

Both ESR and CRP measures should be provided with the initial treatment application and both must be no more than 1 month old. If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reason this criterion cannot be satisfied.

Authority applications must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form [www.medicareaustralia.gov.au] which must include the following:
(i) a copy of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and
(ii) a completed BASDAI Assessment Form [www.medicareaustralia.gov.au]; and
(iii) a completed Exercise Program Self Certification Form included in the supporting information form; and
(iv) a signed patient acknowledgment form. Completion of this form declares that the patient understands and acknowledges that PBS-subsidised treatment with the TNF-alfa antagonists (adalimumab, etanercept or infliximab) for ankylosing spondylitis will cease if they do not demonstrate the response to treatment required to support continuation of PBS-subsidised treatment at any assessment where a response must be demonstrated.

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

A maximum of 16 weeks of treatment with etanercept will be approved under this criterion.

Where fewer than 3 repeats are initially requested with the authority prescription, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone.

Authority Required

Initial 2 (change or re-commencement for all patients)
Initial course of PBS-subsidised treatment with etanercept, by a rheumatologist, of an adult with a documented history of active ankylosing spondylitis who, in this treatment cycle, has received prior PBS-subsidised treatment with either adalimumab, etanercept or infliximab for this condition and has not failed PBS-subsidised therapy with etanercept.

To demonstrate a response to treatment the application must be accompanied by the results of the most recent course of TNF-alfa antagonist therapy within the timeframes specified in the relevant restriction.

Where the most recent course of PBS-subsidised TNF-alfa antagonist treatment was approved under an initial treatment restriction after 1 March 2007, the patient must have been assessed for response to that course following a minimum of 12 weeks of treatment. Where the most recent course of PBS-subsidised TNF-alfa antagonist treatment was approved under an initial treatment restriction prior to 1 March 2007, the patient must have been assessed for response to that course following at least 4 weeks of treatment. These assessments must be provided to Medicare Australia no later than 4 weeks from the date the course was ceased.

If the response assessment to the previous course of TNF-alfa antagonist treatment is not submitted as detailed above, the patient will be deemed to have failed therapy with that particular course of TNF-alfa antagonist.

Authority applications must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form [www.medicareaustralia.gov.au] which includes a completed BASDAI Assessment Form with certification by the prescriber and the patient that the patient did not have access to their baseline BASDAI at the time of their assessment.

A maximum of 16 weeks of treatment with etanercept will be approved under this criterion.

Where fewer than 3 repeats are initially requested with the authority prescription, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone.

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ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
8778B	*Injection set containing 4 vials powder for injection 25 mg and 4 pre-filled syringes solvent 1 mL*	*2*	*3*	*..*	** 1828.57*	*32.90*	*Enbrel*	*WX*
9081Y	*Injection set containing 4 vials powder for injection 50 mg and 4 pre-filled syringes solvent 1 mL*	*1*	*3*	*..*	*1773.94*	*32.90*	*Enbrel*	*WX*
9085E	*Injections 50 mg in 1 mL single use pre-filled syringes, 4*	*1*	*3*	*..*	*1773.94*	*32.90*	*Enbrel*	*WX*

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

Authority Required

Continuing treatment for all patients
Continuing PBS-subsidised treatment, by a rheumatologist, of an adult with a documented history of active ankylosing spondylitis who:
(a) has demonstrated a response to treatment with etanercept; and
(b) whose most recent course of PBS-subsidised therapy in this treatment cycle was with etanercept.

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

For a 'grandfather' patient who does not have baselines prior to commencing treatment with a TNF-alfa antagonist, see Note 5 for a definition of response to treatment.

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

Where the most recent course of PBS-subsidised TNF-alfa antagonist treatment was approved under an initial treatment restriction after 1 March 2007, the patient must have been assessed for response to that course following a minimum of 12 weeks of treatment. Where the most recent course of PBS-subsidised TNF-alfa antagonist treatment was approved under an initial treatment restriction prior to 1 March 2007, the patient must have been assessed for response to that course following at least 4 weeks of treatment.

Applications for continuing treatment must be made in writing and should be posted to Medicare Australia no less than 2 weeks prior to the completion of the current treatment course.

Written applications for authorisation must include:
(a) a completed authority prescription form; and
(b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form [www.medicareaustralia.gov.au] which includes a completed BASDAI Assessment Form with certification by the prescriber and the patient that the patient did not have access to their baseline BASDAI at the time of their continuing treatment assessment.

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

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

Where fewer than 5 repeats are initially requested with the authority prescription, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone.

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ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
8779C	*Injection set containing 4 vials powder for injection 25 mg and 4 pre-filled syringes solvent 1 mL*	*2*	*5*	*..*	** 1828.57*	*32.90*	*Enbrel*	*WX*
9082B	*Injection set containing 4 vials powder for injection 50 mg and 4 pre-filled syringes solvent 1 mL*	*1*	*5*	*..*	*1773.94*	*32.90*	*Enbrel*	*WX*
9086F	*Injections 50 mg in 1 mL single use pre-filled syringes, 4*	*1*	*5*	*..*	*1773.94*	*32.90*	*Enbrel*	*WX*

NOTE:
No applications for increased maximum quantities and/or repeats will be authorised.
NOTE:
TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS

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

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological agents at any 1 time. Where the term 'biological agents' appears in the following NOTES and restrictions, it only refers to adalimumab, etanercept and infliximab.

From 1 August 2006, all patients will be able to commence a 'Biological Treatment Cycle' (Cycle), where they may trial adalimumab, etanercept or infliximab without having to meet the initial treatment criteria, that is they will not need to experience a disease flare, when swapping to the alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

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

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

The 5-year break in therapy will be measured from the date the last approval for PBS-subsidised treatment was granted in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Cycle.

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

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

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

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

How to prescribe biological agents for the treatment of severe active psoriatic arthritis after 1 August 2006.

(1) Initial treatment.

continued ☞

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer

Applications for initial treatment should be made where:
(i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); and
(ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; and
(iii) patients wish to re-commence treatment with a specific biological agent following a break in PBS-subsidised therapy with that specific agent (Initial 2).

All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 16 weeks of therapy for all agents except for infliximab, for which a maximum of 22 weeks will be authorised. It is recommended that patients be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological agent supply.

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

Grandfather patients.

Applications for patients who commenced treatment with etanercept prior to 17 March 2005 or adalimumab and infliximab prior to 16 March 2006, may apply for initial PBS-subsidised treatment as continuing therapy under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with any biological agent prior to PBS listing of that agent.

Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment for all agents. Approval will be based on the criteria included in the relevant restriction.

(2) Continuing treatment.

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

Patients must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.

(3) Swapping therapy.

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

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

Patients may alternate between therapy with any biological agent of their choice (1 at a time) providing:
(i) they have not received PBS-subsidised treatment with that particular biological agent previously; or
(ii) they have demonstrated an adequate response to that particular biological agent if they have previously trialled it on the PBS.

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

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Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer

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

(4) Baseline measurements to determine response.

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

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.

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

Patients who wish to trial a second or subsequent treatment Cycle following a break in PBS-subsidised biological therapy of at least 5 years, must re-qualify for initial treatment with respect to both the indices of disease severity. Patients must have received treatment with methotrexate or sulfasalazine or leflunomide, at an adequate dose, for a minimum of 3 months at the time the ESR or CRP levels and the active joint counts are measured.

Authority Required

Initial 1

Initial PBS-subsidised treatment with etanercept, by a rheumatologist or clinical immunologist with expertise in the management of psoriatic arthritis, of adults who:

(1) have severe active psoriatic arthritis; and

(2) have received no prior PBS-subsidised biological treatment for this condition in this Treatment Cycle; and

(3) have failed to achieve an adequate response to:

(a) methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months; and

(b) sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months; or

(c) leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months.

Patients must have had the psoriatic component of their disease confirmed by a dermatologist or by biopsy at any time.

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity to necessitate permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of acceptable toxicities, including severity, can be found on the Medicare Australia website (www.medicareaustralia.gov.au).

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ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer

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

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

The authority application must be made in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes details of the patient's ESR and CRP measurements and the patient's active joint count which must have been assessed no earlier than 1 month prior to the date of application; and
(3) a copy of the signed patient acknowledgement form which is included in the Supporting Information Form. Completion of this form declares that the patient understands and acknowledges that PBS-subsidised treatment will cease if they do not demonstrate the response to treatment required to support continuation of PBS-subsidised treatment at any assessment where a response must be demonstrated.

Where fewer than 3 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Patients who fail to demonstrate a response to treatment with etanercept under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug, in this Treatment Cycle.

Authority Required

Initial 2
Initial PBS-subsidised treatment with etanercept, by a rheumatologist or clinical immunologist with expertise in the management of psoriatic arthritis, of adults who:
(1) have a documented history of severe active psoriatic arthritis; and
(2) have received prior PBS-subsidised biological treatment for this condition in this Treatment Cycle and are eligible to receive further biological therapy; and
(3) have not failed treatment with etanercept during the current Treatment Cycle.

Applications for patients who have demonstrated a response to PBS-subsidised etanercept treatment within this Treatment Cycle and who wish to re-commence etanercept treatment within the same Cycle following a break in therapy, will only be approved where evidence of a response to the patient's most recent course of PBS-subsidised etanercept treatment has been submitted to Medicare Australia within 1 month of cessation of treatment.

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

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

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ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
	The authority application must be made in writing and must include: ***(1) a completed authority prescription form; and*** ***(2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].*** ***Where fewer than 3 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).*** ***Patients who fail to demonstrate a response to treatment with etanercept under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug, in this Treatment Cycle.*** ***Once patients fail to respond to treatment with 3 biological agents, they are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may re-commence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.***							
9035M	***Injection set containing 4 vials powder for injection 25 mg and 4 pre-filled syringes solvent 1 mL***	***2***	***3***	***..***	**** 1828.57***	***32.90***	***Enbrel***	***WX***
9083C	***Injection set containing 4 vials powder for injection 50 mg and 4 pre-filled syringes solvent 1 mL***	***1***	***3***	***..***	***1773.94***	***32.90***	***Enbrel***	***WX***
9087G	***Injections 50 mg in 1 mL single use pre-filled syringes, 4***	***1***	***3***	***..***	***1773.94***	***32.90***	***Enbrel***	***WX***
	NOTE: ***No applications for increased maximum quantities and/or repeats will be authorised.***							
	Authority Required ***Initial 3*** ***Initial PBS-subsidised supply for continuing treatment with etanercept, by a rheumatologist or clinical immunologist with expertise in the management of psoriatic arthritis, of adults who:*** ***(1) have a documented history of severe active psoriatic arthritis; and*** ***(2) were receiving treatment with etanercept prior to 17 March 2005; and*** ***(3) have demonstrated a response as specified in the criteria for continuing PBS-subsidised treatment with etanercept.*** ***The authority application must be made in writing and must include:*** ***(1) a completed authority prescription form; and*** ***(2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and*** ***(3) a copy of the signed patient acknowledgement form which is included in the Supporting Information Form. Completion of this form declares that the patient understands and acknowledges that PBS-subsidised treatment will cease if they do not demonstrate the response to treatment required to support continuation of PBS-subsidised treatment at any assessment where a response must be demonstrated.*** ***A maximum of 24 weeks of treatment with etanercept will be authorised under this restriction.*** ***Where fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).***							

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ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
	Patients who fail to demonstrate a response to treatment with etanercept under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug, in this Treatment Cycle.							
	Patients may qualify for PBS-subsidised treatment under this restriction once only.							
	Authority Required							
	Continuing treatment							
	Continuing PBS-subsidised treatment with etanercept, by a rheumatologist or clinical immunologist with expertise in the management of psoriatic arthritis, of adults:							
	(1) who have a documented history of severe active psoriatic arthritis; and							
	(2) whose most recent course of PBS-subsidised biological agent for this condition in the current Treatment Cycle was with etanercept; and							
	(3) who, at the time of application, demonstrate an adequate response to treatment with etanercept.							
	An adequate response to treatment with etanercept is defined as:							
	an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following:							
	(i) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or							
	(ii) a reduction in the number of the following major active joints, from at least 4, by at least 50%:							
	— elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or							
	— shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).							
	The authority application must be made in writing and must include:							
	(1) a completed authority prescription form; and							
	(2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].							
	All applications for continuing treatment with etanercept must include a measurement of response to the prior course of therapy. This assessment must be provided to Medicare Australia no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with etanercept, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with the initial treatment course.							
	Where fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).							
	Patients who fail to demonstrate a response to treatment with etanercept under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug, in this Treatment Cycle.							
	Once patients fail to respond to treatment with 3 biological agents, they are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may re-commence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.							
9036N	***Injection set containing 4 vials powder for injection 25 mg and 4 pre-filled syringes solvent 1 mL***	***2***	***5***	***..***	**** 1828.57***	***32.90***	***Enbrel***	***WX***
9084D	***Injection set containing 4 vials powder for injection 50 mg and 4 pre-filled syringes solvent 1 mL***	***1***	***5***	***..***	***1773.94***	***32.90***	***Enbrel***	***WX***

continued ☞

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
9088H	***Injections 50 mg in 1 mL single use pre-filled syringes, 4***	***1***	***5***	***..***	***1773.94***	***32.90***	***Enbrel***	***WX***

NOTE:

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

NOTE:

TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying anti-rheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, etanercept, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-1 inhibitor (anakinra) and the T-cell co-stimulation modulator (abatacept).

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

PBS-subsidised infliximab, anakinra, rituximab and abatacept must be used in combination with methotrexate at a dose of at least 7.5 mg weekly. Where a patient cannot tolerate 7.5 mg of methotrexate weekly, they are only eligible to receive PBS-subsidised etanercept and adalimumab.

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

From 1 March 2008, under the PBS, all patients will be able to commence a Treatment Cycle where they may trial PBS-subsidised bDMARD agents without having to experience a disease flare when swapping to an alternate agent. Under these interchangeability arrangements, within a single Treatment Cycle, a patient may continue to receive long-term treatment with a bDMARD while they continue to show a response to therapy.

A patient who received PBS-subsidised bDMARD treatment prior to 1 March 2008 is considered to be in their first Cycle as of 1 March 2008.

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

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a Treatment Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised bDMARD therapy before they are eligible to commence the next Cycle.

For patients who have failed PBS-subsidised treatment with 3 bDMARDs prior to 1 March 2008 please contact Medicare Australia on 1800 700 270.

The 5-year break is measured from the date of the last approval for PBS-subsidised bDMARD treatment in the most recent Cycle to the date of the first application for initial treatment with a bDMARD under the new Treatment Cycle.

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

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

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

If patients fail to respond to a particular bDMARD within a single Treatment Cycle, they are not eligible to receive further PBS-subsidised treatment with that drug until they commence the next Cycle.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 March 2008.

continued ☞

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer

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

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for etanercept, adalimumab, anakinra and abatacept, 22 weeks of therapy for infliximab and 2 infusions of rituximab.

From 1 March 2008, a patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to Medicare Australia within 4 weeks.

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

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

Rituximab patients:
A further application may be submitted to Medicare Australia 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

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

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

Assessments of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Rituximab patients:
A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.

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

(2) Swapping therapy.

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

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ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer

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

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

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

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

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

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

NOTE:

(3) Baseline measurements to determine response.

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

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

The baseline joint and blood counts should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment.

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

A patient who wishes to trial a second or subsequent Treatment Cycle following a break in PBS-subsidised bDMARD therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have received treatment with at least 1 non-biological DMARD, at an adequate dose, for a minimum of 3 months at the time the ESR and/or CRP levels and the active joint count are measured.

(5) Patients 'grandfathered' onto PBS-subsidised treatment with rituximab or abatacept.

From 1 March 2008, a patient who commenced treatment with rituximab for severe rheumatoid arthritis prior to 7 March 2007 or abatacept for severe rheumatoid arthritis prior to 1 November 2007 and who was 'grandfathered' on to PBS-subsidised therapy, and who continues to receive treatment in the same Treatment Cycle, will have further applications for treatment with rituximab or abatacept assessed under the continuing treatment restriction.

continued ☞

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer

A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment with abatacept will be authorised under this criterion.

'Grandfather' arrangements will only apply for the first Treatment Cycle. For the second and subsequent Cycles, a 'grandfather' patient must requalify for initial treatment under the criteria that applies to a new patient. See 'Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' above for further details.

Authority Required

Initial 1 (new patients)
Application for initial PBS-subsidised treatment with etanercept, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of adults who:
(a) have severe active rheumatoid arthritis; and
(b) have received no prior PBS-subsidised treatment with a bDMARD for this condition in this treatment cycle; and
(c) have failed to achieve an adequate response to the following treatments:
(i) methotrexate at a dose of at least 20 mg weekly; and
(ii) methotrexate (at a minimum dose of 7.5 mg weekly), in combination with 2 other non-biological disease modifying anti-rheumatic drugs (DMARDs), for a minimum of 3 months; and
(iii) a minimum of 3 months' treatment with:
— leflunomide alone; or
— leflunomide in combination with methotrexate; or
— cyclosporin.

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of the accepted toxicities, including severity, can be found on the Medicare Australia website [www.medicareaustralia.gov.au].

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

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.

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

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ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer

The authority application must be made in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes details of the patient's ESR and CRP measurements and the patient's active joint count which must have been assessed no earlier than 1 month prior to the date of application; and
(3) a signed patient acknowledgement.

A maximum of 16 weeks of treatment will be authorised under this restriction.

Where fewer than 3 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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

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

Authority Required

Initial 2 (change or re-commencement)
Application for an initial course of PBS-subsidised treatment with etanercept, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of adults who:
(a) have a documented history of severe active rheumatoid arthritis; and
(b) have received prior PBS-subsidised bDMARD treatment for this condition in this treatment cycle and are eligible to receive further bDMARD therapy.

The authority application must be made in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].

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

A maximum of 16 weeks of treatment will be authorised under this restriction.

Where fewer than 3 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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

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ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer

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

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

Authority Required

Initial treatment, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of patients aged 18 years or older with a documented history of severe active polyarticular course juvenile chronic arthritis with onset prior to the age of 18 years; AND
(a) who have signed a patient agreement form indicating that they understand and acknowledge that PBS-subsidised treatment will cease if the predetermined response criteria do not support continuation of PBS-subsidised treatment; AND
(b) who have failed to achieve an adequate response to methotrexate at a dose of at least 20 mg weekly; AND
(c) who have failed to achieve an adequate response to methotrexate, in combination with 2 other disease modifying anti-rheumatic drugs (DMARDs), for a minimum of 3 months; AND
(d) who have subsequently failed to achieve an adequate response following a minimum of 3 months' treatment with:

(i) leflunomide alone; or
(ii) leflunomide in combination with methotrexate; or
(iii) cyclosporin.

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, or intolerance of a severity necessitating permanent treatment withdrawal develops during the relevant period of use, the patient is exempted from demonstrating an inadequate response to the above treatment regimens. Details of the contraindication or intolerance, including the degree of toxicity, must be provided at the time of application.

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

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

The authority application must be in writing and must include sufficient information to determine the patient's eligibility according to the above criteria. The date of joint assessment must be provided.

Where fewer than 3 repeats are requested at the time of the initial authority application, authority approvals for sufficient repeats to complete a maximum of 4 months of treatment may be requested by telephone. Under no circumstances will telephone approvals be granted for initial or continuing authority applications, or for treatment that would otherwise extend the initial treatment period beyond 4 months.

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ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
	The assessment of the patient's response to the initial course of treatment should be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. Applications for continuing treatment with etanercept should be made prior to the completion of 16 weeks of treatment to ensure continuity for those patients who meet the criteria.							
8637N	***Injection set containing 4 vials powder for injection 25 mg and 4 pre-filled syringes solvent 1 mL***	***2***	***3***	***..***	**** 1828.57***	***32.90***	***Enbrel***	***WX***
8861J	***Injection set containing 4 vials powder for injection 50 mg and 4 pre-filled syringes solvent 1 mL***	***1***	***3***	***..***	***1773.94***	***32.90***	***Enbrel***	***WX***
9089J	***Injections 50 mg in 1 mL single use pre-filled syringes, 4***	***1***	***3***	***..***	***1773.94***	***32.90***	***Enbrel***	***WX***

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

Authority Required

Continuing treatment

Continuing PBS-subsidised treatment with etanercept, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of adults:
(a) who have a documented history of severe active rheumatoid arthritis; and
(b) who have demonstrated an adequate response to treatment with etanercept; and
(c) whose most recent course of PBS-subsidised bDMARD treatment in this treatment cycle was with etanercept.

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

The authority application must be made in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].

A maximum of 24 weeks of treatment will be approved under this restriction.

Where fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
	All applications for continuing treatment with etanercept must include a measurement of response to the prior course of therapy. This assessment must be provided to Medicare Australia no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with etanercept, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.							
	Patients who fail to demonstrate a response to treatment with etanercept under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug, in this treatment cycle. Patients may re-trial etanercept after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised bDMARD was approved in this cycle and the date of the first application under the new cycle.							
	Authority Required ***Initial PBS-subsidised supply for continuing treatment, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of patients aged 18 years or older with a documented history of severe active polyarticular course juvenile chronic arthritis with onset prior to the age of 18 years, and who were receiving treatment with etanercept prior to 1 December 2002; AND*** ***(a) who have signed a patient agreement form indicating that they understand and acknowledge that PBS-subsidised treatment will cease if the predetermined response criteria do not support continuation of PBS-subsidised treatment; AND*** ***(b) who have demonstrated a response as specified in the criteria for continuing PBS-subsidised treatment with etanercept.*** ***The authority application must be in writing and must include sufficient information to determine the patient's eligibility. The date of assessment of the patient must be provided.***							
	Authority Required ***Continuing PBS-subsidised treatment, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of patients aged 18 years or older with a documented history of severe active polyarticular course juvenile chronic arthritis with onset prior to the age of 18 years, who, at the time of application, demonstrate an adequate response to treatment with etanercept as manifested by:*** ***an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND 1 or more of the following:*** ***(i) an active joint count of fewer than 10 active (swollen and tender) joints; or*** ***(ii) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or*** ***(iii) a reduction in the number of the following active joints, from at least 4, by at least 50%:*** ***— elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or*** ***— shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).*** ***All authority applications for continuing treatment with etanercept must be in writing and must include sufficient information to determine the patient's response according to the above criteria. The date of assessment of the patient must be provided.*** ***Patients who fail to demonstrate an adequate response, as specified in the criteria for continuing treatment with etanercept, will not be eligible to recommence treatment with etanercept within 12 months of the date on which treatment was ceased.*** ***Where re-treatment with etanercept after a break in PBS-subsidised treatment with the drug is being sought, the reason for and date of cessation of the previous treatment course with etanercept must be included in the application.***							
8638P	***Injection set containing 4 vials powder for injection 25 mg and 4 pre-filled syringes solvent 1 mL***	***2***	***5***	***..***	**** 1828.57***	***32.90***	***Enbrel***	***WX***

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ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
8862K	***Injection set containing 4 vials powder for injection 50 mg and 4 pre-filled syringes solvent 1 mL***	***1***	***5***	***..***	***1773.94***	***32.90***	***Enbrel***	***WX***
9090K	***Injections 50 mg in 1 mL single use pre-filled syringes, 4***	***1***	***5***	***..***	***1773.94***	***32.90***	***Enbrel***	***WX***

NOTE:
No applications for increased maximum quantities and/or repeats will be authorised.
NOTE:
TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents efalizumab, etanercept and infliximab, for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological agents' appears in the following NOTES and restrictions, it only refers to efalizumab, etanercept and infliximab.

From 1 December 2007, all patients will be able to commence a 'Biological Treatment Cycle' (Cycle), where they may trial efalizumab, etanercept or infliximab without having to meet the initial treatment criteria, that is they will not need to experience a disease flare when swapping to an alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

A patient who received PBS-subsidised biological agent treatment for chronic plaque psoriasis prior to 1 December 2007 is considered to be in their first Cycle as of 1 December 2007.

Patients are eligible for PBS-subsidised treatment with only 1 biological agent at any 1 time.

Within the same Treatment Cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for a PBS-subsidised biological agent, they must change to an alternate agent if they wish to continue PBS-subsidised biological treatment. A patient who, prior to 1 December 2007, was authorised to receive PBS-subsidised initial treatment for chronic plaque psoriasis with the same agent twice, is exempt from this condition in respect of applications approved prior to 1 December 2007.

Initial treatment with efalizumab consists of 16 weeks of therapy, with infliximab consists of 22 weeks of therapy, and with etanercept consists of 12 weeks of active therapy followed by a biological treatment-free period of at least 12 weeks. Response to treatment for all 3 agents must be assessed after 12 weeks of treatment.

Following demonstration of response to initial treatment, these biological agents are available as continuing therapy. Ongoing access to continuing treatment is available for as long as the response to therapy is sustained. In the case of efalizumab and infliximab, continuing treatment consists of 24 weeks of continuous active treatment. In the case of etanercept, continuing treatment consists of 12 weeks of active therapy followed by a biological treatment-free period of at least 12 weeks.

Patients must be assessed for response to each course of continuing treatment according to the criteria included in the relevant continuing treatment restriction.

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

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

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ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer

Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle.

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

How to prescribe biological agents for the treatment of severe chronic plaque psoriasis after 1 December 2007.

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Application for approval for initial treatment.

Applications for a course of initial treatment should be made in the following situations:
(i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); and
(ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under '(4) Swapping therapy' below]; and
(iii) patients who wish to re-commence treatment following a break in PBS-subsidised therapy with that agent (Initial 2).

All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 16 weeks of therapy in the case of efalizumab, 12 weeks of therapy in the case of etanercept, and 22 weeks of treatment in the case of infliximab. Approval will be based on the criteria included in the relevant initial treatment restriction.

Grandfather patients (Infliximab only).

Applications for patients who commenced treatment with infliximab prior to 7 March 2007, may apply for initial PBS-subsidised treatment as continuing therapy under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with a biological agent prior to PBS listing of that agent.

Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment. Approval will be based on the criteria included in the relevant restriction.

(2) Assessment of response to initial treatment.

When prescribing efalizumab or infliximab, where the initial treatment course is for 16 or 22 weeks respectively, a PASI assessment must be conducted after at least 12 weeks of treatment. This assessment must be submitted to Medicare Australia within 1 month of the completion of this initial treatment course. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with efalizumab or infliximab. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

Applications for continuing treatment with efalizumab or infliximab must also be submitted to Medicare Australia prior to the completion of this initial course of therapy to ensure continuity of treatment for those patients who meet the continuation criterion and wish to continue on treatment with either efalizumab or infliximab.

When prescribing etanercept, a PASI assessment must be conducted at the completion of the 12 week initial treatment course. This assessment, which will be used to determine eligibility for future treatment according to the criterion included in the relevant continuing treatment restriction, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with etanercept. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

(3) Application for continuing treatment.

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ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer

As stated above, following the completion of an initial treatment course of efalizumab or infliximab to which an adequate response has been demonstrated, patients may qualify to receive up to 24 weeks of continuing treatment with efalizumab or infliximab. Patients are eligible to continue to receive continuous treatment with efalizumab or infliximab in 24 week courses providing they continue to sustain a response.

For second and subsequent courses of PBS-subsidised treatment with efalizumab or infliximab it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

At the completion of an initial 12 week treatment course of etanercept to which an adequate response has been demonstrated, followed by a biological treatment-free period of at least 12 weeks, patients may qualify to receive continuing treatment with etanercept. Continuing treatment is available in the form of 12 weeks of active etanercept treatment followed by a biological treatment-free period of at least 12 weeks. Patients are eligible to receive continuing treatment with etanercept on this cyclical basis, for as long as they continue to sustain a response. Continuing applications must be submitted at least 12 weeks after cessation of the most recent course of etanercept treatment.

A PASI assessment must be conducted for each course of continuing treatment for each biological agent, according to the requirements set out in the relevant restriction. Assessment of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia no later than 1 month from the date that course was completed or treatment was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to sustain a response to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

NOTE:

(4) Swapping therapy.

Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate agent within the same Treatment Cycle without having to requalify with respect to disease severity (i.e. a PASI score of greater than 15), or prior treatment requirements.

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

Patients may trial an alternate biological agent at any time, regardless of whether they are receiving therapy with a biological agent at the time of the application or not. However, they cannot swap to a particular agent if they have failed to respond to treatment with that particular agent in the same Cycle.

Patients who commenced treatment with infliximab prior to 7 March 2007 access these interchangeability arrangements in the same way as patients who have not.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required 12 week biological treatment-free period applying to patients who have demonstrated a response to their most recent course of etanercept. This means that patients who have demonstrated a response to a 12 week course of etanercept must have a PBS-subsidised biological therapy treatment-free period of at least 12 weeks, immediately following this course of treatment, before swapping to efalizumab or infliximab. Patients who fail to respond to etanercept and who qualify and wish to try a course of efalizumab or infliximab, may do so without having to have any treatment-free period.

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

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

(5) Baseline measurements to determine response.

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ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer

Medicare Australia will determine whether a response to treatment has been demonstrated, based on the baseline PASI assessment submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment authority is submitted within a Treatment Cycle and subsequent response will be assessed according to this revised PASI score.

For new patients and patients commencing a new Cycle, the first baseline PASI assessment must be conducted, preferably while the patient is still receiving their most recent prior therapy, but no later than 1 month following cessation of such therapy, as outlined in the relevant restriction. This is not required for any subsequent PASI scores provided for these patients within the same Cycle, nor for patients who received initial PBS-subsidised therapy under a 'grandfather' restriction.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatment applications.

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

Patients who wish to trial a second or subsequent Biological Treatment Cycle, following a break in PBS-subsidised biological therapy of at least 5 years, must requalify for initial treatment according to the criteria of the relevant restriction and index of disease severity. Patients must have had at least 1 prior treatment, as listed in the criteria, for a minimum of 6 weeks, and must have a PASI assessment conducted preferably whilst still on treatment, but no later than 1 month following cessation of treatment. The PASI assessment must be no older than 1 month at the time of application.

Authority Required

Initial treatment [Initial 1, Whole body (New patients — No prior biological agent)]
Initial treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over who:
(a) have severe chronic plaque psoriasis where lesions have been present for at least 6 months from the time of initial diagnosis; and
(b) have not received any prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle; and
(c) have signed a patient acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment (whole body); and
(d) have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 3 of the following 4 treatments:
(i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; and/or
(ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; and/or
(iii) cyclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; and/or
(iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks.

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity to necessitate permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of acceptable toxicities including severity, associated with phototherapy, methotrexate, cyclosporin and acitretin, can be found on the Medicare Australia website (www.medicareaustralia.gov.au).

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ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer

The following initiation criterion indicates failure to achieve an adequate response and must be demonstrated in all patients at the time of the application:
(a) A current Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.
(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 1 month following cessation of each course of treatment.
(c) The most recent PASI assessment must be no more than 1 month old at the time of application.

Applications for authorisation must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and
(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy]; and
(iii) the signed patient acknowledgement.

A maximum of 12 weeks of treatment with etanercept will be authorised under this restriction.

Where fewer than 2 repeats are requested at the time of the authority application, authority approvals for sufficient repeats to complete a maximum of 12 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period beyond 12 weeks.

A PASI assessment of the patient's response must be made at the completion of this 12 week initial treatment course. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with etanercept. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

Patients who demonstrate a response to treatment according to the response criterion included in the continuing treatment restriction for etanercept, may access continuing treatment with etanercept following a biological treatment-free period of at least 12 weeks.

Patients who fail to demonstrate such a response to etanercept treatment may trial an alternate biological agent according to the interchangeability arrangements for biological agents for the treatment of severe chronic plaque psoriasis, without having to have a 12 week treatment-free period before doing so.

Authority Required

Initial or re-Treatment [Initial 2, Whole body (Received prior biological agent under PBS)]
Treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over who:
(a) have a documented history of severe chronic plaque psoriasis; and
(b) have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle; and
(c) have not failed PBS-subsidised therapy with etanercept for the treatment of this condition in the current Treatment Cycle.

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ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer

Applications for authorisation must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and
(ii) details of prior biological treatment, including dosage, date and duration of treatment.

Applications for patients who have demonstrated a response to PBS-subsidised etanercept treatment within this Treatment Cycle and who wish to re-commence etanercept treatment within the same Cycle following a break in therapy, will only be approved where evidence of the patient's response to their most recent course of PBS-subsidised etanercept treatment has been submitted to Medicare Australia within 1 month of cessation of treatment.

A maximum of 12 weeks of treatment with etanercept will be authorised under this restriction.

Where fewer than 2 repeats are requested at the time of the authority application, authority approvals for sufficient repeats to complete a maximum of 12 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period beyond 12 weeks.

A PASI assessment of the patient's response must be made at the completion of this 12 week course of treatment. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with etanercept. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

Patients who demonstrate a response to treatment according to the response criterion included in the continuing treatment restriction for etanercept, may access continuing treatment with etanercept following a biological treatment-free period of at least 12 weeks.

Patients who fail to demonstrate such a response to etanercept treatment and who qualify to trial an alternate biological agent according to the interchangeability arrangements for biological agents for the treatment of severe chronic plaque psoriasis, may do so without having to have a 12 week treatment-free period.

Patients who fail to demonstrate a response to treatment with each of the biological agents, efalizumab, etanercept and infliximab, are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may re-commence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

Authority Required

Continuing treatment (Whole body)
Continuing PBS-subsidised treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over:
(a) who have a documented history of severe chronic plaque psoriasis; and
(b) whose most recent course of PBS-subsidised biological treatment for this condition in this Treatment Cycle was with etanercept; and
(c) who have demonstrated an adequate response to their most recent course of treatment with etanercept.

An adequate response to treatment is defined as:
A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the pre-biological treatment baseline value for this Treatment Cycle.

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ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer

This assessment must be after 12 weeks of etanercept treatment and must be provided to Medicare Australia no later than 4 weeks from the cessation of that treatment course.

Applications for authorisation must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
(i) the completed Psoriasis Area and Severity Index (PASI) calculation sheet along with the date of the assessment of the patient's condition.

Approval will be based on the PASI assessment of response to the most recent course of treatment with etanercept.

A maximum of 12 weeks of treatment with etanercept will be authorised under this restriction.

Where fewer than 2 repeats are requested at the time of the authority application, authority approvals for sufficient repeats to complete a maximum of 12 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for continuing authority applications, or for treatment that would otherwise extend the treatment period beyond 12 weeks.

A PASI assessment of the patient's response must be made at the completion of each 12 week active treatment course. This assessment must be submitted to Medicare Australia no later than 1 month from the date of completion of this course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with etanercept. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

Patients who demonstrate a response to treatment according to the response criterion included in this restriction, may access further continuing treatment with etanercept, following a biological treatment-free period of at least 12 weeks.

Continuing treatment is available in the form of 12 weeks of active etanercept treatment followed by a biological treatment-free period of at least 12 weeks. Patients are eligible to receive continuing treatment with etanercept on this cyclical basis, for as long as they continue to sustain a response. Continuing applications for treatment must be submitted at least 12 weeks after cessation of the most recent course of etanercept treatment.

Patients who fail to demonstrate such a response to etanercept treatment and who qualify to trial an alternate biological agent according to the interchangeability arrangements for biological agents for the treatment of severe chronic plaque psoriasis, may do so without having to have a 12 week treatment-free period.

Patients who fail to demonstrate a response to treatment with each of the biological agents, efalizumab, etanercept and infliximab, are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may re-commence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

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ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer

Authority Required

Initial treatment [Initial 1, Face, hand, foot (New patients — No prior biological agent)]
Initial treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over who:
(a) have severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis; and
(b) have not received any prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle; and
(c) have signed a patient acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment (face, hand, foot); and
(d) have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 3 of the following 4 treatments:
(i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; and/or
(ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; and/or
(iii) cyclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; and/or
(iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks.

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity to necessitate permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of acceptable toxicities including severity, associated with phototherapy, methotrexate, cyclosporin and acitretin, can be found on the Medicare Australia website (www.medicareaustralia.gov.au).

The following initiation criterion indicates failure to achieve an adequate response and must be demonstrated in all patients at the time of the application:
(a) Chronic plaque psoriasis classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where:
(i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment; or
(ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.
(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 1 month following cessation of each course of treatment.
(c) The most recent PASI assessment must be no more than 1 month old at the time of application.

Applications for authorisation must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and
(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy]; and
(iii) the signed patient acknowledgement.

A maximum of 12 weeks of treatment with etanercept will be authorised under this restriction.

continued ☞

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer

Where fewer than 2 repeats are requested at the time of the authority application, authority approvals for sufficient repeats to complete a maximum of 12 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period beyond 12 weeks.

A PASI assessment of the patient's response must be made at the completion of this 12 week initial treatment course. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with etanercept. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

Patients who demonstrate a response to treatment according to the response criterion included in the continuing treatment restriction for etanercept, may access continuing treatment with etanercept following a biological treatment-free period of at least 12 weeks.

Patients who fail to demonstrate such a response to etanercept treatment may trial an alternate biological agent according to the interchangeability arrangements for biological agents for the treatment of severe chronic plaque psoriasis, without having to have a 12 week treatment-free period before doing so.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

Authority Required

Initial or re-Treatment [Initial 2, Face, hand, foot (Received prior biological agent under PBS)]
Treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over who:
(a) have a documented history of severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot; and

(b) have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle; and
(c) have not failed PBS-subsidised therapy with etanercept for the treatment of this condition in the current Treatment Cycle.

Applications for authorisation must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and
(ii) details of prior biological treatment, including dosage, date and duration of treatment.

Applications for patients who have demonstrated a response to PBS-subsidised etanercept treatment within this Treatment Cycle and who wish to re-commence etanercept treatment within the same Cycle following a break in therapy, will only be approved where evidence of the patient's response to their most recent course of PBS-subsidised etanercept treatment has been submitted to Medicare Australia within 1 month of cessation of treatment.

A maximum of 12 weeks of treatment with etanercept will be authorised under this restriction.

Where fewer than 2 repeats are requested at the time of the authority application, authority approvals for sufficient repeats to complete a maximum of 12 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period beyond 12 weeks.

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ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer

A PASI assessment of the patient's response must be made at the completion of this 12 week treatment course. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with etanercept. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

Patients who demonstrate a response to treatment according to the response criterion included in the continuing treatment restriction for etanercept, may access continuing treatment with etanercept following a biological treatment-free period of at least 12 weeks.

Patients who fail to demonstrate such a response to etanercept treatment and who qualify to trial an alternate biological agent according to the interchangeability arrangements for biological agents for the treatment of chronic plaque psoriasis, may do so without having to have a 12 week treatment-free period.

The PASI assessment for continuing treatment must be performed on the same affected area assessed at baseline.

Patients who fail to demonstrate a response to treatment with each of the biological agents, efalizumab, etanercept and infliximab, are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may re-commence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

Authority Required

Continuing treatment (Face, hand, foot)
Continuing PBS-subsidised treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over:
(a) who have a documented history of severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot; and
(b) whose most recent course of PBS-subsidised biological treatment for this condition in this Treatment Cycle was with etanercept; and
(c) who have demonstrated an adequate response to treatment with etanercept.

An adequate response to etanercept treatment is defined as the plaque or plaques assessed prior to biological treatment showing:
(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the pre-biological treatment baseline values; or
(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the pre-biological treatment baseline value.

This assessment must be made after 12 weeks of etanercept treatment and must be provided to Medicare Australia no later than 4 weeks from the cessation of that treatment course.

Applications for authorisation must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
(i) the completed Psoriasis Area and Severity Index (PASI) calculation sheet and face, hand, foot area diagrams along with the date of the assessment of the patient's condition [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].

A maximum of 12 weeks of treatment with etanercept will be authorised under this restriction.

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ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
	Where fewer than 2 repeats are requested at the time of the authority application, authority approvals for sufficient repeats to complete a maximum of 12 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for continuing authority applications, or for treatment that would otherwise extend the treatment period beyond 12 weeks.							
	A PASI assessment of the patient's response must be made at the completion of each 12 week active treatment course. This assessment must be submitted to Medicare Australia no later than 1 month from the date of completion of this course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with etanercept. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.							
	Patients who demonstrate a response to treatment according to the response criterion included in this restriction, may access further continuing treatment with etanercept, following a biological treatment-free period of at least 12 weeks.							
	Continuing treatment is available in the form of 12 weeks of active etanercept treatment followed by a biological treatment-free period of at least 12 weeks. Patients are eligible to receive continuing treatment with etanercept on this cyclical basis, for as long as they continue to sustain a response. Continuing applications can only be submitted at least 12 weeks after cessation of the most recent course of etanercept treatment.							
	Patients who fail to demonstrate such a response to etanercept treatment and who qualify to trial an alternate biological agent according to the interchangeability arrangements for biological agents for the treatment of severe chronic plaque psoriasis, may do so without having to have a 12 week treatment-free period.							
	The PASI assessment for continuing treatment must be performed on the same affected area assessed at baseline.							
	Patients who fail to demonstrate a response to treatment with each of the biological agents, efalizumab, etanercept and infliximab, are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may re-commence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.							
9037P	***Injection set containing 4 vials powder for injection 25 mg and 4 pre-filled syringes solvent 1 mL***	***2***	***2***	***..***	**** 1828.57***	***32.90***	***Enbrel***	***WX***
9038Q	***Injection set containing 4 vials powder for injection 50 mg and 4 pre-filled syringes solvent 1 mL***	***1***	***2***	***..***	***1773.94***	***32.90***	***Enbrel***	***WX***
9091L	***Injections 50 mg in 1 mL single use pre-filled syringes, 4***	***1***	***2***	***..***	***1773.94***	***32.90***	***Enbrel***	***WX***
	NOTE: ***No applications for increased maximum quantities and/or repeats will be authorised.***							

• *Interleukin inhibitors*

ANAKINRA

NOTE:

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

Written applications for authority to prescribe anakinra should be forwarded to:

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ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer

Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

Further prescribing information is on the Medicare Australia website at www.medicareaustralia.gov.au.

NOTE:
TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying anti-rheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, etanercept, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-1 inhibitor (anakinra) and the T-cell co-stimulation modulator (abatacept).

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

PBS-subsidised infliximab, anakinra, rituximab and abatacept must be used in combination with methotrexate at a dose of at least 7.5 mg weekly. Where a patient cannot tolerate 7.5 mg of methotrexate weekly, they are only eligible to receive PBS-subsidised etanercept and adalimumab.

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

From 1 March 2008, under the PBS, all patients will be able to commence a Treatment Cycle where they may trial PBS-subsidised bDMARD agents without having to experience a disease flare when swapping to an alternate agent. Under these interchangeability arrangements, within a single Treatment Cycle, a patient may continue to receive long-term treatment with a bDMARD while they continue to show a response to therapy.

A patient who received PBS-subsidised bDMARD treatment prior to 1 March 2008 is considered to be in their first Cycle as of 1 March 2008.

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

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a Treatment Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised bDMARD therapy before they are eligible to commence the next Cycle.

For patients who have failed PBS-subsidised treatment with 3 bDMARDs prior to 1 March 2008 please contact Medicare Australia on 1800 700 270.

The 5-year break is measured from the date of the last approval for PBS-subsidised bDMARD treatment in the most recent Cycle to the date of the first application for initial treatment with a bDMARD under the new Treatment Cycle.

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

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

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

If patients fail to respond to a particular bDMARD within a single Treatment Cycle, they are not eligible to receive further PBS-subsidised treatment with that drug until they commence the next Cycle.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 March 2008.

continued ☞

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer

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

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for etanercept, adalimumab, anakinra and abatacept, 22 weeks of therapy for infliximab and 2 infusions of rituximab.

From 1 March 2008, a patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to Medicare Australia within 4 weeks.

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

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

Rituximab patients:
A further application may be submitted to Medicare Australia 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

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

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

Assessments of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Rituximab patients:
A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.

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

(2) Swapping therapy.

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

continued ☞

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer

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

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

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

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

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

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

NOTE:

(3) Baseline measurements to determine response.

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

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

The baseline joint and blood counts should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment.

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

A patient who wishes to trial a second or subsequent Treatment Cycle following a break in PBS-subsidised bDMARD therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have received treatment with at least 1 non-biological DMARD, at an adequate dose, for a minimum of 3 months at the time the ESR and/or CRP levels and the active joint count are measured.

(5) Patients 'grandfathered' onto PBS-subsidised treatment with rituximab or abatacept.

From 1 March 2008, a patient who commenced treatment with rituximab for severe rheumatoid arthritis prior to 7 March 2007 or abatacept for severe rheumatoid arthritis prior to 1 November 2007 and who was 'grandfathered' on to PBS-subsidised therapy, and who continues to receive treatment in the same Treatment Cycle, will have further applications for treatment with rituximab or abatacept assessed under the continuing treatment restriction.

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ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer

A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment with abatacept will be authorised under this criterion.

'Grandfather' arrangements will only apply for the first Treatment Cycle. For the second and subsequent Cycles, a 'grandfather' patient must requalify for initial treatment under the criteria that applies to a new patient. See 'Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' above for further details.

Authority Required

Initial 1 (new patients)
Application for initial PBS-subsidised treatment with anakinra, in combination with methotrexate at a dose of at least 7.5 mg weekly, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of adults who:
(a) have severe active rheumatoid arthritis; and
(b) have received no prior PBS-subsidised treatment with a bDMARD for this condition in this treatment cycle; and
(c) have failed to achieve an adequate response to the following treatments:
(i) methotrexate at a dose of at least 20 mg weekly; and
(ii) methotrexate (at a minimum dose of 7.5 mg weekly), in combination with 2 other non-biological disease modifying anti-rheumatic drugs (DMARDs), for a minimum of 3 months; and
(iii) a minimum of 3 months' treatment with:
— leflunomide alone; or
— leflunomide in combination with methotrexate; or
— cyclosporin.

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of the accepted toxicities, including severity, can be found on the Medicare Australia website [www.medicareaustralia.gov.au].

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

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.

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

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ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer

The authority application must be made in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes details of the patient's ESR and CRP measurements and the patient's active joint count which must have been assessed no earlier than 1 month prior to the date of application; and
(3) a signed patient acknowledgement.

A maximum of 16 weeks of treatment will be authorised under this restriction.

Where fewer than 3 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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

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

Authority Required

Initial 2 (change or re-commencement)
Application for an initial course of PBS-subsidised treatment with anakinra, in combination with methotrexate at a dose of at least 7.5 mg weekly, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of adults who:
(a) have a documented history of severe active rheumatoid arthritis; and
(b) have received prior PBS-subsidised bDMARD treatment for this condition in this treatment cycle and are eligible to receive further bDMARD therapy.

The authority application must be made in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].

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

A maximum of 16 weeks of treatment will be authorised under this restriction.

Where fewer than 3 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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

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ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
	Where the most recent course of PBS-subsidised anakinra treatment was approved under the continuing treatment criteria, patients must have been assessed for response, and the assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.							
	Patients who fail to demonstrate a response to treatment with anakinra under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug, in this treatment cycle. Patients may re-trial anakinra after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised bDMARD was approved in this cycle and the date of the first application under the new cycle.							
8773R	***Injection 100 mg in 0.67 mL single use pre-filled syringe***	***28***	***3***	***..***	***1364.45***	***32.90***	***Kineret***	***AN***

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

Authority Required

Continuing treatment

Continuing PBS-subsidised treatment with anakinra, in combination with methotrexate at a dose of at least 7.5 mg weekly, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of adults:
(a) who have a documented history of severe active rheumatoid arthritis; and
(b) who have demonstrated an adequate response to treatment with anakinra; and
(c) whose most recent course of PBS-subsidised bDMARD treatment in this treatment cycle was with anakinra.

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

The authority application must be made in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].

A maximum of 24 weeks of treatment will be approved under this restriction.

Where fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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

continued ☞

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
	Patients who fail to demonstrate a response to treatment with anakinra under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug, in this treatment cycle. Patients may re-trial anakinra after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised bDMARD was approved in this cycle and the date of the first application under the new cycle.							
8774T	***Injection 100 mg in 0.67 mL single use pre-filled syringe***	***28***	***5***	***..***	***1364.45***	***32.90***	***Kineret***	***AN***

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

• *Calcineurin inhibitors*

CYCLOSPORIN
CAUTION:
Careful monitoring of patients is mandatory.

Authority Required

Maintenance therapy, following initiation and stabilisation of treatment with cyclosporin, of:

- ***(a) patients with organ or tissue transplants. Therapy must remain under the supervision and direction of the transplant unit reviewing the patient. The name of the specialised transplant unit reviewing treatment and the date of the latest review at the specialised transplant unit must be included in the authority application; or***
- ***(b) patients with severe atopic dermatitis for whom other systemic therapies are ineffective or inappropriate. Therapy must remain under the supervision and direction of a dermatologist, clinical immunologist or specialised unit reviewing the patient. The name of the dermatologist, clinical immunologist or specialised unit reviewing treatment and the date of the latest review must be included in the authority application; or***
- ***(c) patients with severe psoriasis for whom other systemic therapies are ineffective or inappropriate and in whom the disease has caused significant interference with quality of life. Therapy must remain under the supervision and direction of a dermatologist or specialised unit reviewing the patient. The name of the dermatologist or specialised unit reviewing treatment and the date of the latest review must be included in the authority application; or***
- ***(d) patients with nephrotic syndrome in whom steroids and cytostatic drugs have failed or are not tolerated or are considered inappropriate and in whom renal function is unimpaired. Therapy must remain under the supervision and direction of a nephrologist or specialised unit reviewing the patient. The name of the nephrologist or specialised unit reviewing treatment and the date of the latest review must be included in the authority application; or***
- ***(e) patients with severe active rheumatoid arthritis for whom classical slow-acting anti-rheumatic agents (including methotrexate) are ineffective or inappropriate. Therapy must remain under the supervision and direction of a rheumatologist, clinical immunologist or specialised unit reviewing the patient. The name of the rheumatologist, clinical immunologist or specialised unit reviewing treatment and the date of the latest review must be included in the authority application;***

Management (which includes initiation, stabilisation and review of therapy) by:

- ***(a) dermatologists or clinical immunologists of patients with severe atopic dermatitis for whom other systemic therapies are ineffective or inappropriate; or***
- ***(b) dermatologists of patients with severe psoriasis for whom other systemic therapies are ineffective or inappropriate and in whom the disease has caused significant interference with quality of life; or***
- ***(c) rheumatologists or clinical immunologists of patients with severe active rheumatoid arthritis for whom classical slow-acting anti-rheumatic agents (including methotrexate) are ineffective or inappropriate.***

8657P	***Capsule 10 mg***	***120***	***3***	***..***	**** 93.99***	***32.90***	***Neoral 10***	***NV***

continued ☞

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Proprietary Name and Manufacturer	
8658Q	***Capsule 25 mg***	***60***	***3***	***..***	**** 102.49***	***32.90***	***a***	***Cicloral***	***SZ***
				B2.28	**** 104.77***	***32.90***	***a***	***Neoral 25***	***NV***
8659R	***Capsule 50 mg***	***60***	***3***	***..***	**** 206.51***	***32.90***	***a***	***Cicloral***	***SZ***
				B2.24	**** 208.75***	***32.90***	***a***	***Neoral 50***	***NV***
8660T	***Capsule 100 mg***	***60***	***3***	***..***	**** 395.87***	***32.90***	***a***	***Cicloral***	***SZ***
				B2.26	**** 398.13***	***32.90***	***a***	***Neoral 100***	***NV***
8661W	***Oral liquid 100 mg per mL, 50 mL***	***2***	***3***	***..***	**** 712.23***	***32.90***		***Neoral***	***NV***

TACROLIMUS
CAUTION:
Careful monitoring of patients is mandatory.

Authority Required

➢ ***Maintenance therapy, following initiation and stabilisation of treatment with tacrolimus, of patients with organ or tissue transplants. Therapy must remain under the supervision and direction of the transplant unit reviewing the patient. The name of the specialised transplant unit reviewing treatment and the date of the latest review at the specialised transplant unit must be included in the authority application.***

8646C	***Capsule 500 micrograms***	***100***	***3***	***..***	***225.42***	***32.90***		***Prograf***	***JC***
8647D	***Capsule 1 mg***	***100***	***3***	***..***	***426.84***	***32.90***		***Prograf***	***JC***
8648E	***Capsule 5 mg***	***50***	***3***	***..***	***1052.87***	***32.90***		***Prograf***	***JC***

• *Other immunosuppressants*

AZATHIOPRINE

2688L	Tablet 25 mg	100	2	..	36.75	32.90	a	Azahexal	SZ
				B1.19	37.94	32.90	a	Imuran	GK
2687K	Tablet 50 mg	100	2	..	56.07	32.90	a	Azahexal	SZ
							a	Azamun	GM
							a	Azapin	SI
							a	GenRx Azathioprine	GX
							a	Thioprine	AF
				B1.09	57.16	32.90	a	Imuran	GK

METHOTREXATE

1622J	Tablet 2.5 mg	30	5	..	13.11	14.14	a	Methoblastin	PH
							a	HH	
2272N	Tablet 10 mg	15	1	..	22.37	23.40		Methoblastin	PH

continued ☞

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
	METHOTREXATE							
	Restricted Benefit							
	For patients requiring doses greater than 20 mg per week.							
1623K	***Tablet 10 mg***	***50***	***2***	***..***	***47.00***	***32.90***	***Methoblastin***	***PH***

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Proprietary Name and Manufacturer	
	ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS								
	Antiinflammatory and antirheumatic products, non-steroids								
	• ***Acetic acid derivatives and related substances***								
	DICLOFENAC SODIUM								
1302M	Suppository 100 mg	40	3	..	* 24.49	25.52		Voltaren 100	NV
	DICLOFENAC SODIUM								
	Restricted Benefit								
	Chronic arthropathies (including osteoarthritis) with an inflammatory component;								
	Bone pain due to malignant disease.								
1299J	***Tablet 25 mg (enteric coated)***	***100***	***3***	***..***	**** 12.63***	***13.66***	[a]	***Chem mart Diclofenac***	***CH***
							[a]	***Clonac 25***	***AW***
							[a]	***Diclofenac-GA***	***GN***
							[a]	***Diclohexal***	***SZ***
							[a]	***Dinac***	***GM***
							[a]	***GenRx Diclofenac***	***GX***
							[a]	***Terry White Chemists Diclofenac***	***TW***
				..	***12.64***	***13.67***	[a]	***Fenac 25***	***AF***
				B1.96	**** 14.59***	***13.66***	[a]	***Voltaren 25***	***NV***
1300K	***Tablet 50 mg (enteric coated)***	***50***	***3***	***..***	***10.62***	***11.65***	[a]	***Chem mart Diclofenac***	***CH***
							[a]	***Clonac 50***	***AW***
							[a]	***Diclohexal***	***SZ***
							[a]	***Dinac***	***GM***
							[a]	***Fenac***	***AF***
							[a]	***GenRx Diclofenac***	***GX***
							[a]	***Terry White Chemists Diclofenac***	***TW***
				B1.96	***12.58***	***11.65***	[a]	***Voltaren 50***	***NV***
	INDOMETHACIN								
2757D	Suppository 100 mg	40	3	..	* 22.07	23.10		Indocid	AS

continued ☞

MUSCULO-SKELETAL SYSTEM—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Proprietary Name and Manufacturer	
	INDOMETHACIN								
	Restricted Benefit ***Chronic arthropathies (including osteoarthritis) with an inflammatory component;*** ***Bone pain due to malignant disease.***								
2454E	***Capsule 25 mg***	***100***	***3***	***..***	**** 11.65***	***12.68***	***a***	***Arthrexin***	***AF***
				B 0.92	**** 12.57***	***12.68***	***a***	***Indocid***	***AS***
	SULINDAC								
	Restricted Benefit ***Chronic arthropathies (including osteoarthritis) with an inflammatory component;*** ***Bone pain due to malignant disease.***								
2047R	***Tablet 100 mg***	***100***	***3***	***..***	**** 15.91***	***16.94***		***Aclin***	***AF***
2048T	***Tablet 200 mg***	***50***	***3***	***..***	***14.85***	***15.88***		***Aclin 200***	***AF***
	• ***Oxicams***								
	MELOXICAM **NOTE:** ***The use of meloxicam for the treatment of the following conditions is not subsidised through the PBS:*** ***(a) acute pain;*** ***(b) soft tissue injury;*** ***(c) arthrosis without an inflammatory component.***								
	Restricted Benefit ***Symptomatic treatment of osteoarthritis;*** ***Symptomatic treatment of rheumatoid arthritis.***								
8561N	***Tablet 7.5 mg***	***30***	***3***	***..***	***21.68***	***22.71***	***a***	***Chem mart Meloxicam 7.5 mg***	***CH***
							a	***GenRx Meloxicam***	***GX***
							a	***Meloxibell***	***BF***
							a	***Meloxicam-GA***	***GM***
							a	***Meloxicam Ranbaxy***	***RA***
							a	***Meloxicam Sandoz***	***SZ***
							a	***Meloxicam Winthrop***	***WA***
							a	***Movalis 7.5***	***SI***
							a	***Moxicam 7.5***	***AF***
							a	***Pharmacor Meloxicam 7.5***	***CR***
							a	***Terry White Chemists Meloxicam 7.5 mg***	***TW***
				B 1.61	***23.29***	***22.71***	***a***	***Mobic***	***BY***

continued ☞

MUSCULO-SKELETAL SYSTEM—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Proprietary Name and Manufacturer	
8562P	*Tablet 15 mg*	*30*	*3*	*..*	*28.86*	*29.89*	*a*	*Chem mart Meloxicam 15 mg*	*CH*
							a	*GenRx Meloxicam*	*GX*
							a	*Meloxibell*	*BF*
							a	*Meloxicam-GA*	*GM*
							a	*Meloxicam Ranbaxy*	*RA*
							a	*Meloxicam Sandoz*	*SZ*
							a	*Meloxicam Winthrop*	*WA*
							a	*Movalis 15*	*SI*
							a	*Moxicam 15*	*AF*
							a	*Pharmacor Meloxicam 15*	*CR*
							a	*Terry White Chemists Meloxicam 15 mg*	*TW*
				B1.63	*30.49*	*29.89*	*a*	*Mobic*	*BY*
8887R	*Capsule 7.5 mg*	*30*	*3*	*..*	*21.68*	*22.71*	*a*	*Mobic*	*BY*
							a	*Movalis 7.5*	*SI*
8888T	*Capsule 15 mg*	*30*	*3*	*..*	*28.86*	*29.89*	*a*	*Mobic*	*BY*
							a	*Movalis 15*	*SI*
	PIROXICAM								
	Restricted Benefit *Chronic arthropathies (including osteoarthritis) with an inflammatory component.*								
1895R	*Dispersible tablet 10 mg*	*50*	*3*	*..*	*12.07*	*13.10*	*a*	*Mobilis D-10*	*AF*
				B2.09	*14.16*	*13.10*	*a*	*Feldene-D*	*PF*
1896T	*Dispersible tablet 20 mg*	*25*	*3*	*..*	*11.77*	*12.80*	*a*	*Mobilis D-20*	*AF*
				B2.07	*13.84*	*12.80*	*a*	*Feldene-D*	*PF*
1897W	*Capsule 10 mg*	*50*	*3*	*..*	*12.07*	*13.10*	*a*	*Chem mart Piroxicam*	*CH*
							a	*GenRx Piroxicam*	*GX*
							a	*Mobilis 10*	*AF*
							a	*Terry White Chemists Piroxicam*	*TW*
				B2.09	*14.16*	*13.10*	*a*	*Feldene*	*PF*

continued ☞

MUSCULO-SKELETAL SYSTEM—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Proprietary Name and Manufacturer	
1898X	***Capsule 20 mg***	***25***	***3***	***..***	***11.77***	***12.80***	***a***	***Chem mart Piroxicam***	***CH***
							a	***GenRx Piroxicam***	***GX***
							a	***Mobilis 20***	***AF***
							a	***Terry White Chemists Piroxicam***	***TW***
				B2.07	***13.84***	***12.80***	***a***	***Feldene***	***PF***
	• ***Propionic acid derivatives*** IBUPROFEN								
3192B	Tablet 400 mg	30	..	..	8.76	9.79		Brufen	AB
	IBUPROFEN								
	Restricted Benefit ***Chronic arthropathies (including osteoarthritis) with an inflammatory component;*** ***Bone pain due to malignant disease.***								
3198H	***Tablet 200 mg***	***100***	***3***	***..***	**** 11.63***	***12.66***		***Rafen 200***	***AF***
3190X	***Tablet 400 mg***	***90***	***3***	***..***	**** 14.30***	***15.33***		***Brufen***	***AB***
	KETOPROFEN								
1588N	Suppository 100 mg	40	3	..	* 24.87	25.90		Orudis	SW
	KETOPROFEN								
	Restricted Benefit ***Chronic arthropathies (including osteoarthritis) with an inflammatory component.***								
1590Q	***Capsule 200 mg (sustained release)***	***28***	***3***	***..***	***19.47***	***20.50***	***a***	***Oruvail SR***	***AV***
				B2.30	***21.77***	***20.50***	***a***	***Orudis SR 200***	***SW***
	NAPROXEN								
	Restricted Benefit ***Chronic arthropathies (including osteoarthritis) with an inflammatory component;*** ***Bone pain due to malignant disease.***								
1674D	***Tablet 250 mg***	***100***	***3***	***..***	**** 13.29***	***14.32***	***a***	***Inza 250***	***AF***
				B2.34	**** 15.63***	***14.32***	***a***	***Naprosyn***	***RO***
1659H	***Tablet 500 mg***	***50***	***3***	***..***	***12.48***	***13.51***	***a***	***Inza 500***	***AF***
				B1.36	***13.84***	***13.51***	***a***	***Naprosyn***	***RO***

continued ☞

MUSCULO-SKELETAL SYSTEM—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Proprietary Name and Manufacturer	
1614Y	*Tablet 750 mg (sustained release)*	*28*	*3*	*..*	*11.95*	*12.98*	*a*	*Proxen SR 750*	*MD*
				B1.27	*13.22*	*12.98*	*a*	*Naprosyn SR750*	*RO*
1615B	*Tablet 1 g (sustained release)*	*28*	*3*	*..*	*13.94*	*14.97*	*a*	*Proxen SR 1000*	*MD*
				B1.34	*15.28*	*14.97*	*a*	*Naprosyn SR1000*	*RO*

Authority Required (STREAMLINED)

2270

Chronic arthropathies (including osteoarthritis) with an inflammatory component in patients unable to take a solid dose form of a non-steroidal anti-inflammatory agent;

2271

Bone pain due to malignant disease in patients unable to take a solid dose form of a non-steroidal anti-inflammatory agent.

1658G	*Oral suspension 125 mg per 5 mL, 474 mL*	*‡ 1*	*3*	*..*	*77.74*	*32.90*		*Naprosyn*	*RO*

NAPROXEN SODIUM

Restricted Benefit

Chronic arthropathies (including osteoarthritis) with an inflammatory component;

Bone pain due to malignant disease.

1795L	*Tablet 550 mg*	*50*	*3*	*..*	*12.67*	*13.70*	*a*	*Crysanal*	*MD*
				B2.29	*14.96*	*13.70*	*a*	*Anaprox 550*	*RO*

NOTE:

Naproxen sodium 550 mg is approximately equivalent to 500 mg of naproxen acid.

TIAPROFENIC ACID

CAUTION:

Cystitis and other urinary disorders have been reported with this drug.

NOTE:

The recommended maximum dose is 600 mg per day.

Restricted Benefit

Chronic arthropathies (including osteoarthritis) with an inflammatory component.

2103Q	*Tablet 300 mg*	*60*	*3*	*..*	*17.15*	*18.18*		*Surgam*	*SW*

• *Fenamates*

MEFENAMIC ACID

Restricted Benefit

Dysmenorrhoea;

Menorrhagia.

1824B	*Capsule 250 mg*	*50*	*2*	*..*	*17.73*	*18.76*		*Ponstan*	*PD*

MUSCULO-SKELETAL SYSTEM—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
	• *Coxibs*							
	CELECOXIB							
	NOTE:							
	The use of celecoxib for the treatment of the following conditions is not subsidised through the PBS:							
	(a) acute pain;							
	(b) soft tissue injury;							
	(c) arthrosis without an inflammatory component.							
	Restricted Benefit							
	Symptomatic treatment of osteoarthritis;							
	Symptomatic treatment of rheumatoid arthritis.							
8439E	***Capsule 100 mg***	***60***	***3***	***..***	***31.88***	***32.90***	***Celebrex***	***PH***
8440F	***Capsule 200 mg***	***30***	***3***	***..***	***31.88***	***32.90***	***Celebrex***	***PH***
	Specific antirheumatic agents							
	• *Quinolines*							
	HYDROXYCHLOROQUINE SULFATE							
1512N	Tablet 200 mg	100	1	..	37.16	32.90	Plaquenil	SW
	• *Gold preparations*							
	AURANOFIN							
	CAUTION:							
	Regular blood and urine checks are essential.							
1095P	Tablet 3 mg	60	5	..	63.12	32.90	Ridaura	GH
	SODIUM AUROTHIOMALATE							
	CAUTION:							
	Regular blood and urine checks are essential.							
2016D	Injection 10 mg	10	..	..	52.87	32.90	Myocrisin	SW
2017E	Injection 20 mg	10	1	..	80.03	32.90	Myocrisin	SW
2018F	Injection 50 mg	10	1	..	124.36	32.90	Myocrisin	SW
	• *Penicillamine and similar agents*							
	PENICILLAMINE							
	CAUTION:							
	Regular blood and urine checks are essential.							
2721F	Tablet 125 mg	100	1	..	31.20	32.23	D-Penamine	AL
2838J	Tablet 250 mg	100	1	..	43.08	32.90	D-Penamine	AL
	• *Other specific antirheumatic agents*							
	LEFLUNOMIDE							
	For listings see Generic/Proprietary Index							

MUSCULO-SKELETAL SYSTEM—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Proprietary Name and Manufacturer	
	MUSCLE RELAXANTS								
	Muscle relaxants, centrally acting agents								
	• ***Other centrally acting agents***								
	BACLOFEN								
2729P	Tablet 10 mg	100	5	..	31.65	32.68	a	Baclo	GM
							a	Chem mart Baclofen	CH
							a	Clofen 10	AF
							a	GenRx Baclofen	GX
							a	Stelax 10	SI
							a	Terry White Chemists Baclofen	TW
				B2.26	33.91	32.68	a	Lioresal 10	NV
2730Q	Tablet 25 mg	100	5	..	59.66	32.90	a	Baclo	GM
							a	Chem mart Baclofen	CH
							a	Clofen 25	AF
							a	GenRx Baclofen	GX
							a	Stelax 25	SI
							a	Terry White Chemists Baclofen	TW
				B2.18	61.84	32.90	a	Lioresal 25	NV
	Muscle relaxants, directly acting agents								
	• ***Dantrolene and derivatives***								
	DANTROLENE SODIUM								
	Restricted Benefit								
	Treatment of chronic spasticity.								
1779P	***Capsule 25 mg***	***100***	***2***	***..***	***59.05***	***32.90***		***Dantrium***	***PU***
1780Q	***Capsule 50 mg***	***100***	***2***	***..***	***66.99***	***32.90***		***Dantrium***	***PU***

MUSCULO-SKELETAL SYSTEM—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Proprietary Name and Manufacturer	
	ANTIGOUT PREPARATIONS								
	Antigout preparations								
	• ***Preparations inhibiting uric acid production***								
	ALLOPURINOL								
	NOTE:								
	The dose should be adjusted in accordance with renal function.								
2600W	Tablet 100 mg	200	2	..	12.76	13.79	a	Allohexal	SZ
							a	Allosig	FM
							a	Chem mart Allopurinol	CH
							a	GenRx Allopurinol	GX
							a	Terry White Chemists Allopurinol	TW
				..	* 12.77	13.80	a	Progout 100	AF
				B1.91	14.67	13.79	a	Zyloprim	SI
2604C	Tablet 300 mg	60	2	..	9.99	11.02	a	Allohexal	SZ
							a	Allosig	FM
							a	Chem mart Allopurinol	CH
							a	GenRx Allopurinol	GX
							a	Progout 300	AF
							a	Terry White Chemists Allopurinol	TW
				B1.80	11.79	11.02	a	Zyloprim	SI
	• ***Preparations increasing uric acid excretion***								
	PROBENECID								
1940D	Tablet 500 mg	100	5	..	75.26	32.90		Pro-Cid	PL
	• ***Preparations with no effect on uric acid metabolism***								
	COLCHICINE								
1227N	Tablet 500 micrograms	100	2	..	10.91	11.94	a	Lengout	LN
				B0.91	11.82	11.94	a	Colgout	AS

MUSCULO-SKELETAL SYSTEM—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Proprietary Name and Manufacturer	

DRUGS FOR TREATMENT OF BONE DISEASES

Drugs affecting bone structure and mineralization

- ***Bisphosphonates***

ALENDRONATE SODIUM

Authority Required (STREAMLINED)

2645

Treatment as the sole PBS-subsidised anti-resorptive agent for osteoporosis in a patient aged 70 years of age or older with a Bone Mineral Density (BMD) T-score of -3.0 or less.

The date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

Authority Required (STREAMLINED)

2646

Treatment as the sole PBS-subsidised anti-resorptive agent for established osteoporosis in patients with fracture due to minimal trauma. The fracture must have been demonstrated radiologically and the year of plain x-ray or CT-scan or MRI scan must be documented in the patient's medical records when treatment is initiated.

A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

NOTE:

Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, disodium etidronate, raloxifene hydrochloride, strontium ranelate and zoledronic acid.

8511Y	*Tablet equivalent to 70 mg alendronic acid*	*4*	*5*	*..*	*46.87*	*32.90*	*a*	*Adronat*	*AF*
							a	*Alendrobell 70mg*	*BF*
							a	*Alendronate-GA*	*GM*
							a	*Alendronate Sandoz*	*SZ*
							a	*Alendro Once Weekly*	*SI*
							a	*APO-Alendronate*	*TX*
							a	*Chem mart Alendronate 70mg*	*CH*
							a	*Ossmax 70mg*	*RA*
							a	*Terry White Chemists Alendronate 70mg*	*TW*
				B1.42	*48.29*	*32.90*	*a*	*Fosamax Once Weekly*	*MK*

continued ☞

MUSCULO-SKELETAL SYSTEM—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Proprietary Name and Manufacturer	
	Authority Required (STREAMLINED) **1392** ***Symptomatic Paget's disease of bone.***								
8090T	***Tablet equivalent to 40 mg alendronic acid***	*30*	*5*	*..*	*138.14*	*32.90*		***Fosamax 40 mg***	***MK***
	DISODIUM ETIDRONATE								
	Authority Required (STREAMLINED) **1849** ***Symptomatic Paget's disease of bone when calcitonin has been found to be unsatisfactory due to lack of efficacy;*** **1850** ***Symptomatic Paget's disease of bone when calcitonin has been found to be unsatisfactory due to unacceptable side effects;*** **1153** ***Heterotopic ossification.***								
2920Q	***Tablet 200 mg***	*60*	*5*	*..*	*114.74*	*32.90*		***Didronel***	***PU***
	DISODIUM PAMIDRONATE								
	Authority Required (STREAMLINED) **1392** ***Symptomatic Paget's disease of bone.***								
8461H	***Concentrated injection 15 mg in 5 mL***	*4*	*..*	*..*	** 263.79*	*32.90*	*a*	***Pamisol***	***HH***
8208B	***Injection set containing 4 vials powder for I.V. infusion 15 mg and 4 ampoules solvent 5 mL***	*1*	*..*	*..*	*263.78*	*32.90*	*a*	***Aredia 15 mg***	***NV***
	NOTE: ***The concentrated injection 15 mg and powder for I.V. infusion 15 mg (after reconstitution) are bioequivalent.***								
8462J	***Concentrated injection 30 mg in 10 mL***	*2*	*..*	*..*	** 263.79*	*32.90*	*a*	***Pamisol***	***HH***
8209C	***Injection set containing 2 vials powder for I.V. infusion 30 mg and 2 ampoules solvent 10 mL***	*1*	*..*	*..*	*263.78*	*32.90*	*a*	***Aredia 30 mg***	***NV***
	NOTE: ***The concentrated injection 30 mg and powder for I.V. infusion 30 mg (after reconstitution) are bioequivalent.***								
8463K	***Concentrated injection 60 mg in 10 mL***	*1*	*..*	*..*	*263.78*	*32.90*		***Pamisol***	***HH***
	IBANDRONIC ACID								
	Restricted Benefit ***Bone metastases from breast cancer.***								
9357L	***Tablet 50 mg (as ibandronate sodium monohydrate)***	*28*	*2*	*..*	*341.91*	*32.90*		***Bondronat***	***HH***

MUSCULO-SKELETAL SYSTEM—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
	RISEDRONATE SODIUM							
	Authority Required (STREAMLINED) **3070** ***Treatment as the sole PBS-subsidised anti-resorptive agent for corticosteroid-induced osteoporosis in a patient currently on long-term (at least 3 months), high-dose (at least 7.5 mg per day prednisolone or equivalent) corticosteroid therapy with a Bone Mineral Density (BMD) T-score of -1.5 or less.*** ***The duration and dose of corticosteroid therapy together with the date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.***							
	Authority Required (STREAMLINED) **2645** ***Treatment as the sole PBS-subsidised anti-resorptive agent for osteoporosis in a patient aged 70 years of age or older with a Bone Mineral Density (BMD) T-score of -3.0 or less.*** ***The date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.***							
	Authority Required (STREAMLINED) **2646** ***Treatment as the sole PBS-subsidised anti-resorptive agent for established osteoporosis in patients with fracture due to minimal trauma. The fracture must have been demonstrated radiologically and the year of plain x-ray or CT-scan or MRI scan must be documented in the patient's medical records when treatment is initiated.*** ***A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.***							
	NOTE: ***Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, disodium etidronate, raloxifene hydrochloride, strontium ranelate and zoledronic acid.***							
8481J	***Tablet 5 mg***	***28***	***5***	***..***	***52.91***	***32.90***	***Actonel***	***SW***
8621R	***Tablet 35 mg***	***4***	***5***	***..***	***52.91***	***32.90***	***Actonel Once-a-Week***	***SW***
	Authority Required (STREAMLINED) **1392** ***Symptomatic Paget's disease of bone.***							
8482K	***Tablet 30 mg***	***28***	***1***	***..***	***304.19***	***32.90***	***Actonel***	***SW***
	SODIUM CLODRONATE TETRAHYDRATE							
	Restricted Benefit ***Maintenance treatment of hypercalcaemia of malignancy refractory to anti-neoplastic therapy;*** ***Multiple myeloma;*** ***Bone metastases from breast cancer.***							
8132B	***Capsule equivalent to 400 mg sodium clodronate***	***100***	***2***	***..***	***333.65***	***32.90***	***Bonefos***	***SC***

continued ☞

MUSCULO-SKELETAL SYSTEM—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
8265B	***Tablet equivalent to 800 mg sodium clodronate***	***60***	***2***	***..***	***391.01***	***32.90***	***Bonefos 800 mg***	***SC***
	TILUDRONATE DISODIUM							
	Authority Required (STREAMLINED) **1392** ***Symptomatic Paget's disease of bone.***							
8267D	***Tablet equivalent to 200 mg tiludronic acid***	***56***	***2***	***..***	***304.19***	***32.90***	***Skelid***	***HH***
	ZOLEDRONIC ACID							
	Authority Required ***Treatment as the sole PBS-subsidised anti-resorptive agent for established osteoporosis in women with fracture due to minimal trauma.*** ***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;*** ***Treatment as the sole PBS-subsidised anti-resorptive agent for established osteoporosis in men with hip fracture due to minimal trauma.*** ***In all cases, the fracture must have been demonstrated radiologically and the year of plain x-ray or CT-scan or MRI scan must be documented in the patient's medical records when treatment is initiated.*** ***Only 1 treatment each year for 3 consecutive years per patient will be PBS-subsidised.*** **NOTE:** ***Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, disodium etidronate, raloxifene hydrochloride, strontium ranelate and zoledronic acid.***							
9288W	***Solution for I.V. infusion 5 mg (as monohydrate) in 100 mL***	***1***	***..***	***..***	***559.36***	***32.90***	***Aclasta***	***NV***

MUSCULO-SKELETAL SYSTEM—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
	• *Bisphosphonates, combinations*							
	ALENDRONATE SODIUM with COLECALCIFEROL							
	Authority Required (STREAMLINED)							
	2645							
	Treatment as the sole PBS-subsidised anti-resorptive agent for osteoporosis in a patient aged 70 years of age or older with a Bone Mineral Density (BMD) T-score of -3.0 or less.							
	The date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.							
	Authority Required (STREAMLINED)							
	2646							
	Treatment as the sole PBS-subsidised anti-resorptive agent for established osteoporosis in patients with fracture due to minimal trauma. The fracture must have been demonstrated radiologically and the year of plain x-ray or CT-scan or MRI scan must be documented in the patient's medical records when treatment is initiated.							
	A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.							
	NOTE:							
	Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, disodium etidronate, raloxifene hydrochloride, strontium ranelate and zoledronic acid.							
9012H	*Tablet equivalent to 70 mg alendronic acid with 70 micrograms colecalciferol*	*4*	*5*	*..*	*46.87*	*32.90*	*Fosamax Plus*	*MK*
	NOTE:							
	Fosamax Plus provides a supplemental intake of vitamin D. The amount of colecalciferol present in Fosamax Plus is not sufficient to use as the sole treatment for correction of vitamin D deficiency.							
9183H	*Tablet equivalent to 70 mg alendronic acid with 140 micrograms colecalciferol*	*4*	*5*	*..*	*46.87*	*32.90*	*Fosamax Plus 70 mg/140 mcg*	*MK*

MUSCULO-SKELETAL SYSTEM—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	

DISODIUM ETIDRONATE and CALCIUM CARBONATE

Authority Required (STREAMLINED)

2646

Treatment as the sole PBS-subsidised anti-resorptive agent for established osteoporosis in patients with fracture due to minimal trauma. The fracture must have been demonstrated radiologically and the year of plain x-ray or CT-scan or MRI scan must be documented in the patient's medical records when treatment is initiated.

A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

NOTE:

Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, disodium etidronate, raloxifene hydrochloride, strontium ranelate and zoledronic acid.

8056B	*Pack containing 28 tablets disodium etidronate 200 mg and 76 tablets calcium carbonate 1.25 g (equivalent to 500 mg calcium)*	*‡ 1*	*1*	*..*	*70.26*	*32.90*	*Didrocal*	*PU*

NOTE:

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

MUSCULO-SKELETAL SYSTEM—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
	RISEDRONATE SODIUM and CALCIUM CARBONATE							
	Authority Required (STREAMLINED) **3070** ***Treatment as the sole PBS-subsidised anti-resorptive agent for corticosteroid-induced osteoporosis in a patient currently on long-term (at least 3 months), high-dose (at least 7.5 mg per day prednisolone or equivalent) corticosteroid therapy with a Bone Mineral Density (BMD) T-score of -1.5 or less.*** ***The duration and dose of corticosteroid therapy together with the date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.***							
	Authority Required (STREAMLINED) **2645** ***Treatment as the sole PBS-subsidised anti-resorptive agent for osteoporosis in a patient aged 70 years of age or older with a Bone Mineral Density (BMD) T-score of -3.0 or less.*** ***The date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.***							
	Authority Required (STREAMLINED) **2646** ***Treatment as the sole PBS-subsidised anti-resorptive agent for established osteoporosis in patients with fracture due to minimal trauma. The fracture must have been demonstrated radiologically and the year of plain x-ray or CT-scan or MRI scan must be documented in the patient's medical records when treatment is initiated.*** ***A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.***							
	NOTE: ***Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, disodium etidronate, raloxifene hydrochloride, strontium ranelate and zoledronic acid.***							
8899J	***Pack containing 4 tablets risedronate sodium 35 mg and 24 tablets calcium carbonate 1.25 g (equivalent to 500 mg calcium)***	***‡ 1***	***5***	***..***	***52.91***	***32.90***	***Actonel Combi***	***SW***

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
	RISEDRONATE SODIUM and CALCIUM CARBONATE with COLECALCIFEROL							
	Authority Required (STREAMLINED) **2645** ***Treatment as the sole PBS-subsidised anti-resorptive agent for osteoporosis in a patient aged 70 years of age or older with a Bone Mineral Density (BMD) T-score of -3.0 or less.*** ***The date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.***							
	Authority Required (STREAMLINED) **2646** ***Treatment as the sole PBS-subsidised anti-resorptive agent for established osteoporosis in patients with fracture due to minimal trauma. The fracture must have been demonstrated radiologically and the year of plain x-ray or CT-scan or MRI scan must be documented in the patient's medical records when treatment is initiated.*** ***A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.***							
	NOTE: ***Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, disodium etidronate, raloxifene hydrochloride, strontium ranelate and zoledronic acid.***							
9147K	***Pack containing 4 tablets risedronate sodium 35 mg and 24 sachets containing granules of calcium carbonate 2.5 g (equivalent to 1 g calcium) with colecalciferol 22 micrograms***	*‡ 1*	*5*	*..*	*52.91*	*32.90*	***Actonel Combi D***	***SW***

MUSCULO-SKELETAL SYSTEM—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	

• *Other drugs affecting bone structure and mineralization*

CALCITRIOL

Authority Required (STREAMLINED)

1165
Hypocalcaemia due to renal disease;

1166
Hypoparathyroidism;

1167
Hypophosphataemic rickets;

1467
Vitamin D-resistant rickets;

2636
Treatment for established osteoporosis in patients with fracture due to minimal trauma. The fracture must have been demonstrated radiologically and the year of plain x-ray or CT-scan or MRI scan must be documented in the patient's medical records when treatment is initiated.
A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

2502Q	*Capsule 0.25 microgram*	*100*	*3*	*..*	*42.82*	*32.90*	[a] *Calcitriol-DP*	*GM*
							[a] *Citrihexal*	*SZ*
							[a] *GenRx Calcitriol*	*GX*
							[a] *Kosteo*	*SI*
							[a] *Rocaltrol*	*RO*
							[a] *Sical*	*AF*

RALOXIFENE HYDROCHLORIDE

Authority Required (STREAMLINED)

2647
Treatment as the sole PBS-subsidised anti-resorptive agent for established post-menopausal osteoporosis in patients with fracture due to minimal trauma. The fracture must have been demonstrated radiologically and the year of plain x-ray or CT-scan or MRI scan must be documented in the patient's medical records when treatment is initiated.
A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

NOTE:
Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, disodium etidronate, raloxifene hydrochloride, strontium ranelate and zoledronic acid.

8363E	*Tablet 60 mg*	*28*	*5*	*..*	*57.44*	*32.90*	*Evista*	*LY*

MUSCULO-SKELETAL SYSTEM—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
	STRONTIUM RANELATE							
	Authority Required (STREAMLINED) **2758** ***Treatment as the sole PBS-subsidised anti-resorptive agent for osteoporosis in a woman aged 70 years or older with a bone mineral density (BMD) T-score of -3.0 or less.*** ***The date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.***							
	Authority Required (STREAMLINED) **2647** ***Treatment as the sole PBS-subsidised anti-resorptive agent for established post-menopausal osteoporosis in patients with fracture due to minimal trauma. The fracture must have been demonstrated radiologically and the year of plain x-ray or CT-scan or MRI scan must be documented in the patient's medical records when treatment is initiated.*** ***A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.***							
	NOTE: ***Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, disodium etidronate, raloxifene hydrochloride, strontium ranelate and zoledronic acid.***							
3036T	***Sachet containing granules for oral suspension 2 g***	***28***	***5***	***..***	***52.91***	***32.90***	***Protos 2 g***	***SE***

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Proprietary Name and Manufacturer	
	ANALGESICS								
	Opioids								
	• ***Natural opium alkaloids***								
	CODEINE PHOSPHATE								
1214X	Tablet 30 mg	20	..	..	16.44	17.47		FM	
	CODEINE PHOSPHATE with PARACETAMOL								
1215Y	Tablet 30 mg-500 mg	20	..	..	7.65	8.68	a	Codalgin Forte	FM
							a	Codapane Forte	AL
							a	Comfarol Forte	SZ
							a	Dolaforte	CO
							a	Prodeine Forte	AV
				B2.80	10.45	8.68	a	Panadeine Forte	SW

NOTE:
Authorities for increased maximum quantities and/or repeats will not be granted except as detailed under the 'Authority required' listing of codeine phosphate with paracetamol below.

CODEINE PHOSPHATE with PARACETAMOL

Authority Required
Severe disabling pain not responding to non-narcotic analgesics.

NOTE:
Each authority approval will be limited to no more than 240 tablets per month for no more than 6 months.

8785J	***Tablet 30 mg-500 mg***	***60***	***..***	***..***	**** 10.97***	***12.00***	***a***	***Codalgin Forte***	***FM***
							a	***Codapane Forte***	***AL***
							a	***Comfarol Forte***	***SZ***
							a	***Dolaforte***	***CO***
							a	***Prodeine Forte***	***AV***
				B8.40	**** 19.37***	***12.00***	***a***	***Panadeine Forte***	***SW***
	HYDROMORPHONE HYDROCHLORIDE								
	CAUTION:								
	The risk of drug dependence is high.								
8420E	Injection 2 mg in 1 mL	5	..	..	13.51	14.54		Dilaudid	MF
8421F	Injection 10 mg in 1 mL	5	..	..	18.87	19.90		Dilaudid-HP	MF
8422G	Injection 50 mg in 5 mL	5	..	..	47.07	32.90		Dilaudid-HP	MF
8423H	Injection 500 mg in 50 mL	1	..	..	74.98	32.90		Dilaudid-HP	MF

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continued ☞

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
	HYDROMORPHONE HYDROCHLORIDE							
	CAUTION:							
	The risk of drug dependence is high.							
	Restricted Benefit							
	Severe disabling pain not responding to non-narcotic analgesics.							
	NOTE:							
	Authorities for increased maximum quantities and/or repeats will be granted only for:							
	(i) severe disabling pain associated with proven malignant neoplasia; or							
	(ii) chronic severe disabling pain not responding to non-narcotic analgesics where the total duration of narcotic analgesic treatment is less than 12 months; or							
	(iii) first application for treatment beyond 12 months of chronic severe disabling pain not responding to non-narcotic analgesics where the patient's pain management has been reviewed through consultation by the patient with another medical practitioner, and the clinical need for continuing narcotic analgesic treatment has been confirmed. The date of the consultation must be no more than 3 months prior to the application for a PBS authority. The full name of the medical practitioner consulted and the date of consultation are to be provided at the time of application; or							
	(iv) subsequent application for treatment of chronic severe disabling pain not responding to non-narcotic analgesics where a PBS authority prescription for treatment beyond 12 months has previously been issued for this patient.							
8541M	***Tablet 2 mg***	***20***	***..***	***..***	***13.79***	***14.82***	***Dilaudid***	***MF***
8542N	***Tablet 4 mg***	***20***	***..***	***..***	***18.85***	***19.88***	***Dilaudid***	***MF***
8543P	***Tablet 8 mg***	***20***	***..***	***..***	***28.61***	***29.64***	***Dilaudid***	***MF***
8424J	***Oral liquid 1 mg per mL, 473 mL***	***1***	***..***	***..***	***49.09***	***32.90***	***Dilaudid***	***MF***
	MORPHINE HYDROCHLORIDE							
	CAUTION:							
	The risk of drug dependence is high.							
	Restricted Benefit							
	Severe disabling pain not responding to non-narcotic analgesics.							
	NOTE:							
	Authorities for increased maximum quantities and/or repeats will be granted only for:							
	(i) severe disabling pain associated with proven malignant neoplasia; or							
	(ii) chronic severe disabling pain not responding to non-narcotic analgesics where the total duration of narcotic analgesic treatment is less than 12 months; or							
	(iii) first application for treatment beyond 12 months of chronic severe disabling pain not responding to non-narcotic analgesics where the patient's pain management has been reviewed through consultation by the patient with another medical practitioner, and the clinical need for continuing narcotic analgesic treatment has been confirmed. The date of the consultation must be no more than 3 months prior to the application for a PBS authority. The full name of the medical practitioner consulted and the date of consultation are to be provided at the time of application; or							
	(iv) subsequent application for treatment of chronic severe disabling pain not responding to non-narcotic analgesics where a PBS authority prescription for treatment beyond 12 months has previously been issued for this patient.							

continued ☞

NERVOUS SYSTEM—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
2122Q	***Oral solution 2 mg per mL, 200 mL***	***1***	***..***	***..***	***18.73***	***19.76***	***Ordine 2***	***MF***
2123R	***Oral solution 5 mg per mL, 200 mL***	***1***	***..***	***..***	***21.64***	***22.67***	***Ordine 5***	***MF***
2124T	***Oral solution 10 mg per mL, 200 mL***	***1***	***..***	***..***	***26.24***	***27.27***	***Ordine 10***	***MF***
	MORPHINE SULFATE **CAUTION:** The risk of drug dependence is high.							
1644M	Injection 10 mg in 1 mL	5	..	..	13.77	14.80	HH	
1645N	Injection 15 mg in 1 mL	5	..	..	14.13	15.16	HH	
1647Q	Injection 30 mg in 1 mL	5	..	..	15.61	16.64	HH	

MORPHINE SULFATE
CAUTION:
The risk of drug dependence is high.

Restricted Benefit
Severe disabling pain due to cancer not responding to non-narcotic analgesics.

8669G	***Tablet 10 mg***	***20***	***..***	***..***	***14.85***	***15.88***	***Sevredol***	***MF***
8670H	***Tablet 20 mg***	***20***	***..***	***..***	***15.99***	***17.02***	***Sevredol***	***MF***

Restricted Benefit
Severe disabling pain not responding to non-narcotic analgesics.

NOTE:
Authorities for increased maximum quantities and/or repeats will be granted only for:

(i) severe disabling pain associated with proven malignant neoplasia; or

(ii) chronic severe disabling pain not responding to non-narcotic analgesics where the total duration of narcotic analgesic treatment is less than 12 months; or

(iii) first application for treatment beyond 12 months of chronic severe disabling pain not responding to non-narcotic analgesics where the patient's pain management has been reviewed through consultation by the patient with another medical practitioner, and the clinical need for continuing narcotic analgesic treatment has been confirmed. The date of the consultation must be no more than 3 months prior to the application for a PBS authority. The full name of the medical practitioner consulted and the date of consultation are to be provided at the time of application; or

(iv) subsequent application for treatment of chronic severe disabling pain not responding to non-narcotic analgesics where a PBS authority prescription for treatment beyond 12 months has previously been issued for this patient.

1646P	***Tablet 30 mg***	***20***	***..***	***..***	***14.53***	***15.56***	***Anamorph***	***FM***

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continued ☞

NERVOUS SYSTEM—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
	Restricted Benefit ***Chronic severe disabling pain not responding to non-narcotic analgesics.***							
	NOTE: ***Authorities for increased maximum quantities and/or repeats will be granted only for:*** ***(i) chronic severe disabling pain associated with proven malignant neoplasia; or*** ***(ii) chronic severe disabling pain not responding to non-narcotic analgesics where the total duration of narcotic analgesic treatment is less than 12 months; or*** ***(iii) first application for treatment beyond 12 months of chronic severe disabling pain not responding to non-narcotic analgesics where the patient's pain management has been reviewed through consultation by the patient with another medical practitioner, and the clinical need for continuing narcotic analgesic treatment has been confirmed. The date of the consultation must be no more than 3 months prior to the application for a PBS authority. The full name of the medical practitioner consulted and the date of consultation are to be provided at the time of application; or*** ***(iv) subsequent application for treatment of chronic severe disabling pain not responding to non-narcotic analgesics where a PBS authority prescription for treatment beyond 12 months has previously been issued for this patient.***							
8035X	***Tablet 5 mg (controlled release)***	***20***	***..***	***..***	***15.89***	***16.92***	***MS Contin***	***MF***
1653B	***Tablet 10 mg (controlled release)***	***20***	***..***	***..***	***17.97***	***19.00***	***MS Contin***	***MF***
8489T	***Tablet 15 mg (controlled release)***	***20***	***..***	***..***	***21.52***	***22.55***	***MS Contin***	***MF***
1654C	***Tablet 30 mg (controlled release)***	***20***	***..***	***..***	***31.44***	***32.47***	***MS Contin***	***MF***
1655D	***Tablet 60 mg (controlled release)***	***20***	***..***	***..***	***47.92***	***32.90***	***MS Contin***	***MF***
1656E	***Tablet 100 mg (controlled release)***	***20***	***..***	***..***	***62.58***	***32.90***	***MS Contin***	***MF***
8349K	***Capsule 10 mg (containing sustained release pellets)***	***20***	***..***	***..***	***17.97***	***19.00***	***Kapanol***	***GK***
2839K	***Capsule 20 mg (containing sustained release pellets)***	***20***	***..***	***..***	***22.20***	***23.23***	***Kapanol***	***GK***
8491X	***Capsule 30 mg (controlled release)***	***10***	***..***	***..***	***21.52***	***22.55***	***MS Mono***	***MF***
2840L	***Capsule 50 mg (containing sustained release pellets)***	***20***	***..***	***..***	***37.75***	***32.90***	***Kapanol***	***GK***
8492Y	***Capsule 60 mg (controlled release)***	***10***	***..***	***..***	***31.44***	***32.47***	***MS Mono***	***MF***
8493B	***Capsule 90 mg (controlled release)***	***10***	***..***	***..***	***36.15***	***32.90***	***MS Mono***	***MF***
2841M	***Capsule 100 mg (containing sustained release pellets)***	***20***	***..***	***..***	***60.83***	***32.90***	***Kapanol***	***GK***
8494C	***Capsule 120 mg (controlled release)***	***10***	***..***	***..***	***47.92***	***32.90***	***MS Mono***	***MF***
8490W	***Sachet containing controlled release granules for oral suspension, 20 mg per sachet***	***20***	***..***	***..***	***48.36***	***32.90***	***MS Contin Suspension 20 mg***	***MF***

continued ☞

NERVOUS SYSTEM—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
8146R	***Sachet containing controlled release granules for oral suspension, 30 mg per sachet***	***20***	***..***	***..***	***49.60***	***32.90***	***MS Contin Suspension 30 mg***	***MF***
8305D	***Sachet containing controlled release granules for oral suspension, 60 mg per sachet***	***20***	***..***	***..***	***54.95***	***32.90***	***MS Contin Suspension 60 mg***	***MF***
8306E	***Sachet containing controlled release granules for oral suspension, 100 mg per sachet***	***20***	***..***	***..***	***67.09***	***32.90***	***MS Contin Suspension 100 mg***	***MF***

Authority Required
Chronic severe disabling pain due to cancer.

8453X	***Tablet 200 mg (controlled release)***	***20***	***..***	***..***	***104.50***	***32.90***	***MS Contin***	***MF***
8454Y	***Sachet containing controlled release granules for oral suspension, 200 mg per sachet***	***20***	***..***	***..***	***125.62***	***32.90***	***MS Contin Suspension 200 mg***	***MF***

MORPHINE TARTRATE
CAUTION:
The risk of drug dependence is high.

1607N	Injection 120 mg in 1.5 mL	5	..	..	31.13	32.16	HH	

OXYCODONE
CAUTION:
The risk of drug dependence is high.

Restricted Benefit
Severe disabling pain not responding to non-narcotic analgesics.

NOTE:
Authorities for increased maximum quantities and/or repeats will be granted only for:

(i) severe disabling pain associated with proven malignant neoplasia; or

(ii) chronic severe disabling pain not responding to non-narcotic analgesics where the total duration of narcotic analgesic treatment is less than 12 months; or

(iii) first application for treatment beyond 12 months of chronic severe disabling pain not responding to non-narcotic analgesics where the patient's pain management has been reviewed through consultation by the patient with another medical practitioner, and the clinical need for continuing narcotic analgesic treatment has been confirmed. The date of the consultation must be no more than 3 months prior to the application for a PBS authority. The full name of the medical practitioner consulted and the date of consultation are to be provided at the time of application; or

(iv) subsequent application for treatment of chronic severe disabling pain not responding to non-narcotic analgesics where a PBS authority prescription for treatment beyond 12 months has previously been issued for this patient.

2481N	***Suppository 30 mg***	***12***	***..***	***..***	***43.23***	***32.90***	***Proladone***	***PL***

NERVOUS SYSTEM—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
	OXYCODONE HYDROCHLORIDE							
	CAUTION:							
	The risk of drug dependence is high.							
	Restricted Benefit							
	Severe disabling pain not responding to non-narcotic analgesics.							
	NOTE:							
	Authorities for increased maximum quantities and/or repeats will be granted only for:							
	(i) severe disabling pain associated with proven malignant neoplasia; or							
	(ii) chronic severe disabling pain not responding to non-narcotic analgesics where the total duration of narcotic analgesic treatment is less than 12 months; or							
	(iii) first application for treatment beyond 12 months of chronic severe disabling pain not responding to non-narcotic analgesics where the patient's pain management has been reviewed through consultation by the patient with another medical practitioner, and the clinical need for continuing narcotic analgesic treatment has been confirmed. The date of the consultation must be no more than 3 months prior to the application for a PBS authority. The full name of the medical practitioner consulted and the date of consultation are to be provided at the time of application; or							
	(iv) subsequent application for treatment of chronic severe disabling pain not responding to non-narcotic analgesics where a PBS authority prescription for treatment beyond 12 months has previously been issued for this patient.							
2622B	***Tablet 5 mg***	***20***	***..***	***..***	***11.87***	***12.90***	***Endone***	***SI***
8464L	***Capsule 5 mg***	***20***	***..***	***..***	***11.87***	***12.90***	***OxyNorm***	***MF***
8501K	***Capsule 10 mg***	***20***	***..***	***..***	***14.99***	***16.02***	***OxyNorm***	***MF***
8502L	***Capsule 20 mg***	***20***	***..***	***..***	***19.72***	***20.75***	***OxyNorm***	***MF***
8644Y	***Oral solution 5 mg per 5 mL, 250 mL***	***1***	***..***	***..***	***20.29***	***21.32***	***OxyNorm Liquid 5mg/5mL***	***MF***
	Restricted Benefit							
	Chronic severe disabling pain not responding to non-narcotic analgesics.							
	NOTE:							
	Authorities for increased maximum quantities and/or repeats will be granted only for:							
	(i) chronic severe disabling pain associated with proven malignant neoplasia; or							
	(ii) chronic severe disabling pain not responding to non-narcotic analgesics where the total duration of narcotic analgesic treatment is less than 12 months; or							
	(iii) first application for treatment beyond 12 months of chronic severe disabling pain not responding to non-narcotic analgesics where the patient's pain management has been reviewed through consultation by the patient with another medical practitioner, and the clinical need for continuing narcotic analgesic treatment has been confirmed. The date of the consultation must be no more than 3 months prior to the application for a PBS authority. The full name of the medical practitioner consulted and the date of consultation are to be provided at the time of application; or							
	(iv) subsequent application for treatment of chronic severe disabling pain not responding to non-narcotic analgesics where a PBS authority prescription for treatment beyond 12 months has previously been issued for this patient.							

continued ☞

NERVOUS SYSTEM—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
8681X	*Tablet 5 mg (controlled release)*	*20*	*..*	*..*	*20.75*	*21.78*	*OxyContin*	*MF*
8385H	*Tablet 10 mg (controlled release)*	*20*	*..*	*..*	*21.52*	*22.55*	*OxyContin*	*MF*
8386J	*Tablet 20 mg (controlled release)*	*20*	*..*	*..*	*31.44*	*32.47*	*OxyContin*	*MF*
8387K	*Tablet 40 mg (controlled release)*	*20*	*..*	*..*	*47.92*	*32.90*	*OxyContin*	*MF*
8388L	*Tablet 80 mg (controlled release)*	*20*	*..*	*..*	*71.27*	*32.90*	*OxyContin*	*MF*

• *Phenylpiperidine derivatives*

FENTANYL

CAUTION:

The risk of drug dependence is high.

Restricted Benefit

Chronic severe disabling pain not responding to non-narcotic analgesics.

NOTE:

Authorities for increased maximum quantities and/or repeats will be granted only for:

(i) chronic severe disabling pain associated with proven malignant neoplasia; or

(ii) chronic severe disabling pain not responding to non-narcotic analgesics where the total duration of narcotic analgesic treatment is less than 12 months; or

(iii) first application for treatment beyond 12 months of chronic severe disabling pain not responding to non-narcotic analgesics where the patient's pain management has been reviewed through consultation by the patient with another medical practitioner, and the clinical need for continuing narcotic analgesic treatment has been confirmed. The date of the consultation must be no more than 3 months prior to the application for a PBS authority. The full name of the medical practitioner consulted and the date of consultation are to be provided at the time of application; or

(iv) subsequent application for treatment of chronic severe disabling pain not responding to non-narcotic analgesics where a PBS authority prescription for treatment beyond 12 months has previously been issued for this patient.

8878G	*Transdermal patch 2.1 mg (releasing approximately 12 micrograms per hour)*	*5*	*..*	*..*	*46.73*	*32.90*	*Durogesic 12*	*JC*
8891Y	*Transdermal patch 4.2 mg (releasing approximately 25 micrograms per hour)*	*5*	*..*	*..*	*55.85*	*32.90*	*Durogesic 25*	*JC*
8892B	*Transdermal patch 8.4 mg (releasing approximately 50 micrograms per hour)*	*5*	*..*	*..*	*94.95*	*32.90*	*Durogesic 50*	*JC*
8893C	*Transdermal patch 12.6 mg (releasing approximately 75 micrograms per hour)*	*5*	*..*	*..*	*126.85*	*32.90*	*Durogesic 75*	*JC*
8894D	*Transdermal patch 16.8 mg (releasing approximately 100 micrograms per hour)*	*5*	*..*	*..*	*155.33*	*32.90*	*Durogesic 100*	*JC*

continued ☞

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
	NOTE: ***Durogesic is not recommended in opioid naive patients with non-cancer pain, because of a high incidence of adverse events in these patients. Patients with cancer pain may be initiated on the lowest strength patch (12 micrograms per hour).***							
	• *Diphenylpropylamine derivatives* ***METHADONE HYDROCHLORIDE*** **CAUTION:** ***The risk of drug dependence is high.*** **Restricted Benefit** ***Severe disabling pain not responding to non-narcotic analgesics.*** **NOTE:** ***Authorities for increased maximum quantities and/or repeats will be granted only for:*** ***(i) severe disabling pain associated with proven malignant neoplasia; or*** ***(ii) chronic severe disabling pain not responding to non-narcotic analgesics where the total duration of narcotic analgesic treatment is less than 12 months; or*** ***(iii) first application for treatment beyond 12 months of chronic severe disabling pain not responding to non-narcotic analgesics where the patient's pain management has been reviewed through consultation by the patient with another medical practitioner, and the clinical need for continuing narcotic analgesic treatment has been confirmed. The date of the consultation must be no more than 3 months prior to the application for a PBS authority. The full name of the medical practitioner consulted and the date of consultation are to be provided at the time of application; or*** ***(iv) subsequent application for treatment of chronic severe disabling pain not responding to non-narcotic analgesics where a PBS authority prescription for treatment beyond 12 months has previously been issued for this patient.***							
1609Q	***Tablet 10 mg***	***20***	***..***	***..***	***15.17***	***16.20***	***Physeptone***	***SI***
1606M	***Injection 10 mg in 1 mL***	***5***	***..***	***..***	**** 39.67***	***32.90***	***Physeptone***	***SI***
	• *Oripavine derivatives* ***BUPRENORPHINE*** **CAUTION:** ***The risk of drug dependence is high.*** **Restricted Benefit** ***Chronic severe disabling pain not responding to non-narcotic analgesics.*** **NOTE:** ***Authorities for increased maximum quantities and/or repeats will be granted only for:*** ***(i) chronic severe disabling pain associated with proven malignant neoplasia; or*** ***(ii) chronic severe disabling pain not responding to non-narcotic analgesics where the total duration of narcotic analgesic treatment is less than 12 months; or***								

continued ☞

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Proprietary Name and Manufacturer	
	(iii) first application for treatment beyond 12 months of chronic severe disabling pain not responding to non-narcotic analgesics where the patient's pain management has been reviewed through consultation by the patient with another medical practitioner, and the clinical need for continuing narcotic analgesic treatment has been confirmed. The date of the consultation must be no more than 3 months prior to the application for a PBS authority. The full name of the medical practitioner consulted and the date of consultation are to be provided at the time of application; or								
	(iv) subsequent application for treatment of chronic severe disabling pain not responding to non-narcotic analgesics where a PBS authority prescription for treatment beyond 12 months has previously been issued for this patient.								
8865N	***Transdermal patch 5 mg (releasing approximately 5 micrograms per hour)***	***2***	***..***	***..***	***26.27***	***27.30***		***Norspan***	***MF***
8866P	***Transdermal patch 10 mg (releasing approximately 10 micrograms per hour)***	***2***	***..***	***..***	***40.34***	***32.90***		***Norspan***	***MF***
8867Q	***Transdermal patch 20 mg (releasing approximately 20 micrograms per hour)***	***2***	***..***	***..***	***55.65***	***32.90***		***Norspan***	***MF***
	• *Other opioids*								
	TRAMADOL HYDROCHLORIDE								
	Restricted Benefit								
	For acute pain where aspirin and/or paracetamol alone are inappropriate or have failed.								
	NOTE:								
	No applications for increased maximum quantities and/or repeats will be authorised.								
8455B	***Capsule 50 mg***	***20***	***..***	***..***	***8.73***	***9.76***	[a]	***Chem mart Tramadol***	***CH***
							[a]	***GenRx Tramadol***	***GX***
							[a]	***Terry White Chemists Tramadol***	***TW***
							[a]	***Tramedo***	***AF***
							[a]	***Zydol***	***AW***
				[B]2.42	***11.15***	***9.76***	[a]	***Tramal***	***CS***

continued ☞

NERVOUS SYSTEM—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Proprietary Name and Manufacturer	
	Restriction Benefit ***For dosage titration in chronic pain where aspirin and/or paracetamol alone are inappropriate or have failed.***								
	NOTE: ***No applications for increased maximum quantities and/or repeats will be authorised.***								
8611F	*Capsule 50 mg*	*20*	*2*	*..*	*8.73*	*9.76*	[a]	*Chem mart Tramadol*	*CH*
							[a]	*GenRx Tramadol*	*GX*
							[a]	*Terry White Chemists Tramadol*	*TW*
							[a]	*Tramedo*	*AF*
							[a]	*Zydol*	*AW*
				[B]2.42	*11.15*	*9.76*	[a]	*Tramal*	*CS*
	Restriction Benefit ***For pain where aspirin and/or paracetamol alone are inappropriate or have failed.***								
	NOTE: ***Authorities for increased maximum quantities and/or repeats will be granted only for severe disabling pain not responding to non-narcotic analgesics.***								
2527B	*Tablet 50 mg (twice daily sustained release)*	*20*	*..*	*..*	*11.20*	*12.23*		*Tramal SR 50*	*CS*
8523N	*Tablet 100 mg (twice daily sustained release)*	*20*	*..*	*..*	*13.43*	*14.46*	[a]	*Tramahexal SR*	*SZ*
							[a]	*Tramedo SR 100*	*AF*
							[a]	*Zydol SR 100*	*AW*
				[B]4.51	*17.94*	*14.46*	[a]	*Tramal SR 100*	*CS*
9199E	*Tablet 100 mg (once a day extended release)*	*10*	*..*	*..*	*12.94*	*13.97*		*Durotram XR*	*IA*
8524P	*Tablet 150 mg (twice daily sustained release)*	*20*	*..*	*..*	*16.02*	*17.05*	[a]	*Tramahexal SR*	*SZ*
							[a]	*Tramedo SR 150*	*AF*
							[a]	*Zydol SR 150*	*AW*
				[B]5.37	*21.39*	*17.05*	[a]	*Tramal SR 150*	*CS*
8525Q	*Tablet 200 mg (twice daily sustained release)*	*20*	*..*	*..*	*18.20*	*19.23*	[a]	*Tramahexal SR*	*SZ*
							[a]	*Tramedo SR 200*	*AF*
							[a]	*Zydol SR 200*	*AW*
				[B]6.09	*24.29*	*19.23*	[a]	*Tramal SR 200*	*CS*
9200F	*Tablet 200 mg (once a day extended release)*	*10*	*..*	*..*	*15.91*	*16.94*		*Durotram XR*	*IA*
9201G	*Tablet 300 mg (once a day extended release)*	*10*	*..*	*..*	*19.36*	*20.39*		*Durotram XR*	*IA*
8843K	*Oral drops 100 mg per mL, 10 mL*	*‡ 1*	*..*	*..*	*13.28*	*14.31*		*Tramal*	*CS*

continued ☞

NERVOUS SYSTEM—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
	Restricted Benefit ***Short-term treatment of acute pain.*** **NOTE:** ***No applications for increased maximum quantities and/or repeats will be authorised.***							
8582Q	***Injection 100 mg in 2 mL***	***5***	***..***	***..***	***13.87***	***14.90***	***Tramal 100***	***CS***
	Other analgesics and antipyretics							
	• ***Salicylic acid and derivatives*** ASPIRIN							
1010E	Tablet 300 mg (dispersible)	96	1	..	8.21	9.24	Solprin	RC
	• ***Anilides*** PARACETAMOL							
1746X	Tablet 500 mg	100	1	..	7.99	9.02	[a] Chem mart Chemadol	CH
							[a] Dymadon P	PC
							[a] Febridol	GM
							[a] Panamax	SW
							[a] Paracetamol Sandoz	SZ
							[b] Parahexal	HX
							[a] Paralgin	FM
							[b] Parmol	SI
							[a] Pharmacy Choice Paracetamol	YM
							[a] Terry White Chemists Paracetamol	TW
1747Y	Oral liquid 120 mg per 5 mL, 100 mL	‡ 1	2	..	8.95	9.98	Panamax	SW
1770E	Oral liquid 240 mg per 5 mL, 200 mL	‡ 1	2	..	10.25	11.28	Panamax 240 Elixir	SW

continued ☞

NERVOUS SYSTEM—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
	PARACETAMOL							
	Restricted Benefit ***Chronic arthropathies.***							
8784H	***Tablet 500 mg***	***300***	***4***	***..***	**** 11.99***	***13.02***	[a] ***Chem mart Chemadol***	***CH***
							[a] ***Dymadon P***	***PC***
							[a] ***Febridol***	***GM***
							[a] ***Panamax***	***SW***
							[a] ***Paracetamol Sandoz***	***SZ***
							[b] ***Parahexal***	***HX***
							[a] ***Paralgin***	***FM***
							[b] ***Parmol***	***SI***
							[a] ***Pharmacy Choice Paracetamol***	***YM***
							[a] ***Terry White Chemists Paracetamol***	***TW***
	Restricted Benefit ***Relief of persistent pain associated with osteoarthritis.***							
8814X	***Tablet 665 mg (modified release)***	***192***	***5***	***..***	**** 16.21***	***17.24***	***Panadol Osteo***	***GC***
	Antimigraine preparations							
	• ***Ergot alkaloids***							
	DIHYDROERGOTAMINE MESYLATE							
1323P	Injection 1 mg in 1 mL	5	..	..	16.63	17.66	Dihydergot	NV
	METHYSERGIDE							
2826R	Tablet 1 mg	100	2	..	* 44.53	32.90	Deseril	LM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Proprietary Name and Manufacturer	
	• *Selective 5HT$_1$-receptor agonists*								
	SUMATRIPTAN								
	CAUTION:								
	Sumatriptan is contraindicated in patients with known or suspected coronary artery disease. The drug should not be used within 24 hours of ergotamine or dihydroergotamine use.								
	Authority Required (STREAMLINED)								
	2663								
	Migraine attacks in patients receiving, or who have failed a reasonable trial of, prophylactic medication and where attacks in the past have usually failed to respond to oral therapy with ergotamine and other appropriate agents, or in whom these agents are contraindicated.								
	NOTE:								
	No applications for increased maximum quantities and/or repeats will be authorised.								
8341B	***Nasal spray 20 mg in 0.1 mL single dose unit***	***2***	***5***	***..***	***19.63***	***20.66***		***Imigran***	***GK***
	SUMATRIPTAN SUCCINATE								
	CAUTION:								
	Sumatriptan is contraindicated in patients with known or suspected coronary artery disease. The drug should not be used within 24 hours of ergotamine or dihydroergotamine use.								
	Authority Required (STREAMLINED)								
	2663								
	Migraine attacks in patients receiving, or who have failed a reasonable trial of, prophylactic medication and where attacks in the past have usually failed to respond to oral therapy with ergotamine and other appropriate agents, or in whom these agents are contraindicated.								
	NOTE:								
	No applications for increased maximum quantities and/or repeats will be authorised.								
8144P	***Tablet 50 mg (base)***	***4***	***5***	***..***	***25.08***	***26.11***	[a]	***Sumagran 50***	***SI***
				..	**** 25.09***	***26.12***	[a]	***Imigran***	***GK***
							[a]	***Sumatab***	***AF***
8885P	***Tablet 50 mg (base) (fast disintegrating)***	***4***	***5***	***..***	**** 25.09***	***26.12***		***Imigran FDT***	***GK***
	• *Other antimigraine preparations*								
	CYPROHEPTADINE HYDROCHLORIDE								
	Restricted Benefit								
	Prevention of migraine.								
	NOTE:								
	Cyproheptadine hydrochloride is not PBS-subsidised for use in hay fever or atopy.								
1798P	***Tablet 4 mg***	***100***	***2***	***..***	**** 13.77***	***14.80***		***Periactin***	***AS***
	PIZOTIFEN MALATE								
3074T	Tablet 500 micrograms (base)	100	2	..	21.32	22.35		Sandomigran 0.5	NV

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
	ANTIEPILEPTICS							
	Antiepileptics							
	• ***Barbiturates and derivatives***							
	PHENOBARBITONE							
	Restricted Benefit ***Epilepsy.***							
1850J	***Tablet 30 mg***	***200***	***4***	***..***	***14.85***	***15.88***	***SI***	
	PHENOBARBITONE SODIUM							
	Restricted Benefit ***Epilepsy.***							
1853M	***Injection 200 mg in 1 mL***	***5***	***..***	***..***	***32.82***	***32.90***	***FM***	
	PRIMIDONE							
1939C	Tablet 250 mg	200	2	..	52.12	32.90	Mysoline	LM
	• ***Hydantoin derivatives*** PHENYTOIN							
1249R	Tablet 50 mg	200	2	..	29.69	30.72	Dilantin Infatabs	PF
2692Q	Paediatric oral suspension 30 mg per 5 mL, 500 mL	‡ 1	3	..	21.18	22.21	Dilantin	PF
	PHENYTOIN SODIUM							
1873N	Capsule 30 mg	200	2	..	28.75	29.78	Dilantin Sodium	PF
1874P	Capsule 100 mg	200	2	..	29.69	30.72	Dilantin Sodium	PF
	• ***Succinimide derivatives*** ETHOSUXIMIDE							
1413J	Capsule 250 mg	200	2	..	53.67	32.90	Zarontin	PF
1414K	Paediatric syrup 250 mg per 5 mL, 200 mL	‡ 1	5	..	24.86	25.89	Zarontin	PF
	• ***Benzodiazepine derivatives*** ***CLONAZEPAM***							
	Restricted Benefit ***Epilepsy.***							
1807D	***Injection 1 mg in 2 mL (set containing solution 1 mg in 1 mL and 1 mL diluent)***	***5***	***..***	***..***	***18.15***	***19.18***	***Rivotril***	***RO***

continued ☞

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Proprietary Name and Manufacturer	
	Authority Required ***Neurologically proven epilepsy.***								
	CAUTION: ***Abuse of clonazepam has been reported. Refer to the current product information.***								
1805B	***Tablet 500 micrograms***	***200***	***2***	***..***	**** 19.77***	***20.80***	***a***	***Paxam 0.5***	***AF***
				B3.58	**** 23.35***	***20.80***	***a***	***Rivotril***	***RO***
1806C	***Tablet 2 mg***	***200***	***2***	***..***	**** 31.91***	***32.90***	***a***	***Paxam 2***	***AF***
				B4.08	**** 35.99***	***32.90***	***a***	***Rivotril***	***RO***
1808E	***Oral liquid 2.5 mg per mL, 10 mL***	***2***	***..***	***..***	**** 14.61***	***15.64***		***Rivotril***	***RO***
	NITRAZEPAM								
	Authority Required ***Myoclonic epilepsy;*** ***Malignant neoplasia (late stage);*** ***For use by patients who are receiving long-term nursing care on account of age, infirmity or other condition in hospitals, nursing homes or residential facilities and who have been demonstrated, within the past 6 months, to be benzodiazepine dependent by an unsuccessful attempt at gradual withdrawal;*** ***For use by a patient who is receiving long-term nursing care and in respect of whom a Carer Allowance is payable as a disabled adult and who has been demonstrated, within the past 6 months, to be benzodiazepine dependent by an unsuccessful attempt at gradual withdrawal.***								
2732T	***Tablet 5 mg***	***50***	***5***	***..***	**** 8.93***	***9.96***	***a***	***Alodorm***	***AF***
				B3.06	**** 11.99***	***9.96***	***a***	***Mogadon***	***VT***
	[For other listings for this drug see Generic/Proprietary Index]								
	• ***Carboxamide derivatives*** CARBAMAZEPINE								
2422L	Tablet 100 mg	200	2	..	18.71	19.74	a	Carbamazepine Sandoz	SZ
				B2.55	21.26	19.74	a	Tegretol 100	NV
2419H	Tablet 200 mg	200	2	..	29.77	30.80	a	Carbamazepine Sandoz	SZ
							a	Teril	AF
				B2.74	32.51	30.80	a	Tegretol 200	NV
2426Q	Tablet 200 mg (controlled release)	200	2	..	30.26	31.29		Tegretol CR 200	NV
2431Y	Tablet 400 mg (controlled release)	200	2	..	50.59	32.90		Tegretol CR 400	NV
2427R	Oral suspension 100 mg per 5 mL, 300 mL	‡ 1	5	..	20.92	21.95		Tegretol Liquid	NV

NERVOUS SYSTEM—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Proprietary Name and Manufacturer	
	OXCARBAZEPINE								
	Authority Required (STREAMLINED) **1587** ***Treatment of partial epileptic seizures and primary generalised tonic-clonic seizures, which are not controlled satisfactorily by other anti-epileptic drugs.***								
8584T	***Tablet 150 mg***	***100***	***5***	***..***	***71.84***	***32.90***		***Trileptal***	***NV***
8585W	***Tablet 300 mg***	***100***	***5***	***..***	***114.65***	***32.90***		***Trileptal***	***NV***
8586X	***Tablet 600 mg***	***100***	***5***	***..***	***187.55***	***32.90***		***Trileptal***	***NV***
8588B	***Oral suspension 60 mg per mL, 250 mL***	***2***	***5***	***..***	**** 137.69***	***32.90***		***Trileptal***	***NV***
	• ***Fatty acid derivatives*** SODIUM VALPROATE **CAUTION:** There are reports of fatal hepatotoxicity, particularly in children. There is increasing evidence of dose-related teratogenesis from this drug.								
2294R	Crushable tablet 100 mg	200	2	..	* 31.57	32.60		Epilim	SW
2289L	Tablet 200 mg (enteric coated)	200	2	..	* 33.43	32.90	[a]	Sodium Valproate Sandoz	SZ
							[a]	Valpro 200	AF
							[a]	Valproate Winthrop EC 200	WA
				B1.50	* 34.93	32.90	[a]	Epilim EC	SW
2290M	Tablet 500 mg (enteric coated)	200	2	..	* 57.95	32.90	[a]	Sodium Valproate Sandoz	SZ
							[a]	Valpro 500	AF
							[a]	Valproate Winthrop EC 500	WA
				B1.50	* 59.45	32.90	[a]	Epilim EC	SW
2293Q	Oral liquid 200 mg per 5 mL, 300 mL	2	2	..	* 34.49	32.90		Epilim Liquid	SW
2295T	Syrup 200 mg per 5 mL, 300 mL	2	2	..	* 34.49	32.90		Epilim Syrup	SW
	TIAGABINE HYDROCHLORIDE								
	Authority Required (STREAMLINED) **2664** ***Treatment of partial epileptic seizures which are not controlled satisfactorily by other anti-epileptic drugs.***								
8221Q	***Tablet 5 mg (base)***	***100***	***5***	***..***	**** 72.21***	***32.90***		***Gabitril***	***OA***
8222R	***Tablet 10 mg (base)***	***100***	***5***	***..***	**** 138.41***	***32.90***		***Gabitril***	***OA***
8223T	***Tablet 15 mg (base)***	***100***	***5***	***..***	**** 196.45***	***32.90***		***Gabitril***	***OA***

NERVOUS SYSTEM—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Proprietary Name and Manufacturer	
	VIGABATRIN								
	CAUTION:								
	Visual field defects have been reported with this drug.								
	Authority Required (STREAMLINED)								
	1426								
	Treatment of epileptic seizures which are not controlled satisfactorily by other anti-epileptic drugs.								
2667J	***Tablet 500 mg***	***100***	***5***	***..***	***100.50***	***32.90***		***Sabril***	***SW***
2668K	***Oral powder, sachet 500 mg***	***60***	***5***	***..***	***67.27***	***32.90***		***Sabril***	***SW***
	• ***Other antiepileptics***								
	GABAPENTIN								
	Authority Required (STREAMLINED)								
	2664								
	Treatment of partial epileptic seizures which are not controlled satisfactorily by other anti-epileptic drugs.								
8505P	***Capsule 100 mg***	***100***	***5***	***..***	***23.38***	***24.41***	[a]	***DBL Gabapentin***	***HH***
							[a]	***Gabatine 100***	***SI***
							[a]	***Gantin***	***AW***
							[a]	***Neurontin***	***PF***
							[a]	***Nupentin 100***	***AF***
1834M	***Capsule 300 mg***	***100***	***5***	***..***	***61.58***	***32.90***	[a]	***DBL Gabapentin***	***HH***
							[a]	***Douglas Gabapentin 300mg***	***GM***
							[a]	***Gabahexal 300mg***	***SZ***
							[a]	***Gabapentin 300***	***CR***
							[a]	***Gabatine 300***	***SI***
							[a]	***Gantin***	***AW***
							[a]	***GenRx Gabapentin***	***GX***
							[a]	***Neurontin***	***PF***
							[a]	***Nupentin 300***	***AF***
							[a]	***Pendine 300***	***AL***
1835N	***Capsule 400 mg***	***100***	***5***	***..***	***81.81***	***32.90***	[a]	***DBL Gabapentin***	***HH***
							[a]	***Douglas Gabapentin 400mg***	***GM***
							[a]	***Gabahexal 400mg***	***SZ***
							[a]	***Gabapentin 400***	***CR***
							[a]	***Gabatine 400***	***SI***
							[a]	***Gantin***	***AW***
							[a]	***GenRx Gabapentin***	***GX***
							[a]	***Neurontin***	***PF***
							[a]	***Nupentin 400***	***AF***
							[a]	***Pendine 400***	***AL***

continued ☞

NERVOUS SYSTEM—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Proprietary Name and Manufacturer	
8559L	*Tablet 600 mg*	*100*	*5*	*..*	*126.34*	*32.90*	*a*	*Gabahexal 600mg*	*SZ*
							a	*Gabaran*	*RA*
							a	*GenRx Gabapentin*	*GX*
							a	*Neurontin*	*PF*
8389M	*Tablet 800 mg*	*100*	*5*	*..*	*166.43*	*32.90*	*a*	*Gabaran*	*RA*
							a	*Gantin*	*AW*
							a	*GenRx Gabapentin*	*GX*
							a	*Neurontin*	*PF*
							a	*Pendine 800*	*AF*
	LAMOTRIGINE								
	Authority Required (STREAMLINED)								
	1426								
	Treatment of epileptic seizures which are not controlled satisfactorily by other anti-epileptic drugs.								
8063J	*Tablet 5 mg*	*56*	*5*	*..*	*16.32*	*17.35*	*a*	*Lamogine*	*AF*
							a	*Seaze 5*	*SI*
				B0.76	*17.08*	*17.35*	*a*	*Lamictal*	*GK*
2848X	*Tablet 25 mg*	*56*	*5*	*..*	*28.97*	*30.00*	*a*	*GenRx Lamotrigine*	*GX*
							a	*Lamidus*	*RA*
							a	*Lamogine*	*AF*
							a	*Lamotrigine-DP*	*GM*
							a	*Lamotrigine-GA*	*GN*
							a	*Lamotrigine generichealth*	*GQ*
							a	*Lamotrigine Sandoz*	*SZ*
							a	*Seaze 25*	*SI*
				B0.77	*29.74*	*30.00*	*a*	*Lamictal*	*GK*
2849Y	*Tablet 50 mg*	*56*	*5*	*..*	*43.81*	*32.90*	*a*	*GenRx Lamotrigine*	*GX*
							a	*Lamidus*	*RA*
							a	*Lamogine*	*AF*
							a	*Lamotrigine-DP*	*GM*
							a	*Lamotrigine-GA*	*GN*
							a	*Lamotrigine generichealth*	*GQ*
							a	*Lamotrigine Sandoz*	*SZ*
							a	*Seaze 50*	*SI*
				B0.66	*44.47*	*32.90*	*a*	*Lamictal*	*GK*

continued ☞

NERVOUS SYSTEM—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
2850B	***Tablet 100 mg***	***56***	***5***	***..***	***67.06***	***32.90***	[a] ***GenRx Lamotrigine***	***GX***
							[a] ***Lamidus***	***RA***
							[a] ***Lamogine***	***AF***
							[a] ***Lamotrigine-DP***	***GM***
							[a] ***Lamotrigine-GA***	***GN***
							[a] ***Lamotrigine generichealth***	***GQ***
							[a] ***Lamotrigine Sandoz***	***SZ***
							[a] ***Seaze 100***	***SI***
				B0.73	***67.79***	***32.90***	[a] ***Lamictal***	***GK***
2851C	***Tablet 200 mg***	***56***	***5***	***..***	***108.58***	***32.90***	[a] ***GenRx Lamotrigine***	***GX***
							[a] ***Lamidus***	***RA***
							[a] ***Lamogine***	***AF***
							[a] ***Lamotrigine-DP***	***GM***
							[a] ***Lamotrigine-GA***	***GN***
							[a] ***Lamotrigine generichealth***	***GQ***
							[a] ***Lamotrigine Sandoz***	***SZ***
							[a] ***Seaze 200***	***SI***
				B0.72	***109.30***	***32.90***	[a] ***Lamictal***	***GK***

LEVETIRACETAM

Authority Required

Treatment of partial epileptic seizures, which are not controlled satisfactorily by other anti-epileptic drugs in a patient unable to take a solid dose form of levetiracetam.

9169N	***Oral solution 100 mg per mL, 300 mL***	***‡ 1***	***5***	***..***	***110.99***	***32.90***	***Keppra***	***UC***

SULTHIAME

2099L	Tablet 50 mg	200	2	..	45.69	32.90	Ospolot	PL
2100M	Tablet 200 mg	200	2	..	98.14	32.90	Ospolot	PL

TOPIRAMATE

Authority Required (STREAMLINED)

2797

Treatment of partial epileptic seizures, primary generalised tonic-clonic epileptic seizures and seizures of the Lennox-Gastaut syndrome, which are not controlled satisfactorily by other anti-epileptic drugs.

Authority Required (STREAMLINED)

2799

continued ☞

NERVOUS SYSTEM—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
	Prophylaxis of migraine in a patient who has experienced an average of 3 or more migraines per month over a period of at least 6 months, and who:							
	(a) has a contraindication to beta-blockers, as described in the relevant TGA-approved Product Information; OR							
	(b) has experienced intolerance of a severity necessitating permanent withdrawal during treatment with a beta-blocker;							
	AND							
	(c) has a contraindication to pizotifen because the weight gain associated with this drug poses an unacceptable risk; OR							
	(d) has experienced intolerance of a severity necessitating permanent withdrawal during treatment with pizotifen.							
	Details of the contraindication and/or intolerance(s) must be documented in the patient's medical records when treatment is initiated.							
8163P	***Tablet 25 mg***	***60***	***5***	***..***	***41.74***	***32.90***	***Topamax***	***JC***
8164Q	***Tablet 50 mg***	***60***	***5***	***..***	***62.42***	***32.90***	***Topamax***	***JC***
	Authority Required (STREAMLINED)							
	2797							
	Treatment of partial epileptic seizures, primary generalised tonic-clonic epileptic seizures and seizures of the Lennox-Gastaut syndrome, which are not controlled satisfactorily by other anti-epileptic drugs.							
8165R	***Tablet 100 mg***	***60***	***5***	***..***	***96.75***	***32.90***	***Topamax***	***JC***
8166T	***Tablet 200 mg***	***60***	***5***	***..***	***158.45***	***32.90***	***Topamax***	***JC***
	Authority Required (STREAMLINED)							
	2798							
	Treatment of partial epileptic seizures, primary generalised tonic-clonic epileptic seizures and seizures of the Lennox-Gastaut syndrome, which are not controlled satisfactorily by other anti-epileptic drugs in patients unable to take a solid dose form of topiramate.							
8371N	***Capsule 15 mg***	***60***	***5***	***..***	***33.52***	***32.90***	***Topamax Sprinkle***	***JC***
8372P	***Capsule 25 mg***	***60***	***5***	***..***	***42.91***	***32.90***	***Topamax Sprinkle***	***JC***
8520K	***Capsule 50 mg***	***60***	***5***	***..***	***63.89***	***32.90***	***Topamax Sprinkle***	***JC***
	ANTI-PARKINSON DRUGS							
	Anticholinergic agents							
	• ***Tertiary amines***							
	BENZHEXOL HYDROCHLORIDE							
1109J	Tablet 2 mg	200	2	..	14.89	15.92	Artane	SI
1110K	Tablet 5 mg	200	1	..	21.58	22.61	Artane	SI
	BIPERIDEN HYDROCHLORIDE							
2544X	Tablet 2 mg	200	2	..	* 20.45	21.48	Akineton	LM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Proprietary Name and Manufacturer	
	• *Ethers of tropine or tropine derivatives*								
	BENZTROPINE MESYLATE								
2362H	Tablet 2 mg	60	2	..	12.33	13.36		Benztrop	PL
3038X	Injection 2 mg in 2 mL	5	..	..	22.41	23.44		Cogentin	FK
	Dopaminergic agents								
	• *Dopa and dopa derivatives*								
	LEVODOPA with BENSERAZIDE								
8218M	Dispersible tablet 50 mg-12.5 mg	100	5	..	22.57	23.60		Madopar Rapid 62.5	RO
8219N	Dispersible tablet 100 mg-25 mg	100	5	..	38.49	32.90		Madopar Rapid 125	RO
2229H	Tablet 100 mg-25 mg	100	5	..	38.49	32.90		Madopar 125	RO
2228G	Tablet 200 mg-50 mg	100	5	..	49.58	32.90		Madopar	RO
2227F	Capsule 50 mg-12.5 mg	100	5	..	22.57	23.60		Madopar 62.5	RO
2225D	Capsule 100 mg-25 mg	100	5	..	38.49	32.90		Madopar 125	RO
2231K	Capsule 100 mg-25 mg (sustained release)	100	5	..	41.57	32.90		Madopar HBS	RO
2226E	Capsule 200 mg-50 mg	100	5	..	49.58	32.90		Madopar	RO
	LEVODOPA with CARBIDOPA								
1242J	Tablet 100 mg-25 mg	100	5	..	39.86	32.90	[a]	Kinson	AF
				B5.22	45.08	32.90	[a]	Sinemet 100/25	MK
1245M	Tablet 250 mg-25 mg	100	5	..	46.80	32.90	[a]	Levohexal	SZ
				B3.10	49.90	32.90	[a]	Sinemet	MK

LEVODOPA with CARBIDOPA

Authority Required (STREAMLINED)

1257

Parkinson's disease where fluctuations in motor function are not adequately controlled by frequent dosing with conventional formulations of levodopa with decarboxylase inhibitor.

1255C	***Tablet 200 mg-50 mg (modified release)***	***100***	***5***	***..***	***67.44***	***32.90***		***Sinemet CR***	***MK***

NERVOUS SYSTEM—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
	LEVODOPA with CARBIDOPA and ENTACAPONE							
	Authority Required (STREAMLINED)							
	2059							
	Parkinson's disease in patients being treated with levodopa—decarboxylase inhibitor combinations who are experiencing fluctuations in motor function due to end-of-dose effect;							
	2060							
	Parkinson's disease in patients stabilised on concomitant treatment with levodopa—decarboxylase inhibitor combinations and entacapone.							
8797B	*Tablet 50 mg-12.5 mg-200 mg*	*200*	*4*	*..*	** 311.45*	*32.90*	*Stalevo 50/12.5/ 200mg*	*NV*
8798C	*Tablet 100 mg-25 mg-200 mg*	*200*	*4*	*..*	** 341.49*	*32.90*	*Stalevo 100/25/ 200mg*	*NV*
8799D	*Tablet 150 mg-37.5 mg-200 mg*	*200*	*4*	*..*	** 371.53*	*32.90*	*Stalevo 150/37.5/ 200mg*	*NV*
9292C	*Tablet 200 mg-50 mg-200 mg*	*200*	*4*	*..*	** 399.19*	*32.90*	*Stalevo 200/50/ 200mg*	*NV*
	• Adamantane derivatives							
	AMANTADINE HYDROCHLORIDE							
	Restricted Benefit							
	Parkinson's disease which is not drug induced.							
3016R	*Capsule 100 mg*	*100*	*5*	*..*	*43.87*	*32.90*	*Symmetrel 100*	*NV*
	• Dopamine agonists							
	BROMOCRIPTINE MESYLATE							
	Restricted Benefit							
	Acromegaly;							
	Parkinson's disease;							
	Pathological hyperprolactinaemia where surgery is not indicated;							
	Pathological hyperprolactinaemia where surgery has already been used with incomplete resolution;							
	Pathological hyperprolactinaemia where radiotherapy is not indicated;							
	Pathological hyperprolactinaemia where radiotherapy has already been used with incomplete resolution.							
1443Y	*Tablet 2.5 mg (base)*	*60*	*5*	*..*	*32.30*	*32.90*	*[a] Kripton 2.5*	*AF*
				[B]2.92	*35.22*	*32.90*	*[a] Parlodel*	*NV*
1446D	*Capsule 5 mg (base)*	*60*	*5*	*..*	*49.82*	*32.90*	*[a] Kripton 5*	*AF*
				[B]2.91	*52.73*	*32.90*	*[a] Parlodel*	*NV*
1445C	*Capsule 10 mg (base)*	*100*	*5*	*..*	*155.51*	*32.90*	*[a] Kripton 10*	*AF*
				[B]3.08	*158.59*	*32.90*	*[a] Parlodel*	*NV*

[For other listings for this drug see Generic/Proprietary Index]

NERVOUS SYSTEM—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
	CABERGOLINE							
	Restricted Benefit ***Parkinson's disease.***							
8393R	***Tablet 1 mg***	***30***	***5***	***..***	***69.49***	***32.90***	***Cabaser***	***PU***
8394T	***Tablet 2 mg***	***30***	***5***	***..***	***91.10***	***32.90***	***Cabaser***	***PU***
	PERGOLIDE MESYLATE							
	Restricted Benefit ***Parkinson's disease as adjunctive therapy in patients being treated with levodopa—decarboxylase inhibitor combinations.***							
2808T	***Tablet 50 micrograms (base)***	***100***	***..***	***..***	***52.50***	***32.90***	***Permax***	***AS***
2809W	***Tablet 250 micrograms (base)***	***100***	***5***	***..***	***65.75***	***32.90***	***Permax***	***AS***
2810X	***Tablet 1 mg (base)***	***100***	***5***	***..***	***241.26***	***32.90***	***Permax***	***AS***
	PRAMIPEXOLE HYDROCHLORIDE **CAUTION:** ***Episodes of sudden onset of sleep without warning, during activity, have been reported with this drug.***							
	Restricted Benefit ***Parkinson's disease as adjunctive therapy in patients being treated with levodopa—decarboxylase inhibitor combinations.***							
9151P	***Tablet 125 micrograms***	***30***	***..***	***..***	***11.40***	***12.43***	***Sifrol***	***BY***
9152Q	***Tablet 250 micrograms***	***100***	***5***	***..***	***41.31***	***32.90***	***Sifrol***	***BY***
9153R	***Tablet 1 mg***	***100***	***5***	***..***	***151.71***	***32.90***	***Sifrol***	***BY***
	• Monoamine oxidase type B inhibitors ***SELEGILINE HYDROCHLORIDE***							
	Restricted Benefit ***Late stage Parkinson's disease as adjunctive therapy in patients being treated with levodopa—decarboxylase inhibitor combinations.***							
1973W	***Tablet 5 mg***	***100***	***5***	***..***	***55.16***	***32.90***	[a] ***Eldepryl*** [a] ***Selgene***	***GM*** ***AF***
	• Other dopaminergic agents ***ENTACAPONE***							
	Authority Required (STREAMLINED) **2067** ***Parkinson's disease as adjunctive therapy in patients being treated with levodopa—decarboxylase inhibitor combinations who are experiencing fluctuations in motor function due to end-of-dose effect.***							
8367J	***Tablet 200 mg***	***200***	***4***	***..***	**** 281.39***	***32.90***	***Comtan***	***NV***

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
	PSYCHOLEPTICS							
	Antipsychotics							
	• ***Phenothiazine with aliphatic side-chain***							
	CHLORPROMAZINE HYDROCHLORIDE							
1196Y	Tablet 10 mg	100	5	..	10.06	11.09	Largactil	SW
1197B	Tablet 25 mg	100	5	..	10.66	11.69	Largactil	SW
1199D	Tablet 100 mg	100	5	..	17.01	18.04	Largactil	SW
1201F	Mixture 25 mg per 5 mL, 100 mL	‡ 1	5	..	11.27	12.30	Largactil	SW
1195X	Injection 50 mg in 2 mL	10	..	..	16.39	17.42	Largactil	SW
	• ***Phenothiazine with piperazine structure***							
	FLUPHENAZINE DECANOATE							
1046C	Injection 12.5 mg in 0.5 mL	5	..	..	18.79	19.82	Modecate	BQ
3098C	Injection 25 mg in 1 mL	5	..	..	25.95	26.98	Modecate	BQ
1001Q	Injection 50 mg in 2 mL	5	..	..	37.22	32.90	Modecate	BQ
	TRIFLUOPERAZINE HYDROCHLORIDE							
2185B	Tablet 1 mg (base)	100	5	..	12.88	13.91	Stelazine	GH
2386N	Tablet 2 mg (base)	100	5	..	13.05	14.08	Stelazine	GH
2186C	Tablet 5 mg (base)	100	5	..	13.43	14.46	Stelazine	GH
	• ***Phenothiazines with piperidine structure***							
	PERICYAZINE							
3052P	Tablet 2.5 mg	100	5	..	9.98	11.01	Neulactil	SW
3053Q	Tablet 10 mg	100	5	..	14.03	15.06	Neulactil	SW
	• ***Butyrophenone derivatives***							
	HALOPERIDOL							
2761H	Tablet 500 micrograms	100	5	..	9.62	10.65	Serenace	SI
2767P	Tablet 1.5 mg	100	5	..	10.10	11.13	Serenace	SI
2770T	Tablet 5 mg	50	5	..	10.11	11.14	Serenace	SI
2763K	Oral liquid 2 mg per mL, 100 mL	‡ 1	5	..	17.04	18.07	Serenace	SI
2768Q	Injection 5 mg in 1 mL	10	..	..	21.85	22.88	Serenace	SI

NERVOUS SYSTEM—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
	HALOPERIDOL DECANOATE							
2765M	I.M. injection equivalent to 50 mg haloperidol in 1 mL	5	..	..	26.24	27.27	Haldol decanoate	JC
2766N	I.M. injection equivalent to 150 mg haloperidol in 3 mL	5	..	..	45.80	32.90	Haldol decanoate	JC
	• *Indole derivatives*							
	ZIPRASIDONE HYDROCHLORIDE							
	Authority Required (STREAMLINED) **1589** ***Schizophrenia.***							
9070J	***Capsule 20 mg (base)***	***60***	***5***	***..***	***94.97***	***32.90***	***Zeldox***	***PF***
9071K	***Capsule 40 mg (base)***	***60***	***5***	***..***	***183.96***	***32.90***	***Zeldox***	***PF***
9072L	***Capsule 60 mg (base)***	***60***	***5***	***..***	***266.67***	***32.90***	***Zeldox***	***PF***
9073M	***Capsule 80 mg (base)***	***60***	***5***	***..***	***347.56***	***32.90***	***Zeldox***	***PF***
	• *Thioxanthene derivatives*							
	FLUPENTHIXOL DECANOATE							
2255Q	Oily I.M. injection 20 mg in 1 mL	5	..	..	18.79	19.82	Fluanxol Depot	LU
2256R	Oily I.M. injection 40 mg in 2 mL	5	..	..	25.95	26.98	Fluanxol Depot	LU
2257T	Oily I.M. injection 100 mg in 1 mL	5	..	..	44.44	32.90	Fluanxol Concentrated Depot	LU
	ZUCLOPENTHIXOL DECANOATE							
8097E	Oily I.M. injection 200 mg in 1 mL	5	..	..	24.91	25.94	Clopixol Depot	LU
	• *Diazepines, oxazepines and thiazepines*							
	OLANZAPINE							
	Authority Required (STREAMLINED) **1589** ***Schizophrenia;*** **2044** ***Maintenance treatment of bipolar I disorder.***							
8170B	***Tablet 2.5 mg***	***28***	***5***	***..***	***53.12***	***32.90***	***Zyprexa***	***LY***
8185T	***Tablet 5 mg***	***28***	***5***	***..***	***98.84***	***32.90***	***Zyprexa***	***LY***
8186W	***Tablet 7.5 mg***	***28***	***5***	***..***	***146.68***	***32.90***	***Zyprexa***	***LY***
8187X	***Tablet 10 mg***	***28***	***5***	***..***	***193.57***	***32.90***	***Zyprexa***	***LY***

continued ☞

NERVOUS SYSTEM—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
8433W	*Wafer 5 mg*	*28*	*5*	*..*	*98.84*	*32.90*	*Zyprexa Zydis*	*LY*
8434X	*Wafer 10 mg*	*28*	*5*	*..*	*193.57*	*32.90*	*Zyprexa Zydis*	*LY*
	QUETIAPINE FUMARATE							
	Authority Required (STREAMLINED) **1589** *Schizophrenia;* **2765** *Monotherapy, for up to 6 months, of an episode of acute mania associated with bipolar I disorder.*							
8456C	*Tablet 25 mg (base)*	*60*	*5*	*..*	*53.23*	*32.90*	*Seroquel*	*AP*
8457D	*Tablet 100 mg (base)*	*90*	*5*	*..*	*142.28*	*32.90*	*Seroquel*	*AP*
8458E	*Tablet 200 mg (base)*	*60*	*5*	*..*	*191.92*	*32.90*	*Seroquel*	*AP*
8580N	*Tablet 300 mg (base)*	*60*	*5*	*..*	*271.65*	*32.90*	*Seroquel*	*AP*
	Authority Required (STREAMLINED) **1589** *Schizophrenia.*							
9202H	*Tablet (modified release) equivalent to 50 mg quetiapine*	*60*	*5*	*..*	*100.68*	*32.90*	*Seroquel XR*	*AP*
9203J	*Tablet (modified release) equivalent to 200 mg quetiapine*	*60*	*5*	*..*	*196.14*	*32.90*	*Seroquel XR*	*AP*
9204K	*Tablet (modified release) equivalent to 300 mg quetiapine*	*60*	*5*	*..*	*276.55*	*32.90*	*Seroquel XR*	*AP*
9205L	*Tablet (modified release) equivalent to 400 mg quetiapine*	*60*	*5*	*..*	*369.71*	*32.90*	*Seroquel XR*	*AP*
	• ***Benzamides***							
	AMISULPRIDE							
	Authority Required (STREAMLINED) **1589** *Schizophrenia.*							
8594H	*Tablet 100 mg*	*30*	*5*	*..*	*33.83*	*32.90*	[a] *Amisulpride 100 Winthrop*	*WA*
							[a] *Amisulpride Sandoz*	*SZ*
							[a] *Solian 100*	*SW*

continued ☞

NERVOUS SYSTEM—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
8595J	***Tablet 200 mg***	***60***	***5***	***..***	***120.75***	***32.90***	[a] ***Amisulpride 200 Winthrop***	***WA***
							[a] ***Amisulpride Sandoz***	***SZ***
							[a] ***Solian 200***	***SW***
8596K	***Tablet 400 mg***	***60***	***5***	***..***	***223.38***	***32.90***	[a] ***Amipride 400***	***SI***
							[a] ***Amisulpride 400 Winthrop***	***WA***
							[a] ***Amisulpride Sandoz***	***SZ***
							[a] ***Solian 400***	***SW***
8736T	***Oral solution 100 mg per mL, 60 mL***	***2***	***5***	***..***	**** 148.31***	***32.90***	***Solian Solution***	***SW***

• *Lithium*

LITHIUM CARBONATE

For listings see Generic/Proprietary Index

• *Other antipsychotics*

ARIPIPRAZOLE

Authority Required (STREAMLINED)
1589
Schizophrenia.

8717T	***Tablet 10 mg***	***30***	***5***	***..***	***156.02***	***32.90***	***Abilify***	***BQ***
8718W	***Tablet 15 mg***	***30***	***5***	***..***	***217.55***	***32.90***	***Abilify***	***BQ***
8719X	***Tablet 20 mg***	***30***	***5***	***..***	***259.60***	***32.90***	***Abilify***	***BQ***
8720Y	***Tablet 30 mg***	***30***	***5***	***..***	***311.10***	***32.90***	***Abilify***	***BQ***

PALIPERIDONE

Authority Required (STREAMLINED)
1589
Schizophrenia.

9140C	***Tablet 3 mg (prolonged release)***	***28***	***5***	***..***	***248.48***	***32.90***	***Invega***	***JC***
9141D	***Tablet 6 mg (prolonged release)***	***28***	***5***	***..***	***248.48***	***32.90***	***Invega***	***JC***
9142E	***Tablet 9 mg (prolonged release)***	***28***	***5***	***..***	***248.48***	***32.90***	***Invega***	***JC***
9194X	***Tablet 12 mg (prolonged release)***	***28***	***5***	***..***	***248.48***	***32.90***	***Invega***	***JC***

NERVOUS SYSTEM—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Proprietary Name and Manufacturer	
	RISPERIDONE								
	Authority Required (STREAMLINED)								
	2061								
	Behavioural disturbances characterised by psychotic symptoms and aggression in patients with dementia where non-pharmacological methods have been unsuccessful.								
	CAUTION:								
	In placebo controlled trials in elderly patients with dementia there was a significantly higher incidence of cerebrovascular adverse events, such as stroke (including fatalities) and transient ischaemic attacks, in patients treated with risperidone compared with patients treated with placebo.								
	Authority Required (STREAMLINED)								
	3083								
➢	***Treatment under the supervision of a paediatrician or psychiatrist, in combination with non-pharmacological measures, of severe behavioural disturbances in a patient aged less than 18 years with autism.***								
	Continuing PBS-subsidised treatment under the supervision of a paediatrician or psychiatrist, in combination with non-pharmacological measures, of severe behavioural disturbances in a patient 18 years of age or older with autism who was commenced on PBS-subsidised treatment with risperidone prior to turning 18 years of age.								
	Behaviour disturbances are defined as severe aggression and injuries to self or others where non-pharmacological methods alone have been unsuccessful.								
	The diagnosis of autism must be made based on the Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV) or ICD-10 international classification of mental and behavioural disorders.								
8787L	*Tablet 0.5 mg*	*60*	*2*	*..*	*36.48*	*32.90*	[a]	*Risperidone-GA*	*GM*
							[a]	*Rixadone*	*AF*
				..	* *36.50*	*32.90*	[a]	*APO-Risperidone*	*TX*
							[a]	*Rispa*	*SI*
							[a]	*Risperdal*	*JC*
8788M	*Tablet 0.5 mg (orally disintegrating)*	*56*	*2*	*..*	* *34.45*	*32.90*		*Risperdal Quicklet*	*JC*
8789N	*Tablet 1 mg*	*60*	*2*	*..*	*64.30*	*32.90*	[a]	*APO-Risperidone*	*TX*
							[a]	*Rispa*	*SI*
							[a]	*Risperdal*	*JC*
							[a]	*Risperidone-GA*	*GM*
							[a]	*Risperidone generichealth*	*GQ*
							[a]	*Rixadone*	*AF*
8790P	*Tablet 1 mg (orally disintegrating)*	*56*	*2*	*..*	* *60.41*	*32.90*		*Risperdal Quicklet*	*JC*
9293D	*Oral solution 1 mg per mL, 100 mL*	*‡ 1*	*2*	*..*	*117.60*	*32.90*		*Risperdal*	*JC*

Authority Required (STREAMLINED)

3083

continued ☞

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Proprietary Name and Manufacturer	
➢	***Treatment under the supervision of a paediatrician or psychiatrist, in combination with non-pharmacological measures, of severe behavioural disturbances in a patient aged less than 18 years with autism.***								
	Continuing PBS-subsidised treatment under the supervision of a paediatrician or psychiatrist, in combination with non-pharmacological measures, of severe behavioural disturbances in a patient 18 years of age or older with autism who was commenced on PBS-subsidised treatment with risperidone prior to turning 18 years of age.								
	Behaviour disturbances are defined as severe aggression and injuries to self or others where non-pharmacological methods alone have been unsuccessful.								
	The diagnosis of autism must be made based on the Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV) or ICD-10 international classification of mental and behavioural disorders.								
9079W	*Tablet 2 mg*	*60*	*2*	*..*	*123.15*	*32.90*	[a]	*APO-Risperidone*	*TX*
							[a]	*Rispa*	*SI*
							[a]	*Risperdal*	*JC*
							[a]	*Risperidone-GA*	*GM*
							[a]	*Risperidone generichealth*	*GQ*
							[a]	*Rixadone*	*AF*
9080X	*Tablet 2 mg (orally disintegrating)*	*56*	*2*	*..*	** 115.35*	*32.90*		*Risperdal Quicklet*	*JC*

Authority Required (STREAMLINED)
1589
Schizophrenia.

Authority Required (STREAMLINED)
2272
Adjunctive therapy to mood stabilisers for up to 6 months, of an episode of acute mania associated with bipolar I disorder.

3169T	*Tablet 1 mg*	*60*	*5*	*..*	*64.30*	*32.90*	[a]	*APO-Risperidone*	*TX*
							[a]	*Rispa*	*SI*
							[a]	*Risperdal*	*JC*
							[a]	*Risperidone-GA*	*GM*
							[a]	*Risperidone generichealth*	*GQ*
							[a]	*Rixadone*	*AF*
8792R	*Tablet 1 mg (orally disintegrating)*	*56*	*5*	*..*	** 60.41*	*32.90*		*Risperdal Quicklet*	*JC*
3170W	*Tablet 2 mg*	*60*	*5*	*..*	*123.15*	*32.90*	[a]	*APO-Risperidone*	*TX*
							[a]	*Rispa*	*SI*
							[a]	*Risperdal*	*JC*
							[a]	*Risperidone-GA*	*GM*
							[a]	*Risperidone generichealth*	*GQ*
							[a]	*Rixadone*	*AF*
8794W	*Tablet 2 mg (orally disintegrating)*	*56*	*5*	*..*	** 115.35*	*32.90*		*Risperdal Quicklet*	*JC*

continued ☞

NERVOUS SYSTEM—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Proprietary Name and Manufacturer	
3171X	***Tablet 3 mg***	***60***	***5***	***..***	***180.16***	***32.90***	[a]	***APO-Risperidone***	***TX***
							[a]	***Rispa***	***SI***
							[a]	***Risperdal***	***JC***
							[a]	***Risperidone-GA***	***GM***
							[a]	***Risperidone generichealth***	***GQ***
							[a]	***Rixadone***	***AF***
9075P	***Tablet 3 mg (orally disintegrating)***	***56***	***5***	***..***	**** 168.55***	***32.90***		***Risperdal Quicklet***	***JC***
3172Y	***Tablet 4 mg***	***60***	***5***	***..***	***235.00***	***32.90***	[a]	***APO-Risperidone***	***TX***
							[a]	***Rispa***	***SI***
							[a]	***Risperdal***	***JC***
							[a]	***Risperidone-GA***	***GM***
							[a]	***Risperidone generichealth***	***GQ***
							[a]	***Rixadone***	***AF***
9076Q	***Tablet 4 mg (orally disintegrating)***	***56***	***5***	***..***	**** 220.93***	***32.90***		***Risperdal Quicklet***	***JC***
8100H	***Oral solution 1 mg per mL, 100 mL***	***‡ 1***	***5***	***..***	***117.60***	***32.90***		***Risperdal***	***JC***

Authority Required (STREAMLINED)
1589
Schizophrenia.

8869T	***Tablet 0.5 mg***	***60***	***5***	***..***	***36.48***	***32.90***	[a]	***Risperidone-GA***	***GM***
							[a]	***Rixadone***	***AF***
				..	**** 36.50***	***32.90***	[a]	***APO-Risperidone***	***TX***
							[a]	***Rispa***	***SI***
							[a]	***Risperdal***	***JC***
8870W	***Tablet 0.5 mg (orally disintegrating)***	***56***	***5***	***..***	**** 34.45***	***32.90***		***Risperdal Quicklet***	***JC***
8780D	***Powder for I.M. injection 25 mg (modified release) with 2 mL diluent in pre-filled syringe***	***2***	***5***	***..***	**** 320.71***	***32.90***		***Risperdal Consta***	***JC***
8781E	***Powder for I.M. injection 37.5 mg (modified release) with 2 mL diluent in pre-filled syringe***	***2***	***5***	***..***	**** 409.97***	***32.90***		***Risperdal Consta***	***JC***
8782F	***Powder for I.M. injection 50 mg (modified release) with 2 mL diluent in pre-filled syringe***	***2***	***5***	***..***	**** 499.33***	***32.90***		***Risperdal Consta***	***JC***

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Proprietary Name and Manufacturer	
	Anxiolytics								
	• ***Benzodiazepine derivatives***								
	ALPRAZOLAM								
	Authority Required								
	Panic disorder where other treatments have failed or are inappropriate.								
2130D	***Tablet 250 micrograms***	***50***	***..***	***..***	***9.12***	***10.15***	[a]	***Alprax 0.25***	***SI***
							[a]	***Kalma 0.25***	***AF***
							[a]	***Zamhexal 0.25mg***	***SZ***
				B0.81	***9.93***	***10.15***	[a]	***Xanax***	***PH***
2131E	***Tablet 500 micrograms***	***50***	***..***	***..***	***11.05***	***12.08***	[a]	***Alprax 0.5***	***SI***
							[a]	***Kalma 0.5***	***AF***
							[a]	***Zamhexal 0.5mg***	***SZ***
				B0.87	***11.92***	***12.08***	[a]	***Xanax***	***PH***
2132F	***Tablet 1 mg***	***50***	***2***	***..***	***14.80***	***15.83***	[a]	***Alprax 1***	***SI***
							[a]	***Alprazolam-DP***	***GM***
							[a]	***Chem mart Alprazolam***	***CH***
							[a]	***GenRx Alprazolam***	***GX***
							[a]	***Kalma 1***	***AF***
							[a]	***Terry White Chemists Alprazolam***	***TW***
							[a]	***Zamhexal 1.0mg***	***SZ***
				B1.03	***15.83***	***15.83***	[a]	***Xanax***	***PH***
8118G	***Tablet 2 mg***	***50***	***2***	***..***	***19.63***	***20.66***	[a]	***Alprax 2***	***SI***
							[a]	***Alprazolam-DP***	***GM***
							[a]	***Chem mart Alprazolam***	***CH***
							[a]	***GenRx Alprazolam***	***GX***
							[a]	***Kalma 2***	***AF***
							[a]	***Terry White Chemists Alprazolam***	***TW***
							[a]	***Zamhexal 2mg***	***SZ***
				B1.25	***20.88***	***20.66***	[a]	***Xanax Tri-Score***	***PH***
	DIAZEPAM								
3161J	Tablet 2 mg	50	..	..	7.36	8.39	[a]	Antenex 2	AF
							[a]	Valpam 2	SI
				B0.59	7.95	8.39		Ducene	SU
				B0.86	8.22	8.39	[a]	Valium	RO

continued ☞

NERVOUS SYSTEM—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Proprietary Name and Manufacturer	
3162K	Tablet 5 mg	50	..	..	7.50	8.53	a	Antenex 5	AF
							a	Diazepam-DP	GM
							a	Ranzepam	RA
							a	Valpam 5	SI
				B0.63	8.13	8.53		Ducene	SU
				B0.88	8.38	8.53	a	Valium	RO
2558P	Injection 10 mg in 2 mL	5	..	..	11.86	12.89		HH	

NOTE:
Authorities for increased maximum quantities and/or repeats for the oral forms of diazepam will be granted only for

(i) the treatment of disabling spasticity; or

(ii) malignant neoplasia (late stage); or

(iii) use by patients who are receiving long-term nursing care on account of age, infirmity or other condition in hospitals, nursing homes or residential facilities and who have been demonstrated, within the past six months, to be benzodiazepine dependent by an unsuccessful attempt at gradual withdrawal; or

(iv) use by a patient who is receiving long-term nursing care and in respect of whom a Carer Allowance is payable as a disabled adult and who has been demonstrated, within the past six months, to be benzodiazepine dependent by an unsuccessful attempt at gradual withdrawal.

Up to six months' treatment (i.e. one month's treatment with five repeats) may be requested.

OXAZEPAM

3132W	Tablet 15 mg	25	..	..	7.27	8.30	a	Alepam 15	AF
				B1.78	9.05	8.30	a	Serepax	SI
3133X	Tablet 30 mg	25	..	..	7.46	8.49	a	Alepam 30	AF
							a	Murelax	FM
				B1.90	9.36	8.49	a	Serepax	SI

NOTE:
Authorities for increased maximum quantities and/or repeats will not be granted except as detailed under the 'Authority required' listing of oxazepam below.

continued ☞

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Proprietary Name and Manufacturer	
	OXAZEPAM								
	Authority Required ***Malignant neoplasia (late stage);*** ***For use by patients who are receiving long-term nursing care on account of age, infirmity or other condition in hospitals, nursing homes or residential facilities and who have been demonstrated, within the past 6 months, to be benzodiazepine dependent by an unsuccessful attempt at gradual withdrawal;*** ***For use by a patient who is receiving long-term nursing care and in respect of whom a Carer Allowance is payable as a disabled adult and who has been demonstrated, within the past 6 months, to be benzodiazepine dependent by an unsuccessful attempt at gradual withdrawal.***								
3134Y	***Tablet 15 mg***	***50***	***5***	***..***	**** 8.55***	***9.58***	***a***	***Alepam 15***	***AF***
				B 3.56	**** 12.11***	***9.58***	***a***	***Serepax***	***SI***
3135B	***Tablet 30 mg***	***50***	***5***	***..***	**** 8.93***	***9.96***	***a***	***Alepam 30***	***AF***
							a	***Murelax***	***FM***
				B 3.80	**** 12.73***	***9.96***	***a***	***Serepax***	***SI***
	• ***Other anxiolytics*** ***CLOMIPRAMINE HYDROCHLORIDE***								
	Restricted Benefit ***Cataplexy associated with narcolepsy;*** ***Obsessive-compulsive disorder;*** ***Phobic disorders in adults.***								
1561E	***Tablet 25 mg***	***50***	***2***	***..***	***16.40***	***17.43***	***a***	***Chem mart Clomipramine***	***CH***
							a	***GenRx Clomipramine***	***GX***
							a	***Placil***	***AF***
							a	***Terry White Chemists Clomipramine***	***TW***
				B 3.26	***19.66***	***17.43***	***a***	***Anafranil 25***	***NV***
	Hypnotics and sedatives								
	• ***Benzodiazepine derivatives*** NITRAZEPAM								
2723H	Tablet 5 mg	25	..	..	7.46	8.49	a	Alodorm	AF
				B 1.53	8.99	8.49	a	Mogadon	VT
	NOTE: Authorities for increased maximum quantities and/or repeats will not be granted except as detailed under the 'Authority required' listing of nitrazepam below.								

continued ☞

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Proprietary Name and Manufacturer	
	NITRAZEPAM								
	Authority Required ***Myoclonic epilepsy;*** ***Malignant neoplasia (late stage);*** ***For use by patients who are receiving long-term nursing care on account of age, infirmity or other condition in hospitals, nursing homes or residential facilities and who have been demonstrated, within the past 6 months, to be benzodiazepine dependent by an unsuccessful attempt at gradual withdrawal;*** ***For use by a patient who is receiving long-term nursing care and in respect of whom a Carer Allowance is payable as a disabled adult and who has been demonstrated, within the past 6 months, to be benzodiazepine dependent by an unsuccessful attempt at gradual withdrawal.***								
2732T	***Tablet 5 mg***	***50***	***5***	***..***	**** 8.93***	***9.96***	***a***	***Alodorm***	***AF***
				B3.06	**** 11.99***	***9.96***	***a***	***Mogadon***	***VT***
	TEMAZEPAM								
2089Y	Tablet 10 mg	25	..	..	7.46	8.49	a	Temaze	AF
							a	Temtabs	FM
				B1.38	8.84	8.49	a	Normison	SI
	NOTE: Authorities for increased maximum quantities and/or repeats will not be granted except as detailed under the 'Authority required' listing of temazepam below.								
	TEMAZEPAM								
	Authority Required ***Malignant neoplasia (late stage);*** ***For use by patients who are receiving long-term nursing care on account of age, infirmity or other condition in hospitals, nursing homes or residential facilities and who have been demonstrated, within the past 6 months, to be benzodiazepine dependent by an unsuccessful attempt at gradual withdrawal;*** ***For use by a patient who is receiving long-term nursing care and in respect of whom a Carer Allowance is payable as a disabled adult and who has been demonstrated, within the past 6 months, to be benzodiazepine dependent by an unsuccessful attempt at gradual withdrawal.***								
2088X	***Tablet 10 mg***	***50***	***5***	***..***	**** 8.93***	***9.96***	***a***	***Temaze***	***AF***
							a	***Temtabs***	***FM***
				B2.76	**** 11.69***	***9.96***	***a***	***Normison***	***SI***

PSYCHOANALEPTICS

Antidepressants

• *Non-selective monoamine reuptake inhibitors*

AMITRIPTYLINE HYDROCHLORIDE

2417F	Tablet 10 mg	50	2	..	8.01	9.04	Endep 10	AF
2418G	Tablet 25 mg	50	2	..	8.13	9.16	Endep 25	AF

continued ☞

NERVOUS SYSTEM—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Proprietary Name and Manufacturer	
2429W	Tablet 50 mg	50	2	..	8.46	9.49		Endep 50	AF
	CLOMIPRAMINE HYDROCHLORIDE								
	Restricted Benefit ***Cataplexy associated with narcolepsy;*** ***Obsessive-compulsive disorder;*** ***Phobic disorders in adults.***								
1561E	***Tablet 25 mg***	***50***	***2***	***..***	***16.40***	***17.43***	[a]	***Chem mart Clomipramine***	***CH***
							[a]	***GenRx Clomipramine***	***GX***
							[a]	***Placil***	***AF***
							[a]	***Terry White Chemists Clomipramine***	***TW***
				B3.26	***19.66***	***17.43***	[a]	***Anafranil 25***	***NV***
	DOTHIEPIN HYDROCHLORIDE								
1357K	Capsule 25 mg	50	2	..	8.53	9.56	[a]	Dothep 25	AF
				B1.58	10.11	9.56	[a]	Prothiaden	AB
1358L	Tablet 75 mg	30	2	..	8.53	9.56	[a]	Dothep 75	AF
				B0.81	9.34	9.56	[a]	Prothiaden	AB
	DOXEPIN HYDROCHLORIDE								
1012G	Tablet 50 mg (base)	50	2	..	9.28	10.31		Deptran 50	AF
1011F	Capsule 10 mg (base)	50	2	..	8.54	9.57		Deptran 10	AF
				B1.87	10.41	9.57		Sinequan	PF
1013H	Capsule 25 mg (base)	50	2	..	8.97	10.00		Deptran 25	AF
				B1.57	10.54	10.00		Sinequan	PF
	IMIPRAMINE HYDROCHLORIDE								
2420J	Tablet 10 mg	50	2	..	8.24	9.27	[a]	Tolerade 10	LN
				B2.97	11.21	9.27	[a]	Tofranil 10	NV
2421K	Tablet 25 mg	50	2	..	8.24	9.27	[a]	Tolerade 25	LN
				B2.97	11.21	9.27	[a]	Tofranil 25	NV
	NORTRIPTYLINE HYDROCHLORIDE								
	Restricted Benefit ***Major depression where other antidepressant therapy has failed;*** ***Major depression where other antidepressant therapy is contraindicated.***								
2522R	***Tablet 10 mg (base)***	***50***	***2***	***..***	***12.89***	***13.92***		***Allegron***	***AS***
2523T	***Tablet 25 mg (base)***	***50***	***2***	***..***	***14.67***	***15.70***		***Allegron***	***AS***

NERVOUS SYSTEM—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Proprietary Name and Manufacturer	
	• *Selective serotonin reuptake inhibitors*								
	CITALOPRAM HYDROBROMIDE								
	Restricted Benefit								
	Major depressive disorders.								
8702B	***Tablet 10 mg (base)***	***28***	***5***	***..***	***16.88***	***17.91***		***Celapram***	***AF***
8220P	***Tablet 20 mg (base)***	***28***	***5***	***..***	***22.52***	***23.55***	[a]	***Celapram***	***AF***
							[a]	***Celica***	***RA***
							[a]	***Chem mart Citalopram***	***CH***
							[a]	***Ciazil***	***GM***
							[a]	***Citalobell***	***BF***
							[a]	***Citalopram 20***	***CR***
							[a]	***Citalopram Winthrop***	***WA***
							[a]	***GenRx Citalopram***	***GX***
							[a]	***Talam***	***SI***
							[a]	***Talohexal***	***SZ***
							[a]	***Terry White Chemists Citalopram***	***TW***
				B4.45	***26.97***	***23.55***	[a]	***Cipramil***	***LU***
8703C	***Tablet 40 mg (base)***	***28***	***5***	***..***	***33.96***	***32.90***		***Celapram***	***AF***
								GenRx Citalopram	***GX***
								Talohexal	***SZ***

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Proprietary Name and Manufacturer	
	ESCITALOPRAM OXALATE								
	Restricted Benefit ***Major depressive disorders.***								
	Restricted Benefit ***Moderate to severe generalised anxiety disorder (GAD), as defined by Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV) criteria, in a patient who has not responded to non-pharmacological therapy and:*** ***(a) for whom a GP Mental Health Care Plan, as described under item 2710 of the Medicare Benefits Schedule, has been prepared; or*** ***(b) who has been assessed by a psychiatrist;*** ***Continuing PBS subsidised treatment, for moderate to severe generalised anxiety disorder (GAD), of a patient commenced on escitalopram prior to 1 March 2008.***								
	Restricted Benefit ***Moderate to severe social anxiety disorder (social phobia, SAD), as described by Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV) criteria, in a patient who has not responded to non-pharmacological therapy and:*** ***(a) for whom a GP Mental Health Care Plan, as described under item 2710 of the Medicare Benefits Schedule, has been prepared; or*** ***(b) who has been assessed by a psychiatrist;*** ***Continuing PBS subsidised treatment, for moderate to severe social anxiety disorder (social phobia, SAD), of a patient commenced on escitalopram prior to 1 March 2008.***								
8700X	***Tablet 10 mg (base)***	***28***	***5***	***..***	***28.98***	***30.01***	***a***	***Esipram***	***CF***
				B 4.89	***33.87***	***30.01***	***a***	***Lexapro***	***LU***
8701Y	***Tablet 20 mg (base)***	***28***	***5***	***..***	***29.12***	***30.15***	***a***	***Esipram***	***CF***
				B 7.16	***36.28***	***30.15***	***a***	***Lexapro***	***LU***
	FLUOXETINE HYDROCHLORIDE								
	Restricted Benefit ***Major depressive disorders;*** ***Obsessive-compulsive disorder.***								
8270G	***Tablet 20 mg (base) (dispersible)***	***28***	***5***	***..***	***20.38***	***21.41***	***a***	***Lovan 20 Tab***	***AL***
				B 4.13	***24.51***	***21.41***	***a***	***Prozac Tab***	***LY***

continued ☞

NERVOUS SYSTEM—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Proprietary Name and Manufacturer	
1434L	***Capsule 20 mg (base)***	***28***	***5***	***..***	***20.38***	***21.41***	[a]	***Auscap***	***SI***
							[a]	***Chem mart Fluoxetine***	***CH***
							[a]	***Fluohexal***	***SZ***
							[a]	***Fluoxebell***	***BF***
							[a]	***Fluoxetine 20***	***CR***
							[a]	***Fluoxetine-DP***	***GM***
							[a]	***GenRx Fluoxetine***	***GX***
							[a]	***Lovan***	***AL***
							[a]	***Terry White Chemists Fluoxetine***	***TW***
							[a]	***Zactin***	***AF***
				B4.13	***24.51***	***21.41***	[a]	***Prozac 20***	***LY***
	FLUVOXAMINE MALEATE								
	Restricted Benefit ***Major depressive disorders; Obsessive-compulsive disorder.***								
8512B	***Tablet 50 mg***	***30***	***5***	***..***	***19.94***	***20.97***	[a]	***Faverin 50***	***SI***
							[a]	***Movox 50***	***AL***
							[a]	***Voxam***	***SZ***
				B2.96	***22.90***	***20.97***	[a]	***Luvox***	***SM***
8174F	***Tablet 100 mg***	***30***	***5***	***..***	***27.12***	***28.15***	[a]	***Faverin 100***	***SI***
							[a]	***Movox 100***	***AF***
							[a]	***Voxam***	***SZ***
				B2.95	***30.07***	***28.15***	[a]	***Luvox***	***SM***

NERVOUS SYSTEM—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Proprietary Name and Manufacturer	
	PAROXETINE								
	Restricted Benefit ***Major depressive disorders;*** ***Obsessive-compulsive disorder;*** ***Panic disorder.***								
2242B	***Tablet 20 mg (as hydrochloride)***	***30***	***5***	***..***	***25.05***	***26.08***	ᵃ	***Chem mart Paroxetine***	***CH***
							ᵃ	***Extine 20***	***SI***
							ᵃ	***GenRx Paroxetine***	***GX***
							ᵃ	***Paroxetine 20***	***CR***
							ᵃ	***Paroxetine-DP***	***GM***
							ᵃ	***Paroxetine Sandoz***	***SZ***
							ᵃ	***Paroxetine Winthrop***	***WA***
							ᵃ	***Paxtine***	***AF***
							ᵃ	***Terry White Chemists Paroxetine***	***TW***
				ʙ0.86	***25.91***	***26.08***	ᵃ	***Aropax***	***GK***
9197C	***Tablet 20 mg (as mesilate)***	***30***	***5***	***..***	***25.05***	***26.08***	ᵃ	***Paroxetine generichealth***	***GQ***

NOTE:
Bioequivalence has been demonstrated between paroxetine tablet 20 mg (as hydrochloride) and paroxetine tablet 20 mg (as mesilate).

NERVOUS SYSTEM—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Proprietary Name and Manufacturer	
	SERTRALINE HYDROCHLORIDE								
	Restricted Benefit								
	Major depressive disorders.								
2236Q	***Tablet 50 mg (base)***	***30***	***5***	***..***	***24.23***	***25.26***	***a***	***Chem mart Sertraline***	***CH***
							a	***Concorz***	***SZ***
							a	***Eleva 50***	***AF***
							a	***GenRx Sertraline***	***GX***
							a	***Sertra 50***	***SI***
							a	***Sertraline 50***	***CR***
							a	***Sertraline-GA***	***GM***
							a	***Sertraline generichealth***	***GQ***
							a	***Sertraline Winthrop***	***WA***
							a	***Setrona***	***RA***
							a	***Terry White Chemists Sertraline***	***TW***
							a	***Xydep 50***	***AW***
				B0.41	***24.64***	***25.26***	***a***	***Zoloft***	***PF***
2237R	***Tablet 100 mg (base)***	***30***	***5***	***..***	***24.23***	***25.26***	***a***	***Chem mart Sertraline***	***CH***
							a	***Concorz***	***SZ***
							a	***Eleva 100***	***AF***
							a	***GenRx Sertraline***	***GX***
							a	***Sertra 100***	***SI***
							a	***Sertraline 100***	***CR***
							a	***Sertraline-GA***	***GM***
							a	***Sertraline generichealth***	***GQ***
							a	***Sertraline Winthrop***	***WA***
							a	***Setrona***	***RA***
							a	***Terry White Chemists Sertraline***	***TW***
							a	***Xydep 100***	***AW***
				B0.41	***24.64***	***25.26***	***a***	***Zoloft***	***PF***

continued ☞

NERVOUS SYSTEM—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Proprietary Name and Manufacturer	
	Restriction Benefit								
	Obsessive-compulsive disorder;								
	Panic disorder where other treatments have failed or are inappropriate.								
8836C	***Tablet 50 mg (base)***	***30***	***5***	***..***	***24.23***	***25.26***	[a]	***Eleva 50***	***AF***
							[a]	***Xydep 50***	***AW***
				B0.41	***24.64***	***25.26***	[a]	***Zoloft***	***PF***
8837D	***Tablet 100 mg (base)***	***30***	***5***	***..***	***24.23***	***25.26***	[a]	***Eleva 100***	***AF***
							[a]	***Xydep 100***	***AW***
				B0.41	***24.64***	***25.26***	[a]	***Zoloft***	***PF***
	• ***Monoamine oxidase inhibitors, non-selective***								
	PHENELZINE SULFATE								
	CAUTION:								
	This drug is an irreversible monoamine oxidase inhibitor.								
	Restriction Benefit								
	Depression where all other anti-depressant therapy has failed or is inappropriate.								
2856H	***Tablet 15 mg (base)***	***100***	***1***	***..***	***99.67***	***32.90***		***Nardil***	***LM***
	TRANYLCYPROMINE SULFATE								
	CAUTION:								
	This drug is an irreversible monoamine oxidase inhibitor.								
2444P	Tablet 10 mg (base)	50	2	..	33.12	32.90		Parnate	GH
	• ***Monoamine oxidase type A inhibitors***								
	MOCLOBEMIDE								
	Restriction Benefit								
	Major depressive disorders.								
1900B	***Tablet 150 mg***	***60***	***5***	***..***	***18.33***	***19.36***	[a]	***Amira 150***	***AF***
							[a]	***Chem mart Moclobemide***	***CH***
							[a]	***Clobemix***	***GM***
							[a]	***GenRx Moclobemide***	***GX***
							[a]	***Mohexal***	***SZ***
							[a]	***Terry White Chemists Moclobemide***	***TW***
				B0.72	***19.05***	***19.36***	[a]	***Aurorix***	***RO***

continued ☞

NERVOUS SYSTEM—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Proprietary Name and Manufacturer	
8003F	***Tablet 300 mg***	***60***	***5***	***..***	***29.75***	***30.78***	[a]	***Amira 300***	***AF***
							[a]	***Chem mart Moclobemide***	***CH***
							[a]	***Clobemix***	***GM***
							[a]	***GenRx Moclobemide***	***GX***
							[a]	***Maosig***	***SI***
							[a]	***Mohexal***	***SZ***
							[a]	***Terry White Chemists Moclobemide***	***TW***
				[B]1.45	***31.20***	***30.78***	[a]	***Aurorix 300 mg***	***RO***

• *Other antidepressants*

DESVENLAFAXINE SUCCINATE

Restricted Benefit
Major depressive disorders.

9366Y	***Tablet 50 mg (base) (extended release)***	***28***	***5***	***..***	***42.88***	***32.90***		***Pristiq***	***WX***
9367B	***Tablet 100 mg (base) (extended release)***	***28***	***5***	***..***	***49.99***	***32.90***		***Pristiq***	***WX***

DULOXETINE HYDROCHLORIDE

Restricted Benefit
Major depressive disorders.

9155W	***Capsule 30 mg (base)***	***28***	***..***	***..***	***37.79***	***32.90***		***Cymbalta***	***LY***
9156X	***Capsule 60 mg (base)***	***28***	***5***	***..***	***49.99***	***32.90***		***Cymbalta***	***LY***

LITHIUM CARBONATE

3059B	Tablet 250 mg	200	2	..	16.46	17.49		Lithicarb	AS
8290H	Tablet 450 mg (slow release)	200	2	..	* 33.87	32.90		Quilonum SR	GK

MIANSERIN HYDROCHLORIDE
CAUTION:
Neutropenia and agranulocytosis are more frequent in the elderly, especially in the early months of therapy.

Restricted Benefit
Severe depression.

1627P	***Tablet 10 mg***	***50***	***5***	***..***	***15.51***	***16.54***	[a]	***Lumin 10***	***AF***
				[B]1.99	***17.50***	***16.54***	[a]	***Tolvon***	***SH***
1628Q	***Tablet 20 mg***	***50***	***5***	***..***	***26.09***	***27.12***	[a]	***Lumin 20***	***AF***
				[B]2.97	***29.06***	***27.12***	[a]	***Tolvon***	***SH***

NERVOUS SYSTEM—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Proprietary Name and Manufacturer	
	MIRTAZAPINE								
	Restricted Benefit ***Major depressive disorders.***								
9365X	***Tablet 15 mg***	***30***	***5***	***..***	***19.94***	***20.97***		***Axit 15***	***AF***
8855C	***Tablet 15 mg (orally disintegrating)***	***30***	***5***	***..***	***19.94***	***20.97***		***Avanza SolTab***	***SH***
8513C	***Tablet 30 mg***	***30***	***5***	***..***	***26.91***	***27.94***	***a***	***Axit 30***	***AF***
							a	***Chem mart Mirtazapine***	***CH***
							a	***GenRx Mirtazapine***	***GX***
							a	***Mirtazapine-DP***	***GM***
							a	***Mirtazapine Sandoz***	***SZ***
							a	***Mirtazon***	***SI***
							a	***Terry White Chemists Mirtazapine***	***TW***
				B1.70	***28.61***	***27.94***	***a***	***Avanza***	***SH***
8856D	***Tablet 30 mg (orally disintegrating)***	***30***	***5***	***..***	***26.91***	***27.94***		***Avanza SolTab***	***SH***
8883M	***Tablet 45 mg***	***30***	***5***	***..***	***40.81***	***32.90***	***a***	***APO-Mirtazapine***	***TX***
							a	***Chem mart Mirtazapine***	***CH***
							a	***Mirtazapine Sandoz***	***SZ***
							a	***Mirtazon***	***SI***
							a	***Terry White Chemists Mirtazapine***	***TW***
				B1.49	***42.30***	***32.90***	***a***	***Avanza***	***SH***
8857E	***Tablet 45 mg (orally disintegrating)***	***30***	***5***	***..***	***40.81***	***32.90***		***Avanza SolTab***	***SH***
	REBOXETINE MESILATE								
	Restricted Benefit ***Major depressive disorders.***								
8583R	***Tablet 4 mg (base)***	***60***	***5***	***..***	***38.33***	***32.90***		***Edronax***	***PH***
	VENLAFAXINE HYDROCHLORIDE								
	Restricted Benefit ***Major depressive disorders.***								
8868R	***Capsule 37.5 mg (base) (modified release)***	***28***	***..***	***..***	***27.10***	***28.13***		***Efexor-XR***	***WX***
8301X	***Capsule 75 mg (base) (modified release)***	***28***	***5***	***..***	***44.51***	***32.90***		***Efexor-XR***	***WX***

continued ☞

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
8302Y	***Capsule 150 mg (base) (modified release)***	***28***	***5***	***..***	***52.19***	***32.90***	***Efexor-XR***	***WX***

Psychostimulants, agents used for ADHD and nootropics

• *Centrally acting sympathomimetics*

ATOMOXETINE HYDROCHLORIDE

Authority Required

Initial sole PBS-subsidised treatment of attention-deficit hyperactivity disorder (ADHD) diagnosed between the ages of 6 and 18 years inclusive, by a paediatrician or psychiatrist according to the DSM-IV criteria, where:

(a) treatment with dexamphetamine sulfate or methylphenidate hydrochloride poses an unacceptable medical risk due to the following contraindications as specified in the TGA-approved product information:

(1) The patient has a history of substance abuse or misuse (other than alcohol); and/or

(2) The patient has comorbid motor tics or Tourette's Syndrome; and/or

(3) The patient has comorbid severe anxiety diagnosed according to the DSM-IV; or

(b) treatment with dexamphetamine sulfate or methylphenidate hydrochloride has resulted in the development or worsening of a comorbid mood disorder (diagnosed according to the DSM-IV criteria i.e. anxiety disorder, obsessive compulsive disorder, depressive disorder) of a severity necessitating permanent stimulant treatment withdrawal; or

where the combination of stimulant treatment with another agent would pose an unacceptable medical risk of a severity necessitating permanent stimulant treatment withdrawal; or

(c) treatment with dexamphetamine sulfate AND methylphenidate hydrochloride has resulted in the development of adverse reactions of a severity necessitating permanent treatment withdrawal:

(1) Adverse effects on growth and weight; and/or

(2) Adverse effects on sleep including insomnia; and/or

(3) Adverse effects on appetite including anorexia.

NOTE:

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

Authority Required

Continuing sole PBS-subsidised treatment where the patient has previously been issued with an authority prescription for this drug.

NOTE:

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

9092M	***Capsule 10 mg (base)***	***56***	***5***	***..***	**** 220.75***	***32.90***	***Strattera***	***LY***
9093N	***Capsule 18 mg (base)***	***56***	***5***	***..***	**** 220.75***	***32.90***	***Strattera***	***LY***
9094P	***Capsule 25 mg (base)***	***56***	***5***	***..***	**** 220.75***	***32.90***	***Strattera***	***LY***
9095Q	***Capsule 40 mg (base)***	***56***	***5***	***..***	**** 220.75***	***32.90***	***Strattera***	***LY***
9096R	***Capsule 60 mg (base)***	***56***	***5***	***..***	**** 220.75***	***32.90***	***Strattera***	***LY***
9289X	***Capsule 80 mg (base)***	***28***	***5***	***..***	***146.68***	***32.90***	***Strattera***	***LY***
9290Y	***Capsule 100 mg (base)***	***28***	***5***	***..***	***146.68***	***32.90***	***Strattera***	***LY***

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Proprietary Name and Manufacturer	
	DEXAMPHETAMINE SULFATE								
	NOTE:								
	Care must be taken to comply with the provisions of State/Territory law when prescribing dexamphetamine.								
	Authority Required								
	Use in attention deficit hyperactivity disorder, in accordance with State/Territory law;								
	Narcolepsy.								
1165H	***Tablet 5 mg***	***100***	***5***	***..***	***17.76***	***18.79***		***SI***	
	METHYLPHENIDATE HYDROCHLORIDE								
	NOTE:								
	Care must be taken to comply with the provisions of State/Territory law when prescribing methylphenidate hydrochloride.								
	Authority Required								
	Use in attention deficit hyperactivity disorder, in accordance with State/Territory law.								
8839F	***Tablet 10 mg***	***100***	***5***	***..***	***15.50***	***16.53***	[a]	***Attenta***	***AF***
				B1.37	***16.87***	***16.53***	[a]	***Ritalin 10***	***NV***
	Authority Required								
	Treatment of attention deficit hyperactivity disorder (ADHD) in a patient aged 6 to 18 years inclusive, who has demonstrated a response to immediate release methylphenidate hydrochloride with no emergence of serious adverse events, and who requires continuous coverage over 12 hours.								
2387P	***Tablet 18 mg (extended release)***	***30***	***5***	***..***	***52.87***	***32.90***		***Concerta***	***JC***
2172H	***Tablet 27 mg (extended release)***	***30***	***5***	***..***	***57.23***	***32.90***		***Concerta***	***JC***
2388Q	***Tablet 36 mg (extended release)***	***30***	***5***	***..***	***61.93***	***32.90***		***Concerta***	***JC***
2432B	***Tablet 54 mg (extended release)***	***30***	***5***	***..***	***72.52***	***32.90***		***Concerta***	***JC***
	Authority Required								
	Treatment of attention deficit hyperactivity disorder in a patient aged 6 to 18 years inclusive, who has demonstrated a response to immediate release methylphenidate hydrochloride with no emergence of serious adverse events, and who requires continuous coverage over 8 hours.								
2276T	***Capsule 20 mg (modified release)***	***30***	***5***	***..***	***45.77***	***32.90***		***Ritalin LA***	***NV***
2280B	***Capsule 30 mg (modified release)***	***30***	***5***	***..***	***53.62***	***32.90***		***Ritalin LA***	***NV***
2283E	***Capsule 40 mg (modified release)***	***30***	***5***	***..***	***56.28***	***32.90***		***Ritalin LA***	***NV***
	MODAFINIL								
	NOTE:								
	Any queries concerning the arrangements to prescribe modafinil may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).								
	Written applications for authority to prescribe modafinil should be forwarded to:								

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Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
	Medicare Australia ***Prior Written Approval of Specialised Drugs*** ***Reply Paid 9826*** ***GPO Box 9826*** ***HOBART TAS 7001*** ***Further prescribing information is on the Medicare Australia website at www.medicareaustralia.gov.au.*** **NOTE:** ***Modafinil is not PBS-subsidised when used in combination with PBS-subsidised dexamphetamine sulfate.*** **Authority Required** ***Initial treatment, by a qualified sleep medicine practitioner or neurologist, of patients with narcolepsy where:*** ***(i) therapy with dexamphetamine sulfate poses an unacceptable medical risk; or*** ***(ii) intolerance to dexamphetamine sulfate of a severity necessitating permanent treatment withdrawal develops.*** ***The presence of any 1 of the following indicates treatment with dexamphetamine sulfate poses an unacceptable medical risk:*** ***(a) a psychiatric disorder;*** ***(b) a cardiac disorder;*** ***(c) a history of substance abuse;*** ***(d) glaucoma;*** ***(e) any other absolute contraindication to dexamphetamine sulfate as specified in the TGA-approved Product Information.*** ***Patients must meet the following definition of narcolepsy:*** ***Excessive daytime sleepiness, recurrent naps or lapses into sleep occurring almost daily for at least 3 months and:*** ***(i) a definite history of cataplexy and a Multiple Sleep Latency Test (MSLT) with a mean sleep latency less than or equal to 8 minutes; or*** ***(ii) a MSLT with a mean sleep latency less than or equal to 8 minutes and 2 or more sleep onset rapid eye movement (REM) periods; or*** ***(iii) an electroencephalographic (EEG) recording showing the pathologically rapid development of REM sleep.*** ***The MSLT must be preceded by nocturnal polysomnography. Sleep prior to the MSLT must be at least 6 hours.*** ***The authority application must be made in writing and must include the following:*** ***(a) a completed authority prescription form; and*** ***(b) a completed Modafinil (Modavigil) PBS Authority Application for Use in the Treatment of Narcolepsy - Supporting Information Form [www.medicareaustralia.gov.au]; and*** ***(c) details of the contraindication or intolerance to dexamphetamine sulfate; and*** ***(d) either:*** ***(i) the result and date of the polysomnography test and MSLT conducted by, or under the supervision of, a qualified sleep medicine practitioner; or*** ***(ii) the result and date of the EEG, conducted by, or under the supervision of, a neurologist.*** ***The polysomnography, MSLT or EEG test reports must be provided with the authority application.*** **Authority Required** ***Continuing treatment of narcolepsy, where the patient has previously been issued with an authority prescription for this drug.***							
8816B	***Tablet 100 mg***	***120***	***5***	***..***	**** 346.55***	***32.90***	***Modavigil***	***CS***

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer

Anti-dementia drugs

• *Anticholinesterases*

DONEPEZIL HYDROCHLORIDE

Authority Required

INITIAL APPLICATION FOR THE TREATMENT OF MILD TO MODERATELY SEVERE ALZHEIMER'S DISEASE — Patients with an (S)MMSE of 10 or more.
Initial treatment, as the sole PBS-subsidised therapy, of mild to moderately severe Alzheimer's disease. Confirmation of this diagnosis must be made by a specialist/consultant physician (including a psychiatrist).

The authority application must include the result of the baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE). This baseline (S)MMSE must be a score of 10 or more. If this score is 25 - 30 points, the result of a baseline Alzheimer's Disease Assessment Scale, cognitive sub-scale (ADAS-Cog) may also be specified.

If an ADAS-Cog score is not supplied with the initial application, this scale cannot be used for the purpose of fulfilling the criteria for continued PBS supply.

This application must be made in writing, but initial supply may be sought by telephone.
For telephone applications, up to a maximum of 2 months' initial therapy will be authorised. This telephone application must be followed by a written authority application for no more than 1 month's therapy and sufficient repeats to complete a maximum of up to 6 months' initial treatment.
For written applications where no prior telephone approval has been issued, up to a maximum of 1 month's therapy plus 5 repeats will be authorised;

CONTINUING TREATMENT — (S)MMSE or ADAS-Cog improvement.
Continuing treatment, as the sole PBS-subsidised therapy, following initial PBS-subsidised therapy, of mild to moderately severe Alzheimer's disease in patients with demonstrated improvement in cognitive function as measured by:
(a) for patients with a baseline (S)MMSE score of 10 or more and less than 25, an increase of at least 2 points from baseline on the Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE);
(b) for patients with a baseline (S)MMSE score of at least 25 points, a decrease of at least 4 points from baseline on the Alzheimer's Disease Assessment Scale, cognitive sub-scale (ADAS-Cog) or an increase of at least 2 points from baseline on the Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE).

The initial authority application for continuing treatment must include the relevant result from the (S)MMSE or the ADAS-Cog and must be in writing.

Subsequent applications for continuing treatment can be made by telephone.

Authority Required

INITIAL APPLICATION FOR THE TREATMENT OF MILD TO MODERATELY SEVERE ALZHEIMER'S DISEASE — Patients with an (S)MMSE of 9 or less who require a clinician's assessment.
Initial treatment, as the sole PBS-subsidised therapy, of mild to moderately severe Alzheimer's disease of patients with a baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE) score of 9 or less, who are unable to register a score of 10 or more for reasons other than their Alzheimer's disease, as specified below. Confirmation of this diagnosis must be made by a specialist/consultant physician (including a psychiatrist).

Such patients will need to be assessed using the Clinicians Interview Based Impression of Severity (CIBIS) scale. The authority application must include the result of the baseline (S)MMSE and specify to which group(s) (see below) the patient belongs.

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Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
	This application must be made in writing, but initial supply may be sought by telephone. ***For telephone applications, up to a maximum of 2 months' initial therapy will be authorised. This telephone application must be followed by a written authority application for no more than 1 month's therapy and sufficient repeats to complete a maximum of up to 6 months' initial treatment.*** ***For written applications where no prior telephone approval has been issued, up to a maximum of 1 month's therapy plus 5 repeats will be authorised.*** ***Patients who qualify under this criterion are from 1 or more of the following groups:*** ***(1) Unable to communicate adequately because of lack of competence in English, in people of non-English speaking background;*** ***(2) Limited education, as defined by less than 6 years of education, or who are illiterate or innumerate;*** ***(3) Aboriginal or Torres Strait Islanders who, by virtue of cultural factors, are unable to complete an (S)MMSE test;*** ***(4) Intellectual (developmental or acquired) disability, eg Down's syndrome;*** ***(5) Significant sensory impairment despite best correction, which precludes completion of an (S)MMSE test;*** ***(6) Prominent dysphasia, out of proportion to other cognitive and functional impairment;*** ***CONTINUING TREATMENT — Clinician assessed improvement.*** ***Continuing treatment, as the sole PBS-subsidised therapy, following initial PBS-subsidised therapy, of mild to moderately severe Alzheimer's disease in patients with demonstrated improvement in function, based on a rating of "very much improved" or "much improved" on the Clinicians Interview Based Impression of Change (CIBIC) scale, which must be assessed by the same clinician who initiated treatment.*** ***The initial authority application for continuing treatment must state the improvement achieved on the CIBIC scale and must be in writing.*** ***Subsequent applications for continuing treatment can be made by telephone.***							
8495D	***Tablet 5 mg***	***28***	***5***	***..***	***155.02***	***32.90***	***Aricept***	***PF***
8496E	***Tablet 10 mg***	***28***	***5***	***..***	***155.02***	***32.90***	***Aricept***	***PF***
	GALANTAMINE HYDROBROMIDE							
	Authority Required ***INITIAL APPLICATION FOR THE TREATMENT OF MILD TO MODERATELY SEVERE ALZHEIMER'S DISEASE — Patients with an (S)MMSE of 10 or more.*** ***Initial treatment, as the sole PBS-subsidised therapy, of mild to moderately severe Alzheimer's disease. Confirmation of this diagnosis must be made by a specialist/consultant physician (including a psychiatrist).*** ***The authority application must include the result of the baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE). This baseline (S)MMSE must be a score of 10 or more. If this score is 25 - 30 points, the result of a baseline Alzheimer's Disease Assessment Scale, cognitive sub-scale (ADAS-Cog) may also be specified.*** ***If an ADAS-Cog score is not supplied with the initial application, this scale cannot be used for the purpose of fulfilling the criteria for continued PBS supply.*** ***This application must be made in writing, but initial supply may be sought by telephone.*** ***For telephone applications, up to a maximum of 2 months' initial therapy will be authorised. This telephone application must be followed by a written authority application for no more than 1 month's therapy and sufficient repeats to complete a maximum of up to 6 months' initial treatment.*** ***For written applications where no prior telephone approval has been issued, up to a maximum of 1 month's therapy plus 5 repeats will be authorised;***							

continued ☞

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer

CONTINUING TREATMENT — (S)MMSE or ADAS-Cog improvement.
Continuing treatment, as the sole PBS-subsidised therapy, following initial PBS-subsidised therapy, of mild to moderately severe Alzheimer's disease in patients with demonstrated improvement in cognitive function as measured by:
(a) for patients with a baseline (S)MMSE score of 10 or more and less than 25, an increase of at least 2 points from baseline on the Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE);
(b) for patients with a baseline (S)MMSE score of at least 25 points, a decrease of at least 4 points from baseline on the Alzheimer's Disease Assessment Scale, cognitive sub-scale (ADAS-Cog) or an increase of at least 2 points from baseline on the Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE).

The initial authority application for continuing treatment must include the relevant result from the (S)MMSE or the ADAS-Cog and must be in writing.

Subsequent applications for continuing treatment can be made by telephone.

Authority Required

INITIAL APPLICATION FOR THE TREATMENT OF MILD TO MODERATELY SEVERE ALZHEIMER'S DISEASE — Patients with an (S)MMSE of 9 or less who require a clinician's assessment.
Initial treatment, as the sole PBS-subsidised therapy, of mild to moderately severe Alzheimer's disease of patients with a baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE) score of 9 or less, who are unable to register a score of 10 or more for reasons other than their Alzheimer's disease, as specified below. Confirmation of this diagnosis must be made by a specialist/consultant physician (including a psychiatrist).

Such patients will need to be assessed using the Clinicians Interview Based Impression of Severity (CIBIS) scale. The authority application must include the result of the baseline (S)MMSE and specify to which group(s) (see below) the patient belongs.

This application must be made in writing, but initial supply may be sought by telephone.
For telephone applications, up to a maximum of 2 months' initial therapy will be authorised. This telephone application must be followed by a written authority application for no more than 1 month's therapy and sufficient repeats to complete a maximum of up to 6 months' initial treatment.
For written applications where no prior telephone approval has been issued, up to a maximum of 1 month's therapy plus 5 repeats will be authorised.

Patients who qualify under this criterion are from 1 or more of the following groups:
(1) Unable to communicate adequately because of lack of competence in English, in people of non-English speaking background;
(2) Limited education, as defined by less than 6 years of education, or who are illiterate or innumerate;
(3) Aboriginal or Torres Strait Islanders who, by virtue of cultural factors, are unable to complete an (S)MMSE test;

(4) Intellectual (developmental or acquired) disability, eg Down's syndrome;
(5) Significant sensory impairment despite best correction, which precludes completion of an (S)MMSE test;
(6) Prominent dysphasia, out of proportion to other cognitive and functional impairment;

CONTINUING TREATMENT — Clinician assessed improvement.
Continuing treatment, as the sole PBS-subsidised therapy, following initial PBS-subsidised therapy, of mild to moderately severe Alzheimer's disease in patients with demonstrated improvement in function, based on a rating of "very much improved" or "much improved" on the Clinicians Interview Based Impression of Change (CIBIC) scale, which must be assessed by the same clinician who initiated treatment.

The initial authority application for continuing treatment must state the improvement achieved on the CIBIC scale and must be in writing.

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Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
	Subsequent applications for continuing treatment can be made by telephone.							
8770N	***Capsule 8 mg (base) (prolonged release)***	***28***	***5***	***..***	***130.39***	***32.90***	***Reminyl***	***JC***
8771P	***Capsule 16 mg (base) (prolonged release)***	***28***	***5***	***..***	***158.16***	***32.90***	***Reminyl***	***JC***
8772Q	***Capsule 24 mg (base) (prolonged release)***	***28***	***5***	***..***	***187.34***	***32.90***	***Reminyl***	***JC***

RIVASTIGMINE

Authority Required

INITIAL APPLICATION FOR THE TREATMENT OF MILD TO MODERATELY SEVERE ALZHEIMER'S DISEASE — Patients with an (S)MMSE of 10 or more.
Initial treatment, as the sole PBS-subsidised therapy, of mild to moderately severe Alzheimer's disease. Confirmation of this diagnosis must be made by a specialist/consultant physician (including a psychiatrist).

The authority application must include the result of the baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE). This baseline (S)MMSE must be a score of 10 or more. If this score is 25 - 30 points, the result of a baseline Alzheimer's Disease Assessment Scale, cognitive sub-scale (ADAS-Cog) may also be specified.

If an ADAS-Cog score is not supplied with the initial application, this scale cannot be used for the purpose of fulfilling the criteria for continued PBS supply.

This application must be made in writing, but initial supply may be sought by telephone.
For telephone applications, up to a maximum of 2 months' initial therapy will be authorised. This telephone application must be followed by a written authority application for no more than 1 month's therapy and sufficient repeats to complete a maximum of up to 6 months' initial treatment.
For written applications where no prior telephone approval has been issued, up to a maximum of 1 month's therapy plus 5 repeats will be authorised;

CONTINUING TREATMENT — (S)MMSE or ADAS-Cog improvement.
Continuing treatment, as the sole PBS-subsidised therapy, following initial PBS-subsidised therapy, of mild to moderately severe Alzheimer's disease in patients with demonstrated improvement in cognitive function as measured by:
(a) for patients with a baseline (S)MMSE score of 10 or more and less than 25, an increase of at least 2 points from baseline on the Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE);
(b) for patients with a baseline (S)MMSE score of at least 25 points, a decrease of at least 4 points from baseline on the Alzheimer's Disease Assessment Scale, cognitive sub-scale (ADAS-Cog) or an increase of at least 2 points from baseline on the Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE).

The initial authority application for continuing treatment must include the relevant result from the (S)MMSE or the ADAS-Cog and must be in writing.

Subsequent applications for continuing treatment can be made by telephone.

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Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
	Authority Required ***INITIAL APPLICATION FOR THE TREATMENT OF MILD TO MODERATELY SEVERE ALZHEIMER'S DISEASE — Patients with an (S)MMSE of 9 or less who require a clinician's assessment.*** ***Initial treatment, as the sole PBS-subsidised therapy, of mild to moderately severe Alzheimer's disease of patients with a baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE) score of 9 or less, who are unable to register a score of 10 or more for reasons other than their Alzheimer's disease, as specified below. Confirmation of this diagnosis must be made by a specialist/consultant physician (including a psychiatrist).*** ***Such patients will need to be assessed using the Clinicians Interview Based Impression of Severity (CIBIS) scale. The authority application must include the result of the baseline (S)MMSE and specify to which group(s) (see below) the patient belongs.*** ***This application must be made in writing, but initial supply may be sought by telephone.*** ***For telephone applications, up to a maximum of 2 months' initial therapy will be authorised. This telephone application must be followed by a written authority application for no more than 1 month's therapy and sufficient repeats to complete a maximum of up to 6 months' initial treatment.*** ***For written applications where no prior telephone approval has been issued, up to a maximum of 1 month's therapy plus 5 repeats will be authorised.*** ***Patients who qualify under this criterion are from 1 or more of the following groups:*** ***(1) Unable to communicate adequately because of lack of competence in English, in people of non-English speaking background;*** ***(2) Limited education, as defined by less than 6 years of education, or who are illiterate or innumerate;*** ***(3) Aboriginal or Torres Strait Islanders who, by virtue of cultural factors, are unable to complete an (S)MMSE test;*** ***(4) Intellectual (developmental or acquired) disability, eg Down's syndrome;*** ***(5) Significant sensory impairment despite best correction, which precludes completion of an (S)MMSE test;*** ***(6) Prominent dysphasia, out of proportion to other cognitive and functional impairment;*** ***CONTINUING TREATMENT — Clinician assessed improvement.*** ***Continuing treatment, as the sole PBS-subsidised therapy, following initial PBS-subsidised therapy, of mild to moderately severe Alzheimer's disease in patients with demonstrated improvement in function, based on a rating of "very much improved" or "much improved" on the Clinicians Interview Based Impression of Change (CIBIC) scale, which must be assessed by the same clinician who initiated treatment.*** ***The initial authority application for continuing treatment must state the improvement achieved on the CIBIC scale and must be in writing.*** ***Subsequent applications for continuing treatment can be made by telephone.***							
9161E	***Transdermal patch 9 mg (releasing approximately 4.6 mg per 24 hours)***	***30***	***5***	***..***	***165.66***	***32.90***	***Exelon Patch 5***	***NV***
9162F	***Transdermal patch 18 mg (releasing approximately 9.5 mg per 24 hours)***	***30***	***5***	***..***	***165.66***	***32.90***	***Exelon Patch 10***	***NV***

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer

RIVASTIGMINE HYDROGEN TARTRATE

Authority Required

INITIAL APPLICATION FOR THE TREATMENT OF MILD TO MODERATELY SEVERE ALZHEIMER'S DISEASE — Patients with an (S)MMSE of 10 or more.
Initial treatment, as the sole PBS-subsidised therapy, of mild to moderately severe Alzheimer's disease. Confirmation of this diagnosis must be made by a specialist/consultant physician (including a psychiatrist).

The authority application must include the result of the baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE). This baseline (S)MMSE must be a score of 10 or more. If this score is 25 - 30 points, the result of a baseline Alzheimer's Disease Assessment Scale, cognitive sub-scale (ADAS-Cog) may also be specified.

If an ADAS-Cog score is not supplied with the initial application, this scale cannot be used for the purpose of fulfilling the criteria for continued PBS supply.

This application must be made in writing, but initial supply may be sought by telephone.
For telephone applications, up to a maximum of 2 months' initial therapy will be authorised. This telephone application must be followed by a written authority application for no more than 1 month's therapy and sufficient repeats to complete a maximum of up to 6 months' initial treatment.
For written applications where no prior telephone approval has been issued, up to a maximum of 1 month's therapy plus 5 repeats will be authorised;

CONTINUING TREATMENT — (S)MMSE or ADAS-Cog improvement.
Continuing treatment, as the sole PBS-subsidised therapy, following initial PBS-subsidised therapy, of mild to moderately severe Alzheimer's disease in patients with demonstrated improvement in cognitive function as measured by:
(a) for patients with a baseline (S)MMSE score of 10 or more and less than 25, an increase of at least 2 points from baseline on the Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE);
(b) for patients with a baseline (S)MMSE score of at least 25 points, a decrease of at least 4 points from baseline on the Alzheimer's Disease Assessment Scale, cognitive sub-scale (ADAS-Cog) or an increase of at least 2 points from baseline on the Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE).

The initial authority application for continuing treatment must include the relevant result from the (S)MMSE or the ADAS-Cog and must be in writing.

Subsequent applications for continuing treatment can be made by telephone.

Authority Required

INITIAL APPLICATION FOR THE TREATMENT OF MILD TO MODERATELY SEVERE ALZHEIMER'S DISEASE — Patients with an (S)MMSE of 9 or less who require a clinician's assessment.
Initial treatment, as the sole PBS-subsidised therapy, of mild to moderately severe Alzheimer's disease of patients with a baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE) score of 9 or less, who are unable to register a score of 10 or more for reasons other than their Alzheimer's disease, as specified below. Confirmation of this diagnosis must be made by a specialist/consultant physician (including a psychiatrist).

Such patients will need to be assessed using the Clinicians Interview Based Impression of Severity (CIBIS) scale. The authority application must include the result of the baseline (S)MMSE and specify to which group(s) (see below) the patient belongs.

continued ☞

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
	This application must be made in writing, but initial supply may be sought by telephone. ***For telephone applications, up to a maximum of 2 months' initial therapy will be authorised. This telephone application must be followed by a written authority application for no more than 1 month's therapy and sufficient repeats to complete a maximum of up to 6 months' initial treatment.*** ***For written applications where no prior telephone approval has been issued, up to a maximum of 1 month's therapy plus 5 repeats will be authorised.*** ***Patients who qualify under this criterion are from 1 or more of the following groups:*** ***(1) Unable to communicate adequately because of lack of competence in English, in people of non-English speaking background;*** ***(2) Limited education, as defined by less than 6 years of education, or who are illiterate or innumerate;*** ***(3) Aboriginal or Torres Strait Islanders who, by virtue of cultural factors, are unable to complete an (S)MMSE test;*** ***(4) Intellectual (developmental or acquired) disability, eg Down's syndrome;*** ***(5) Significant sensory impairment despite best correction, which precludes completion of an (S)MMSE test;*** ***(6) Prominent dysphasia, out of proportion to other cognitive and functional impairment;*** ***CONTINUING TREATMENT — Clinician assessed improvement.*** ***Continuing treatment, as the sole PBS-subsidised therapy, following initial PBS-subsidised therapy, of mild to moderately severe Alzheimer's disease in patients with demonstrated improvement in function, based on a rating of "very much improved" or "much improved" on the Clinicians Interview Based Impression of Change (CIBIC) scale, which must be assessed by the same clinician who initiated treatment.*** ***The initial authority application for continuing treatment must state the improvement achieved on the CIBIC scale and must be in writing.*** ***Subsequent applications for continuing treatment can be made by telephone.***							
8497F	***Capsule 1.5 mg (base)***	***56***	***5***	***..***	***155.02***	***32.90***	***Exelon***	***NV***
8498G	***Capsule 3 mg (base)***	***56***	***5***	***..***	***155.02***	***32.90***	***Exelon***	***NV***
8499H	***Capsule 4.5 mg (base)***	***56***	***5***	***..***	***155.02***	***32.90***	***Exelon***	***NV***
8500J	***Capsule 6 mg (base)***	***56***	***5***	***..***	***155.02***	***32.90***	***Exelon***	***NV***
8563Q	***Oral solution 2 mg (base) per mL, 120 mL***	***‡ 1***	***5***	***..***	***155.02***	***32.90***	***Exelon***	***NV***

• *Other anti-dementia drugs*

MEMANTINE HYDROCHLORIDE

Authority Required

INITIAL APPLICATION FOR THE TREATMENT OF MODERATELY SEVERE ALZHEIMER'S DISEASE — Patients with an (S)MMSE of 10 to 14.

Initial treatment, as the sole PBS-subsidised therapy, of moderately severe Alzheimer's disease. Confirmation of this diagnosis must be made by a specialist/consultant physician (including a psychiatrist).

The authority application must include the result of the baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE). This baseline (S)MMSE must be a score of 10 to 14.

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Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer

This application must be made in writing, but initial supply may be sought by telephone.
For telephone applications, up to a maximum of 2 months' initial therapy will be authorised. This telephone application must be followed by a written authority application for no more than 1 month's therapy and sufficient repeats to complete a maximum of up to 6 months' initial treatment.
For written applications where no prior telephone approval has been issued, up to a maximum of 1 month's therapy plus 5 repeats will be authorised;

CONTINUING TREATMENT — (S)MMSE improvement.
Continuing treatment, as the sole PBS-subsidised therapy, following initial PBS-subsidised therapy, of moderately severe Alzheimer's disease in patients with demonstrated improvement in cognitive function as measured by an increase of at least 2 points from baseline on the Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE).

The initial authority application for continuing treatment must include the relevant result from the (S)MMSE and must be in writing.

Subsequent applications for continuing treatment can be made by telephone.

Authority Required

INITIAL APPLICATION FOR THE TREATMENT OF MODERATELY SEVERE ALZHEIMER'S DISEASE — Patients with an (S)MMSE of 9 or less who require a clinician's assessment.
Initial treatment, as the sole PBS-subsidised therapy, of moderately severe Alzheimer's disease of patients with a baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE) score of 9 or less, who are unable to register a score of 10 to 14 for reasons other than their Alzheimer's disease, as specified below. Confirmation of this diagnosis must be made by a specialist/consultant physician (including a psychiatrist).

Such patients will need to be assessed using the Clinicians Interview Based Impression of Severity (CIBIS) scale. The authority application must include the result of the baseline (S)MMSE and specify to which group(s) (see below) the patient belongs.

This application must be made in writing, but initial supply may be sought by telephone.
For telephone applications, up to a maximum of 2 months' initial therapy will be authorised. This telephone application must be followed by a written authority application for no more than 1 month's therapy and sufficient repeats to complete a maximum of up to 6 months' initial treatment.
For written applications where no prior telephone approval has been issued, up to a maximum of 1 month's therapy plus 5 repeats will be authorised.

Patients who qualify under this criterion are from 1 or more of the following groups:
(1) Unable to communicate adequately because of lack of competence in English, in people of non-English speaking background;
(2) Limited education, as defined by less than 6 years of education, or who are illiterate or innumerate;
(3) Aboriginal or Torres Strait Islanders who, by virtue of cultural factors, are unable to complete an (S)MMSE test;

(4) Intellectual (developmental or acquired) disability, eg Down's syndrome;
(5) Significant sensory impairment despite best correction, which precludes completion of an (S)MMSE test;
(6) Prominent dysphasia, out of proportion to other cognitive and functional impairment;

CONTINUING TREATMENT — Clinician assessed improvement.
Continuing treatment, as the sole PBS-subsidised therapy, following initial PBS-subsidised therapy, of moderately severe Alzheimer's disease in patients with demonstrated improvement in function, based on a rating of "very much improved" or "much improved" on the Clinicians Interview Based Impression of Change (CIBIC) scale, which must be assessed by the same clinician who initiated treatment.

The initial authority application for continuing treatment must state the improvement achieved on the CIBIC scale and must be in writing.

continued ☞

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
	Subsequent applications for continuing treatment can be made by telephone.							
	Authority Required ***APPLICATION FOR THE TREATMENT OF MODERATELY SEVERE ALZHEIMER'S DISEASE — Patients who commenced treatment prior to 1 March 2008.*** ***Continuing treatment, as the sole PBS-subsidised therapy, of a patient commenced on memantine prior to 1 March 2008.*** ***Applications for continuing treatment can be made by telephone.***							
1956Y	***Tablet 10 mg***	***56***	***5***	***..***	***123.22***	***32.90***	***Ebixa***	***LU***
2059J	***Oral drops 10 mg per g, 50 g***	***‡ 1***	***5***	***..***	***110.67***	***32.90***	***Ebixa***	***LU***
	OTHER NERVOUS SYSTEM DRUGS							
	Parasympathomimetics							
	• ***Anticholinesterases***							
	PYRIDOSTIGMINE BROMIDE							
2724J	Tablet 10 mg	100	5	..	19.24	20.27	Mestinon	VT
1959D	Tablet 60 mg	150	5	..	55.57	32.90	Mestinon	VT
2608G	Tablet 180 mg (modified release)	100	5	..	114.04	32.90	Mestinon Timespan	VT
	• ***Choline esters***							
	BETHANECHOL CHLORIDE							
1062X	Tablet 10 mg	100	2	..	20.60	21.63	Uro-Carb	HA
	Drugs used in addictive disorders							
	• ***Drugs used in nicotine dependence***							
	BUPROPION HYDROCHLORIDE							
	NOTE: ***Only one course of PBS-subsidised bupropion hydrochloride will be authorised per 12 months. The period between commencing a course of bupropion hydrochloride and varenicline tartrate must be at least 6 months. A course of treatment with bupropion hydrochloride is 9 weeks. No increased maximum quantities or repeats will be authorised. Clinical review is recommended within 2 to 3 weeks of the original prescription being requested.***							
	Authority Required ***Commencement of short-term, sole PBS-subsidised, therapy as an aid to achieving abstinence in a patient who has indicated they are ready to cease smoking and:*** ***(a) who has entered a comprehensive support and counselling program; or*** ***(b) who is entering a comprehensive support and counselling program during the consultation at which this authority is requested.*** ***Details of the program must be specified in the authority application.***							
8465M	***Tablet 150 mg (sustained release)***	***30***	***..***	***..***	***76.83***	***32.90***	***[a] Clorprax***	***HX***
							[a] Prexaton	***AF***
				B0.85	***77.68***	***32.90***	***[a] Zyban***	***GK***

continued ☞

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Proprietary Name and Manufacturer	
	Authority Required ***Completion of short-term, sole PBS-subsidised, therapy as an aid to achieving abstinence in a patient who has previously been issued with an authority prescription for this drug and who is enrolled in a comprehensive support and counselling program.***								
8710K	***Tablet 150 mg (sustained release)***	***90***	***..***	***..***	***168.10***	***32.90***	[a]	***Clorprax***	***HX***
							[a]	***Prexaton***	***AF***
				B0.86	***168.96***	***32.90***	[a]	***Zyban***	***GK***
	NICOTINE **Authority Required** ***Nicotine dependence in an Aboriginal or a Torres Strait Islander person as the sole PBS-subsidised therapy.*** **NOTE:** ***Only 2 courses of PBS-subsidised nicotine replacement therapy will be authorised per year.*** ***No applications for increased maximum quantities and/or repeats will be authorised.*** ***Benefit is improved if used in conjunction with a comprehensive support and counselling program.***								
9198D	***Transdermal patch releasing approximately 15 mg per 16 hours***	***28***	***2***	***..***	***54.79***	***32.90***		***Nicorette Patch***	***JT***
	VARENICLINE **NOTE:** ***Only one course of PBS-subsidised varenicline tartrate will be authorised per year. The period between commencing a course of varenicline tartrate and bupropion hydrochloride must be at least 6 months. A course of treatment with varenicline tartrate is 12 weeks. No increased maximum quantities or repeats will be authorised. Clinical review is recommended within 2 to 3 weeks of the original prescription being requested.*** **Authority Required** ***Commencement of short-term, sole PBS-subsidised, therapy as an aid to achieving abstinence in a patient who has indicated they are ready to cease smoking and:*** ***(a) who has entered a comprehensive support and counselling program; or*** ***(b) who is entering a comprehensive support and counselling program during the consultation at which this authority is requested.*** ***Details of the program must be specified in the authority application.***								
9128K	***Box containing 11 tablets 0.5 mg (as tartrate) and 14 tablets 1 mg (as tartrate) in the first pack and 28 tablets 1 mg (as tartrate) in the second pack***	***‡ 1***	***..***	***..***	***103.33***	***32.90***		***Champix***	***PF***
	Authority Required ***Completion of short-term, sole PBS-subsidised, therapy as an aid to achieving abstinence in a patient who has previously been issued with an authority prescription for this drug and who is enrolled in a comprehensive support and counselling program.***								
9129L	***Tablet 1 mg (as tartrate)***	***112***	***..***	***..***	**** 232.63***	***32.90***		***Champix***	***PF***

NERVOUS SYSTEM—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Proprietary Name and Manufacturer	
	• *Drugs used in alcohol dependence*								
	ACAMPROSATE CALCIUM								
	Authority Required (STREAMLINED)								
	2665								
	For use within a comprehensive treatment program for alcohol dependence with the goal of maintaining abstinence.								
	NOTE:								
	No applications for increased maximum quantities and/or repeats will be authorised.								
8357W	***Tablet 333 mg (enteric coated)***	***180***	***1***	***..***	***166.15***	***32.90***		***Campral***	***AF***
	NALTREXONE HYDROCHLORIDE								
	CAUTION:								
	Naltrexone hydrochloride is contraindicated in patients receiving opioid drugs.								
	Authority Required								
	For use within a comprehensive treatment program for alcohol dependence with the goal of maintaining abstinence.								
	NOTE:								
	No applications for increased maximum quantities and/or repeats will be authorised.								
8370M	***Tablet 50 mg***	***30***	***1***	***..***	***143.33***	***32.90***	[a]	***Naltrexone QP***	***XF***
							[a]	***ReVia***	***BQ***
	Other nervous system drugs								
	• *Other nervous system drugs*								
	RILUZOLE								
	Authority Required								
	Initial treatment of amyotrophic lateral sclerosis, as diagnosed by a neurologist, in patients with disease duration of 5 years or less and who have at least 60 percent of predicted forced vital capacity within 2 months prior to commencing riluzole therapy and who:								
	(1) are ambulatory, and								
	(a) have not undergone tracheostomy, and								
	(b) have not experienced respiratory failure; OR								
	(2) are not ambulatory, and								
	(a) have not undergone tracheostomy, and								
	(b) have not experienced respiratory failure, and								
	(c) are either able to use upper limbs or able to swallow.								
	The date of diagnosis and the date and results of spirometry (in terms of percent of predicted forced vital capacity) must be supplied with the initial authority application.								
	Authority Required								
	Continuing treatment of amyotrophic lateral sclerosis in patients who have previously been issued with an authority prescription for this drug and who:								
	(1) are ambulatory, and								
	(a) have not undergone tracheostomy, and								
	(b) have not experienced respiratory failure; OR								
	(2) are not ambulatory, and								
	(a) have not undergone tracheostomy, and								
	(b) have not experienced respiratory failure, and								
	(c) are either able to use upper limbs or able to swallow.								

continued ☞

NERVOUS SYSTEM—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
8664B	***Tablet 50 mg***	***56***	***5***	***..***	***661.57***	***32.90***	***Rilutek***	***SW***
	TETRABENAZINE							
	Authority Required (STREAMLINED)							
	1161							
	Hyperkinetic extrapyramidal disorders.							
1330B	***Tablet 25 mg***	***112***	***5***	***..***	***337.12***	***32.90***	***OA***	

ANTIPARASITIC PRODUCTS, INSECTICIDES AND REPELLENTS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Proprietary Name and Manufacturer	

ANTIPROTOZOALS

Agents against amoebiasis and other protozoal diseases

- ***Nitroimidazole derivatives***

METRONIDAZOLE

For listings see Generic/Proprietary Index

METRONIDAZOLE BENZOATE

For listings see Generic/Proprietary Index

TINIDAZOLE

For listings see Generic/Proprietary Index

- ***Other agents against amoebiasis and other protozoal diseases***

ATOVAQUONE

Authority Required (STREAMLINED)
1433
Treatment of mild to moderate Pneumocystis carinii pneumonia in adult patients who are intolerant of trimethoprim/sulfamethoxazole therapy.

8300W	***Oral suspension 750 mg per 5 mL, 210 mL***	***‡ 1***	***..***	***..***	***862.78***	***32.90***		***Wellvone***	***GK***

PYRIMETHAMINE

1966L	Tablet 25 mg	50	..	..	14.28	15.31		Daraprim	GK

Antimalarials

- ***Methanolquinolines***

QUININE BISULFATE
CAUTION:
Severe thrombocytopenia has been reported with this drug.

Authority Required (STREAMLINED)
2142
Malaria.

1972T	***Tablet 300 mg***	***50***	***2***	***..***	***12.02***	***13.05***		***Quinbisul***	***AS***

QUININE SULFATE
CAUTION:
Severe thrombocytopenia has been reported with this drug.

Authority Required (STREAMLINED)
2142
Malaria.

1975Y	***Tablet 300 mg***	***50***	***2***	***..***	***12.02***	***13.05***	[a]	***Quinsul***	***LN***
				B2.17	***14.19***	***13.05***	[a]	***Quinate***	***AS***

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
	ANTHELMINTICS							
	Antinematodal agents							
	• ***Benzimidazole derivatives***							
	ALBENDAZOLE							
	Authority Required (STREAMLINED) **2446** ***Treatment of whipworm infestation in an Aboriginal or a Torres Strait Islander person.***							
9047E	***Tablet 200 mg***	***6***	***..***	***..***	***32.67***	***32.90***	***Zentel***	***GK***
	Authority Required (STREAMLINED) **1525** ***Treatment of tapeworm infestation.***							
8503M	***Tablet 200 mg***	***6***	***1***	***..***	***32.67***	***32.90***	***Zentel***	***GK***
	Authority Required (STREAMLINED) **1496** ***For the treatment of hydatid disease in conjunction with surgery or when a surgical cure cannot be achieved or where surgery cannot be used.***							
8459F	***Tablet 400 mg***	***60***	***2***	***..***	***184.82***	***32.90***	***Eskazole***	***GK***
	• ***Tetrahydropyrimidine derivatives***							
	PYRANTEL EMBONATE							
3047J	Tablet 125 mg (base)	6	..	..	7.61	8.64	Anthel 125	AF
3048K	Tablet 250 mg (base)	6	..	..	9.05	10.08	Anthel 250	AF
	• ***Avermectines***							
	IVERMECTIN							
	Authority Required (STREAMLINED) **1242** ***Onchocerciasis;*** **1388** ***Strongyloidiasis.***							
8359Y	***Tablet 3 mg***	***4***	***..***	***..***	***30.88***	***31.91***	***Stromectol***	***MK***

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
	ECTOPARASITICIDES, INCL. SCABICIDES, INSECTICIDES AND REPELLENTS							
	Ectoparasiticides, incl. scabicides							
	• ***Pyrethrines, incl. synthetic compounds***							
	PERMETHRIN							
3054R	Cream 50 mg per g (5%), 30 g	‡ 1	1	..	16.34	17.37	Lyclear	JT

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Proprietary Name and Manufacturer	
	DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES								
	Adrenergics, inhalants								
	• ***Selective beta-2-adrenoceptor agonists***								
	EFORMOTEROL FUMARATE DIHYDRATE								
	Restricted Benefit ***Patients with frequent episodes of asthma who are currently receiving treatment with oral corticosteroids;*** ***Patients with frequent episodes of asthma who are currently receiving treatment with optimal doses of inhaled corticosteroids.***								
8136F	***Capsule containing powder for oral inhalation 12 micrograms (for use in Foradile Aerolizer)***	***60***	***5***	***..***	***36.90***	***32.90***		***Foradile***	***NV***
8239P	***Powder for oral inhalation in breath actuated device 6 micrograms per dose (60 doses)***	***‡ 1***	***5***	***..***	***25.95***	***26.98***		***Oxis Turbuhaler***	***AP***
8240Q	***Powder for oral inhalation in breath actuated device 12 micrograms per dose (60 doses)***	***‡ 1***	***5***	***..***	***36.01***	***32.90***		***Oxis Turbuhaler***	***AP***
	SALBUTAMOL SULFATE								
1099W	Capsule containing powder for oral inhalation 200 micrograms (base) (for use in Ventolin Rotahaler)	200	5	..	* 18.07	19.10		Ventolin Rotacaps	GK
8288F	Oral pressurised inhalation 100 micrograms (base) per dose (200 doses), CFC-free formulation	2	5	.. B1.18	* 14.79 * 15.97	15.82 15.82	a a a	Airomir Asmol CFC-free Ventolin CFC-free	IA AL GK
	SALBUTAMOL SULFATE								
	Restricted Benefit ***Patients unable to achieve co-ordinated use of other metered dose inhalers containing this drug.***								
8354Q	***Oral pressurised inhalation in breath actuated device 100 micrograms (base) per dose (200 doses), CFC-free formulation***	***2***	***5***	***..***	**** 38.17***	***32.90***		***Airomir Autohaler***	***IA***

continued ☞

RESPIRATORY SYSTEM—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
	Restricted Benefit ***Asthma in patients unable to use this drug delivered from an oral pressurised inhalation device via a spacer;*** ***Chronic obstructive pulmonary disease in patients unable to use this drug delivered from an oral pressurised inhalation device via a spacer.***							
2000G	***Nebuliser solution single dose units 2.5 mg (base) in 2.5 mL, 30***	***2***	***5***	***..***	**** 18.51***	***19.54***	[a] ***Asmol 2.5 uni-dose***	***AF***
							[a] ***Butamol 2.5***	***SI***
							[a] ***GenRx Salbutamol***	***GX***
							[a] ***Pharmacor Salbutamol 2.5***	***CR***
							[a] ***Salbutamol-GA***	***GM***
							[a] ***Salbutamol Sandoz***	***SZ***
							[a] ***PU***	
				B1.46	**** 19.97***	***19.54***	[a] ***Ventolin Nebules***	***GK***
2001H	***Nebuliser solution single dose units 5 mg (base) in 2.5 mL, 30***	***2***	***5***	***..***	**** 19.21***	***20.24***	[a] ***Asmol 5 uni-dose***	***AF***
							[a] ***Butamol 5***	***SI***
							[a] ***GenRx Salbutamol***	***GX***
							[a] ***Pharmacor Salbutamol 5***	***CR***
							[a] ***Salbutamol-GA***	***GM***
							[a] ***Salbutamol Sandoz***	***SZ***
				B1.46	**** 20.67***	***20.24***	[a] ***Ventolin Nebules***	***GK***
2003K	***Nebuliser solution 5 mg (base) per mL (0.5%), 30 mL***	***2***	***2***	***..***	**** 10.59***	***11.62***	***PU***	
	SALMETEROL XINAFOATE							
	Restricted Benefit ***Patients with frequent episodes of asthma who are currently receiving treatment with oral corticosteroids;*** ***Patients with frequent episodes of asthma who are currently receiving treatment with optimal doses of inhaled corticosteroids.***							
8141L	***Powder for oral inhalation in breath actuated device 50 micrograms (base) per dose (60 doses)***	***‡ 1***	***5***	***..***	***36.90***	***32.90***	***Serevent Accuhaler***	***GK***
	TERBUTALINE SULFATE							
1252X	Powder for oral inhalation in breath actuated device 500 micrograms per dose (200 doses)	‡ 1	5	..	17.40	18.43	Bricanyl Turbuhaler	AP

continued ☞

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
	TERBUTALINE SULFATE							
	Restricted Benefit ***Asthma in patients unable to use this drug delivered from a breath actuated device;*** ***Chronic obstructive pulmonary disease in patients unable to use this drug delivered from a breath actuated device.***							
1251W	***Nebuliser solution single dose units 5 mg in 2 mL, 30***	***2***	***5***	***..***	**** 40.37***	***32.90***	***Bricanyl Respules***	***AP***

• *Adrenergics and other drugs for obstructive airway diseases*

BUDESONIDE with EFORMOTEROL FUMARATE DIHYDRATE

Restricted Benefit

Patients who previously had frequent episodes of asthma while receiving treatment with oral corticosteroids and who have been stabilised on concomitant inhaled eformoterol fumarate dihydrate and budesonide;

Patients who previously had frequent episodes of asthma while receiving treatment with optimal doses of inhaled corticosteroids and who have been stabilised on concomitant inhaled eformoterol fumarate dihydrate and budesonide;

For single maintenance and reliever therapy in a patient who experiences frequent asthma symptoms while receiving treatment with oral corticosteroids;

For single maintenance and reliever therapy in a patient who experiences frequent asthma symptoms while receiving treatment with inhaled corticosteroids;

For maintenance and reliever therapy in a patient who experiences frequent asthma symptoms while receiving treatment with a combination of an inhaled corticosteroid and a long-acting beta-2 agonist.

8796Y	***Powder for oral inhalation in breath actuated device 100 micrograms-6 micrograms per dose (120 doses)***	***‡ 1***	***5***	***..***	***54.04***	***32.90***	***Symbicort Turbuhaler 100/6***	***AP***
8625Y	***Powder for oral inhalation in breath actuated device 200 micrograms-6 micrograms per dose (120 doses)***	***‡ 1***	***5***	***..***	***58.34***	***32.90***	***Symbicort Turbuhaler 200/6***	***AP***

Restricted Benefit

Patients who previously had frequent episodes of asthma while receiving treatment with oral corticosteroids and who have been stabilised on concomitant inhaled eformoterol fumarate dihydrate and budesonide;

Patients who previously had frequent episodes of asthma while receiving treatment with optimal doses of inhaled corticosteroids and who have been stabilised on concomitant inhaled eformoterol fumarate dihydrate and budesonide.

NOTE:

Symbicort 400/12 is not recommended nor PBS-subsidised for use as 'maintenance and reliever' therapy.

8750M	***Powder for oral inhalation in breath actuated devices 400 micrograms-12 micrograms per dose (60 doses), 2***	***1***	***5***	***..***	***86.46***	***32.90***	***Symbicort Turbuhaler 400/12***	***AP***

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
	FLUTICASONE PROPIONATE with SALMETEROL XINAFOATE							
	Restricted Benefit ***Patients who previously had frequent episodes of asthma while receiving treatment with oral corticosteroids and who have been stabilised on concomitant inhaled salmeterol xinafoate and fluticasone propionate;*** ***Patients who previously had frequent episodes of asthma while receiving treatment with optimal doses of inhaled corticosteroids and who have been stabilised on concomitant inhaled salmeterol xinafoate and fluticasone propionate.***							
8517G	***Oral pressurised inhalation 50 micrograms-25 micrograms (base) per dose (120 doses), CFC-free formulation***	***‡ 1***	***5***	***..***	***46.77***	***32.90***	***Seretide MDI 50/25***	***GK***
8518H	***Oral pressurised inhalation 125 micrograms-25 micrograms (base) per dose (120 doses), CFC-free formulation***	***‡ 1***	***5***	***..***	***58.88***	***32.90***	***Seretide MDI 125/25***	***GK***
8430Q	***Powder for oral inhalation in breath actuated device 100 micrograms-50 micrograms (base) per dose (60 doses)***	***‡ 1***	***5***	***..***	***46.77***	***32.90***	***Seretide Accuhaler 100/50***	***GK***
8431R	***Powder for oral inhalation in breath actuated device 250 micrograms-50 micrograms (base) per dose (60 doses)***	***‡ 1***	***5***	***..***	***58.88***	***32.90***	***Seretide Accuhaler 250/50***	***GK***
	Restricted Benefit ***Patients who previously had frequent episodes of asthma while receiving treatment with oral corticosteroids and who have been stabilised on concomitant inhaled salmeterol xinafoate and fluticasone propionate;*** ***Patients who previously had frequent episodes of asthma while receiving treatment with optimal doses of inhaled corticosteroids and who have been stabilised on concomitant inhaled salmeterol xinafoate and fluticasone propionate;*** ***Symptomatic treatment of chronic obstructive pulmonary disease (COPD), where the FEV1 is less than 50% predicted normal and there is a history of repeated exacerbations with significant symptoms despite regular beta-2 agonist bronchodilator therapy.*** **NOTE:** ***Seretide is not indicated for the initiation of bronchodilator therapy in COPD.***							
8519J	***Oral pressurised inhalation 250 micrograms-25 micrograms (base) per dose (120 doses), CFC-free formulation***	***‡ 1***	***5***	***..***	***78.24***	***32.90***	***Seretide MDI 250/25***	***GK***

continued ☞

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
8432T	***Powder for oral inhalation in breath actuated device 500 micrograms-50 micrograms (base) per dose (60 doses)***	***‡ 1***	***5***	***..***	***78.24***	***32.90***	***Seretide Accuhaler 500/50***	***GK***

Other drugs for obstructive airway diseases, inhalants

• *Glucocorticoids*

BECLOMETHASONE DIPROPIONATE

8406K	Oral pressurised inhalation 50 micrograms per dose (200 doses), CFC-free formulation	‡ 1	5	..	18.86	19.89	Qvar 50	IA
8407L	Oral pressurised inhalation 100 micrograms per dose (200 doses), CFC-free formulation	‡ 1	5	..	33.03	32.90	Qvar 100	IA

BECLOMETHASONE DIPROPIONATE

Restricted Benefit

Patients unable to achieve co-ordinated use of other metered dose inhalers containing this drug.

8408M	***Oral pressurised inhalation in breath actuated device 50 micrograms per dose (200 doses), CFC-free formulation***	***‡ 1***	***5***	***..***	***27.44***	***28.47***	***Qvar 50 Autohaler***	***IA***
8409N	***Oral pressurised inhalation in breath actuated device 100 micrograms per dose (200 doses), CFC-free formulation***	***‡ 1***	***5***	***..***	***38.70***	***32.90***	***Qvar 100 Autohaler***	***IA***

BUDESONIDE

2070Y	Powder for oral inhalation in breath actuated device 100 micrograms per dose (200 doses)	‡ 1	5	..	22.91	23.94	Pulmicort Turbuhaler	AP
2071B	Powder for oral inhalation in breath actuated device 200 micrograms per dose (200 doses)	‡ 1	5	..	30.65	31.68	Pulmicort Turbuhaler	AP
2072C	Powder for oral inhalation in breath actuated device 400 micrograms per dose (200 doses)	‡ 1	5	..	45.41	32.90	Pulmicort Turbuhaler	AP

continued ☞

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
	BUDESONIDE							
	Authority Required (STREAMLINED) **1351** ***Severe chronic asthma in patients who require long-term steroid therapy and who are unable to use other forms of inhaled steroid therapy.***							
2065Q	***Nebuliser suspension single dose units 500 micrograms in 2 mL, 30***	***‡ 1***	***5***	***..***	***37.43***	***32.90***	***Pulmicort Respules***	***AP***
2066R	***Nebuliser suspension single dose units 1 mg in 2 mL, 30***	***‡ 1***	***5***	***..***	***48.57***	***32.90***	***Pulmicort Respules***	***AP***
	CICLESONIDE							
8853Y	Oral pressurised inhalation 80 micrograms per dose (120 doses), CFC-free formulation	‡ 1	5	..	25.72	26.75	Alvesco 80	NQ
8854B	Oral pressurised inhalation 160 micrograms per dose (120 doses), CFC-free formulation	‡ 1	5	..	41.82	32.90	Alvesco 160	NQ
	FLUTICASONE PROPIONATE							
8516F	Oral pressurised inhalation 50 micrograms per dose (120 doses), CFC-free formulation	‡ 1	5	..	16.66	17.69	Flixotide Junior	GK
8345F	Oral pressurised inhalation 125 micrograms per dose (120 doses), CFC-free formulation	‡ 1	5	..	30.23	31.26	Flixotide	GK
8346G	Oral pressurised inhalation 250 micrograms per dose (120 doses), CFC-free formulation	‡ 1	1	..	49.29	32.90	Flixotide	GK
8147T	Powder for oral inhalation in breath actuated device 100 micrograms per dose (60 doses)	‡ 1	5	..	16.66	17.69	Flixotide Junior Accuhaler	GK
8148W	Powder for oral inhalation in breath actuated device 250 micrograms per dose (60 doses)	‡ 1	5	..	30.23	31.26	Flixotide Accuhaler	GK
8149X	Powder for oral inhalation in breath actuated device 500 micrograms per dose (60 doses)	‡ 1	1	..	49.29	32.90	Flixotide Accuhaler	GK
	• ***Anticholinergics***							
	IPRATROPIUM BROMIDE							
8671J	Oral pressurised inhalation 21 micrograms per dose (200 doses), CFC-free formulation	2	5	..	* 34.85	32.90	Atrovent	BY

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
	IPRATROPIUM BROMIDE							
	Restricted Benefit ***Asthma in patients unable to use this drug delivered from an oral pressurised inhalation device via a spacer;*** ***Chronic obstructive pulmonary disease in patients unable to use this drug delivered from an oral pressurised inhalation device via a spacer.***							
1542E	***Nebuliser solution single dose units 250 micrograms (anhydrous) in 1 mL, 30***	***2***	***5***	***..***	**** 36.85***	***32.90***	***[a] Aeron 250***	***SI***
							[a] APO-Ipratropium	***TX***
							[a] Apoven 250	***GM***
							[a] Ipratrin	***AF***
							[a] Ipravent	***PU***
				B0.72	**** 37.57***	***32.90***	***[a] Atrovent***	***BY***
8238N	***Nebuliser solution single dose units 500 micrograms (anhydrous) in 1 mL, 30***	***2***	***5***	***..***	**** 42.21***	***32.90***	***[a] Aeron 500***	***SI***
							[a] APO-Ipratropium	***TX***
							[a] Apoven 500	***GM***
							[a] Ipratrin Adult	***AF***
							[a] Ipravent	***PU***
				B0.62	**** 42.83***	***32.90***	***[a] Atrovent Adult***	***BY***
	TIOTROPIUM BROMIDE MONOHYDRATE							
	Restricted Benefit ***For the long-term maintenance treatment of bronchospasm and dyspnoea associated with chronic obstructive pulmonary disease.***							
8626B	***Capsule containing powder for oral inhalation 18 micrograms (base) (for use in HandiHaler)***	***30***	***5***	***..***	***76.46***	***32.90***	***Spiriva***	***BY***
	• *Antiallergic agents, excl. corticosteroids*							
	NEDOCROMIL SODIUM							
8365G	Oral pressurised inhalation 2 mg per dose (112 doses), CFC-free formulation	‡ 1	5	..	37.26	32.90	Tilade CFC-Free	SW
	SODIUM CROMOGLYCATE							
2878L	Capsule containing powder for oral inhalation 20 mg (for use in Intal Spinhaler or Intal Halermatic)	100	5	..	32.53	32.90	Intal Spincaps	GM
2872E	Oral pressurised inhalation 1 mg per dose (200 doses)	‡ 1	5	..	31.35	32.38	Intal	SW
8767K	Oral pressurised inhalation 1 mg per dose (200 doses), CFC-free formulation	‡ 1	5	..	31.35	32.38	Intal CFC-Free	SW
8334P	Oral pressurised inhalation 5 mg per dose (112 doses), CFC-free formulation	‡ 1	5	..	37.24	32.90	Intal Forte CFC-Free	SW

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
	Adrenergics for systemic use							
	• ***Alpha- and beta-adrenoceptor agonists***							
	ADRENALINE							
1016L	Injection 1 mg in 1 mL (1 in 1,000)	5	1	..	19.91	20.94	AP	
	ADRENALINE							
	Authority Required							
	Initial supply for anticipated emergency treatment of acute allergic reactions with anaphylaxis in a patient who:							
	(a) has been assessed to be at significant risk of anaphylaxis by, or in consultation with, a clinical immunologist, allergist, paediatrician or respiratory physician. The name of the specialist consulted must be provided at the time of application for initial supply; or							
	(b) has been discharged from hospital or an emergency department after treatment with adrenaline for acute allergic reaction with anaphylaxis;							
	Continuing supply for anticipated emergency treatment of acute allergic reactions with anaphylaxis, where the patient has previously been issued with an authority prescription for this drug.							
	NOTE:							
	The auto-injector should be provided in the framework of a comprehensive anaphylaxis prevention program and an emergency action plan including training in recognition of the symptoms of anaphylaxis and the use of the auto-injector device. (For further information see the Australasian Society of Clinical Immunology and Allergy website at www.allergy.org.au.)							
8697R	***I.M. injection 150 micrograms in 0.3 mL single dose syringe auto-injector***	***1***	***..***	***..***	***105.57***	***32.90***	***EpiPen Jr.***	***AL***
8698T	***I.M. injection 300 micrograms in 0.3 mL single dose syringe auto-injector***	***1***	***..***	***..***	***105.57***	***32.90***	***EpiPen***	***AL***
	NOTE:							
	Authorities for increased maximum quantities, up to a maximum of 2, may be authorised for children aged less than 17 years where 2 auto-injectors are necessary to ensure 1 is on hand at all times. No increased maximum quantities will be authorised for patients aged 17 years or older.							
	No repeats will be issued.							
	• ***Selective beta-2-adrenoceptor agonists***							
	SALBUTAMOL SULFATE							
1103C	Syrup 2 mg (base) per 5 mL, 150 mL	2	5	..	* 21.77	22.80	Ventolin	GK
	TERBUTALINE SULFATE							
1034K	Injection 500 micrograms in 1 mL	5	..	..	30.16	31.19	Bricanyl	AP

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
	Other systemic drugs for obstructive airway diseases							
	• ***Xanthines***							
	THEOPHYLLINE							
	CAUTION:							
	Because of variable effects of food on absorption of sustained release theophylline preparations, patients stabilised on one brand should not be changed to another without appropriate monitoring.							
8230E	Tablet 200 mg (sustained release)	100	5	..	11.73	12.76	Nuelin-SR 200	IA
2634P	Tablet 250 mg (sustained release)	100	5	..	12.89	13.92	Nuelin-SR 250	IA
8231F	Tablet 300 mg (sustained release)	100	5	..	14.27	15.30	Nuelin-SR 300	IA
2614N	Syrup 133.3 mg per 25 mL, 500 mL	‡ 1	5	..	10.39	11.42	Nuelin	IA
	• ***Leukotriene receptor antagonists***							
	MONTELUKAST SODIUM							
	NOTE:							
	Montelukast sodium is not PBS-subsidised for use in children with moderate or severe asthma. It is not intended as an alternative for children who require a corticosteroid as a preventer medication. Montelukast sodium is not PBS-subsidised for use in combination with other preventer medications. PBS subsidy for montelukast sodium will therefore cease for patients who require a preventer medication in addition to montelukast sodium.							
	NOTE:							
	No applications for increased maximum quantities and/or repeats will be authorised.							
	Authority Required (STREAMLINED)							
	2617							
	First-line preventer medication, as the single preventer agent for children aged 2 to 5 years with frequent intermittent or mild persistent asthma, as an alternative to sodium cromoglycate or nedocromil sodium.							
8627C	***Chewable tablet 4 mg (base)***	***28***	***5***	***..***	***47.50***	***32.90***	***Singulair***	***MK***
	Authority Required (STREAMLINED)							
	2618							
	First-line preventer medication, as the single preventer agent for children aged 6 to 14 years with frequent intermittent or mild persistent asthma, as an alternative to sodium cromoglycate or nedocromil sodium.							
8628D	***Chewable tablet 5 mg (base)***	***28***	***5***	***..***	***47.50***	***32.90***	***Singulair***	***MK***
	COUGH AND COLD PREPARATIONS							
	Expectorants, excl. combinations with cough suppressants							
	• ***Mucolytics***							
	ACETYLCYSTEINE							
	Restricted Benefit							
	Bronchiectasis;							
	Cystic fibrosis.							
8747J	***Sterile inhalation solution 200 mg per mL (20%), 5 mL***	***30***	***3***	***..***	**** 146.54***	***32.90***	***Mucomyst***	***BQ***

RESPIRATORY SYSTEM—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer
	Cough suppressants, excl. combinations with expectorants						
	• ***Opium alkaloids and derivatives***						
	CODEINE PHOSPHATE						
1214X	Tablet 30 mg	20	..	..	16.44	17.47	FM
	ANTIHISTAMINES FOR SYSTEMIC USE						
	Antihistamines for systemic use						
	• ***Phenothiazine derivatives***						
	PROMETHAZINE HYDROCHLORIDE						
1948M	Injection 50 mg in 2 mL	10	..	..	* 21.89	22.92	HH

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
	OPHTHALMOLOGICALS							
	Antiinfectives							
	• ***Antibiotics***							
	AZITHROMYCIN							
	Restricted Benefit ***Trachoma.***							
	NOTE: ***No applications for increased maximum quantities and/or repeats will be authorised.***							
8336R	***Tablet 500 mg***	***2***	***2***	***..***	***23.46***	***24.49***	***Zithromax***	***PF***
8201P	***Powder for oral suspension 200 mg per 5 mL, 15 mL***	***‡ 1***	***..***	***..***	***# 22.98***	***24.37***	***Zithromax***	***PF***
	CHLORAMPHENICOL							
2360F	Eye drops 5 mg per mL (0.5%), 10 mL	‡ 1	2	..	8.88	9.91	Chloromycetin Chlorsig	PF SI
1171P	Eye ointment 10 mg per g (1%), 4 g	‡ 1	..	..	9.33	10.36	Chloromycetin Chlorsig	PF SI
	GENTAMICIN SULFATE							
	Restricted Benefit ***Invasive ocular infection;*** ***Perioperative use in ophthalmic surgery;*** ***Suspected pseudomonal eye infection.***							
1441W	***Eye drops 3 mg (base) per mL (0.3%), 5 mL***	***‡ 1***	***2***	***..***	***18.59***	***19.62***	***Genoptic***	***AG***
	TOBRAMYCIN							
	Restricted Benefit ***Invasive ocular infection;*** ***Perioperative use in ophthalmic surgery;*** ***Suspected pseudomonal eye infection.***							
2328M	***Eye drops 3 mg per mL (0.3%), 5 mL***	***‡ 1***	***2***	***..***	***18.85***	***19.88***	***Tobrex***	***AQ***
2329N	***Eye ointment 3 mg per g (0.3%), 3.5 g***	***‡ 1***	***..***	***..***	***21.58***	***22.61***	***Tobrex***	***AQ***
	• ***Sulfonamides***							
	SULFACETAMIDE SODIUM							
2063N	Eye drops 100 mg per mL (10%), 15 mL	‡ 1	2	..	13.35	14.38	Bleph 10	AG

SENSORY ORGANS—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Proprietary Name and Manufacturer	
	• *Antivirals*								
	ACICLOVIR								
	Restricted Benefit								
	Herpes simplex keratitis.								
1002R	***Eye ointment 30 mg per g (3%), 4.5 g***	***‡ 1***	***..***	***..***	***34.63***	***32.90***		***Zovirax***	***GK***
	• *Other antiinfectives*								
	CIPROFLOXACIN								
	Authority Required								
	Bacterial keratitis.								
1217C	***Eye drops 3 mg per mL (0.3%), 5 mL***	***2***	***..***	***..***	**** 25.91***	***26.94***	***a***	***CiloQuin***	***IQ***
				B1.84	**** 27.75***	***26.94***	***a***	***Ciloxan***	***AQ***
	OFLOXACIN								
	Authority Required								
	Bacterial keratitis.								
8383F	***Eye drops 3 mg per mL (0.3%), 5 mL***	***2***	***..***	***..***	**** 31.71***	***32.74***		***Ocuflox***	***AG***
	Antiinflammatory agents								
	• *Corticosteroids, plain*								
	DEXAMETHASONE								
1288T	Eye drops 1 mg per mL (0.1%), 5 mL	‡ 1	2	..	10.18	11.21		Maxidex	AQ
	FLUOROMETHOLONE								
1204J	Eye drops 1 mg per mL (0.1%), 5 mL	‡ 1	5	..	10.18	11.21		Flucon FML Liquifilm	AQ AG
	FLUOROMETHOLONE ACETATE								
1438Q	Eye drops 1 mg per mL (0.1%), 5 mL	‡ 1	2	..	10.18	11.21		Flarex	AQ
	HYDROCORTISONE ACETATE								
1497T	Eye ointment 5 mg per g (0.5%), 5 g	‡ 1	..	..	11.35	12.38		Hycor	SI
2441L	Eye ointment 10 mg per g (1%), 5 g	‡ 1	..	..	12.65	13.68		Hycor	SI

SENSORY ORGANS—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Proprietary Name and Manufacturer	
	• *Corticosteroids and mydriatics in combination*								
	PREDNISOLONE ACETATE with PHENYLEPHRINE HYDROCHLORIDE								
	Restricted Benefit								
	Corneal grafts;								
	Uveitis.								
3112T	***Eye drops 10 mg-1.2 mg per mL (1%-0.12%), 10 mL***	***‡ 1***	***2***	***..***	***21.53***	***22.56***		***Prednefrin Forte***	***AG***
	• *Antiinflammatory agents, non-steroids*								
	FLURBIPROFEN SODIUM								
8699W	Eye drops 300 micrograms per mL (0.03%), single dose units 0.4 mL, 5	1	..	..	14.94	15.97		Ocufen	AG
	Antiglaucoma preparations and miotics								
	• *Sympathomimetics in glaucoma therapy*								
	APRACLONIDINE HYDROCHLORIDE								
	Restricted Benefit								
	Short-term reduction of intra-ocular pressure in patients already on maximally tolerated anti-glaucoma therapy.								
8083K	***Eye drops 5 mg (base) per mL (0.5%), 10 mL***	***‡ 1***	***2***	***..***	***39.79***	***32.90***		***Iopidine 0.5%***	***AQ***
	BRIMONIDINE TARTRATE								
8351M	Eye drops 2 mg per mL (0.2%), 5 mL	‡ 1	5	..	20.56	21.59	a	Enidin	PE
				B1.74	22.30	21.59	a	Alphagan	AG
	BRIMONIDINE TARTRATE with TIMOLOL MALEATE								
	Restricted Benefit								
	Reduction of elevated intra-ocular pressure in patients with open-angle glaucoma who are not adequately controlled with timolol maleate 5 mg (base) per mL (0.5%) eye drops;								
	Reduction of elevated intra-ocular pressure in patients with ocular hypertension who are not adequately controlled with timolol maleate 5 mg (base) per mL (0.5%) eye drops.								
8826M	***Eye drops 2 mg-5 mg (base) per mL (0.2%-0.5%), 5 mL***	***‡ 1***	***5***	***..***	***26.76***	***27.79***		***Combigan***	***AG***
	• *Parasympathomimetics*								
	PILOCARPINE HYDROCHLORIDE								
2595N	Eye drops 10 mg per mL (1%), 15 mL	‡ 1	5	..	12.48	13.51		Isopto Carpine	AQ
				..	12.48	13.51	a	Pilopt	PE
				B2.97	15.45	13.51	a	P.V. Carpine	AG

continued ☞

SENSORY ORGANS—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Proprietary Name and Manufacturer	
2596P	Eye drops 20 mg per mL (2%), 15 mL	‡ 1	5	..	13.81	14.84		Isopto Carpine	AQ
				..	13.81	14.84	a	Pilopt	PE
				B2.96	16.77	14.84	a	P.V. Carpine	AG
2598R	Eye drops 40 mg per mL (4%), 15 mL	‡ 1	5	..	16.83	17.86		Isopto Carpine	AQ
				..	16.83	17.86	a	Pilopt	PE
				B2.83	19.66	17.86	a	P.V. Carpine	AG
2779G	Eye drops 60 mg per mL (6%), 15 mL	‡ 1	5	..	21.61	22.64	a	Pilopt	PE
				B2.86	24.47	22.64	a	P.V. Carpine	AG
	• *Carbonic anhydrase inhibitors*								
	ACETAZOLAMIDE								
1004W	Tablet 250 mg	100	3	..	23.36	24.39		Diamox	SI
	BRINZOLAMIDE								
8483L	Eye drops 10 mg per mL (1%), 5 mL	‡ 1	5	..	21.27	22.30	a	BrinzoQuin	IQ
				B1.03	22.30	22.30	a	Azopt	AQ
	DORZOLAMIDE HYDROCHLORIDE								
8488R	Eye drops 20 mg (base) per mL (2%), 5 mL	‡ 1	5	..	20.86	21.89		Trusopt	MK
	DORZOLAMIDE HYDROCHLORIDE with TIMOLOL MALEATE								
	Restricted Benefit								
	Reduction of elevated intra-ocular pressure in patients with open-angle glaucoma who are not adequately controlled with timolol maleate 5 mg (base) per mL (0.5%) eye drops;								
	Reduction of elevated intra-ocular pressure in patients with ocular hypertension who are not adequately controlled with timolol maleate 5 mg (base) per mL (0.5%) eye drops.								
8567X	***Eye drops 20 mg (base)-5 mg (base) per mL (2%-0.5%), 5 mL***	***‡ 1***	***5***	***..***	***27.06***	***28.09***		***Cosopt***	***MK***
	• *Beta blocking agents*								
	BETAXOLOL HYDROCHLORIDE								
2811Y	Eye drops, suspension, 2.5 mg (base) per mL (0.25%), 5 mL	‡ 1	5	..	14.10	15.13		Betoptic S	AQ
2825Q	Eye drops, solution, 5 mg (base) per mL (0.5%), 5 mL	‡ 1	5	..	14.10	15.13	a	BetoQuin	IQ
				B1.99	16.09	15.13	a	Betoptic	AQ
	TIMOLOL MALEATE								
8803H	Eye gel 1 mg (base) per g (0.1%), 5 g	‡ 1	5	..	11.37	12.40		Nyogel	NV

continued ☞

SENSORY ORGANS—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Proprietary Name and Manufacturer	
1278G	Eye drops 2.5 mg (base) per mL (0.25%), 5 mL	‡ 1	5	..	11.37	12.40	a	Tenopt	SI
				B1.18	12.55	12.40	a	Timoptol	FR
1279H	Eye drops 5 mg (base) per mL (0.5%), 5 mL	‡ 1	5	..	12.19	13.22	a	Tenopt	SI
				B1.17	13.36	13.22	a	Timoptol	FR
1925H	Eye drops (gellan gum solution) 2.5 mg (base) per mL (0.25%), 2.5 mL	‡ 1	5	..	11.37	12.40		Timoptol XE	MK
1926J	Eye drops (gellan gum solution) 5 mg (base) per mL (0.5%), 2.5 mL	‡ 1	5	..	12.19	13.22		Timoptol XE	MK
	• ***Prostaglandin analogues***								
	BIMATOPROST								
8620Q	Eye drops 300 micrograms per mL (0.03%), 3 mL	‡ 1	5	..	38.62	32.90		Lumigan	AG
	LATANOPROST								
8243W	Eye drops 50 micrograms per mL (0.005%), 2.5 mL	‡ 1	5	..	38.62	32.90		Xalatan	PU
	LATANOPROST with TIMOLOL MALEATE								
	Restricted Benefit								
	Reduction of elevated intra-ocular pressure in patients with open-angle glaucoma who are not adequately controlled with timolol maleate 5 mg (base) per mL (0.5%) eye drops or latanoprost eye drops;								
	Reduction of elevated intra-ocular pressure in patients with ocular hypertension who are not adequately controlled with timolol maleate 5 mg (base) per mL (0.5%) eye drops or latanoprost eye drops.								
8895E	***Eye drops 50 micrograms-5 mg (base) per mL (0.005%-0.5%), 2.5 mL***	***‡ 1***	***5***	***..***	***43.54***	***32.90***		***Xalacom***	***PF***
	TRAVOPROST								
8597L	Eye drops 40 micrograms per mL (0.004%), 2.5 mL	‡ 1	5	..	38.62	32.90		Travatan	AQ
	TRAVOPROST with TIMOLOL MALEATE								
	Restricted Benefit								
	Reduction of elevated intra-ocular pressure in patients with open-angle glaucoma who are not adequately controlled with timolol maleate 5 mg (base) per mL (0.5%) eye drops or latanoprost eye drops or travoprost eye drops;								
	Reduction of elevated intra-ocular pressure in patients with ocular hypertension who are not adequately controlled with timolol maleate 5 mg (base) per mL (0.5%) eye drops or latanoprost eye drops or travoprost eye drops.								
9057Q	***Eye drops 40 micrograms-5 mg (base) per mL (0.004%-0.5%), 2.5 mL***	***‡ 1***	***5***	***..***	***43.54***	***32.90***		***Duotrav***	***AQ***

SENSORY ORGANS—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Proprietary Name and Manufacturer	
	Mydriatics and cycloplegics								
	• ***Anticholinergics***								
	ATROPINE SULFATE								
1093M	Eye drops 10 mg per mL (1%), 15 mL	‡ 1	2	..	11.17	12.20		Atropt	SI
	HOMATROPINE HYDROBROMIDE								
2541R	Eye drops 20 mg per mL (2%), 15 mL	‡ 1	2	..	17.54	18.57		Isopto Homatropine	AQ
	Decongestants and antiallergics								
	• ***Other antiallergics***								
	SODIUM CROMOGLYCATE								
	Restricted Benefit								
	Vernal kerato-conjunctivitis.								
1127H	***Eye drops 20 mg per mL (2%), 10 mL***	***‡ 1***	***5***	***..***	***14.26***	***15.29***	***a***	***Cromolux***	***AE***
							a	***Opticrom***	***SW***
	Ocular vascular disorder agents								
	• ***Antineovascularisation agents***								
	ANECORTAVE ACETATE								
	Authority Required								
	Initial treatment by an ophthalmologist, as the sole PBS-subsidised therapy, of predominantly (greater than or equal to 50%) classic, subfoveal choroidal neovascularisation (CNV) due to age-related macular degeneration (AMD), as diagnosed by fluorescein angiography, in a patient with a baseline visual acuity equal to or better than 6/60 (20/200).								
	No more than 10 treatments (1 initial and 9 continuing) per eye will be authorised.								
	Authority approvals will be administered by the PBS and Specialised Drugs Branch of Medicare Australia.								
	The first authority application for each eye must be made in writing, and must include: (a) a completed authority prescription form; and (b) a completed Subfoveal Choroidal Neovascularisation (CNV) - PBS Supporting Information Form [www.medicareaustralia.gov.au]; and (c) a copy of the fluorescein angiogram demonstrating that the CNV is predominantly classic (greater than or equal to 50%).								
	Written applications for authority to prescribe anecortave acetate should be forwarded to:								
	Medicare Australia Prior Written Approval of Specialised Drugs Reply Paid 9826 GPO Box 9826 HOBART TAS 7001.								
	Alternatively, the first authority application may be faxed to Medicare Australia on (03) 6215 5474 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Medicare Australia will then contact the prescriber by telephone. The original documentation must be posted to the above address after approval has been gained.								

continued ☞

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	

Authority Required

Continuing treatment by an ophthalmologist, as the sole PBS-subsidised therapy, of predominantly (greater than or equal to 50%) classic, subfoveal choroidal neovascularisation (CNV) due to age-related macular degeneration (AMD) where the patient has previously been granted an authority prescription for the same eye.

No more than 10 treatments (1 initial and 9 continuing) per eye will be authorised.

Authority approvals will be administered by the PBS and Specialised Drugs Branch of Medicare Australia. Authority applications for continuing treatment in the same eye may be made by telephone on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

2514H	***Suspension for injection 15 mg in 0.5 mL***	***1***	***..***	***..***	***2015.93***	***32.90***	***Retaane***	***AQ***

RANIBIZUMAB

Authority Required

Initial treatment by an ophthalmologist, as the sole PBS-subsidised therapy, of subfoveal choroidal neovascularisation (CNV) due to age-related macular degeneration (AMD), as diagnosed by fluorescein angiography.

Where a fluoroscein angiogram cannot be performed due to a contraindication as listed in the TGA-approved product information, details of the contraindication must be provided. A copy of the report of an alternative method of diagnosis must be included in the application, for example, optical coherence tomography (OCT) or red free photography.

Authority approvals will be administered by the PBS and Specialised Drugs Branch of Medicare Australia.

The first authority application for each eye must be made in writing, and must include:
(a) a completed authority prescription form; and
(b) a completed Subfoveal Choroidal Neovascularisation (CNV) - PBS Supporting Information Form [www.medicareaustralia.gov.au]; and
(c) a copy of the fluorescein angiogram or alternative method of diagnosis where applicable.

Written applications for authority to prescribe ranibizumab should be forwarded to:

Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001.

Alternatively, the first authority application may be faxed to Medicare Australia on (03) 6215 5474 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Medicare Australia will then contact the prescriber by telephone. The original documentation must be posted to the above address after approval has been gained.

Authority Required

Continuing treatment by an ophthalmologist, as the sole PBS-subsidised therapy, of subfoveal choroidal neovascularisation (CNV) due to age-related macular degeneration (AMD) where the patient has previously been granted an authority prescription for the same eye.

Authority approvals will be administered by the PBS and Specialised Drugs Branch of Medicare Australia. Authority applications for continuing treatment in the same eye may be made by telephone on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

1382R	***Solution for intravitreal injection 3 mg in 0.3 mL***	***1***	***2***	***..***	***1975.93***	***32.90***	***Lucentis***	***NV***

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer

VERTEPORFIN

Authority Required

Initial treatment by an ophthalmologist, as the sole PBS-subsidised therapy, of predominantly (greater than or equal to 50%) classic, subfoveal choroidal neovascularisation (CNV) due to age-related macular degeneration (AMD), as diagnosed by fluorescein angiography, in a patient with a baseline visual acuity equal to or better than 6/60 (20/200).

Authority approvals will be administered by the PBS and Specialised Drugs Branch of Medicare Australia.

The first authority application for each eye must be made in writing, and must include:
(a) a completed authority prescription form; and
(b) a completed Subfoveal Choroidal Neovascularisation (CNV) - PBS Supporting Information Form [www.medicareaustralia.gov.au]; and
(c) a copy of the fluorescein angiogram demonstrating that the CNV is predominantly classic (greater than or equal to 50%).

Written applications for authority to prescribe verteporfin should be forwarded to:

Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001.

Alternatively, the first authority application may be faxed to Medicare Australia on (03) 6215 5474 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Medicare Australia will then contact the prescriber by telephone. The original documentation must be posted to the above address after approval has been gained.

No more than 15 treatments (1 initial and 14 continuing) per eye will be authorised.

Medicare Australia should be notified if treatment is abandoned prior to completion of the laser activation step but after infusion of verteporfin. Telephone 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). The reason treatment is abandoned must be provided. Where such notification has been made, the treatment so affected will not count towards the maximum.

Authority Required

Initial PBS-subsidised treatment by an ophthalmologist, as the sole PBS-subsidised therapy, of predominantly (greater than or equal to 50%) classic, subfoveal choroidal neovascularisation (CNV) due to macular degeneration where the patient has been authorised by the Angiogram Review Panel to receive treatment with verteporfin in the same eye under the MBS Visudyne Therapy Program.

Authority approvals will be administered by the PBS and Specialised Drugs Branch of Medicare Australia.

The first authority application for each eye must be made in writing, and must include:
(a) a completed authority prescription form; and
(b) a completed Subfoveal Choroidal Neovascularisation (CNV) - PBS Supporting Information Form [www.medicareaustralia.gov.au], which includes the date of review by the Angiogram Review Panel and the number of treatments administered in that eye under the MBS Visudyne Therapy Program; and
(c) a copy of the fluorescein angiogram demonstrating that the CNV is predominantly classic (greater than or equal to 50%).

Written applications for authority to prescribe verteporfin should be forwarded to:

Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001.

continued ☞

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Proprietary Name and Manufacturer	
	Alternatively, the first authority application may be faxed to Medicare Australia on (03) 6215 5474 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Medicare Australia will then contact the prescriber by telephone. The original documentation must be posted to the above address after approval has been gained.								
	A patient is eligible for a total of 15 subsidised treatments per eye. This maximum includes treatments administered under the MBS Visudyne Therapy Program and the PBS.								
	Medicare Australia should be notified if treatment is abandoned prior to completion of the laser activation step but after infusion of verteporfin. Telephone 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). The reason treatment is abandoned must be provided. Where such notification has been made, the treatment so affected will not count towards the maximum.								
	Authority Required								
	Continuing treatment by an ophthalmologist, as the sole PBS-subsidised therapy, of predominantly (greater than or equal to 50%) classic, subfoveal choroidal neovascularisation (CNV) due to macular degeneration where the patient has previously been granted an authority prescription for the same eye.								
	A patient is eligible for a total of 15 subsidised treatments per eye. This maximum includes treatments administered under the MBS Visudyne Therapy Program and the PBS.								
	Medicare Australia should be notified if treatment is abandoned prior to completion of the laser activation step but after infusion of verteporfin. Telephone 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). The reason treatment is abandoned must be provided. Where such notification has been made, the treatment so affected will not count towards the maximum.								
	Authority approvals will be administered by the PBS and Specialised Drugs Branch of Medicare Australia. Authority applications for continuing treatment in the same eye may be made by telephone on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).								
1349B	***Powder for I.V. infusion 15 mg***	***1***	***..***	***..***	***2245.93***	***32.90***		***Visudyne***	***NV***
	Other ophthalmologicals								
	• ***Other ophthalmologicals***								
	CARBOMER 974								
	Authority Required (STREAMLINED)								
	1359								
	Severe dry eye syndrome in patients who are sensitive to preservatives in multi-dose eye drops.								
8514D	***Ocular lubricating gel 3 mg per g (0.3%), single dose units 0.5 g, 30***	***3***	***5***	***..***	**** 35.63***	***32.90***		***Poly Gel***	***AQ***
	CARBOMER 980								
	Restricted Benefit								
	Severe dry eye syndrome, including Sjogren's syndrome.								
8384G	***Ocular lubricating gel 2 mg per g (0.2%), 10 g***	***‡ 1***	***5***	***..***	***10.08***	***11.11***		***GelTears***	***BU***
				..	***10.08***	***11.11***	***a***	***PAA***	***NM***
				B 1.00	***11.08***	***11.11***	***a***	***Viscotears Liquid Gel***	***NV***

continued ☞

SENSORY ORGANS—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Proprietary Name and Manufacturer	
	Restriction Benefit								
	For use in patients who have severe dry eye syndrome, including Sjogren's syndrome, and who are receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements.								
	NOTE:								
	No applications for increased maximum quantities and/or repeats will be authorised.								
9210R	*Ocular lubricating gel 2 mg per g (0.2%), 10 g*	*‡ 1*	*11*	*..*	*10.08*	*11.11*		*GelTears*	*BU*
				..	*10.08*	*11.11*	*a*	*PAA*	*NM*
				B 1.00	*11.08*	*11.11*	*a*	*Viscotears Liquid Gel*	*NV*
	Authority Required (STREAMLINED)								
	1359								
	Severe dry eye syndrome in patients who are sensitive to preservatives in multi-dose eye drops.								
8578L	*Eye drops 2 mg per g (0.2%), single dose units 0.6 mL, 30*	*3*	*5*	*..*	** 35.03*	*32.90*		*Viscotears*	*NV*
	CARMELLOSE SODIUM								
	Restriction Benefit								
	Severe dry eye syndrome, including Sjogren's syndrome.								
8548X	*Eye drops 5 mg per mL (0.5%), 15 mL*	*‡ 1*	*5*	*..*	*10.16*	*11.19*		*Refresh Tears Plus*	*AG*
8593G	*Eye drops 10 mg per mL (1%), 15 mL*	*‡ 1*	*5*	*..*	*10.16*	*11.19*		*Refresh Liquigel*	*AG*
	Restriction Benefit								
	For use in patients who have severe dry eye syndrome, including Sjogren's syndrome, and who are receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements.								
	NOTE:								
	No applications for increased maximum quantities and/or repeats will be authorised.								
9211T	*Eye drops 5 mg per mL (0.5%), 15 mL*	*‡ 1*	*11*	*..*	*10.16*	*11.19*		*Refresh Tears Plus*	*AG*
9212W	*Eye drops 10 mg per mL (1%), 15 mL*	*‡ 1*	*11*	*..*	*10.16*	*11.19*		*Refresh Liquigel*	*AG*
	Authority Required (STREAMLINED)								
	1359								
	Severe dry eye syndrome in patients who are sensitive to preservatives in multi-dose eye drops.								
8823J	*Eye drops 2.5 mg per mL (0.25%), single dose units 0.6 mL, 24*	*4*	*5*	*..*	** 39.99*	*32.90*		*TheraTears*	*CX*

continued ☞

SENSORY ORGANS—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Proprietary Name and Manufacturer	
2338C	***Eye drops 5 mg per mL (0.5%), single dose units 0.4 mL, 30***	***3***	***5***	***..***	**** 35.63***	***32.90***		***Cellufresh***	***AG***
2324H	***Eye drops 10 mg per mL (1%), single dose units 0.4 mL, 30***	***3***	***5***	***..***	**** 35.63***	***32.90***		***Celluvisc***	***AG***
8824K	***Ocular lubricating gel 10 mg per mL (1%), single dose units 0.6 mL, 28***	***3***	***5***	***..***	**** 33.65***	***32.90***		***TheraTears***	***CX***
	CARMELLOSE SODIUM with GLYCERIN								
	Restricted Benefit ***Severe dry eye syndrome, including Sjogren's syndrome.***								
9355J	***Eye drops 5 mg-9 mg per mL (0.5%-0.9%), 15 mL***	***‡ 1***	***3***	***..***	***10.16***	***11.19***		***Optive***	***AG***
	NOTE: ***The shelf life of Optive is 6 months from the date of opening.***								
	Restricted Benefit ***For use in patients who have severe dry eye syndrome, including Sjogren's syndrome, and who are receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements.***								
	NOTE: ***No applications for increased maximum quantities and/or repeats will be authorised.***								
9356K	***Eye drops 5 mg-9 mg per mL (0.5%-0.9%), 15 mL***	***‡ 1***	***7***	***..***	***10.16***	***11.19***		***Optive***	***AG***
	NOTE: ***The shelf life of Optive is 6 months from the date of opening.***								
	HYPROMELLOSE								
	Restricted Benefit ***Severe dry eye syndrome, including Sjogren's syndrome.***								
8287E	***Eye drops 3 mg per mL (0.3%), 15 mL (contains sodium perborate as preservative)***	***‡ 1***	***5***	***..***	***10.08***	***11.11***	*a*	***In a Wink Moisturising***	***NM***
				B1.86	***11.94***	***11.11***	*a*	***Genteal***	***NV***
2956N	***Eye drops 5 mg per mL (0.5%), 15 mL***	***‡ 1***	***5***	***..***	***10.08***	***11.11***		***Methopt***	***SI***

continued ☞

SENSORY ORGANS—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Proprietary Name and Manufacturer	
	Restriction Benefit ***For use in patients who have severe dry eye syndrome, including Sjogren's syndrome, and who are receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements.***								
	NOTE: ***No applications for increased maximum quantities and/or repeats will be authorised.***								
9213X	*Eye drops 3 mg per mL (0.3%), 15 mL (contains sodium perborate as preservative)*	*‡ 1*	*11*	*..* *B1.86*	*10.08* *11.94*	*11.11* *11.11*	*a* *a*	*In a Wink Moisturising* *Genteal*	*NM* *NV*
9214Y	*Eye drops 5 mg per mL (0.5%), 15 mL*	*‡ 1*	*11*	*..*	*10.08*	*11.11*		*Methopt*	*SI*
	HYPROMELLOSE with CARBOMER 980								
	Restriction Benefit ***Severe dry eye syndrome, including Sjogren's syndrome.***								
8564R	*Ocular lubricating gel 3 mg-2 mg per g (0.3%-0.2%), 10 g*	*‡ 1*	*5*	*..* *B1.86*	*10.08* *11.94*	*11.11* *11.11*	*a* *a*	*HPMC PAA* *Genteal gel*	*NM* *NV*
	Restriction Benefit ***For use in patients who have severe dry eye syndrome, including Sjogren's syndrome, and who are receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements.***								
	NOTE: ***No applications for increased maximum quantities and/or repeats will be authorised.***								
9215B	*Ocular lubricating gel 3 mg-2 mg per g (0.3%-0.2%), 10 g*	*‡ 1*	*11*	*..* *B1.86*	*10.08* *11.94*	*11.11* *11.11*	*a* *a*	*HPMC PAA* *Genteal gel*	*NM* *NV*
	HYPROMELLOSE with DEXTRAN								
	Restriction Benefit ***Severe dry eye syndrome, including Sjogren's syndrome.***								
1509K	*Eye drops 3 mg-1 mg per mL (0.3%-0.1%), 15 mL*	*‡ 1*	*5*	*..* *B1.67*	*10.08* *11.75*	*11.11* *11.11*	*a* *a*	*Poly-Tears* *Tears Naturale*	*IQ* *AQ*

continued ☞

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Proprietary Name and Manufacturer	
	Restriction Benefit ***For use in patients who have severe dry eye syndrome, including Sjogren's syndrome, and who are receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements.***								
	NOTE: ***No applications for increased maximum quantities and/or repeats will be authorised.***								
9216C	***Eye drops 3 mg-1 mg per mL (0.3%-0.1%), 15 mL***	***‡ 1***	***11***	***..*** ***B 1.67***	***10.08*** ***11.75***	***11.11*** ***11.11***	***a*** ***a***	***Poly-Tears*** ***Tears Naturale***	***IQ*** ***AQ***
	Authority Required (STREAMLINED) **1359** ***Severe dry eye syndrome in patients who are sensitive to preservatives in multi-dose eye drops.***								
8299T	***Eye drops 3 mg-1 mg per mL (0.3%-0.1%), single dose units 0.4 mL, 28***	***3***	***5***	***..***	**** 33.65***	***32.90***		***Bion Tears***	***AQ***
	PARAFFIN								
1754H	Compound eye ointment 3.5 g	2	5	.. B 2.06	* 21.07 * 23.13	22.10 22.10	a a	Poly Visc Duratears	IQ AQ
1750D	Pack containing 2 tubes compound eye ointment 3.5 g	‡ 1	5	.. .. B 2.24	21.06 21.06 23.30	22.09 22.09 22.09	 a a	Poly Visc Ircal Lacri-Lube	IQ PE AG
	PARAFFIN								
	Restriction Benefit ***For use in patients who are receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements.***								
	NOTE: ***No applications for increased maximum quantities and/or repeats will be authorised.***								
9217D	***Compound eye ointment 3.5 g***	***2***	***11***	***..*** ***B 2.06***	**** 21.07*** **** 23.13***	***22.10*** ***22.10***	***a*** ***a***	***Poly Visc*** ***Duratears***	***IQ*** ***AQ***
9218E	***Pack containing 2 tubes compound eye ointment 3.5 g***	***‡ 1***	***11***	***..*** ***..*** ***B 2.24***	***21.06*** ***21.06*** ***23.30***	***22.09*** ***22.09*** ***22.09***	 ***a*** ***a***	***Poly Visc*** ***Ircal*** ***Lacri-Lube***	***IQ*** ***PE*** ***AG***

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Proprietary Name and Manufacturer	
	POLYETHYLENE GLYCOL 400 with PROPYLENE GLYCOL								
	Restricted Benefit ***Severe dry eye syndrome, including Sjogren's syndrome.***								
8676P	*Eye drops 4 mg-3 mg per mL (0.4%-0.3%), 15 mL*	*‡ 1*	*5*	*..*	*10.16*	*11.19*		*Systane*	*AQ*
	Restricted Benefit ***For use in patients who have severe dry eye syndrome, including Sjogren's syndrome, and who are receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements.*** **NOTE:** ***No applications for increased maximum quantities and/or repeats will be authorised.***								
9219F	*Eye drops 4 mg-3 mg per mL (0.4%-0.3%), 15 mL*	*‡ 1*	*11*	*..*	*10.16*	*11.19*		*Systane*	*AQ*
	Authority Required (STREAMLINED) **1359** ***Severe dry eye syndrome in patients who are sensitive to preservatives in multi-dose eye drops.***								
9170P	*Eye drops 4 mg-3 mg per mL (0.4%-0.3%), single dose units 0.8 mL, 28*	*2*	*5*	*..*	** 33.65*	*32.90*		*Systane*	*AQ*
	POLYVINYL ALCOHOL								
	Restricted Benefit ***Severe dry eye syndrome, including Sjogren's syndrome.***								
2682E	*Eye drops 14 mg per mL (1.4%), 15 mL*	*‡ 1*	*5*	*..*	*10.08*	*11.11*	*a*	*PVA Tears*	*PE*
				B1.71	*11.79*	*11.11*	*a*	*Liquifilm Tears*	*AG*
8831T	*Eye drops 14 mg per mL (1.4%), 15 mL (contains sodium chlorite/hydrogen peroxide as preservative)*	*‡ 1*	*5*	*..*	*10.08*	*11.11*		*Vistil*	*AE*
2681D	*Eye drops 30 mg per mL (3%), 15 mL*	*‡ 1*	*5*	*..*	*10.08*	*11.11*	*a*	*PVA Forte*	*PE*
				B5.94	*16.02*	*11.11*	*a*	*Liquifilm Forte*	*AG*
8832W	*Eye drops 30 mg per mL (3%), 15 mL (contains sodium chlorite/hydrogen peroxide as preservative)*	*‡ 1*	*5*	*..*	*10.08*	*11.11*		*Vistil Forte*	*AE*

continued ☞

SENSORY ORGANS—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Proprietary Name and Manufacturer	
	Restricted Benefit ***For use in patients who have severe dry eye syndrome, including Sjogren's syndrome, and who are receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements.***								
	NOTE: ***No applications for increased maximum quantities and/or repeats will be authorised.***								
9220G	***Eye drops 14 mg per mL (1.4%), 15 mL***	***‡ 1***	***11***	***..***	***10.08***	***11.11***	***a***	***PVA Tears***	***PE***
				B1.71	***11.79***	***11.11***	***a***	***Liquifilm Tears***	***AG***
9221H	***Eye drops 14 mg per mL (1.4%), 15 mL (contains sodium chlorite/hydrogen peroxide as preservative)***	***‡ 1***	***11***	***..***	***10.08***	***11.11***		***Vistil***	***AE***
9222J	***Eye drops 30 mg per mL (3%), 15 mL***	***‡ 1***	***11***	***..***	***10.08***	***11.11***	***a***	***PVA Forte***	***PE***
				B5.94	***16.02***	***11.11***	***a***	***Liquifilm Forte***	***AG***
9223K	***Eye drops 30 mg per mL (3%), 15 mL (contains sodium chlorite/hydrogen peroxide as preservative)***	***‡ 1***	***11***	***..***	***10.08***	***11.11***		***Vistil Forte***	***AE***
	TAMARINDUS INDICA SEED POLYSACCHARIDE								
	Authority Required (STREAMLINED) **1359** ***Severe dry eye syndrome in patients who are sensitive to preservatives in multi-dose eye drops.***								
2248H	***Eye drops 10 mg per mL (1%), 0.5 mL, 20***	***3***	***5***	***..***	**** 35.63***	***32.90***		***Visine Professional***	***JT***

OTOLOGICALS

Antiinfectives

• *Antiinfectives*

CHLORAMPHENICOL

1172Q	Ear drops (aqueous) 5 mg per mL (0.5%), 5 mL	‡ 1	2	..	10.62	11.65		Chloromycetin	PF

CIPROFLOXACIN

Authority Required
Treatment of chronic suppurative otitis media in an Aboriginal or a Torres Strait Islander person aged 1 month or older.

2480M	***Ear drops 3 mg per mL (0.3%), 5 mL***	***‡ 1***	***1***	***..***	***18.85***	***19.88***		***Ciloxan***	***AQ***

NEOMYCIN UNDECENOATE with BACITRACIN ZINC

2296W	Ear ointment 12 mg (3.5 mg base)-400 units per g, 10 g	‡ 1	..	..	8.22	9.25		Nemdyn	HA

SENSORY ORGANS—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Proprietary Name and Manufacturer	
	Corticosteroids and antiinfectives in combination								
	• ***Corticosteroids and antiinfectives in combination***								
	DEXAMETHASONE with FRAMYCETIN SULFATE and GRAMICIDIN								
2781J	Ear drops	‡ 1	2	..	8.34	9.37	a	Otodex	AV
	500 micrograms-5 mg-50 micrograms per mL, 8 mL			B2.00	10.34	9.37	a	Sofradex	SW
	TRIAMCINOLONE ACETONIDE with NEOMYCIN SULFATE, GRAMICIDIN and NYSTATIN								
2971J	Ear drops 1 mg-2.5 mg (base)-250 micrograms-100,000 units per g (0.1%-0.25%-0.025%-100,000 units per g), 7.5 mL	‡ 1	2	..	10.95	11.98	a	Otocomb Otic	BC
				B1.07	12.02	11.98	a	Kenacomb Otic	BQ
2974M	Ear ointment 1 mg-2.5 mg (base)-250 micrograms-100,000 units per g (0.1%-0.25%-0.025%-100,000 units per g), 5 g	‡ 1	2	..	7.85	8.88	a	Otocomb Otic	BC
				B1.08	8.93	8.88	a	Kenacomb Otic	BQ

OPHTHALMOLOGICAL AND OTOLOGICAL PREPARATIONS

Antiinfectives

• ***Antiinfectives***

FRAMYCETIN SULFATE

1440T	Eye and ear drops 5 mg per mL (0.5%), 8 mL	‡ 1	2	..	9.68	10.71		Soframycin	SW

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
	ALLERGENS							
	Allergens							
	• ***Allergen extracts***							
	INSECT ALLERGEN EXTRACT—HONEY BEE VENOM							
2886X	Injection set containing 550 micrograms	1	..	..	204.71	32.90	Albey Bee Venom	ES
	INSECT ALLERGEN EXTRACT—PAPER WASP VENOM							
	NOTE:							
	Paper wasp venom is not European wasp venom.							
2918N	Injection set containing 550 micrograms	1	..	..	204.71	32.90	Albey Paper Wasp Venom	ES
	INSECT ALLERGEN EXTRACT—YELLOW JACKET VENOM							
2883R	Injection set containing 550 micrograms	1	..	..	204.71	32.90	Albey Yellow Jacket Venom	ES
	ALL OTHER THERAPEUTIC PRODUCTS							
	All other therapeutic products							
	• ***Antidotes***							
	NALOXONE HYDROCHLORIDE							
1752F	Injection 800 micrograms in 2 mL	1	..	..	27.89	28.92	Naloxone Min-I-Jet	CS
1753G	Injection 2 mg in 5 mL	1	..	..	40.93	32.90	Naloxone Min-I-Jet	CS
	• ***Drugs for treatment of hyperkalemia and hyperphosphatemia***							
	SEVELAMER HYDROCHLORIDE							
	Authority Required							
	Maintenance therapy, following initiation and stabilisation of treatment with sevelamer hydrochloride, of hyperphosphataemia in a patient with chronic kidney disease on dialysis whose serum phosphate is not controlled on other products and where:							
	(a) serum phosphate is greater than 1.6 mmol per L; or							
	(b) the serum calcium times phosphate product is greater than 4.0.							
	at the commencement of therapy.							
2142R	***Tablet 800 mg***	***180***	***5***	***..***	***357.30***	***32.90***	***Renagel***	***GZ***

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Proprietary Name and Manufacturer	
	• ***Detoxifying agents for antineoplastic treatment***								
	CALCIUM FOLINATE								
8740B	Injection equivalent to 50 mg folinic acid in 5 mL	5	5	..	* 154.39	32.90	a	Leucovorin Calcium	HH
				..	* 154.39	32.90	a	Leucovorin Calcium	PF
				..	154.39	32.90	a	Calcium Folinate Ebewe	IT
8812T	Injection equivalent to 100 mg folinic acid in 10 mL	10	1	..	272.99	32.90	a	Leucovorin Calcium	PF
				..	* 272.99	32.90	a	Calcium Folinate Ebewe	IT
9041W	Injection equivalent to 300 mg folinic acid in 30 mL	4	1	..	* 315.23	32.90		Leucovorin Calcium	HH
	CALCIUM FOLINATE								
	Restricted Benefit								
	Antidote to folic acid antagonists.								
2308L	***Tablet equivalent to 15 mg folinic acid***	***10***	***..***	***..***	***101.50***	***32.90***		***Leucovorin Calcium***	***HH***
	MESNA								
	Restricted Benefit								
	Adjunctive therapy for use with ifosfamide or high dose cyclophosphamide.								
8078E	***Solution for I.V. injection 400 mg in 4 mL***	***15***	***5***	***..***	***72.38***	***32.90***		***Uromitexan***	***BX***
8079F	***Solution for I.V. injection 1 g in 10 mL***	***15***	***5***	***..***	***157.74***	***32.90***		***Uromitexan***	***BX***

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
	• ***Drugs for treatment of hypercalcemia***							
	SODIUM ACID PHOSPHATE							
	Authority Required (STREAMLINED)							
	1099 ***Familial hypophosphataemia;***							
	1157 ***Hypercalcaemia;***							
	1167 ***Hypophosphataemic rickets;***							
	1467 ***Vitamin D-resistant rickets.***							
2946C	***Compound effervescent tablet containing elemental phosphorus 500 mg, sodium 469 mg (20.4 mmol), potassium 123 mg (3.1 mmol)***	***100***	***5***	***..***	***81.20***	***32.90***	***Phosphate Sandoz***	***NV***
	DIAGNOSTIC AGENTS							
	Urine tests							
	• ***Urine tests***							
	COPPER SULFATE							
1228P	Diagnostic compound tablets, 36	2	3	..	* 71.05	32.90	Clinitest	BN
	COPPER SULFATE							
	Restricted Benefit ***For use in patients who are receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements.***							
	NOTE: ***No applications for increased maximum quantities and/or repeats will be authorised.***							
9251X	***Diagnostic compound tablets, 36***	***2***	***6***	***..***	**** 71.05***	***32.90***	***Clinitest***	***BN***
	GLUCOSE and KETONE INDICATOR—URINE							
3106L	Reagent strips, 50	2	2	..	* 16.87	17.90	Keto-Diabur- Test 5000	RD
3107M	Reagent strips, 50	2	2	..	* 16.99	18.02	Keto-Diastix	BN

continued ☞

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
	GLUCOSE and KETONE INDICATOR—URINE							
	Restricted Benefit ***For use in patients who are receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements.***							
	NOTE: ***No applications for increased maximum quantities and/or repeats will be authorised.***							
9254C	***Reagent strips, 50***	***2***	***4***	***..***	**** 16.87***	***17.90***	***Keto-Diabur- Test 5000***	***RD***
9255D	***Reagent strips, 50***	***2***	***4***	***..***	**** 16.99***	***18.02***	***Keto-Diastix***	***BN***
	GLUCOSE INDICATOR—URINE							
2352T	Reagent strips, 50	2	2	..	* 19.39	20.42	Clinistix	BN
3104J	Reagent strips, 50	2	2	..	* 18.41	19.44	Diastix	BN
	GLUCOSE INDICATOR—URINE							
	Restricted Benefit ***For use in patients who are receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements.***							
	NOTE: ***No applications for increased maximum quantities and/or repeats will be authorised.***							
9252Y	***Reagent strips, 50***	***2***	***4***	***..***	**** 19.39***	***20.42***	***Clinistix***	***BN***
9253B	***Reagent strips, 50***	***2***	***4***	***..***	**** 18.41***	***19.44***	***Diastix***	***BN***
	Other diagnostic agents							
	• ***Tests for diabetes***							
	GLUCOSE INDICATOR—BLOOD							
9193W	Electrode strips, 25	4	5	..	* 52.75	32.90	On-Call Plus	PZ
2979T	Electrode strips, 50	2	5	..	* 52.75	32.90	Accu-Chek Performa	RD
2891E	Electrode strips, 50	2	5	..	* 52.75	32.90	Advantage II	RD
9358M	Electrode strips, 50	2	5	..	* 52.75	32.90	FreeStyle	MS
8890X	Electrode strips, 50	2	5	..	* 52.75	32.90	Freestyle Papillon	MS
1820T	Electrode strips, 50	2	5	..	* 52.75	32.90	Glucoboy	DB
9013J	Electrode strips, 50	2	5	..	* 52.75	32.90	Glucocard 01 Sensor	OZ
8766J	Electrode strips, 50	2	5	..	* 52.75	32.90	GlucoCare Super Sensor	OZ

continued ☞

VARIOUS—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
8749L	Electrode strips, 50	2	5	..	* 52.75	32.90	GlucoOz	OZ
8682Y	Electrode strips, 50	2	5	..	* 52.75	32.90	MWD Pen Sensor Strips	WF
8723D	Electrode strips, 50	2	5	..	* 52.75	32.90	Omnitest EZ	BR
9063B	Electrode strips, 50	2	5	..	* 52.75	32.90	Omnitest Plus	BR
2263D	Electrode strips, 50	2	5	..	* 52.75	32.90	Optium Omega	MS
8825L	Electrode strips, 50	2	5	..	* 52.75	32.90	TrueTrack	DB
9154T	Electrode strips, 100	‡ 1	5	..	52.73	32.90	FreeStyle Lite	MS
8522M	Electrode strips, 100	‡ 1	5	..	52.73	32.90	Optium glucose	MS
8573F	Electrode strips, 100	‡ 1	5	..	52.73	32.90	SofTact	MS
8608C	Electrode strips, 100	‡ 1	5	..	52.73	32.90	TrueSense	MS
8190C	Reagent strips, 50	2	5	..	* 52.75	32.90	Accu-Chek Active	RD
8739Y	Reagent strips, 50	2	5	..	* 52.75	32.90	Accu-Chek Go	RD
8806L	Reagent strips, 51	2	5	..	* 52.75	32.90	Accu-Chek Integra	RD
2890D	Reagent strips, 50	2	5	..	* 52.75	32.90	Betachek	NA
2860M	Reagent strips, 50	2	5	..	* 52.75	32.90	Betachek G5	NA
8759B	Reagent strips, 50	2	5	..	* 52.75	32.90	CareSens	LB
2914J	Reagent strips, 50	2	5	..	* 45.47	32.90	Glucoflex-R	NA
2917M	Reagent strips, 50	2	5	..	* 45.47	32.90	Glucostix	BN
8795X	Reagent strips, 50	2	5	..	* 52.75	32.90	SensoCard	PX

GLUCOSE INDICATOR—BLOOD

Restricted Benefit

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

NOTE:

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

9256E	***Electrode strips, 25***	***4***	***11***	..	**** 52.75***	***32.90***	***On-Call Plus***	***PZ***
9257F	***Electrode strips, 50***	***2***	***11***	..	**** 52.75***	***32.90***	***Accu-Chek Performa***	***RD***
9258G	***Electrode strips, 50***	***2***	***11***	..	**** 52.75***	***32.90***	***Advantage II***	***RD***
9359N	***Electrode strips, 50***	***2***	***11***	..	**** 52.75***	***32.90***	***FreeStyle***	***MS***
9259H	***Electrode strips, 50***	***2***	***11***	..	**** 52.75***	***32.90***	***Freestyle Papillon***	***MS***

continued ☞

VARIOUS—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
9260J	*Electrode strips, 50*	*2*	*11*	*..*	** 52.75*	*32.90*	*Glucoboy*	*DB*
9261K	*Electrode strips, 50*	*2*	*11*	*..*	** 52.75*	*32.90*	*Glucocard 01 Sensor*	*OZ*
9262L	*Electrode strips, 50*	*2*	*11*	*..*	** 52.75*	*32.90*	*GlucoCare Super Sensor*	*OZ*
9263M	*Electrode strips, 50*	*2*	*11*	*..*	** 52.75*	*32.90*	*GlucoOz*	*OZ*
9264N	*Electrode strips, 50*	*2*	*11*	*..*	** 52.75*	*32.90*	*MWD Pen Sensor Strips*	*WF*
9265P	*Electrode strips, 50*	*2*	*11*	*..*	** 52.75*	*32.90*	*Omnitest EZ*	*BR*
9266Q	*Electrode strips, 50*	*2*	*11*	*..*	** 52.75*	*32.90*	*Omnitest Plus*	*BR*
9267R	*Electrode strips, 50*	*2*	*11*	*..*	** 52.75*	*32.90*	*Optium Omega*	*MS*
9268T	*Electrode strips, 50*	*2*	*11*	*..*	** 52.75*	*32.90*	*TrueTrack*	*DB*
9269W	*Electrode strips, 100*	*‡ 1*	*11*	*..*	*52.73*	*32.90*	*FreeStyle Lite*	*MS*
9270X	*Electrode strips, 100*	*‡ 1*	*11*	*..*	*52.73*	*32.90*	*Optium glucose*	*MS*
9271Y	*Electrode strips, 100*	*‡ 1*	*11*	*..*	*52.73*	*32.90*	*SofTact*	*MS*
9272B	*Electrode strips, 100*	*‡ 1*	*11*	*..*	*52.73*	*32.90*	*TrueSense*	*MS*
9273C	*Reagent strips, 50*	*2*	*11*	*..*	** 52.75*	*32.90*	*Accu-Chek Active*	*RD*
9274D	*Reagent strips, 50*	*2*	*11*	*..*	** 52.75*	*32.90*	*Accu-Chek Go*	*RD*
9275E	*Reagent strips, 51*	*2*	*11*	*..*	** 52.75*	*32.90*	*Accu-Chek Integra*	*RD*
9276F	*Reagent strips, 50*	*2*	*11*	*..*	** 52.75*	*32.90*	*Betachek*	*NA*
9277G	*Reagent strips, 50*	*2*	*11*	*..*	** 52.75*	*32.90*	*Betachek G5*	*NA*
9278H	*Reagent strips, 50*	*2*	*11*	*..*	** 52.75*	*32.90*	*CareSens*	*LB*
9279J	*Reagent strips, 50*	*2*	*11*	*..*	** 45.47*	*32.90*	*Glucoflex-R*	*NA*
9280K	*Reagent strips, 50*	*2*	*11*	*..*	** 45.47*	*32.90*	*Glucostix*	*BN*
9281L	*Reagent strips, 50*	*2*	*11*	*..*	** 52.75*	*32.90*	*SensoCard*	*PX*

Authority Required (STREAMLINED)

1769

Patients who have previously received this product as a pharmaceutical benefit;

1770

Patients who have purchased a meter to be used with this product prior to 1 August 2003.

2926B	*Electrode strips, 100*	*‡ 1*	*5*	*..*	*54.23*	*32.90*	*Precision Plus*	*MS*

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
	GENERAL NUTRIENTS							
	Other nutrients							
	• ***Other nutrients***							
	AMYLOPECTIN, MODIFIED LONG CHAIN							
	Restricted Benefit							
	Glycogen storage disease.							
9386B	***Sachets 60 g, 30***	***4***	***5***	***..***	**** 751.87***	***32.90***	***Glycosade***	***VF***
	TRIGLYCERIDES, MEDIUM CHAIN							
	NOTE:							
	No applications for increased maximum quantities and/or repeats will be authorised.							
	Authority Required							
	Chylous ascites;							
	Chylothorax;							
	Fat malabsorption due to liver disease, short gut syndrome, cystic fibrosis and gastrointestinal disorders;							
	Hyperlipoproteinaemia type 1;							
	Intractable childhood epilepsy or cerebrospinal fluid glucose transporter defect, requiring a ketogenic diet;							
	Long chain fatty acid oxidation disorders.							
3128P	***Oil 500 mL***	***2***	***5***	***..***	**** 51.95***	***32.90***	***MCT Oil***	***SB***
	• ***Fat/carbohydrates/proteins/minerals/vitamins, combinations***							
	AMINO ACIDS—SYNTHETIC, FORMULA							
	Authority Required							
	Initial treatment for up to 3 months, by a clinical immunologist, suitably qualified allergist or gastroenterologist in a patient 18 years of age or less with eosinophilic oesophagitis who requires an amino acid based formula as a component of a dietary elimination programme. Treatment with oral steroids should not be commenced during the period of initial treatment.							
	Eosinophilic oesophagitis is demonstrated by the following criteria:							
	(i) Chronic symptoms of reflux that persisted despite a 2-month trial of a proton pump inhibitor or chronic dysphagia; and							
	(ii) A lack of demonstrable anatomic abnormality with the exception of stricture, which can be attributable to eosinophilic oesophagitis; and							
	(iii) Eosinophilic infiltration of the oesophagus, demonstrated by oesophageal biopsy specimens obtained by endoscopy and where the most densely involved oesophageal biopsy had 20 or more eosinophils in any single 400 x high powered field, along with normal antral and duodenal biopsies.							
	The date of birth of the patient must be included in the authority.							

continued ☞

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
	Authority Required ***Continuing treatment by a clinical immunologist, suitably qualified allergist or gastroenterologist in a patient 18 years of age or less with eosinophilic oesophagitis who has responded to an initial course of PBS-subsidised treatment. Response to initial treatment is demonstrated by oesophageal biopsy specimens obtained by endoscopy, where the most densely involved oesophageal biopsy had 5 or less eosinophils in any single 400 x high powered field, along with normal antral and duodenal biopsies. The response criteria will not be deemed to have been met if oral steroids were commenced during initial treatment.*** **NOTE:** ***Authorities for increased maximum quantities, up to a maximum of 52, may be authorised.***							
2250K	***Compound powder 400 g***	***12***	***5***	***..***	**** 531.23***	***32.90***	***EleCare***	***AB***
	Authority Required ***Initial treatment, for up to 3 months, for combined intolerance (not infant colic) to cows' milk protein, soy protein and protein hydrolysate formulae in a child up to the age of 2 years. Combined intolerance is demonstrated when the child has failed to respond to a strict cows' milk protein free and strict soy protein free diet with a protein hydrolysate (with or without medium chain triglycerides) as the principal formula. The date of birth of the patient must be included in the authority application;*** ***Initial treatment, in consultation with a paediatric gastroenterologist or specialist allergist, for up to 3 months, of a child up to the age of 2 years with severe intolerance (not infant colic) to cows' milk protein. The date of birth of the patient must be included in the authority application.*** **NOTE:** ***No applications for increased maximum quantities and/or repeats will be authorised.***							
8574G	***Compound powder 400 g***	***8***	***5***	***..***	**** 360.71***	***32.90***	***EleCare***	***AB***
8443J	***Compound powder 400 g***	***8***	***5***	***..***	**** 360.71***	***32.90***	***Neocate***	***SB***
8754R	***Compound powder 400 g***	***8***	***5***	***..***	**** 360.71***	***32.90***	***Neocate Advance***	***SB***
2244D	***Compound powder 400 g***	***8***	***5***	***..***	**** 360.71***	***32.90***	***Neocate Advance Tropical Flavour***	***SB***

continued ☞

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
	Authority Required ***Continuing treatment for combined intolerance (not infant colic) to cows' milk protein, soy protein and protein hydrolysate formulae in a child up to the age of 2 years, where the child has been assessed by a suitably qualified allergist or paediatrician. The date of birth of the patient must be included in the authority application;*** ***Treatment for combined intolerance (not infant colic) to cows' milk protein, soy protein and protein hydrolysate formulae in a child aged 2 years and over, where the child is assessed by a suitably qualified allergist or paediatrician at intervals not greater than 6 months. The date of birth of the patient must be included in the authority application;*** ***Continuing treatment for severe intolerance (not infant colic) to cows' milk protein in a child up to the age of 2 years, where the child has been assessed by a paediatric gastroenterologist or specialist allergist and soy protein and protein hydrolysate formulae are not tolerated or not likely to be tolerated. The date of birth of the patient must be included in the authority application;*** ***Treatment for severe intolerance (not infant colic) to cows' milk protein in a child aged 2 years and over, where the child is assessed by a paediatric gastroenterologist or specialist allergist at intervals not greater that 6 months. The date of birth of the patient must be included in the authority application;*** ***Severe intestinal malabsorption including short bowel syndrome where protein hydrolysate formulae have failed;*** ***Severe intestinal malabsorption including short bowel syndrome where the patient has been receiving parenteral nutrition.*** **NOTE:** ***Authorities for increased maximum quantities, up to a maximum of 20, may be authorised.***							
8575H	***Compound powder 400 g***	***8***	***5***	***..***	**** 360.71***	***32.90***	***EleCare***	***AB***
3066J	***Compound powder 400 g***	***8***	***5***	***..***	**** 360.71***	***32.90***	***Neocate***	***SB***
8755T	***Compound powder 400 g***	***8***	***5***	***..***	**** 360.71***	***32.90***	***Neocate Advance***	***SB***
2553J	***Compound powder 400 g***	***8***	***5***	***..***	**** 360.71***	***32.90***	***Neocate Advance Tropical Flavour***	***SB***
	AMINO ACID SYNTHETIC FORMULA supplemented with LONG CHAIN POLYUNSATURATED FATTY ACIDS **Authority Required** ***Initial treatment, for up to 3 months, for combined intolerance (not infant colic) to cows' milk protein, soy protein and protein hydrolysate formulae in a child up to the age of 2 years. Combined intolerance is demonstrated when the child has failed to respond to a strict cows' milk protein free and strict soy protein free diet with a protein hydrolysate (with or without medium chain triglycerides) as the principal formula. The date of birth of the patient must be included in the authority application;*** ***Initial treatment, in consultation with a paediatric gastroenterologist or specialist allergist, for up to 3 months, of a child up to the age of 2 years with severe intolerance (not infant colic) to cows' milk protein. The date of birth of the patient must be included in the authority application.*** **NOTE:** ***No applications for increased maximum quantities and/or repeats will be authorised.***							
2246F	***Compound powder 400 g***	***8***	***5***	***..***	**** 367.43***	***32.90***	***Neocate LCP***	***SB***

continued ☞

VARIOUS—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
	Authority Required ***Continuing treatment for combined intolerance (not infant colic) to cows' milk protein, soy protein and protein hydrolysate formulae in a child up to the age of 2 years, where the child has been assessed by a suitably qualified allergist or paediatrician. The date of birth of the patient must be included in the authority application;*** ***Treatment for combined intolerance (not infant colic) to cows' milk protein, soy protein and protein hydrolysate formulae in a child aged 2 years and over, where the child is assessed by a suitably qualified allergist or paediatrician at intervals not greater than 6 months. The date of birth of the patient must be included in the authority application;*** ***Continuing treatment for severe intolerance (not infant colic) to cows' milk protein in a child up to the age of 2 years, where the child has been assessed by a paediatric gastroenterologist or specialist allergist and soy protein and protein hydrolysate formulae are not tolerated or not likely to be tolerated. The date of birth of the patient must be included in the authority application;*** ***Treatment for severe intolerance (not infant colic) to cows' milk protein in a child aged 2 years and over, where the child is assessed by a paediatric gastroenterologist or specialist allergist at intervals not greater that 6 months. The date of birth of the patient must be included in the authority application;*** ***Severe intestinal malabsorption including short bowel syndrome where protein hydrolysate formulae have failed;*** ***Severe intestinal malabsorption including short bowel syndrome where the patient has been receiving parenteral nutrition.*** **NOTE:** ***Authorities for increased maximum quantities, up to a maximum of 20, may be authorised.***							
2560R	***Compound powder 400 g***	***8***	***5***	***..***	**** 367.43***	***32.90***	***Neocate LCP***	***SB***

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
	PROTEIN HYDROLYSATE FORMULA with MEDIUM CHAIN TRIGLYCERIDES							
	NOTE:							
	No applications for increased maximum quantities and/or repeats will be authorised.							
	Authority Required							
	Initial treatment, for up to 3 months, for intolerance (not infant colic) to both cows' milk protein and soy protein in a child up to the age of 2 years. Intolerance is demonstrated when the child has failed to respond to a strict cows' milk protein free diet with a soy protein as the principal formula. The date of birth of the patient must be included in the authority application;							
	Continuing treatment for intolerance (not infant colic) to both cows' milk protein and soy protein in a child up to the age of 2 years, where clinical improvement has been demonstrated with the protein hydrolysate formula with medium chain triglycerides. The date of birth of the patient must be included in the authority application;							
	Continuing treatment for intolerance (not infant colic) to both cows' milk protein and soy protein in a child aged 2 years and over, where the child has been assessed by a suitably qualified allergist or paediatrician. The date of birth of the patient must be included in the authority application.							
	Authority Required							
	Initial treatment, in consultation with a paediatric gastroenterologist or specialist allergist, for up to 3 months, of a child up to the age of 2 years with severe intolerance (not infant colic) to cows' milk protein. The date of birth of the patient must be included in the authority application;							
	Continuing treatment for severe intolerance (not infant colic) to cows' milk protein in a child up to the age of 2 years, where clinical improvement has been demonstrated with the protein hydrolysate formula with medium chain triglycerides and soy protein is not tolerated or is likely not to be tolerated. The date of birth of the patient must be included in the authority application;							
	Continuing treatment for severe intolerance (not infant colic) to cows' milk protein in a child aged 2 years and over, where the child has been assessed by a paediatric gastroenterologist or specialist allergist. The date of birth of the patient must be included in the authority application.							
	Authority Required							
	Biliary atresia;							
	Chronic liver failure with fat malabsorption;							
	Chylous ascites;							
	Chylothorax;							
	Cystic fibrosis;							
	Enterokinase deficiency;							
	Proven fat malabsorption;							
	Severe diarrhoea of greater than 2 weeks' duration in an infant aged less than 4 months. The date of birth of the patient must be included in the authority application;							
	Severe intestinal malabsorption including short bowel syndrome.							
2676W	***Compound powder 400 g***	***8***	***5***	***..***	**** 171.51***	***32.90***	***Alfaré***	***NT***

continued ☞

VARIOUS—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
	Authority Required ***Initial treatment, for up to 3 months, for intolerance (not infant colic) to both cows' milk protein and soy protein in a child up to the age of 2 years. Intolerance is demonstrated when the child has failed to respond to a strict cows' milk protein free diet with a soy protein as the principal formula. The date of birth of the patient must be included in the authority application;*** ***Continuing treatment for intolerance (not infant colic) to both cows' milk protein and soy protein in a child up to the age of 2 years, where clinical improvement has been demonstrated with the protein hydrolysate formula with medium chain triglycerides. The date of birth of the patient must be included in the authority application;*** ***Continuing treatment for intolerance (not infant colic) to both cows' milk protein and soy protein in a child aged 2 years and over, where the child has been assessed by a suitably qualified allergist or paediatrician. The date of birth of the patient must be included in the authority application.***							
	Authority Required ***Initial treatment, in consultation with a paediatric gastroenterologist or specialist allergist, for up to 3 months, of a child up to the age of 2 years with severe intolerance (not infant colic) to cows' milk protein. The date of birth of the patient must be included in the authority application;*** ***Continuing treatment for severe intolerance (not infant colic) to cows' milk protein in a child up to the age of 2 years, where clinical improvement has been demonstrated with the protein hydrolysate formula with medium chain triglycerides and soy protein is not tolerated or is likely not to be tolerated. The date of birth of the patient must be included in the authority application;*** ***Continuing treatment for severe intolerance (not infant colic) to cows' milk protein in a child aged 2 years and over, where the child has been assessed by a paediatric gastroenterologist or specialist allergist. The date of birth of the patient must be included in the authority application.***							
	Authority Required ***Biliary atresia;*** ***Chronic liver failure with fat malabsorption;*** ***Chylous ascites;*** ***Cystic fibrosis;*** ***Enterokinase deficiency;*** ***Proven fat malabsorption;*** ***Severe diarrhoea of greater than 2 weeks' duration in an infant aged less than 4 months. The date of birth of the patient must be included in the authority application;*** ***Severe intestinal malabsorption including short bowel syndrome.***							
8259Q	***Compound powder 450 g***	***8***	***5***	***..***	**** 109.43***	***32.90***	***Pepti-Junior Gold***	***NU***

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
	TRIGLYCERIDES—MEDIUM CHAIN, FORMULA							
	NOTE:							
	No applications for increased maximum quantities and/or repeats will be authorised.							
	Restricted Benefit							
	Chylous ascites;							
	Chylothorax;							
	Fat malabsorption due to liver disease, short gut syndrome, cystic fibrosis and gastrointestinal disorders;							
	Hyperlipoproteinaemia type 1;							
	Long chain fatty acid oxidation disorders.							
	NOTE:							
	Monogen is not indicated for the treatment of intractable childhood epilepsy or cerebrospinal fluid glucose transporter defect requiring a ketogenic diet.							
8478F	***Compound powder 400 g***	***8***	***5***	***..***	**** 420.87***	***32.90***	***Monogen***	***SB***
	Restricted Benefit							
	Chylous ascites;							
	Chylothorax;							
	Fat malabsorption due to liver disease, short gut syndrome, cystic fibrosis and gastrointestinal disorders.							
	NOTE:							
	Caprilon is not indicated for the treatment of intractable childhood epilepsy or cerebrospinal fluid glucose transporter defect requiring a ketogenic diet, long chain fatty acid oxidation disorders or hyperlipoproteinaemia type 1.							
8629E	***Compound powder 420 g***	***8***	***5***	***..***	**** 467.03***	***32.90***	***Caprilon***	***SB***
	• Milk substitutes							
	MILK POWDER—LACTOSE FREE FORMULA							
	Authority Required							
	Acute lactose intolerance in infants up to the age of 12 months. The date of birth of the patient must be included in the authority application.							
	NOTE:							
	No applications for increased maximum quantities and/or repeats will be authorised. No more than 1 application per patient will be authorised.							
8282X	***Infant formula powder 900 g***	***5***	***..***	***..***	**** 96.74***	***32.90***	***S-26 LF***	***WX***
2350Q	***Lactose-predigested powder infant formula 900 g***	***5***	***..***	***..***	**** 88.49***	***32.90***	***Karicare De-Lact***	***NU***

continued ☞

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
	Authority Required ***Proven chronic lactose intolerance in infants up to the age of 12 months. The date of birth of the patient must be included in the authority application. Lactose intolerance must have been proven by either:*** ***(a) relief of symptoms on supervised withdrawal of lactose from the diet for 3 or 4 days and subsequent re-emergence of symptoms on rechallenge with lactose containing formulae or milk or food; or*** ***(b) not less than 0.5% reducing substance in stool exudate tested with copper sulfate diagnostic compound tablet; or*** ***(c) hydrogen breath test.*** **NOTE:** ***No applications for increased maximum quantities and/or repeats will be authorised.***							
8283Y	***Infant formula powder 900 g***	***5***	***5***	***..***	**** 96.74***	***32.90***	***S-26 LF***	***WX***
2349P	***Lactose-predigested powder infant formula 900 g***	***5***	***5***	***..***	**** 88.49***	***32.90***	***Karicare De-Lact***	***NU***
	MILK POWDER—LACTOSE MODIFIED **Authority Required** ***Acute lactose intolerance in children aged 1 year and over. The date of birth of the patient must be included in the authority application.*** **NOTE:** ***No applications for increased maximum quantities and/or repeats will be authorised. No more than 1 application per patient will be authorised.***							
2358D	***Lactose-predigested powder 900 g***	***3***	***1***	***..***	**** 62.60***	***32.90***	***Digestelact***	***SJ***
	Authority Required ***Proven chronic lactose intolerance in children aged 1 year and over who are significantly malnourished. The date of birth of the patient must be included in the authority application. Lactose intolerance must have been proven by either:*** ***(a) relief of symptoms on supervised withdrawal of lactose from the diet for 3 or 4 days and subsequent re-emergence of symptoms on rechallenge with lactose containing formulae or milk or food; or*** ***(b) not less than 0.5% reducing substance in stool exudate tested with copper sulfate diagnostic compound tablet; or*** ***(c) hydrogen breath test.*** **NOTE:** ***No applications for increased maximum quantities and/or repeats will be authorised.***							
2357C	***Lactose-predigested powder 900 g***	***3***	***10***	***..***	**** 62.60***	***32.90***	***Digestelact***	***SJ***
	MILK POWDER—SYNTHETIC **NOTE:** ***No applications for increased maximum quantities and/or repeats will be authorised.*** **Authority Required** ***Hypercalcaemia in children under the age of 4 years.***							
3092R	***Low calcium compound powder 400 g***	***8***	***5***	***..***	**** 380.95***	***32.90***	***Locasol***	***NU***

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
	• ***Other combinations of nutrients***							
	AMINO ACID FORMULA without METHIONINE, THREONINE and VALINE and low in ISOLEUCINE							
	Restricted Benefit ***Methylmalonic acidaemia;*** ***Propionic acidaemia.***							
3079C	***Powder 200 g***	*5*	*5*	*..*	** 1047.99*	*32.90*	***XMTVI Asadon***	***SB***
	AMINO ACID FORMULA without PHENYLALANINE							
	Restricted Benefit ***Phenylketonuria.***							
8554F	***Capsules 500 mg, 200***	*16*	*5*	*..*	** 1275.91*	*32.90*	***Phlexy-10***	***SB***
8678R	***Tablets 1 g, 75***	*24*	*5*	*..*	** 1426.55*	*32.90*	***Phlexy-10***	***SB***
8706F	***Bars 42 g, 20***	*10*	*5*	*..*	** 1570.89*	*32.90*	***Phlexy-10***	***SB***
2347M	***Sachets containing powder 20 g, 30***	*7*	*5*	*..*	** 1462.48*	*32.90*	***Phlexy-10 Drink Mix***	***SB***
3072Q	***Powder 250 g***	*8*	*5*	*..*	** 1209.43*	*32.90*	***PK AID II***	***SB***
	AMINO ACID FORMULA without PHENYLALANINE, and VITAMINS with MINERALS							
	Restricted Benefit ***Phenylketonuria.***							
1411G	***Pack containing 60 sachets of phenylalanine-free amino acid formula powder 17 g, and 60 tablets containing vitamins and minerals***	*3*	*5*	*..*	** 1639.64*	*32.90*	***add-ins***	***SB***
	AMINO ACID FORMULA without PHENYLALANINE, TYROSINE and METHIONINE							
	Restricted Benefit ***Tyrosinaemia.***							
2379F	***Powder 500 g***	*4*	*5*	*..*	** 2671.55*	*32.90*	***XPTM Tyrosidon***	***SB***
	AMINO ACID FORMULA with VITAMINS, MINERALS and LONG CHAIN POLYUNSATURATED FATTY ACIDS without PHENYLALANINE							
	Restricted Benefit ***Phenylketonuria.***							
8479G	***Infant formula, powder 400 g***	*8*	*5*	*..*	** 703.19*	*32.90*	***XP Analog LCP***	***SB***

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
	AMINO ACID FORMULA with VITAMINS and MINERALS without LYSINE and low in TRYPTOPHAN							
	Restricted Benefit ***An infant or young child with proven glutaric aciduria type 1.***							
2650L	***Infant formula, powder 400 g***	***8***	***5***	***..***	**** 673.27***	***32.90***	***XLYS, LOW TRY Analog***	***SB***
	Restricted Benefit ***A child aged less than 7 years with proven glutaric aciduria type 1.***							
2646G	***Powder 500 g***	***8***	***5***	***..***	**** 1624.23***	***32.90***	***XLYS, LOW TRY Maxamaid***	***SB***
	AMINO ACID FORMULA with VITAMINS and MINERALS without METHIONINE							
	Restricted Benefit ***For infants and very young children with pyridoxine non-responsive homocystinuria.***							
8417B	***Infant formula, powder 400 g***	***8***	***5***	***..***	**** 768.87***	***32.90***	***XMET Analog***	***SB***
	Restricted Benefit ***Pyridoxine non-responsive homocystinuria.***							
8677Q	***Sachets 20 g, 30***	***4***	***5***	***..***	**** 1797.99***	***32.90***	***HCU gel***	***VF***
8744F	***Sachets 25 g, 30***	***4***	***5***	***..***	**** 3097.95***	***32.90***	***HCU express***	***VF***
8328H	***Powder 500 g***	***8***	***5***	***..***	**** 1784.31***	***32.90***	***XMET Maxamaid***	***SB***
8416Y	***Powder 500 g***	***8***	***5***	***..***	**** 2704.31***	***32.90***	***XMET Maxamum***	***SB***
9133Q	***Oral liquid 130 mL, 30***	***4***	***5***	***..***	**** 3097.95***	***32.90***	***HCU Cooler***	***VF***
	AMINO ACID FORMULA with VITAMINS and MINERALS without METHIONINE, THREONINE and VALINE and low in ISOLEUCINE							
	Restricted Benefit ***Methylmalonic acidaemia;*** ***Propionic acidaemia.***							
8058D	***Infant formula, powder 400 g***	***8***	***5***	***..***	**** 629.03***	***32.90***	***XMTVI Analog***	***SB***
8059E	***Powder 500 g***	***8***	***5***	***..***	**** 1542.31***	***32.90***	***XMTVI Maxamaid***	***SB***
8061G	***Powder 500 g***	***8***	***5***	***..***	**** 1931.51***	***32.90***	***XMTVI Maxamum***	***SB***

VARIOUS—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
	AMINO ACID FORMULA with VITAMINS and MINERALS without PHENYLALANINE							
	Restricted Benefit ***Phenylketonuria.***							
8555G	***Sachets 20 g, 30***	***4***	***5***	***..***	**** 890.59***	***32.90***	***PKU-gel***	***VF***
8591E	***Sachets 25 g, 30***	***4***	***5***	***..***	**** 1548.71***	***32.90***	***PKU-Express***	***VF***
8804J	***Sachets 27.8 g, 30***	***3***	***5***	***..***	**** 1549.01***	***32.90***	***Lophlex***	***SB***
8613H	***Sachets 29 g, 30***	***4***	***5***	***..***	**** 891.67***	***32.90***	***Minaphlex***	***SB***
8727H	***Sachets 50 g, 30***	***3***	***5***	***..***	**** 1511.63***	***32.90***	***XP Maxamum***	***SB***
2737C	***Infant formula, powder 400 g***	***8***	***5***	***..***	**** 605.99***	***32.90***	***XP Analog***	***SB***
8467P	***Powder 325 g***	***10***	***5***	***..***	**** 861.39***	***32.90***	***Phenex-2***	***AB***
8545R	***Powder 400 g***	***8***	***5***	***..***	**** 848.15***	***32.90***	***Phenex-2***	***AB***
2738D	***Powder 500 g***	***8***	***5***	***..***	**** 883.59***	***32.90***	***XP Maxamaid***	***SB***
2739E	***Powder 500 g***	***8***	***5***	***..***	**** 1351.99***	***32.90***	***XP Maxamum***	***SB***
8746H	***Oral liquid 250 mL***	***90***	***5***	***..***	**** 1312.84***	***32.90***	***Easiphen***	***SB***
2382J	***Oral liquid 87 mL, 30***	***4***	***5***	***..***	**** 1034.35***	***32.90***	***PKU Cooler 10***	***VF***
9021T	***Oral liquid 125 mL, 30***	***3***	***5***	***..***	**** 1549.01***	***32.90***	***Lophlex LQ***	***SB***
8846N	***Oral liquid 130 mL, 30***	***4***	***5***	***..***	**** 1547.91***	***32.90***	***PKU Cooler 15***	***VF***
2474F	***Oral liquid 174 mL, 30***	***4***	***5***	***..***	**** 2053.59***	***32.90***	***PKU Cooler 20***	***VF***
	AMINO ACID FORMULA with VITAMINS and MINERALS without PHENYLALANINE and TYROSINE							
	Restricted Benefit ***Tyrosinaemia.***							
8631G	***Sachets 20 g, 30***	***4***	***5***	***..***	**** 1797.99***	***32.90***	***TYR gel***	***VF***
8667E	***Sachets 25 g, 30***	***4***	***5***	***..***	**** 3097.95***	***32.90***	***TYR Express***	***VF***
8445L	***Infant formula, powder 400 g***	***8***	***5***	***..***	**** 768.87***	***32.90***	***XPhen, Tyr Analog***	***SB***
8446M	***Powder 500 g***	***8***	***5***	***..***	**** 1784.31***	***32.90***	***XPhen, Tyr Maxamaid***	***SB***
3078B	***Powder 500 g***	***8***	***5***	***..***	**** 2704.31***	***32.90***	***XPhen, Tyr Maxamum***	***SB***
9132P	***Oral liquid 130 mL, 30***	***4***	***5***	***..***	**** 3097.95***	***32.90***	***TYR Cooler***	***VF***

VARIOUS—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
	AMINO ACID FORMULA with VITAMINS and MINERALS without VALINE, LEUCINE and ISOLEUCINE							
	Restricted Benefit ***Maple syrup urine disease.***							
8592F	***Sachets 20 g, 30***	***4***	***5***	***..***	**** 1797.99***	***32.90***	***MSUD-gel***	***VF***
8632H	***Sachets 25 g, 30***	***4***	***5***	***..***	**** 3097.95***	***32.90***	***MSUD Express***	***VF***
8745G	***Sachets 29 g, 30***	***4***	***5***	***..***	**** 1800.03***	***32.90***	***Mapleflex***	***SB***
2380G	***Infant formula, powder 400 g***	***8***	***5***	***..***	**** 768.87***	***32.90***	***MSUD Analog***	***SB***
8310J	***Powder 500 g***	***4***	***5***	***..***	**** 2671.55***	***32.90***	***MSUD AID III***	***SB***
8260R	***Powder 500 g***	***8***	***5***	***..***	**** 1784.31***	***32.90***	***MSUD Maxamaid***	***SB***
8057C	***Powder 500 g***	***8***	***5***	***..***	**** 2704.31***	***32.90***	***MSUD Maxamum***	***SB***
2375B	***Oral liquid 130 mL, 30***	***4***	***5***	***..***	**** 3097.95***	***32.90***	***MSUD Express Cooler***	***VF***
	CARBOHYDRATE, FAT, VITAMINS, MINERALS and TRACE ELEMENTS							
	Restricted Benefit ***Patients with proven inborn errors of protein metabolism who are unable to meet their energy requirements with permitted food and formulae.***							
8576J	***Powder 400 g***	***8***	***5***	***..***	**** 260.07***	***32.90***	***Pro-Phree***	***AB***
8369L	***Powder 400 g***	***8***	***5***	***..***	**** 291.03***	***32.90***	***Energivit***	***SB***
	CYSTINE with CARBOHYDRATE							
	Restricted Benefit ***Pyridoxine non-responsive homocystinuria.***							
9164H	***Sachets 4 g containing 500 mg cystine, 30***	***4***	***5***	***..***	**** 515.59***	***32.90***	***Cystine Amino Acid Supplement***	***VF***
	ESSENTIAL AMINO ACIDS FORMULA with MINERALS and VITAMIN C							
	Restricted Benefit ***Gyrate atrophy of the choroid and retina;*** ***Urea cycle disorders.***							
8001D	***Powder 200 g***	***10***	***5***	***..***	**** 633.69***	***32.90***	***Dialamine***	***SB***
2027Q	***Powder 400 g***	***5***	***5***	***..***	**** 633.74***	***32.90***	***Dialamine***	***SB***

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
	ESSENTIAL AMINO ACIDS FORMULA with VITAMINS and MINERALS							
	Restricted Benefit ***Gyrate atrophy of the choroid and retina;*** ***Urea cycle disorders.***							
9385Y	***Sachets 12.5 g, 50***	***4***	***5***	***..***	**** 1516.07***	***32.90***	***EAA Supplement***	***VF***
	ISOLEUCINE with CARBOHYDRATE							
	Restricted Benefit ***Maple syrup urine disease.***							
9134R	***Sachets 4 g containing 50 mg isoleucine, 30***	***4***	***5***	***..***	**** 515.59***	***32.90***	***Isoleucine Amino Acid Supplement***	***VF***
	MILK PROTEIN and FAT FORMULA with VITAMINS and MINERALS—CARBOHYDRATE FREE							
	Restricted Benefit ***Patients with intractable seizures requiring treatment with a ketogenic diet;*** ***Glucose transport protein defects;*** ***Pyruvate dehydrogenase deficiency;*** ***Infants and young children with glucose-galactose intolerance and multiple monosaccharide intolerance.***							
8630F	***Powder 225 g***	***24***	***5***	***..***	**** 647.99***	***32.90***	***Carbohydrate Free Mixture***	***SB***
	MINERAL MIXTURE **NOTE:** ***For use with Amino Acid Formula without Phenylalanine.***							
	Restricted Benefit ***Metabolic disorders.***							
1451J	***Powder 250 g***	***‡ 1***	***5***	***..***	***58.11***	***32.90***	***Metabolic Mineral Mixture***	***SB***
	PHENYLALANINE with CARBOHYDRATE							
	Restricted Benefit ***Tyrosinaemia.***							
9384X	***Sachets 4 g containing 50 mg phenylalanine, 30***	***4***	***5***	***..***	**** 515.59***	***32.90***	***Phenylalanine Amino Acid Supplement***	***VF***

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
	SOY PROTEIN and FAT FORMULA with VITAMINS and MINERALS—CARBOHYDRATE FREE							
	Restricted Benefit ***Patients with intractable seizures requiring treatment with a ketogenic diet;*** ***Glucose transport protein defects;*** ***Pyruvate dehydrogenase deficiency;*** ***Infants and young children with glucose-galactose intolerance and multiple monosaccharide intolerance.***							
8577K	***Liquid 384 mL***	***120***	***5***	***..***	**** 669.59***	***32.90***	***RCF***	***AB***
	TRIGLYCERIDES, MEDIUM CHAIN and LONG CHAIN with GLUCOSE POLYMER							
	Restricted Benefit ***Patients with proven inborn errors of protein metabolism who are unable to meet their energy requirements with permitted food and formulae.***							
3136C	***Compound powder 400 g***	***8***	***5***	***..***	**** 295.11***	***32.90***	***Duocal***	***SB***
	TRIGLYCERIDES—MEDIUM CHAIN, FORMULA **NOTE:** ***No applications for increased maximum quantities and/or repeats will be authorised.*** **Authority Required** ***Chylous ascites;*** ***Chylothorax;*** ***Fat malabsorption due to liver disease, short gut syndrome, cystic fibrosis and gastrointestinal disorders;*** ***Hyperlipoproteinaemia type 1;*** ***Long chain fatty acid oxidation disorders.*** **NOTE:** ***MCT Pro-Cal is not indicated for the treatment of intractable childhood epilepsy or cerebrospinal fluid glucose transporter defect requiring a ketogenic diet.***							
9383W	***Sachets 16 g, 25***	***4***	***5***	***..***	**** 215.19***	***32.90***	***MCT Pro-Cal***	***VF***
	TYROSINE with CARBOHYDRATE							
	Restricted Benefit ***Phenylketonuria.***							
9165J	***Sachets 4 g containing 1 g tyrosine, 30***	***4***	***5***	***..***	**** 515.59***	***32.90***	***Tyrosine Amino Acid Supplement***	***VF***
	VALINE with CARBOHYDRATE							
	Restricted Benefit ***Maple syrup urine disease.***							
9135T	***Sachets 4 g containing 50 mg valine, 30***	***4***	***5***	***..***	**** 515.59***	***32.90***	***Valine Amino Acid Supplement***	***VF***

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
	WHEY PROTEIN FORMULA supplemented with AMINO ACIDS, LONG CHAIN POLYUNSATURATED FATTY ACIDS, VITAMINS and MINERALS, and low in PROTEIN, PHOSPHATE, POTASSIUM and LACTOSE							
	Authority Required ***Infants and young children with chronic renal failure requiring treatment with a low protein and a low phosphorus diet, or a low protein, a low phosphorus and a low potassium diet.***							
9382T	***Sachets 100 g, 10***	***8***	***5***	***..***	**** 1328.87***	***32.90***	***RenaStart***	***VF***
	WHEY PROTEIN FORMULA supplemented with AMINO ACIDS, VITAMINS and MINERALS, and low in PROTEIN, PHOSPHATE, POTASSIUM and LACTOSE							
	Authority Required ***Infants and young children with chronic renal failure requiring treatment with a low protein and a low phosphorus diet, or a low protein, a low phosphorus and a low potassium diet.***							
8587Y	***Powder 400 g***	***16***	***5***	***..***	**** 1065.51***	***32.90***	***Kindergen***	***SB***

ALL OTHER NON-THERAPEUTIC PRODUCTS

All other non-therapeutic products

- ***Solvents and diluting agents, incl. irrigating solutions***

SODIUM CHLORIDE

2026P	Injection 9 mg per mL (0.9%), 10 mL	5	1	..	17.73	18.76	PF	

PREPARATIONS WHICH MAY BE PRESCRIBED FOR PATIENTS RECEIVING PALLIATIVE CARE

The prescribing of medications listed in this section is in accordance with the requirements for General Pharmaceutical Benefits in the Schedule unless otherwise detailed in the listing for the item.

In addition, certain additional principles have been applied by the Pharmaceutical Benefits Advisory Committee (PBAC) in recommending for whom these medications may be prescribed, and the number of repeats that may be approved by Medicare Australia. These principles have been encompassed in the listings for the items, and further details are provided below to help doctors prescribing under this section.

For the purposes of this section a patient receiving palliative care is defined as:

- *A patient with an active, progressive, far-advanced disease for whom the prognosis is limited and the focus of care is the quality of life.*

The provision for increased maximum quantities and up to 3 repeats on the *initial* authority prescription is intended to provide up to 4 months' therapy in total. Where *continuing* treatment is required the provision of repeats is subject to confirmation by the prescriber that a palliative care physician or palliative care service has been consulted regarding the care of the patient.

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

When a Palliative Care authority application is for a drug of addiction, the following guidelines apply:

- the maximum quantity authorised is generally for 1 month’s therapy;
- where supply for a longer period is warranted, quantities are for up to 3 months’ therapy;
- telephone approvals are limited to 1 month’s therapy.

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

Prescribers should be aware that patients receiving palliative care may also access PBS items included in the general part of the Schedule of Pharmaceutical Benefits including narcotic preparations, according to the restrictions that apply to individual items and the requirements that apply to the general part of the Schedule.

PREPARATIONS WHICH MAY BE PRESCRIBED FOR PATIENTS RECEIVING PALLIATIVE CARE-cont.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	

ALIMENTARY TRACT AND METABOLISM

STOMATOLOGICAL PREPARATIONS

Stomatological preparations

- ***Other agents for local oral treatment***

BENZYDAMINE HYDROCHLORIDE

Authority Required

Initial supply (for up to 4 months) for palliative care patients where a painful mouth is a problem;

Continuing supply for palliative care patients where a painful mouth is a problem, and where consultation with a palliative care specialist or service has occurred.

NOTE:

No applications for increased repeats will be authorised.

5385K	***Mouth and throat rinse 22.5 mg per 15 mL, 500 mL***	***‡ 1***	***3***	***..***	***21.09***	***22.12***	***Difflam***	***IA***

Authority Required

Continuing supply for palliative care patients where a painful mouth is a problem.

NOTE:

No applications for repeats will be authorised.

5386L	***Mouth and throat rinse 22.5 mg per 15 mL, 500 mL***	***‡ 1***	***..***	***..***	***21.09***	***22.12***	***Difflam***	***IA***

CARMELLOSE SODIUM

Authority Required

Initial supply (for up to 4 months) for palliative care patients where dry mouth is a symptom;

Continuing supply for palliative care patients where dry mouth is a symptom, and where consultation with a palliative care specialist or service has occurred.

NOTE:

No applications for increased repeats will be authorised.

5333Q	***Mouth spray 10 mg per mL, 25 mL***	***‡ 1***	***3***	***..***	***9.77***	***10.80***	***Aquae***	***HA***
5334R	***Mouth spray 10 mg per mL, 100 mL***	***‡ 1***	***3***	***..***	***11.79***	***12.82***	***Aquae***	***HA***

Authority Required

Continuing supply for palliative care patients where dry mouth is a symptom.

NOTE:

No applications for repeats will be authorised.

5335T	***Mouth spray 10 mg per mL, 25 mL***	***‡ 1***	***..***	***..***	***9.77***	***10.80***	***Aquae***	***HA***
5336W	***Mouth spray 10 mg per mL, 100 mL***	***‡ 1***	***..***	***..***	***11.79***	***12.82***	***Aquae***	***HA***

PREPARATIONS WHICH MAY BE PRESCRIBED FOR PATIENTS RECEIVING PALLIATIVE CARE-cont.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
	DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS							
	Belladonna and derivatives, plain							
	• ***Belladonna alkaloids semisynthetic, quaternary ammonium compounds***							
	HYOSCINE BUTYLBROMIDE							
	Authority Required ***Initial supply (for up to 4 months) for palliative care patients where colicky pain is a symptom;*** ***Continuing supply for palliative care patients where colicky pain is a symptom, and where consultation with a palliative care specialist or service has occurred.*** **NOTE:** ***No applications for increased repeats will be authorised.***							
5317W	***Injection 20 mg in 1 mL***	***5***	***3***	***..***	***20.95***	***21.98***	***Buscopan***	***BY***
	Authority Required ***Continuing supply for palliative care patients where colicky pain is a symptom.*** **NOTE:** ***No applications for repeats will be authorised.***							
5318X	***Injection 20 mg in 1 mL***	***5***	***..***	***..***	***20.95***	***21.98***	***Buscopan***	***BY***
	ANTIEMETICS AND ANTINAUSEANTS							
	Antiemetics and antinauseants							
	• ***Other antiemetics***							
	PROMETHAZINE HYDROCHLORIDE							
	Authority Required ***Initial supply (for up to 4 months) for palliative care patients where nausea and/or vomiting is a problem;*** ***Continuing supply for palliative care patients where nausea and/or vomiting is a problem, and where consultation with a palliative care specialist or service has occurred.*** **NOTE:** ***No applications for increased repeats will be authorised.***							
5325G	***Tablet 10 mg***	***50***	***3***	***..***	***14.24***	***15.27***	***Phenergan***	***SW***
5326H	***Tablet 25 mg***	***50***	***3***	***..***	***16.33***	***17.36***	***Phenergan***	***SW***
5327J	***Oral liquid 5 mg per 5 mL, 100 mL***	***‡ 1***	***3***	***..***	***14.24***	***15.27***	***Phenergan***	***SW***

continued ☞

PREPARATIONS WHICH MAY BE PRESCRIBED FOR PATIENTS RECEIVING PALLIATIVE CARE-cont.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Proprietary Name and Manufacturer	
	Authority Required *Continuing supply for palliative care patients where nausea and/or vomiting is a problem.* **NOTE:** *No applications for repeats will be authorised.*								
5328K	*Tablet 10 mg*	*50*	*..*	*..*	*14.24*	*15.27*		*Phenergan*	*SW*
5329L	*Tablet 25 mg*	*50*	*..*	*..*	*16.33*	*17.36*		*Phenergan*	*SW*
5330M	*Oral liquid 5 mg per 5 mL, 100 mL*	*‡ 1*	*..*	*..*	*14.24*	*15.27*		*Phenergan*	*SW*
	LAXATIVES								
	Laxatives								
	• ***Contact laxatives***								
	BISACODYL								
	Authority Required *Initial supply (for up to 4 months) for palliative care patients where constipation is a problem;* *Continuing supply for palliative care patients where constipation is a problem, and where consultation with a palliative care specialist or service has occurred.* **NOTE:** *No applications for increased repeats will be authorised.*								
5301B	*Tablet 5 mg*	*200*	*3*	*..*	*14.17*	*15.20*		*Bisalax* *Lax-Tab*	*AS* *AE*
5303D	*Suppositories 10 mg, 10*	*3*	*3*	*..*	** 21.44*	*22.47*	*a*	*Petrus Bisacodyl Suppositories*	*PP*
				B1.14	** 22.58*	*22.47*	*a*	*Dulcolax*	*BY*
5304E	*Suppositories 10 mg, 12*	*3*	*3*	*..*	** 18.62*	*19.65*		*Fleet Laxative Suppositories* *Petrus Bisacodyl Suppositories*	*FL* *PP*
	Authority Required *Continuing supply for palliative care patients where constipation is a problem.* **NOTE:** *No applications for repeats will be authorised.*								
5305F	*Tablet 5 mg*	*200*	*..*	*..*	*14.17*	*15.20*		*Bisalax* *Lax-Tab*	*AS* *AE*
5307H	*Suppositories 10 mg, 10*	*3*	*..*	*..*	** 21.44*	*22.47*	*a*	*Petrus Bisacodyl Suppositories*	*PP*
				B1.14	** 22.58*	*22.47*	*a*	*Dulcolax*	*BY*

continued ☞

PREPARATIONS WHICH MAY BE PRESCRIBED FOR PATIENTS RECEIVING PALLIATIVE CARE-cont.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
5308J	***Suppositories 10 mg, 12***	***3***	***..***	***..***	**** 18.62***	***19.65***	***Fleet Laxative Suppositories***	***FL***
							Petrus Bisacodyl Suppositories	***PP***

• *Bulk producers*

STERCULIA with FRANGULA BARK

Authority Required

Initial supply (for up to 4 months) for palliative care patients where constipation is a problem;

Continuing supply for palliative care patients where constipation is a problem, and where consultation with a palliative care specialist or service has occurred.

NOTE:

No applications for increased repeats will be authorised.

5322D	***Granules 620 mg-80 mg per g (62%-8%), 500 g***	***‡ 1***	***3***	***..***	***24.52***	***25.55***	***Normacol Plus***	***NE***

Authority Required

Continuing supply for palliative care patients where constipation is a problem.

NOTE:

No applications for repeats will be authorised.

5324F	***Granules 620 mg-80 mg per g (62%-8%), 500 g***	***‡ 1***	***..***	***..***	***24.52***	***25.55***	***Normacol Plus***	***NE***

• *Osmotically acting laxatives*

LACTULOSE

Authority Required

Initial supply (for up to 4 months) for palliative care patients where constipation is a problem;

Continuing supply for palliative care patients where constipation is a problem, and where consultation with a palliative care specialist or service has occurred.

NOTE:

No applications for increased repeats will be authorised.

5387M	***Mixture 3.34 g per 5 mL, 500 mL***	***‡ 1***	***3***	***..***	***13.80***	***14.83***	[a] ***Actilax***	***AF***
							[a] ***Genlac***	***AW***
							[a] ***GenRx Lactulose***	***GX***
							[a] ***Lac-Dol***	***GM***
							[a] ***Lactocur***	***SZ***
				B1.67	***15.47***	***14.83***	[a] ***Duphalac***	***SM***

continued ☞

PREPARATIONS WHICH MAY BE PRESCRIBED FOR PATIENTS RECEIVING PALLIATIVE CARE-cont.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
	Authority Required ***Continuing supply for palliative care patients where constipation is a problem.*** **NOTE:** ***No applications for repeats will be authorised.***							
5388N	***Mixture 3.34 g per 5 mL, 500 mL***	***‡ 1***	***..***	***..***	***13.80***	***14.83***	[a] ***Actilax***	***AF***
							[a] ***Genlac***	***AW***
							[a] ***GenRx Lactulose***	***GX***
							[a] ***Lac-Dol***	***GM***
							[a] ***Lactocur***	***SZ***
				[B]1.67	***15.47***	***14.83***	[a] ***Duphalac***	***SM***
	MACROGOL 3350 **Authority Required** ***Initial supply (for up to 4 months) for palliative care patients where constipation is a problem;*** ***Continuing supply for palliative care patients where constipation is a problem, and where consultation with a palliative care specialist or service has occurred.*** **NOTE:** ***No applications for increased repeats will be authorised.***							
5419F	***Sachets containing powder for solution 6.563 g with electrolytes, 30***	***‡ 1***	***3***	***..***	***18.10***	***19.13***	***Movicol-Half***	***NE***
5389P	***Sachets containing powder for solution 13.125 g with electrolytes, 30***	***‡ 1***	***3***	***..***	***24.36***	***25.39***	***Movicol***	***NE***
	Authority Required ***Continuing supply for palliative care patients where constipation is a problem.*** **NOTE:** ***No applications for repeats will be authorised.***							
5420G	***Sachets containing powder for solution 6.563 g with electrolytes, 30***	***‡ 1***	***..***	***..***	***18.10***	***19.13***	***Movicol-Half***	***NE***
5390Q	***Sachets containing powder for solution 13.125 g with electrolytes, 30***	***‡ 1***	***..***	***..***	***24.36***	***25.39***	***Movicol***	***NE***

PREPARATIONS WHICH MAY BE PRESCRIBED FOR PATIENTS RECEIVING PALLIATIVE CARE-cont.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
	• ***Enemas***							
	BISACODYL							
	Authority Required ***Initial supply (for up to 4 months) for palliative care patients where constipation is a problem;*** ***Continuing supply for palliative care patients where constipation is a problem, and where consultation with a palliative care specialist or service has occurred.*** **NOTE:** ***No applications for increased repeats will be authorised.***							
5302C	***Enemas 10 mg in 5 mL, 25***	***‡ 1***	***3***	***..***	***37.97***	***32.90***	***Bisalax***	***AS***
	Authority Required ***Continuing supply for palliative care patients where constipation is a problem.*** **NOTE:** ***No applications for repeats will be authorised.***							
5306G	***Enemas 10 mg in 5 mL, 25***	***‡ 1***	***..***	***..***	***37.97***	***32.90***	***Bisalax***	***AS***
	SORBITOL with SODIUM CITRATE and SODIUM LAURYL SULFOACETATE							
	Authority Required ***Initial supply (for up to 4 months) for palliative care patients where constipation is a problem;*** ***Continuing supply for palliative care patients where constipation is a problem, and where consultation with a palliative care specialist or service has occurred.*** **NOTE:** ***No applications for increased repeats will be authorised.***							
5331N	***Enemas 3.125 g-450 mg-45 mg in 5 mL, 12***	***2***	***3***	***..***	**** 36.15***	***32.90***	***Microlax***	***JT***
	Authority Required ***Continuing supply for palliative care patients where constipation is a problem.*** **NOTE:** ***No applications for repeats will be authorised.***							
5332P	***Enemas 3.125 g-450 mg-45 mg in 5 mL, 12***	***2***	***..***	***..***	**** 36.15***	***32.90***	***Microlax***	***JT***

PREPARATIONS WHICH MAY BE PRESCRIBED FOR PATIENTS RECEIVING PALLIATIVE CARE-cont.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer
	• *Other laxatives*						
	GLYCEROL						
	Authority Required						
	Initial supply (for up to 4 months) for palliative care patients where constipation is a problem;						
	Continuing supply for palliative care patients where constipation is a problem, and where consultation with a palliative care specialist or service has occurred.						
	NOTE:						
	No applications for increased repeats will be authorised.						
5311M	***Suppositories 700 mg (for infants), 12***	***3***	***3***	***..***	**** 17.48***	***18.51***	***PP***
5312N	***Suppositories 1.4 g (for children), 12***	***3***	***3***	***..***	**** 17.87***	***18.90***	***PP***
5313P	***Suppositories 2.8 g (for adults), 12***	***3***	***3***	***..***	**** 18.32***	***19.35***	***PP***
	Authority Required						
	Continuing supply for palliative care patients where constipation is a problem.						
	NOTE:						
	No applications for repeats will be authorised.						
5314Q	***Suppositories 700 mg (for infants), 12***	***3***	***..***	***..***	**** 17.48***	***18.51***	***PP***
5315R	***Suppositories 1.4 g (for children), 12***	***3***	***..***	***..***	**** 17.87***	***18.90***	***PP***
5316T	***Suppositories 2.8 g (for adults), 12***	***3***	***..***	***..***	**** 18.32***	***19.35***	***PP***

PREPARATIONS WHICH MAY BE PRESCRIBED FOR PATIENTS RECEIVING PALLIATIVE CARE-cont.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Proprietary Name and Manufacturer	
	MUSCULO-SKELETAL SYSTEM								
	ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS								
	Antiinflammatory and antirheumatic products, non-steroids								
	• ***Acetic acid derivatives and related substances***								
	DICLOFENAC SODIUM								
	Authority Required								
	Initial supply (for up to 4 months) for palliative care patients where severe pain is a problem;								
	Continuing supply for palliative care patients where severe pain is a problem, and where consultation with a palliative care specialist or service has occurred.								
	NOTE:								
	No applications for increased repeats will be authorised.								
5361E	*Tablet 25 mg (enteric coated)*	*100*	*3*	*..*	** 12.63*	*13.66*	*a*	*Chem mart Diclofenac*	*CH*
							a	*Clonac 25*	*AW*
							a	*Diclofenac-GA*	*GN*
							a	*Diclohexal*	*SZ*
							a	*Dinac*	*GM*
							a	*GenRx Diclofenac*	*GX*
							a	*Terry White Chemists Diclofenac*	*TW*
				..	*12.64*	*13.67*	*a*	*Fenac 25*	*AF*
				B1.96	** 14.59*	*13.66*	*a*	*Voltaren 25*	*NV*
5362F	*Tablet 50 mg (enteric coated)*	*50*	*3*	*..*	*10.62*	*11.65*	*a*	*Chem mart Diclofenac*	*CH*
							a	*Clonac 50*	*AW*
							a	*Diclohexal*	*SZ*
							a	*Dinac*	*GM*
							a	*Fenac*	*AF*
							a	*GenRx Diclofenac*	*GX*
							a	*Terry White Chemists Diclofenac*	*TW*
				B1.96	*12.58*	*11.65*	*a*	*Voltaren 50*	*NV*
5363G	*Suppository 100 mg*	*40*	*3*	*..*	** 24.49*	*25.52*		*Voltaren 100*	*NV*

continued ☞

PREPARATIONS WHICH MAY BE PRESCRIBED FOR PATIENTS RECEIVING PALLIATIVE CARE-cont.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Proprietary Name and Manufacturer	
	Authority Required ***Continuing supply for palliative care patients where severe pain is a problem.*** **NOTE:** ***No applications for repeats will be authorised.***								
5364H	*Tablet 25 mg (enteric coated)*	*100*	*..*	*..*	** 12.63*	*13.66*	*a*	*Chem mart Diclofenac*	*CH*
							a	*Clonac 25*	*AW*
							a	*Diclofenac-GA*	*GN*
							a	*Diclohexal*	*SZ*
							a	*Dinac*	*GM*
							a	*GenRx Diclofenac*	*GX*
							a	*Terry White Chemists Diclofenac*	*TW*
				..	*12.64*	*13.67*	*a*	*Fenac 25*	*AF*
				B1.96	** 14.59*	*13.66*	*a*	*Voltaren 25*	*NV*
5365J	*Tablet 50 mg (enteric coated)*	*50*	*..*	*..*	*10.62*	*11.65*	*a*	*Chem mart Diclofenac*	*CH*
							a	*Clonac 50*	*AW*
							a	*Diclohexal*	*SZ*
							a	*Dinac*	*GM*
							a	*Fenac*	*AF*
							a	*GenRx Diclofenac*	*GX*
							a	*Terry White Chemists Diclofenac*	*TW*
				B1.96	*12.58*	*11.65*	*a*	*Voltaren 50*	*NV*
5366K	*Suppository 100 mg*	*40*	*..*	*..*	** 24.49*	*25.52*		*Voltaren 100*	*NV*
	INDOMETHACIN **Authority Required** ***Initial supply (for up to 4 months) for palliative care patients where severe pain is a problem;*** ***Continuing supply for palliative care patients where severe pain is a problem, and where consultation with a palliative care specialist or service has occurred.*** **NOTE:** ***No applications for increased repeats will be authorised.***								
5377B	*Capsule 25 mg*	*100*	*3*	*..*	** 11.65*	*12.68*	*a*	*Arthrexin*	*AF*
				B0.92	** 12.57*	*12.68*	*a*	*Indocid*	*AS*
5378C	*Suppository 100 mg*	*40*	*3*	*..*	** 22.07*	*23.10*		*Indocid*	*AS*

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PREPARATIONS WHICH MAY BE PRESCRIBED FOR PATIENTS RECEIVING PALLIATIVE CARE-cont.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Proprietary Name and Manufacturer	
	Authority Required ***Continuing supply for palliative care patients where severe pain is a problem.***								
	NOTE: ***No applications for repeats will be authorised.***								
5379D	***Capsule 25 mg***	***100***	***..***	***..***	**** 11.65***	***12.68***	***a***	***Arthrexin***	***AF***
				B0.92	**** 12.57***	***12.68***	***a***	***Indocid***	***AS***
5380E	***Suppository 100 mg***	***40***	***..***	***..***	**** 22.07***	***23.10***		***Indocid***	***AS***
	SULINDAC								
	Authority Required ***Initial supply (for up to 4 months) for palliative care patients where severe pain is a problem;*** ***Continuing supply for palliative care patients where severe pain is a problem, and where consultation with a palliative care specialist or service has occurred.***								
	NOTE: ***No applications for increased repeats will be authorised.***								
5381F	***Tablet 100 mg***	***100***	***3***	***..***	**** 15.91***	***16.94***		***Aclin***	***AF***
5382G	***Tablet 200 mg***	***50***	***3***	***..***	***14.85***	***15.88***		***Aclin 200***	***AF***
	Authority Required ***Continuing supply for palliative care patients where severe pain is a problem.***								
	NOTE: ***No applications for repeats will be authorised.***								
5383H	***Tablet 100 mg***	***100***	***..***	***..***	**** 15.91***	***16.94***		***Aclin***	***AF***
5384J	***Tablet 200 mg***	***50***	***..***	***..***	***14.85***	***15.88***		***Aclin 200***	***AF***
	• Propionic acid derivatives ***IBUPROFEN***								
	Authority Required ***Initial supply (for up to 4 months) for palliative care patients where severe pain is a problem;*** ***Continuing supply for palliative care patients where severe pain is a problem, and where consultation with a palliative care specialist or service has occurred.***								
	NOTE: ***No applications for increased repeats will be authorised.***								
5367L	***Tablet 200 mg***	***100***	***3***	***..***	**** 11.63***	***12.66***		***Rafen 200***	***AF***
5368M	***Tablet 400 mg***	***90***	***3***	***..***	**** 14.30***	***15.33***		***Brufen***	***AB***

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PREPARATIONS WHICH MAY BE PRESCRIBED FOR PATIENTS RECEIVING PALLIATIVE CARE-cont.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Proprietary Name and Manufacturer	
	Authority Required *Continuing supply for palliative care patients where severe pain is a problem.* **NOTE:** *No applications for repeats will be authorised.*								
5369N	*Tablet 200 mg*	*100*	*..*	*..*	* *11.63*	*12.66*		*Rafen 200*	*AF*
5370P	*Tablet 400 mg*	*90*	*..*	*..*	* *14.30*	*15.33*		*Brufen*	*AB*
	NAPROXEN **Authority Required** *Initial supply (for up to 4 months) for palliative care patients where severe pain is a problem;* *Continuing supply for palliative care patients where severe pain is a problem, and where consultation with a palliative care specialist or service has occurred.* **NOTE:** *No applications for increased repeats will be authorised.*								
5345H	*Tablet 250 mg*	*100*	*3*	*..*	* *13.29*	*14.32*	a	*Inza 250*	*AF*
				B *2.34*	* *15.63*	*14.32*	a	*Naprosyn*	*RO*
5346J	*Tablet 500 mg*	*50*	*3*	*..*	*12.48*	*13.51*	a	*Inza 500*	*AF*
				B *1.36*	*13.84*	*13.51*	a	*Naprosyn*	*RO*
5347K	*Tablet 750 mg (sustained release)*	*28*	*3*	*..*	*11.95*	*12.98*	a	*Proxen SR 750*	*MD*
				B *1.27*	*13.22*	*12.98*	a	*Naprosyn SR750*	*RO*
5348L	*Tablet 1 g (sustained release)*	*28*	*3*	*..*	*13.94*	*14.97*	a	*Proxen SR 1000*	*MD*
				B *1.34*	*15.28*	*14.97*	a	*Naprosyn SR1000*	*RO*
	Authority Required *Continuing supply for palliative care patients where severe pain is a problem.* **NOTE:** *No applications for repeats will be authorised.*								
5349M	*Tablet 250 mg*	*100*	*..*	*..*	* *13.29*	*14.32*	a	*Inza 250*	*AF*
				B *2.34*	* *15.63*	*14.32*	a	*Naprosyn*	*RO*
5350N	*Tablet 500 mg*	*50*	*..*	*..*	*12.48*	*13.51*	a	*Inza 500*	*AF*
				B *1.36*	*13.84*	*13.51*	a	*Naprosyn*	*RO*
5351P	*Tablet 750 mg (sustained release)*	*28*	*..*	*..*	*11.95*	*12.98*	a	*Proxen SR 750*	*MD*
				B *1.27*	*13.22*	*12.98*	a	*Naprosyn SR750*	*RO*
5352Q	*Tablet 1 g (sustained release)*	*28*	*..*	*..*	*13.94*	*14.97*	a	*Proxen SR 1000*	*MD*
				B *1.34*	*15.28*	*14.97*	a	*Naprosyn SR1000*	*RO*

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PREPARATIONS WHICH MAY BE PRESCRIBED FOR PATIENTS RECEIVING PALLIATIVE CARE-cont.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Proprietary Name and Manufacturer	
	Authority Required ***Initial supply (for up to 4 months) for palliative care patients where severe pain is a problem in patients unable to take a solid dose form of a non-steroidal anti-inflammatory agent;*** ***Continuing supply for palliative care patients where severe pain is a problem, and where consultation with a palliative care specialist or service has occurred, in patients unable to take a solid dose form of a non-steroidal anti-inflammatory agent.*** **NOTE:** ***No applications for increased repeats will be authorised.***								
5397C	***Oral suspension 125 mg per 5 mL, 474 mL***	***‡ 1***	***3***	***..***	***77.74***	***32.90***		***Naprosyn***	***RO***
	Authority Required ***Continuing supply for palliative care patients where severe pain is a problem in patients unable to take a solid dose form of a non-steroidal anti-inflammatory agent.*** **NOTE:** ***No applications for repeats will be authorised.***								
5398D	***Oral suspension 125 mg per 5 mL, 474 mL***	***‡ 1***	***..***	***..***	***77.74***	***32.90***		***Naprosyn***	***RO***
	NAPROXEN SODIUM **Authority Required** ***Initial supply (for up to 4 months) for palliative care patients where severe pain is a problem;*** ***Continuing supply for palliative care patients where severe pain is a problem, and where consultation with a palliative care specialist or service has occurred.*** **NOTE:** ***No applications for increased repeats will be authorised.***								
5353R	***Tablet 550 mg***	***50***	***3***	***..***	***12.67***	***13.70***	***a***	***Crysanal***	***MD***
				B2.29	***14.96***	***13.70***	***a***	***Anaprox 550***	***RO***
	NOTE: ***Naproxen sodium 550 mg is approximately equivalent to 500 mg of naproxen acid.***								
	Authority Required ***Continuing supply for palliative care patients where severe pain is a problem.*** **NOTE:** ***No applications for repeats will be authorised.***								
5354T	***Tablet 550 mg***	***50***	***..***	***..***	***12.67***	***13.70***	***a***	***Crysanal***	***MD***
				B2.29	***14.96***	***13.70***	***a***	***Anaprox 550***	***RO***
	NOTE: ***Naproxen sodium 550 mg is approximately equivalent to 500 mg of naproxen acid.***								

PREPARATIONS WHICH MAY BE PRESCRIBED FOR PATIENTS RECEIVING PALLIATIVE CARE-cont.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	

NERVOUS SYSTEM

ANALGESICS

Opioids

• *Natural opium alkaloids*

MORPHINE SULFATE

CAUTION:

The risk of drug dependence is high.

Authority Required

Initial supply (for up to 3 months) for palliative care patients with severe disabling pain not responding to non-narcotic analgesics;

Continuing supply (for up to 3 months) for palliative care patients with severe disabling pain not responding to non-narcotic analgesics, and where consultation with a palliative care specialist or service has occurred.

NOTE:

Telephone approvals are limited to 1 month's therapy.

5393W	*Tablet 10 mg*	*20*	*2*	*..*	*14.85*	*15.88*	*Sevredol*	*MF*
5394X	*Tablet 20 mg*	*20*	*2*	*..*	*15.99*	*17.02*	*Sevredol*	*MF*

Authority Required

Continuing supply (for up to 1 month) for palliative care patients with severe disabling pain not responding to non-narcotic analgesics.

NOTE:

No applications for repeats will be authorised.

5395Y	*Tablet 10 mg*	*20*	*..*	*..*	*14.85*	*15.88*	*Sevredol*	*MF*
5396B	*Tablet 20 mg*	*20*	*..*	*..*	*15.99*	*17.02*	*Sevredol*	*MF*

Authority Required

Initial supply (for up to 3 months) for palliative care patients with chronic severe disabling pain not responding to non-narcotic analgesics;

Continuing supply (for up to 3 months) for palliative care patients with chronic severe disabling pain not responding to non-narcotic analgesics, and where consultation with a palliative care specialist or service has occurred.

NOTE:

Telephone approvals are limited to 1 month's therapy.

5391R	*Tablet 200 mg (controlled release)*	*20*	*2*	*..*	*104.50*	*32.90*	*MS Contin*	*MF*

continued ☞

PREPARATIONS WHICH MAY BE PRESCRIBED FOR PATIENTS RECEIVING PALLIATIVE CARE-cont.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
	Authority Required ***Continuing supply (for up to 1 month) for palliative care patients with chronic severe disabling pain not responding to non-narcotic analgesics.*** **NOTE:** ***No applications for repeats will be authorised.***							
5392T	*Tablet 200 mg (controlled release)*	*20*	*..*	*..*	*104.50*	*32.90*	*MS Contin*	*MF*
	• ***Phenylpiperidine derivatives*** ***FENTANYL*** **CAUTION:** ***The risk of drug dependence is high.***							
	Authority Required ***Initial supply for dose titration for breakthrough pain in palliative care patients with cancer who are receiving opioids for their persistent pain and where further escalation in the dose of morphine for breakthrough pain results in intolerable adverse effects.*** **NOTE:** ***No applications for increased repeats will be authorised.***							
5401G	*Lozenges 200 micrograms (as citrate), 3*	*3*	*..*	*..*	** 115.17*	*32.90*	*Actiq*	*OA*
5402H	*Lozenges 400 micrograms (as citrate), 3*	*3*	*..*	*..*	** 115.17*	*32.90*	*Actiq*	*OA*
5403J	*Lozenges 600 micrograms (as citrate), 3*	*3*	*..*	*..*	** 115.17*	*32.90*	*Actiq*	*OA*
5404K	*Lozenges 800 micrograms (as citrate), 3*	*3*	*..*	*..*	** 115.17*	*32.90*	*Actiq*	*OA*
5405L	*Lozenges 1200 micrograms (as citrate), 3*	*3*	*..*	*..*	** 115.17*	*32.90*	*Actiq*	*OA*
5406M	*Lozenges 1600 micrograms (as citrate), 3*	*3*	*..*	*..*	** 115.17*	*32.90*	*Actiq*	*OA*
	Authority Required ***First continuing supply (for up to 3 months) for breakthrough pain in palliative care patients with cancer who are receiving opioids for their persistent pain and where further escalation in the dose of morphine for breakthrough pain results in intolerable adverse effects;*** ***Second and subsequent continuing supply (for up to 3 months) for breakthrough pain in palliative care patients with cancer who are receiving opioids for their persistent pain and where further escalation in the dose of morphine for breakthrough pain results in intolerable adverse effects, where consultation with a palliative care specialist or service has occurred.*** **NOTE:** ***No applications for increased repeats will be authorised.*** ***Telephone approvals are limited to 1 month's therapy.***							
5407N	*Lozenges 200 micrograms (as citrate), 3*	*20*	*2*	*..*	** 679.70*	*32.90*	*Actiq*	*OA*
5408P	*Lozenges 400 micrograms (as citrate), 3*	*20*	*2*	*..*	** 679.70*	*32.90*	*Actiq*	*OA*

continued ☞

PREPARATIONS WHICH MAY BE PRESCRIBED FOR PATIENTS RECEIVING PALLIATIVE CARE-cont.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
5409Q	*Lozenges 600 micrograms (as citrate), 3*	*20*	*2*	*..*	** 679.70*	*32.90*	*Actiq*	*OA*
5410R	*Lozenges 800 micrograms (as citrate), 3*	*20*	*2*	*..*	** 679.70*	*32.90*	*Actiq*	*OA*
5411T	*Lozenges 1200 micrograms (as citrate), 3*	*20*	*2*	*..*	** 679.70*	*32.90*	*Actiq*	*OA*
5412W	*Lozenges 1600 micrograms (as citrate), 3*	*20*	*2*	*..*	** 679.70*	*32.90*	*Actiq*	*OA*

Authority Required

Second and subsequent continuing supply (for up to 1 month) for breakthrough pain in palliative care patients with cancer who are receiving opioids for their persistent pain and where further escalation in the dose of morphine for breakthrough pain results in intolerable adverse effects.

NOTE:

No applications for increased repeats will be authorised.

5413X	*Lozenges 200 micrograms (as citrate), 3*	*20*	*..*	*..*	** 679.70*	*32.90*	*Actiq*	*OA*
5414Y	*Lozenges 400 micrograms (as citrate), 3*	*20*	*..*	*..*	** 679.70*	*32.90*	*Actiq*	*OA*
5415B	*Lozenges 600 micrograms (as citrate), 3*	*20*	*..*	*..*	** 679.70*	*32.90*	*Actiq*	*OA*
5416C	*Lozenges 800 micrograms (as citrate), 3*	*20*	*..*	*..*	** 679.70*	*32.90*	*Actiq*	*OA*
5417D	*Lozenges 1200 micrograms (as citrate), 3*	*20*	*..*	*..*	** 679.70*	*32.90*	*Actiq*	*OA*
5418E	*Lozenges 1600 micrograms (as citrate), 3*	*20*	*..*	*..*	** 679.70*	*32.90*	*Actiq*	*OA*

• *Diphenylpropylamine derivatives*

METHADONE HYDROCHLORIDE

CAUTION:

The risk of drug dependence is high.

Authority Required

Initial supply (for up to 3 months) for palliative care patients with chronic severe disabling pain not responding to non-narcotic analgesics;

Continuing supply (for up to 3 months) for palliative care patients with chronic severe disabling pain not responding to non-narcotic analgesics, and where consultation with a palliative care specialist or service has occurred.

NOTE:

Telephone approvals are limited to 1 month's therapy.

5399E	*Oral liquid 25 mg per 5 mL, 200 mL*	*1*	*2*	*..*	*17.85*	*18.88*	*SI*	

continued ☞

PREPARATIONS WHICH MAY BE PRESCRIBED FOR PATIENTS RECEIVING PALLIATIVE CARE-cont.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
	Authority Required ***Continuing supply (for up to 1 month) for palliative care patients with chronic severe disabling pain not responding to non-narcotic analgesics.*** **NOTE:** ***No applications for repeats will be authorised.***							
5400F	***Oral liquid 25 mg per 5 mL, 200 mL***	***1***	***..***	***..***	***17.85***	***18.88***	***SI***	
	Other analgesics and antipyretics • ***Anilides*** ***PARACETAMOL*** **Authority Required** ***Initial supply (for up to 4 months) for palliative care patients for analgesia or fever where alternative therapy cannot be tolerated;*** ***Continuing supply for palliative care patients for analgesia or fever where alternative therapy cannot be tolerated, and where consultation with a palliative care specialist or service has occurred.*** **NOTE:** ***No applications for increased repeats will be authorised.***							
5343F	***Tablet 665 mg (modified release)***	***192***	***3***	***..***	**** 16.21***	***17.24***	***Panadol Osteo***	***GC***
5319Y	***Suppositories 500 mg, 24***	***‡ 1***	***3***	***..***	***26.39***	***27.42***	***Panadol***	***GC***
	Authority Required ***Continuing supply for palliative care patients for analgesia or fever where alternative therapy cannot be tolerated.*** **NOTE:** ***No applications for repeats will be authorised.***							
5344G	***Tablet 665 mg (modified release)***	***192***	***..***	***..***	**** 16.21***	***17.24***	***Panadol Osteo***	***GC***
5320B	***Suppositories 500 mg, 24***	***‡ 1***	***..***	***..***	***26.39***	***27.42***	***Panadol***	***GC***

PREPARATIONS WHICH MAY BE PRESCRIBED FOR PATIENTS RECEIVING PALLIATIVE CARE-cont.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Proprietary Name and Manufacturer	
	ANTIEPILEPTICS								
	Antiepileptics								
	• Benzodiazepine derivatives								
	CLONAZEPAM								
	Authority Required ***Initial supply (for up to 4 months) for palliative care patients for the prevention of epilepsy;*** ***Continuing supply for palliative care patients for the prevention of epilepsy, where consultation with a palliative care specialist or service has occurred.***								
	NOTE: ***No applications for increased repeats will be authorised.***								
5337X	*Tablet 500 micrograms*	*100*	*3*	*..*	*12.88*	*13.91*	[a]	*Paxam 0.5*	*AF*
				B1.79	*14.67*	*13.91*	[a]	*Rivotril*	*RO*
5338Y	*Tablet 2 mg*	*100*	*3*	*..*	*18.95*	*19.98*	[a]	*Paxam 2*	*AF*
				B2.04	*20.99*	*19.98*	[a]	*Rivotril*	*RO*
5339B	*Oral liquid 2.5 mg per mL, 10 mL*	*2*	*3*	*..*	** 14.61*	*15.64*		*Rivotril*	*RO*
	Authority Required ***Continuing supply for palliative care patients for the prevention of epilepsy.***								
	NOTE: ***No applications for repeats will be authorised.***								
5340C	*Tablet 500 micrograms*	*100*	*..*	*..*	*12.88*	*13.91*	[a]	*Paxam 0.5*	*AF*
				B1.79	*14.67*	*13.91*	[a]	*Rivotril*	*RO*
5341D	*Tablet 2 mg*	*100*	*..*	*..*	*18.95*	*19.98*	[a]	*Paxam 2*	*AF*
				B2.04	*20.99*	*19.98*	[a]	*Rivotril*	*RO*
5342E	*Oral liquid 2.5 mg per mL, 10 mL*	*2*	*..*	*..*	** 14.61*	*15.64*		*Rivotril*	*RO*

PREPARATIONS WHICH MAY BE PRESCRIBED FOR PATIENTS RECEIVING PALLIATIVE CARE-cont.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Proprietary Name and Manufacturer	
	PSYCHOLEPTICS								
	Anxiolytics								
	• ***Benzodiazepine derivatives***								
	DIAZEPAM								
	Authority Required ***Initial supply (for up to 4 months) for palliative care patients where anxiety is a problem;*** ***Continuing supply for palliative care patients where anxiety is a problem, and where consultation with a palliative care specialist or service has occurred.*** **NOTE:** ***No applications for increased repeats will be authorised.***								
5355W	*Tablet 2 mg*	*50*	*3*	*..*	*7.36*	*8.39*	[a]	*Antenex 2*	*AF*
							[a]	*Valpam 2*	*SI*
				[B]0.59	*7.95*	*8.39*		*Ducene*	*SU*
				[B]0.86	*8.22*	*8.39*	[a]	*Valium*	*RO*
5356X	*Tablet 5 mg*	*50*	*3*	*..*	*7.50*	*8.53*	[a]	*Antenex 5*	*AF*
							[a]	*Diazepam-DP*	*GM*
							[a]	*Ranzepam*	*RA*
							[a]	*Valpam 5*	*SI*
				[B]0.63	*8.13*	*8.53*		*Ducene*	*SU*
				[B]0.88	*8.38*	*8.53*	[a]	*Valium*	*RO*
	Authority Required ***Continuing supply for palliative care patients where anxiety is a problem.*** **NOTE:** ***No applications for repeats will be authorised.***								
5357Y	*Tablet 2 mg*	*50*	*..*	*..*	*7.36*	*8.39*	[a]	*Antenex 2*	*AF*
							[a]	*Valpam 2*	*SI*
				[B]0.59	*7.95*	*8.39*		*Ducene*	*SU*
				[B]0.86	*8.22*	*8.39*	[a]	*Valium*	*RO*
5358B	*Tablet 5 mg*	*50*	*..*	*..*	*7.50*	*8.53*	[a]	*Antenex 5*	*AF*
							[a]	*Diazepam-DP*	*GM*
							[a]	*Ranzepam*	*RA*
							[a]	*Valpam 5*	*SI*
				[B]0.63	*8.13*	*8.53*		*Ducene*	*SU*
				[B]0.88	*8.38*	*8.53*	[a]	*Valium*	*RO*

PREPARATIONS WHICH MAY BE PRESCRIBED FOR PATIENTS RECEIVING PALLIATIVE CARE-cont.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Proprietary Name and Manufacturer	
	OXAZEPAM								
	Authority Required ***Initial supply (for up to 4 months) for palliative care patients where anxiety is a problem;*** ***Continuing supply for palliative care patients where anxiety is a problem, and where consultation with a palliative care specialist or service has occurred.*** **NOTE:** ***No applications for increased repeats will be authorised.***								
5371Q	***Tablet 15 mg***	***50***	***3***	***..***	**** 8.55***	***9.58***	***a***	***Alepam 15***	***AF***
				B 3.56	**** 12.11***	***9.58***	***a***	***Serepax***	***SI***
5372R	***Tablet 30 mg***	***50***	***3***	***..***	**** 8.93***	***9.96***	***a***	***Alepam 30***	***AF***
							a	***Murelax***	***FM***
				B 3.80	**** 12.73***	***9.96***	***a***	***Serepax***	***SI***
	Authority Required ***Continuing supply for palliative care patients where anxiety is a problem.*** **NOTE:** ***No applications for repeats will be authorised.***								
5373T	***Tablet 15 mg***	***50***	***..***	***..***	**** 8.55***	***9.58***	***a***	***Alepam 15***	***AF***
				B 3.56	**** 12.11***	***9.58***	***a***	***Serepax***	***SI***
5374W	***Tablet 30 mg***	***50***	***..***	***..***	**** 8.93***	***9.96***	***a***	***Alepam 30***	***AF***
							a	***Murelax***	***FM***
				B 3.80	**** 12.73***	***9.96***	***a***	***Serepax***	***SI***
	Hypnotics and sedatives								
	• ***Benzodiazepine derivatives***								
	NITRAZEPAM								
	Authority Required ***Initial supply (for up to 4 months) for palliative care patients where insomnia is a problem;*** ***Continuing supply for palliative care patients where insomnia is a problem, and where consultation with a palliative care specialist or service has occurred.*** **NOTE:** ***No applications for increased repeats will be authorised.***								
5359C	***Tablet 5 mg***	***50***	***3***	***..***	**** 8.93***	***9.96***	***a***	***Alodorm***	***AF***
				B 3.06	**** 11.99***	***9.96***	***a***	***Mogadon***	***VT***

continued ☞

PREPARATIONS WHICH MAY BE PRESCRIBED FOR PATIENTS RECEIVING PALLIATIVE CARE-cont.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Proprietary Name and Manufacturer	
	Authority Required ***Continuing supply for palliative care patients where insomnia is a problem.*** **NOTE:** ***No applications for repeats will be authorised.***								
5360D	*Tablet 5 mg*	*50*	*..*	*..*	** 8.93*	*9.96*	*a*	*Alodorm*	*AF*
				B3.06	** 11.99*	*9.96*	*a*	*Mogadon*	*VT*
	TEMAZEPAM								
	Authority Required ***Initial supply (for up to 4 months) for palliative care patients where insomnia is a problem;*** ***Continuing supply for palliative care patients where insomnia is a problem, and where consultation with a palliative care specialist or service has occurred.*** **NOTE:** ***No applications for increased repeats will be authorised.***								
5375X	*Tablet 10 mg*	*50*	*3*	*..*	** 8.93*	*9.96*	*a*	*Temaze*	*AF*
							a	*Temtabs*	*FM*
				B2.76	** 11.69*	*9.96*	*a*	*Normison*	*SI*
	Authority Required ***Continuing supply for palliative care patients where insomnia is a problem.*** **NOTE:** ***No applications for repeats will be authorised.***								
5376Y	*Tablet 10 mg*	*50*	*..*	*..*	** 8.93*	*9.96*	*a*	*Temaze*	*AF*
							a	*Temtabs*	*FM*
				B2.76	** 11.69*	*9.96*	*a*	*Normison*	*SI*

PREPARATIONS WHICH MAY BE PRESCRIBED BY PARTICIPATING DENTAL PRACTITIONERS FOR DENTAL TREATMENT ONLY

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
	ALIMENTARY TRACT AND METABOLISM							
	STOMATOLOGICAL PREPARATIONS							
	Stomatological preparations							
	• ***Antiinfectives and antiseptics for local oral treatment***							
	AMPHOTERICIN							
3306B	Lozenge 10 mg	20	..	..	10.20	11.23	Fungilin	BQ
	NYSTATIN							
3343Y	Oral suspension 100,000 units per mL, 24 mL	‡ 1	..	..	10.42	11.45	Mycostatin Nilstat	BQ SI
	• ***Other agents for local oral treatment***							
	BENZYDAMINE HYDROCHLORIDE							
	Restricted Benefit ***Radiation induced mucositis.***							
5032W	***Mouth and throat rinse 22.5 mg per 15 mL, 500 mL***	***‡ 1***	***..***	***..***	***21.09***	***22.12***	***Difflam***	***IA***
	DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS							
	Belladonna and derivatives, plain							
	• ***Belladonna alkaloids, tertiary amines***							
	ATROPINE SULFATE							
5022H	Injection 600 micrograms in 1 mL	10	..	..	20.11	21.14	AP	
	Propulsives							
	• ***Propulsives***							
	METOCLOPRAMIDE HYDROCHLORIDE							
5151D	Tablet 10 mg	25	..	..	7.61	8.64	Pramin	AF
				B3.01	10.62	8.64	Maxolon	VT
5153F	Injection 10 mg in 2 mL	10	..	..	12.56	13.59	Maxolon	VT

PREPARATIONS WHICH MAY BE PRESCRIBED BY PARTICIPATING DENTAL PRACTITIONERS FOR DENTAL TREATMENT ONLY—cont.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Proprietary Name and Manufacturer	
	ANTIEMETICS AND ANTINAUSEANTS								
	Antiemetics and antinauseants								
	• ***Other antiemetics***								
	PROCHLORPERAZINE								
	CAUTION:								
	Prochlorperazine may be associated with parkinsonism and tardive dyskinesia and should be used for short-term treatment only.								
5205Y	Tablet containing prochlorperazine maleate 5 mg	25	..	..	9.59	10.62	a	Stemzine	AV
				B2.50	12.09	10.62	a	Stemetil	SW
5206B	Injection containing prochlorperazine mesylate 12.5 mg in 1 mL	10	..	..	16.39	17.42		Stemetil	SW
5208D	Suppositories containing prochlorperazine equivalent to 25 mg prochlorperazine maleate, 5	‡ 1	..	..	19.50	20.53		Stemetil	SW
	PROMETHAZINE HYDROCHLORIDE								
3374N	Injection 50 mg in 2 mL	10	..	..	* 21.89	22.92		HH	
	ANTIDIARRHEALS, INTESTINAL ANTIINFLAMMATORY/ ANTIINFECTIVE AGENTS								
	Intestinal antiinfectives								
	• ***Antibiotics***								
	NYSTATIN								
3342X	Tablet 500,000 units	50	..	..	17.55	18.58		Nilstat	SI
3345C	Capsule 500,000 units	50	..	..	17.55	18.58		Nilstat	SI
	BLOOD AND BLOOD FORMING ORGANS								
	BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS								
	I.V. solutions								
	• ***Solutions for parenteral nutrition***								
	GLUCOSE								
5106R	I.V. infusion 278 mmol (anhydrous) per L (5%), 1 L	5	..	..	* 25.49	26.52		BX	
	• ***Solutions affecting the electrolyte balance***								
	SODIUM CHLORIDE								
5212H	I.V. infusion 154 mmol per L (0.9%), 1 L	5	..	..	* 25.49	26.52		BX	
5213J	I.V. infusion 513 mmol per L (3%), 1 L	2	..	..	* 17.79	18.82		BX	

PREPARATIONS WHICH MAY BE PRESCRIBED BY PARTICIPATING DENTAL PRACTITIONERS FOR DENTAL TREATMENT ONLY—cont.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
	SODIUM CHLORIDE with GLUCOSE							
5214K	I.V. infusion 31 mmol-222 mmol (anhydrous) per L (0.18%-4%), 1 L	5	..	..	* 25.49	26.52	BX	
5215L	I.V. infusion 19 mmol-104 mmol (anhydrous) per 500 mL (0.225%-3.75%), 500 mL	5	..	..	* 31.59	32.62	BX	
5216M	I.V. infusion 39 mmol-69 mmol (anhydrous) per 500 mL (0.45%-2.5%), 500 mL	5	..	..	* 31.59	32.62	BX	

CARDIOVASCULAR SYSTEM

CARDIAC THERAPY

Antiarrhythmics, class I and III

- ***Antiarrhythmics, class IB***

LIGNOCAINE HYDROCHLORIDE

5142P	Injection 100 mg in 5 mL	5	..	..	36.90	32.90	PF	

Cardiac stimulants excl. cardiac glycosides

- ***Adrenergic and dopaminergic agents***

ADRENALINE

5004J	Injection 1 mg in 1 mL (1 in 1,000)	5	..	..	19.91	20.94	AP	

Vasodilators used in cardiac diseases

- ***Organic nitrates***

GLYCERYL TRINITRATE

5108W	Tablets 600 micrograms, 100	‡ 1	..	..	11.96	12.99	a	Lycinate	FM
				B1.64	13.60	12.99	a	Anginine Stabilised	SI

DERMATOLOGICALS

CORTICOSTEROIDS, DERMATOLOGICAL PREPARATIONS

Corticosteroids, plain

- ***Corticosteroids, weak (group I)***

HYDROCORTISONE ACETATE

Restricted Benefit

Treatment of corticosteroid-responsive dermatoses.

5111B	***Cream 10 mg per g (1%), 30 g***	***‡ 1***	***..***	***..***	***8.61***	***9.64***	***a***	***Cortic-DS 1%***	***FM***
				B1.90	***10.51***	***9.64***	***a***	***Sigmacort***	***SI***

continued ☞

PREPARATIONS WHICH MAY BE PRESCRIBED BY PARTICIPATING DENTAL PRACTITIONERS FOR DENTAL TREATMENT ONLY—cont.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Proprietary Name and Manufacturer	
5113D	***Cream 10 mg per g (1%), 50 g***	***‡ 1***	***..***	***..***	***8.27***	***9.30***	***a***	***Cortic-DS 1%***	***FM***
				B0.08	***8.35***	***9.30***		***Cortef***	***DT***
				B1.91	***10.18***	***9.30***	***a***	***Sigmacort***	***SI***
5112C	***Topical ointment 10 mg per g (1%), 30 g***	***‡ 1***	***..***	***..***	***8.61***	***9.64***	***a***	***Cortic-DS 1%***	***FM***
				B1.90	***10.51***	***9.64***	***a***	***Sigmacort***	***SI***
5114E	***Topical ointment 10 mg per g (1%), 50 g***	***‡ 1***	***..***	***..***	***8.27***	***9.30***	***a***	***Cortic-DS 1%***	***FM***
				B1.91	***10.18***	***9.30***	***a***	***Sigmacort***	***SI***

SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS

CORTICOSTEROIDS FOR SYSTEMIC USE

Corticosteroids for systemic use, plain

- ***Glucocorticoids***

BETAMETHASONE ACETATE with BETAMETHASONE SODIUM PHOSPHATE

Restricted Benefit

For local intra-articular or peri-articular infiltration;

Keloid;

Lichen planus hypertrophic.

5034Y	***Injection 3 mg-3.9 mg (equivalent to 5.7 mg betamethasone) in 1 mL***	***5***	***..***	***..***	***25.74***	***26.77***		***Celestone Chronodose***	***SH***

HYDROCORTISONE SODIUM SUCCINATE

Restricted Benefit

For use in a hospital.

5118J	***Injection equivalent to 100 mg hydrocortisone with 2 mL solvent***	***6***	***..***	***..***	**** 38.15***	***32.90***		***Solu-Cortef***	***PH***
5119K	***Injection equivalent to 250 mg hydrocortisone with 2 mL solvent***	***6***	***..***	***..***	**** 61.61***	***32.90***		***Solu-Cortef***	***PH***

METHYLPREDNISOLONE ACETATE

Restricted Benefit

For local intra-articular or peri-articular infiltration.

5148Y	***Injection 40 mg in 1 mL***	***5***	***..***	***..***	***24.38***	***25.41***	***a***	***Depo-Nisolone***	***KR***
				B0.76	***25.14***	***25.41***	***a***	***Depo-Medrol***	***PH***

PREPARATIONS WHICH MAY BE PRESCRIBED BY PARTICIPATING DENTAL PRACTITIONERS FOR DENTAL TREATMENT ONLY—cont.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
	TRIAMCINOLONE ACETONIDE							
	Restricted Benefit							
	For local intra-articular or peri-articular infiltration;							
	Keloid;							
	Lichen planus hypertrophic.							
5233K	***Injection 10 mg in 1 mL***	***5***	***..***	***..***	***25.74***	***26.77***	***Kenacort-A10***	***BQ***

PANCREATIC HORMONES

Glycogenolytic hormones

• ***Glycogenolytic hormones***

GLUCAGON HYDROCHLORIDE

5105Q	Injection set containing 1 mg (1 i.u.) and 1 mL solvent in disposable syringe	1	..	..	42.93	32.90	GlucaGen Hypokit	NO

ANTIINFECTIVES FOR SYSTEMIC USE

ANTIBACTERIALS FOR SYSTEMIC USE

Tetracyclines

• ***Tetracyclines***

DOXYCYCLINE

5082L	Tablet 100 mg (as monohydrate)	7	..	..	8.04	9.07	[a] Chem mart Doxycycline	CH
							[a] Doxyhexal	SZ
							[a] GenRx Doxycycline	GX
							[a] Terry White Chemists Doxycycline	TW
3321T	Tablet 100 mg (as hydrochloride)	7	..	..	8.04	9.07	[a] Doxsig	SI
							[a] Doxy-100	GM
							[a] Doxylin 100	AF
				B1.19	9.23	9.07	[a] Vibramycin	PF

NOTE:

Bioequivalence has been demonstrated between doxycycline tablet 100 mg (as hydrochloride) and doxycycline tablet 100 mg (as monohydrate).

3322W	Capsule 100 mg (as hydrochloride)	7	..	..	8.04	9.07	[a] DBL Doxycycline	FA
				B1.15	9.19	9.07	[a] Doryx	HH

PREPARATIONS WHICH MAY BE PRESCRIBED BY PARTICIPATING DENTAL PRACTITIONERS FOR DENTAL TREATMENT ONLY—cont.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
	Beta-lactam antibacterials, penicillins							
	• ***Penicillins with extended spectrum***							
	AMOXYCILLIN							
3301R	Capsule 250 mg	20	..	..	8.12	9.15	[a] Alphamox 250	AF
							[a] Amohexal	HX
							[a] Amoxycillin-DP	GM
							[a] APO-Amoxycillin	TX
							[a] Chem mart Amoxycillin	CH
							[a] Cilamox	SI
							[a] GenRx Amoxycillin	GX
							[a] Terry White Chemists Amoxycillin	TW
				[B]0.79	8.91	9.15	[a] Amoxil	GK
3300Q	Capsule 500 mg	20	..	..	10.22	11.25	[a] Alphamox 500	AF
							[a] Amohexal	HX
							[a] Amoxycillin-DP	GM
							[a] Amoxycillin Sandoz	SZ
							[a] APO-Amoxycillin	TX
							[a] Chem mart Amoxycillin	CH
							[a] Cilamox	SI
							[a] GenRx Amoxycillin	GX
							[a] Moxacin	AS
							[a] Terry White Chemists Amoxycillin	TW
				[B]0.80	11.02	11.25	[a] Amoxil	GK
3309E	Sachet containing oral powder 3 g	1	..	..	8.68	9.71	Amoxil	GK

continued ☞

PREPARATIONS WHICH MAY BE PRESCRIBED BY PARTICIPATING DENTAL PRACTITIONERS FOR DENTAL TREATMENT ONLY—cont.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
3302T	Powder for syrup 125 mg per 5 mL, 100 mL	‡ 1	..	..	# 10.42	11.81	[a] Alphamox 125	AF
							[a] Amoxycillin Sandoz	SZ
							[a] Bgramin	GM
							[a] Chem mart Amoxycillin	CH
							[a] GenRx Amoxycillin	GX
							[a] Ranmoxy	RA
							[a] Terry White Chemists Amoxycillin	TW
				B0.95	# 11.37	11.81	[a] Amoxil	GK
3393N	Powder for syrup 250 mg per 5 mL, 100 mL	‡ 1	..	..	# 11.26	12.65	[a] Alphamox 250	AF
							[a] Amohexal	HX
							[a] Amoxycillin Sandoz	SZ
							[a] Bgramin	GM
							[a] Chem mart Amoxycillin	CH
							[a] Cilamox	SI
							[a] GenRx Amoxycillin	GX
							[a] Ranmoxy	RA
							[a] Terry White Chemists Amoxycillin	TW
				B0.79	# 12.05	12.65	[a] Amoxil Forte	GK
5225B	Powder for oral suspension 500 mg per 5 mL, 100 mL	‡ 1	..	..	# 14.27	15.66	Maxamox	SZ
	AMPICILLIN							
3313J	Powder for injection 500 mg	5	..	..	10.65	11.68	[a] Austrapen	LN
							[a] Ibimicyn	GM
3314K	Powder for injection 1 g	5	..	..	13.64	14.67	[a] Aspen Ampicyn	AS
							[a] Austrapen	LN
							[a] Ibimicyn	GM
	• ***Beta-lactamase sensitive penicillins***							
	BENZATHINE BENZYLPENICILLIN							
5027N	Injection 900 mg in 2.3 mL single use pre-filled syringe	10	..	..	292.68	32.90	Bicillin L-A	AS

PREPARATIONS WHICH MAY BE PRESCRIBED BY PARTICIPATING DENTAL PRACTITIONERS FOR DENTAL TREATMENT ONLY—cont.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
	BENZYLPENICILLIN							
3398W	Powder for injection 600 mg	10	..	..	* 40.39	32.90	BenPen	CS
3399X	Powder for injection 3 g	10	..	..	* 62.49	32.90	BenPen	CS
	PHENOXYMETHYLPENICILLIN							
3360W	Tablet 250 mg	50	..	..	* 11.15	12.18	Abbocillin-VK Filmtab	SI
3361X	Tablet 500 mg	50	..	..	* 13.63	14.66	Abbocillin-VK Filmtab	SI
3363B	Capsule 250 mg	50	..	..	10.98	12.01	LPV	AS
				..	10.98	12.01	[a] Cilicaine VK	FM
							[a] Cilopen VK	GM
							[a] Penhexal VK	HX
3364C	Capsule 500 mg	50	..	..	13.41	14.44	LPV	AS
				..	13.41	14.44	[a] Cilicaine VK	FM
							[a] Cilopen VK	GM
							[a] Penhexal VK	HX
5012T	Oral suspension 150 mg (as benzathine) per 5 mL, 100 mL	2	..	..	* 21.97	23.00	Abbocillin-V Cilicaine V	SI FM
	PROCAINE PENICILLIN							
3371K	Injection 1.5 g	5	..	..	87.97	32.90	Cilicaine	SI
	• *Beta-lactamase resistant penicillins*							
	DICLOXACILLIN							
	Restricted Benefit							
	Serious staphylococcal infections.							
5096F	***Capsule 250 mg***	***24***	**..**	**..**	***11.02***	***12.05***	[a] ***Diclocil***	***BQ***
							[a] ***Dicloxsig***	***SI***
							[a] ***Distaph 250***	***AF***
5097G	***Capsule 500 mg***	***24***	**..**	**..**	***16.51***	***17.54***	[a] ***Diclocil***	***BQ***
							[a] ***Dicloxsig***	***SI***
							[a] ***Distaph 500***	***AF***
	FLUCLOXACILLIN							
	CAUTION:							
	Severe cholestatic hepatitis has been reported with this drug. Significant risk factors are age, particularly greater than 55 years, and duration of treatment longer than 14 days.							
5094D	Powder for injection 500 mg	5	..	..	15.06	16.09	[a] Flubiclox	GM
							[a] Flucil	AS

continued ☞

PREPARATIONS WHICH MAY BE PRESCRIBED BY PARTICIPATING DENTAL PRACTITIONERS FOR DENTAL TREATMENT ONLY—cont.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Proprietary Name and Manufacturer	
5095E	Powder for injection 1 g	5	..	..	20.23	21.26	[a]	Flubiclox	GM
							[a]	Flucil	AS
							[a]	HH	

FLUCLOXACILLIN
CAUTION:
Severe cholestatic hepatitis has been reported with this drug. Significant risk factors are age, particularly greater than 55 years, and duration of treatment longer than 14 days.

Restricted Benefit
Serious staphylococcal infections.

5090X	***Capsule 250 mg (as sodium)***	***24***	***..***	***..***	***11.02***	***12.05***	[a]	***Flopen***	***AS***
							[a]	***Staphylex 250***	***AF***
5091Y	***Capsule 500 mg (as sodium)***	***24***	***..***	***..***	***16.51***	***17.54***	[a]	***Flopen***	***AS***
							[a]	***Staphylex 500***	***AF***
5257Q	***Powder for oral liquid 125 mg (as sodium) per 5 mL, 100 mL***	***‡ 1***	***..***	***..***	***# 15.94***	***17.33***		***LN***	
5258R	***Powder for oral liquid 250 mg (as sodium) per 5 mL, 100 mL***	***‡ 1***	***..***	***..***	***# 19.65***	***21.04***		***LN***	

• *Combinations of penicillins, incl. beta-lactamase inhibitors*

AMOXYCILLIN with CLAVULANIC ACID
CAUTION:
Hepatotoxicity has been reported with this drug.

Restricted Benefit
Infections where resistance to amoxycillin is suspected;
Infections where resistance to amoxycillin is proven.

5008N	***Tablet 500 mg-125 mg***	***10***	***..***	***..***	***11.73***	***12.76***	[a]	***Clamoxyl Duo***	***AL***
							[a]	***Curam 500/125***	***SZ***
							[a]	***GA-Amclav 500/125***	***GM***
							[a]	***Moxiclav Duo 500/125***	***AW***
				B1.55	***13.28***	***12.76***	[a]	***Augmentin Duo***	***GK***

continued ☞

PREPARATIONS WHICH MAY BE PRESCRIBED BY PARTICIPATING DENTAL PRACTITIONERS FOR DENTAL TREATMENT ONLY—cont.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Proprietary Name and Manufacturer	
5006L	***Tablet 875 mg-125 mg***	***10***	***..***	***..***	***14.17***	***15.20***	***a***	***Chem mart Amoxycillin and Clavulanic Acid***	***CH***
							a	***Clamoxyl Duo forte***	***AL***
							a	***Clavycillin 875/125***	***CR***
							a	***Curam 875/125***	***SZ***
							a	***GA-Amclav Forte 875/125***	***GM***
							a	***GenRx Amoxycillin and Clavulanic Acid***	***GX***
							a	***Moxiclav Duo Forte 875/125***	***AW***
							a	***Terry White Chemists Amoxycillin and Clavulanic Acid***	***TW***
				B2.04	***16.21***	***15.20***	***a***	***Augmentin Duo forte***	***GK***
5009P	***Powder for syrup 125 mg-31.25 mg per 5 mL, 75 mL***	***‡ 1***	***..***	***..***	***# 12.05***	***13.44***	***a***	***Clamoxyl***	***AL***
				B1.51	***# 13.56***	***13.44***	***a***	***Augmentin***	***GK***
5011R	***Powder for syrup 400 mg-57 mg per 5 mL, 60 mL***	***‡ 1***	***..***	***..***	***# 13.56***	***14.95***	***a***	***Clamoxyl Duo 400***	***AL***
				B1.54	***# 15.10***	***14.95***	***a***	***Augmentin Duo 400***	***GK***

TICARCILLIN with CLAVULANIC ACID

Restricted Benefit

Infections where positive bacteriological evidence confirms that this antibiotic is an appropriate therapeutic agent.

5230G	***Powder for injection 3 g-100 mg (solvent required)*** ***(code 7043Q applies to above item with approved solvent)***	***10***	***..***	***..***	***162.89***	***32.90***		***Timentin***	***GK***

Other beta-lactam antibacterials

- ***First-generation cephalosporins***

CEFALOTIN

3376Q	Powder for injection 1 g	10	..	..	40.35	32.90	a	Cefalotin Sandoz	SZ
							a	Keflin Neutral	AS
							a	HH	

PREPARATIONS WHICH MAY BE PRESCRIBED BY PARTICIPATING DENTAL PRACTITIONERS FOR DENTAL TREATMENT ONLY—cont.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
	CEPHALEXIN							
3317N	Capsule 250 mg	20	..	..	8.42	9.45	[a] Cefalexin Sandoz	SZ
							[a] Cephabell	BF
							[a] Cephalexin Max	XF
							[a] Cephatrust 250	MI
							[a] Chem mart Cephalexin	CH
							[a] Cilex	GM
							[a] GenRx Cephalexin	GX
							[a] Ialex	LN
							[a] Ibilex 250	AF
							[a] Rancef	RA
							[a] Sporahexal	HX
							[a] Terry White Chemists Cephalexin	TW
				[B]3.30	11.72	9.45	[a] Keflex	AS
3318P	Capsule 500 mg	20	..	..	10.34	11.37	[a] Cefalexin Sandoz	SZ
							[a] Cephabell	BF
							[a] Cephalexin Max	XF
							[a] Cephatrust 500	MI
							[a] Chem mart Cephalexin	CH
							[a] Cilex	GM
							[a] GenRx Cephalexin	GX
							[a] Ialex	LN
							[a] Ibilex 500	AF
							[a] Rancef	RA
							[a] Sporahexal	HX
							[a] Terry White Chemists Cephalexin	TW
				[B]4.41	14.75	11.37	[a] Keflex	AS
3319Q	Granules for syrup 125 mg per 5 mL, 100 mL	‡ 1	..	..	# 11.41	12.80	[a] Cefalexin Sandoz	SZ
							[a] Chem mart Cephalexin	CH
							[a] Cilex	GM
							[a] GenRx Cephalexin	GX
							[a] Ialex	LN
							[a] Ibilex 125	AF
							[a] Terry White Chemists Cephalexin	TW
				[B]3.55	# 14.96	12.80	[a] Keflex	AS

continued ☞

PREPARATIONS WHICH MAY BE PRESCRIBED BY PARTICIPATING DENTAL PRACTITIONERS FOR DENTAL TREATMENT ONLY—cont.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
3320R	Granules for syrup 250 mg per 5 mL, 100 mL	‡ 1	..	..	# 12.81	14.20	[a] Cefalexin Sandoz	SZ
							[a] Chem mart Cephalexin	CH
							[a] Cilex	GM
							[a] GenRx Cephalexin	GX
							[a] Ialex	LN
							[a] Ibilex 250	AF
							[a] Terry White Chemists Cephalexin	TW
				B4.38	# 17.19	14.20	[a] Keflex	AS
	• ***Second-generation cephalosporins***							
	CEFACLOR							
	CAUTION:							
	Serum sickness-like reactions have been reported with this drug, especially in children.							
5045M	Tablet 375 mg (sustained release)	10	..	..	12.46	13.49	[a] Cefaclor-GA	GN
							[a] Chem mart Cefaclor CD	CH
							[a] Douglas Cefaclor-CD	GM
							[a] GenRx Cefaclor CD	GX
							[a] Karlor CD	LN
							[a] Keflor CD	AF
							[a] Ozcef	RA
							[a] Terry White Chemists Cefaclor CD	TW
				B5.20	17.66	13.49	[a] Ceclor CD	AS
5046N	Powder for oral suspension 125 mg per 5 mL, 100 mL	‡ 1	..	..	# 13.07	14.46	[a] Aclor 125	AW
							[a] Cefaclor Sandoz	SZ
							[a] Chem mart Cefaclor	CH
							[a] GenRx Cefaclor	GX
							[a] Keflor	AF
							[a] Ozcef	RA
							[a] Terry White Chemists Cefaclor	TW
				B4.18	# 17.25	14.46	[a] Ceclor	AS

continued ☞

PREPARATIONS WHICH MAY BE PRESCRIBED BY PARTICIPATING DENTAL PRACTITIONERS FOR DENTAL TREATMENT ONLY—cont.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Proprietary Name and Manufacturer	
5047P	Powder for oral suspension 250 mg per 5 mL, 75 mL	‡ 1	..	..	# 13.40	14.79	a	Aclor 250	AW
							a	Cefaclor Sandoz	SZ
							a	Chem mart Cefaclor	CH
							a	GenRx Cefaclor	GX
							a	Keflor	AF
							a	Ozcef	RA
							a	Terry White Chemists Cefaclor	TW
				B4.37	# 17.77	14.79	a	Ceclor	AS
	CEFUROXIME AXETIL								
5052X	Tablet 250 mg (base)	14	..	..	18.19	19.22		Zinnat	GK

• *Third-generation cephalosporins*

CEFOTAXIME

Restricted Benefit

Infections where positive bacteriological evidence confirms that this antibiotic is an appropriate therapeutic agent.

5048Q	***Powder for injection 1 g***	***10***	..	..	***27.27***	***28.30***	a	***HH***	
				B25.10	**** 52.39***	***28.32***	a	***Cefotaxime Sandoz***	***SZ***
5049R	***Powder for injection 2 g***	***10***	..	..	***44.60***	***32.90***	a	***HH***	
				B46.50	**** 91.09***	***32.90***	a	***Cefotaxime Sandoz***	***SZ***

Sulfonamides and trimethoprim

• *Combinations of sulfonamides and trimethoprim, incl. derivatives*

TRIMETHOPRIM with SULFAMETHOXAZOLE

CAUTION:

There is an increased risk of severe adverse reactions with this combination in the elderly.

3389J	Tablet 80 mg-400 mg	10	..	..	8.24	9.27		Resprim	AF
3390K	Tablet 160 mg-800 mg	10	..	..	8.96	9.99	a	Bactrim DS	RO
							a	Resprim Forte	AF
				B1.10	10.06	9.99	a	Septrin Forte	SI
3391L	Oral suspension 40 mg-200 mg per 5 mL, 100 mL	‡ 1	..	..	8.62	9.65		Bactrim	RO
				B1.46	10.08	9.65		Septrin	SI

Macrolides, lincosamides and streptogramins

• *Macrolides*

ERYTHROMYCIN

3325B	Capsule 250 mg	25	..	..	9.00	10.03	a	DBL Erythromycin	FA
				B1.35	10.35	10.03	a	Eryc	HH

PREPARATIONS WHICH MAY BE PRESCRIBED BY PARTICIPATING DENTAL PRACTITIONERS FOR DENTAL TREATMENT ONLY—cont.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Proprietary Name and Manufacturer	
	ERYTHROMYCIN ETHYL SUCCINATE								
3336N	Tablet 400 mg (base)	25	..	..	8.93	9.96	a	E-Mycin	AF
				B2.36	11.29	9.96	a	E.E.S. 400 Filmtab	LM
3334L	Powder for oral liquid 200 mg (base) per 5 mL, 100 mL	‡ 1	..	..	# 11.00	12.39	a	E-Mycin 200	AF
				B1.67	# 12.67	12.39	a	E.E.S. 200	LM
3337P	Powder for oral liquid 400 mg (base) per 5 mL, 100 mL	‡ 1	..	..	# 12.23	13.62	a	E-Mycin 400	AF
				B1.35	# 13.58	13.62	a	E.E.S. Granules	LM
	ERYTHROMYCIN LACTOBIONATE								
5088T	Powder for I.V. infusion 1 g (base)	5	..	..	* 50.94	32.90		Erythrocin-I.V.	LM
	• *Lincosamides*								
	CLINDAMYCIN								
	Restricted Benefit								
	Gram-positive coccal infections where these cannot be safely and effectively treated with a penicillin.								
5057E	***Capsule 150 mg***	***24***	***..***	***..***	***19.33***	***20.36***	***a***	***Cleocin***	***KR***
				B1.45	***20.78***	***20.36***	***a***	***Dalacin C***	***PH***
	LINCOMYCIN								
5144R	Injection 600 mg in 2 mL	5	..	..	30.65	31.68		Lincocin	PH
	Other antibacterials								
	• *Glycopeptide antibacterials*								
	VANCOMYCIN								
	Restricted Benefit								
	Prophylaxis of endocarditis in patients hypersensitive to penicillin.								
3323X	***Powder for injection 500 mg (500,000 i.u.) vancomycin activity***	***2***	***..***	***..***	**** 46.09***	***32.90***	***a***	***Vancocin CP***	***AS***
							a	***Vancomycin Sandoz***	***SZ***
							a	***HH***	
5083M	***Powder for injection 1 g (1,000,000 i.u.) vancomycin activity***	***1***	***..***	***..***	***46.07***	***32.90***	***a***	***Vancomycin Sandoz***	***SZ***
							a	***HH***	
	• *Imidazole derivatives*								
	METRONIDAZOLE								
3339R	Tablet 200 mg	21	..	..	7.53	8.56	a	Metrogyl 200	AF
							a	Metronide 200	AV
				B2.30	9.83	8.56	a	Flagyl	SW
5159M	Tablet 400 mg	5	..	..	7.45	8.48		Metrogyl 400	AF

continued ☞

PREPARATIONS WHICH MAY BE PRESCRIBED BY PARTICIPATING DENTAL PRACTITIONERS FOR DENTAL TREATMENT ONLY—cont.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Proprietary Name and Manufacturer	
5157K	Suppositories 500 mg, 10	‡ 1	..	..	22.73	23.76		Flagyl	SW
	METRONIDAZOLE								
	Restricted Benefit								
	Treatment of anaerobic infections.								
5155H	***Tablet 400 mg***	***21***	..	..	***9.60***	***10.63***	[a]	***Metrogyl 400***	***AF***
							[a]	***Metronide 400***	***AV***
				B2.30	***11.90***	***10.63***	[a]	***Flagyl***	***SW***
	Restricted Benefit								
	Treatment, in a hospital, of acute anaerobic sepsis.								
5154G	***I.V. infusion 500 mg in 100 mL***	***5***	..	..	**** 31.54***	***32.57***	[a]	***BX***	
				..	**** 31.54***	***32.57***	[a]	***DBL Metronidazole Intravenous Infusion***	***HH***
							[a]	***Metronidazole Sandoz***	***SZ***
	METRONIDAZOLE BENZOATE								
3341W	Oral suspension 320 mg per 5 mL (equivalent to 200 mg metronidazole in 5 mL), 100 mL	‡ 1	..	..	16.74	17.77		Flagyl S	SW

MUSCULO-SKELETAL SYSTEM

ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS

Antiinflammatory and antirheumatic products, non-steroids

- ***Acetic acid derivatives and related substances***

DICLOFENAC SODIUM

5079H	Suppository 100 mg	40	..	..	* 24.49	25.52		Voltaren 100	NV

continued ☞

PREPARATIONS WHICH MAY BE PRESCRIBED BY PARTICIPATING DENTAL PRACTITIONERS FOR DENTAL TREATMENT ONLY—cont.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Proprietary Name and Manufacturer	
	DICLOFENAC SODIUM								
	Restricted Benefit								
	Chronic arthropathies (including osteoarthritis) with an inflammatory component;								
	Bone pain due to malignant disease.								
5076E	***Tablet 25 mg (enteric coated)***	***100***	***..***	***..***	**** 12.63***	***13.66***	[a]	***Chem mart Diclofenac***	***CH***
							[a]	***Clonac 25***	***AW***
							[a]	***Diclofenac-GA***	***GN***
							[a]	***Diclohexal***	***SZ***
							[a]	***Dinac***	***GM***
							[a]	***GenRx Diclofenac***	***GX***
							[a]	***Terry White Chemists Diclofenac***	***TW***
				..	***12.64***	***13.67***	[a]	***Fenac 25***	***AF***
				[B]1.96	**** 14.59***	***13.66***	[a]	***Voltaren 25***	***NV***
5077F	***Tablet 50 mg (enteric coated)***	***50***	***..***	***..***	***10.62***	***11.65***	[a]	***Chem mart Diclofenac***	***CH***
							[a]	***Clonac 50***	***AW***
							[a]	***Diclohexal***	***SZ***
							[a]	***Dinac***	***GM***
							[a]	***Fenac***	***AF***
							[a]	***GenRx Diclofenac***	***GX***
							[a]	***Terry White Chemists Diclofenac***	***TW***
				[B]1.96	***12.58***	***11.65***	[a]	***Voltaren 50***	***NV***
	INDOMETHACIN								
5128X	Suppository 100 mg	40	..	..	* 22.07	23.10		Indocid	AS

	INDOMETHACIN								
	Restricted Benefit								
	Chronic arthropathies (including osteoarthritis) with an inflammatory component;								
	Bone pain due to malignant disease.								
5126T	***Capsule 25 mg***	***100***	***..***	***..***	**** 11.65***	***12.68***	[a]	***Arthrexin***	***AF***
				[B]0.92	**** 12.57***	***12.68***	[a]	***Indocid***	***AS***

PREPARATIONS WHICH MAY BE PRESCRIBED BY PARTICIPATING DENTAL PRACTITIONERS FOR DENTAL TREATMENT ONLY—cont.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Proprietary Name and Manufacturer	
	SULINDAC								
	Restricted Benefit								
	Chronic arthropathies (including osteoarthritis) with an inflammatory component;								
	Bone pain due to malignant disease.								
5217N	***Tablet 100 mg***	***100***	***..***	***..***	**** 15.91***	***16.94***		***Aclin***	***AF***
5218P	***Tablet 200 mg***	***50***	***..***	***..***	***14.85***	***15.88***		***Aclin 200***	***AF***
	• *Oxicams*								
	PIROXICAM								
	Restricted Benefit								
	Chronic arthropathies (including osteoarthritis) with an inflammatory component.								
5201R	***Dispersible tablet 10 mg***	***50***	***..***	***..***	***12.07***	***13.10***	[a]	***Mobilis D-10***	***AF***
				B2.09	***14.16***	***13.10***	[a]	***Feldene-D***	***PF***
5202T	***Dispersible tablet 20 mg***	***25***	***..***	***..***	***11.77***	***12.80***	[a]	***Mobilis D-20***	***AF***
				B2.07	***13.84***	***12.80***	[a]	***Feldene-D***	***PF***
5203W	***Capsule 10 mg***	***50***	***..***	***..***	***12.07***	***13.10***	[a]	***Chem mart Piroxicam***	***CH***
							[a]	***GenRx Piroxicam***	***GX***
							[a]	***Mobilis 10***	***AF***
							[a]	***Terry White Chemists Piroxicam***	***TW***
				B2.09	***14.16***	***13.10***	[a]	***Feldene***	***PF***
5204X	***Capsule 20 mg***	***25***	***..***	***..***	***11.77***	***12.80***	[a]	***Chem mart Piroxicam***	***CH***
							[a]	***GenRx Piroxicam***	***GX***
							[a]	***Mobilis 20***	***AF***
							[a]	***Terry White Chemists Piroxicam***	***TW***
				B2.07	***13.84***	***12.80***	[a]	***Feldene***	***PF***
	• *Propionic acid derivatives*								
	IBUPROFEN								
5124Q	Tablet 400 mg	30	..	..	8.76	9.79		Brufen	AB

continued ☞

PREPARATIONS WHICH MAY BE PRESCRIBED BY PARTICIPATING DENTAL PRACTITIONERS FOR DENTAL TREATMENT ONLY—cont.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Proprietary Name and Manufacturer	
	IBUPROFEN								
	Restricted Benefit ***Chronic arthropathies (including osteoarthritis) with an inflammatory component;*** ***Bone pain due to malignant disease.***								
5121M	***Tablet 200 mg***	***100***	***..***	***..***	**** 11.63***	***12.66***		***Rafen 200***	***AF***
5123P	***Tablet 400 mg***	***90***	***..***	***..***	**** 14.30***	***15.33***		***Brufen***	***AB***
	KETOPROFEN								
5139L	Suppository 100 mg	40	..	..	* 24.87	25.90		Orudis	SW
	KETOPROFEN								
	Restricted Benefit ***Chronic arthropathies (including osteoarthritis) with an inflammatory component.***								
5136H	***Capsule 200 mg (sustained release)***	***28***	***..***	***..***	***19.47***	***20.50***	***a***	***Oruvail SR***	***AV***
				B2.30	***21.77***	***20.50***	***a***	***Orudis SR 200***	***SW***
	NAPROXEN								
	Restricted Benefit ***Chronic arthropathies (including osteoarthritis) with an inflammatory component;*** ***Bone pain due to malignant disease.***								
5176K	***Tablet 250 mg***	***100***	***..***	***..***	**** 13.29***	***14.32***	***a***	***Inza 250***	***AF***
				B2.34	**** 15.63***	***14.32***	***a***	***Naprosyn***	***RO***
5177L	***Tablet 500 mg***	***50***	***..***	***..***	***12.48***	***13.51***	***a***	***Inza 500***	***AF***
				B1.36	***13.84***	***13.51***	***a***	***Naprosyn***	***RO***
5178M	***Tablet 750 mg (sustained release)***	***28***	***..***	***..***	***11.95***	***12.98***	***a***	***Proxen SR 750***	***MD***
				B1.27	***13.22***	***12.98***	***a***	***Naprosyn SR750***	***RO***
5179N	***Tablet 1 g (sustained release)***	***28***	***..***	***..***	***13.94***	***14.97***	***a***	***Proxen SR 1000***	***MD***
				B1.34	***15.28***	***14.97***	***a***	***Naprosyn SR1000***	***RO***
	NAPROXEN SODIUM								
	Restricted Benefit ***Chronic arthropathies (including osteoarthritis) with an inflammatory component;*** ***Bone pain due to malignant disease.***								
5186Y	***Tablet 550 mg***	***50***	***..***	***..***	***12.67***	***13.70***	***a***	***Crysanal***	***MD***
				B2.29	***14.96***	***13.70***	***a***	***Anaprox 550***	***RO***

NOTE:
Naproxen sodium 550 mg is approximately equivalent to 500 mg of naproxen acid.

PREPARATIONS WHICH MAY BE PRESCRIBED BY PARTICIPATING DENTAL PRACTITIONERS FOR DENTAL TREATMENT ONLY—cont.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
	NERVOUS SYSTEM							
	ANALGESICS							
	Opioids							
	• ***Natural opium alkaloids***							
	CODEINE PHOSPHATE							
5063L	Tablet 30 mg	20	..	..	16.44	17.47	FM	
	NOTE: Prescribing of drugs of addiction by dentists is not permitted in some States/Territories.							
	CODEINE PHOSPHATE with PARACETAMOL							
3316M	Tablet 30 mg-500 mg	20	..	..	7.65	8.68	[a] Codalgin Forte	FM
							[a] Codapane Forte	AL
							[a] Comfarol Forte	SZ
							[a] Dolaforte	CO
							[a] Prodeine Forte	AV
				B2.80	10.45	8.68	[a] Panadeine Forte	SW
	HYDROMORPHONE HYDROCHLORIDE **CAUTION:** The risk of drug dependence is high.							
5129Y	Injection 2 mg in 1 mL	5	..	..	13.51	14.54	Dilaudid	MF
5130B	Injection 10 mg in 1 mL	5	..	..	18.87	19.90	Dilaudid-HP	MF
5131C	Injection 50 mg in 5 mL	5	..	..	47.07	32.90	Dilaudid-HP	MF
	NOTE: Prescribing of drugs of addiction by dentists is not permitted in some States/Territories.							
	HYDROMORPHONE HYDROCHLORIDE **CAUTION:** ***The risk of drug dependence is high.***							
	Restricted Benefit ***Severe disabling pain not responding to non-narcotic analgesics.***							
5115F	***Tablet 2 mg***	***20***	..	..	***13.79***	***14.82***	***Dilaudid***	***MF***
5116G	***Tablet 4 mg***	***20***	..	..	***18.85***	***19.88***	***Dilaudid***	***MF***
5117H	***Tablet 8 mg***	***20***	..	..	***28.61***	***29.64***	***Dilaudid***	***MF***
5132D	***Oral liquid 1 mg per mL, 473 mL***	***1***	..	..	***49.09***	***32.90***	***Dilaudid***	***MF***
	NOTE: ***Prescribing of drugs of addiction by dentists is not permitted in some States/Territories.***							

PREPARATIONS WHICH MAY BE PRESCRIBED BY PARTICIPATING DENTAL PRACTITIONERS FOR DENTAL TREATMENT ONLY—cont.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
	MORPHINE HYDROCHLORIDE							
	CAUTION:							
	The risk of drug dependence is high.							
	Restricted Benefit							
	Severe disabling pain not responding to non-narcotic analgesics.							
5237P	***Oral solution 2 mg per mL, 200 mL***	***1***	***..***	***..***	***18.73***	***19.76***	***Ordine 2***	***MF***
5238Q	***Oral solution 5 mg per mL, 200 mL***	***1***	***..***	***..***	***21.64***	***22.67***	***Ordine 5***	***MF***
5239R	***Oral solution 10 mg per mL, 200 mL***	***1***	***..***	***..***	***26.24***	***27.27***	***Ordine 10***	***MF***
	NOTE:							
	Prescribing of drugs of addiction by dentists is not permitted in some States/Territories.							
	MORPHINE SULFATE							
	CAUTION:							
	The risk of drug dependence is high.							
5168B	Injection 10 mg in 1 mL	5	..	..	13.77	14.80	HH	
5169C	Injection 15 mg in 1 mL	5	..	..	14.13	15.16	HH	
5170D	Injection 30 mg in 1 mL	5	..	..	15.61	16.64	HH	
	NOTE:							
	Prescribing of drugs of addiction by dentists is not permitted in some States/Territories.							
	MORPHINE SULFATE							
	CAUTION:							
	The risk of drug dependence is high.							
	Restricted Benefit							
	Severe disabling pain not responding to non-narcotic analgesics.							
5163R	***Tablet 30 mg***	***20***	***..***	***..***	***14.53***	***15.56***	***Anamorph***	***FM***
	NOTE:							
	Prescribing of drugs of addiction by dentists is not permitted in some States/Territories.							
	Restricted Benefit							
	Chronic severe disabling pain not responding to non-narcotic analgesics.							
5162Q	***Tablet 5 mg (controlled release)***	***20***	***..***	***..***	***15.89***	***16.92***	***MS Contin***	***MF***
5164T	***Tablet 10 mg (controlled release)***	***20***	***..***	***..***	***17.97***	***19.00***	***MS Contin***	***MF***
5161P	***Tablet 15 mg (controlled release)***	***20***	***..***	***..***	***21.52***	***22.55***	***MS Contin***	***MF***
5165W	***Tablet 30 mg (controlled release)***	***20***	***..***	***..***	***31.44***	***32.47***	***MS Contin***	***MF***

continued ☞

PREPARATIONS WHICH MAY BE PRESCRIBED BY PARTICIPATING DENTAL PRACTITIONERS FOR DENTAL TREATMENT ONLY—cont.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
5166X	*Tablet 60 mg (controlled release)*	*20*	*..*	*..*	*47.92*	*32.90*	*MS Contin*	*MF*
5167Y	*Tablet 100 mg (controlled release)*	*20*	*..*	*..*	*62.58*	*32.90*	*MS Contin*	*MF*
5246D	*Capsule 10 mg (containing sustained release pellets)*	*20*	*..*	*..*	*17.97*	*19.00*	*Kapanol*	*GK*
5240T	*Capsule 20 mg (containing sustained release pellets)*	*20*	*..*	*..*	*22.20*	*23.23*	*Kapanol*	*GK*
5064M	*Capsule 30 mg (controlled release)*	*10*	*..*	*..*	*21.52*	*22.55*	*MS Mono*	*MF*
5241W	*Capsule 50 mg (containing sustained release pellets)*	*20*	*..*	*..*	*37.75*	*32.90*	*Kapanol*	*GK*
5065N	*Capsule 60 mg (controlled release)*	*10*	*..*	*..*	*31.44*	*32.47*	*MS Mono*	*MF*
5066P	*Capsule 90 mg (controlled release)*	*10*	*..*	*..*	*36.15*	*32.90*	*MS Mono*	*MF*
5242X	*Capsule 100 mg (containing sustained release pellets)*	*20*	*..*	*..*	*60.83*	*32.90*	*Kapanol*	*GK*
5067Q	*Capsule 120 mg (controlled release)*	*10*	*..*	*..*	*47.92*	*32.90*	*MS Mono*	*MF*
5171E	*Sachet containing controlled release granules for oral suspension, 20 mg per sachet*	*20*	*..*	*..*	*48.36*	*32.90*	*MS Contin Suspension 20 mg*	*MF*
5243Y	*Sachet containing controlled release granules for oral suspension, 30 mg per sachet*	*20*	*..*	*..*	*49.60*	*32.90*	*MS Contin Suspension 30 mg*	*MF*
5244B	*Sachet containing controlled release granules for oral suspension, 60 mg per sachet*	*20*	*..*	*..*	*54.95*	*32.90*	*MS Contin Suspension 60 mg*	*MF*
5245C	*Sachet containing controlled release granules for oral suspension, 100 mg per sachet*	*20*	*..*	*..*	*67.09*	*32.90*	*MS Contin Suspension 100 mg*	*MF*
	NOTE: *Prescribing of drugs of addiction by dentists is not permitted in some States/Territories.*							
	OXYCODONE **CAUTION:** *The risk of drug dependence is high.*							
	Restricted Benefit *Severe disabling pain not responding to non-narcotic analgesics.*							
5194J	*Suppository 30 mg*	*12*	*..*	*..*	*43.23*	*32.90*	*Proladone*	*PL*
	NOTE: *Prescribing of drugs of addiction by dentists is not permitted in some States/Territories.*							

PREPARATIONS WHICH MAY BE PRESCRIBED BY PARTICIPATING DENTAL PRACTITIONERS FOR DENTAL TREATMENT ONLY—cont.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
	OXYCODONE HYDROCHLORIDE							
	CAUTION:							
	The risk of drug dependence is high.							
	Restricted Benefit							
	Severe disabling pain not responding to non-narcotic analgesics.							
5195K	***Tablet 5 mg***	***20***	***..***	***..***	***11.87***	***12.90***	***Endone***	***SI***
5191F	***Capsule 5 mg***	***20***	***..***	***..***	***11.87***	***12.90***	***OxyNorm***	***MF***
5197M	***Capsule 10 mg***	***20***	***..***	***..***	***14.99***	***16.02***	***OxyNorm***	***MF***
5198N	***Capsule 20 mg***	***20***	***..***	***..***	***19.72***	***20.75***	***OxyNorm***	***MF***
5190E	***Oral solution 5 mg per 5 mL, 250 mL***	***1***	***..***	***..***	***20.29***	***21.32***	***OxyNorm Liquid 5mg/5mL***	***MF***
	NOTE:							
	Prescribing of drugs of addiction by dentists is not permitted in some States/Territories.							
	Restricted Benefit							
	Chronic severe disabling pain not responding to non-narcotic analgesics.							
5227D	***Tablet 5 mg (controlled release)***	***20***	***..***	***..***	***20.75***	***21.78***	***OxyContin***	***MF***
5247E	***Tablet 10 mg (controlled release)***	***20***	***..***	***..***	***21.52***	***22.55***	***OxyContin***	***MF***
5248F	***Tablet 20 mg (controlled release)***	***20***	***..***	***..***	***31.44***	***32.47***	***OxyContin***	***MF***
5249G	***Tablet 40 mg (controlled release)***	***20***	***..***	***..***	***47.92***	***32.90***	***OxyContin***	***MF***
5250H	***Tablet 80 mg (controlled release)***	***20***	***..***	***..***	***71.27***	***32.90***	***OxyContin***	***MF***
	NOTE:							
	Prescribing of drugs of addiction by dentists is not permitted in some States/Territories.							

PREPARATIONS WHICH MAY BE PRESCRIBED BY PARTICIPATING DENTAL PRACTITIONERS FOR DENTAL TREATMENT ONLY—cont.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Proprietary Name and Manufacturer	
	• Other opioids								
	TRAMADOL HYDROCHLORIDE								
	Restricted Benefit								
	For acute pain where aspirin and/or paracetamol alone are inappropriate or have failed;								
	For dosage titration in chronic pain where aspirin and/or paracetamol alone are inappropriate or have failed.								
5232J	*Capsule 50 mg*	*20*	*..*	*..*	*8.73*	*9.76*	[a]	*Chem mart Tramadol*	*CH*
							[a]	*GenRx Tramadol*	*GX*
							[a]	*Terry White Chemists Tramadol*	*TW*
							[a]	*Tramedo*	*AF*
							[a]	*Zydol*	*AW*
				[B]2.42	*11.15*	*9.76*	[a]	*Tramal*	*CS*
	Restricted Benefit								
	For pain where aspirin and/or paracetamol alone are inappropriate or have failed.								
3338Q	*Tablet 50 mg (twice daily sustained release)*	*20*	*..*	*..*	*11.20*	*12.23*		*Tramal SR 50*	*CS*
5234L	*Tablet 100 mg (twice daily sustained release)*	*20*	*..*	*..*	*13.43*	*14.46*	[a]	*Tramahexal SR*	*SZ*
							[a]	*Tramedo SR 100*	*AF*
							[a]	*Zydol SR 100*	*AW*
				[B]4.51	*17.94*	*14.46*	[a]	*Tramal SR 100*	*CS*
5001F	*Tablet 100 mg (once a day extended release)*	*10*	*..*	*..*	*12.94*	*13.97*		*Durotram XR*	*IA*
5235M	*Tablet 150 mg (twice daily sustained release)*	*20*	*..*	*..*	*16.02*	*17.05*	[a]	*Tramahexal SR*	*SZ*
							[a]	*Tramedo SR 150*	*AF*
							[a]	*Zydol SR 150*	*AW*
				[B]5.37	*21.39*	*17.05*	[a]	*Tramal SR 150*	*CS*
5236N	*Tablet 200 mg (twice daily sustained release)*	*20*	*..*	*..*	*18.20*	*19.23*	[a]	*Tramahexal SR*	*SZ*
							[a]	*Tramedo SR 200*	*AF*
							[a]	*Zydol SR 200*	*AW*
				[B]6.09	*24.29*	*19.23*	[a]	*Tramal SR 200*	*CS*
5002G	*Tablet 200 mg (once a day extended release)*	*10*	*..*	*..*	*15.91*	*16.94*		*Durotram XR*	*IA*
5003H	*Tablet 300 mg (once a day extended release)*	*10*	*..*	*..*	*19.36*	*20.39*		*Durotram XR*	*IA*
5150C	*Oral drops 100 mg per mL, 10 mL*	*‡ 1*	*..*	*..*	*13.28*	*14.31*		*Tramal*	*CS*

continued ☞

PREPARATIONS WHICH MAY BE PRESCRIBED BY PARTICIPATING DENTAL PRACTITIONERS FOR DENTAL TREATMENT ONLY—cont.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
	Restricted Benefit							
	Short-term treatment of acute pain.							
5231H	***Injection 100 mg in 2 mL***	***5***	***..***	***..***	***13.87***	***14.90***	***Tramal 100***	***CS***
	Other analgesics and antipyretics							
	• ***Salicylic acid and derivatives***							
	ASPIRIN							
5018D	Tablet 300 mg (dispersible)	96	..	..	8.21	9.24	Solprin	RC
	• ***Anilides***							
	PARACETAMOL							
5196L	Tablet 500 mg	100	..	..	7.99	9.02	[a] Chem mart Chemadol	CH
							[a] Dymadon P	PC
							[a] Febridol	GM
							[a] Panamax	SW
							[a] Paracetamol Sandoz	SZ
							[b] Parahexal	HX
							[a] Paralgin	FM
							[b] Parmol	SI
							[a] Pharmacy Choice Paracetamol	YM
							[a] Terry White Chemists Paracetamol	TW
3348F	Oral liquid 120 mg per 5 mL, 100 mL	‡ 1	..	..	8.95	9.98	Panamax	SW
3349G	Oral liquid 240 mg per 5 mL, 200 mL	‡ 1	..	..	10.25	11.28	Panamax 240 Elixir	SW

continued ☞

PREPARATIONS WHICH MAY BE PRESCRIBED BY PARTICIPATING DENTAL PRACTITIONERS FOR DENTAL TREATMENT ONLY—cont.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Proprietary Name and Manufacturer	
	PARACETAMOL								
	Restricted Benefit								
	Chronic arthropathies.								
5224Y	***Tablet 500 mg***	***300***	***..***	***..***	**** 11.99***	***13.02***	[a]	***Chem mart Chemadol***	***CH***
							[a]	***Dymadon P***	***PC***
							[a]	***Febridol***	***GM***
							[a]	***Panamax***	***SW***
							[a]	***Paracetamol Sandoz***	***SZ***
							[b]	***Parahexal***	***HX***
							[a]	***Paralgin***	***FM***
							[b]	***Parmol***	***SI***
							[a]	***Pharmacy Choice Paracetamol***	***YM***
							[a]	***Terry White Chemists Paracetamol***	***TW***
	ANTIEPILEPTICS								
	Antiepileptics								
	• ***Carboxamide derivatives***								
	CARBAMAZEPINE								
5039F	Tablet 100 mg	200	..	..	18.71	19.74	[a]	Carbamazepine Sandoz	SZ
				B2.55	21.26	19.74	[a]	Tegretol 100	NV
5040G	Tablet 200 mg	200	..	..	29.77	30.80	[a]	Carbamazepine Sandoz	SZ
							[a]	Teril	AF
				B2.74	32.51	30.80	[a]	Tegretol 200	NV
5038E	Tablet 200 mg (controlled release)	200	..	..	30.26	31.29		Tegretol CR 200	NV
5037D	Tablet 400 mg (controlled release)	200	..	..	50.59	32.90		Tegretol CR 400	NV
5041H	Oral suspension 100 mg per 5 mL, 300 mL	‡ 1	..	..	20.92	21.95		Tegretol Liquid	NV
	ANTI-PARKINSON DRUGS								
	Anticholinergic agents								
	• ***Ethers of tropine or tropine derivatives***								
	BENZTROPINE MESYLATE								
5031T	Injection 2 mg in 2 mL	5	..	..	22.41	23.44		Cogentin	FK

PREPARATIONS WHICH MAY BE PRESCRIBED BY PARTICIPATING DENTAL PRACTITIONERS FOR DENTAL TREATMENT ONLY—cont.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
	PSYCHOLEPTICS							
	Anxiolytics							
	• ***Benzodiazepine derivatives***							
	DIAZEPAM							
5071X	Tablet 2 mg	50	..	..	7.36	8.39	[a] Antenex 2	AF
							[a] Valpam 2	SI
				[B]0.59	7.95	8.39	Ducene	SU
				[B]0.86	8.22	8.39	[a] Valium	RO
5072Y	Tablet 5 mg	50	..	..	7.50	8.53	[a] Antenex 5	AF
							[a] Diazepam-DP	GM
							[a] Ranzepam	RA
							[a] Valpam 5	SI
				[B]0.63	8.13	8.53	Ducene	SU
				[B]0.88	8.38	8.53	[a] Valium	RO
5073B	Injection 10 mg in 2 mL	5	..	..	11.86	12.89	HH	
	OXAZEPAM							
5192G	Tablet 15 mg	25	..	..	7.27	8.30	[a] Alepam 15	AF
				[B]1.78	9.05	8.30	[a] Serepax	SI
5193H	Tablet 30 mg	25	..	..	7.46	8.49	[a] Alepam 30	AF
							[a] Murelax	FM
				[B]1.90	9.36	8.49	[a] Serepax	SI
	Hypnotics and sedatives							
	• ***Benzodiazepine derivatives***							
	NITRAZEPAM							
5189D	Tablet 5 mg	25	..	..	7.46	8.49	[a] Alodorm	AF
				[B]1.53	8.99	8.49	[a] Mogadon	VT
	TEMAZEPAM							
5221T	Tablet 10 mg	25	..	..	7.46	8.49	[a] Temaze	AF
							[a] Temtabs	FM
				[B]1.38	8.84	8.49	[a] Normison	SI
	RESPIRATORY SYSTEM							
	DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES							
	Adrenergics for systemic use							
	• ***Alpha- and beta-adrenoceptor agonists***							
	ADRENALINE							
5004J	Injection 1 mg in 1 mL (1 in 1,000)	5	..	..	19.91	20.94	AP	

PREPARATIONS WHICH MAY BE PRESCRIBED BY PARTICIPATING DENTAL PRACTITIONERS FOR DENTAL TREATMENT ONLY—cont.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
	SENSORY ORGANS							
	OPHTHALMOLOGICALS							
	Antiinfectives							
	• ***Antibiotics***							
	CHLORAMPHENICOL							
5055C	Eye drops 5 mg per mL (0.5%), 10 mL	‡ 1	..	..	8.88	9.91	Chloromycetin Chlorsig	PF SI
	VARIOUS							
	ALL OTHER THERAPEUTIC PRODUCTS							
	All other therapeutic products							
	• ***Antidotes***							
	NALOXONE HYDROCHLORIDE							
5174H	Injection 800 micrograms in 2 mL	1	..	..	27.89	28.92	Naloxone Min-I-Jet	CS
5175J	Injection 2 mg in 5 mL	1	..	..	40.93	32.90	Naloxone Min-I-Jet	CS
	ALL OTHER NON-THERAPEUTIC PRODUCTS							
	All other non-therapeutic products							
	• ***Solvents and diluting agents, incl. irrigating solutions***							
	SODIUM CHLORIDE							
5211G	Injection 9 mg per mL (0.9%), 10 mL	5	..	..	17.73	18.76	PF	

PREPARATIONS WHICH MAY BE PRESCRIBED BY AUTHORISED OPTOMETRISTS FOR OPTOMETRICAL TREATMENT ONLY

From 1 January 2008, optometrists accredited to prescribe under State or Territory legislation can apply for approval as PBS prescribers (*authorised optometrists*). Information for optometrists on becoming a PBS prescriber is available on the Medicare Australia website at: www.medicareaustralia.gov.au

The medications listed in this section are for prescribing by authorised optometrists only. Optometrists must not write PBS prescriptions for medicines listed elsewhere in the PBS Schedule.

The Pharmaceutical Benefits Advisory Committee (PBAC) is responsible for making recommendations regarding preparations for inclusion in the optometrist section.

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

Optometrist PBS prescriptions are identifiable by colour, and include the words 'PBS/RPBS optometrist'. Prescriptions must include the optometrist's PBS prescriber number. The same optometrist prescription form is used to prescribe unrestricted, restricted or authority items. Only one item is allowed per form. Optometrist PBS prescriptions may include repeats.

Regulation 24 does not apply for optometrist prescribing. An optometrist cannot direct that original and repeat supplies of pharmaceutical benefits be supplied at the one time.

Authority prescriptions: Authority prescriptions for authority required items, or for increased quantities or repeats, require prior approval from Medicare Australia or the DVA for each prescription. (Refer to details in the Explanatory Notes section under Prescribing Medicines — Information for PBS prescribers and Supplying Medicines — What Pharmacists Need to Know, for more information on authority prescriptions.) DVA approval for non-Schedule items is not available for optometrist prescribing.

RPBS: Optometrists approved as PBS prescribers may write prescriptions for supply under the RPBS. The list of optometrist medicines under the RPBS is the same as the PBS. There are no optometrist listings in the Repatriation Schedule for prescribing for veterans only. There is no provision for optometrist prescribers to request approval to prescribe items that are not included in the PBS optometrist list (non-Schedule items).

State and Territory requirements: Optometrists may prescribe medications as private prescriptions according to their State/Territory prescribing accreditation. The medicines which can be prescribed differ between States and Territories. It is the optometrist's responsibility to ensure adherence to State/Territory law for all prescriptions (PBS and private) and additionally to all PBS requirements for PBS/RPBS prescriptions.

GENERAL STATEMENT FOR TOPICAL ANTI-GLAUCOMA DRUGS PRESCRIBED BY AUTHORISED OPTOMETRISTS AS PHARMACEUTICAL BENEFITS

Use the following guidelines to determine patient eligibility for subsidisation under the PBS for the following drugs prescribed by authorised optometrists:

- Betaxolol hydrochloride
- Bimatoprost
- Brimonidine tartrate
- Brimonidine tartrate with timolol maleate
- Brinzolamide
- Dorzolamide hydrochloride
- Dorzolamide hydrochloride with timolol maleate
- Latanoprost
- Latanoprost with timolol maleate
- Pilocarpine hydrochloride
- Timolol maleate
- Travoprost
- Travoprost with timolol maleate

By writing a PBS prescription, the prescriber is certifying the criteria set out in these guidelines are satisfied, and use is in accordance with the registered indications – refer to the current Product Information for details.

GUIDELINES FOR SHARED CARE OF GLAUCOMA PATIENTS

Under these guidelines, authorised optometrists who are approved to use therapeutic drugs in their practices and who have adequate professional indemnity cover, will be able to co-manage glaucoma patients in a shared care arrangement with an ophthalmologist.

Initial Referral to Ophthalmologist

An authorised optometrist who makes a provisional diagnosis of glaucoma is to refer the patient to an ophthalmologist for confirmation of the diagnosis and the development of a management plan.

Where clinically important delays are expected before the patient's first review by an ophthalmologist, the optometrist should seek interim advice on the patient's management from the ophthalmologist by telephone (or alternate means).

The patient's consent is to be obtained by the ophthalmologist and optometrist for all aspects of the management plan, including the sharing of care between the two practitioners, and the communication of clinical information to the patient's nominated general practitioner.

Once the diagnosis of glaucoma is confirmed by the ophthalmologist and a treatment plan is in place for the patient, the optometrist can perform ongoing reviews to monitor the patient and prescribe topical drugs under the PBS providing that:

- Periodic review demonstrates the treatment to be effective, and
- Changes to management are only initiated following consultation between treating practitioners.

Patient Management Plan

The management plan must be in writing and specify the following:

1. All the agreed components of treatment including any drug therapy;
2. Target pressures and action to be taken if these are not achieved within a specified time frame;
3. An agreed approach to monitoring visual fields and optic disc imaging and action to be taken following changes in visual fields;
4. Triggers for referral for more immediate ophthalmological review;
5. Likely side effects from agreed treatment and the action to be taken to address these;
6. An agreed schedule for patient review by both practitioners;
7. Who is responsible for performing each of the required tests and the required frequency for performing them;
8. An agreed method for timely communication of clinical findings between the two practitioners and the patient's nominated general practitioner.

Ophthalmologists must be available for consultation by the treating optometrist and for consultation by the patient where that consultation has been recommended or requested by the optometrist.

The involvement of a pharmacist to provide medicines information, advice relating to administration and techniques to limit systemic absorption and side effects of ophthalmic medications is recommended.

PREPARATIONS WHICH MAY BE PRESCRIBED BY AUTHORISED OPTOMETRISTS FOR OPTOMETRICAL TREATMENT ONLY-cont.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
	SENSORY ORGANS							
	OPHTHALMOLOGICALS							
	Antiinfectives							
	• ***Antibiotics***							
	CHLORAMPHENICOL							
5512D	Eye drops 5 mg per mL (0.5%), 10 mL	‡ 1	2	..	8.88	9.91	Chloromycetin Chlorsig	PF SI
5511C	Eye ointment 10 mg per g (1%), 4 g	‡ 1	..	..	9.33	10.36	Chloromycetin Chlorsig	PF SI
	• ***Sulfonamides***							
	SULFACETAMIDE SODIUM							
5530C	Eye drops 100 mg per mL (10%), 15 mL	‡ 1	2	..	13.35	14.38	Bleph 10	AG
	• ***Antivirals***							
	ACICLOVIR							
	Restricted Benefit ***Herpes simplex keratitis.***							
5501M	***Eye ointment 30 mg per g (3%), 4.5 g***	***‡ 1***	***..***	***..***	***34.63***	***32.90***	***Zovirax***	***GK***
	Antiinflammatory agents							
	• ***Corticosteroids, plain***							
	FLUOROMETHOLONE							
5513E	Eye drops 1 mg per mL (0.1%), 5 mL	‡ 1	..	..	10.18	11.21	Flucon FML Liquifilm	AQ AG
	NOTE: No applications for increased maximum quantities and/or repeats will be authorised.							
	FLUOROMETHOLONE ACETATE							
5533F	Eye drops 1 mg per mL (0.1%), 5 mL	‡ 1	..	..	10.18	11.21	Flarex	AQ
	NOTE: No applications for increased maximum quantities and/or repeats will be authorised.							
	HYDROCORTISONE ACETATE							
5515G	Eye ointment 5 mg per g (0.5%), 5 g	‡ 1	..	..	11.35	12.38	Hycor	SI
5516H	Eye ointment 10 mg per g (1%), 5 g	‡ 1	..	..	12.65	13.68	Hycor	SI
	NOTE: No applications for increased maximum quantities and/or repeats will be authorised.							

PREPARATIONS WHICH MAY BE PRESCRIBED BY AUTHORISED OPTOMETRISTS FOR OPTOMETRICAL TREATMENT ONLY-cont.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Proprietary Name and Manufacturer	
	• *Antiinflammatory agents, non-steroids*								
	FLURBIPROFEN SODIUM								
5514F	Eye drops 300 micrograms per mL (0.03%), single dose units 0.4 mL, 5	1	..	..	14.94	15.97		Ocufen	AG
	Antiglaucoma preparations and miotics								
	• *Sympathomimetics in glaucoma therapy*								
	BRIMONIDINE TARTRATE								
5534G	Eye drops 2 mg per mL (0.2%), 5 mL	‡ 1	5	..	20.56	21.59	[a]	Enidin	PE
				B1.74	22.30	21.59	[a]	Alphagan	AG
	BRIMONIDINE TARTRATE with TIMOLOL MALEATE								
	Restricted Benefit								
	Reduction of elevated intra-ocular pressure in patients with open-angle glaucoma who are not adequately controlled with timolol maleate 5 mg (base) per mL (0.5%) eye drops;								
	Reduction of elevated intra-ocular pressure in patients with ocular hypertension who are not adequately controlled with timolol maleate 5 mg (base) per mL (0.5%) eye drops.								
5535H	***Eye drops 2 mg-5 mg (base) per mL (0.2%-0.5%), 5 mL***	***‡ 1***	***5***	***..***	***26.76***	***27.79***		***Combigan***	***AG***
	• *Parasympathomimetics*								
	PILOCARPINE HYDROCHLORIDE								
5536J	Eye drops 10 mg per mL (1%), 15 mL	‡ 1	5	..	12.48	13.51		Isopto Carpine	AQ
				..	12.48	13.51	[a]	Pilopt	PE
				B2.97	15.45	13.51	[a]	P.V. Carpine	AG
5537K	Eye drops 20 mg per mL (2%), 15 mL	‡ 1	5	..	13.81	14.84		Isopto Carpine	AQ
				..	13.81	14.84	[a]	Pilopt	PE
				B2.96	16.77	14.84	[a]	P.V. Carpine	AG
5538L	Eye drops 40 mg per mL (4%), 15 mL	‡ 1	5	..	16.83	17.86		Isopto Carpine	AQ
				..	16.83	17.86	[a]	Pilopt	PE
				B2.83	19.66	17.86	[a]	P.V. Carpine	AG
5539M	Eye drops 60 mg per mL (6%), 15 mL	‡ 1	5	..	21.61	22.64	[a]	Pilopt	PE
				B2.86	24.47	22.64	[a]	P.V. Carpine	AG
	• *Carbonic anhydrase inhibitors*								
	BRINZOLAMIDE								
5540N	Eye drops 10 mg per mL (1%), 5 mL	‡ 1	5	..	21.27	22.30	[a]	BrinzoQuin	IQ
				B1.03	22.30	22.30	[a]	Azopt	AQ

PREPARATIONS WHICH MAY BE PRESCRIBED BY AUTHORISED OPTOMETRISTS FOR OPTOMETRICAL TREATMENT ONLY-cont.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Proprietary Name and Manufacturer	
	DORZOLAMIDE HYDROCHLORIDE								
5541P	Eye drops 20 mg (base) per mL (2%), 5 mL	‡ 1	5	..	20.86	21.89		Trusopt	MK
	DORZOLAMIDE HYDROCHLORIDE with TIMOLOL MALEATE								
	Restricted Benefit								
	Reduction of elevated intra-ocular pressure in patients with open-angle glaucoma who are not adequately controlled with timolol maleate 5 mg (base) per mL (0.5%) eye drops;								
	Reduction of elevated intra-ocular pressure in patients with ocular hypertension who are not adequately controlled with timolol maleate 5 mg (base) per mL (0.5%) eye drops.								
5542Q	***Eye drops 20 mg (base)-5 mg (base) per mL (2%-0.5%), 5 mL***	***‡ 1***	***5***	***..***	***27.06***	***28.09***		***Cosopt***	***MK***
	• Beta blocking agents								
	BETAXOLOL HYDROCHLORIDE								
5543R	Eye drops, suspension, 2.5 mg (base) per mL (0.25%), 5 mL	‡ 1	5	..	14.10	15.13		Betoptic S	AQ
5544T	Eye drops, solution, 5 mg (base) per mL (0.5%), 5 mL	‡ 1	5	.. B1.99	14.10 16.09	15.13 15.13	a a	BetoQuin Betoptic	IQ AQ
	TIMOLOL MALEATE								
5546X	Eye gel 1 mg (base) per g (0.1%), 5 g	‡ 1	5	..	11.37	12.40		Nyogel	NV
5547Y	Eye drops 2.5 mg (base) per mL (0.25%), 5 mL	‡ 1	5	.. B1.18	11.37 12.55	12.40 12.40	a a	Tenopt Timoptol	SI FR
5548B	Eye drops 5 mg (base) per mL (0.5%), 5 mL	‡ 1	5	.. B1.17	12.19 13.36	13.22 13.22	a a	Tenopt Timoptol	SI FR
5549C	Eye drops (gellan gum solution) 2.5 mg (base) per mL (0.25%), 2.5 mL	‡ 1	5	..	11.37	12.40		Timoptol XE	MK
5550D	Eye drops (gellan gum solution) 5 mg (base) per mL (0.5%), 2.5 mL	‡ 1	5	..	12.19	13.22		Timoptol XE	MK
	• Prostaglandin analogues								
	BIMATOPROST								
5551E	Eye drops 300 micrograms per mL (0.03%), 3 mL	‡ 1	5	..	38.62	32.90		Lumigan	AG
	LATANOPROST								
5552F	Eye drops 50 micrograms per mL (0.005%), 2.5 mL	‡ 1	5	..	38.62	32.90		Xalatan	PU

PREPARATIONS WHICH MAY BE PRESCRIBED BY AUTHORISED OPTOMETRISTS FOR OPTOMETRICAL TREATMENT ONLY-cont.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
	LATANOPROST with TIMOLOL MALEATE							
	Restricted Benefit ***Reduction of elevated intra-ocular pressure in patients with open-angle glaucoma who are not adequately controlled with timolol maleate 5 mg (base) per mL (0.5%) eye drops or latanoprost eye drops;*** ***Reduction of elevated intra-ocular pressure in patients with ocular hypertension who are not adequately controlled with timolol maleate 5 mg (base) per mL (0.5%) eye drops or latanoprost eye drops.***							
5553G	***Eye drops 50 micrograms-5 mg (base) per mL (0.005%-0.5%), 2.5 mL***	***‡ 1***	***5***	***..***	***43.54***	***32.90***	***Xalacom***	***PF***
	TRAVOPROST							
5554H	Eye drops 40 micrograms per mL (0.004%), 2.5 mL	‡ 1	5	..	38.62	32.90	Travatan	AQ
	TRAVOPROST with TIMOLOL MALEATE							
	Restricted Benefit ***Reduction of elevated intra-ocular pressure in patients with open-angle glaucoma who are not adequately controlled with timolol maleate 5 mg (base) per mL (0.5%) eye drops or latanoprost eye drops or travoprost eye drops;*** ***Reduction of elevated intra-ocular pressure in patients with ocular hypertension who are not adequately controlled with timolol maleate 5 mg (base) per mL (0.5%) eye drops or latanoprost eye drops or travoprost eye drops.***							
5555J	***Eye drops 40 micrograms-5 mg (base) per mL (0.004%-0.5%), 2.5 mL***	***‡ 1***	***5***	***..***	***43.54***	***32.90***	***Duotrav***	***AQ***
	Decongestants and antiallergics							
	• ***Other antiallergics***							
	SODIUM CROMOGLYCATE							
	Restricted Benefit ***Vernal kerato-conjunctivitis.***							
5529B	***Eye drops 20 mg per mL (2%), 10 mL***	***‡ 1***	***5***	***..***	***14.26***	***15.29***	***[a] Cromolux*** ***[a] Opticrom***	***AE*** ***SW***
	Other ophthalmologicals							
	• ***Other ophthalmologicals***							
	CARBOMER 974							
	Authority Required ***Severe dry eye syndrome in patients who are sensitive to preservatives in multi-dose eye drops.***							
5502N	***Ocular lubricating gel 3 mg per g (0.3%), single dose units 0.5 g, 30***	***3***	***5***	***..***	**** 35.63***	***32.90***	***Poly Gel***	***AQ***

PREPARATIONS WHICH MAY BE PRESCRIBED BY AUTHORISED OPTOMETRISTS FOR OPTOMETRICAL TREATMENT ONLY-cont.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
	CARBOMER 980							
	Restricted Benefit ***Severe dry eye syndrome, including Sjogren's syndrome.***							
5503P	***Ocular lubricating gel 2 mg per g (0.2%), 10 g***	***‡ 1***	***5***	***..***	***10.08***	***11.11***	***GelTears***	***BU***
				..	***10.08***	***11.11***	***[a] PAA***	***NM***
				[B]1.00	***11.08***	***11.11***	***[a] Viscotears Liquid Gel***	***NV***
	Authority Required ***Severe dry eye syndrome in patients who are sensitive to preservatives in multi-dose eye drops.***							
5504Q	***Eye drops 2 mg per g (0.2%), single dose units 0.6 mL, 30***	***3***	***5***	***..***	**** 35.03***	***32.90***	***Viscotears***	***NV***
	CARMELLOSE SODIUM							
	Restricted Benefit ***Severe dry eye syndrome, including Sjogren's syndrome.***							
5507W	***Eye drops 5 mg per mL (0.5%), 15 mL***	***‡ 1***	***5***	***..***	***10.16***	***11.19***	***Refresh Tears Plus***	***AG***
5508X	***Eye drops 10 mg per mL (1%), 15 mL***	***‡ 1***	***5***	***..***	***10.16***	***11.19***	***Refresh Liquigel***	***AG***
	Authority Required ***Severe dry eye syndrome in patients who are sensitive to preservatives in multi-dose eye drops.***							
5509Y	***Eye drops 2.5 mg per mL (0.25%), single dose units 0.6 mL, 24***	***4***	***5***	***..***	**** 39.99***	***32.90***	***TheraTears***	***CX***
5506T	***Eye drops 5 mg per mL (0.5%), single dose units 0.4 mL, 30***	***3***	***5***	***..***	**** 35.63***	***32.90***	***Cellufresh***	***AG***
5505R	***Eye drops 10 mg per mL (1%), single dose units 0.4 mL, 30***	***3***	***5***	***..***	**** 35.63***	***32.90***	***Celluvisc***	***AG***
5510B	***Ocular lubricating gel 10 mg per mL (1%), single dose units 0.6 mL, 28***	***3***	***5***	***..***	**** 33.65***	***32.90***	***TheraTears***	***CX***
	CARMELLOSE SODIUM with GLYCERIN							
	Restricted Benefit ***Severe dry eye syndrome, including Sjogren's syndrome.***							
5556K	***Eye drops 5 mg-9 mg per mL (0.5%-0.9%), 15 mL***	***‡ 1***	***3***	***..***	***10.16***	***11.19***	***Optive***	***AG***
	NOTE: ***The shelf life of Optive is 6 months from the date of opening.***							

PREPARATIONS WHICH MAY BE PRESCRIBED BY AUTHORISED OPTOMETRISTS FOR OPTOMETRICAL TREATMENT ONLY-cont.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Proprietary Name and Manufacturer	
	HYPROMELLOSE								
	Restricted Benefit *Severe dry eye syndrome, including Sjogren's syndrome.*								
5518K	*Eye drops 3 mg per mL (0.3%), 15 mL (contains sodium perborate as preservative)*	*‡ 1*	*5*	*..*	*10.08*	*11.11*	*a*	*In a Wink Moisturising*	*NM*
				B1.86	*11.94*	*11.11*	*a*	*Genteal*	*NV*
5517J	*Eye drops 5 mg per mL (0.5%), 15 mL*	*‡ 1*	*5*	*..*	*10.08*	*11.11*		*Methopt*	*SI*
	HYPROMELLOSE with CARBOMER 980								
	Restricted Benefit *Severe dry eye syndrome, including Sjogren's syndrome.*								
5519L	*Ocular lubricating gel 3 mg-2 mg per g (0.3%-0.2%), 10 g*	*‡ 1*	*5*	*..*	*10.08*	*11.11*	*a*	*HPMC PAA*	*NM*
				B1.86	*11.94*	*11.11*	*a*	*Genteal gel*	*NV*
	HYPROMELLOSE with DEXTRAN								
	Restricted Benefit *Severe dry eye syndrome, including Sjogren's syndrome.*								
5520M	*Eye drops 3 mg-1 mg per mL (0.3%-0.1%), 15 mL*	*‡ 1*	*5*	*..*	*10.08*	*11.11*	*a*	*Poly-Tears*	*IQ*
				B1.67	*11.75*	*11.11*	*a*	*Tears Naturale*	*AQ*
	Authority Required *Severe dry eye syndrome in patients who are sensitive to preservatives in multi-dose eye drops.*								
5521N	*Eye drops 3 mg-1 mg per mL (0.3%-0.1%), single dose units 0.4 mL, 28*	*3*	*5*	*..*	** 33.65*	*32.90*		*Bion Tears*	*AQ*
	PARAFFIN								
5523Q	Compound eye ointment 3.5 g	2	5	..	* 21.07	22.10	a	Poly Visc	IQ
				B2.06	* 23.13	22.10	a	Duratears	AQ
5522P	Pack containing 2 tubes compound eye ointment 3.5 g	‡ 1	5	..	21.06	22.09		Poly Visc	IQ
				..	21.06	22.09	a	Ircal	PE
				B2.24	23.30	22.09	a	Lacri-Lube	AG
	POLYETHYLENE GLYCOL 400 with PROPYLENE GLYCOL								
	Restricted Benefit *Severe dry eye syndrome, including Sjogren's syndrome.*								
5524R	*Eye drops 4 mg-3 mg per mL (0.4%-0.3%), 15 mL*	*‡ 1*	*5*	*..*	*10.16*	*11.19*		*Systane*	*AQ*

continued ☞

PREPARATIONS WHICH MAY BE PRESCRIBED BY AUTHORISED OPTOMETRISTS FOR OPTOMETRICAL TREATMENT ONLY-cont.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Proprietary Name and Manufacturer	
	Authority Required ***Severe dry eye syndrome in patients who are sensitive to preservatives in multi-dose eye drops.***								
5532E	***Eye drops 4 mg-3 mg per mL (0.4%-0.3%), single dose units 0.8 mL, 28***	***2***	***5***	***..***	**** 33.65***	***32.90***		***Systane***	***AQ***
	POLYVINYL ALCOHOL								
	Restricted Benefit ***Severe dry eye syndrome, including Sjogren's syndrome.***								
5526W	***Eye drops 14 mg per mL (1.4%), 15 mL***	***‡ 1***	***5***	***..***	***10.08***	***11.11***	***a***	***PVA Tears***	***PE***
				B1.71	***11.79***	***11.11***	***a***	***Liquifilm Tears***	***AG***
5527X	***Eye drops 14 mg per mL (1.4%), 15 mL (contains sodium chlorite/hydrogen peroxide as preservative)***	***‡ 1***	***5***	***..***	***10.08***	***11.11***		***Vistil***	***AE***
5525T	***Eye drops 30 mg per mL (3%), 15 mL***	***‡ 1***	***5***	***..***	***10.08***	***11.11***	***a***	***PVA Forte***	***PE***
				B5.94	***16.02***	***11.11***	***a***	***Liquifilm Forte***	***AG***
5528Y	***Eye drops 30 mg per mL (3%), 15 mL (contains sodium chlorite/hydrogen peroxide as preservative)***	***‡ 1***	***5***	***..***	***10.08***	***11.11***		***Vistil Forte***	***AE***
	TAMARINDUS INDICA SEED POLYSACCHARIDE								
	Authority Required ***Severe dry eye syndrome in patients who are sensitive to preservatives in multi-dose eye drops.***								
5531D	***Eye drops 10 mg per mL (1%), 0.5 mL, 20***	***3***	***5***	***..***	**** 35.63***	***32.90***		***Visine Professional***	***JT***

SECTION 100 ITEMS

In addition to the drugs and medicinal preparations available under normal PBS arrangements listed in this Schedule, a number of drugs are also available as pharmaceutical benefits but are distributed under alternative arrangements where these are considered more appropriate.

These alternative arrangements are provided for under section 100 of the *National Health Act 1953*. Several programs exist for the provision of drugs as pharmaceutical benefits in this way and this section lists those drugs which are available under the following programs:

HIGHLY SPECIALISED DRUGS PROGRAM

BOTULINUM TOXIN PROGRAM

HUMAN GROWTH HORMONE PROGRAM

IVF/GIFT PROGRAM

OPIATE DEPENDENCE TREATMENT PROGRAM

SPECIAL AUTHORITY PROGRAM

Complete details concerning the availability of drugs as benefits under these programs may be obtained by telephoning the relevant contact number(s) shown in each section, or in certain cases, by referring to the telephone number provided for individual drugs listings.

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer $	Proprietary Name and Manufacturer

HIGHLY SPECIALISED DRUGS PROGRAM

The Australian Government provides funding for certain specialised medications under the Highly Specialised Drugs Program. Highly Specialised Drugs are medicines for the treatment of chronic conditions which, because of their clinical use or other special features, are restricted to supply through public and private hospitals having access to appropriate specialist facilities. To prescribe these drugs as pharmaceutical benefit items, medical practitioners are required to be affiliated with these specialist hospital units. A general practitioner or non-specialist hospital doctor may only prescribe Highly Specialised Drugs to provide maintenance therapy under the guidance of the treating specialist.

Benefits are available for the listed clinical indications only. There is no facility for individual patient approval for indications outside those listed.

To gain access to a Commonwealth funded drug under this program, a patient must attend a participating hospital and be a day admitted patient, a non-admitted patient or a patient on discharge, be under appropriate specialist medical care, meet the specific medical criteria and be an Australian resident in Australia (or other eligible person).

A patient will be required to pay a contribution for each supply of a highly specialised drug at a similar rate to the Pharmaceutical Benefits Scheme. Commonwealth subsidy is not available for hospital in-patients.

Reciprocal Health Care Agreement – Where a patient is entitled to be treated as an eligible person as a visitor from a country with which Australia has entered into a Reciprocal Health Care Agreement, the supply will be limited to the original prescription only. Repeat prescriptions for these patients are not permitted.

Private Hospitals – **In addition to the above requirements**, for Highly Specialised Drugs prescribed through private hospitals, claiming and approval of authority prescriptions is administered by Medicare Australia. Highly Specialised Drugs are authority required items. Medical practitioners must seek approval to prescribe these items as pharmaceutical benefits prior to their dispensing under the PBS. Approval of authority prescriptions by Medicare Australia may be obtained either by posting an Authority Prescription Form to Medicare Australia, or by using Medicare Australia's Authority Freecall service (1800 888 333). **Prescribers must quote the provider number of the hospital when applying**. Not more than two months' supply (one month's supply in the case of Clozapine), with provision for up to 5 repeats, will be authorised. Prescriptions for Highly Specialised Drugs can be dispensed by an approved private hospital's dispensary or by a community pharmacy.

The remuneration rates for Highly Specialised Drugs prescribed through private hospitals comprise the normal PBS ready- prepared dispensing fee plus a mark-up ascertained as follows:

- 10% for drugs with a price ex-manufacturer of less than $40;
- $4 for drugs with a price ex-manufacturer of between $40 and $100;
- 4% for drugs with a price ex-manufacturer of between $100.01 and $1000;
- $40 for drugs with a price ex-manufacturer of greater than $1000.

Public Hospitals – For Highly Specialised Drugs prescribed through public hospitals, claiming and access to the program is administered by the States/Territories Health Departments. Prescriptions for Highly Specialised Drugs can be dispensed by public hospital pharmacies.

If you would like further information about the Highly Specialised Drugs Program, please contact your pharmacy, Medicare Australia (Ph: 132 290) or the Australian Government adviser, the Highly Specialised Drugs Working Party Secretariat (Ph: (02) 6289 2331).

For information on Pharmaceutical Benefits Pricing Authority therapeutic relativity sheets please visit www.health.gov.au and search for 'relativity sheets'.

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer $	Proprietary Name and Manufacturer	

HIGHLY SPECIALISED DRUGS PROGRAM

ABACAVIR SULFATE

Private hospital authority required
Treatment of HIV infection in patients with:
(a) CD4 cell counts of less than 500 per cubic millimetre; or
(b) viral load of greater than 10,000 copies per mL.

6264Q	*Tablet 300 mg (base)*	*60*	*423.00*	*Ziagen*	*GK*
6265R	*Oral solution 20 mg (base) per mL, 240 mL*	*1*	*82.14*	*Ziagen*	*GK*

NOTE:
These prices are based on special supply arrangements—see Pharmaceutical Benefits Pricing Authority relativity sheet for full details.

ABACAVIR SULFATE with LAMIVUDINE

Private hospital authority required
Treatment of HIV infection in patients over 12 years of age, weighing 40 kg or more, with:
(a) CD4 cell counts of less than 500 per cubic millimetre; or
(b) viral load of greater than 10,000 copies per mL.

6458X	*Tablet 600 mg (base)-300 mg*	*30*	*564.00*	*Kivexa*	*GK*

ABACAVIR SULFATE with LAMIVUDINE and ZIDOVUDINE

Private hospital authority required
Treatment of HIV infection in patients over 12 years of age, weighing 40 kg or more, with:
(a) CD4 cell counts of less than 500 per cubic millimetre; or
(b) viral load of greater than 10,000 copies per mL.

6327B	*Tablet 300 mg (base)-150 mg-300 mg*	*60*	*852.00*	*Trizivir*	*GK*

ABATACEPT
NOTE:
Any queries concerning the arrangements to prescribe abatacept may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written applications for authority to prescribe abatacept should be forwarded to:

Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

Further prescribing information is on the Medicare Australia website at www.medicareaustralia.gov.au.

NOTE:
TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying anti-rheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, etanercept, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-1 inhibitor (anakinra) and the T-cell co-stimulation modulator (abatacept).

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

continued ☞

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer $	Proprietary Name and Manufacturer

PBS-subsidised infliximab, anakinra, rituximab and abatacept must be used in combination with methotrexate at a dose of at least 7.5 mg weekly. Where a patient cannot tolerate 7.5 mg of methotrexate weekly, they are only eligible to receive PBS-subsidised etanercept and adalimumab.

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

From 1 March 2008, under the PBS, all patients will be able to commence a Treatment Cycle where they may trial PBS-subsidised bDMARD agents without having to experience a disease flare when swapping to an alternate agent. Under these interchangeability arrangements, within a single Treatment Cycle, a patient may continue to receive long-term treatment with a bDMARD while they continue to show a response to therapy.

A patient who received PBS-subsidised bDMARD treatment prior to 1 March 2008 is considered to be in their first Cycle as of 1 March 2008.

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

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a Treatment Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised bDMARD therapy before they are eligible to commence the next Cycle.

For patients who have failed PBS-subsidised treatment with 3 bDMARDs prior to 1 March 2008 please contact Medicare Australia on 1800 700 270.

The 5-year break is measured from the date of the last approval for PBS-subsidised bDMARD treatment in the most recent Cycle to the date of the first application for initial treatment with a bDMARD under the new Treatment Cycle.

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

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

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

If patients fail to respond to a particular bDMARD within a single Treatment Cycle, they are not eligible to receive further PBS-subsidised treatment with that drug until they commence the next Cycle.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 March 2008.

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

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for etanercept, adalimumab, anakinra and abatacept, 22 weeks of therapy for infliximab and 2 infusions of rituximab.

From 1 March 2008, a patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to Medicare Australia within 4 weeks.

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

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

continued ☞

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer $	Proprietary Name and Manufacturer

Rituximab patients:
A further application may be submitted to Medicare Australia 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

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

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

Assessments of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Rituximab patients:
A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.

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

(2) Swapping therapy.

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

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

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

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

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

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

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

NOTE:
(3) Baseline measurements to determine response.

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

continued ☞

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer $	Proprietary Name and Manufacturer

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

The baseline joint and blood counts should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment.

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

A patient who wishes to trial a second or subsequent Treatment Cycle following a break in PBS-subsidised bDMARD therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have received treatment with at least 1 non-biological DMARD, at an adequate dose, for a minimum of 3 months at the time the ESR and/or CRP levels and the active joint count are measured.

(5) Patients 'grandfathered' onto PBS-subsidised treatment with rituximab or abatacept.

From 1 March 2008, a patient who commenced treatment with rituximab for severe rheumatoid arthritis prior to 7 March 2007 or abatacept for severe rheumatoid arthritis prior to 1 November 2007 and who was 'grandfathered' on to PBS-subsidised therapy, and who continues to receive treatment in the same Treatment Cycle, will have further applications for treatment with rituximab or abatacept assessed under the continuing treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment with abatacept will be authorised under this criterion.

'Grandfather' arrangements will only apply for the first Treatment Cycle. For the second and subsequent Cycles, a 'grandfather' patient must requalify for initial treatment under the criteria that applies to a new patient. See 'Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' above for further details.

Public and private hospital authority required

Initial 1 (new patients)

Application for initial PBS-subsidised treatment with abatacept, in combination with methotrexate at a dose of at least 7.5 mg weekly, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of adults who:

(a) have severe active rheumatoid arthritis; and

(b) have received no prior PBS-subsidised treatment with a bDMARD for this condition in this treatment cycle; and

(c) have failed to achieve an adequate response to the following treatments:

(i) methotrexate at a dose of at least 20 mg weekly; and

(ii) methotrexate (at a minimum dose of 7.5 mg weekly), in combination with 2 other non-biological disease modifying anti-rheumatic drugs (DMARDs), for a minimum of 3 months; and

(iii) a minimum of 3 months' treatment with:

— leflunomide alone; or

— leflunomide in combination with methotrexate; or

— cyclosporin.

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of the accepted toxicities, including severity, can be found on the Medicare Australia website [www.medicareaustralia.gov.au].

continued ☞

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer $	Proprietary Name and Manufacturer

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

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.

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

The authority application must be made in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes details of the patient's ESR and CRP measurements and the patient's active joint count which must have been assessed no earlier than 1 month prior to the date of application; and
(3) a signed patient acknowledgement.

A maximum of 16 weeks of treatment will be authorised under this restriction.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion. Up to a maximum of 4 repeats may be authorised.

Where fewer than 4 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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

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

Public and private hospital authority required
Initial 2 (change or re-commencement)
Application for an initial course of PBS-subsidised treatment with abatacept, in combination with methotrexate at a dose of at least 7.5 mg weekly, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of adults who:
(a) have a documented history of severe active rheumatoid arthritis; and
(b) have received prior PBS-subsidised bDMARD treatment for this condition in this treatment cycle and are eligible to receive further bDMARD therapy.

The authority application must be made in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].

continued ☞

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer $	Proprietary Name and Manufacturer

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

A maximum of 16 weeks of treatment will be authorised under this restriction.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion. Up to a maximum of 4 repeats may be authorised.

Where fewer than 4 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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

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

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

Public and private hospital authority required

Initial 3 ('grandfather' patients)
Initial PBS-subsidised supply for continuing treatment with abatacept, in combination with methotrexate at a dose of at least 7.5 mg weekly, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of an adult who:
(a) has a documented history of severe active rheumatoid arthritis; and
(b) was receiving treatment with abatacept prior to 1 November 2007; and
(c) has demonstrated a response as specified in the criteria for continuing PBS-subsidised treatment with abatacept.

The authority application must be made in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form [www.medicareaustralia.gov.au] which includes the signed patient acknowledgement.

The same indices of disease severity used to establish baseline at the commencement of treatment with a bDMARD must be used for assessment of all continuing applications.

The assessment of the patient's response to a continuing course of therapy must be made within 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled in order to ensure continuity of treatment for those patients who meet the continuation criterion.

A maxiumum of 24 weeks of treatment with abatacept will be approved under this criterion.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion. Up to a maximum of 5 repeats may be authorised.

Where fewer than 5 repeats are initially requested with the authority prescription, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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

continued ☞

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer $	Proprietary Name and Manufacturer	

Patients who fail to demonstrate a response to treatment with 3 bDMARDs are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may re-commence a new bDMARD Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised bDMARD was approved in this Cycle and the date of the first application under the new Cycle.

Public and private hospital authority required

Continuing treatment

Continuing PBS-subsidised treatment with abatacept, in combination with methotrexate at a dose of at least 7.5 mg weekly, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of adults:

(a) who have a documented history of severe active rheumatoid arthritis; and

(b) who have demonstrated an adequate response to treatment with abatacept; and

(c) whose most recent course of PBS-subsidised bDMARD treatment in this treatment cycle was with abatacept.

An adequate response to treatment is defined as:

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

AND either of the following:

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

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

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

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

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

(1) a completed authority prescription form; and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].

A maximum of 24 weeks of treatment will be approved under this restriction.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion. Up to a maximum of 5 repeats may be authorised.

Where fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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

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

9621J	***Powder for I.V. infusion 250 mg***	***1***	***504.43***	***Orencia***	***BQ***

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer $	Proprietary Name and Manufacturer	
	ADEFOVIR DIPIVOXIL				
	Private hospital authority required ***Chronic hepatitis B in a patient who has failed antihepadnaviral therapy and who satisfies all of the following criteria:*** ***(1)(a) Repeatedly elevated serum ALT levels while on concurrent antihepadnaviral therapy of greater than or equal to 6 months duration in conjunction with documented chronic hepatitis B infection; or*** ***(b) Repeatedly elevated HBV DNA levels one log greater than the nadir value or failure to achieve a 1 log reduction in HBV DNA within 3 months, whilst on previous antihepadnaviral therapy except in patients with evidence of poor compliance;*** ***(2) Female patients of child-bearing age are not pregnant, not breast-feeding, and are using an effective form of contraception.*** ***Persons with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy.*** **NOTE:** ***Patients should have undergone a liver biopsy at some point since initial diagnosis to obtain histological evidence of chronic hepatitis.*** ***Patients may receive treatment in combination with lamivudine but not with other PBS-subsidised antihepadnaviral therapy.***				
6450L	***Tablet 10 mg***	***30***	***625.00***	***Hepsera***	***GI***
	APOMORPHINE HYDROCHLORIDE				
	Private hospital authority required ***Parkinson's disease in patients severely disabled by motor fluctuations which do not respond to other therapy.***				
9607P	***Injection 20 mg in 2 mL***	***5***	***77.86***	***Apomine***	***HH***
	ATAZANAVIR				
	Private hospital authority required ***Treatment, in combination with 2 or more other antiretroviral drugs, of HIV infection in patients with:*** ***(a) CD4 cell counts of less than 500 per cubic millimetre; or*** ***(b) viral load of greater than 10,000 copies per mL.***				
6451M	***Capsule 150 mg (as sulfate)***	***60***	***521.91***	***Reyataz***	***BQ***
6452N	***Capsule 200 mg (as sulfate)***	***60***	***695.88***	***Reyataz***	***BQ***
9614B	***Capsule 300 mg (as sulfate)***	***30***	***521.91***	***Reyataz***	***BQ***
	AZITHROMYCIN				
	Private hospital authority required ***Prophylaxis against Mycobacterium avium complex infections in HIV-positive patients with CD4 cell counts of less than 75 per cubic millimetre.***				
6221K	***Tablet 600 mg***	***8***	***67.82***	***Zithromax***	***PF***
	BACLOFEN				
	Private hospital authority required ***Severe chronic spasticity, where oral antispastic agents have failed or have caused unacceptable side effects, in patients with chronic spasticity:*** ***(a) of cerebral origin; or*** ***(b) due to multiple sclerosis; or***				

continued ☞

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer $	Proprietary Name and Manufacturer	
	(c) due to spinal cord injury; or				
	(d) due to spinal cord disease.				
6284R	***Intrathecal injection 10 mg in 5 mL***	***1***	***148.37***	***Lioresal Intrathecal***	***NV***

BOSENTAN MONOHYDRATE

CAUTION:

Bosentan monohydrate is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 3 months following cessation of treatment with this drug.

NOTE:

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

Written applications for authority to prescribe bosentan monohydrate should be forwarded to:

Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

NOTE:

Bosentan monohydrate is not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with scleroderma, where the total lung capacity is less than 70% of that predicted.

Bosentan monohydrate is not PBS-subsidised when used in combination with PBS-subsidised iloprost trometamol, PBS-subsidised epoprostenol sodium, PBS-subsidised sildenafil citrate or PBS-subsidised sitaxentan sodium.

The following provides some explanatory notes regarding the availability of PBS-subsidised treatment with:
(a) bosentan monohydrate, of primary pulmonary hypertension, pulmonary arterial hypertension secondary to scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology), in patients with disease of WHO Functional Class III or IV severity; AND
(b) iloprost trometamol, of primary pulmonary hypertension, drug-induced pulmonary arterial hypertension or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class III or IV severity; AND
(c) epoprostenol sodium, of primary pulmonary hypertension, in patients with disease of WHO Functional Class III or IV severity; AND
(d) sildenafil citrate, of primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class III severity; AND
(e) sitaxentan sodium, of primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class III severity.

Adult patients:
From 1 April 2008, adult patients with primary pulmonary hypertension will be able to access, through the PBS, bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate (WHO Class III only) or sitaxentan sodium (WHO Class III only). Once these patients are approved initial treatment with 1 of these 5 drugs, they may swap between bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate and sitaxentan sodium at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary. (New baselines may be submitted where the patient has failed to respond to their current treatment.)

Patients may only swap to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate or sitaxentan sodium if they have not failed prior PBS-subsidised treatment with that drug.

continued ☞

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer $	Proprietary Name and Manufacturer

Adult patients with pulmonary arterial hypertension secondary to scleroderma will be able to access, through the PBS, bosentan monohydrate, iloprost trometamol, sildenafil citrate (WHO Class III only) or sitaxentan sodium (WHO Class III only). Once these patients are approved initial treatment with 1 of these 4 drugs, they may swap between bosentan monohydrate, iloprost trometamol, sildenafil citrate and sitaxentan sodium at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary. (New baselines may be submitted where the patient has failed to respond to their current treatment.)

Patients may only swap to bosentan monohydrate, iloprost trometamol, sildenafil citrate or sitaxentan sodium if they have not failed prior PBS-subsidised treatment with that drug.

Adult patients with pulmonary arterial hypertension secondary to connective tissue disease other than scleroderma will be able to access, through the PBS, iloprost trometamol, sildenafil citrate (WHO Class III only) or sitaxentan sodium (WHO Class III only). Once these patients are approved initial treatment with 1 of these 3 drugs, they may swap between iloprost trometamol, sildenafil citrate and sitaxentan sodium at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary. (New baselines may be submitted where the patient has failed to respond to their current treatment.)

Patients may only swap to iloprost trometamol, sildenafil citrate or sitaxentan sodium if they have not failed prior PBS-subsidised treatment with that drug.

Patients with drug-induced pulmonary arterial hypertension are only eligible for treatment with iloprost trometamol. They may not swap to bosentan monohydrate, epoprostenol sodium, sildenafil citrate or sitaxentan sodium.

Patients with pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are only eligible for treatment with bosentan monohydrate. They may not swap to epoprostenol sodium, iloprost trometamol, sildenafil citrate or sitaxentan sodium.

Patients under 18 years of age:
From 1 April 2008, patients aged less than 18 years with primary pulmonary hypertension are eligible to receive PBS-subsidised treatment with bosentan monohydrate, epoprostenol sodium, iloprost trometamol, sildenafil citrate (WHO Class III only) or sitaxentan sodium (WHO Class III only). Once these patients are approved initial treatment with 1 of these 5 drugs, they may swap between bosentan monohydrate, epoprostenol sodium, iloprost trometamol, sildenafil citrate and sitaxentan sodium at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary. (New baselines may be submitted where the patient has failed to respond to their current treatment.)

Patients may only swap to bosentan monohydrate, epoprostenol sodium, iloprost trometamol, sildenafil citrate or sitaxentan sodium if they have not failed prior PBS-subsidised treatment with that drug.

1. Definition of primary pulmonary hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease, including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology).

Primary pulmonary hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease, including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows:
(i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary capillary wedge pressure (PCWP) less than 18 mmHg; or
(ii) mPAP greater than 30 mmHg with exercise and PCWP less than 18 mmHg; or
(iii) where a right heart catheter cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

2. Definition of WHO Functional Class III or IV disease severity.

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Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer $	Proprietary Name and Manufacturer

(a) WHO Functional Class III disease severity is defined as follows:
Patients with pulmonary hypertension resulting in marked limitation of physical activity who are comfortable at rest and on ordinary physical activity experience dyspnoea or fatigue, chest pain or near syncope.
(b) WHO Functional Class IV disease severity is defined as follows:
Patients with the inability to carry out any physical activity without symptoms. These patients manifest signs of right heart failure. Dyspnoea and/or fatigue may even be present at rest. Discomfort is increased by any physical activity.

3. Designated hospitals.

Refer to the Medicare Australia website at www.medicareaustralia.gov.au for a list of designated hospitals.

4. Test requirements to establish baseline for initiation of treatment and response to treatment for continuation of treatment.

(a) Initiation of treatment.
The first written application for PBS-subsidised treatment with the first of either bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate or sitaxentan sodium should be accompanied by the results of a right heart catheter (RHC) composite assessment, plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:
(1) RHC plus ECHO composite assessments;
(2) RHC composite assessment plus 6MWT;
(3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted to Medicare Australia for consideration based on the results of the following test combinations, which are listed in descending order of preference:
(1) ECHO composite assessment plus 6MWT;
(2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a reason outlining why the particular test/s could not be conducted must be provided with the authority application.

NOTE:
Where patients were initiated on PBS-subsidised treatment either with bosentan monohydrate on or after 1 March 2004, with iloprost trometamol on or after 1 April 2005, with epoprostenol sodium on or after 1 August 2006, with sildenafil citrate on or after 1 March 2007, with sitaxentan sodium on or after 1 April 2008, or with bosentan monohydrate (for PAH associated with congenital systemic-to-pulmonary shunt) on or after 1 August 2008, the test results provided with the initial application must be no more than 2 months old at the time of application. These results will form the baseline against which response assessments will be made.

Where patients received treatment with either bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate or sitaxentan sodium prior to being commenced on PBS-subsidised treatment with the first of either bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate or sitaxentan sodium, the test requirements above still apply. The results that will form the baseline against which response assessments will be made will be those measured at the time patients commenced non-PBS-subsidised treatment with either bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate or sitaxentan sodium, whichever of the 5 drugs the patient received first.

(b) Continuation of treatment.
The following list outlines the preferred test combination, in descending order, for the purposes of continuation of PBS-subsidised treatment:
(1) RHC plus ECHO composite assessments plus 6MWT;
(2) RHC plus ECHO composite assessments;
(3) RHC composite assessment plus 6MWT;
(4) ECHO composite assessment plus 6MWT;
(5) RHC composite assessment only;
(6) ECHO composite assessment only.

continued ☞

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer $	Proprietary Name and Manufacturer

The results of the same tests as conducted at baseline should be provided with each written continuing treatment application (i.e. every 6 months), except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a reason why the test(s) could not be conducted must be provided with the application.

The test(s) results provided with the application for continuing treatment must be no more than 2 months old at the time of application.

5. Definition of response to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, sitaxentan sodium or prior vasodilator treatment.

For adult patients with 2 or more baseline tests, response to treatment is defined as 2 or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For adult patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For adult patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least 1 of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

6. Authority approval requirements. [The following 2 sections are only relevant to the PBS listing of bosentan monohydrate. The requirements specific to iloprost trometamol, epoprostenol sodium, sildenafil citrate or sitaxentan sodium are given in parts 6 and 7 of the NOTE included in the iloprost trometamol, epoprostenol sodium, sildenafil citrate or sitaxentan sodium Schedule entry respectively.]

(a) Initiation of PBS-subsidised treatment with bosentan monohydrate, where the patient has not received prior PBS-subsidised treatment with iloprost trometamol, epoprostenol sodium, sildenafil citrate or sitaxentan sodium.
All applications for initial treatment must be made in writing, must include 2 separate authority prescriptions and must be submitted to Medicare Australia for authorisation. The total duration of initial PBS-subsidised treatment that will be approved with this first written application is up to 6 months.

Approvals for the first authority prescription will be limited to 1 month of therapy with the 62.5 mg strength tablet, with the quantity approved based on the dosage recommendations in the Therapeutic Goods Administration (TGA)-approved Product Information. No repeats will be authorised for this prescription. The second authority prescription may be written for either the 62.5 mg tablet or the 125 mg tablet strengths. Where the 62.5 mg tablet strength is required, please contact Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) for further advice. Approvals for the second authority prescription will be limited to 1 month of treatment, with the quantity approved based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 4 repeats. The approved second authority prescription will be returned to the prescriber by Medicare Australia 2 weeks after the date of the approval of the first authority prescription, to allow for the uninterrupted completion of the 6 month initial treatment course. Medicare Australia will contact prescribers prior to dispatch of the second authority prescription to confirm the tablet strength required for the patient.

(b) Continuation of treatment.
Written applications for continuing treatment must be submitted to Medicare Australia for authorisation every 6 months. Approvals will be limited to provide sufficient supply for up to a maximum of 6 months of treatment, based on the dosage recommendations in the TGA-approved Product Information.

Applications for continuing treatment will only be approved for patients who have currently demonstrated a response to treatment with bosentan monohydrate.

The assessment of the patient's response to the first and subsequent 6 month courses of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated. Applications for continuing treatment with bosentan monohydrate should be made prior to the completion of the 6 month treatment course to ensure continuity for those patients who respond to treatment, as assessed by the treating physician.

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Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer $	Proprietary Name and Manufacturer

(c) Swapping between bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate and sitaxentan sodium.

For eligible patients, applications to swap between these 5 drugs must be made under the relevant initial treatment restriction. Patients should be assessed for response to the treatment they are ceasing at the time the application to swap therapy is being made. Patients who fail to demonstrate a response or for whom no assessment results are submitted with the application to swap therapy may not re-commence PBS-subsidised treatment with the drug they are ceasing.

It is important that patients are assessed for response to every course of treatment approved within the timeframes specified in the relevant restriction, in order to maximise the choice of treatment.

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

(d) Cessation of treatment.

Patients who fail to demonstrate a response to PBS-subsidised bosentan monohydrate treatment at the times where an assessment is required must cease PBS-subsidised bosentan monohydrate therapy.

For patients ceasing treatment, approval will only be granted to provide sufficient supply of the 62.5 mg tablet strength to allow gradual dose reduction over a period of no more than 1 month duration. Prescribers should telephone Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) to receive authorisation for this final supply and to ensure no unintended break in treatment occurs.

7. Re-treatment with bosentan monohydrate.

Patients who do not respond to treatment are not eligible to receive further PBS-subsidised treatment with bosentan monohydrate under any circumstances.

8. Further information.

A tabulated representation of the above information and the restriction can be obtained from the Medicare Australia website at www.medicareaustralia.gov.au.

Public and private hospital authority required

Initial (new adult patients)

Application for initial PBS-subsidised treatment with bosentan monohydrate of adult patients who have not received prior PBS-subsidised treatment with iloprost trometamol, epoprostenol sodium, sildenafil citrate or sitaxentan sodium and who have been assessed by a physician from a designated hospital to have:

(a) WHO Functional Class III primary pulmonary hypertension and a mean right atrial pressure of 8 mmHg or less, as measured by RHC, unless a RHC is contraindicated on clinical grounds; OR

(b) WHO Functional Class III pulmonary arterial hypertension secondary to scleroderma and a mean right atrial pressure of 8 mmHg or less, as measured by RHC, unless a RHC is contraindicated on clinical grounds.

Patients must have failed to respond [see Note for definition of response] to 6 or more weeks of appropriate vasodilator treatment unless intolerance or a contraindication to such treatment exists.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted to Medicare Australia for consideration based on the test results of the ECHO composite assessment plus 6MWT or the ECHO composite assessment only.

continued ☞

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer $	Proprietary Name and Manufacturer

Applications for authorisation must be in writing and must include:
(1) two completed authority prescription forms [see Note for authority approval requirements]; and
(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form [www.medicareaustralia.gov.au] which includes results from the 3 tests below, where available:
(i) RHC composite assessment; and
(ii) ECHO composite assessment; and
(iii) 6MWT; and
(3) a signed patient acknowledgment indicating that the patient understands and acknowledges that PBS-subsidised treatment with bosentan monohydrate for primary pulmonary hypertension, pulmonary arterial hypertension secondary to scleroderma or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology), OR with iloprost trometamol for primary pulmonary hypertension, drug-induced pulmonary arterial hypertension or pulmonary arterial hypertension secondary to connective tissue disease, OR with epoprostenol sodium for primary pulmonary hypertension, OR with sildenafil citrate for primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, OR with sitaxentan sodium for primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, will cease if the treating physician determines that the patient has not achieved a response to treatment [see Note for definition of response].

Details of prior vasodilator treatment, including the dose and duration of treatment, must be provided at the time of application. Where the patient has an adverse event to a vasodilator or where vasodilator treatment is contraindicated, details on the nature of the adverse event or contraindication according to the TGA-approved Product Information must also be provided with the application.

Where fewer than 3 tests (see requirement 2 above) are able to be performed on clinical grounds, a reason outlining why the particular test/s could not be conducted must be provided with the authority application [see Note for test requirements].

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. No repeats will be authorised for the first authority prescription issued under this criterion [see Note for full details of authority approval requirements]. A maximum of 4 repeats will be authorised for the second authority prescription issued under this criterion. Where fewer than 4 repeats are initially requested with the second authority prescription, authority approvals for sufficient repeats to complete a maximum of 6 months of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Public and private hospital authority required

Initial (new adult patients)
Application for initial PBS-subsidised treatment with bosentan monohydrate of adult patients who have not received prior PBS-subsidised treatment with iloprost trometamol, epoprostenol sodium, sildenafil citrate or sitaxentan sodium and who have been assessed by a physician from a designated hospital to have:
(a) WHO Functional Class III primary pulmonary hypertension and a mean right atrial pressure greater than 8 mmHg, as measured by RHC, unless a RHC is contraindicated on clinical grounds; OR
(b) WHO Functional Class III pulmonary arterial hypertension secondary to scleroderma and a mean right atrial pressure greater than 8 mmHg, as measured by RHC, unless a RHC is contraindicated on clinical grounds; OR
(c) WHO Functional Class IV primary pulmonary hypertension; OR
(d) WHO Functional Class IV pulmonary arterial hypertension secondary to scleroderma.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted to Medicare Australia for consideration based on the test results of the ECHO composite assessment plus 6MWT or the ECHO composite assessment only.

continued ☞

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer $	Proprietary Name and Manufacturer

Applications for authorisation must be in writing and must include:
(1) two completed authority prescription forms [see Note for authority approval requirements]; and
(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form [www.medicareaustralia.gov.au] which includes results from the 3 tests below, where available:
(i) RHC composite assessment; and
(ii) ECHO composite assessment; and
(iii) 6MWT; and
(3) a signed patient acknowledgment indicating that the patient understands and acknowledges that PBS-subsidised treatment with bosentan monohydrate for primary pulmonary hypertension, pulmonary arterial hypertension secondary to scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology), OR with iloprost trometamol for primary pulmonary hypertension, drug-induced pulmonary arterial hypertension or pulmonary arterial hypertension secondary to connective tissue disease, OR with epoprostenol sodium for primary pulmonary hypertension, OR with sildenafil citrate for primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, OR with sitaxentan sodium for primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, will cease if the treating physician determines that the patient has not achieved a response to treatment [see Note for definition of response].

Where fewer than 3 tests (see requirement 2 above) are able to be performed on clinical grounds, a reason outlining why the particular test/s could not be conducted must be provided with the authority application [see Note for test requirements].

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. No repeats will be authorised for the first authority prescription issued under this criterion [see Note for full details of authority approval requirements]. A maximum of 4 repeats will be authorised for the second authority prescription issued under this criterion. Where fewer than 4 repeats are initially requested with the second authority prescription, authority approvals for sufficient repeats to complete a maximum of 6 months of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Public and private hospital authority required

Initial (new patients under 18 years of age)
Application for initial PBS-subsidised treatment of patients aged less than 18 years who have not received prior PBS-subsidised treatment with epoprostenol sodium or sildenafil citrate and who have been assessed by a physician from a designated hospital to have:
WHO Functional Class III primary pulmonary hypertension and either a mean right atrial pressure of 8 mmHg or less, as measured by RHC, or, where a RHC cannot be performed on clinical grounds, normal right ventricular function as assessed by ECHO.

Patients must have failed to respond [see Note for definition of response] to 6 or more weeks of appropriate prior vasodilator treatment unless intolerance or a contraindication to such treatment exists.

Applications for authorisation must be in writing and must include:
(1) two completed authority prescription forms [see Note for authority approval requirements]; and
(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form [www.medicareaustralia.gov.au] which includes results from the 3 tests below, where available:
(i) RHC composite assessment; and
(ii) ECHO composite assessment; and
(iii) 6MWT; and
(3) a patient acknowledgment, signed by the parent or authorised guardian, indicating that they understand and acknowledge that PBS-subsidised treatment with bosentan monohydrate, epoprostenol sodium or sildenafil citrate for primary pulmonary hypertension will cease if the treating physician determines that the patient has not achieved a response to treatment [see Note for definition of response].

Details of prior vasodilator treatment, including the dose and duration of treatment, must be provided at the time of application. Where the patient has an adverse event to a vasodilator or where vasodilator treatment is contraindicated, details on the nature of the adverse event or contraindication according to the TGA-approved Product Information must also be provided with the application.

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Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer $	Proprietary Name and Manufacturer

Where fewer than 3 tests (see requirement 2 above) are able to be performed on clinical grounds, a reason outlining why the particular test/s could not be conducted must be provided with the authority application [see Note for test requirements].

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. No repeats will be authorised for the first authority prescription issued under this criterion [see Note for full details of authority approval requirements]. A maximum of 4 repeats will be authorised for the second authority prescription issued under this criterion. Where fewer than 4 repeats are initially requested with the second authority prescription, authority approvals for sufficient repeats to complete a maximum of 6 months of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Public and private hospital authority required

Initial (new patients under 18 years of age)
Application for initial PBS-subsidised treatment of patients aged less than 18 years who have not received prior PBS-subsidised treatment with epoprostenol sodium or sildenafil citrate and who have been assessed by a physician from a designated hospital to have:
(a) WHO Functional Class III primary pulmonary hypertension and either a mean right atrial pressure greater than 8 mmHg, as measured by RHC, or, where a RHC cannot be performed on clinical grounds, right ventricular dysfunction as assessed by ECHO; OR
(b) WHO Functional Class IV primary pulmonary hypertension.

Applications for authorisation must be in writing and must include:
(1) two completed authority prescription forms [see Note for authority approval requirements]; and
(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form [www.medicareaustralia.gov.au] which includes results from the 3 tests below, where available:
(i) RHC composite assessment; and
(ii) ECHO composite assessment; and
(iii) 6MWT; and
(3) a patient acknowledgment, signed by the parent or authorised guardian, indicating that they understand and acknowledge that PBS-subsidised treatment with bosentan monohydrate, epoprostenol sodium or sildenafil citrate for primary pulmonary hypertension will cease if the treating physician determines that the patient has not achieved a response to treatment [see Note for definition of response].

Where fewer than 3 tests (see requirement 2 above) are able to be performed on clinical grounds, a reason outlining why the particular test/s could not be conducted must be provided with the authority application [see Note for test requirements].

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. No repeats will be authorised for the first authority prescription issued under this criterion [see Note for full details of authority approval requirements]. A maximum of 4 repeats will be authorised for the second authority prescription issued under this criterion. Where fewer than 4 repeats are initially requested with the second authority prescription, authority approvals for sufficient repeats to complete a maximum of 6 months of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Public and private hospital authority required

Initial (new patients)
Application for initial PBS-subsidised treatment with bosentan monohydrate of a patient who has been assessed by a physician from a designated hospital to have WHO Functional Class III or IV pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology).

continued ☞

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer $	Proprietary Name and Manufacturer

Applications for authorisation must be in writing and must include:
(1) two completed authority prescription forms [see Note for authority approval requirements]; and
(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form [www.medicareaustralia.gov.au] which includes results from the 3 tests below, where available:
(i) RHC composite assessment; and
(ii) ECHO composite assessment; and
(iii) 6MWT; and
(3) a signed patient acknowledgment indicating that the patient understands and acknowledges that PBS-subsidised treatment with bosentan monohydrate for primary pulmonary hypertension, pulmonary arterial hypertension secondary to scleroderma or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology), OR with iloprost trometamol for primary pulmonary hypertension, drug-induced pulmonary arterial hypertension or pulmonary arterial hypertension secondary to connective tissue disease, OR with epoprostenol sodium for primary pulmonary hypertension, OR with sildenafil citrate for primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, OR with sitaxentan sodium for primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, will cease if the treating physician determines that the patient has not achieved a response to treatment [see Note for definition of response].

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted to Medicare Australia for consideration based on the test results of the ECHO composite assessment plus 6MWT or the ECHO composite assessment only.

Where fewer than 3 tests (see requirement 2 above) are able to be performed on clinical grounds, a reason outlining why the particular test/s could not be conducted must be provided with the authority application [see Note for test requirements].

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. No repeats will be authorised for the first authority prescription issued under this criterion [see Note for full details of authority approval requirements]. A maximum of 4 repeats will be authorised for the second authority prescription issued under this criterion. Where fewer than 4 repeats are initially requested with the second authority prescription, authority approvals for sufficient repeats to complete a maximum of 6 months of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Public and private hospital authority required

Initial (grandfather patients)
Application for initial PBS-subsidised treatment with bosentan monohydrate of a patient who was receiving treatment with bosentan monohydrate prior to 1 August 2008 and who has been assessed by a physician from a designated hospital to have pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology).

continued ☞

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer $	Proprietary Name and Manufacturer

Applications for authorisation must be in writing and must include:
(1) a completed authority prescription form [see Note for authority approval requirements]; and
(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form [www.medicareaustralia.gov.au] which includes results from the 3 tests below, where available:
(i) RHC composite assessment; and
(ii) ECHO composite assessment; and
(iii) 6MWT; and
(3) a signed patient acknowledgment indicating that the patient understands and acknowledges that PBS-subsidised treatment with bosentan monohydrate for primary pulmonary hypertension, pulmonary arterial hypertension secondary to scleroderma or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology), OR with iloprost trometamol for primary pulmonary hypertension, drug-induced pulmonary arterial hypertension or pulmonary arterial hypertension secondary to connective tissue disease, OR with epoprostenol sodium for primary pulmonary hypertension, OR with sildenafil citrate for primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, OR with sitaxentan sodium for primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, will cease if the treating physician determines that the patient has not achieved a response to treatment [see Note for definition of response].

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted to Medicare Australia for consideration based on the test results of the ECHO composite assessment plus 6MWT or the ECHO composite assessment only.

Where fewer than 3 tests (see requirement 2 above) are able to be performed on clinical grounds, a reason outlining why the particular test/s could not be conducted must be provided with the authority application [see Note for test requirements].

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. The number of repeats authorised will be dependent on the duration of prior bosentan monohydrate therapy. Where patients have received less than 6 months of non-PBS-subsidised treatment with bosentan monohydrate, sufficient repeats to allow the patient to complete a total of 6 months of combined PBS-subsidised and non-PBS-subsidised therapy may be requested. Where patients have received 6 months or more of non-PBS-subsidised treatment with bosentan monohydrate, a maximum of 5 repeats may be requested. Where fewer than the maximum allowable number of repeats are requested at the time of application, authority approvals for the remainder of the allowable repeats may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Public and private hospital authority required

Initial (change or re-commencement for adult patients)
Application for initial treatment with bosentan monohydrate of adult patients with either of the following:
(a) primary pulmonary hypertension or pulmonary arterial hypertension secondary to scleroderma who wish to re-commence PBS-subsidised bosentan monohydrate after a break in therapy and who have demonstrated a response to their most recent course of PBS-subsidised treatment with bosentan monohydrate; OR
(b) primary pulmonary hypertension or pulmonary arterial hypertension secondary to scleroderma and whose most recent course of PBS-subsidised treatment was with iloprost trometamol, sildenafil citrate or sitaxentan sodium; OR
(c) primary pulmonary hypertension and whose most recent course of PBS-subsidised treatment was with epoprostenol sodium.

Applications for authorisation must be in writing and must include:
(1) two completed authority prescription forms [see Note for authority approval requirements]; and
(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form [www.medicareaustralia.gov.au] which includes the results on which approval for the first application for PBS-subsidised bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate or sitaxentan sodium, whichever was initiated first, was granted; and
(3) the date of the first application for PBS-subsidised treatment with bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate or sitaxentan sodium, whichever was initiated first; and
(4) the results of the patient's response to treatment with their last course of PBS-subsidised bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate or sitaxentan sodium.

continued ☞

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer $	Proprietary Name and Manufacturer

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. No repeats will be authorised for the first authority prescription issued under this criterion [see Note for full details of authority approval requirements]. A maximum of 4 repeats will be authorised for the second authority prescription issued under this criterion. Where fewer than 4 repeats are initially requested with the second authority prescription, authority approvals for sufficient repeats to complete a maximum of 6 months of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Public and private hospital authority required

Initial (change or re-commencement for patients under 18 years of age)
Application for initial treatment with bosentan monohydrate of patients aged less than 18 years with either of the following:
(a) primary pulmonary hypertension who wish to re-commence PBS-subsidised bosentan monohydrate after a break in therapy and who have demonstrated a response to their most recent course of PBS-subsidised treatment with bosentan monohydrate; OR
(b) primary pulmonary hypertension and whose most recent course of PBS-subsidised treatment was with epoprostenol sodium or sildenafil citrate.

Applications for authorisation must be in writing and must include:
(1) two completed authority prescription forms [see Note for authority approval requirements]; and
(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form [www.medicareaustralia.gov.au] which includes the results on which approval for the first application for PBS-subsidised bosentan monohydrate, epoprostenol sodium or sildenafil citrate, whichever was initiated first, was granted; and
(3) the date of the first application for PBS-subsidised treatment with bosentan monohydrate, epoprostenol sodium or sildenafil citrate, whichever was initiated first; and
(4) the results of the patient's response to treatment with their last course of PBS-subsidised bosentan monohydrate, epoprostenol sodium or sildenafil citrate.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. No repeats will be authorised for the first authority prescription issued under this criterion [see Note for full details of authority approval requirements]. A maximum of 4 repeats will be authorised for the second authority prescription issued under this criterion. Where fewer than 4 repeats are initially requested with the second authority prescription, authority approvals for sufficient repeats to complete a maximum of 6 months of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Public and private hospital authority required

Continuing treatment (all patients)
Continuing PBS-subsidised treatment with bosentan monohydrate of patients who have received approval for initial PBS-subsidised treatment with bosentan monohydrate and who have been assessed by a physician from a designated hospital to have achieved a response to their most recent course of bosentan monohydrate treatment [see Note for definition of response].

Applications for authorisation must be in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form [www.medicareaustralia.gov.au] which includes results from the 3 tests below, where available:
(i) RHC composite assessment; and
(ii) ECHO composite assessment; and
(iii) 6MWT.

Where fewer than 3 tests (see requirement 2 above) are able to be performed on clinical grounds, a reason outlining why the particular test/s could not be conducted must be provided with the authority application [see Note for test requirements].

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. A maximum of 5 repeats will be authorised.

continued ☞

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer $	Proprietary Name and Manufacturer	

Where fewer than 5 repeats are initially requested under this criterion, authority approvals for sufficient repeats to complete a maximum of 6 months of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Public and private hospital authority required

Cessation of treatment (all patients)

Final PBS-subsidised supply for patients with WHO Functional Class III or IV primary pulmonary hypertension or WHO Functional Class III or IV pulmonary arterial hypertension secondary to scleroderma or WHO Functional Class III or IV pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology), who have not responded to bosentan monohydrate therapy [see Note for definition of response], to allow for gradual cessation of treatment.

Applications for authorisation under this criterion should be made on the telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) [see Note on authority approval requirements].

Approval will only be granted for the 62.5 mg tablet strength. The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment.

Under no circumstances will telephone approvals be granted for treatment that would extend the final treatment period beyond 1 month.

6429J	*Tablet 62.5 mg (base)*	*60*	*4035.00*	*Tracleer*	*AT*
6430K	*Tablet 125 mg (base)*	*60*	*4035.00*	*Tracleer*	*AT*

NOTE:

These prices are based on special supply arrangements—see Pharmaceutical Benefits Pricing Authority relativity sheet for full details.

CIDOFOVIR

Private hospital authority required

Treatment of cytomegalovirus retinitis in patients with AIDS.

6247T	*Solution for I.V. infusion 375 mg (anhydrous) in 5 mL single use vial*	*1*	*900.00*	*Vistide*	*PU*

CINACALCET HYDROCHLORIDE

Private hospital authority required

Management, including initiation and stabilisation, by a nephrologist, of a patient with chronic kidney disease on dialysis who has sustained secondary hyperparathyroidism with iPTH of at least 50 pmol per L, not responding to conventional therapy.

NOTE:

During the titration phase, intact PTH should be monitored 4 weekly (measured at least 12 hours post dose) and dose titrated until an appropriate iPTH concentration is achieved. During the titration phase, approval will be limited to sufficient supply for 4 weeks treatment at a time, with doses between 30 and 180 mg per day according to the patient's response and tolerability.

During the maintenance phase, approval will be limited to provide sufficient quantity for 4 weeks treatment up to a maximum of 6 months supply for doses between 30 and 180 mg per day according to the patient's response and tolerability. Intact PTH should be monitored quarterly (measured at least 12 hours post dose) and dose adjusted as necessary to maintain an appropriate iPTH concentration.

"Sustained" means the abnormality was detected on at least 2 blood samples collected over a period of 2 to 4 months.

continued ☞

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer $		Proprietary Name and Manufacturer	
	Private hospital authority required ***Management, including initiation and stabilisation, by a nephrologist, of a patient with chronic kidney disease on dialysis who has sustained secondary hyperparathyroidism with iPTH of at least 15 pmol per L and less than 50 pmol per L AND an (adjusted) serum calcium concentration at least 2.6 mmol per L, not responding to conventional treatment.*** **NOTE:** ***During the titration phase, intact PTH should be monitored 4 weekly (measured at least 12 hours post dose) and dose titrated until an appropriate iPTH concentration is achieved. During the titration phase, approval will be limited to sufficient supply for 4 weeks treatment at a time, with doses between 30 and 180 mg per day according to the patient's response and tolerability.*** ***During the maintenance phase, approval will be limited to provide sufficient quantity for 4 weeks treatment up to a maximum of 6 months supply for doses between 30 and 180 mg per day according to the patient's response and tolerability. Intact PTH should be monitored quarterly (measured at least 12 hours post dose) and dose adjusted as necessary to maintain an appropriate iPTH concentration.*** ***"Sustained" means the abnormality was detected on at least 2 blood samples collected over a period of 2 to 4 months.***					
9625N	*Tablet 30 mg (base)*	*28*	*296.86*		*Sensipar*	*AN*
9626P	*Tablet 60 mg (base)*	*28*	*593.72*		*Sensipar*	*AN*
9627Q	*Tablet 90 mg (base)*	*28*	*890.58*		*Sensipar*	*AN*
	CLARITHROMYCIN **Private hospital authority required** ***Treatment of Mycobacterium avium complex infections.***					
6151R	*Tablet 250 mg*	*100*	*36.12*		*Klacid*	*AB*
6152T	*Tablet 500 mg*	*100*	*72.24*		*Klacid*	*AB*
	CLOZAPINE **Private hospital authority required** ***Schizophrenia in patients who are:*** ***(a) non-responsive to other neuroleptic agents; or*** ***(b) intolerant of other neuroleptic agents.***					
6101D	*Tablet 25 mg*	*100*	*70.56*	[a]	*Clopine 25*	*HH*
				[a]	*Clozaril 25*	*NV*
6417R	*Tablet 50 mg*	*100*	*141.12*		*Clopine 50*	*HH*
6102E	*Tablet 100 mg*	*100*	*264.60*	[a]	*Clopine 100*	*HH*
				[a]	*Clozaril 100*	*NV*
6418T	*Tablet 200 mg*	*100*	*529.20*		*Clopine 200*	*HH*
9632Y	*Oral liquid 50 mg per mL, 100 mL*	*1*	*135.00*		*Clopine Suspension*	*HH*
	CYCLOSPORIN **CAUTION:** ***Careful monitoring of patients is mandatory.*** **Private hospital authority required** ***Management of rejection in patients following organ or tissue transplantation, under the supervision and direction of a transplant unit. Management includes initiation, stabilisation and review of therapy as required;***					

continued ☞

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer $		Proprietary Name and Manufacturer	
	Management (which includes initiation, stabilisation and review of therapy) by:					
	(a) dermatologists or clinical immunologists of patients with severe atopic dermatitis for whom other systemic therapies are ineffective or inappropriate; or					
	(b) dermatologists of patients with severe psoriasis for whom other systemic therapies are ineffective or inappropriate and in whom the disease has caused significant interference with quality of life; or					
	(c) nephrologists of patients with nephrotic syndrome in patients in whom steroids and cytostatic drugs have failed or are not tolerated or are considered inappropriate and in whom renal function is unimpaired; or					
	(d) rheumatologists or clinical immunologists of patients with severe active rheumatoid arthritis for whom classical slow-acting anti-rheumatic agents (including methotrexate) are ineffective or inappropriate.					
6232B	***Capsule 10 mg***	***60***	***37.20***		***Neoral 10***	***NV***
6352H	***Capsule 25 mg***	***30***	***40.80***	[a]	***Cicloral***	***SZ***
				[a]	***Neoral 25***	***NV***
	NOTE:					
	A brand premium of $0.97 applies to Neoral 25 brand. Both brands may not be available in all hospitals.					
6353J	***Capsule 50 mg***	***30***	***84.87***	[a]	***Cicloral***	***SZ***
				[a]	***Neoral 50***	***NV***
	NOTE:					
	A brand premium of $1.05 applies to Neoral 50 brand. Both brands may not be available in all hospitals.					
6354K	***Capsule 100 mg***	***30***	***172.92***	[a]	***Cicloral***	***SZ***
				[a]	***Neoral 100***	***NV***
	NOTE:					
	A brand premium of $1.06 applies to Neoral 100 brand. Both brands may not be available in all hospitals.					
6125J	***Oral liquid 100 mg per mL, 50 mL***	***1***	***315.79***		***Neoral***	***NV***
	Private hospital authority required					
	For use by organ or tissue transplant recipients.					
6109M	***Solution concentrate for I.V. infusion 50 mg in 1 mL***	***10***	***54.10***		***Sandimmun***	***NV***
	DARBEPOETIN ALFA					
	Private hospital authority required					
	Treatment of anaemia requiring transfusion, defined as a haemoglobin level of less than 100 g per L, where intrinsic renal disease, as assessed by a nephrologist, is the primary cause of the anaemia.					
6320P	***Injection 10 micrograms in 0.4 mL pre-filled syringe***	***4***	***187.41***		***Aranesp***	***AN***
6321Q	***Injection 20 micrograms in 0.5 mL pre-filled syringe***	***4***	***352.96***		***Aranesp***	***AN***
6488L	***Injection 20 micrograms in 0.5 mL pre-filled injection pen***	***1***	***88.24***		***Aranesp SureClick***	***AN***
6322R	***Injection 30 micrograms in 0.3 mL pre-filled syringe***	***4***	***482.87***		***Aranesp***	***AN***
6323T	***Injection 40 micrograms in 0.4 mL pre-filled syringe***	***4***	***586.10***		***Aranesp***	***AN***
6489M	***Injection 40 micrograms in 0.4 mL pre-filled injection pen***	***1***	***146.53***		***Aranesp SureClick***	***AN***
6324W	***Injection 50 micrograms in 0.5 mL pre-filled syringe***	***4***	***724.62***		***Aranesp***	***AN***
6325X	***Injection 60 micrograms in 0.3 mL pre-filled syringe***	***4***	***850.87***		***Aranesp***	***AN***
6490N	***Injection 60 micrograms in 0.3 mL pre-filled injection pen***	***1***	***212.72***		***Aranesp SureClick***	***AN***

continued ☞

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer $	Proprietary Name and Manufacturer	
6438W	*Injection 80 micrograms in 0.4 mL pre-filled syringe*	*4*	*1120.00*	*Aranesp*	*AN*
6491P	*Injection 80 micrograms in 0.4 mL pre-filled injection pen*	*1*	*280.00*	*Aranesp SureClick*	*AN*
6326Y	*Injection 100 micrograms in 0.5 mL pre-filled syringe*	*4*	*1379.21*	*Aranesp*	*AN*
6492Q	*Injection 100 micrograms in 0.5 mL pre-filled injection pen*	*1*	*344.80*	*Aranesp SureClick*	*AN*
6365B	*Injection 150 micrograms in 0.3 mL pre-filled syringe*	*4*	*2055.00*	*Aranesp*	*AN*
6493R	*Injection 150 micrograms in 0.3 mL pre-filled injection pen*	*1*	*513.75*	*Aranesp SureClick*	*AN*

DARUNAVIR

Private hospital authority required

Treatment, in combination with other antiretroviral agents, and co-administered with 100 mg ritonavir twice daily, of HIV infection in an antiretroviral experienced patient with:
(a) evidence of HIV replication (viral load greater than 10,000 copies per mL); and/or
(b) CD4 cell counts of less than 500 per cubic millimetre.
A patient must have failed previous treatment with, or have resistance to, 3 different antiretroviral regimens which have included:
(i) at least 1 non-nucleoside reverse transcriptase inhibitor; and
(ii) at least 1 nucleoside reverse transcriptase inhibitor; and
(iii) at least 2 protease inhibitors.

9616D	*Tablet 300 mg (as ethanolate)*	*120*	*1101.38*	*Prezista*	*JC*

DEFERASIROX

Private hospital authority required

Chronic iron overload in adults, adolescents and children 6 years and older associated with disorders of erythropoiesis;

Chronic iron overload in paediatric patients aged 2 to 5 years, associated with disorders of erythropoiesis, who are intolerant to desferrioxamine or in whom desferrioxamine has proven ineffective.

6499C	*Tablet 125 mg (dispersible)*	*28*	*233.58*	*Exjade*	*NV*
6500D	*Tablet 250 mg (dispersible)*	*28*	*467.15*	*Exjade*	*NV*
9600G	*Tablet 500 mg (dispersible)*	*28*	*934.30*	*Exjade*	*NV*

NOTE:
These prices are based on special supply arrangements—see Pharmaceutical Benefits Pricing Authority relativity sheet for full details.

DEFERIPRONE

Private hospital authority required

Iron overload in patients with thalassaemia major who are unable to take desferrioxamine therapy;

Iron overload in patients with thalassaemia major in whom desferrioxamine therapy has proven ineffective.

6416Q	*Tablet 500 mg*	*100*	*450.56*	*Ferriprox*	*OA*

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer $		Proprietary Name and Manufacturer	
	DELAVIRDINE MESYLATE					
	Private hospital authority required ***Treatment of HIV infection in patients with:*** ***(a) CD4 cell counts of less than 500 per cubic millimetre; or*** ***(b) viral load of greater than 10,000 copies per mL.***					
6243N	***Tablet 100 mg***	***360***	***271.58***		***Rescriptor***	***PF***
	DESFERRIOXAMINE MESYLATE					
	Private hospital authority required ***Disorders of erythropoiesis associated with treatment-related chronic iron overload.***					
6113R	***Powder for injection 500 mg***	***10***	***97.02***	[a]	***HH***	
				[a]	***Desferal 500 mg***	***NV***
	NOTE: ***A brand premium of $8.03 applies to Desferal 500 mg brand. Both brands may not be available in all hospitals.***					
6270B	***Powder for injection 2 g***	***1***	***38.81***	[a]	***HH***	
				[a]	***Desferal 2 g***	***NV***
	NOTE: ***A brand premium of $0.39 applies to Desferal 2 g brand. Both brands may not be available in all hospitals.***					
	DIDANOSINE					
	Private hospital authority required ***Treatment of HIV infection in patients with:*** ***(a) CD4 cell counts of less than 500 per cubic millimetre; or*** ***(b) viral load of greater than 10,000 copies per mL.***					
6298L	***Capsule 125 mg (containing enteric coated beadlets)***	***30***	***102.12***		***Videx EC***	***BQ***
6299M	***Capsule 200 mg (containing enteric coated beadlets)***	***30***	***163.40***		***Videx EC***	***BQ***
6300N	***Capsule 250 mg (containing enteric coated beadlets)***	***30***	***204.24***		***Videx EC***	***BQ***
6301P	***Capsule 400 mg (containing enteric coated beadlets)***	***30***	***326.79***		***Videx EC***	***BQ***
	DISODIUM PAMIDRONATE					
	Private hospital authority required ***Treatment of hypercalcaemia of malignancy refractory to anti-neoplastic therapy.***					
6286W	***Concentrated injection 15 mg in 5 mL***	***1***	***55.75***	[a]	***Pamisol***	***HH***
6290C	***Injection set containing 4 vials powder for I.V. infusion 15 mg and 4 ampoules solvent 5 mL***	***1***	***223.02***	[a]	***Aredia 15 mg***	***NV***
	NOTE: ***The concentrated injection 15 mg and powder for I.V. infusion 15 mg (after reconstitution) are bioequivalent.***					
6287X	***Concentrated injection 30 mg in 10 mL***	***1***	***111.51***	[a]	***Pamisol***	***HH***
6279L	***Injection set containing 2 vials powder for I.V. infusion 30 mg and 2 ampoules solvent 10 mL***	***1***	***223.02***	[a]	***Aredia 30 mg***	***NV***
	NOTE: ***The concentrated injection 30 mg and powder for I.V. infusion 30 mg (after reconstitution) are bioequivalent.***					
6288Y	***Concentrated injection 60 mg in 10 mL***	***1***	***223.02***		***Pamisol***	***HH***

continued ☞

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer $		Proprietary Name and Manufacturer	
	Private hospital authority required ***Treatment of hypercalcaemia of malignancy refractory to anti-neoplastic therapy.***					
	Private hospital authority required ***Multiple myeloma;*** ***Bone metastases from breast cancer.***					
6289B	***Concentrated injection 90 mg in 10 mL***	***1***	***334.53***	[a]	***Pamisol***	***HH***
6223M	***Injection set containing 1 vial powder for I.V. infusion 90 mg and 1 ampoule solvent 10 mL***	***1***	***334.53***	[a]	***Aredia 90 mg***	***NV***
	NOTE: ***The concentrated injection 90 mg and powder for I.V. infusion 90 mg (after reconstitution) are bioequivalent.***					

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer $	Proprietary Name and Manufacturer	
	DORNASE ALFA				
	Private hospital authority required ***Use by cystic fibrosis patients who satisfy all of the following criteria:*** ***(1) are 5 years of age or older;*** ***(2) have a FVC greater than 40% predicted for age, gender and height;*** ***(3) have evidence of chronic suppurative lung disease (cough and sputum most days of the week, or greater than 3 respiratory tract infections of more than 2 weeks' duration in any 12 months, or objective evidence of obstructive airways disease);*** ***(4) are participating in a 4 week trial as detailed below or have achieved a 10% or greater improvement in FEV1 (compared to baseline established prior to dornase alfa treatment) after a 4 week trial.*** ***In order for patients to be eligible for participation in the HSD program, the following conditions must be met:*** ***(1) Patients must be assessed at cystic fibrosis clinics/centres which are under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis and the prescribing of dornase alfa under the HSD program is limited to such physicians. If attendance at such units is not possible because of geographical isolation, management (including prescribing) may be by specialist physician or paediatrician in consultation with such a unit;*** ***(2) The measurement of lung function is to be conducted by independent (other than the treating doctor) experienced personnel at established lung function testing laboratories, unless this is not possible because of geographical isolation;*** ***(3) Prior to dornase alfa therapy, a baseline measurement of FEV1 must be undertaken during a stable period of the disease;*** ***(4) Initial therapy is limited to 4 weeks' treatment with dornase alfa at a dose of 2.5 mg daily;*** ***(5) At or towards the end of the initial 4 weeks' trial, patients must be reassessed and a further FEV1 measurement be undertaken (single test under conditions as above). Patients who achieve a 10% or greater improvement in FEV1 (compared to baseline established prior to dornase alfa treatment) are eligible for continued subsidy under the HSD program at a dose of 2.5 mg daily;*** ***(6) Patients who fail to meet a 10% or greater improvement in FEV1 after the initial 4 weeks' treatment at a dose of 2.5 mg daily, may have 1 further trial in the next 12 months but not before 3 months after the initial trial;*** ***(7) Following an initial 6 months' therapy, a global assessment must be undertaken involving the patient, the patient's family (in the case of paediatric patients) and the treating physician(s) to establish that all agree that dornase alfa treatment is continuing to produce worthwhile benefits. (Dornase alfa therapy should cease if there is not general agreement of benefit as there is always the possibility of harm from unnecessary use.) Further reassessments are to be undertaken at six-monthly intervals;*** ***(8) Other aspects of treatment, such as physiotherapy, must be continued;*** ***(9) Where there is documented evidence that a patient already receiving dornase alfa therapy would have met the criteria for subsidy (i.e. satisfied the criteria for the 4 week trial and achieved a 10% or greater improvement in FEV1) then the patient is eligible to continue treatment under the HSD program. Where such evidence is not available, patients will need to satisfy the initiation and continuation criteria as for new patients. (Four weeks is considered a suitable wash-out period).*** **NOTE:** ***It is highly desirable that all patients be included in the national cystic fibrosis patient data-base.***				
6120D	***Solution for inhalation 2.5 mg (2,500 units) in 2.5 mL***	***30***	***1180.00***	***Pulmozyme***	***RO***
	DOXORUBICIN HYDROCHLORIDE, PEGYLATED LIPOSOMAL				
	Private hospital authority required ***Treatment of AIDS-related Kaposi's sarcoma in patients with CD4 cell counts of less than 200 per cubic millimetre and:*** ***(a) extensive mucocutaneous involvement; or*** ***(b) extensive visceral involvement.***				
6249X	***Suspension for I.V. infusion 20 mg in 10 mL***	***1***	***622.99***	***Caelyx***	***SH***

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer $	Proprietary Name and Manufacturer	
	EFAVIRENZ				
	Private hospital authority required ***Treatment of HIV infection in patients with:*** ***(a) CD4 cell counts of less than 500 per cubic millimetre; or*** ***(b) viral load of greater than 10,000 copies per mL.***				
9618F	***Tablet 200 mg***	***90***	***452.64***	***Stocrin***	***MK***
6356M	***Tablet 600 mg***	***30***	***452.64***	***Stocrin***	***MK***
6372J	***Oral solution 30 mg per mL, 180 mL***	***1***	***135.79***	***Stocrin***	***MK***
	NOTE: ***These prices are based on special supply arrangements—see Pharmaceutical Benefits Pricing Authority relativity sheet for full details.***				
	EMTRICITABINE				
	Private hospital authority required ***Treatment of HIV infection in patients with:*** ***(a) CD4 cell counts of less than 500 per cubic millimetre; or*** ***(b) viral load of greater than 10,000 copies per mL.***				
6137B	***Capsule 200 mg***	***30***	***282.00***	***Emtriva***	***GI***
	ENFUVIRTIDE				
	Private hospital authority required ***Treatment, in combination with other antiretroviral agents, of HIV infection in antiretroviral experienced patients with treatment failure characterised by:*** ***(a) evidence of HIV replication, despite ongoing therapy; or*** ***(b) treatment-limiting toxicity to previous antiretroviral agents.*** ***Patients must have failed previous treatment with 3 different antiretroviral regimens. At least 1 of each of the following classes of antiretroviral drugs must have been attempted:*** ***(i) at least 1 non-nucleoside reverse transcriptase inhibitor; and*** ***(ii) at least 1 nucleoside reverse transcriptase inhibitor; and*** ***(iii) at least 1 protease inhibitor.***				
6455R	***Pack containing 60 vials powder for injection 90 mg with 60 vials water for injections 1.1 mL (with syringes and swabs)***	***‡ 1***	***2213.00***	***Fuzeon***	***RO***
	ENTECAVIR MONOHYDRATE				
	Private hospital authority required ***Patients with chronic hepatitis B who satisfy all of the following criteria:*** ***(1) Histological evidence of chronic hepatitis on liver biopsy (except in patients with coagulation disorders considered severe enough to prevent liver biopsy);*** ***(2)(a) Abnormal serum ALT levels in conjunction with documented chronic hepatitis B infection; or*** ***(b) Elevated HBV DNA levels in conjunction with documented chronic hepatitis B infection;*** ***(3) Female patients of child-bearing age are not pregnant, not breast-feeding, and are using an effective form of contraception.*** ***Persons with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy.***				
	NOTE: ***PBS-subsidised entecavir monohydrate must be used as monotherapy.***				

continued ☞

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer $	Proprietary Name and Manufacturer	
9602J	*Tablet 0.5 mg*	*30*	*384.30*	*Baraclude*	*BQ*

Private hospital authority required

Patients with chronic hepatitis B who have failed lamivudine therapy and who satisfy all of the following criteria:
(1)(a) Repeatedly elevated serum ALT levels while on concurrent antihepadnaviral therapy of greater than or equal to 6 months duration in conjunction with documented chronic hepatitis B infection; or
(b) Repeatedly elevated HBV DNA levels one log greater than the nadir value or failure to achieve a 1 log reduction in HBV DNA within 3 months, whilst on previous antihepadnaviral therapy except in patients with evidence of poor compliance;
(2) Female patients of child-bearing age are not pregnant, not breast-feeding, and are using an effective form of contraception.
Persons with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy.

NOTE:
Patients should have undergone a liver biopsy at some point since initial diagnosis to obtain histological evidence of chronic hepatitis.
PBS-subsidised entecavir monohydrate must be used as monotherapy.

9603K	*Tablet 1 mg*	*30*	*625.00*	*Baraclude*	*BQ*

EPOETIN ALFA

Private hospital authority required

Treatment of anaemia requiring transfusion, defined as a haemoglobin level of less than 100 g per L, where intrinsic renal disease, as assessed by a nephrologist, is the primary cause of the anaemia.

6251B	*Injection 1,000 units in 0.5 mL pre-filled syringe*	*6*	*147.00*	*Eprex 1000*	*JC*
6204M	*Injection 2,000 units in 0.5 mL pre-filled syringe*	*6*	*272.00*	*Eprex 2000*	*JC*
6205N	*Injection 3,000 units in 0.3 mL pre-filled syringe*	*6*	*351.00*	*Eprex 3000*	*JC*
6206P	*Injection 4,000 units in 0.4 mL pre-filled syringe*	*6*	*447.00*	*Eprex 4000*	*JC*
6302Q	*Injection 5,000 units in 0.5 mL pre-filled syringe*	*6*	*556.50*	*Eprex 5000*	*JC*
6303R	*Injection 6,000 units in 0.6 mL pre-filled syringe*	*6*	*660.60*	*Eprex 6000*	*JC*
6305W	*Injection 8,000 units in 0.8 mL pre-filled syringe*	*6*	*856.80*	*Eprex 8000*	*JC*
6207Q	*Injection 10,000 units in 1 mL pre-filled syringe*	*6*	*1037.00*	*Eprex 10000*	*JC*
6434P	*Injection 20,000 units in 0.5 mL pre-filled syringe*	*6*	*2040.00*	*Eprex 20,000*	*JC*
9623L	*Injection 30,000 units in 0.75 mL pre-filled syringe*	*6*	*3015.00*	*Eprex 30,000*	*JC*
6339P	*Injection 40,000 units in 1 mL pre-filled syringe*	*1*	*660.00*	*Eprex 40,000*	*JC*

EPOETIN BETA

Private hospital authority required

Treatment of anaemia requiring transfusion, defined as a haemoglobin level of less than 100 g per L, where intrinsic renal disease, as assessed by a nephrologist, is the primary cause of the anaemia.

6479B	*Injection 1,000 units in 0.3 mL pre-filled syringe*	*6*	*147.00*	*NeoRecormon*	*RO*
6480C	*Injection 2,000 units in 0.3 mL pre-filled syringe*	*6*	*272.00*	*NeoRecormon*	*RO*

continued ☞

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer $	Proprietary Name and Manufacturer	
6481D	*Injection 3,000 units in 0.3 mL pre-filled syringe*	*6*	*351.00*	*NeoRecormon*	*RO*
6482E	*Injection 4,000 units in 0.3 mL pre-filled syringe*	*6*	*447.00*	*NeoRecormon*	*RO*
6483F	*Injection 5,000 units in 0.3 mL pre-filled syringe*	*6*	*556.50*	*NeoRecormon*	*RO*
6484G	*Injection 6,000 units in 0.3 mL pre-filled syringe*	*6*	*660.60*	*NeoRecormon*	*RO*
6485H	*Injection 10,000 units in 0.6 mL pre-filled syringe*	*6*	*1037.00*	*NeoRecormon*	*RO*
6486J	*Injection 20,000 units in 0.6 mL pre-filled syringe*	*6*	*2040.00*	*NeoRecormon*	*RO*
6487K	*Injection 30,000 units in 0.6 mL pre-filled syringe*	*1*	*502.50*	*NeoRecormon*	*RO*

EPOPROSTENOL SODIUM

NOTE:

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

Written applications for authority to prescribe epoprostenol sodium should be forwarded to:

Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

NOTE:

Epoprostenol sodium is not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with scleroderma, where the total lung capacity is less than 70% of that predicted.

Epoprostenol sodium is not PBS-subsidised when used in combination with PBS-subsidised bosentan monohydrate, PBS-subsidised iloprost trometamol, PBS-subsidised sildenafil citrate or PBS-subsidised sitaxentan sodium.

The following provides some explanatory notes regarding the availability of PBS-subsidised treatment with:
(a) bosentan monohydrate, of primary pulmonary hypertension or pulmonary arterial hypertension secondary to scleroderma, in patients with disease of WHO Functional Class III or IV severity; AND
(b) iloprost trometamol, of primary pulmonary hypertension, drug-induced pulmonary arterial hypertension or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class III or IV severity; AND
(c) epoprostenol sodium, of primary pulmonary hypertension, in patients with disease of WHO Functional Class III or IV severity; AND
(d) sildenafil citrate, of primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class III severity; AND
(e) sitaxentan sodium, of primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class III severity.

Adult patients:
From 1 April 2008, adult patients with primary pulmonary hypertension will be able to access, through the PBS, bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate (WHO Class III only) or sitaxentan sodium (WHO Class III only). Once these patients are approved initial treatment with 1 of these 5 drugs, they may swap between bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate and sitaxentan sodium at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary. (New baselines may be submitted where the patient has failed to respond to their current treatment.)

Patients may only swap to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate or sitaxentan sodium if they have not failed prior PBS-subsidised treatment with that drug.

continued ☞

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer $	Proprietary Name and Manufacturer

Adult patients with pulmonary arterial hypertension secondary to scleroderma will be able to access, through the PBS, bosentan monohydrate, iloprost trometamol, sildenafil citrate (WHO Class III only) or sitaxentan sodium (WHO Class III only). Once these patients are approved initial treatment with 1 of these 4 drugs, they may swap between bosentan monohydrate, iloprost trometamol, sildenafil citrate and sitaxentan sodium at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary. (New baselines may be submitted where the patient has failed to respond to their current treatment.)

Patients may only swap to bosentan monohydrate, iloprost trometamol, sildenafil citrate or sitaxentan sodium if they have not failed prior PBS-subsidised treatment with that drug.

Adult patients with pulmonary arterial hypertension secondary to connective tissue disease other than scleroderma will be able to access, through the PBS, iloprost trometamol, sildenafil citrate (WHO Class III only) or sitaxentan sodium (WHO Class III only). Once these patients are approved initial treatment with 1 of these 3 drugs, they may swap between iloprost trometamol, sildenafil citrate and sitaxentan sodium at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary. (New baselines may be submitted where the patient has failed to respond to their current treatment.)

Patients may only swap to iloprost trometamol, sildenafil citrate or sitaxentan sodium if they have not failed prior PBS-subsidised treatment with that drug.

Patients with drug-induced pulmonary arterial hypertension are only eligible for treatment with iloprost trometamol. They may not swap to bosentan monohydrate, epoprostenol sodium, sildenafil citrate or sitaxentan sodium.

Patients under 18 years of age:
From 1 April 2008, patients aged less than 18 years with primary pulmonary hypertension are eligible to receive PBS-subsidised treatment with bosentan monohydrate, epoprostenol sodium, iloprost trometamol, sildenafil citrate (WHO Class III only) or sitaxentan sodium (WHO Class III only). Once these patients are approved initial treatment with 1 of these 5 drugs, they may swap between bosentan monohydrate, epoprostenol sodium, iloprost trometamol, sildenafil citrate and sitaxentan sodium at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary. (New baselines may be submitted where the patient has failed to respond to their current treatment.)

Patients may only swap to bosentan monohydrate, epoprostenol sodium, iloprost trometamol, sildenafil citrate or sitaxentan sodium if they have not failed prior PBS-subsidised treatment with that drug.

1. Definition of primary pulmonary hypertension, drug-induced pulmonary arterial hypertension or pulmonary arterial hypertension secondary to connective tissue disease, including scleroderma.

Primary pulmonary hypertension, drug-induced pulmonary arterial hypertension or pulmonary arterial hypertension secondary to connective tissue disease, including scleroderma, are defined as follows:
(i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary capillary wedge pressure (PCWP) less than 18 mmHg; or
(ii) mPAP greater than 30 mmHg with exercise and PCWP less than 18 mmHg; or
(iii) where a right heart catheter cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

2. Definition of WHO Functional Class III or IV disease severity.

(a) WHO Functional Class III disease severity is defined as follows:
Patients with pulmonary hypertension resulting in marked limitation of physical activity who are comfortable at rest and on ordinary physical activity experience dyspnoea or fatigue, chest pain or near syncope.
(b) WHO Functional Class IV disease severity is defined as follows:
Patients with the inability to carry out any physical activity without symptoms. These patients manifest signs of right heart failure. Dyspnoea and/or fatigue may even be present at rest. Discomfort is increased by any physical activity.

3. Designated hospitals.

continued ☞

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer $	Proprietary Name and Manufacturer

Refer to the Medicare Australia website at www.medicareaustralia.gov.au for a list of designated hospitals.

4. Test requirements to establish baseline for initiation of treatment and response to treatment for continuation of treatment.

(a) Initiation of treatment.
The first written application for PBS-subsidised treatment with the first of either bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate or sitaxentan sodium should be accompanied by the results of a right heart catheter (RHC) composite assessment, plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:
(1) RHC plus ECHO composite assessments;
(2) RHC composite assessment plus 6MWT;
(3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted to Medicare Australia for consideration based on the results of the following test combinations, which are listed in descending order of preference:
(1) ECHO composite assessment plus 6MWT;
(2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a reason outlining why the particular test/s could not be conducted must be provided with the authority application.

NOTE:
Where patients were initiated on PBS-subsidised treatment either with bosentan monohydrate on or after 1 March 2004, with iloprost trometamol on or after 1 April 2005, with epoprostenol sodium on or after 1 August 2006, with sildenafil citrate on or after 1 March 2007, with sitaxentan sodium on or after 1 April 2008, or with bosentan monohydrate (for PAH associated with congenital systemic-to-pulmonary shunt) on or after 1 August 2008, the test results provided with the initial application must be no more than 2 months old at the time of application. These results will form the baseline against which response assessments will be made.

Where patients received treatment with either bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate or sitaxentan sodium prior to being commenced on PBS-subsidised treatment with the first of either bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate or sitaxentan sodium, the test requirements above still apply. The results that will form the baseline against which response assessments will be made will be those measured at the time patients commenced non-PBS-subsidised treatment with either bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate or sitaxentan sodium, whichever of the 5 drugs the patient received first.

(b) Continuation of treatment.
The following list outlines the preferred test combination, in descending order, for the purposes of continuation of PBS-subsidised treatment:
(1) RHC plus ECHO composite assessments plus 6MWT;
(2) RHC plus ECHO composite assessments;
(3) RHC composite assessment plus 6MWT;
(4) ECHO composite assessment plus 6MWT;
(5) RHC composite assessment only;
(6) ECHO composite assessment only.

The results of the same tests as conducted at baseline should be provided with each written continuing treatment application (i.e. every 6 months), except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a reason why the test(s) could not be conducted must be provided with the application.

The test(s) results provided with the application for continuing treatment must be no more than 2 months old at the time of application.

continued ☞

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer $	Proprietary Name and Manufacturer

5. Definition of response to epoprostenol sodium, bosentan monohydrate, iloprost trometamol, sildenafil citrate, sitaxentan sodium or prior vasodilator treatment.

For adult patients with 2 or more baseline tests, response to treatment is defined as 2 or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For adult patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For adult patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least 1 of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

6. Authority approval requirements. [The following 2 sections are only relevant to the PBS listing of epoprostenol sodium. The requirements specific to bosentan monohydrate, iloprost trometamol, sildenafil citrate and sitaxentan sodium are given in parts 6 and 7 of the NOTE included in the bosentan monohydrate, iloprost trometamol, sildenafil citrate and sitaxentan sodium Schedule entry respectively.]

(a) Initiation of PBS-subsidised treatment with epoprostenol sodium, where the patient has not received prior PBS-subsidised treatment with bosentan monohydrate, iloprost trometamol, sildenafil citrate or sitaxentan sodium. All applications for initial treatment must be made in writing, must include an authority prescription and must be submitted to Medicare Australia for authorisation. The total duration of initial PBS-subsidised treatment that will be approved with this first written application is up to 6 months, based on the dosage recommendations in the TGA-approved Product Information.

(b) Continuation of treatment.
Written applications for continuing treatment must be submitted to Medicare Australia for authorisation every 6 months. Approvals will be limited to provide sufficient supply for up to a maximum of 6 months of treatment, based on the dosage recommendations in the TGA-approved Product Information.

Applications for continuing treatment will only be approved for patients who have currently demonstrated a response to treatment with epoprostenol sodium.

The assessment of the patient's response to the first and subsequent 6 month courses of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated. Applications for continuing treatment with epoprostenol sodium should be made prior to the completion of the 6 month treatment course to ensure continuity for those patients who respond to treatment, as assessed by the treating physician.

(c) Swapping between bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate and sitaxentan sodium.
For eligible patients, applications to swap between these 5 drugs must be made under the relevant initial treatment restriction. Patients should be assessed for response to the treatment they are ceasing at the time the application to swap therapy is being made. Patients who fail to demonstrate a response or for whom no assessment results are submitted with the application to swap therapy may not re-commence PBS-subsidised treatment with the drug they are ceasing.

It is important that patients are assessed for response to every course of treatment approved within the timeframes specified in the relevant restriction, in order to maximise the choice of treatment.

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

(d) Cessation of treatment.
Patients who fail to demonstrate a response to PBS-subsidised epoprostenol sodium treatment at the times where an assessment is required must cease PBS-subsidised epoprostenol sodium therapy.

7. Re-treatment with epoprostenol sodium.

Patients who do not respond to treatment are not eligible to receive further PBS-subsidised treatment with epoprostenol sodium under any circumstances.

8. Further information.

A tabulated representation of the above information and the restriction can be obtained from the Medicare Australia website at www.medicareaustralia.gov.au.

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Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer $	Proprietary Name and Manufacturer

Public and private hospital authority required

Initial (new adult patients)

Application for initial PBS-subsidised treatment with epoprostenol sodium of adult patients who have not received prior PBS-subsidised treatment with bosentan monohydrate, iloprost trometamol, sildenafil citrate or sitaxentan sodium and who have been assessed by a physician from a designated hospital to have:
WHO Functional Class III primary pulmonary hypertension and a mean right atrial pressure of 8 mmHg or less, as measured by RHC, unless a RHC is contraindicated on clinical grounds.

Patients must have failed to respond [see Note for definition of response] to 6 or more weeks of appropriate vasodilator treatment unless intolerance or a contraindication to such treatment exists.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted to Medicare Australia for consideration based on the test results of the ECHO composite assessment plus 6MWT or the ECHO composite assessment only.

Applications for authorisation must be in writing and must include:
(1) a completed authority prescription form [see Note for authority approval requirements]; and
(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form [www.medicareaustralia.gov.au] which includes results from the 3 tests below, where available:
(i) RHC composite assessment; and
(ii) ECHO composite assessment; and
(iii) 6MWT; and
(3) a signed patient acknowledgment indicating that the patient understands and acknowledges that PBS-subsidised treatment with epoprostenol sodium for primary pulmonary hypertension, OR with iloprost trometamol for primary pulmonary hypertension, drug-induced pulmonary arterial hypertension or pulmonary arterial hypertension secondary to connective tissue disease, OR with bosentan monohydrate for primary pulmonary hypertension or pulmonary arterial hypertension secondary to scleroderma, OR with sildenafil citrate for primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, OR with sitaxentan sodium for primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, will cease if the treating physician determines that the patient has not achieved a response to treatment [see Note for definition of response].

Details of prior vasodilator treatment, including the dose and duration of treatment, must be provided at the time of application. Where the patient has an adverse event to a vasodilator or where vasodilator treatment is contraindicated, details on the nature of the adverse event or contraindication according to the TGA-approved Product Information must also be provided with the application.

Where fewer than 3 tests (see requirement 2 above) are able to be performed on clinical grounds, a reason outlining why the particular test/s could not be conducted must be provided with the authority application [see Note for test requirements].

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. A maximum of 5 repeats may be requested. Where fewer than 5 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 6 months of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Public and private hospital authority required

Initial (new adult patients)

Application for initial PBS-subsidised treatment with epoprostenol sodium of adult patients who have not received prior PBS-subsidised treatment with bosentan monohydrate, iloprost trometamol, sildenafil citrate or sitaxentan sodium and who have been assessed by a physician from a designated hospital to have:
(a) WHO Functional Class III primary pulmonary hypertension and a mean right atrial pressure greater than 8 mmHg, as measured by RHC, unless a RHC is contraindicated on clinical grounds; OR
(b) WHO Functional Class IV primary pulmonary hypertension.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted to Medicare Australia for consideration based on the test results of the ECHO composite assessment plus 6MWT or the ECHO composite assessment only.

continued ☞

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer $	Proprietary Name and Manufacturer

Applications for authorisation must be in writing and must include:
(1) a completed authority prescription form [see Note for authority approval requirements]; and
(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form [www.medicareaustralia.gov.au] which includes results from the 3 tests below, where available:
(i) RHC composite assessment; and
(ii) ECHO composite assessment; and
(iii) 6MWT; and
(3) a signed patient acknowledgment indicating that the patient understands and acknowledges that PBS-subsidised treatment with epoprostenol sodium for primary pulmonary hypertension, OR with iloprost trometamol for primary pulmonary hypertension, drug-induced pulmonary arterial hypertension or pulmonary arterial hypertension secondary to connective tissue disease, OR with bosentan monohydrate for primary pulmonary hypertension or pulmonary arterial hypertension secondary to scleroderma, OR with sildenafil citrate for primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, OR with sitaxentan sodium for primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, will cease if the treating physician determines that the patient has not achieved a response to treatment [see Note for definition of response].

Where fewer than 3 tests (see requirement 2 above) are able to be performed on clinical grounds, a reason outlining why the particular test/s could not be conducted must be provided with the authority application [see Note for test requirements].

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. A maximum of 5 repeats may be requested. Where fewer than 5 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 6 months of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Public and private hospital authority required

Initial (new patients under 18 years of age)
Application for initial PBS-subsidised treatment of patients aged less than 18 years who have not received prior PBS-subsidised treatment with bosentan monohydrate or sildenafil citrate and who have been assessed by a physician from a designated hospital to have WHO Functional Class III primary pulmonary hypertension with a mean right atrial pressure of 8 mmHg or less, as measured by RHC, or, where a RHC cannot be performed on clinical grounds, normal right ventricular function as assessed by ECHO.

Patients must have failed to respond [see Note for definition of response] to 6 or more weeks of appropriate prior vasodilator treatment unless intolerance or a contraindication to such treatment exists.

Applications for authorisation must be in writing and must include:
(1) a completed authority prescription form [see Note for authority approval requirements]; and
(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form [www.medicareaustralia.gov.au] which includes results from the 3 tests below, where available:
(i) RHC composite assessment; and
(ii) ECHO composite assessment; and
(iii) 6MWT; and
(3) a patient acknowledgment, signed by the parent or authorised guardian, indicating that they understand and acknowledge that PBS-subsidised treatment with epoprostenol sodium, bosentan monohydrate or sildenafil citrate for primary pulmonary hypertension will cease if the treating physician determines that the patient has not achieved a response to treatment [see Note for definition of response].

Details of prior vasodilator treatment, including the dose and duration of treatment, must be provided at the time of application. Where the patient has an adverse event to a vasodilator or where vasodilator treatment is contraindicated, details on the nature of the adverse event or contraindication according to the TGA-approved Product Information must also be provided with the application.

Where fewer than 3 tests (see requirement 2 above) are able to be performed on clinical grounds, a reason outlining why the particular test/s could not be conducted must be provided with the authority application [see Note for test requirements].

continued ☞

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer $	Proprietary Name and Manufacturer

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. A maximum of 5 repeats will be authorised under this criterion. Where fewer than 5 repeats are initially requested, authority approvals for sufficient repeats to complete a maximum of 6 months of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Public and private hospital authority required

Initial (new patients under 18 years of age)
Application for initial PBS-subsidised treatment of patients aged less than 18 years who have not received prior PBS-subsidised treatment with bosentan monohydrate or sildenafil citrate and who have been assessed by a physician from a designated hospital to have:
(a) WHO Functional Class III primary pulmonary hypertension and either a mean right atrial pressure greater than 8 mmHg, as measured by RHC, or, where a RHC cannot be performed on clinical grounds, right ventricular dysfunction as assessed by ECHO; OR
(b) WHO Functional Class IV primary pulmonary hypertension.

Applications for authorisation must be in writing and must include:
(1) a completed authority prescription form [see Note for authority approval requirements]; and
(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form [www.medicareaustralia.gov.au] which includes results from the 3 tests below, where available:
(i) RHC composite assessment; and
(ii) ECHO composite assessment; and
(iii) 6MWT; and
(3) a patient acknowledgment, signed by the parent or authorised guardian, indicating that they understand and acknowledge that PBS-subsidised treatment with epoprostenol sodium, bosentan monohydrate or sildenafil citrate for primary pulmonary hypertension will cease if the treating physician determines that the patient has not achieved a response to treatment [see Note for definition of response].

Where fewer than 3 tests (see requirement 2 above) are able to be performed on clinical grounds, a reason outlining why the particular test/s could not be conducted must be provided with the authority application [see Note for test requirements].

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. A maximum of 5 repeats will be authorised under this criterion. Where fewer than 5 repeats are initially requested, authority approvals for sufficient repeats to complete a maximum of 6 months of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Public and private hospital authority required

Initial (change or re-commencement for all adult patients)
Application for initial PBS-subsidised treatment with epoprostenol sodium of adult patients with either of the following:
(a) primary pulmonary hypertension who wish to re-commence PBS-subsidised epoprostenol sodium after a break in therapy and who have demonstrated a response to their most recent course of PBS-subsidised treatment with epoprostenol sodium; OR
(b) primary pulmonary hypertension and whose most recent course of PBS-subsidised treatment was with bosentan monohydrate, iloprost trometamol, sildenafil citrate or sitaxentan sodium.

Applications for authorisation must be in writing and must include:
(1) a completed authority prescription form [see Note for authority approval requirements]; and
(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form [www.medicareaustralia.gov.au] which includes the results on which approval for the first application for PBS-subsidised epoprostenol sodium, iloprost trometamol, bosentan monohydrate, sildenafil citrate or sitaxentan sodium, whichever was initiated first, was granted; and
(3) the date of the first application for PBS-subsidised treatment with epoprostenol sodium, iloprost trometamol, bosentan monohydrate, sildenafil citrate or sitaxentan sodium, whichever was initiated first; and
(4) the results of the patient's response to treatment with their last course of PBS-subsidised epoprostenol sodium, iloprost trometamol, bosentan monohydrate, sildenafil citrate or sitaxentan sodium.

continued ☞

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer $	Proprietary Name and Manufacturer	

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. A maximum of 5 repeats may be requested. Where fewer than 5 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 6 months of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Public and private hospital authority required

Initial (change or re-commencement for all patients under 18 years of age)
Application for initial PBS-subsidised treatment with epoprostenol sodium of patients aged less than 18 years with either of the following:
(a) primary pulmonary hypertension who wish to re-commence PBS-subsidised epoprostenol sodium after a break in therapy and who have demonstrated a response to their most recent course of PBS-subsidised treatment with epoprostenol sodium; OR
(b) primary pulmonary hypertension and whose most recent course of PBS-subsidised treatment was with bosentan monohydrate or sildenafil citrate.

Applications for authorisation must be in writing and must include:
(1) a completed authority prescription form [see Note for authority approval requirements]; and
(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form [www.medicareaustralia.gov.au] which includes the results on which approval for the first application for PBS-subsidised epoprostenol sodium, bosentan monohydrate or sildenafil citrate, whichever was initiated first, was granted; and
(3) the date of the first application for PBS-subsidised treatment with epoprostenol sodium, bosentan monohydrate or sildenafil citrate, whichever was initiated first; and
(4) the results of the patient's response to treatment with their last course of PBS-subsidised epoprostenol sodium, bosentan monohydrate or sildenafil citrate.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. A maximum of 5 repeats may be requested. Where fewer than 5 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 6 months of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Public and private hospital authority required

Continuing treatment (all patients)
Continuing PBS-subsidised treatment with epoprostenol sodium of patients who have received approval for initial PBS-subsidised treatment with epoprostenol sodium, and who have been assessed by a physician from a designated hospital to have achieved a response to their most recent course of epoprostenol sodium treatment [see Note for definition of response].

Applications for authorisation must be in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form [www.medicareaustralia.gov.au] which includes results from the 3 tests below, where available:
(i) RHC composite assessment; and
(ii) ECHO composite assessment; and
(iii) 6MWT.

Where fewer than 3 tests (see requirement 2 above) are able to be performed on clinical grounds, a reason outlining why the particular test/s could not be conducted must be provided with the authority application [see Note for test requirements].

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. A maximum of 5 repeats may be requested. Where fewer than 5 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 6 months of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer $	Proprietary Name and Manufacturer	
6477X	*Powder for I.V. infusion 500 micrograms (base) with diluent*	*1*	*41.69*	*Flolan*	*GK*

continued ☞

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer $	Proprietary Name and Manufacturer	
6478Y	***Powder for I.V. infusion 1.5 mg (base) with diluent***	***1***	***83.37***	***Flolan***	***GK***

ETANERCEPT

NOTE:

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

Written applications for authority to prescribe etanercept should be forwarded to:

Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

Further prescribing information is on the Medicare Australia website at www.medicareaustralia.gov.au.

Public and private hospital authority required

Initial treatment by a paediatric rheumatologist, or under the supervision of a paediatric rheumatology treatment centre, of patients under 18 years who have severe active polyarticular course juvenile chronic arthritis; AND
(a) whose parent or authorised guardian has signed a patient agreement form indicating that they understand and acknowledge that PBS-subsidised treatment will cease if the predetermined response criteria do not support continuation of PBS-subsidised treatment; AND
(b) who have demonstrated either:
(i) severe intolerance of, or toxicity due to, methotrexate (see below for definition of severe intolerance and toxicity); or
(ii) failure to achieve an adequate response to 1 or more of the following treatment regimens:
— oral or parenteral methotrexate at a dose of at least 20 mg per square metre weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; or
— oral methotrexate at a dose of at least 10 mg per square metre weekly together with at least 1 other DMARD, alone or in combination with corticosteroids, for a minimum of 3 months. (Note: use of alternative DMARDs in children is dependent on approval by the Therapeutic Goods Administration as age restrictions may apply.)

Severe intolerance is defined as intractable nausea and vomiting and general malaise unresponsive to manoeuvres, including reducing or omitting concomitant NSAIDs on the day of methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses over 24 hours.

Toxicity is defined as evidence of hepatotoxicity with repeated elevations of transaminases, bone marrow suppression temporally related to methotrexate use, pneumonitis, or serious sepsis.

The following criteria must be met in order to demonstrate failure to achieve an adequate response to either of the above treatment regimens:
(a) an active joint count of at least 20 active (swollen and tender) joints; OR
(b) at least 4 active joints from the following list:
(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

If treatment with methotrexate alone or in combination with another DMARD is contraindicated according to the relevant TGA-approved Product Information, or intolerance develops during the period of use such that permanent withdrawal is necessary and a suitably effective treatment regimen cannot be implemented, this exempts the requirement to demonstrate an inadequate response within the time period specified above for these agents.

The authority application must be in writing and must include the information used to determine the patient's eligibility under the criteria above. The date of the joint assessment must be provided.

Only 16 weeks of treatment will be approved. The assessment of the patient's response to initial treatment should be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated.

continued ☞

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer $	Proprietary Name and Manufacturer	
	Public and private hospital authority required ***Initial PBS-subsidised supply for continuing treatment by a rheumatologist, or under the supervision of a paediatric rheumatology treatment centre, of severe active polyarticular course juvenile chronic arthritis in patients receiving treatment with etanercept prior to 1 December 2002; AND*** ***(a) whose parent or authorised guardian has signed a patient agreement form indicating that they understand and acknowledge that PBS-subsidised treatment will cease if the predetermined response criteria do not support continuation of PBS-subsidised treatment; AND*** ***(b) who have demonstrated a response as specified in the criteria for continuing PBS-subsidised treatment with etanercept.*** ***The authority application must be in writing and must include sufficient information to determine the patient's eligibility. The date of the joint assessment must be provided.*** ***Only 6 months of treatment will be approved.*** **Public and private hospital authority required** ***Continuing PBS-subsidised treatment by a rheumatologist, or under the supervision of a paediatric rheumatology treatment centre, of severe active polyarticular course juvenile chronic arthritis in patients who have demonstrated an adequate response to treatment with etanercept as manifested by:*** ***(a) an active joint count of fewer than 10 active (swollen and tender) joints; OR*** ***(b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; OR*** ***(c) a reduction in the number of the following active joints, from at least 4, by at least 50%:*** ***(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or*** ***(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).*** ***All authority applications for continuing treatment with etanercept must be in writing and must include sufficient information to determine the patient's response according to the above criteria. The date of the joint assessment must be provided.*** ***Only 6 months of treatment per application will be approved. Applications for continuing treatment with etanercept should be made prior to the completion of 16 weeks of treatment to ensure continuity for those patients who meet the criteria.*** ***Patients who fail to demonstrate an adequate response, as specified in the criteria for continuing treatment with etanercept, will not be eligible to recommence treatment with etanercept within 12 months of the date on which treatment was ceased.*** ***Withdrawal of treatment with etanercept should be considered in patients who have achieved and sustained complete remission of disease for 12 months. Subsequent applications for PBS-subsidised re-treatment with etanercept will be subject to the authority conditions applying to initial treatment and will not be authorised within 12 months of the date on which treatment with etanercept was ceased.*** ***Where re-treatment with etanercept after a break in PBS-subsidised treatment with the drug is being sought, the reason for and date of cessation of the previous treatment course with etanercept must be included in the application.***				
6367D	***Injection set containing 4 vials powder for injection 25 mg and 4 pre-filled syringes solvent 1 mL***	***1***	***815.00***	***Enbrel***	***WX***

continued ☞

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer $	Proprietary Name and Manufacturer	
	Public and private hospital authority required				
	Continuing PBS-subsidised treatment by a rheumatologist, or under the supervision of a paediatric rheumatology treatment centre, of severe active polyarticular course juvenile chronic arthritis in patients 18 years or older who have demonstrated an adequate response to treatment with etanercept as manifested by:				
	(a) an active joint count of fewer than 10 active (swollen and tender) joints; OR				
	(b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; OR				
	(c) a reduction in the number of the following active joints, from at least 4, by at least 50%:				
	(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or				
	(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).				
	All authority applications for continuing treatment with etanercept must be in writing and must include sufficient information to determine the patient's response according to the above criteria. The date of the joint assessment must be provided.				
	Only 6 months of treatment per application will be approved. Applications for continuing treatment with etanercept should be made prior to the completion of 16 weeks of treatment to ensure continuity for those patients who meet the criteria.				
	Patients who fail to demonstrate an adequate response, as specified in the criteria for continuing treatment with etanercept, will not be eligible to recommence treatment with etanercept within 12 months of the date on which treatment was ceased.				
	Withdrawal of treatment with etanercept should be considered in patients who have achieved and sustained complete remission of disease for 12 months. Subsequent applications for PBS-subsidised re-treatment with etanercept will be subject to the authority conditions applying to initial treatment and will not be authorised within 12 months of the date on which treatment with etanercept was ceased.				
	Where re-treatment with etanercept after a break in PBS-subsidised treatment with the drug is being sought, the reason for and date of cessation of the previous treatment course with etanercept must be included in the application.				
	Where a patient with severe active polyarticular course juvenile chronic arthritis continues treatment with etanercept and is 18 years or older, etanercept 50 mg may be prescribed.				
9615C	***Injections 50 mg in 1 mL single use pre-filled syringes, 4***	***1***	***1630.01***	***Enbrel***	***WX***
	EVEROLIMUS				
	CAUTION:				
	Careful monitoring of patients is mandatory.				
	Private hospital authority required				
	Management of rejection, under the supervision and direction of a transplant unit, in patients receiving this drug for:				
	(a) prophylaxis of renal allograft rejection. Management includes initiation, stabilisation and review of therapy as required; or				
	(b) prophylaxis of cardiac allograft rejection. Management includes initiation, stabilisation and review of therapy as required.				
6459Y	***Tablet 0.25 mg***	***60***	***240.30***	***Certican***	***NV***
6460B	***Tablet 0.5 mg***	***60***	***480.60***	***Certican***	***NV***
6461C	***Tablet 0.75 mg***	***60***	***720.90***	***Certican***	***NV***

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer $	Proprietary Name and Manufacturer

FILGRASTIM

Private hospital authority required

For use in a patient undergoing induction and consolidation therapy for acute myeloid leukaemia;

Mobilisation of peripheral blood progenitor cells to facilitate harvest of such cells for autologous transplantation into a patient with a non-myeloid malignancy who has had myeloablative or myelosuppressive therapy;

Mobilisation of peripheral blood progenitor cells, in a normal volunteer, for use in allogeneic transplantation;

A patient receiving marrow-ablative chemotherapy and subsequent bone marrow transplantation;

A patient with a non-myeloid malignancy receiving marrow-ablative chemotherapy and subsequent autologous peripheral blood progenitor cell transplantation;

A patient with breast cancer receiving standard dose adjuvant chemotherapy who has had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned;

A patient receiving first-line chemotherapy for B-cell chronic lymphocytic leukaemia with fludarabine and cyclophosphamide who has had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned;

A patient receiving first-line chemotherapy for Hodgkin disease who has had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned;

A patient receiving chemotherapy for myeloma who has had a prior episode of febrile neutropenia, and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned;

A patient with severe congenital neutropenia (absolute neutrophil count of less than 100 million cells per litre measured on 3 occasions, with readings at least 2 weeks apart, and in whom a bone marrow examination has shown evidence of maturational arrest of the neutrophil lineage);

A patient with severe chronic neutropenia (absolute neutrophil count of less than 1,000 million cells per litre measured on 3 occasions, with readings at least 2 weeks apart, or evidence of neutrophil dysfunction, and, either having experienced a life-threatening infectious episode requiring hospitalisation and treatment with intravenous antibiotics in the previous 12 months, or having recurrent clinically significant infections (a minimum of 3 in the previous 12 months));

A patient with chronic cyclic neutropenia (absolute neutrophil count of less than 500 million cells per litre lasting for 3 days per cycle, measured over 3 separate cycles, and, either having experienced a life-threatening infectious episode requiring hospitalisation and treatment with intravenous antibiotics, or having recurrent clinically significant infections (a minimum of 3 in the previous 12 months)).

Private hospital authority required

A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in:

- ***(a) acute lymphoblastic leukaemia; or***
- ***(b) breast cancer (adjuvant chemotherapy with docetaxel in combination with an anthracycline and cyclophosphamide); or***
- ***(c) germ cell tumours; or***
- ***(d) infants and children with CNS tumours; or***
- ***(e) neuroblastoma; or***
- ***(f) non-Hodgkin lymphoma (aggressive grades; or low grade receiving an anthracycline-containing regimen); or***

continued ☞

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer $	Proprietary Name and Manufacturer	
	(g) relapsed Hodgkin disease; or				
	(h) sarcoma.				
6126K	***Injection 300 micrograms in 1 mL***	***10***	***1504.00***	***Neupogen***	***AN***
6291D	***Injection 300 micrograms in 0.5 mL single use pre-filled syringe***	***10***	***1504.00***	***Neupogen***	***AN***
6127L	***Injection 480 micrograms in 1.6 mL***	***10***	***2407.00***	***Neupogen***	***AN***
6292E	***Injection 480 micrograms in 0.5 mL single use pre-filled syringe***	***10***	***2407.00***	***Neupogen***	***AN***
	FOSAMPRENAVIR CALCIUM				
	Private hospital authority required ***Treatment, in combination with 2 or more other antiretroviral drugs, of HIV infection in patients with:*** ***(a) CD4 cell counts of less than 500 per cubic millimetre; or*** ***(b) viral load of greater than 10,000 copies per mL.***				
6453P	***Tablet 700 mg (base)***	***60***	***568.74***	***Telzir***	***GK***
	NOTE: ***This price is based on special supply arrangements—see Pharmaceutical Benefits Pricing Authority relativity sheet for full details.***				
6454Q	***Oral liquid 50 mg (base) per mL, 225 mL***	***1***	***101.56***	***Telzir***	***GK***
	FOSCARNET SODIUM				
	Private hospital authority required ***Treatment of cytomegalovirus retinitis in patients with AIDS;*** ***Treatment of aciclovir-resistant herpes simplex virus infection in immunocompromised patients with HIV infection.***				
6134W	***I.V. infusion 24 mg per mL, 250 mL***	***6***	***395.00***	***Foscavir***	***AP***
	GANCICLOVIR				
	Private hospital authority required ***Cytomegalovirus retinitis in severely immunocompromised patients.***				
6256G	***Intravitreal implant 4.5 mg***	***1***	***6000.00***	***Vitrasert***	***BU***
	GANCICLOVIR SODIUM				
	Private hospital authority required ***Cytomegalovirus retinitis in severely immunocompromised patients;*** ***Prophylaxis of cytomegalovirus disease in bone marrow transplant patients at risk of cytomegalovirus disease;*** ***Prophylaxis of cytomegalovirus disease in solid organ transplant patients at risk of cytomegalovirus disease.***				
6136Y	***Powder for I.V. infusion equivalent to 500 mg ganciclovir***	***5***	***280.00***	***Cymevene***	***RO***
	IBANDRONIC ACID				
	Private hospital authority required ***Bone metastases from breast cancer.***				
9619G	***Concentrated injection for I.V. infusion 6 mg (as ibandronate sodium monohydrate) in 6 mL***	***1***	***341.36***	***Bondronat***	***HH***

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer $	Proprietary Name and Manufacturer

ILOPROST TROMETAMOL

NOTE:

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

Written applications for authority to prescribe iloprost trometamol should be forwarded to:

Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

NOTE:

Iloprost trometamol is not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with scleroderma, where the total lung capacity is less than 70% of that predicted.

Iloprost trometamol is not PBS-subsidised when used in combination with PBS-subsidised bosentan monohydrate, PBS-subsidised epoprostenol sodium, PBS-subsidised sildenafil citrate or PBS-subsidised sitaxentan sodium.

The following provides some explanatory notes regarding the availability of PBS-subsidised treatment with:
(a) bosentan monohydrate, of primary pulmonary hypertension or pulmonary arterial hypertension secondary to scleroderma, in patients with disease of WHO Functional Class III or IV severity; AND
(b) iloprost trometamol, of primary pulmonary hypertension, drug-induced pulmonary arterial hypertension or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class III or IV severity; AND
(c) epoprostenol sodium, of primary pulmonary hypertension, in patients with disease of WHO Functional Class III or IV severity; AND
(d) sildenafil citrate, of primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class III severity; AND
(e) sitaxentan sodium, of primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class III severity.

Adult patients:
From 1 April 2008, adult patients with primary pulmonary hypertension will be able to access, through the PBS, bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate (WHO Class III only) or sitaxentan sodium (WHO Class III only). Once these patients are approved initial treatment with 1 of these 5 drugs, they may swap between bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate and sitaxentan sodium at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary. (New baselines may be submitted where the patient has failed to respond to their current treatment.)

Patients may only swap to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate or sitaxentan sodium if they have not failed prior PBS-subsidised treatment with that drug.

Adult patients with pulmonary arterial hypertension secondary to scleroderma will be able to access, through the PBS, bosentan monohydrate, iloprost trometamol, sildenafil citrate (WHO Class III only) or sitaxentan sodium (WHO Class III only). Once these patients are approved initial treatment with 1 of these 4 drugs, they may swap between bosentan monohydrate, iloprost trometamol, sildenafil citrate and sitaxentan sodium at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary. (New baselines may be submitted where the patient has failed to respond to their current treatment.)

Patients may only swap to bosentan monohydrate, iloprost trometamol, sildenafil citrate or sitaxentan sodium if they have not failed prior PBS-subsidised treatment with that drug.

continued ☞

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer $	Proprietary Name and Manufacturer

Adult patients with pulmonary arterial hypertension secondary to connective tissue disease other than scleroderma will be able to access, through the PBS, iloprost trometamol, sildenafil citrate (WHO Class III only) or sitaxentan sodium (WHO Class III only). Once these patients are approved initial treatment with 1 of these 3 drugs, they may swap between iloprost trometamol, sildenafil citrate and sitaxentan sodium at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary. (New baselines may be submitted where the patient has failed to respond to their current treatment.)

Patients may only swap to iloprost trometamol, sildenafil citrate or sitaxentan sodium if they have not failed prior PBS-subsidised treatment with that drug.

Patients with drug-induced pulmonary arterial hypertension are only eligible for treatment with iloprost trometamol. They may not swap to bosentan monohydrate, epoprostenol sodium, sildenafil citrate or sitaxentan sodium.

Patients under 18 years of age:
From 1 April 2008, patients aged less than 18 years with primary pulmonary hypertension are eligible to receive PBS-subsidised treatment with bosentan monohydrate, epoprostenol sodium, iloprost trometamol, sildenafil citrate (WHO Class III only) or sitaxentan sodium (WHO Class III only). Once these patients are approved initial treatment with 1 of these 5 drugs, they may swap between bosentan monohydrate, epoprostenol sodium, iloprost trometamol, sildenafil citrate and sitaxentan sodium at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary. (New baselines may be submitted where the patient has failed to respond to their current treatment.)

Patients may only swap to bosentan monohydrate, epoprostenol sodium, iloprost trometamol, sildenafil citrate or sitaxentan sodium if they have not failed prior PBS-subsidised treatment with that drug.

1. Definition of primary pulmonary hypertension, drug-induced pulmonary arterial hypertension or pulmonary arterial hypertension secondary to connective tissue disease, including scleroderma.

Primary pulmonary hypertension, drug-induced pulmonary arterial hypertension or pulmonary arterial hypertension secondary to connective tissue disease, including scleroderma, are defined as follows:
(i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary capillary wedge pressure (PCWP) less than 18 mmHg; or
(ii) mPAP greater than 30 mmHg with exercise and PCWP less than 18 mmHg; or
(iii) where a right heart catheter cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

2. Definition of WHO Functional Class III or IV disease severity.

(a) WHO Functional Class III disease severity is defined as follows:
Patients with pulmonary hypertension resulting in marked limitation of physical activity who are comfortable at rest and on ordinary physical activity experience dyspnoea or fatigue, chest pain or near syncope.
(b) WHO Functional Class IV disease severity is defined as follows:
Patients with the inability to carry out any physical activity without symptoms. These patients manifest signs of right heart failure. Dyspnoea and/or fatigue may even be present at rest. Discomfort is increased by any physical activity.

3. Designated hospitals.

Refer to the Medicare Australia website at www.medicareaustralia.gov.au for a list of designated hospitals.

4. Test requirements to establish baseline for initiation of treatment and response to treatment for continuation of treatment.

(a) Initiation of treatment.
The first written application for PBS-subsidised treatment with the first of either bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate or sitaxentan sodium should be accompanied by the results of a right heart catheter (RHC) composite assessment, plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements.

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Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer $	Proprietary Name and Manufacturer

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:
(1) RHC plus ECHO composite assessments;
(2) RHC composite assessment plus 6MWT;
(3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted to Medicare Australia for consideration based on the results of the following test combinations, which are listed in descending order of preference:
(1) ECHO composite assessment plus 6MWT;
(2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a reason outlining why the particular test/s could not be conducted must be provided with the authority application.

NOTE:
Where patients were initiated on PBS-subsidised treatment either with bosentan monohydrate on or after 1 March 2004, with iloprost trometamol on or after 1 April 2005, with epoprostenol sodium on or after 1 August 2006, with sildenafil citrate on or after 1 March 2007, with sitaxentan sodium on or after 1 April 2008, or with bosentan monohydrate (for PAH associated with congenital systemic-to-pulmonary shunt) on or after 1 August 2008, the test results provided with the initial application must be no more than 2 months old at the time of application. These results will form the baseline against which response assessments will be made.

Where patients received treatment with either bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate or sitaxentan sodium prior to being commenced on PBS-subsidised treatment with the first of either bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate or sitaxentan sodium, the test requirements above still apply. The results that will form the baseline against which response assessments will be made will be those measured at the time patients commenced non-PBS-subsidised treatment with either bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate or sitaxentan sodium, whichever of the 5 drugs the patient received first.

(b) Continuation of treatment.
The following list outlines the preferred test combination, in descending order, for the purposes of continuation of PBS-subsidised treatment:
(1) RHC plus ECHO composite assessments plus 6MWT;
(2) RHC plus ECHO composite assessments;
(3) RHC composite assessment plus 6MWT;
(4) ECHO composite assessment plus 6MWT;
(5) RHC composite assessment only;
(6) ECHO composite assessment only.

The results of the same tests as conducted at baseline should be provided with each written continuing treatment application (i.e. every 6 months), except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a reason why the test(s) could not be conducted must be provided with the application.

The test(s) results provided with the application for continuing treatment must be no more than 2 months old at the time of application.

5. Definition of response to iloprost trometamol, bosentan monohydrate, epoprostenol sodium, sildenafil citrate, sitaxentan sodium or prior vasodilator treatment.

For adult patients with 2 or more baseline tests, response to treatment is defined as 2 or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For adult patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For adult patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

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Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer $	Proprietary Name and Manufacturer

6. Authority approval requirements. [The following 2 sections are only relevant to the PBS listing of iloprost trometamol. The requirements specific to bosentan monohydrate, epoprostenol sodium, sildenafil citrate and sitaxentan sodium are given in parts 6 and 7 of the NOTE included in the bosentan monohydrate, epoprostenol sodium, sildenafil citrate and sitaxentan sodium Schedule entry respectively.]

(a) Initiation of PBS-subsidised treatment with iloprost trometamol, where the patient has not received prior PBS-subsidised treatment with bosentan monohydrate, epoprostenol sodium, sildenafil citrate or sitaxentan sodium. All applications for initial treatment must be made in writing, must include an authority prescription and must be submitted to Medicare Australia for authorisation. The total duration of initial PBS-subsidised treatment that will be approved with this first written application is up to 6 months, based on the dosage recommendations in the TGA-approved Product Information.

(b) Continuation of treatment.
Written applications for continuing treatment must be submitted to Medicare Australia for authorisation every 6 months. Approvals will be limited to provide sufficient supply for up to a maximum of 6 months of treatment, based on the dosage recommendations in the TGA-approved Product Information.

Applications for continuing treatment will only be approved for patients who have currently demonstrated a response to treatment with iloprost trometamol.

The assessment of the patient's response to the first and subsequent 6 month courses of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated. Applications for continuing treatment with iloprost trometamol should be made prior to the completion of the 6 month treatment course to ensure continuity for those patients who respond to treatment, as assessed by the treating physician.

(c) Swapping between bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate and sitaxentan sodium.
For eligible patients, applications to swap between these 5 drugs must be made under the relevant initial treatment restriction. Patients should be assessed for response to the treatment they are ceasing at the time the application to swap therapy is being made. Patients who fail to demonstrate a response or for whom no assessment results are submitted with the application to swap therapy may not re-commence PBS-subsidised treatment with the drug they are ceasing.

It is important that patients are assessed for response to every course of treatment approved within the timeframes specified in the relevant restriction, in order to maximise the choice of treatment.

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

(d) Cessation of treatment.
Patients who fail to demonstrate a response to PBS-subsidised iloprost trometamol treatment at the times where an assessment is required must cease PBS-subsidised iloprost trometamol therapy.

7. Re-treatment with iloprost trometamol.

Patients who do not respond to treatment are not eligible to receive further PBS-subsidised treatment with iloprost trometamol under any circumstances.

8. Further information.

A tabulated representation of the above information and the restriction can be obtained from the Medicare Australia website at www.medicareaustralia.gov.au.

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Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer $	Proprietary Name and Manufacturer

Public and private hospital authority required

Initial (new patients)

Application for initial PBS-subsidised treatment with iloprost trometamol of patients who have not received prior PBS-subsidised treatment with bosentan monohydrate, epoprostenol sodium, sildenafil citrate or sitaxentan sodium and who have been assessed by a physician from a designated hospital to have:
(a) WHO Functional Class III primary pulmonary hypertension and a mean right atrial pressure of 8 mmHg or less, as measured by RHC, unless a RHC is contraindicated on clinical grounds; OR
(b) WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease and a mean right atrial pressure of 8 mmHg or less, as measured by RHC, unless a RHC is contraindicated on clinical grounds; OR
(c) WHO Functional Class III drug-induced pulmonary arterial hypertension and a mean right atrial pressure of 8 mmHg or less, as measured by RHC, unless a RHC is contraindicated on clinical grounds.

Patients must have failed to respond [see Note for definition of response] to 6 or more weeks of appropriate vasodilator treatment unless intolerance or a contraindication to such treatment exists.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted to Medicare Australia for consideration based on the test results of the ECHO composite assessment plus 6MWT or the ECHO composite assessment only.

Applications for authorisation must be in writing and must include:
(1) a completed authority prescription form [see Note for authority approval requirements]; and
(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form [www.medicareaustralia.gov.au] which includes results from the 3 tests below, where available:
(i) RHC composite assessment; and
(ii) ECHO composite assessment; and
(iii) 6MWT; and
(3) a signed patient acknowledgment indicating that the patient understands and acknowledges that PBS-subsidised treatment with iloprost trometamol for primary pulmonary hypertension, drug-induced pulmonary arterial hypertension or pulmonary arterial hypertension secondary to connective tissue disease, OR with bosentan monohydrate for primary pulmonary hypertension or pulmonary arterial hypertension secondary to scleroderma, OR with epoprostenol sodium for primary pulmonary hypertension, OR with sildenafil citrate for primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, OR with sitaxentan sodium for primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, will cease if the treating physician determines that the patient has not achieved a response to treatment [see Note for definition of response].

Details of prior vasodilator treatment, including the dose and duration of treatment, must be provided at the time of application. Where the patient has an adverse event to a vasodilator or where vasodilator treatment is contraindicated, details on the nature of the adverse event or contraindication according to the TGA-approved Product Information must also be provided with the application.

Where fewer than 3 tests (see requirement 2 above) are able to be performed on clinical grounds, a reason outlining why the particular test/s could not be conducted must be provided with the authority application [see Note for test requirements].

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. A maximum of 5 repeats may be requested. Where fewer than 5 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 6 months of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer $	Proprietary Name and Manufacturer

Public and private hospital authority required

Initial (new patients)

Application for initial PBS-subsidised treatment with iloprost trometamol of patients who have not received prior PBS-subsidised treatment with bosentan monohydrate, epoprostenol sodium, sildenafil citrate or sitaxentan sodium and who have been assessed by a physician from a designated hospital to have:

(a) WHO Functional Class III primary pulmonary hypertension and a mean right atrial pressure greater than 8 mmHg, as measured by RHC, unless a RHC is contraindicated on clinical grounds; OR

(b) WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease and a mean right atrial pressure greater than 8 mmHg, as measured by RHC, unless a RHC is contraindicated on clinical grounds; OR

(c) WHO Functional Class III drug-induced pulmonary arterial hypertension and a mean right atrial pressure greater than 8 mmHg, as measured by RHC, unless a RHC is contraindicated on clinical grounds; OR

(d) WHO Functional Class IV primary pulmonary hypertension; OR

(e) WHO Functional Class IV pulmonary arterial hypertension secondary to connective tissue disease; OR

(f) WHO Functional Class IV drug-induced pulmonary arterial hypertension.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted to Medicare Australia for consideration based on the test results of the ECHO composite assessment plus 6MWT or the ECHO composite assessment only.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form [see Note for authority approval requirements]; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form [www.medicareaustralia.gov.au] which includes results from the 3 tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6MWT; and

(3) a signed patient acknowledgment indicating that the patient understands and acknowledges that PBS-subsidised treatment with iloprost trometamol for primary pulmonary hypertension, drug-induced pulmonary arterial hypertension or pulmonary arterial hypertension secondary to connective tissue disease, OR with bosentan monohydrate for primary pulmonary hypertension or pulmonary arterial hypertension secondary to scleroderma, OR with epoprostenol sodium for primary pulmonary hypertension, OR with sildenafil citrate for primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, OR with sitaxentan sodium for primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, will cease if the treating physician determines that the patient has not achieved a response to treatment [see Note for definition of response].

Where fewer than 3 tests (see requirement 2 above) are able to be performed on clinical grounds, a reason outlining why the particular test/s could not be conducted must be provided with the authority application [see Note for test requirements].

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. A maximum of 5 repeats may be requested. Where fewer than 5 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 6 months of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer $	Proprietary Name and Manufacturer

Public and private hospital authority required

Initial (change or re-commencement for all patients)

Application for initial PBS-subsidised treatment with iloprost trometamol of patients with either of the following:
(a) primary pulmonary hypertension, drug-induced pulmonary arterial hypertension or pulmonary arterial hypertension secondary to connective tissue disease who wish to re-commence PBS-subsidised iloprost trometamol after a break in therapy and who have demonstrated a response to their most recent course of PBS-subsidised treatment with iloprost trometamol; OR
(b) primary pulmonary hypertension or pulmonary arterial hypertension secondary to scleroderma and whose most recent course of PBS-subsidised treatment was with bosentan monohydrate; OR
(c) primary pulmonary hypertension and whose most recent course of PBS-subsidised treatment was with epoprostenol sodium; OR
(d) primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease and whose most recent course of PBS-subsidised treatment was with sildenafil citrate; OR
(e) primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease and whose most recent course of PBS-subsidised treatment was with sitaxentan sodium.

Applications for authorisation must be in writing and must include:
(1) a completed authority prescription form [see Note for authority approval requirements]; and
(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form [www.medicareaustralia.gov.au] which includes the results on which approval for the first application for PBS-subsidised iloprost trometamol, bosentan monohydrate, epoprostenol sodium, sildenafil citrate or sitaxentan sodium, whichever was initiated first, was granted; and
(3) the date of the first application for PBS-subsidised treatment with iloprost trometamol, bosentan monohydrate, epoprostenol sodium, sildenafil citrate or sitaxentan sodium, whichever was initiated first; and
(4) the results of the patient's response to treatment with their last course of PBS-subsidised iloprost trometamol, bosentan monohydrate, epoprostenol sodium, sildenafil citrate or sitaxentan sodium.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. A maximum of 5 repeats may be requested. Where fewer than 5 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 6 months of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Public and private hospital authority required

Continuing treatment (all patients)

Continuing PBS-subsidised treatment with iloprost trometamol of patients who have received approval for initial PBS-subsidised treatment with iloprost trometamol, and who have been assessed by a physician from a designated hospital to have achieved a response to their most recent course of iloprost trometamol treatment [see Note for definition of response].

Applications for authorisation must be in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form [www.medicareaustralia.gov.au] which includes results from the 3 tests below, where available:
(i) RHC composite assessment; and
(ii) ECHO composite assessment; and
(iii) 6MWT.

Where fewer than 3 tests (see requirement 2 above) are able to be performed on clinical grounds, a reason outlining why the particular test/s could not be conducted must be provided with the authority application [see Note for test requirements].

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. A maximum of 5 repeats may be requested. Where fewer than 5 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 6 months of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer $	Proprietary Name and Manufacturer	
6456T	***Solution for inhalation 20 micrograms (base) in 2 mL***	***30***	***1076.00***	***Ventavis***	***SC***

NOTE:
This price is based on special supply arrangements—see Pharmaceutical Benefits Pricing Authority relativity sheet for full details.

INDINAVIR SULFATE

Private hospital authority required
Treatment of HIV infection in patients with:
(a) CD4 cell counts of less than 500 per cubic millimetre; or
(b) viral load of greater than 10,000 copies per mL.

6344X	***Capsule 100 mg (base)***	***180***	***113.75***	***Crixivan 100 mg***	***MK***
6201J	***Capsule 200 mg (base)***	***360***	***455.00***	***Crixivan 200 mg***	***MK***
6202K	***Capsule 400 mg (base)***	***180***	***455.00***	***Crixivan 400 mg***	***MK***

INFLIXIMAB
NOTE:
Any queries concerning the arrangements to prescribe infliximab may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written applications for authority to prescribe infliximab should be forwarded to:

Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

Further prescribing information is on the Medicare Australia website at www.medicareaustralia.gov.au.

NOTE:
TREATMENT OF ADULT PATIENTS WITH ACTIVE ANKYLOSING SPONDYLITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and infliximab for adult patients with active ankylosing spondylitis. Where the term 'tumour necrosis factor (TNF) alfa antagonist' appears in the following NOTES and restrictions, it refers to adalimumab, etanercept and infliximab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 TNF-alfa antagonists at any 1 time.

From 1 March 2007, under the PBS, all patients will be able to commence a treatment cycle where they may trial each PBS-subsidised TNF-alfa antagonist without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a TNF-alfa antagonist while they continue to show a response to therapy.

A patient who received PBS-subsidised TNF-alfa antagonist treatment prior to 1 March 2007 is considered to be in their first cycle as of 1 March 2007.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised TNF-alfa antagonist more than once. A patient who, prior to 1 March 2007, was authorised to receive PBS-subsidised initial treatment for ankylosing spondylitis with the same agent twice, is exempt from this condition in respect of applications approved prior to 1 March 2007.

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

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Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer $	Proprietary Name and Manufacturer

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

A patient who has failed fewer than 3 TNF-alfa antagonists in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

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

(1) How to prescribe PBS-subsidised TNF-alfa antagonist therapy after 1 March 2007.

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

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for etanercept and adalimumab and 18 weeks of treatment for infliximab.

From 1 March 2007, a patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.

For second and subsequent courses of PBS-subsidised TNF-alfa antagonist treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

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

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

Assessments of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.

(2) Swapping therapy.

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

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

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

continued ☞

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer $	Proprietary Name and Manufacturer

To avoid confusion, an application for a patient who wishes to swap to an alternate TNF-alfa antagonist should be accompanied by the approved authority prescription or remaining repeats for the TNF-alfa antagonist the patient is ceasing.

(3) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a TNF-alfa antagonist. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and Medicare Australia will assess response according to these revised baseline measurements.

For a new patient, the BASDAI used to determine the baseline must be measured while the patient is receiving NSAID therapy and completing their exercise program. However, this is not required for any subsequent BASDAI results for these patients, nor for patients who were 'grandfathered' on to TNF-alfa antagonist treatment.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response.

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

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

(5) Patients 'grandfathered' onto PBS-subsidised treatment with infliximab.

From 1 March 2007, a patient who commenced treatment with infliximab for active ankylosing spondylitis prior to 1 March 2004 and who was 'grandfathered' onto PBS-subsidised therapy, and who continues to receive treatment in the same treatment cycle, will have further applications for treatment with infliximab assessed under the continuing treatment restriction.

Where pre-TNF-alfa antagonist treatment baselines were not provided, the following criteria must be met to demonstrate a response to treatment:
The BASDAI score must be either:
(i) no more than 20% greater than the score included in the initial application for PBS-subsidised treatment; or
(ii) no greater than 2.
AND
One of the following:
(a) an ESR measurement no greater than 25 mm per hour; or
(b) a CRP measurement no greater than 10 mg per L.

'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must requalify for initial treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' above for further details.

continued ☞

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer $	Proprietary Name and Manufacturer

Public and private hospital authority required

Initial 1 (new patients)

First course of PBS-subsidised treatment with infliximab, by a rheumatologist, of an adult with active ankylosing spondylitis who has radiographically (plain X-ray) confirmed Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis and who has not received any PBS-subsidised treatment with either adalimumab, etanercept or infliximab in this treatment cycle; AND

(a) who has at least 2 of the following:

(i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; or

(ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI) [for further information on the BASMI please refer to the Medicare Australia website at www.medicareaustralia.gov.au]; or

(iii) limitation of chest expansion relative to normal values for age and gender [for chest expansion normal values please refer to the Medicare Australia website at www.medicareaustralia.gov.au]; AND

(b) who has failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months.

The application must include details of the NSAIDs trialled, their doses and duration of treatment. If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used.

If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication.

If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance. Details of the toxicities, including severity, which will be accepted for the purposes of administering this restriction can be found on the Medicare Australia website [www.medicareaustralia.gov.au].

For details on the appropriate minimum exercise program that will be accepted for the purposes of administering this restriction, please refer to the Medicare Australia website at www.medicareaustralia.gov.au.

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

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

(b) an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 10 mg per L.

The BASDAI must be determined at the completion of the 3 month NSAID and exercise trial, but prior to ceasing NSAID treatment. The BASDAI must be no more than 1 month old at the time of initial application.

Both ESR and CRP measures should be provided with the initial treatment application and both must be no more than 1 month old. If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reason this criterion cannot be satisfied.

Authority applications must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form [www.medicareaustralia.gov.au] which must include the following:

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

(ii) a completed BASDAI Assessment Form [www.medicareaustralia.gov.au]; and

(iii) a completed Exercise Program Self Certification Form included in the supporting information form; and

(iv) a signed patient acknowledgment form. Completion of this form declares that the patient understands and acknowledges that PBS-subsidised treatment with the TNF-alfa antagonists (adalimumab, etanercept or infliximab) for ankylosing spondylitis will cease if they do not demonstrate the response to treatment required to support continuation of PBS-subsidised treatment at any assessment where a response must be demonstrated.

continued ☞

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer $	Proprietary Name and Manufacturer

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

A maximum of 18 weeks of treatment with infliximab will be approved under this criterion.

At the time of the authority application, the doctor should request the appropriate number of vials, based on the weight of the patient, to provide for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised.

Where fewer than 3 repeats are initially requested with the authority prescription, authority approvals for sufficient repeats to complete a maximum of 18 weeks of treatment may be requested by telephone.

Public and private hospital authority required

Initial 2 (change or re-commencement for all patients)
Initial course of PBS-subsidised treatment with infliximab, by a rheumatologist, of an adult with a documented history of active ankylosing spondylitis who, in this treatment cycle, has received prior PBS-subsidised treatment with either adalimumab, etanercept or infliximab for this condition and has not failed PBS-subsidised therapy with infliximab.

To demonstrate a response to treatment the application must be accompanied by the results of the most recent course of TNF-alfa antagonist therapy within the timeframes specified in the relevant restriction.

Where the most recent course of PBS-subsidised TNF-alfa antagonist treatment was approved under an initial treatment restriction after 1 March 2007, the patient must have been assessed for response to that course following a minimum of 12 weeks of treatment. Where the most recent course of PBS-subsidised TNF-alfa antagonist treatment was approved under an initial treatment restriction prior to 1 March 2007, the patient must have been assessed for response to that course following at least 4 weeks of treatment. These assessments must be provided to Medicare Australia no later than 4 weeks from the date the course was ceased.

If the response assessment to the previous course of TNF-alfa antagonist treatment is not submitted as detailed above, the patient will be deemed to have failed therapy with that particular course of TNF-alfa antagonist.

Authority applications must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form [www.medicareaustralia.gov.au] which includes a completed BASDAI Assessment Form with certification by the prescriber and the patient that the patient did not have access to their baseline BASDAI at the time of their assessment.

A maximum of 18 weeks of treatment with infliximab will be approved under this criterion.

At the time of the authority application, the doctor should request the appropriate number of vials, based on the weight of the patient, to provide for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised.

Where fewer than 3 repeats are initially requested with the authority prescription, authority approvals for sufficient repeats to complete a maximum of 18 weeks of treatment may be requested by telephone.

Public and private hospital authority required

Continuing treatment for all patients
Continuing PBS-subsidised treatment, by a rheumatologist, of an adult with a documented history of active ankylosing spondylitis who:
(a) has demonstrated a response to treatment with infliximab; and
(b) whose most recent course of PBS-subsidised therapy in this treatment cycle was with infliximab.

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

continued ☞

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer $	Proprietary Name and Manufacturer	

For a 'grandfather' patient who does not have baselines prior to commencing treatment with a TNF-alfa antagonist, see Note 5 for a definition of response to treatment.

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

Where the most recent course of PBS-subsidised TNF-alfa antagonist treatment was approved under an initial treatment restriction after 1 March 2007, the patient must have been assessed for response to that course following a minimum of 12 weeks of treatment. Where the most recent course of PBS-subsidised TNF-alfa antagonist treatment was approved under an initial treatment restriction prior to 1 March 2007, the patient must have been assessed for response to that course following at least 4 weeks of treatment.

Applications for continuing treatment must be made in writing and should be posted to Medicare Australia no less than 2 weeks prior to the completion of the current treatment course.

Written applications for authorisation must include:
(a) a completed authority prescription form; and
(b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form [www.medicareaustralia.gov.au] which includes a completed BASDAI Assessment Form with certification by the prescriber and the patient that the patient did not have access to their baseline BASDAI at the time of their continuing treatment assessment.

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

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

At the time of the authority application, the doctor should request the appropriate number of vials, based on the weight of the patient, to provide for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised.

Where fewer than 3 repeats are initially requested with the authority prescription, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone.

6448J	***Powder for I.V. infusion 100 mg***	***1***	***751.70***	***Remicade***	***SH***

NOTE:

TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying anti-rheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, etanercept, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-1 inhibitor (anakinra) and the T-cell co-stimulation modulator (abatacept).

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

PBS-subsidised infliximab, anakinra, rituximab and abatacept must be used in combination with methotrexate at a dose of at least 7.5 mg weekly. Where a patient cannot tolerate 7.5 mg of methotrexate weekly, they are only eligible to receive PBS-subsidised etanercept and adalimumab.

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

From 1 March 2008, under the PBS, all patients will be able to commence a Treatment Cycle where they may trial PBS-subsidised bDMARD agents without having to experience a disease flare when swapping to an alternate agent. Under these interchangeability arrangements, within a single Treatment Cycle, a patient may continue to receive long-term treatment with a bDMARD while they continue to show a response to therapy.

A patient who received PBS-subsidised bDMARD treatment prior to 1 March 2008 is considered to be in their first Cycle as of 1 March 2008.

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

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Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer $	Proprietary Name and Manufacturer

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a Treatment Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised bDMARD therapy before they are eligible to commence the next Cycle.

For patients who have failed PBS-subsidised treatment with 3 bDMARDs prior to 1 March 2008 please contact Medicare Australia on 1800 700 270.

The 5-year break is measured from the date of the last approval for PBS-subsidised bDMARD treatment in the most recent Cycle to the date of the first application for initial treatment with a bDMARD under the new Treatment Cycle.

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

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

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

If patients fail to respond to a particular bDMARD within a single Treatment Cycle, they are not eligible to receive further PBS-subsidised treatment with that drug until they commence the next Cycle.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 March 2008.

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

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for etanercept, adalimumab, anakinra and abatacept, 22 weeks of therapy for infliximab and 2 infusions of rituximab.

From 1 March 2008, a patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to Medicare Australia within 4 weeks.

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

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

Rituximab patients:
A further application may be submitted to Medicare Australia 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

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

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

Assessments of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

continued ☞

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer $	Proprietary Name and Manufacturer

Rituximab patients:

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.

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

(2) Swapping therapy.

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

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

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

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

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

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

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

NOTE:

(3) Baseline measurements to determine response.

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

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

The baseline joint and blood counts should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment.

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

continued ☞

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer $	Proprietary Name and Manufacturer

A patient who wishes to trial a second or subsequent Treatment Cycle following a break in PBS-subsidised bDMARD therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have received treatment with at least 1 non-biological DMARD, at an adequate dose, for a minimum of 3 months at the time the ESR and/or CRP levels and the active joint count are measured.

(5) Patients 'grandfathered' onto PBS-subsidised treatment with rituximab or abatacept.

From 1 March 2008, a patient who commenced treatment with rituximab for severe rheumatoid arthritis prior to 7 March 2007 or abatacept for severe rheumatoid arthritis prior to 1 November 2007 and who was 'grandfathered' on to PBS-subsidised therapy, and who continues to receive treatment in the same Treatment Cycle, will have further applications for treatment with rituximab or abatacept assessed under the continuing treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment with abatacept will be authorised under this criterion.

'Grandfather' arrangements will only apply for the first Treatment Cycle. For the second and subsequent Cycles, a 'grandfather" patient must requalify for initial treatment under the criteria that applies to a new patient. See 'Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' above for further details.

Public and private hospital authority required

Initial 1 (new patients)

Application for initial PBS-subsidised treatment with infliximab, in combination with methotrexate at a dose of at least 7.5 mg weekly, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of adults who:

(a) have severe active rheumatoid arthritis; and

(b) have received no prior PBS-subsidised treatment with a bDMARD for this condition in this treatment cycle; and

(c) have failed to achieve an adequate response to the following treatments:

(i) methotrexate at a dose of at least 20 mg weekly; and

(ii) methotrexate (at a minimum dose of 7.5 mg weekly), in combination with 2 other non-biological disease modifying anti-rheumatic drugs (DMARDs), for a minimum of 3 months; and

(iii) a minimum of 3 months' treatment with:

— leflunomide alone; or

— leflunomide in combination with methotrexate; or

— cyclosporin.

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of the accepted toxicities, including severity, can be found on the Medicare Australia website [www.medicareaustralia.gov.au].

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

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L;

AND either

(i) a total active joint count of at least 20 active (swollen and tender) joints; or

(ii) at least 4 active joints from the following list of major joints:

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

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

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.

continued ☞

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer $	Proprietary Name and Manufacturer

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

The authority application must be made in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes details of the patient's ESR and CRP measurements and the patient's active joint count which must have been assessed no earlier than 1 month prior to the date of application; and
(3) a signed patient acknowledgement.

A maximum of 22 weeks of treatment will be authorised under this restriction.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 3 mg per kg. Up to a maximum of 3 repeats may be authorised.

Where fewer than 3 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 22 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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

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

Public and private hospital authority required

Initial 2 (change or re-commencement)
Application for an initial course of PBS-subsidised treatment with infliximab, in combination with methotrexate at a dose of at least 7.5 mg weekly, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of adults who:
(a) have a documented history of severe active rheumatoid arthritis; and
(b) have received prior PBS-subsidised bDMARD treatment for this condition in this treatment cycle and are eligible to receive further bDMARD therapy.

The authority application must be made in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].

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

A maximum of 22 weeks of treatment will be authorised under this restriction.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 3 mg per kg. Up to a maximum of 3 repeats may be authorised.

Where fewer than 3 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 22 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

continued ☞

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer $	Proprietary Name and Manufacturer

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

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

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

Public and private hospital authority required

Continuing treatment

Continuing PBS-subsidised treatment with infliximab, in combination with methotrexate at a dose of at least 7.5 mg weekly, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of adults:

(a) who have a documented history of severe active rheumatoid arthritis; and

(b) who have demonstrated an adequate response to treatment with infliximab; and

(c) whose most recent course of PBS-subsidised bDMARD treatment in this treatment cycle was with infliximab.

An adequate response to treatment is defined as:

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

AND either of the following:

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

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

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

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

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

(1) a completed authority prescription form; and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].

A maximum of 24 weeks of treatment will be approved under this restriction.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 3 mg per kg. Up to a maximum of 2 repeats may be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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

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

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Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer $	Proprietary Name and Manufacturer	
6397Q	***Powder for I.V. infusion 100 mg***	***1***	***751.70***	***Remicade***	***SH***

NOTE:

TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS

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

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological agents at any 1 time. Where the term 'biological agents' appears in the following NOTES and restrictions, it only refers to adalimumab, etanercept and infliximab.

From 1 August 2006, all patients will be able to commence a 'Biological Treatment Cycle' (Cycle), where they may trial adalimumab, etanercept or infliximab without having to meet the initial treatment criteria, that is they will not need to experience a disease flare, when swapping to the alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

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

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

The 5-year break in therapy will be measured from the date the last approval for PBS-subsidised treatment was granted in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Cycle.

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

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

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

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

How to prescribe biological agents for the treatment of severe active psoriatic arthritis after 1 August 2006.

(1) Initial treatment.

Applications for initial treatment should be made where:
(i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); and
(ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; and
(iii) patients wish to re-commence treatment with a specific biological agent following a break in PBS-subsidised therapy with that specific agent (Initial 2).

All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 16 weeks of therapy for all agents except for infliximab, for which a maximum of 22 weeks will be authorised. It is recommended that patients be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological agent supply.

continued ☞

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer $	Proprietary Name and Manufacturer

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

Grandfather patients.

Applications for patients who commenced treatment with etanercept prior to 17 March 2005 or adalimumab and infliximab prior to 16 March 2006, may apply for initial PBS-subsidised treatment as continuing therapy under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with any biological agent prior to PBS listing of that agent.

Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment for all agents. Approval will be based on the criteria included in the relevant restriction.

(2) Continuing treatment.

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

Patients must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.

(3) Swapping therapy.

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

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

Patients may alternate between therapy with any biological agent of their choice (1 at a time) providing:
(i) they have not received PBS-subsidised treatment with that particular biological agent previously; or
(ii) they have demonstrated an adequate response to that particular biological agent if they have previously trialled it on the PBS.

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

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

(4) Baseline measurements to determine response.

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

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.

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

continued ☞

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer $	Proprietary Name and Manufacturer

Patients who wish to trial a second or subsequent treatment Cycle following a break in PBS-subsidised biological therapy of at least 5 years, must re-qualify for initial treatment with respect to both the indices of disease severity. Patients must have received treatment with methotrexate or sulfasalazine or leflunomide, at an adequate dose, for a minimum of 3 months at the time the ESR or CRP levels and the active joint counts are measured.

Public and private hospital authority required

Initial 1

Initial PBS-subsidised treatment with infliximab, by a rheumatologist or clinical immunologist with expertise in the management of psoriatic arthritis, of adults who:
(1) have severe active psoriatic arthritis; and
(2) have received no prior PBS-subsidised biological treatment for this condition in this Treatment Cycle; and
(3) have failed to achieve an adequate response to:
(a) methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months; and
(b) sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months; or
(c) leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months.

Patients must have had the psoriatic component of their disease confirmed by a dermatologist or by biopsy at any time.

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity to necessitate permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of acceptable toxicities, including severity, can be found on the Medicare Australia website (www.medicareaustralia.gov.au).

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

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

The authority application must be made in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes details of the patient's ESR and CRP measurements and the patient's active joint count which must have been assessed no earlier than 1 month prior to the date of application; and
(3) a copy of the signed patient acknowledgement form which is included in the Supporting Information Form. Completion of this form declares that the patient understands and acknowledges that PBS-subsidised treatment will cease if they do not demonstrate the response to treatment required to support continuation of PBS-subsidised treatment at any assessment where a response must be demonstrated.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats may be authorised.

continued ☞

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer $	Proprietary Name and Manufacturer

Where fewer than 3 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 22 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Patients who fail to demonstrate a response to treatment with infliximab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug, in this Treatment Cycle.

Public and private hospital authority required

Initial 2

Initial PBS-subsidised treatment with infliximab, by a rheumatologist or clinical immunologist with expertise in the management of psoriatic arthritis, of adults who:

(1) have a documented history of severe active psoriatic arthritis; and

(2) have received prior PBS-subsidised biological treatment for this condition in this Treatment Cycle and are eligible to receive further biological therapy; and

(3) have not failed treatment with infliximab during the current Treatment Cycle.

Applications for patients who have demonstrated a response to PBS-subsidised infliximab treatment within this Treatment Cycle and who wish to re-commence infliximab treatment within the same Cycle following a break in therapy, will only be approved where evidence of a response to the patient's most recent course of PBS-subsidised infliximab treatment has been submitted to Medicare Australia within 1 month of cessation of treatment.

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

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

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

(1) a completed authority prescription form; and

(2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats may be authorised.

Where fewer than 3 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 22 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Patients who fail to demonstrate a response to treatment with infliximab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug, in this Treatment Cycle.

Once patients fail to respond to treatment with 3 biological agents, they are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may re-commence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

Public and private hospital authority required

Initial 3

Initial PBS-subsidised supply for continuing treatment with infliximab, by a rheumatologist or clinical immunologist with expertise in the management of psoriatic arthritis, of adults who:

(1) have a documented history of severe active psoriatic arthritis; and

(2) were receiving treatment with infliximab prior to 16 March 2006; and

(3) have demonstrated a response as specified in the criteria for continuing PBS-subsidised treatment with infliximab.

continued ☞

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer $	Proprietary Name and Manufacturer

The authority application must be made in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and
(3) a copy of the signed patient acknowledgement form which is included in the Supporting Information Form. Completion of this form declares that the patient understands and acknowledges that PBS-subsidised treatment will cease if they do not demonstrate the response to treatment required to support continuation of PBS-subsidised treatment at any assessment where a response must be demonstrated.

A maximum of 24 weeks of treatment with infliximab will be authorised under this restriction.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats may be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Patients who fail to demonstrate a response to treatment with infliximab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug, in this Treatment Cycle.

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

Public and private hospital authority required

Continuing treatment
Continuing PBS-subsidised treatment with infliximab, by a rheumatologist or clinical immunologist with expertise in the management of psoriatic arthritis, of adults:
(1) who have a documented history of severe active psoriatic arthritis; and
(2) whose most recent course of PBS-subsidised biological agent for this condition in the current Treatment Cycle was with infliximab; and
(3) who, at the time of application, demonstrate an adequate response to treatment with infliximab.

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

The authority application must be made in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].

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

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats may be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

continued ☞

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer $	Proprietary Name and Manufacturer	

Patients who fail to demonstrate a response to treatment with infliximab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug, in this Treatment Cycle.

Once patients fail to respond to treatment with 3 biological agents, they are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may re-commence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

6496X ***Powder for I.V. infusion 100 mg*** ***1*** ***751.70*** ***Remicade*** ***SH***

NOTE:

TREATMENT OF ADULT PATIENTS WITH SEVERE REFRACTORY CROHN DISEASE

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab and infliximab for adult patients with severe refractory Crohn disease. Where the term 'tumour necrosis factor (TNF) alfa antagonist' appears in the following NOTES and restrictions, it refers to adalimumab and infliximab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 2 TNF-alfa antagonists at any 1 time.

From 1 August 2008, under the PBS, all patients will be able to commence a treatment cycle where they may trial each PBS-subsidised TNF-alfa antagonist without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a TNF-alfa antagonist while they continue to show a response to therapy.

A patient who received PBS-subsidised TNF-alfa antagonist treatment prior to 1 August 2008 is considered to be in their first cycle as of 1 August 2008.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised TNF-alfa antagonist more than twice.

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

A patient who has failed fewer than 3 trials of TNF-alfa antagonists in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of TNF-alfa antagonists in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

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

(1) How to prescribe PBS-subsidised TNF-alfa antagonist therapy after 1 August 2008.

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

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and 14 weeks of therapy for infliximab.

From 1 August 2008, a patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.

continued ☞

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer $	Proprietary Name and Manufacturer

For second and subsequent courses of PBS-subsidised TNF-alfa antagonist treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

Adalimumab only: Two completed authority prescriptions must be submitted with every initial application for adalimumab. One prescription must be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats. The second prescription must be written for 2 doses of 40 mg and 2 repeats.

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

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

Assessments of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised TNF-alfa antagonist is approved, a patient may swap if eligible to the alternate TNF-alfa antagonist within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Crohn Disease Activity Index (CDAI) Score, evidence of intestinal inflammation), or the prior corticosteroid therapy and immunosuppressive therapy.

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

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

To avoid confusion, an application for a patient who wishes to swap to the alternate TNF-alfa antagonist should be accompanied by the approved authority prescription or remaining repeats for the TNF-alfa antagonist the patient is ceasing.

(3) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements of the CDAI or evidence of intestinal inflammation submitted with the first authority application for a TNF-alfa antagonist. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and Medicare Australia will assess response according to these revised baseline measurements.

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

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

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised TNF-alfa antagonist therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have received treatment with a corticosteroid and at least 1 immunosuppressive agent, at an adequate dose, for a minimum of 3 consecutive months immediately prior to the time the CDAI score or the indices of intestinal inflammation are measured.

(5) Patients 'grandfathered' onto PBS-subsidised treatment with adalimumab or infliximab.

continued ☞

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer $	Proprietary Name and Manufacturer

A patient who commenced treatment with adalimumab for severe refractory Crohn disease prior to 9 November 2007 or infliximab prior to 7 March 2007 and who continues to receive treatment at the time of application, may qualify for treatment under the initial 'grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment with adalimumab or infliximab will be authorised under this criterion.

Following completion of the initial PBS-subsidised course, further applications for treatment with adalimumab or infliximab will be assessed under the continuing treatment restriction.

'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather" patient must requalify for initial treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' above for further details.

Public and private hospital authority required

Initial 1 (new patients)

Initial treatment of Crohn disease in a patient assessed by CDAI.

Initial PBS-subsidised treatment with infliximab by a gastroenterologist or a consultant physician as specified in the NOTE below, of a patient with severe refractory Crohn disease who satisfies the following criteria:
(a) has confirmed Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician as specified in the NOTE below; and
(b) has signed a patient acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and
(c) has failed to achieve an adequate response to prior systemic therapy including:
(i) a tapered course of steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period; and
(ii) immunosuppressive therapy including:
— azathioprine at a dose of at least 2 mg per kg daily for 3 or more months; or
— 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months; or
— methotrexate at a dose of at least 15 mg weekly for 3 or more months.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application. .

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of the accepted toxicities including severity can be found on the Medicare Australia website (www.medicareaustralia.gov.au). .

The following initiation criterion indicates failure to achieve an adequate response and must be demonstrated in all patients at the time of the application:
(a) have a severity of disease activity which results in a Crohn Disease Activity Index (CDAI) Score greater than or equal to 300 as assessed.

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.

The most recent CDAI assessment must be no more than 1 month old at the time of application.

continued ☞

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer $	Proprietary Name and Manufacturer

Applications for authorisation must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
(i) the completed current Crohn Disease Activity Index (CDAI) calculation sheet including the date of assessment of the patient's condition; and
(ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and
(iii) the signed patient acknowledgement.

A maximum quantity and number of repeats to provide for an initial course of infliximab consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete the 3 doses of infliximab may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

A CDAI assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab.

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment.

Public and private hospital authority required

Initial 2
Change or re-commencement of treatment of Crohn disease in a patient assessed by CDAI.

Initial PBS-subsidised treatment with infliximab by a gastroenterologist or a consultant physician as specified in the NOTE below of a patient who:
(a) has a documented history of severe refractory Crohn disease; and
(b) in this treatment cycle, has received prior PBS-subsidised treatment with infliximab or adalimumab for this condition; and
(c) has not failed PBS-subsidised therapy with infliximab for this condition more than once in the current treatment cycle.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

To demonstrate a response to treatment the application must be accompanied by the results of the most recent course of TNF-alfa antagonist therapy within the timeframes specified in the relevant restriction.

Where the most recent course of PBS-subsidised TNF-alfa antagonist treatment was approved under an initial treatment restriction, the patient must have been assessed for response to that course following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

If the response assessment to the previous course of TNF-alfa antagonist treatment is not submitted as detailed above, the patient will be deemed to have failed therapy with that particular course of TNF-alfa antagonist.

continued ☞

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer $	Proprietary Name and Manufacturer

Authority applications must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
(i) the completed current Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient's condition; and
(ii) details of prior TNF alfa antagonist treatment including details of date and duration of treatment.

A maximum quantity and number of repeats to provide for an initial course of infliximb consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete the 3 doses of infliximab may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

A CDAI assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab.

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment.

Public and private hospital authority required

Continuing treatment of Crohn disease in a patient assessed by CDAI.

Continuing PBS-subsidised treatment with infliximab by a gastroenterologist, a consultant physician as specified in the NOTE below or other consultant physician in consultation with a gastroenterologist, of a patient who:
(a) has a documented history of severe refractory Crohn disease; and
(b) has demonstrated or sustained an adequate response to treatment with infliximab.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

An adequate response to infliximab treatment is defined as a reduction in Crohn Disease Activity Index (CDAI) Score to a level no greater than 150.

Applications for authorisation must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
(i) the completed Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient's condition.

The CDAI assessment must be no more than 1 month old at the time of application.

If the application is the first application for continuing treatment with infliximab, a CDAI assessment of the patient's response must be made up to 12 weeks after the first dose so that there is adequate time for a response to be demonstrated.

The assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion.

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with infliximab.

continued ☞

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer $	Proprietary Name and Manufacturer

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

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats will be authorised. No applications for increased repeats will be authorised.

Where fewer than 2 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Public and private hospital authority required

Initial 1

Initial treatment of Crohn disease in a patient with short gut syndrome or an ostomy patient.

Initial PBS-subsidised treatment with infliximab by a gastroenterologist, or consultant physician as specified in the NOTE below of a patient who satisfies the following criteria:
(a) has confirmed Crohn disease defined by standard clinical, endoscopic and/or imaging features, including histological evidence with the diagnosis confirmed by a gastroenterologist or consultant physician as specified in the NOTE below; and
(b) has diagnostic imaging or surgical evidence of short gut syndrome or has an ileostomy or colostomy; and
(c) has evidence of intestinal inflammation; and
(d) has signed a patient acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and
(e) has failed to achieve an adequate response to prior systemic drug therapy including:
(i) a tapered course of steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period; and
(ii) immunosuppressive therapy including:
— azathioprine at a dose of at least 2 mg per kg daily for 3 or more months; or
— 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months; or
— methotrexate at a dose of at least 15 mg weekly for 3 or more months.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of the accepted toxicities including severity can be found on the Medicare Australia website (www.medicareaustralia.gov.au).

The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the application:
(a) have evidence of intestinal inflammation, including:
(i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; AND/OR
(ii) faeces: higher than normal lactoferrin or calprotectin level; AND/OR
(iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery;
AND/OR
(b) be assessed clinically as being in a high faecal output state;
AND/OR
(c) be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of infliximab.

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.

continued ☞

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer $	Proprietary Name and Manufacturer

Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the continuing treatment restriction. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy.

Applications for authorisation must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
(i) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and
(ii) reports and dates of the pathology or diagnostic imaging test(s) nominated as the response criterion, if relevant; and
(iii) date of the most recent clinical assessment; and
(iv) the signed patient acknowledgement.

All assessments, pathology tests and diagnostic imaging studies must be made within 1 month of the date of application.

A maximum quantity and number of repeats to provide for an initial course of infliximab consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete the 3 doses of infliximab may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

The assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab.

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment.

Public and private hospital authority required

Initial 2
Change or re-commencement of treatment of Crohn disease in a patient with short gut syndrome, an ostomy patient or a patient with extensive small intestine disease.

Initial PBS-subsidised treatment with infliximab by a gastroenterologist or a consultant physician as specified in the NOTE below of a patient who:
(a) has a documented history of severe refractory Crohn disease; and
(b) in this treatment cycle, has received prior PBS-subsidised treatment with infliximab or adalimumab for this condition; and
(c) has not failed PBS-subsidised therapy with infliximab for this condition more than once in the current treatment cycle.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

To demonstrate a response to treatment the application must be accompanied by the results of the most recent course of TNF-alfa antagonist therapy within the timeframes specified in the relevant restriction.

continued ☞

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer $	Proprietary Name and Manufacturer

Where the most recent course of PBS-subsidised TNF-alfa antagonist treatment was approved under an initial treatment restriction, the patient must have been assessed for response to that course following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.
If the response assessment to the previous course of TNF-alfa antagonist treatment is not submitted as detailed above, the patient will be deemed to have failed therapy with that particular course of TNF-alfa antagonist.

Authority applications must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
(i) reports and dates of the pathology or diagnostic imaging test(s) nominated as the response criteria, if relevant; and

(ii). details of prior TNF alfa antagonist treatment including details of date and duration of treatment.

A maximum quantity and number of repeats to provide for an initial course of infliximab consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

The assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of therapy so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab.

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment.

Public and private hospital authority required

Continuing treatment of Crohn disease in a patient with short gut syndrome or an ostomy patient.

Continuing PBS-subsidised treatment with infliximab by a gastroenterologist, a consultant physician as specified in the NOTE below or other consultant physician in consultation with a gastroenterologist, of a patient who:
(a) has a documented history of severe refractory Crohn disease with intestinal inflammation and with short gut syndrome or with an ileostomy or colostomy; and
(b) has demonstrated or sustained an adequate response to treatment with infliximab.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

An adequate response to infliximab treatment is defined as:
(a) improvement of intestinal inflammation as demonstrated by:
(i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; AND/OR
(ii) faeces: normalisation of lactoferrin or calprotectin level; AND/OR
(iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or
(b) reversal of high faecal output state; or
(c) avoidance of the need for surgery or total parenteral nutrition (TPN).

continued ☞

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer $	Proprietary Name and Manufacturer

Applications for authorisation must be made in writing and must include:
(a) a completed authority prescription; and
(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
(i) the reports and dates of the pathology or diagnostic imaging test(s) used to assess response to therapy or the date of clinical assessment.

The patient's assessment must be no more than 1 month old at the time of application.

If the application is the first application for continuing treatment with infliximab, an assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.

The assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion.

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with infliximab.

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

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats will be authorised. No applications for increased repeats will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Public and private hospital authority required
Initial 1
Initial treatment of Crohn disease in a patient with extensive small intestine disease.

Initial PBS-subsidised treatment with infliximab by a gastroenterologist or a consultant physician as specified in the NOTE below, of a patient with severe refractory Crohn disease who satisfies the following criteria:
(a) has confirmed Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or consultant physician as specified in the NOTE below; and
(b) has extensive small intestinal disease with radiological evidence of intestinal inflammation affecting more than 50 cm of the small intestine; and
(c) has signed a patient acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and
(d) has failed to achieve an adequate response to prior systemic therapy including:
(i) a tapered course of steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period; and
(ii) immunosuppressive therapy including:
— azathioprine at a dose of at least 2 mg per kg daily for 3 or more months; or
— 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months; or
— methotrexate at a dose of at least 15 mg weekly for 3 or more months.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application.

continued ☞

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer $	Proprietary Name and Manufacturer

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of the accepted toxicities including severity can be found on the Medicare Australia website (www.medicareaustralia.gov.au).

The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the application:
(a) have severity of disease activity which results in a Crohn Disease Activity Index (CDAI) Score greater than or equal to 220;
AND/OR
(b) have evidence of active intestinal inflammation, including:
(i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; AND/OR
(ii) faeces: higher than normal lactoferrin or calprotectin level; AND/OR
(iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery;
AND/OR
(c) be assessed clinically as being in a high faecal output state;
AND/OR
(d) be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of infliximab.

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.

Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the continuing treatment restriction. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy.

Applications for authorisation must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
(i) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and
(ii) (1) reports and dates of the pathology or diagnostic imaging test(s) nominated as the response criterion, if relevant; or
(2) the completed current Crohn Disease Activity Index (CDAI) calculation sheet including the dates of assessment of the patient's condition, if relevant; and
(iii) date of the most recent clinical assessment; and
(iv) the signed patient acknowledgement.

All assessments, pathology tests and diagnostic imaging studies must be made within 1 month of the date of application.

A maximum quantity and number of repeats to provide for an initial course of infliximab consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete the 3 doses of infliximab may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

The assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab.

continued ☞

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer $	Proprietary Name and Manufacturer

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment.

Public and private hospital authority required

Continuing treatment of Crohn disease in a patient with extensive small intestine disease.

Continuing PBS-subsidised treatment with infliximab by a gastroenterologist, or consultant physician as specified in the NOTE below or other consultant physician in consultation with a gastroenterologist, of a patient who:
(a) has a documented history of severe refractory Crohn disease with extensive intestinal inflammation affecting more than 50 cm of the small intestine; and
(b) has demonstrated or sustained an adequate response to treatment with infliximab.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

An adequate response to infliximab treatment is defined as:
(a) a reduction in Crohn Disease Activity Index (CDAI) Score to no greater than 150; or
(b) improvement of intestinal inflammation as demonstrated by:
(i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; AND/OR
(ii) faeces: normalisation of lactoferrin or calprotectin level; AND/OR
(iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or
(c) reversal of high faecal output state; or
(d) avoidance of the need for surgery or total parenteral nutrition (TPN).

Applications for authorisation must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
(i) the completed Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient's condition; or
(ii) the reports and dates of the pathology test or diagnostic imaging test(s) used to assess response to therapy; or
(iii) the date of clinical assessment.

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

If the application is the first application for continuing treatment with infliximab, an assessment of the patient's response must be made up to 12 weeks after the first dose (6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.

The assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion.

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with infliximab.

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

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats will be authorised. No applications for increased repeats will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

continued ☞

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer $	Proprietary Name and Manufacturer

Public and private hospital authority required

Initial 3 (grandfather)

Initial PBS-subsidised treatment of Crohn disease in a patient assessed by CDAI who has previously received non-PBS-subsidised therapy with infliximab.

Initial PBS-subsidised supply for continuing treatment with infliximab by a gastroenterologist, a consultant physician as specified in the NOTE below, or other consultant physician in consultation with a gastroenterologist of a patient who:
(a) has a documented history of severe refractory Crohn disease and was receiving treatment with infliximab prior to 7 March 2007; and
(b) had a Crohn Disease Activity Index (CDAI) Score of greater than or equal to 300 prior to commencing treatment with infliximab. Where a baseline CDAI assessment is not available, please call Medicare Australia on 1800 700 270 to discuss; and
(c) has signed a patient acknowledgement indicating that they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and
(d) has demonstrated or sustained an adequate response to treatment with infliximab. For advice please contact Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

An adequate response to infliximab treatment is defined as a reduction in Crohn Disease Activity Index (CDAI) Score to no greater than 150.

Applications for authorisation must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
(i) the completed current and baseline Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient's condition; and
(ii) the signed patient acknowledgement.

The current CDAI assessment must be no more than 1 month old at the time of application. The baseline CDAI assessment must be from immediately prior to commencing treatment with infliximab.

The assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion.

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with infliximab.

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

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats will be authorised. No applications for increased repeats will be authorised.

Where fewer than 2 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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

Public and private hospital authority required

Initial 3

Initial PBS-subsidised treatment of Crohn disease in a patient with short gut syndrome, an ostomy patient, or a patient with extensive small intestine disease, who has previously received non-PBS-subsidised therapy with infliximab.

continued ☞

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer $	Proprietary Name and Manufacturer

Initial PBS-subsidised supply for continuing treatment with infliximab by a gastroenterologist, a consultant physician as specified in the NOTE below, or other consultant physician in consultation with a gastroenterologist, of a patient who:
(a) has a documented history of severe refractory Crohn disease and was receiving treatment with infliximab prior to 7 March 2007; and
(b) (1) has a history of extensive small intestinal disease with radiological evidence of intestinal inflammation affecting more than 50 cm of the small intestine; or
(2) has diagnostic imaging or surgical evidence of short gut syndrome or has an ileostomy or colostomy with a documented history of intestinal inflammation; and
(c) has signed a patient acknowledgement indicating that they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and
(d) has demonstrated or sustained an adequate response to treatment with infliximab according to the criteria included in the relevant continuation restriction. For advice please contact Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

The same criteria used to determine an inadequate response to prior treatment at baseline must be used to determine response to treatment and eligibility for continuing therapy, according to the criteria included in the continuing treatment restriction.

An adequate response to infliximab treatment is defined as:
(a) a reduction in Crohn Disease Activity Index (CDAI) Score to no greater than 150; or
(b) improvement of intestinal inflammation as demonstrated by:
(i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; AND/OR
(ii) faeces: normalisation of lactoferrin or calprotectin level; AND/OR
(iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or
(c) reversal of high faecal output state; or
(d) avoidance of the need for surgery or total parenteral nutrition (TPN).

Applications for authorisation must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
(i) (1) the completed current and baseline Crohn Disease Activity Index (CDAI) Score calculation sheet, where relevant, including the date of the assessment of the patient's condition; or
(2) the reports and dates of the current and baseline pathology or diagnostic imaging test(s) in order to assess response to therapy; or
(3) the date of clinical assessment(s); and
(ii) the signed patient acknowledgement.

The patient's assessment must be no more than 1 month old at the time of application. The baseline CDAI assessments must be from immediately prior to commencing treatment with infliximab. Where a baseline assessment is not available, please call Medicare Australia on 1800 700 270 to discuss.

The assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion.

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with infliximab.

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

continued ☞

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer $	Proprietary Name and Manufacturer	

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats will be authorised. No applications for increased repeats will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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

9613Y	***Powder for I.V. infusion 100 mg***	***1***	***751.70***	***Remicade***	***SH***

Public and private hospital authority required

Initial treatment of Crohn disease in a paediatric patient.

Initial PBS-subsidised treatment by a gastroenterologist, paediatrician or consultant physician as specified in the NOTE below, of a patient aged 6 to 17 years inclusive with moderate to severe refractory Crohn disease who satisfies the following criteria:
(a) has confirmed Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or consultant physician as specified in the NOTE below; and
(b) whose parent or authorised guardian has signed a patient acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and
(c) has failed to achieve an adequate response to 2 of the following 3 conventional prior therapies including:
(i) a tapered course of steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period;

(ii) an 8 week course of enteral nutrition;
(iii) immunosuppressive therapy including:
— azathioprine at a dose of at least 2 mg per kg daily for 3 or more months; or
— 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months; or
— methotrexate at a dose of at least 10 mg per square metre weekly for 3 or more months.

NOTE: Prescribers must be gastoenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of the accepted toxicities including severity can be found on the Medicare Australia website (www.medicareaustralia.gov.au).

The following initiation criterion indicates failure to achieve an adequate response and must be demonstrated in all patients at the time of the application:
(a) severity of disease activity which results in a Paediatric Crohn Disease Activity Index (PCDAI) Score greater than or equal to 30 as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.
(b) The most recent PCDAI assessment must be no more than 1 month old at the time of application.

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.

continued ☞

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer $	Proprietary Name and Manufacturer

Applications for authorisation must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
(i) the completed current Paediatric Crohn Disease Activity Index (PCDAI) calculation sheet including the date of assessment of the patient's condition; and
(ii) details of previous systemic drug therapy [dosage, date of commencement and duration of therapy], or dates of enteral nutrition; and
(iii) the signed patient acknowledgement.

A maximum quantity and number of repeats to provide for an initial course of infliximab consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete the 3 doses of infliximab may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

A PCDAI assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab.

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment.

Public and private hospital authority required

Continuing treatment of Crohn disease in a patient initiated on PBS-subsidised treatment as a paediatric patient.

Continuing PBS-subsidised treatment with infliximab by a gastroenterologist, paediatrician, consultant physician as specified in the NOTE below or other consultant physician in consultation with a gastroenterologist, of a patient who:

(a) has a documented history of moderate to severe refractory Crohn disease; and
(b) has demonstrated or sustained an adequate response to treatment with infliximab.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

An adequate response to infliximab treatment is defined as a reduction in Paediatric Crohn Disease Activity Index (PCDAI) Score by at least 15 points as compared to baseline AND a total PCDAI score of 30 points or less.

Applications for authorisation must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
(i) the completed Paediatric Crohn Disease Activity Index (PCDAI) calculation sheet along with the date of the assessment of the patient's condition.

The PCDAI assessment must be no more than 1 month old at the time of application.

If the application is the first application for continuing treatment with infliximab, a PCDAI assessment of the patient's response must be made up to 12 weeks after the first dose so that there is adequate time for a response to be demonstrated.

The assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion.

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with infliximab.

continued ☞

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer $	Proprietary Name and Manufacturer

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

Patients who fail to demonstrate or sustain a response to treatment with infliximab for Crohn disease as specified in the criteria for continuing treatment with infliximab, will not be eligible to receive PBS-subsidised treatment with this drug within 12 months of the date on which treatment was ceased.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats will be authorised. No applications for increased repeats will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Public and private hospital authority required

Initial PBS-subsidised treatment of Crohn disease in a paediatric patient who has previously received non-PBS-subsidised therapy with infliximab.

Initial PBS-subsidised supply for continuing treatment with infliximab by a gastroenterologist, paediatrician, consultant physician as specified in the NOTE below or other consultant physician in consultation with a gastroenterologist, of a patient aged 6 to 17 years inclusive who:
(a) has a documented history of moderate to severe refractory Crohn disease and was receiving treatment with infliximab prior to 4 July 2007; and
(b) had a Paediatric Crohn Disease Activity Index (PCDAI) Score of greater than 30 prior to commencing treatment with infliximab. Where a baseline CDAI assessment is not available, please call Medicare Australia on 1800 700 270 to discuss; and
(c) whose parent or authorised guardian has signed a patient acknowledgement indicating that they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and
(d) has demonstrated or sustained an adequate response to treatment with infliximab. For advice please contact Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

An adequate response to infliximab treatment is defined as a reduction in Paediatric Crohn Disease Activity Index (PCDAI) Score by at least 15 points as compared to baseline AND a total PCDAI score of 30 points or less.

Applications for authorisation must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
(i) the completed current and baseline Paediatric Crohn Disease Activity Index (PCDAI) calculation sheet along with the date of the assessment of the patient's condition; and
(ii) the signed patient acknowledgement.

The current PCDAI assessment must be no more than 1 month old at the time of application. The baseline PCDAI assessment must be from immediately prior to commencing treatment with infliximab.

The assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion.

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with infliximab.

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

Patients who fail to demonstrate or sustain a response to treatment with infliximab for Crohn disease as specified in the criteria for continuing treatment with infliximab, will not be eligible to recommence PBS-subsidised treatment with this drug within 12 months of the date on which treatment was ceased.

continued ☞

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer $	Proprietary Name and Manufacturer	

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats will be authorised. No applications for increased repeats will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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

9612X ***Powder for I.V. infusion 100 mg*** ***1*** ***751.70*** ***Remicade*** ***SH***

NOTE:

TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents efalizumab, etanercept and infliximab, for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological agents' appears in the following NOTES and restrictions, it only refers to efalizumab, etanercept and infliximab.

From 1 December 2007, all patients will be able to commence a 'Biological Treatment Cycle' (Cycle), where they may trial efalizumab, etanercept or infliximab without having to meet the initial treatment criteria, that is they will not need to experience a disease flare when swapping to an alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

A patient who received PBS-subsidised biological agent treatment for chronic plaque psoriasis prior to 1 December 2007 is considered to be in their first Cycle as of 1 December 2007.

Patients are eligible for PBS-subsidised treatment with only 1 biological agent at any 1 time.

Within the same Treatment Cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for a PBS-subsidised biological agent, they must change to an alternate agent if they wish to continue PBS-subsidised biological treatment. A patient who, prior to 1 December 2007, was authorised to receive PBS-subsidised initial treatment for chronic plaque psoriasis with the same agent twice, is exempt from this condition in respect of applications approved prior to 1 December 2007.

Initial treatment with efalizumab consists of 16 weeks of therapy, with infliximab consists of 22 weeks of therapy, and with etanercept consists of 12 weeks of active therapy followed by a biological treatment-free period of at least 12 weeks. Response to treatment for all 3 agents must be assessed after 12 weeks of treatment.

Following demonstration of response to initial treatment, these biological agents are available as continuing therapy. Ongoing access to continuing treatment is available for as long as the response to therapy is sustained. In the case of efalizumab and infliximab, continuing treatment consists of 24 weeks of continuous active treatment. In the case of etanercept, continuing treatment consists of 12 weeks of active therapy followed by a biological treatment-free period of at least 12 weeks.

Patients must be assessed for response to each course of continuing treatment according to the criteria included in the relevant continuing treatment restriction.

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

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

Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle.

continued ☞

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer $	Proprietary Name and Manufacturer

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

How to prescribe biological agents for the treatment of severe chronic plaque psoriasis after 1 December 2007.

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Application for approval for initial treatment.

Applications for a course of initial treatment should be made in the following situations:
(i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); and
(ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under '(4) Swapping therapy' below]; and
(iii) patients who wish to re-commence treatment following a break in PBS-subsidised therapy with that agent (Initial 2).

All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 16 weeks of therapy in the case of efalizumab, 12 weeks of therapy in the case of etanercept, and 22 weeks of treatment in the case of infliximab. Approval will be based on the criteria included in the relevant initial treatment restriction.

Grandfather patients (Infliximab only).

Applications for patients who commenced treatment with infliximab prior to 7 March 2007, may apply for initial PBS-subsidised treatment as continuing therapy under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with a biological agent prior to PBS listing of that agent.

Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment. Approval will be based on the criteria included in the relevant restriction.

(2) Assessment of response to initial treatment.

When prescribing efalizumab or infliximab, where the initial treatment course is for 16 or 22 weeks respectively, a PASI assessment must be conducted after at least 12 weeks of treatment. This assessment must be submitted to Medicare Australia within 1 month of the completion of this initial treatment course. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with efalizumab or infliximab. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

Applications for continuing treatment with efalizumab or infliximab must also be submitted to Medicare Australia prior to the completion of this initial course of therapy to ensure continuity of treatment for those patients who meet the continuation criterion and wish to continue on treatment with either efalizumab or infliximab.

When prescribing etanercept, a PASI assessment must be conducted at the completion of the 12 week initial treatment course. This assessment, which will be used to determine eligibility for future treatment according to the criterion included in the relevant continuing treatment restriction, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with etanercept. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

(3) Application for continuing treatment.

As stated above, following the completion of an initial treatment course of efalizumab or infliximab to which an adequate response has been demonstrated, patients may qualify to receive up to 24 weeks of continuing treatment with efalizumab or infliximab. Patients are eligible to continue to receive continuous treatment with efalizumab or infliximab in 24 week courses providing they continue to sustain a response.

For second and subsequent courses of PBS-subsidised treatment with efalizumab or infliximab it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

continued ☞

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer $	Proprietary Name and Manufacturer

At the completion of an initial 12 week treatment course of etanercept to which an adequate response has been demonstrated, followed by a biological treatment-free period of at least 12 weeks, patients may qualify to receive continuing treatment with etanercept. Continuing treatment is available in the form of 12 weeks of active etanercept treatment followed by a biological treatment-free period of at least 12 weeks. Patients are eligible to receive continuing treatment with etanercept on this cyclical basis, for as long as they continue to sustain a response. Continuing applications must be submitted at least 12 weeks after cessation of the most recent course of etanercept treatment.

A PASI assessment must be conducted for each course of continuing treatment for each biological agent, according to the requirements set out in the relevant restriction. Assessment of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia no later than 1 month from the date that course was completed or treatment was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to sustain a response to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

NOTE:

(4) Swapping therapy.

Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate agent within the same Treatment Cycle without having to requalify with respect to disease severity (i.e. a PASI score of greater than 15), or prior treatment requirements.

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

Patients may trial an alternate biological agent at any time, regardless of whether they are receiving therapy with a biological agent at the time of the application or not. However, they cannot swap to a particular agent if they have failed to respond to treatment with that particular agent in the same Cycle.

Patients who commenced treatment with infliximab prior to 7 March 2007 access these interchangeability arrangements in the same way as patients who have not.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required 12 week biological treatment-free period applying to patients who have demonstrated a response to their most recent course of etanercept. This means that patients who have demonstrated a response to a 12 week course of etanercept must have a PBS-subsidised biological therapy treatment-free period of at least 12 weeks, immediately following this course of treatment, before swapping to efalizumab or infliximab. Patients who fail to respond to etanercept and who qualify and wish to try a course of efalizumab or infliximab, may do so without having to have any treatment-free period.

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

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

(5) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated, based on the baseline PASI assessment submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment authority is submitted within a Treatment Cycle and subsequent response will be assessed according to this revised PASI score.

For new patients and patients commencing a new Cycle, the first baseline PASI assessment must be conducted, preferably while the patient is still receiving their most recent prior therapy, but no later than 1 month following cessation of such therapy, as outlined in the relevant restriction. This is not required for any subsequent PASI scores provided for these patients within the same Cycle, nor for patients who received initial PBS-subsidised therapy under a 'grandfather' restriction.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatment applications.

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

continued ☞

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer $	Proprietary Name and Manufacturer

Patients who wish to trial a second or subsequent Biological Treatment Cycle, following a break in PBS-subsidised biological therapy of at least 5 years, must requalify for initial treatment according to the criteria of the relevant restriction and index of disease severity. Patients must have had at least 1 prior treatment, as listed in the criteria, for a minimum of 6 weeks, and must have a PASI assessment conducted preferably whilst still on treatment, but no later than 1 month following cessation of treatment. The PASI assessment must be no older than 1 month at the time of application.

Public and private hospital authority required

Initial treatment [Initial 1, Whole body (New patients — No prior biological agent)]
Initial treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over who:
(a) have severe chronic plaque psoriasis where lesions have been present for at least 6 months from the time of initial diagnosis; and
(b) have not received any prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle; and
(c) have signed a patient acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment (whole body); and
(d) have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 3 of the following 4 treatments:
(i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; and/or
(ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; and/or
(iii) cyclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; and/or
(iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks.

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity to necessitate permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of acceptable toxicities including severity, associated with phototherapy, methotrexate, cyclosporin and acitretin, can be found on the Medicare Australia website (www.medicareaustralia.gov.au).

The following initiation criterion indicates failure to achieve an adequate response and must be demonstrated in all patients at the time of the application:
(a) A current Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.
(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 1 month following cessation of each course of treatment.
(c) The most recent PASI assessment must be no more than 1 month old at the time of application.

Applications for authorisation must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and
(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy]; and
(iii) the signed patient acknowledgement.

A maximum of 22 weeks of treatment with infliximab will be authorised under this restriction.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised.

continued ☞

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer $	Proprietary Name and Manufacturer

Where fewer than 3 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 22 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period beyond 22 weeks.

A PASI assessment of the patient's response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

It is recommended that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment.

Public and private hospital authority required

Initial or re-Treatment [Initial 2, Whole body (Received prior biological agent under PBS)]
Treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over who:
(a) have a documented history of severe chronic plaque psoriasis; and
(b) have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle; and
(c) have not failed PBS-subsidised therapy with infliximab for the treatment of this condition in the current Treatment Cycle.

Applications for authorisation must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and
(ii) details of prior biological treatment, including dosage, date and duration of treatment.

Applications for patients who have demonstrated a response to PBS-subsidised infliximab treatment within this Treatment Cycle and who wish to re-commence infliximab treatment within the same Cycle following a break in therapy, will only be approved where evidence of the patient's response to their most recent course of PBS-subsidised infliximab treatment has been submitted to Medicare Australia within 1 month of cessation of treatment.

A maximum of 22 weeks of treatment with infliximab will be authorised under this restriction.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised.

Where fewer than 3 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 22 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period beyond 22 weeks.

A PASI assessment of the patient's response to this course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

continued ☞

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer $	Proprietary Name and Manufacturer

It is recommended that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment.

Patients who fail to demonstrate a response to treatment with each of the biological agents, efalizumab, etanercept and infliximab, are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may re-commence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

Public and private hospital authority required

Initial treatment [Initial 3, Whole body (Grandfather patients)]
Initial PBS-subsidised supply for continuing treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over who:
(a) have a documented history of severe chronic plaque psoriasis and were receiving treatment with infliximab prior to 7 March 2007; and
(b) had a Psoriasis Area and Severity Index (PASI) score of greater than 15 prior to commencing treatment with infliximab; and
(c) have signed a patient acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment (whole body); and
(d) have demonstrated a response as specified in the criterion included in the restriction for continuing PBS-subsidised treatment with infliximab (whole body).

Applications for authorisation must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
(i) the completed Psoriasis Area and Severity Index (PASI) calculation sheet including the date of the assessment of the patient's condition at baseline (prior to initiation of infliximab therapy) and the most recent PASI assessment [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and
(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy]; and
(iii) the signed patient acknowledgement.

A maximum of 24 weeks of treatment with infliximab will be authorised under this restriction.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats will be authorised.

Where fewer than 2 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the treatment period beyond 24 weeks.

A PASI assessment of the patient's response to this initial PBS-subsidised course of therapy must be conducted within 4 weeks prior to completion of this course of treatment. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

The most recent PASI assessment must be no more than 1 month old at the time of application.

It is recommended that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment.

continued ☞

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer $	Proprietary Name and Manufacturer

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

Public and private hospital authority required

Continuing treatment (Whole body)

Continuing PBS-subsidised treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over:

(a) who have a documented history of severe chronic plaque psoriasis; and

(b) whose most recent course of PBS-subsidised biological treatment for this condition in this Treatment Cycle was with infliximab; and

(c) who have demonstrated an adequate response to their most recent course of treatment with infliximab.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the pre-biological treatment baseline value for this Treatment Cycle.

This assessment must be provided to Medicare Australia no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with infliximab, the assessment of response must be after a minimum of 12 weeks of treatment with an initial course.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) the completed Psoriasis Area and Severity Index (PASI) calculation sheet along with the date of the assessment of the patient's condition.

Approval will be based on the PASI assessment of response to the most recent course of treatment with infliximab.

A maximum of 24 weeks of treatment with infliximab will be authorised under this restriction.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for continuing authority applications, or for treatment that would otherwise extend the treatment period beyond 24 weeks.

A PASI assessment of the patient's response must be conducted within 4 weeks prior to completion of this course of treatment. This assessment, which will be used to determine eligibility for further continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

It is recommended that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment.

Patients who fail to demonstrate a response to treatment with each of the biological agents, efalizumab, etanercept and infliximab, are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may re-commence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

continued ☞

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer $	Proprietary Name and Manufacturer

Public and private hospital authority required

Initial treatment [Initial 1, Face, hand, foot (New patients — No prior biological agent)]

Initial treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over who:

(a) have severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis; and

(b) have not received any prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle; and

(c) have signed a patient acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment (face, hand, foot); and

(d) have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 3 of the following 4 treatments:

(i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; and/or

(ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; and/or

(iii) cyclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; and/or

(iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks.

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity to necessitate permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of acceptable toxicities including severity, associated with phototherapy, methotrexate, cyclosporin and acitretin, can be found on the Medicare Australia website (www.medicareaustralia.gov.au).

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

(a) Chronic plaque psoriasis classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where:

(i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment; or

(ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.

(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 1 month following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than 1 month old at the time of application.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy]; and

(iii) the signed patient acknowledgement.

A maximum of 22 weeks of treatment with infliximab will be authorised under this restriction.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised.

continued ☞

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer $	Proprietary Name and Manufacturer

Where fewer than 3 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 22 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period beyond 22 weeks.

A PASI assessment of the patient's response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

It is recommended that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

Public and private hospital authority required

Initial or re-Treatment [Initial 2, Face, hand, foot (Received prior biological agent under PBS)]
Treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over who:
(a) have a documented history of severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot; and
(b) have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle; and
(c) have not failed PBS-subsidised therapy with infliximab for the treatment of this condition in the current Treatment Cycle.

Applications for authorisation must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and
(ii) details of prior biological treatment, including dosage, date and duration of treatment.

Applications for patients who have demonstrated a response to PBS-subsidised infliximab treatment within this Treatment Cycle and who wish to re-commence infliximab treatment within the same Cycle following a break in therapy, will only be approved where evidence of the patient's response to their most recent course of PBS-subsidised infliximab treatment has been submitted to Medicare Australia within 1 month of cessation of treatment.

A maximum of 22 weeks of treatment with infliximab will be authorised under this restriction.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised.

Where fewer than 3 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 22 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period beyond 22 weeks.

continued ☞

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer $	Proprietary Name and Manufacturer

A PASI assessment of the patient's response to this course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

It is recommended that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

Patients who fail to demonstrate a response to treatment with each of the biological agents, efalizumab, etanercept and infliximab, are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may re-commence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

Public and private hospital authority required

Initial treatment [Initial 3, Face, hand, foot (Grandfather patients)]
Initial PBS-subsidised supply for continuing treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over:
(a) who have a documented history of severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot and were receiving treatment with infliximab prior to 7 March 2007; and
(b) whose disease, prior to treatment with infliximab, was of a severity as defined in the initiation criterion included in the initial treatment restriction (Initial 1, New patients — face, hand, foot); and
(c) who have signed a patient acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment (face, hand, foot); and
(d) who have demonstrated a response as specified in the criterion included in the restriction for continuing PBS-subsidised treatment with infliximab (face, hand, foot).

Applications for authorisation must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
(i) the completed Psoriasis Area and Severity Index (PASI) calculation sheet and face, hand, foot area diagrams along with the date of the assessment of the patient's condition at baseline (prior to initiation of infliximab therapy) and the most recent PASI assessment [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and
(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy]; and
(iii) the signed patient acknowledgement.

A maximum of 24 weeks of treatment with infliximab will be authorised under this restriction.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats will be authorised.

Where fewer than 2 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period beyond 24 weeks.

continued ☞

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer $	Proprietary Name and Manufacturer

A PASI assessment of the patient's response to this initial PBS-subsidised course of therapy must be conducted within 4 weeks prior to completion of this course of treatment. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

The most recent PASI assessment must be no more than 1 month old at the time of application.

It is recommended that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment.

The PASI assessment must be performed on the same affected area as assessed at baseline or prior to initiation of infliximab treatment.

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

Public and private hospital authority required

Continuing treatment (Face, hand, foot)
Continuing PBS-subsidised treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over:
(a) who have a documented history of severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot; and
(b) whose most recent course of PBS-subsidised biological treatment for this condition in this Treatment Cycle was with infliximab; and
(c) who have demonstrated an adequate response to treatment with infliximab.

An adequate response to infliximab treatment is defined as the plaque or plaques assessed prior to biological treatment showing:
(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the pre-biological treatment baseline values; or
(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the pre-biological treatment baseline value.

This assessment must be provided to Medicare Australia no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with infliximab, the assessment of response must be after a minimum of 12 weeks of treatment with an initial course.

Applications for authorisation must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
(i) the completed Psoriasis Area and Severity Index (PASI) calculation sheet and face, hand, foot area diagrams along with the date of the assessment of the patient's condition [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].

A maximum of 24 weeks of treatment with infliximab will be authorised under this restriction.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for continuing authority applications, or for treatment that would otherwise extend the treatment period beyond 24 weeks.

continued ☞

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer $	Proprietary Name and Manufacturer	

A PASI assessment of the patient's response must be conducted within 4 weeks prior to completion of this course of treatment. This assessment, which will be used to determine eligibility for further continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

It is recommended that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment.

The PASI assessment for continuing treatment must be performed on the same affected area assessed at baseline.

Patients who fail to demonstrate a response to treatment with each of the biological agents, efalizumab, etanercept and infliximab, are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may re-commence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

9617E	*Powder for I.V. infusion 100 mg*	*1*	*751.70*	*Remicade*	*SH*

INTERFERON ALFA-2a
CAUTION:
Treatment with interferon alfa has been associated with depression and suicide in some patients. Patients with a history of suicidal ideation or depressive illness should be warned of the risks. Psychiatric status during therapy should be monitored.

Private hospital authority required
Use in the treatment of Philadelphia chromosome positive myelogenous leukaemia in the chronic phase;

Patients with chronic hepatitis B who satisfy all of the following criteria:
(1) Histological evidence of chronic hepatitis on liver biopsy (except in patients with coagulation disorders considered severe enough to prevent liver biopsy);
(2)(a) Abnormal serum ALT levels in conjunction with documented chronic hepatitis B infection; or
(b) Elevated HBV DNA levels in conjunction with documented chronic hepatitis B infection;
(3) Are not persons with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L);
(4) Female patients of child-bearing age are not pregnant, not breast-feeding, and are using an effective form of contraception.

6210W	*Injection 3,000,000 i.u. in 0.5 mL single dose pre-filled syringe*	*1*	*29.80*	*Roferon-A*	*RO*
6211X	*Injection 4,500,000 i.u. in 0.5 mL single dose pre-filled syringe*	*1*	*44.70*	*Roferon-A*	*RO*
6212Y	*Injection 6,000,000 i.u. in 0.5 mL single dose pre-filled syringe*	*1*	*59.58*	*Roferon-A*	*RO*
6213B	*Injection 9,000,000 i.u. in 0.5 mL single dose pre-filled syringe*	*1*	*89.38*	*Roferon-A*	*RO*

INTERFERON ALFA-2b
CAUTION:
Treatment with interferon alfa has been associated with depression and suicide in some patients. Patients with a history of suicidal ideation or depressive illness should be warned of the risks. Psychiatric status during therapy should be monitored.

Private hospital authority required
Adjunctive therapy of malignant melanoma following surgery in patients with nodal involvement;

Use in the treatment of Philadelphia chromosome positive myelogenous leukaemia in the chronic phase;

continued ☞

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer $	Proprietary Name and Manufacturer	
	Patients with chronic hepatitis B who satisfy all of the following criteria: ***(1) Histological evidence of chronic hepatitis on liver biopsy (except in patients with coagulation disorders considered severe enough to prevent liver biopsy);*** ***(2)(a) Abnormal serum ALT levels in conjunction with documented chronic hepatitis B infection; or*** ***(b) Elevated HBV DNA levels in conjunction with documented chronic hepatitis B infection;*** ***(3) Are not persons with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L);*** ***(4) Female patients of child-bearing age are not pregnant, not breast-feeding, and are using an effective form of contraception.***				
6246R	***Solution for injection 10,000,000 i.u. in 1 mL single dose vial***	***5***	***496.50***	***Intron A***	***SH***
6253D	***Solution for injection 18,000,000 i.u. in 1.2 mL multi-dose injection pen***	***1***	***178.74***	***Intron A Redipen***	***SH***
6218G	***Solution for injection 18,000,000 i.u. in 3 mL single dose vial***	***1***	***178.74***	***Intron A***	***SH***
6219H	***Solution for injection 25,000,000 i.u. in 2.5 mL single dose vial***	***1***	***248.25***	***Intron A***	***SH***
6254E	***Solution for injection 30,000,000 i.u. in 1.2 mL multi-dose injection pen***	***1***	***297.90***	***Intron A Redipen***	***SH***
6255F	***Solution for injection 60,000,000 i.u. in 1.2 mL multi-dose injection pen***	***1***	***595.80***	***Intron A Redipen***	***SH***
	INTERFERON GAMMA-1b				
	Private hospital authority required ***Treatment of chronic granulomatous disease in patients with frequent and severe infections despite adequate prophylaxis with antimicrobial agents.***				
6148N	***Injection 2,000,000 i.u. in 0.5 mL***	***6***	***1360.90***	***Imukin***	***BY***
	LAMIVUDINE				
	Private hospital authority required ***Patients with chronic hepatitis B who satisfy all of the following criteria:*** ***(1) Histological evidence of chronic hepatitis on liver biopsy (except in patients with coagulation disorders considered severe enough to prevent liver biopsy);*** ***(2)(a) Abnormal serum ALT levels in conjunction with documented chronic hepatitis B infection; or*** ***(b) Elevated HBV DNA levels in conjunction with documented chronic hepatitis B infection;*** ***(3) Female patients of child-bearing age are not pregnant, not breast-feeding, and are using an effective form of contraception.*** ***Persons with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy.***				
6257H	***Tablet 100 mg***	***28***	***149.36***	***Zeffix***	***GK***
	Private hospital authority required ***Treatment of HIV infection in patients with:*** ***(a) CD4 cell counts of less than 500 per cubic millimetre; or*** ***(b) viral load of greater than 10,000 copies per mL.***				
6193Y	***Tablet 150 mg***	***60***	***282.00***	***3TC***	***GK***
6435Q	***Tablet 300 mg***	***30***	***282.00***	***3TC***	***GK***

continued ☞

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer $	Proprietary Name and Manufacturer	
	Private hospital authority required ***Patients with chronic hepatitis B who satisfy all of the following criteria:*** ***(1) Histological evidence of chronic hepatitis on liver biopsy (except in patients with coagulation disorders considered severe enough to prevent liver biopsy);*** ***(2)(a) Abnormal serum ALT levels in conjunction with documented chronic hepatitis B infection; or*** ***(b) Elevated HBV DNA levels in conjunction with documented chronic hepatitis B infection;*** ***(3) Female patients of child-bearing age are not pregnant, not breast-feeding, and are using an effective form of contraception.*** ***Persons with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy.***				
6271C	***Oral solution 5 mg per mL, 240 mL***	***1***	***69.91***	***Zeffix***	***GK***
	Private hospital authority required ***Treatment of HIV infection in patients with:*** ***(a) CD4 cell counts of less than 500 per cubic millimetre; or*** ***(b) viral load of greater than 10,000 copies per mL.***				
6194B	***Oral solution 10 mg per mL, 240 mL***	***1***	***86.48***	***3TC***	***GK***
	LAMIVUDINE with ZIDOVUDINE				
	Private hospital authority required ***Treatment of HIV infection in patients with:*** ***(a) CD4 cell counts of less than 500 per cubic millimetre; or*** ***(b) viral load of greater than 10,000 copies per mL.***				
6234D	***Tablet 150 mg-300 mg***	***60***	***578.60***	***Combivir***	***GK***
	LANREOTIDE ACETATE				
	Private hospital authority required ***Active acromegaly in a patient with persistent elevation of mean growth hormone levels of greater than 2.5 micrograms per litre AND*** ***(a) after failure of other therapy including dopamine agonists; or*** ***(b) as interim treatment while awaiting the effects of radiotherapy and where treatment with dopamine agonists has failed; or*** ***(c) if the patient is unfit for or unwilling to undergo surgery and where radiotherapy is contraindicated.*** ***In a patient treated with radiotherapy, treatment must cease if there is biochemical evidence of remission (normal IGF1) after lanreotide has been withdrawn for at least 4 weeks (6 weeks after the last dose). Lanreotide should be withdrawn every 2 years in the 10 years after radiotherapy for assessment of remission.*** ***Treatment must cease if IGF1 is not lower after 3 months treatment.***				
6332G	***Powder for suspension for injection 30 mg (base) with diluent ampoule***	***1***	***750.00***	***Somatuline LA***	***IS***

continued ☞

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer $	Proprietary Name and Manufacturer	
	Private hospital authority required ***Active acromegaly in a patient with persistent elevation of mean growth hormone levels of greater than 2.5 micrograms per litre AND*** ***(a) after failure of other therapy including dopamine agonists; or*** ***(b) as interim treatment while awaiting the effects of radiotherapy and where treatment with dopamine agonists has failed; or*** ***(c) if the patient is unfit for or unwilling to undergo surgery and where radiotherapy is contraindicated.*** ***In a patient treated with radiotherapy, treatment must cease if there is biochemical evidence of remission (normal IGF1) after lanreotide has been withdrawn for at least 4 weeks (8 weeks after the last dose). Lanreotide should be withdrawn every 2 years in the 10 years after radiotherapy for assessment of remission.*** ***Treatment must cease if IGF1 is not lower after 3 months treatment;*** ***Functional carcinoid tumour causing intractable symptoms. The patient must have experienced on average over 1 week, 3 or more episodes per day of diarrhoea and/or flushing, which persisted despite the use of anti-histamines, anti-serotonin agents and anti-diarrhoea agents, and surgery or antineoplastic therapy must have failed or be inappropriate.*** ***Treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 3 months' therapy at a dose of 120 mg every 28 days. Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose.***				
6423C	***Injection 60 mg (base) in single dose pre-filled syringe***	***1***	***1345.00***	***Somatuline Autogel***	***IS***
6424D	***Injection 90 mg (base) in single dose pre-filled syringe***	***1***	***1790.00***	***Somatuline Autogel***	***IS***
6425E	***Injection 120 mg (base) in single dose pre-filled syringe***	***1***	***2240.00***	***Somatuline Autogel***	***IS***
	LENOGRASTIM				
	Private hospital authority required ***Mobilisation of peripheral blood progenitor cells to facilitate harvest of such cells for reinfusion into patients with non-myeloid malignancies who have had myeloablative or myelosuppressive therapy;*** ***Mobilisation of peripheral blood progenitor cells, in normal volunteers, for use in allogeneic transplantation to facilitate harvest of such cells in healthy donors;*** ***Patients with non-myeloid malignancies receiving marrow-ablative chemotherapy and subsequent peripheral blood progenitor cell or bone marrow transplantation;*** ***Patients being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in:*** ***(a) acute lymphoblastic leukaemia; or*** ***(b) Ewing's sarcoma; or*** ***(c) germ cell tumours; or*** ***(d) infants and children with CNS tumours; or*** ***(e) neuroblastoma; or*** ***(f) non-Hodgkin's lymphoma (intermediate or high grade); or*** ***(g) osteosarcoma; or*** ***(h) relapsed Hodgkin's disease; or*** ***(i) rhabdomyosarcoma;*** ***Patients with breast cancer receiving standard dose adjuvant chemotherapy who have had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned;***				

continued ☞

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer $	Proprietary Name and Manufacturer	
	Patients receiving first-line chemotherapy for Hodgkin's disease who have had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned.				
6337M	***Powder for injection 13,400,000 i.u. (105 micrograms)***	***10***	***512.50***	***Granocyte 13***	***HH***
6338N	***Powder for injection 33,600,000 i.u. (263 micrograms)***	***10***	***1283.60***	***Granocyte 34***	***HH***
	LOPINAVIR with RITONAVIR				
	Private hospital authority required ***Treatment, in combination with 2 or more other antiretroviral drugs, of HIV infection in patients with:*** ***(a) CD4 cell counts of less than 500 per cubic millimetre; or*** ***(b) viral load of greater than 10,000 copies per mL.***				
9633B	***Tablet 100 mg-25 mg***	***60***	***171.25***	***Kaletra***	***AB***
6495W	***Tablet 200 mg-50 mg***	***120***	***685.00***	***Kaletra***	***AB***
6341R	***Oral liquid 400 mg-100 mg per 5 mL, 60 mL***	***1***	***129.00***	***Kaletra***	***AB***
	MYCOPHENOLATE MOFETIL **CAUTION:** ***Careful monitoring of patients is mandatory.***				
	Private hospital authority required ***Management of rejection, under the supervision and direction of a transplant unit, in patients receiving this drug for:*** ***(a) prophylaxis of renal allograft rejection. Management includes initiation, stabilisation and review of therapy as required; or*** ***(b) prophylaxis of cardiac allograft rejection. Management includes initiation, stabilisation and review of therapy as required.***				
6208R	***Capsule 250 mg***	***300***	***555.70***	***CellCept***	***RO***
6209T	***Tablet 500 mg***	***150***	***555.70***	***CellCept***	***RO***
6364Y	***Powder for oral suspension 1 g per 5 mL, 165 mL***	***1***	***244.51***	***CellCept***	***RO***
	MYCOPHENOLATE SODIUM **CAUTION:** ***Careful monitoring of patients is mandatory.***				
	Private hospital authority required ***Management of rejection, under the supervision and direction of a transplant unit, in patients receiving this drug for prophylaxis of renal allograft rejection. Management includes initiation, stabilisation and review of therapy as required.***				
6369F	***Tablet (enteric coated) 180 mg (mycophenolic acid)***	***120***	***222.28***	***Myfortic***	***NV***
6370G	***Tablet (enteric coated) 360 mg (mycophenolic acid)***	***120***	***444.56***	***Myfortic***	***NV***

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer $	Proprietary Name and Manufacturer	
	NATALIZUMAB				
	CAUTION:				
	Progressive multifocal leukoencephalopathy (PML) has been reported with this drug.				
	NOTE:				
	Neurologists prescribing natalizumab under the PBS listing must be registered with the Tysabri Australian Prescribing Program.				
	Private hospital authority required				
	Initial treatment, as monotherapy, by neurologists, of clinically definite relapsing-remitting multiple sclerosis in an ambulatory (without assistance or support) patient 18 years of age or older, who has experienced at least 2 documented attacks of neurological dysfunction, believed to be due to multiple sclerosis, in the preceding 2 years.				
	The diagnosis must be confirmed by magnetic resonance imaging of the brain and/or spinal cord and the date of the scan included in the authority application, unless the authority application is accompanied by written certification provided by a radiologist that an MRI scan is contraindicated because of the risk of physical (not psychological) injury to the patient.				
	A maximum quantity of 6 infusions will be issued with the initial authority.				
	Private hospital authority required				
	Continuing treatment, as monotherapy, of clinically definite relapsing-remitting multiple sclerosis in a patient previously issued with an authority prescription for this drug who does not show continuing progression of disability while on treatment with this drug, and who has demonstrated compliance with, and an ability to tolerate, this therapy.				
	A maximum quantity of 3 infusions will be issued with the continuing authority.				
9624M	***Solution concentrate for I.V. infusion 300 mg in 15 mL***	***1***	***2038.46***	***Tysabri***	***BD***
	NEVIRAPINE				
	Private hospital authority required				
	Treatment of HIV infection in patients with:				
	(a) CD4 cell counts of less than 500 per cubic millimetre; or				
	(b) viral load of greater than 10,000 copies per mL.				
6215D	***Tablet 200 mg***	***60***	***271.58***	***Viramune***	***BY***
	OCTREOTIDE ACETATE				
	Private hospital authority required				
	Active acromegaly in a patient with persistent elevation of mean growth hormone levels of greater than 2.5 micrograms per litre AND				
	(a) after failure of other therapy including dopamine agonists; or				
	(b) as interim treatment while awaiting the effects of radiotherapy and where treatment with dopamine agonists has failed; or				
	(c) if the patient is unfit for or unwilling to undergo surgery and where radiotherapy is contraindicated.				
	In a patient treated with radiotherapy, treatment must cease if there is biochemical evidence of remission (normal IGF1) after octreotide has been withdrawn for at least 4 weeks. Octreotide should be withdrawn every 2 years in the 10 years after radiotherapy for assessment of remission.				
	Treatment must cease if IGF1 is not lower after 3 months treatment at a dose of 100 micrograms 3 times daily;				
	Functional carcinoid tumour or vasoactive intestinal peptide secreting tumour (VIPoma) causing intractable symptoms. The patient must have experienced on average over 1 week, 3 or more episodes per day of diarrhoea and/or flushing, which persisted despite the use of anti-histamines, anti-serotonin agents and anti-diarrhoea agents, and surgery or antineoplastic therapy must have failed or be inappropriate.				
	Treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 2 months' therapy. Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose.				

continued ☞

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer $	Proprietary Name and Manufacturer	
6227R	*Injection 50 micrograms (base) in 1 mL*	*5*	*35.81*	[a] *Sandostatin 0.05* [a] *HH*	*NV*
6228T	*Injection 100 micrograms (base) in 1 mL*	*5*	*71.60*	[a] *Sandostatin 0.1* [a] *HH*	*NV*
6229W	*Injection 500 micrograms (base) in 1 mL*	*5*	*358.41*	[a] *Sandostatin 0.5* [a] *HH*	*NV*

Private hospital authority required

Acromegaly in a patient controlled on Sandostatin subcutaneous injections.
In a patient treated with radiotherapy, treatment must cease if there is biochemical evidence of remission (normal IGF1) after octreotide has been withdrawn for at least 4 weeks (8 weeks after the last dose). Octreotide should be withdrawn every 2 years in the 10 years after radiotherapy for assessment of remission.
Treatment must cease if IGF1 is not lower after 3 months of treatment;

Functional carcinoid tumour or vasoactive intestinal peptide secreting tumour (VIPoma) with symptom control on Sandostatin subcutaneous injections.
Treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 3 months' therapy at a dose of 30 mg every 28 days and having allowed adequate rescue therapy with Sandostatin subcutaneous injections. Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose.

6426F	*Injection (modified release) 10 mg (base) vial and diluent syringe*	*1*	*1362.20*	*Sandostatin LAR*	*NV*
6427G	*Injection (modified release) 20 mg (base) vial and diluent syringe*	*1*	*1813.00*	*Sandostatin LAR*	*NV*
6428H	*Injection (modified release) 30 mg (base) vial and diluent syringe*	*1*	*2268.70*	*Sandostatin LAR*	*NV*

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer $	Proprietary Name and Manufacturer	
	PEGFILGRASTIM				
	Private hospital authority required ***For use in a patient undergoing induction and consolidation therapy for acute myeloid leukaemia;*** ***A patient with breast cancer receiving standard dose adjuvant chemotherapy who has had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned;*** ***A patient receiving first-line chemotherapy for B-cell chronic lymphocytic leukaemia with fludarabine and cyclophosphamide who has had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned;*** ***A patient receiving first-line chemotherapy for Hodgkin disease who has had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned;*** ***A patient receiving chemotherapy for myeloma who has had a prior episode of febrile neutropenia, and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned.***				
	Private hospital authority required ***A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in:*** ***(a) acute lymphoblastic leukaemia; or*** ***(b) breast cancer (adjuvant chemotherapy with docetaxel in combination with an anthracycline and cyclophosphamide); or*** ***(c) germ cell tumours; or*** ***(d) infants and children with CNS tumours; or*** ***(e) neuroblastoma; or*** ***(f) non-Hodgkin lymphoma (aggressive grades; or low grade receiving an anthracycline-containing regimen); or*** ***(g) relapsed Hodgkin disease; or*** ***(h) sarcoma.***				
6363X	***Injection 6 mg in 0.6 mL single use pre-filled syringe***	***1***	***1925.00***	***Neulasta***	***AN***

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer $	Proprietary Name and Manufacturer	
	PEGINTERFERON ALFA-2a				
	CAUTION:				
	Treatment with peginterferon alfa has been associated with depression and suicide in some patients. Patients with a history of suicidal ideation or depressive illness should be warned of the risks. Psychiatric status during therapy should be monitored.				
	Private hospital authority required				
	Monotherapy in patients with chronic hepatitis B and compensated liver disease who satisfy all of the following criteria:				
	(1) Histological evidence of chronic hepatitis on liver biopsy (except in patients with coagulation disorders considered severe enough to prevent liver biopsy);				
	(2)(a) Abnormal serum ALT levels in conjunction with documented chronic hepatitis B infection; or				
	(b) Elevated HBV DNA levels in conjunction with documented chronic hepatitis B infection;				
	(3) Have received no prior peginterferon alfa therapy for the treatment of hepatitis B;				
	(4) Female patients of child-bearing age are not pregnant, not breast-feeding, and are using an effective form of contraception;				
	(5) Are not persons with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L).				
	Treatment is limited to 1 course of treatment for a duration of up to 48 weeks;				
	Treatment, managed by an accredited treatment centre, of chronic hepatitis C in patients 18 years or older who have compensated liver disease and who have received no prior interferon alfa or peginterferon alfa treatment for hepatitis C and have a contraindication to ribavirin, who satisfy all of the following criteria:				
	(1) Documented chronic hepatitis C infection (repeatedly anti-HCV positive and HCV RNA positive);				
	(2) Female patients of child-bearing age are not pregnant, not breast-feeding, and are using an effective form of contraception.				
	The treatment course is limited to up to 48 weeks.				
	Patients may only continue treatment after the first 12 weeks if the result of an HCV RNA quantitative assay (performed at the same laboratory using the same test) shows that the plasma HCV RNA has become undetectable or the viral load has decreased by at least a 2 log drop.				
	NOTE:				
	Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C:				
	(a) a nurse educator/counsellor for patients; and				
	(b) 24 hour access by patients to medical advice; and				
	(c) an established liver clinic; and				
	(d) facilities for safe liver biopsy.				
6439X	***Injection 135 micrograms in 0.5 mL single use pre-filled syringe***	***4***	***1165.90***	***Pegasys***	***RO***
6449K	***Injection 180 micrograms in 0.5 mL single use pre-filled syringe***	***4***	***1350.23***	***Pegasys***	***RO***

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer $	Proprietary Name and Manufacturer	
	PEGINTERFERON ALFA-2b				
	CAUTION:				
	Treatment with peginterferon alfa has been associated with depression and suicide in some patients. Patients with a history of suicidal ideation or depressive illness should be warned of the risks. Psychiatric status during therapy should be monitored.				
	Private hospital authority required				
	Treatment, managed by an accredited treatment centre, of chronic hepatitis C in patients 18 years or older who have compensated liver disease and who have received no prior interferon alfa or peginterferon alfa treatment for hepatitis C and have a contraindication to ribavirin, who satisfy all of the following criteria:				
	(1) Documented chronic hepatitis C infection (repeatedly anti-HCV positive and HCV RNA positive);				
	(2) Female patients of child-bearing age are not pregnant, not breast-feeding, and are using an effective form of contraception.				
	The treatment course is limited to up to 48 weeks.				
	Patients may only continue treatment after the first 12 weeks if the result of an HCV RNA quantitative assay (performed at the same laboratory using the same test) shows that the plasma HCV RNA has become undetectable or the viral load has decreased by at least a 2 log drop.				
	NOTE:				
	Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C:				
	(a) a nurse educator/counsellor for patients; and				
	(b) 24 hour access by patients to medical advice; and				
	(c) an established liver clinic; and				
	(d) facilities for safe liver biopsy.				
6411K	***Powder for injection 50 micrograms with diluent in single use injection pen***	***4***	***920.00***	***PEG-Intron Redipen***	***SH***
6412L	***Powder for injection 80 micrograms with diluent in single use injection pen***	***4***	***1472.00***	***PEG-Intron Redipen***	***SH***
6413M	***Powder for injection 100 micrograms with diluent in single use injection pen***	***4***	***1840.00***	***PEG-Intron Redipen***	***SH***
6414N	***Powder for injection 120 micrograms with diluent in single use injection pen***	***4***	***2208.00***	***PEG-Intron Redipen***	***SH***
6415P	***Powder for injection 150 micrograms with diluent in single use injection pen***	***4***	***2760.00***	***PEG-Intron Redipen***	***SH***
	RALTEGRAVIR POTASSIUM				
	Private hospital authority required				
	Treatment, in combination with other antiretroviral agents, of HIV infection in an antiretroviral experienced patient with:				
	(a) evidence of HIV replication (viral load greater than 10,000 copies per mL); and/or				
	(b) CD4 cell counts of less than 500 per cubic millimetre.				
	A patient must have failed previous treatment with, or have resistance to, 3 different antiretroviral regimens which have included:				
	(i) at least 1 non-nucleoside reverse transcriptase inhibitor; and				
	(ii) at least 1 nucleoside reverse transcriptase inhibitor; and				
	(iii) at least 1 protease inhibitor.				
9629T	***Tablet 400 mg (base)***	***60***	***1146.90***	***Isentress***	***MK***

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer $	Proprietary Name and Manufacturer	

RIBAVIRIN and PEGINTERFERON ALFA-2a

CAUTION:

Treatment with peginterferon alfa has been associated with depression and suicide in some patients. Patients with a history of suicidal ideation or depressive illness should be warned of the risks. Psychiatric status during therapy should be monitored.

CAUTION:

Ribavirin is a category X drug and must not be given to pregnant women. Pregnancy in female patients or in the partners of male patients must be avoided during treatment and during the 6 months period after cessation of treatment.

Private hospital authority required

Patients naive to interferon based therapies (non-pegylated or pegylated).

Treatment, managed by an accredited treatment centre, of chronic hepatitis C in patients 18 years or older who have compensated liver disease and who have received no prior interferon alfa or peginterferon alfa treatment for hepatitis C and who satisfy all of the following criteria:
(1) Documented chronic hepatitis C infection (repeatedly anti-HCV positive and HCV RNA positive);
(2) Female patients of child-bearing age are not pregnant, not breast-feeding, and both patient and their partner are using effective forms of contraception (one for each partner). Male patients and their partners are using effective forms of contraception (one for each partner). Female partners of male patients are not pregnant.
For patients with genotype 2 or 3 hepatitis C without hepatic cirrhosis or bridging fibrosis, the treatment course is limited to 24 weeks. For hepatitis C patients with genotype 1, 4, 5 or 6 and those genotype 2 or 3 patients with hepatic cirrhosis or bridging fibrosis, the treatment course is limited to 48 weeks.
Patients with genotype 1, 4, 5 or 6 who are eligible for 48 weeks of treatment may only continue treatment after the first 12 weeks if the result of an HCV RNA quantitative assay (performed at the same laboratory using the same test) shows that the plasma HCV RNA has become undetectable or the viral load has decreased by at least a 2 log drop. (An HCV RNA assay at week 12 is unnecessary for genotype 2 and 3 patients because of the high likelihood of early viral response by week 12).
Patients with genotype 1, 4, 5 or 6 who are viral positive at week 12 but have attained at least a 2 log drop in viral load may only continue treatment after the first 24 weeks of treatment if plasma HCV RNA is not detectable by an HCV RNA qualitative assay at week 24. Similarly, genotype 2 or 3 patients with hepatic cirrhosis or bridging fibrosis may only continue treatment after the first 24 weeks if plasma HCV RNA is not detectable by an HCV RNA qualitative assay at week 24. An HCV RNA qualitative assay at week 24 is unnecessary for those patients with genotype 1, 4, 5 or 6 who became viral negative at week 12.

NOTE:

Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C:
(a) a nurse educator/counsellor for patients; and
(b) 24 hour access by patients to medical advice; and
(c) an established liver clinic; and
(d) facilities for safe liver biopsy.

6389G	***Pack containing 84 tablets ribavirin 200 mg and 4 pre-filled syringes peginterferon alfa-2a injection 135 micrograms***	***‡ 1***	***1295.60***	***Pegasys RBV***	***RO***
6390H	***Pack containing 112 tablets ribavirin 200 mg and 4 pre-filled syringes peginterferon alfa-2a injection 135 micrograms***	***‡ 1***	***1375.88***	***Pegasys RBV***	***RO***
6391J	***Pack containing 140 tablets ribavirin 200 mg and 4 pre-filled syringes peginterferon alfa-2a injection 135 micrograms***	***‡ 1***	***1456.14***	***Pegasys RBV***	***RO***
6392K	***Pack containing 168 tablets ribavirin 200 mg and 4 pre-filled syringes peginterferon alfa-2a injection 135 micrograms***	***‡ 1***	***1536.42***	***Pegasys RBV***	***RO***
6393L	***Pack containing 84 tablets ribavirin 200 mg and 4 pre-filled syringes peginterferon alfa-2a injection 180 micrograms***	***‡ 1***	***1462.37***	***Pegasys RBV***	***RO***

continued ☞

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer $	Proprietary Name and Manufacturer	
6394M	***Pack containing 112 tablets ribavirin 200 mg and 4 pre-filled syringes peginterferon alfa-2a injection 180 micrograms***	***‡ 1***	***1542.64***	***Pegasys RBV***	***RO***
6395N	***Pack containing 140 tablets ribavirin 200 mg and 4 pre-filled syringes peginterferon alfa-2a injection 180 micrograms***	***‡ 1***	***1622.91***	***Pegasys RBV***	***RO***
6396P	***Pack containing 168 tablets ribavirin 200 mg and 4 pre-filled syringes peginterferon alfa-2a injection 180 micrograms***	***‡ 1***	***1703.18***	***Pegasys RBV***	***RO***

RIBAVIRIN and PEGINTERFERON ALFA-2b

CAUTION:

Treatment with peginterferon alfa has been associated with depression and suicide in some patients. Patients with a history of suicidal ideation or depressive illness should be warned of the risks. Psychiatric status during therapy should be monitored.

CAUTION:

Ribavirin is a category X drug and must not be given to pregnant women. Pregnancy in female patients or in the partners of male patients must be avoided during treatment and during the 6 months period after cessation of treatment.

Private hospital authority required

Patients naive to interferon based therapies (non-pegylated or pegylated).

Treatment, managed by an accredited treatment centre, of chronic hepatitis C in patients 18 years or older who have compensated liver disease and who have received no prior interferon alfa or peginterferon alfa treatment for hepatitis C and who satisfy all of the following criteria:

(1) Documented chronic hepatitis C infection (repeatedly anti-HCV positive and HCV RNA positive);

(2) Female patients of child-bearing age are not pregnant, not breast-feeding, and both patient and their partner are using effective forms of contraception (one for each partner). Male patients and their partners are using effective forms of contraception (one for each partner). Female partners of male patients are not pregnant.

For patients with genotype 2 or 3 hepatitis C without hepatic cirrhosis or bridging fibrosis, the treatment course is limited to 24 weeks. For hepatitis C patients with genotype 1, 4, 5 or 6 and those genotype 2 or 3 patients with hepatic cirrhosis or bridging fibrosis, the treatment course is limited to 48 weeks.

Patients with genotype 1, 4, 5 or 6 who are eligible for 48 weeks of treatment may only continue treatment after the first 12 weeks if the result of an HCV RNA quantitative assay (performed at the same laboratory using the same test) shows that the plasma HCV RNA has become undetectable or the viral load has decreased by at least a 2 log drop. (An HCV RNA assay at week 12 is unnecessary for genotype 2 and 3 patients because of the high likelihood of early viral response by week 12).

Patients with genotype 1, 4, 5 or 6 who are viral positive at week 12 but have attained at least a 2 log drop in viral load may only continue treatment after the first 24 weeks of treatment if plasma HCV RNA is not detectable by an HCV RNA qualitative assay at week 24. Similarly, genotype 2 or 3 patients with hepatic cirrhosis or bridging fibrosis may only continue treatment after the first 24 weeks if plasma HCV RNA is not detectable by an HCV RNA qualitative assay at week 24. An HCV RNA qualitative assay at week 24 is unnecessary for those patients with genotype 1, 4, 5 or 6 who became viral negative at week 12.

NOTE:

Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C:

(a) a nurse educator/counsellor for patients; and

(b) 24 hour access by patients to medical advice; and

(c) an established liver clinic; and

(d) facilities for safe liver biopsy.

continued ☞

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer $	Proprietary Name and Manufacturer	
	Private hospital authority required ***Patients who have failed one prior attempt at interferon based therapies (non-pegylated or pegylated).*** ***Treatment, managed by an accredited treatment centre, of chronic hepatitis C in patients 18 years or older who have compensated liver disease and who have received no more than one prior treatment with interferon alfa or peginterferon alfa for hepatitis C and who satisfy all of the following criteria:*** ***(1) Documented chronic hepatitis C infection (repeatedly anti-HCV positive and HCV RNA positive);*** ***(2) Female patients of child-bearing age are not pregnant, not breast-feeding, and both patient and their partner are using effective forms of contraception (one for each partner). Male patients and their partners are using effective forms of contraception (one for each partner). Female partners of male patients are not pregnant.*** ***The treatment course is limited to 48 weeks. Patients may only continue treatment after the first 12 weeks of treatment if plasma HCV RNA is not detectable by an HCV RNA qualitative assay at week 12.*** **NOTE:** ***Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C:*** ***(a) a nurse educator/counsellor for patients; and*** ***(b) 24 hour access by patients to medical advice; and*** ***(c) an established liver clinic; and*** ***(d) facilities for safe liver biopsy.***				
6399T	***Pack containing 84 capsules ribavirin 200 mg and 4 single use injection pens containing peginterferon alfa-2b powder for injection 50 micrograms with diluent***	***‡ 1***	***917.38***	***Pegatron***	***SH***
6400W	***Pack containing 112 capsules ribavirin 200 mg and 4 single use injection pens containing peginterferon alfa-2b powder for injection 50 micrograms with diluent***	***‡ 1***	***1059.87***	***Pegatron***	***SH***
6401X	***Pack containing 84 capsules ribavirin 200 mg and 4 single use injection pens containing peginterferon alfa-2b powder for injection 80 micrograms with diluent***	***‡ 1***	***1211.36***	***Pegatron***	***SH***
6402Y	***Pack containing 140 capsules ribavirin 200 mg and 4 single use injection pens containing peginterferon alfa-2b powder for injection 80 micrograms with diluent***	***‡ 1***	***1353.83***	***Pegatron***	***SH***
6403B	***Pack containing 168 capsules ribavirin 200 mg and 4 single use injection pens containing peginterferon alfa-2b powder for injection 80 micrograms with diluent***	***‡ 1***	***1353.83***	***Pegatron***	***SH***
6404C	***Pack containing 84 capsules ribavirin 200 mg and 4 single use injection pens containing peginterferon alfa-2b powder for injection 100 micrograms with diluent***	***‡ 1***	***1407.33***	***Pegatron***	***SH***
6405D	***Pack containing 112 capsules ribavirin 200 mg and 4 single use injection pens containing peginterferon alfa-2b powder for injection 100 micrograms with diluent***	***‡ 1***	***1549.81***	***Pegatron***	***SH***
6406E	***Pack containing 84 capsules ribavirin 200 mg and 4 single use injection pens containing peginterferon alfa-2b powder for injection 120 micrograms with diluent***	***‡ 1***	***1603.31***	***Pegatron***	***SH***
6407F	***Pack containing 140 capsules ribavirin 200 mg and 4 single use injection pens containing peginterferon alfa-2b powder for injection 120 micrograms with diluent***	***‡ 1***	***1745.79***	***Pegatron***	***SH***

continued ☞

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer $	Proprietary Name and Manufacturer	
6408G	***Pack containing 84 capsules ribavirin 200 mg and 4 single use injection pens containing peginterferon alfa-2b powder for injection 150 micrograms with diluent***	***‡ 1***	***1897.28***	***Pegatron***	***SH***
6409H	***Pack containing 140 capsules ribavirin 200 mg and 4 single use injection pens containing peginterferon alfa-2b powder for injection 150 micrograms with diluent***	***‡ 1***	***2039.76***	***Pegatron***	***SH***
6410J	***Pack containing 168 capsules ribavirin 200 mg and 4 single use injection pens containing peginterferon alfa-2b powder for injection 150 micrograms with diluent***	***‡ 1***	***2039.76***	***Pegatron***	***SH***
9634C	***Pack containing 196 capsules ribavirin 200 mg and 4 single use injection pens containing peginterferon alfa-2b powder for injection 150 micrograms with diluent***	***‡ 1***	***2182.24***	***Pegatron***	***SH***
	RIFABUTIN				
	Private hospital authority required ***Treatment of Mycobacterium avium complex infections in HIV-positive patients;*** ***Prophylaxis against Mycobacterium avium complex infections in HIV-positive patients with CD4 cell counts of less than 75 per cubic millimetre.***				
6195C	***Capsule 150 mg***	***30***	***147.00***	***Mycobutin***	***PH***
	RITONAVIR				
	Private hospital authority required ***Treatment of HIV infection in patients with:*** ***(a) CD4 cell counts of less than 500 per cubic millimetre; or*** ***(b) viral load of greater than 10,000 copies per mL.***				
6203L	***Capsule 100 mg***	***84***	***106.17***	***Norvir***	***AB***
6494T	***Oral solution 600 mg per 7.5 mL (80 mg per mL), 90 mL***	***1***	***91.00***	***Norvir***	***AB***
	RITUXIMAB **NOTE:** ***Any queries concerning the arrangements to prescribe rituximab may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).*** ***Written applications for authority to prescribe rituximab should be forwarded to:*** ***Medicare Australia*** ***Prior Written Approval of Specialised Drugs*** ***Reply Paid 9826*** ***GPO Box 9826*** ***HOBART TAS 7001*** ***Further prescribing information is on the Medicare Australia website at www.medicareaustralia.gov.au.*** **NOTE:** ***TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS*** ***The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying anti-rheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, etanercept, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-1 inhibitor (anakinra) and the T-cell co-stimulation modulator (abatacept).***				

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

PBS-subsidised infliximab, anakinra, rituximab and abatacept must be used in combination with methotrexate at a dose of at least 7.5 mg weekly. Where a patient cannot tolerate 7.5 mg of methotrexate weekly, they are only eligible to receive PBS-subsidised etanercept and adalimumab.

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

From 1 March 2008, under the PBS, all patients will be able to commence a Treatment Cycle where they may trial PBS-subsidised bDMARD agents without having to experience a disease flare when swapping to an alternate agent. Under these interchangeability arrangements, within a single Treatment Cycle, a patient may continue to receive long-term treatment with a bDMARD while they continue to show a response to therapy.

A patient who received PBS-subsidised bDMARD treatment prior to 1 March 2008 is considered to be in their first Cycle as of 1 March 2008.

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

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a Treatment Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised bDMARD therapy before they are eligible to commence the next Cycle.

For patients who have failed PBS-subsidised treatment with 3 bDMARDs prior to 1 March 2008 please contact Medicare Australia on 1800 700 270.

The 5-year break is measured from the date of the last approval for PBS-subsidised bDMARD treatment in the most recent Cycle to the date of the first application for initial treatment with a bDMARD under the new Treatment Cycle.

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

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

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

If patients fail to respond to a particular bDMARD within a single Treatment Cycle, they are not eligible to receive further PBS-subsidised treatment with that drug until they commence the next Cycle.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 March 2008.

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

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for etanercept, adalimumab, anakinra and abatacept, 22 weeks of therapy for infliximab and 2 infusions of rituximab.

From 1 March 2008, a patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to Medicare Australia within 4 weeks.

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

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For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

Rituximab patients:
A further application may be submitted to Medicare Australia 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

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

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

Assessments of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Rituximab patients:
A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.

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

(2) Swapping therapy.

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

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

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

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

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

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

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

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NOTE:

(3) Baseline measurements to determine response.

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

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

The baseline joint and blood counts should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment.

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

A patient who wishes to trial a second or subsequent Treatment Cycle following a break in PBS-subsidised bDMARD therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have received treatment with at least 1 non-biological DMARD, at an adequate dose, for a minimum of 3 months at the time the ESR and/or CRP levels and the active joint count are measured.

(5) Patients 'grandfathered' onto PBS-subsidised treatment with rituximab or abatacept.

From 1 March 2008, a patient who commenced treatment with rituximab for severe rheumatoid arthritis prior to 7 March 2007 or abatacept for severe rheumatoid arthritis prior to 1 November 2007 and who was 'grandfathered' on to PBS-subsidised therapy, and who continues to receive treatment in the same Treatment Cycle, will have further applications for treatment with rituximab or abatacept assessed under the continuing treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment with abatacept will be authorised under this criterion.

'Grandfather' arrangements will only apply for the first Treatment Cycle. For the second and subsequent Cycles, a 'grandfather' patient must requalify for initial treatment under the criteria that applies to a new patient. See 'Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' above for further details.

Public and private hospital authority required

Initial 2 (change or re-commencement)

Application for an initial course of PBS-subsidised treatment with rituximab, in combination with methotrexate at a dose of at least 7.5 mg weekly, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of an adult who:

(a) has a documented history of severe active rheumatoid arthritis; and

(b) has failed to respond to at least 1 PBS-subsidised TNF-alfa antagonist in this Treatment Cycle; and

(c) has not previously failed to respond to PBS-subsidised rituximab in the current Treatment Cycle.

Applications for patients who have demonstrated a response to PBS-subsidised rituximab treatment within this Treatment Cycle and who wish to re-commence rituximab treatment within the same Cycle following a break in therapy, will only be approved where evidence of a response to the patient's most recent course of PBS-subsidised rituximab treatment has been submitted to Medicare Australia.

A patient may qualify to receive a further course of treatment (1 infusion at week 0 and 1 infusion at week 2) every 24 weeks with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction. The demonstration of response must be submitted to Medicare Australia within 4 weeks of assessment.

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

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The authority application must be made in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form [www.medicareaustralia.gov.au].

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

Patients who fail to demonstrate a response to rituximab treatment and who qualify to trial an alternate bDMARD according to the interchangeability arrangements for bDMARDs for the treatment of severe rheumatoid arthritis, may do so without having to have a 22 week treatment-free period.

Patients who fail to demonstrate a response to treatment with 3 bDMARDs are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may re-commence a new bDMARD Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised bDMARD was approved in this Cycle and the date of the first application under the new Cycle.

Public and private hospital authority required
Initial 3 ('grandfather' patients)
Initial PBS-subsidised supply for continuing treatment with rituximab, in combination with methotrexate at a dose of at least 7.5 mg weekly, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of an adult who:
(a) has a documented history of severe active rheumatoid arthritis; and
(b) was receiving treatment with rituximab prior to 7 March 2007; and
(c) has demonstrated a response as specified in the criteria for continuing PBS-subsidised treatment with rituximab.

The authority application must be made in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form [www.medicareaustralia.gov.au] which includes the signed patient acknowledgement form.

The same indices of disease severity used to establish baseline at the commencement of treatment with a bDMARD must be used for assessment of all continuing applications.

Patients who fail to demonstrate a response to treatment with 3 bDMARDs are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may re-commence a new bDMARD Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised bDMARD was approved in this Cycle and the date of the first application under the new Cycle.

Patients can qualify for PBS-subsidised treatment under this criteria once only.

Public and private hospital authority required
Continuing treatment
Continuing PBS-subsidised treatment with rituximab, in combination with methotrexate at a dose of at least 7.5 mg weekly, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of an adult:
(a) who has a documented history of severe active rheumatoid arthritis; and
(b) who has demonstrated an adequate response to treatment with rituximab; and
(c) whose most recent course of PBS-subsidised bDMARD treatment in this Treatment Cycle was with rituximab.

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	An adequate response to treatment is defined as: ***an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;*** ***AND either of the following:*** ***(i) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or*** ***(ii) a reduction in the number of the following major active joints, from at least 4, by at least 50%:*** ***— elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or*** ***— shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).*** ***The authority application must be made in writing and must include:*** ***(1) a completed authority prescription form; and*** ***(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form [www.medicareaustralia.gov.au].*** ***Patients may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction. The demonstration of response must be submitted to Medicare Australia within 4 weeks of assessment.*** ***The same indices of disease severity used to establish baseline at the commencement of treatment with each initial application must be used for assessment of all continuing applications.*** ***Patients who fail to demonstrate a response to treatment with 3 bDMARDs are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may re-commence a new bDMARD Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised bDMARD was approved in this Cycle and the date of the first application under the new Cycle.***				
9611W	***Solution for I.V. infusion 500 mg in 50 mL***	***1***	***2263.57***	***Mabthera***	***RO***
	SAQUINAVIR MESYLATE **Private hospital authority required** ***Treatment of HIV infection in patients with:*** ***(a) CD4 cell counts of less than 500 per cubic millimetre; or*** ***(b) viral load of greater than 10,000 copies per mL.***				
6498B	***Tablet 500 mg (base)***	***120***	***505.56***	***Invirase***	***RO***
	SEVELAMER HYDROCHLORIDE **Private hospital authority required** ***Management of hyperphosphataemia in a patient with chronic kidney disease on dialysis whose serum phosphate is not controlled on other products and where:*** ***(a) serum phosphate is greater than 1.6 mmol per L; or*** ***(b) the serum calcium times phosphate product is greater than 4.0.*** ***at the commencement of therapy.*** ***Management includes initiation, stabilisation and review of therapy as required.***				
9620H	***Tablet 800 mg***	***180***	***310.00***	***Renagel***	***GZ***

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SILDENAFIL CITRATE

NOTE:

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

Written applications for authority to prescribe sildenafil citrate should be forwarded to:

Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

NOTE:

Sildenafil citrate is not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with scleroderma, where the total lung capacity is less than 70% of that predicted.

Sildenafil citrate is not PBS-subsidised when used in combination with PBS-subsidised bosentan monohydrate, PBS-subsidised iloprost trometamol, PBS-subsidised epoprostenol sodium or PBS-subsidised sitaxentan sodium.

The following provides some explanatory notes regarding the availability of PBS-subsidised treatment with:
(a) bosentan monohydrate, of primary pulmonary hypertension or pulmonary arterial hypertension secondary to scleroderma, in patients with disease of WHO Functional Class III or IV severity; AND
(b) iloprost trometamol, of primary pulmonary hypertension, drug-induced pulmonary arterial hypertension or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class III or IV severity; AND
(c) epoprostenol sodium, of primary pulmonary hypertension, in patients with disease of WHO Functional Class III or IV severity; AND
(d) sildenafil citrate, of primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class III severity; AND
(e) sitaxentan sodium, of primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class III severity.

Adult patients:
From 1 April 2008, adult patients with primary pulmonary hypertension will be able to access, through the PBS, bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate (WHO Class III only) or sitaxentan sodium (WHO Class III only). Once these patients are approved initial treatment with 1 of these 5 drugs, they may swap between bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate and sitaxentan sodium at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary. (New baselines may be submitted where the patient has failed to respond to their current treatment.)

Patients may only swap to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate or sitaxentan sodium if they have not failed prior PBS-subsidised treatment with that drug.

Adult patients with pulmonary arterial hypertension secondary to scleroderma will be able to access, through the PBS, bosentan monohydrate, iloprost trometamol, sildenafil citrate (WHO Class III only) or sitaxentan sodium (WHO Class III only). Once these patients are approved initial treatment with 1 of these 4 drugs, they may swap between bosentan monohydrate, iloprost trometamol, sildenafil citrate and sitaxentan sodium at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary. (New baselines may be submitted where the patient has failed to respond to their current treatment.)

Patients may only swap to bosentan monohydrate, iloprost trometamol, sildenafil citrate or sitaxentan sodium if they have not failed prior PBS-subsidised treatment with that drug.

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Adult patients with pulmonary arterial hypertension secondary to connective tissue disease other than scleroderma will be able to access, through the PBS, iloprost trometamol, sildenafil citrate (WHO Class III only) or sitaxentan sodium (WHO Class III only). Once these patients are approved initial treatment with 1 of these 3 drugs, they may swap between iloprost trometamol, sildenafil citrate and sitaxentan sodium at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary. (New baselines may be submitted where the patient has failed to respond to their current treatment.)

Patients may only swap to iloprost trometamol, sildenafil citrate or sitaxentan sodium if they have not failed prior PBS-subsidised treatment with that drug.

Patients with drug-induced pulmonary arterial hypertension are only eligible for treatment with iloprost trometamol. They may not swap to bosentan monohydrate, epoprostenol sodium, sildenafil citrate or sitaxentan sodium.

Patients under 18 years of age:
From 1 April 2008, patients aged less than 18 years with primary pulmonary hypertension are eligible to receive PBS-subsidised treatment with bosentan monohydrate, epoprostenol sodium, iloprost trometamol, sildenafil citrate (WHO Class III only) or sitaxentan sodium (WHO Class III only). Once these patients are approved initial treatment with 1 of these 5 drugs, they may swap between bosentan monohydrate, epoprostenol sodium, iloprost trometamol, sildenafil citrate and sitaxentan sodium at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary. (New baselines may be submitted where the patient has failed to respond to their current treatment.)

Patients may only swap to bosentan monohydrate, epoprostenol sodium, iloprost trometamol, sildenafil citrate or sitaxentan sodium if they have not failed prior PBS-subsidised treatment with that drug.

1. Definition of primary pulmonary hypertension, drug-induced pulmonary arterial hypertension or pulmonary arterial hypertension secondary to connective tissue disease, including scleroderma.

Primary pulmonary hypertension, drug-induced pulmonary arterial hypertension or pulmonary arterial hypertension secondary to connective tissue disease, including scleroderma, are defined as follows:
(i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary capillary wedge pressure (PCWP) less than 18 mmHg; or
(ii) mPAP greater than 30 mmHg with exercise and PCWP less than 18 mmHg; or
(iii) where a right heart catheter cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

2. Definition of WHO Functional Class III or IV disease severity.

(a) WHO Functional Class III disease severity is defined as follows:
Patients with pulmonary hypertension resulting in marked limitation of physical activity who are comfortable at rest and on ordinary physical activity experience dyspnoea or fatigue, chest pain or near syncope.
(b) WHO Functional Class IV disease severity is defined as follows:
Patients with the inability to carry out any physical activity without symptoms. These patients manifest signs of right heart failure. Dyspnoea and/or fatigue may even be present at rest. Discomfort is increased by any physical activity.

3. Designated hospitals.

Refer to the Medicare Australia website at www.medicareaustralia.gov.au for a list of designated hospitals.

4. Test requirements to establish baseline for initiation of treatment and response to treatment for continuation of treatment.

(a) Initiation of treatment.
The first written application for PBS-subsidised treatment with the first of either bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate or sitaxentan sodium should be accompanied by the results of a right heart catheter (RHC) composite assessment, plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements.

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Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:
(1) RHC plus ECHO composite assessments;
(2) RHC composite assessment plus 6MWT;
(3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted to Medicare Australia for consideration based on the results of the following test combinations, which are listed in descending order of preference:
(1) ECHO composite assessment plus 6MWT;
(2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a reason outlining why the particular test/s could not be conducted must be provided with the authority application.

NOTE:
Where patients were initiated on PBS-subsidised treatment either with bosentan monohydrate on or after 1 March 2004, with iloprost trometamol on or after 1 April 2005, with epoprostenol sodium on or after 1 August 2006, with sildenafil citrate on or after 1 March 2007, with sitaxentan sodium on or after 1 April 2008, or with bosentan monohydrate (for PAH associated with congenital systemic-to-pulmonary shunt) on or after 1 August 2008, the test results provided with the initial application must be no more than 2 months old at the time of application. These results will form the baseline against which response assessments will be made.

Where patients received treatment with either bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate or sitaxentan sodium prior to being commenced on PBS-subsidised treatment with the first of either bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate or sitaxentan sodium, the test requirements above still apply. The results that will form the baseline against which response assessments will be made will be those measured at the time patients commenced non-PBS-subsidised treatment with either bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate or sitaxentan sodium, whichever of the 5 drugs the patient received first.

(b) Continuation of treatment.
The following list outlines the preferred test combination, in descending order, for the purposes of continuation of PBS-subsidised treatment:
(1) RHC plus ECHO composite assessments plus 6MWT;
(2) RHC plus ECHO composite assessments;
(3) RHC composite assessment plus 6MWT;
(4) ECHO composite assessment plus 6MWT;
(5) RHC composite assessment only;
(6) ECHO composite assessment only.

The results of the same tests as conducted at baseline should be provided with each written continuing treatment application (i.e. every 6 months), except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a reason why the test(s) could not be conducted must be provided with the application.

The test(s) results provided with the application for continuing treatment must be no more than 2 months old at the time of application.

5. Definition of response to sildenafil citrate, bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sitaxentan sodium or prior vasodilator treatment.

For adult patients with 2 or more baseline tests, response to treatment is defined as 2 or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For adult patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For adult patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

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For patients aged less than 18 years, response to treatment is defined as at least 1 of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

6. Authority approval requirements. [The following 2 sections are only relevant to the PBS listing of sildenafil citrate. The requirements specific to bosentan monohydrate, iloprost trometamol, epoprostenol sodium and sitaxentan sodium are given in parts 6 and 7 of the NOTE included in the bosentan monohydrate, iloprost trometamol, epoprostenol sodium and sitaxentan sodium Schedule entry respectively.]

(a) Initiation of PBS-subsidised treatment with sildenafil citrate, where the patient has not received prior PBS-subsidised treatment with bosentan monohydrate, iloprost trometamol, epoprostenol sodium or sitaxentan sodium.

All applications for initial treatment must be made in writing, must include an authority prescription and must be submitted to Medicare Australia for authorisation. The total duration of initial PBS-subsidised treatment that will be approved with this first written application is up to 6 months.

(b) Continuation of treatment.
Written applications for continuing treatment must be submitted to Medicare Australia for authorisation every 6 months. Approvals will be limited to provide sufficient supply for up to a maximum of 6 months of treatment, based on the dosage recommendations in the TGA-approved Product Information.

Applications for continuing treatment will only be approved for patients who have currently demonstrated a response to treatment with sildenafil citrate.

The assessment of the patient's response to the first and subsequent 6 month courses of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated. Applications for continuing treatment with sildenafil citrate should be made prior to the completion of the 6 month treatment course to ensure continuity for those patients who respond to treatment, as assessed by the treating physician.

(c) Swapping between bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate and sitaxentan sodium.
For eligible patients, applications to swap between these 5 drugs must be made under the relevant initial treatment restriction. Patients should be assessed for response to the treatment they are ceasing at the time the application to swap therapy is being made. Patients who fail to demonstrate a response or for whom no assessment results are submitted with the application to swap therapy may not re-commence PBS-subsidised treatment with the drug they are ceasing.

It is important that patients are assessed for response to every course of treatment approved within the timeframes specified in the relevant restriction, in order to maximise the choice of treatment.

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

(d) Cessation of treatment.
Patients who fail to demonstrate a response to PBS-subsidised sildenafil citrate treatment at the times where an assessment is required must cease PBS-subsidised sildenafil citrate therapy.

7. Re-treatment with sildenafil citrate.

Patients who do not respond to treatment are not eligible to receive further PBS-subsidised treatment with sildenafil citrate under any circumstances.

8. Further information.

A tabulated representation of the above information and the restriction can be obtained from the Medicare Australia website at www.medicareaustralia.gov.au.

Public and private hospital authority required

Initial (new patients)
Application for initial PBS-subsidised treatment with sildenafil citrate of patients who have not received prior PBS-subsidised treatment with bosentan monohydrate, iloprost trometamol, epoprostenol sodium or sitaxentan sodium and who have been assessed by a physician from a designated hospital to have:
(a) WHO Functional Class III primary pulmonary hypertension and a mean right atrial pressure of 8 mmHg or less, as measured by RHC, unless a RHC is contraindicated on clinical grounds; OR
(b) WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease and a mean right atrial pressure of 8 mmHg or less, as measured by RHC, unless a RHC is contraindicated on clinical grounds.

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Patients must have failed to respond [see Note for definition of response] to 6 or more weeks of appropriate vasodilator treatment unless intolerance or a contraindication to such treatment exists.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted to Medicare Australia for consideration based on the test results of the ECHO composite assessment plus 6MWT or the ECHO composite assessment only.

Applications for authorisation must be in writing and must include:
(1) a completed authority prescription form [see Note for authority approval requirements]; and
(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form [www.medicareaustralia.gov.au] which includes results from the 3 tests below, where available:
(i) RHC composite assessment; and
(ii) ECHO composite assessment; and
(iii) 6MWT; and
(3) a signed patient acknowledgment indicating that the patient understands and acknowledges that PBS-subsidised treatment with sildenafil citrate for primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, OR with epoprostenol sodium for primary pulmonary hypertension, OR with iloprost trometamol for primary pulmonary hypertension, drug-induced pulmonary arterial hypertension or pulmonary arterial hypertension secondary to connective tissue disease, OR with bosentan monohydrate for primary pulmonary hypertension or pulmonary arterial hypertension secondary to scleroderma, OR with sitaxentan sodium for primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, will cease if the treating physician determines that the patient has not achieved a response to treatment [see Note for definition of response].

Details of prior vasodilator treatment, including the dose and duration of treatment, must be provided at the time of application. Where the patient has an adverse event to a vasodilator or where vasodilator treatment is contraindicated, details on the nature of the adverse event or contraindication according to the TGA-approved Product Information must also be provided with the application.

Where fewer than 3 tests (see requirement 2 above) are able to be performed on clinical grounds, a reason outlining why the particular test/s could not be conducted must be provided with the authority application [see Note for test requirements].

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. A maximum of 5 repeats may be requested. Where fewer than 5 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 6 months of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Public and private hospital authority required

Initial (new patients)
Application for initial PBS-subsidised treatment with sildenafil citrate of patients who have not received prior PBS-subsidised treatment with bosentan monohydrate, iloprost trometamol, epoprostenol sodium or sitaxentan sodium and who have been assessed by a physician from a designated hospital to have:
(a) WHO Functional Class III primary pulmonary hypertension and a mean right atrial pressure greater than 8 mmHg, as measured by RHC, unless a RHC is contraindicated on clinical grounds; OR
(b) WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease and a mean right atrial pressure greater than 8 mmHg, as measured by RHC, unless a RHC is contraindicated on clinical grounds.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted to Medicare Australia for consideration based on the test results of the ECHO composite assessment plus 6MWT or the ECHO composite assessment only.

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Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer $	Proprietary Name and Manufacturer

Applications for authorisation must be in writing and must include:
(1) a completed authority prescription form [see Note for authority approval requirements]; and
(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form [www.medicareaustralia.gov.au] which includes results from the 3 tests below, where available:
(i) RHC composite assessment; and
(ii) ECHO composite assessment; and
(iii) 6MWT; and
(3) a signed patient acknowledgment indicating that the patient understands and acknowledges that PBS-subsidised treatment with sildenafil citrate for primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, OR with epoprostenol sodium for primary pulmonary hypertension, OR with iloprost trometamol for primary pulmonary hypertension, drug-induced pulmonary arterial hypertension or pulmonary arterial hypertension secondary to connective tissue disease, OR with bosentan monohydrate for primary pulmonary hypertension or pulmonary arterial hypertension secondary to scleroderma, OR with sitaxentan sodium for primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, will cease if the treating physician determines that the patient has not achieved a response to treatment [see Note for definition of response].

Where fewer than 3 tests (see requirement 2 above) are able to be performed on clinical grounds, a reason outlining why the particular test/s could not be conducted must be provided with the authority application [see Note for test requirements].

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. A maximum of 5 repeats may be requested. Where fewer than 5 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 6 months of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Public and private hospital authority required

Initial (change or re-commencement for all patients)
Application for initial PBS-subsidised treatment with sildenafil citrate of patients with either of the following:
(a) WHO Class III primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease who wish to re-commence PBS-subsidised sildenafil citrate after a break in therapy and who have demonstrated a response to their most recent course of PBS-subsidised treatment with sildenafil citrate; OR
(b) WHO Class III primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease and whose most recent course of PBS-subsidised treatment was with iloprost trometamol; OR
(c) WHO Class III primary pulmonary hypertension or pulmonary arterial hypertension secondary to scleroderma and whose most recent course of PBS-subsidised treatment was with bosentan monohydrate; OR
(d) WHO Class III primary pulmonary hypertension and whose most recent course of PBS-subsidised treatment was with epoprostenol sodium; OR
(e) WHO Class III primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease and whose most recent course of PBS-subsidised treatment was with sitaxentan sodium.

Applications for authorisation must be in writing and must include:
(1) a completed authority prescription form [see Note for authority approval requirements]; and
(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form [www.medicareaustralia.gov.au] which includes the results on which approval for the first application for PBS-subsidised sildenafil citrate, epoprostenol sodium, iloprost trometamol, bosentan monohydrate or sitaxentan sodium, whichever was initiated first, was granted; and
(3) the date of the first application for PBS-subsidised treatment with sildenafil citrate, epoprostenol sodium, iloprost trometamol, bosentan monohydrate or sitaxentan sodium, whichever was initiated first; and
(4) the results of the patient's response to treatment with their last course of PBS-subsidised sildenafil citrate, epoprostenol sodium, iloprost trometamol, bosentan monohydrate or sitaxentan sodium.

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The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. A maximum of 5 repeats may be requested. Where fewer than 5 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 6 months of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Public and private hospital authority required

Continuing treatment (all patients)
Continuing PBS-subsidised treatment with sildenafil citrate of patients who have received approval for initial PBS-subsidised treatment with sildenafil citrate, and who have been assessed by a physician from a designated hospital to have achieved a response to their most recent course of sildenafil citrate treatment [see Note for definition of response].

Applications for authorisation must be in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form [www.medicareaustralia.gov.au] which includes results from the 3 tests below, where available:
(i) RHC composite assessment; and
(ii) ECHO composite assessment; and
(iii) 6MWT.

Where fewer than 3 tests (see requirement 2 above) are able to be performed on clinical grounds, a reason outlining why the particular test/s could not be conducted must be provided with the authority application [see Note for test requirements].

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. A maximum of 5 repeats may be requested. Where fewer than 5 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 6 months of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

9605M	*Tablet 20 mg (base)*	*90*	*898.43*	*Revatio*	*PF*

SIROLIMUS
CAUTION:
Careful monitoring of patients is mandatory.

Private hospital authority required

Management of rejection, under the supervision and direction of a transplant unit, in patients receiving this drug for prophylaxis of renal allograft rejection. Management includes initiation, stabilisation and review of therapy as required.

6436R	*Tablet 1 mg*	*100*	*723.33*	*Rapamune*	*WX*
6457W	*Tablet 2 mg*	*100*	*1446.67*	*Rapamune*	*WX*
6437T	*Oral solution 1 mg per mL, 60 mL*	*1*	*468.00*	*Rapamune*	*WX*

SITAXENTAN SODIUM
CAUTION:
Sitaxentan sodium is a category X drug and must not be given to pregnant women. Pregnancy must be excluded before the start of treatment and avoided during treatment with this drug.

NOTE:
Any queries concerning the arrangements to prescribe sitaxentan sodium may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written applications for authority to prescribe sitaxentan sodium should be forwarded to:

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Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer $	Proprietary Name and Manufacturer

Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

NOTE:

Sitaxentan sodium is not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with scleroderma, where the total lung capacity is less than 70% of that predicted.

Sitaxentan sodium is not PBS-subsidised when used in combination with PBS-subsidised bosentan monohydrate, PBS-subsidised iloprost trometamol, PBS-subsidised epoprostenol sodium or PBS-subsidised sildenafil citrate.

The following provides some explanatory notes regarding the availability of PBS-subsidised treatment with:
(a) bosentan monohydrate, of primary pulmonary hypertension or pulmonary arterial hypertension secondary to scleroderma, in patients with disease of WHO Functional Class III or IV severity; AND
(b) iloprost trometamol, of primary pulmonary hypertension, drug-induced pulmonary arterial hypertension or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class III or IV severity; AND
(c) epoprostenol sodium, of primary pulmonary hypertension, in patients with disease of WHO Functional Class III or IV severity; AND
(d) sildenafil citrate, of primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class III severity; AND
(e) sitaxentan sodium, of primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class III severity.

Adult patients:
From 1 April 2008, adult patients with primary pulmonary hypertension will be able to access, through the PBS, bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate (WHO Class III only) or sitaxentan sodium (WHO Class III only). Once these patients are approved initial treatment with 1 of these 5 drugs, they may swap between bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate and sitaxentan sodium at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary. (New baselines may be submitted where the patient has failed to respond to their current treatment.)

Patients may only swap to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate or sitaxentan sodium if they have not failed prior PBS-subsidised treatment with that drug.

Adult patients with pulmonary arterial hypertension secondary to scleroderma will be able to access, through the PBS, bosentan monohydrate, iloprost trometamol, sildenafil citrate (WHO Class III only) or sitaxentan sodium (WHO Class III only). Once these patients are approved initial treatment with 1 of these 4 drugs, they may swap between bosentan monohydrate, iloprost trometamol, sildenafil citrate and sitaxentan sodium at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary. (New baselines may be submitted where the patient has failed to respond to their current treatment.)

Patients may only swap to bosentan monohydrate, iloprost trometamol, sildenafil citrate or sitaxentan sodium if they have not failed prior PBS-subsidised treatment with that drug.

Adult patients with pulmonary arterial hypertension secondary to connective tissue disease other than scleroderma will be able to access, through the PBS, iloprost trometamol, sildenafil citrate (WHO Class III only) or sitaxentan sodium (WHO Class III only). Once these patients are approved initial treatment with 1 of these 3 drugs, they may swap between iloprost trometamol, sildenafil citrate and sitaxentan sodium at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary. (New baselines may be submitted where the patient has failed to respond to their current treatment.)

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Patients may only swap to iloprost trometamol, sildenafil citrate or sitaxentan sodium if they have not failed prior PBS-subsidised treatment with that drug.

Patients with drug-induced pulmonary arterial hypertension are only eligible for treatment with iloprost trometamol. They may not swap to bosentan monohydrate, epoprostenol sodium, sildenafil citrate or sitaxentan sodium.

Patients under 18 years of age:
From 1 April 2008, patients aged less than 18 years with primary pulmonary hypertension are eligible to receive PBS-subsidised treatment with bosentan monohydrate, epoprostenol sodium, iloprost trometamol, sildenafil citrate (WHO Class III only) or sitaxentan sodium (WHO Class III only). Once these patients are approved initial treatment with 1 of these 5 drugs, they may swap between bosentan monohydrate, epoprostenol sodium, iloprost trometamol, sildenafil citrate and sitaxentan sodium at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary. (New baselines may be submitted where the patient has failed to respond to their current treatment.)

Patients may only swap to bosentan monohydrate, epoprostenol sodium, iloprost trometamol, sildenafil citrate or sitaxentan sodium if they have not failed prior PBS-subsidised treatment with that drug.

1. Definition of primary pulmonary hypertension, drug-induced pulmonary arterial hypertension or pulmonary arterial hypertension secondary to connective tissue disease, including scleroderma.

Primary pulmonary hypertension, drug-induced pulmonary arterial hypertension or pulmonary arterial hypertension secondary to connective tissue disease, including scleroderma, are defined as follows:
(i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary capillary wedge pressure (PCWP) less than 18 mmHg; or
(ii) mPAP greater than 30 mmHg with exercise and PCWP less than 18 mmHg; or
(iii) where a right heart catheter cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

2. Definition of WHO Functional Class III or IV disease severity.

(a) WHO Functional Class III disease severity is defined as follows:
Patients with pulmonary hypertension resulting in marked limitation of physical activity who are comfortable at rest and on ordinary physical activity experience dyspnoea or fatigue, chest pain or near syncope.
(b) WHO Functional Class IV disease severity is defined as follows:
Patients with the inability to carry out any physical activity without symptoms. These patients manifest signs of right heart failure. Dyspnoea and/or fatigue may even be present at rest. Discomfort is increased by any physical activity.

3. Designated hospitals.

Refer to the Medicare Australia website at www.medicareaustralia.gov.au for a list of designated hospitals.

4. Test requirements to establish baseline for initiation of treatment and response to treatment for continuation of treatment.

(a) Initiation of treatment.
(i) New patients.
The first written application for PBS-subsidised treatment with the first of either bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate or sitaxentan sodium should be accompanied by the results of a right heart catheter (RHC) composite assessment, plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:
(1) RHC plus ECHO composite assessments;
(2) RHC composite assessment plus 6MWT;
(3) RHC composite assessment only.

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In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted to Medicare Australia for consideration based on the results of the following test combinations, which are listed in descending order of preference:
(1) ECHO composite assessment plus 6MWT;
(2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a reason outlining why the particular test/s could not be conducted must be provided with the authority application.

NOTE:
Where patients were initiated on PBS-subsidised treatment either with bosentan monohydrate on or after 1 March 2004, with iloprost trometamol on or after 1 April 2005, with epoprostenol sodium on or after 1 August 2006, with sildenafil citrate on or after 1 March 2007, with sitaxentan sodium on or after 1 April 2008, or with bosentan monohydrate (for PAH associated with congenital systemic-to-pulmonary shunt) on or after 1 August 2008, the test results provided with the initial application must be no more than 2 months old at the time of application. These results will form the baseline against which response assessments will be made.

Where patients received treatment with either bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate or sitaxentan sodium prior to being commenced on PBS-subsidised treatment with the first of either bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate or sitaxentan sodium, the test requirements above still apply. The results that will form the baseline against which response assessments will be made will be those measured at the time patients commenced non-PBS-subsidised treatment with either bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate or sitaxentan sodium, whichever of the 5 drugs the patient received first.

(ii) Patients who received non-PBS-subsidised treatment with sitaxentan sodium prior to 1 April 2008.
For patients with primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease who were commenced on sitaxentan sodium treatment prior to 1 April 2008 and who have received less than 6 months of treatment with sitaxentan sodium at the time of application, the first application for PBS-subsidised treatment must include, where available, all 3 test results at the time that the patient commenced treatment with sitaxentan sodium, sildenafil citrate, epoprostenol sodium, bosentan monohydrate or iloprost trometamol, whichever was initiated first.

For patients with primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease who were commenced on sitaxentan sodium treatment prior to 1 April 2008 and who have received 6 or more months of treatment at the time of application, the first application for PBS-subsidised treatment must include, where available, all 3 test results at the time that the patient commenced treatment with sitaxentan sodium, sildenafil citrate, epoprostenol sodium, bosentan monohydrate or iloprost trometamol, whichever was initiated first. The results at the time of application for initial PBS-subsidised treatment must also be provided and must be no older than 3 months.

(b) Continuation of treatment.
The following list outlines the preferred test combination, in descending order, for the purposes of continuation of PBS-subsidised treatment:
(1) RHC plus ECHO composite assessments plus 6MWT;
(2) RHC plus ECHO composite assessments;
(3) RHC composite assessment plus 6MWT;
(4) ECHO composite assessment plus 6MWT;
(5) RHC composite assessment only;
(6) ECHO composite assessment only.

The results of the same tests as conducted at baseline should be provided with each written continuing treatment application (i.e. every 6 months), except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a reason why the test(s) could not be conducted must be provided with the application.

The test(s) results provided with the application for continuing treatment must be no more than 2 months old at the time of application.

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5. Definition of response to sitaxentan sodium, sildenafil citrate, bosentan monohydrate, iloprost trometamol, epoprostenol sodium or prior vasodilator treatment.

For adult patients with 2 or more baseline tests, response to treatment is defined as 2 or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For adult patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For adult patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least 1 of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

6. Authority approval requirements. [The following 2 sections are only relevant to the PBS listing of sitaxentan sodium. The requirements specific to bosentan monohydrate, iloprost trometamol, epoprostenol sodium and sildenafil citrate are given in parts 6 and 7 of the NOTE included in the bosentan monohydrate, iloprost trometamol, epoprostenol sodium and sildenafil citrate Schedule entry respectively.]

(a) Initiation of PBS-subsidised treatment with sitaxentan sodium, where the patient has not received prior PBS-subsidised treatment with bosentan monohydrate, iloprost trometamol, epoprostenol sodium or sildenafil citrate. All applications for initial treatment must be made in writing, must include an authority prescription and must be submitted to Medicare Australia for authorisation. The total duration of initial PBS-subsidised treatment that will be approved with this first written application is up to 6 months.

Patients who commence PBS-subsidised sitaxentan sodium treatment after 1 April 2008 and patients who received 6 or more months of sitaxentan sodium treatment prior to 1 April 2008 are eligible to receive up to 6 months of treatment per authority application.

Patients who commenced treatment with sitaxentan sodium prior to 1 April 2008 and who have received less than 6 months of treatment at the time of application are eligible to receive sufficient supply to allow the patient to complete a total of 6 months of combined PBS-subsidised and non-PBS-subsidised treatment.

All patients with primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease who commenced treatment with sitaxentan sodium prior to 1 April 2008 will be eligible to commence PBS-subsidised treatment with sitaxentan sodium. Thereafter, to be eligible for further PBS-subsidised supply, these patients must demonstrate a response to sitaxentan sodium treatment, as defined above under definition of response.

(b) Continuation of treatment.
Written applications for continuing treatment must be submitted to Medicare Australia for authorisation every 6 months. Approvals will be limited to provide sufficient supply for up to a maximum of 6 months of treatment, based on the dosage recommendations in the TGA-approved Product Information.

Applications for continuing treatment will only be approved for patients who have currently demonstrated a response to treatment with sitaxentan sodium.

The assessment of the patient's response to the first and subsequent 6 month courses of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated. Applications for continuing treatment with sitaxentan sodium should be made prior to the completion of the 6 month treatment course to ensure continuity for those patients who respond to treatment, as assessed by the treating physician.

(c) Swapping between bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate and sitaxentan sodium.
For eligible patients, applications to swap between these 5 drugs must be made under the relevant initial treatment restriction. Patients should be assessed for response to the treatment they are ceasing at the time the application to swap therapy is being made. Patients who fail to demonstrate a response or for whom no assessment results are submitted with the application to swap therapy may not re-commence PBS-subsidised treatment with the drug they are ceasing.

It is important that patients are assessed for response to every course of treatment approved within the timeframes specified in the relevant restriction, in order to maximise the choice of treatment.

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

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Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer $	Proprietary Name and Manufacturer

(d) Cessation of treatment.
Patients who fail to demonstrate a response to PBS-subsidised sitaxentan sodium treatment at the times where an assessment is required must cease PBS-subsidised sitaxentan sodium therapy.

7. Re-treatment with sitaxentan sodium.

Patients who do not respond to treatment are not eligible to receive further PBS-subsidised treatment with sitaxentan sodium under any circumstances.

8. Further information.

A tabulated representation of the above information and the restriction can be obtained from the Medicare Australia website at www.medicareaustralia.gov.au.

Public and private hospital authority required

Initial (new patients)
Application for initial PBS-subsidised treatment with sitaxentan sodium of patients who have not received prior PBS-subsidised treatment with bosentan monohydrate, iloprost trometamol, epoprostenol sodium or sildenafil citrate and who have been assessed by a physician from a designated hospital to have:
(a) WHO Functional Class III primary pulmonary hypertension and a mean right atrial pressure of 8 mmHg or less, as measured by RHC, unless a RHC is contraindicated on clinical grounds; OR
(b) WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease and a mean right atrial pressure of 8 mmHg or less, as measured by RHC, unless a RHC is contraindicated on clinical grounds.

Patients must have failed to respond [see Note for definition of response] to 6 or more weeks of appropriate vasodilator treatment unless intolerance or a contraindication to such treatment exists.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted to Medicare Australia for consideration based on the test results of the ECHO composite assessment plus 6MWT or the ECHO composite assessment only.

Applications for authorisation must be in writing and must include:
(1) a completed authority prescription form [see Note for authority approval requirements]; and
(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form [www.medicareaustralia.gov.au] which includes results from the 3 tests below, where available:
(i) RHC composite assessment; and
(ii) ECHO composite assessment; and
(iii) 6MWT; and
(3) a signed patient acknowledgment indicating that the patient understands and acknowledges that PBS-subsidised treatment with sitaxentan sodium for primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue diease, OR with sildenafil citrate for primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, OR with epoprostenol sodium for primary pulmonary hypertension, OR with iloprost trometamol for primary pulmonary hypertension, drug-induced pulmonary arterial hypertension or pulmonary arterial hypertension secondary to connective tissue disease, OR with bosentan monohydrate for primary pulmonary hypertension or pulmonary arterial hypertension secondary to scleroderma, will cease if the treating physician determines that the patient has not achieved a response to treatment [see Note for definition of response].

Details of prior vasodilator treatment, including the dose and duration of treatment, must be provided at the time of application. Where the patient has an adverse event to a vasodilator or where vasodilator treatment is contraindicated, details on the nature of the adverse event or contraindication according to the TGA-approved Product Information must also be provided with the application.

Where fewer than 3 tests (see requirement 2 above) are able to be performed on clinical grounds, a reason outlining why the particular test/s could not be conducted must be provided with the authority application [see Note for test requirements].

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. A maximum of 5 repeats may be requested. Where fewer than 5 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 6 months of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

continued ☞

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer $	Proprietary Name and Manufacturer

Public and private hospital authority required

Initial (new patients)

Application for initial PBS-subsidised treatment with sitaxentan sodium of patients who have not received prior PBS-subsidised treatment with bosentan monohydrate, iloprost trometamol, epoprostenol sodium or sildenafil citrate and who have been assessed by a physician from a designated hospital to have:

(a) WHO Functional Class III primary pulmonary hypertension and a mean right atrial pressure greater than 8 mmHg, as measured by RHC, unless a RHC is contraindicated on clinical grounds; OR

(b) WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease and a mean right atrial pressure greater than 8 mmHg, as measured by RHC, unless a RHC is contraindicated on clinical grounds.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted to Medicare Australia for consideration based on the test results of the ECHO composite assessment plus 6MWT or the ECHO composite assessment only.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form [see Note for authority approval requirements]; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form [www.medicareaustralia.gov.au] which includes results from the 3 tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6MWT; and

(3) a signed patient acknowledgment indicating that the patient understands and acknowledges that PBS-subsidised treatment with sitaxentan sodium for primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, OR with sildenafil citrate for primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, OR with epoprostenol sodium for primary pulmonary hypertension, OR with iloprost trometamol for primary pulmonary hypertension, drug-induced pulmonary arterial hypertension or pulmonary arterial hypertension secondary to connective tissue disease, OR with bosentan monohydrate for primary pulmonary hypertension or pulmonary arterial hypertension secondary to scleroderma, will cease if the treating physician determines that the patient has not achieved a response to treatment [see Note for definition of response].

Where fewer than 3 tests (see requirement 2 above) are able to be performed on clinical grounds, a reason outlining why the particular test/s could not be conducted must be provided with the authority application [see Note for test requirements].

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. A maximum of 5 repeats may be requested. Where fewer than 5 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 6 months of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Public and private hospital authority required

Initial (grandfather patients)

Application for initial PBS-subsidised treatment with sitaxentan sodium of patients who were receiving treatment with sitaxentan sodium prior to 1 April 2008, who have not received prior PBS-subsidised treatment with bosentan monohydrate, iloprost trometamol, epoprostenol sodium or sildenafil citrate and who have been assessed by a physician from a designated hospital to have:

(a) WHO Functional Class III primary pulmonary hypertension; OR

(b) WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease.

continued ☞

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer $	Proprietary Name and Manufacturer

Applications for authorisation must be in writing and must include:
(1) a completed authority prescription form [see Note for authority approval requirements]; and
(2) (a) for patients who have received less than 6 months of sitaxentan sodium treatment at the time of application — a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form [www.medicareaustralia.gov.au] which includes results of the following 3 tests, where available, at the time treatment with sitaxentan sodium was commenced:
(i) RHC composite assessment; and
(ii) ECHO composite assessment; and
(iii) 6MWT; or
(b) for patients who have received 6 or more months of sitaxentan sodium treatment at the time of application — a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form [www.medicareaustralia.gov.au] which includes results of the following 3 tests, both at the time treatment with sitaxentan sodium was commenced and at the time of application, where available:
(i) RHC composite assessment; and
(ii) ECHO composite assessment; and
(iii) 6MWT; and
(3) the date of commencement of sitaxentan sodium treatment; and
(4) a signed patient acknowledgment indicating that the patient understands and acknowledges that PBS-subsidised treatment with sitaxentan sodium for primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, OR with sildenafil citrate for primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, OR with epoprostenol sodium for primary pulmonary hypertension, OR with iloprost trometamol for primary pulmonary hypertension, drug-induced pulmonary arterial hypertension or pulmonary arterial hypertension secondary to connective tissue disease, OR with bosentan monohydrate for primary pulmonary hypertension or pulmonary arterial hypertension secondary to scleroderma, will cease if the treating physician determines that the patient has not achieved a response to treatment [see Note for definition of response].

Where fewer than 3 tests (see requirement 2 above) are able to be performed on clinical grounds, a reason outlining why the particular test/s could not be conducted must be provided with the authority application [see Note for test requirements].

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. The number of repeats authorised will be dependent on the duration of prior sitaxentan sodium therapy. Where patients have received less than 6 months of non-PBS-subsidised treatment with sitaxentan sodium, sufficient repeats to allow the patient to complete a total of 6 months of combined PBS-subsidised and non-PBS-subsidised therapy may be requested. Where patients have received 6 months or more of non-PBS-subsidised treatment with sitaxentan sodium, a maximum of 5 repeats may be requested. Where fewer than the maximum allowable number of repeats are requested at the time of application, authority approvals for the remainder of the allowable repeats may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Public and private hospital authority required
Initial (change or re-commencement for all patients)
Application for initial PBS-subsidised treatment with sitaxentan sodium of patients with either of the following:
(a) WHO Class III primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease who wish to re-commence PBS-subsidised sitaxentan sodium after a break in therapy and who have demonstrated a response to their most recent course of PBS-subsidised treatment with sitaxentan sodium; OR
(b) WHO Class III primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease and whose most recent course of PBS-subsidised treatment was with iloprost trometamol; OR
(c) WHO Class III primary pulmonary hypertension or pulmonary arterial hypertension secondary to scleroderma and whose most recent course of PBS-subsidised treatment was with bosentan monohydrate; OR
(d) WHO Class III primary pulmonary hypertension and whose most recent course of PBS-subsidised treatment was with epoprostenol sodium; OR
(e) WHO Class III primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease and whose most recent course of PBS-subsidised treatment was with sildenafil citrate.

continued ☞

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer $	Proprietary Name and Manufacturer	
	Applications for authorisation must be in writing and must include: ***(1) a completed authority prescription form [see Note for authority approval requirements]; and*** ***(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form [www.medicareaustralia.gov.au] which includes the results on which approval for the first application for PBS-subsidised sitaxentan sodium, sildenafil citrate, epoprostenol sodium, iloprost trometamol or bosentan monohydrate, whichever was initiated first, was granted; and*** ***(3) the date of the first application for PBS-subsidised treatment with sitaxentan sodium, sildenafil citrate, epoprostenol sodium, iloprost trometamol or bosentan monohydrate, whichever was initiated first; and*** ***(4) the results of the patient's response to treatment with their last course of PBS-subsidised sitaxentan sodium, sildenafil citrate, epoprostenol sodium, iloprost trometamol or bosentan monohydrate.*** ***The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. A maximum of 5 repeats may be requested. Where fewer than 5 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 6 months of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).*** **Public and private hospital authority required** ***Continuing treatment (all patients)*** ***Continuing PBS-subsidised treatment with sitaxentan sodium of patients who have received approval for initial PBS-subsidised treatment with sitaxentan sodium, and who have been assessed by a physician from a designated hospital to have achieved a response to their most recent course of sitaxentan sodium treatment [see Note for definition of response].*** ***Applications for authorisation must be in writing and must include:*** ***(1) a completed authority prescription form; and*** ***(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form [www.medicareaustralia.gov.au] which includes results from the 3 tests below, where available:*** ***(i) RHC composite assessment; and*** ***(ii) ECHO composite assessment; and*** ***(iii) 6MWT.*** ***Where fewer than 3 tests (see requirement 2 above) are able to be performed on clinical grounds, a reason outlining why the particular test/s could not be conducted must be provided with the authority application [see Note for test requirements].*** ***The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. A maximum of 5 repeats may be requested. Where fewer than 5 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 6 months of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).***				
9622K	***Tablet 100 mg***	***30***	***2743.80***	***Thelin***	***CS***
	STAVUDINE **Private hospital authority required** ***Treatment of HIV infection in patients with:*** ***(a) CD4 cell counts of less than 500 per cubic millimetre; or*** ***(b) viral load of greater than 10,000 copies per mL.***				
6186N	***Capsule 20 mg***	***60***	***280.00***	***Zerit***	***BQ***
6189R	***Capsule 30 mg***	***60***	***333.68***	***Zerit***	***BQ***
6190T	***Capsule 40 mg***	***60***	***444.90***	***Zerit***	***BQ***
6250Y	***Powder for oral solution 1 mg per mL, 200 mL***	***1***	***116.68***	***Zerit***	***BQ***

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer $	Proprietary Name and Manufacturer	
	TACROLIMUS				
	CAUTION:				
	Careful monitoring of patients is mandatory.				
	Private hospital authority required				
	Management of rejection in patients following organ or tissue transplantation, under the supervision and direction of a transplant unit. Management includes initiation, stabilisation and review of therapy as required.				
6328C	***Capsule 500 micrograms***	***100***	***187.34***	***Prograf***	***JC***
6216E	***Capsule 1 mg***	***100***	***374.67***	***Prograf***	***JC***
6217F	***Capsule 5 mg***	***50***	***936.68***	***Prograf***	***JC***
	TELBIVUDINE				
	Private hospital authority required				
	Treatment, as sole PBS-subsidised therapy, in a patient with chronic hepatitis B who is nucleoside analogue naive and satisfies all of the following criteria:				
	(1) Histological evidence of chronic hepatitis on liver biopsy (except in patients with coagulation disorders considered severe enough to prevent liver biopsy);				
	(2)(a) Abnormal serum ALT levels in conjunction with documented chronic hepatitis B infection; or				
	(b) Elevated HBV DNA levels in conjunction with documented chronic hepatitis B infection;				
	(3) Female patients of child-bearing age are not pregnant, not breast-feeding, and are using an effective form of contraception.				
	Persons with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy.				
9630W	***Tablet 600 mg***	***28***	***250.88***	***Sebivo***	***NV***
	TENOFOVIR DISOPROXIL FUMARATE				
	Private hospital authority required				
	Treatment of HIV infection in patients with:				
	(a) CD4 cell counts of less than 500 per cubic millimetre; or				
	(b) viral load of greater than 10,000 copies per mL.				
6358P	***Tablet 300 mg***	***30***	***483.10***	***Viread***	***GI***
	TENOFOVIR DISOPROXIL FUMARATE with EMTRICITABINE				
	Private hospital authority required				
	Treatment of HIV infection in patients with:				
	(a) CD4 cell counts of less than 500 per cubic millimetre; or				
	(b) viral load of greater than 10,000 copies per mL.				
6468K	***Tablet 300 mg-200 mg***	***30***	***765.10***	***Truvada***	***GI***

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer $	Proprietary Name and Manufacturer	
	THALIDOMIDE				
	CAUTION:				
	Thalidomide is a category X drug and must not be given to pregnant women. Pregnancy in female patients or in the partners of male patients must be avoided during treatment and for 1 month after cessation of treatment.				
	Private hospital authority required				
	Relapsed or refractory multiple myeloma in patients who have failed at least 1 other treatment.				
	NOTE:				
	Patients receiving thalidomide under the PBS listing must be registered in the Pharmion Risk Management Program.				
6469L	***Capsule 50 mg***	***28***	***420.00***	***Thalidomide Pharmion***	***PI***
	TIPRANAVIR				
	Private hospital authority required				
	Treatment, in combination with other antiretroviral agents, and co-administered with 200 mg ritonavir twice daily, of HIV infection in antiretroviral experienced adults with:				
	(a) evidence of HIV replication (viral load greater than 10,000 copies per mL); and/or				
	(b) CD4 cell counts of less than 500 per cubic millimetre.				
	Patients must have failed previous treatment with, or have resistance to, 3 different antiretroviral regimens which have included:				
	(i) at least 1 non-nucleoside reverse transcriptase inhibitor; and				
	(ii) at least 1 nucleoside reverse transcriptase inhibitor; and				
	(iii) at least 2 protease inhibitors.				
9610T	***Capsule 250 mg***	***120***	***1071.00***	***Aptivus***	***BY***
	NOTE:				
	This price is based on special supply arrangements—see Pharmaceutical Benefits Pricing Authority relativity sheet for full details.				
	VALACICLOVIR HYDROCHLORIDE				
	Private hospital authority required				
	Prophylaxis of cytomegalovirus (CMV) infection and disease following renal transplantation in patients at risk of CMV disease.				
6280M	***Tablet 500 mg (base)***	***100***	***423.18***	***Valtrex***	***GK***
	VALGANCICLOVIR HYDROCHLORIDE				
	Private hospital authority required				
	Cytomegalovirus retinitis in patients with acquired immunodeficiency syndrome;				
	Prophylaxis of cytomegalovirus infection and disease in solid organ transplant patients at risk of cytomegalovirus disease.				
6357N	***Tablet 450 mg (base)***	***60***	***2245.80***	***Valcyte***	***RO***
	ZIDOVUDINE				
	Private hospital authority required				
	Treatment of HIV infection in patients with:				
	(a) CD4 cell counts of less than 500 per cubic millimetre; or				
	(b) viral load of greater than 10,000 copies per mL.				
6153W	***Capsule 100 mg***	***100***	***205.46***	***Retrovir***	***GK***

continued ☞

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer $	Proprietary Name and Manufacturer	
6154X	*Capsule 250 mg*	*60*	*308.19*	*Retrovir*	*GK*
6155Y	*Syrup 10 mg per mL, 200 mL*	*1*	*44.88*	*Retrovir*	*GK*

ZOLEDRONIC ACID

Private hospital authority required

Multiple myeloma;

Bone metastases from breast cancer;

Bone metastases from hormone-resistant prostate cancer, with demonstration of biochemical progression of disease despite maximal therapy with hormonal treatments;

Treatment of hypercalcaemia of malignancy refractory to anti-neoplastic therapy.

6371H	*Injection concentrate for I.V. infusion 4 mg (as monohydrate) in 5 mL*	*1*	*450.00*	*Zometa*	*NV*

NOTE:
This price is based on special supply arrangements—see Pharmaceutical Benefits Pricing Authority relativity sheet for full details.

BOTULINUM TOXIN PROGRAM

BOTULINUM TOXIN TYPE A PURIFIED NEUROTOXIN COMPLEX
NOTE:
Arrangements to prescribe this item should be made by medical practitioners with Medicare Australia, contact telephone number 1800 700 270.

Treatment of blepharospasm associated with dystonia, including benign blepharospasm and VIIth nerve disorders (hemifacial spasm) in patients 12 years and older;

Treatment of dynamic equinus foot deformity due to spasticity in an ambulant paediatric cerebral palsy patient aged from 2 to 17 years inclusive;

Continuing PBS-subsidised treatment of dynamic equinus foot deformity due to spasticity in an ambulant cerebral palsy patient 18 years of age or older who was commenced on PBS-subsidised treatment with botulinum toxin type A purified neurotoxin complex as a paediatric patient;

Treatment of spasmodic torticollis, either as monotherapy or as adjunctive therapy to current standard care.

6103F	*Lyophilised powder for I.M. injection 100 units*	*1*	*415.50*	*Botox*	*AG*

NOTE:
The units used to express the potency of botulinum toxin preparations currently available for PBS subsidy are not equivalent.

CLOSTRIDIUM BOTULINUM TYPE A TOXIN—HAEMAGGLUTININ COMPLEX
NOTE:
Arrangements to prescribe this item should be made by medical practitioners with Medicare Australia, contact telephone number 1800 700 270.

Treatment of dynamic equinus foot deformity due to spasticity in an ambulant paediatric cerebral palsy patient aged from 2 to 17 years inclusive;

Continuing PBS-subsidised treatment of dynamic equinus foot deformity due to spasticity in an ambulant cerebral palsy patient 18 years of age or older who was commenced on PBS-subsidised treatment with clostridium botulinum type A toxin-haemagglutinin complex as a paediatric patient;

Treatment of spasmodic torticollis, either as monotherapy or as adjunctive therapy to current standard care;

continued ☞

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer $	Proprietary Name and Manufacturer	
	Treatment of moderate to severe spasticity [defined as MAS greater than or equal to 3 using modified Ashworth scale] of the upper limb in adults following a stroke, as second line therapy when standard management has failed (e.g. physiotherapy and/or oral spasticity agents) or as an adjunct to physical therapy. ***Maximum number of treatments to be authorised is 4 per upper limb per lifetime. Treatment should not be initiated until 3 to 6 months post-stroke in patients who do not have established severe contracture. Treatment should be discontinued if the patient does not respond (decrease of MAS greater than 1 in at least one joint) after two treatments.*** ***Contraindications to treatment include established severe contracture, known sensitivity to botulinum toxin.***				
6293F	***Lyophilised powder for I.M. injection 500 units***	***1***	***650.00***	***Dysport***	***IS***
	NOTE: ***The units used to express the potency of botulinum toxin preparations currently available for PBS subsidy are not equivalent.***				

HUMAN GROWTH HORMONE PROGRAM

SOMATROPIN (Recombinant human growth hormone)

Short stature in accordance with the 'Guidelines for the Availability of Human Growth Hormone (hGH) as a Pharmaceutical Benefit'.

NOTE:
These guidelines may be obtained from the Department of Health and Ageing's internet site at http://www.health.gov.au/internet/main/publishing.nsf/Content/pbs-hghguidelines-contents, or from:

Growth Hormone Program
Access and Systems Branch
Department of Health and Ageing
GPO Box 9848
CANBERRA ACT 2601
Contact telephone number (02) 6289 7274

6266T	***Injection 4 mg (12 i.u.) vial with 3.5 mL diluent (with preservative)***	***1***	***198.00***	***Zomacton***	***FP***
6330E	***Injection 5 mg (15 i.u.) in 1 mL cartridge (with preservative)***	***1***	***247.50***	***Genotropin***	***PH***
6476W	***Solution for injection 5 mg (15 i.u.) in 1.5 mL cartridge (with preservative)***	***1***	***247.50***	***Omnitrope***	***SZ***
6295H	***Solution for injection 5 mg (15 i.u.) in 1.5 mL cartridge (with preservative)***	***1***	***247.50***	***Norditropin SimpleXx***	***NO***
6465G	***Solution for injection 5 mg (15 i.u.) in 1.5 mL cartridge (with preservative)***	***1***	***315.50***	***Norditropin NordiFlex***	***NO***
	NOTE: ***This price is based on special supply arrangements—see Pharmaceutical Benefits Pricing Authority relativity sheet for full details.***				
6169Q	***Injection 18 i.u. (6 mg) cartridge with 3.15 mL diluent (with preservative)***	***1***	***297.00***	***Humatrope***	***LY***
6329D	***Injection 8 mg (24 i.u.) vial with 1.37 mL diluent cartridge (with preservative) (for use with one.click auto-injector)***	***1***	***396.00***	***Saizen 8 mg click.easy***	***SG***
6296J	***Solution for injection 10 mg (30 i.u.) in 1.5 mL cartridge (with preservative)***	***1***	***495.00***	***Norditropin SimpleXx***	***NO***
6466H	***Solution for injection 10 mg (30 i.u.) in 1.5 mL cartridge (with preservative)***	***1***	***631.00***	***Norditropin NordiFlex***	***NO***

continued ☞

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer $	Proprietary Name and Manufacturer	
	NOTE: ***This price is based on special supply arrangements—see Pharmaceutical Benefits Pricing Authority relativity sheet for full details.***				
9604L	*Solution for injection 10 mg (30 i.u.) in 2 mL cartridge (with preservative)*	*1*	*495.00*	*NutropinAq*	*IS*
6170R	*Injection 36 i.u. (12 mg) cartridge with 3.15 mL diluent (with preservative)*	*1*	*594.00*	*Humatrope*	*LY*
6312F	*Injection 12 mg (36 i.u.) in 1 mL cartridge (with preservative)*	*1*	*594.00*	*Genotropin*	*PH*
6297K	*Solution for injection 15 mg (45 i.u.) in 1.5 mL cartridge (with preservative)*	*1*	*742.50*	*Norditropin SimpleXx*	*NO*
6467J	*Solution for injection 15 mg (45 i.u.) in 1.5 mL cartridge (with preservative)*	*1*	*946.50*	*Norditropin NordiFlex*	*NO*
	NOTE: ***This price is based on special supply arrangements—see Pharmaceutical Benefits Pricing Authority relativity sheet for full details.***				
6345Y	*Injection 72 i.u. (24 mg) cartridge with 3.15 mL diluent (with preservative)*	*1*	*1188.00*	*Humatrope*	*LY*
9628R	*Injection 0.6 mg (1.8 i.u.) with diluent in single use syringe (without preservative)*	*7*	*207.90*	*Genotropin MiniQuick*	*PH*
6313G	*Injection 0.8 mg (2.4 i.u.) with diluent in single use syringe (without preservative)*	*7*	*277.20*	*Genotropin MiniQuick*	*PH*
6314H	*Injection 1 mg (3 i.u.) with diluent in single use syringe (without preservative)*	*7*	*346.50*	*Genotropin MiniQuick*	*PH*
6315J	*Injection 1.2 mg (3.6 i.u.) with diluent in single use syringe (without preservative)*	*7*	*415.80*	*Genotropin MiniQuick*	*PH*
6316K	*Injection 1.4 mg (4.2 i.u.) with diluent in single use syringe (without preservative)*	*7*	*485.10*	*Genotropin MiniQuick*	*PH*
6317L	*Injection 1.6 mg (4.8 i.u.) with diluent in single use syringe (without preservative)*	*7*	*554.40*	*Genotropin MiniQuick*	*PH*
6318M	*Injection 1.8 mg (5.4 i.u.) with diluent in single use syringe (without preservative)*	*7*	*623.70*	*Genotropin MiniQuick*	*PH*
6319N	*Injection 2 mg (6 i.u.) with diluent in single use syringe (without preservative)*	*7*	*693.00*	*Genotropin MiniQuick*	*PH*

IVF/GIFT PROGRAM

CHORIOGONADOTROPIN ALFA

Patients who are receiving medical treatment as described in items 13200 or 13203 of the Medicare Benefits Schedule.

NOTE:
Arrangements to prescribe this item should be made by medical practitioners with Medicare Australia, contact telephone number 1800 700 270.

9631X	*Solution for injection 250 micrograms in 0.5 mL pre-filled syringe*	*1*	*54.80*	*Ovidrel*	*SG*

continued ☞

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer $	Proprietary Name and Manufacturer	
	NOTE: ***This price is based on special supply arrangements—see Pharmaceutical Benefits Pricing Authority relativity sheet for full details. Relativity sheets are available on the Department of Health and Ageing's internet site (visit www.health.gov.au and search for 'relativity sheets').***				
	FOLLITROPIN ALFA				
	Patients who are receiving medical treatment as described in items 13200 or 13203 of the Medicare Benefits Schedule.				
	NOTE: ***Arrangements to prescribe this item should be made by medical practitioners with Medicare Australia, contact telephone number 1800 700 270.***				
6373K	***Injection set containing 1 vial powder for injection 75 i.u. and 1 pre-filled syringe solvent 1 mL***	***1***	***36.00***	***Gonal-f 75***	***SG***
6374L	***Injection set containing 10 vials powder for injection 75 i.u. and 10 pre-filled syringes solvent 1 mL***	***1***	***360.00***	***Gonal-f 75***	***SG***
6431L	***Injection 300 i.u. in 0.5 mL multi-dose cartridge***	***1***	***144.00***	***Gonal-f Pen***	***SG***
6376N	***Injection set containing 1 vial powder for injection 450 i.u. and 1 pre-filled syringe solvent 1 mL***	***1***	***216.00***	***Gonal-f***	***SG***
6432M	***Injection 450 i.u. in 0.75 mL multi-dose cartridge***	***1***	***216.00***	***Gonal-f Pen***	***SG***
6433N	***Injection 900 i.u. in 1.5 mL multi-dose cartridge***	***1***	***432.00***	***Gonal-f Pen***	***SG***
6375M	***Injection set containing 1 vial powder for injection 1,050 i.u. and 1 pre-filled syringe solvent 2 mL***	***1***	***504.00***	***Gonal-f***	***SG***
	FOLLITROPIN BETA				
	Patients who are receiving medical treatment as described in items 13200 or 13203 of the Medicare Benefits Schedule.				
	NOTE: ***Arrangements to prescribe this item should be made by medical practitioners with Medicare Australia, contact telephone number 1800 700 270.***				
6335K	***Solution for injection 300 i.u. in 0.36 mL multi-dose cartridge***	***1***	***144.04***	***Puregon 300 IU/ 0.36 mL***	***SH***
6336L	***Solution for injection 600 i.u. in 0.72 mL multi-dose cartridge***	***1***	***288.09***	***Puregon 600 IU/ 0.72 mL***	***SH***
6464F	***Solution for injection 900 i.u. in 1.08 mL multi-dose cartridge***	***1***	***432.11***	***Puregon 900 IU/ 1.08 mL***	***SH***
	HUMAN CHORIONIC GONADOTROPHIN				
	Patients who are receiving medical treatment as described in items 13200 or 13203 of the Medicare Benefits Schedule.				
	NOTE: ***Arrangements to prescribe this item should be made by medical practitioners with Medicare Australia, contact telephone number 1800 700 270.***				
6176C	***Injection set containing 3 ampoules powder for injection 500 units and 3 ampoules solvent 1 mL***	***1***	***19.77***	***Pregnyl***	***SH***
6178E	***Injection set containing 3 ampoules powder for injection 1,500 units and 3 ampoules solvent 1 mL***	***1***	***28.06***	***Pregnyl***	***SH***

continued ☞

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer $	Proprietary Name and Manufacturer	
6181H	***Injection set containing 3 ampoules powder for injection 5,000 units and 3 ampoules solvent 1 mL***	***1***	***34.47***	***Pregnyl***	***SH***

PROGESTERONE

For luteal phase support in patients who are receiving medical treatment as described in item 13200 of the Medicare Benefits Schedule. The luteal phase is defined as the time span from embryo transfer until implantation confirmed by positive B-hCG measurement.

NOTE:
Arrangements to prescribe this item should be made by medical practitioners with Medicare Australia, contact telephone number 1800 700 270.

6366C	***Vaginal gel (prolonged release) 90 mg in single dose pre-filled applicator***	***15***	***148.50***	***Crinone 8%***	***SG***

NOTE:
This price is based on special supply arrangements—see Pharmaceutical Benefits Pricing Authority relativity sheet for full details. Relativity sheets are available on the Department of Health and Ageing's internet site (visit www.health.gov.au and search for 'relativity sheets').

9608Q	***Pessary 100 mg***	***15***	***43.50***	***ON***	
9609R	***Pessary 200 mg***	***15***	***48.00***	***ON***	

OPIATE DEPENDENCE TREATMENT PROGRAM

The Australian Government funds the cost of buprenorphine hydrochloride, buprenorphine hydrochloride with naloxone hydrochloride and methadone hydrochloride supplied as pharmaceutical benefits through clinics and pharmacies approved by State and Territory governments. For further information about this program, please contact your State or Territory Government.

BUPRENORPHINE HYDROCHLORIDE

Treatment of opiate dependence, including maintenance and detoxification (withdrawal), within a framework of medical, social and psychological treatment.

NOTE:
Treatment must be in accordance with the law of the relevant State or Territory.

6307Y	***Sublingual tablet 400 micrograms (base)***	***7***	***6.16***	***Subutex***	***RC***
6308B	***Sublingual tablet 2 mg (base)***	***7***	***10.50***	***Subutex***	***RC***
6309C	***Sublingual tablet 8 mg (base)***	***7***	***30.10***	***Subutex***	***RC***

BUPRENORPHINE HYDROCHLORIDE with NALOXONE HYDROCHLORIDE

Treatment of opiate dependence within a framework of medical, social and psychological treatment.

NOTE:
Treatment must be in accordance with the law of the relevant State or Territory.

6470M	***Sublingual tablet 2 mg (base)-0.5 mg (base)***	***28***	***42.00***	***Suboxone***	***RC***
6471N	***Sublingual tablet 8 mg (base)-2 mg (base)***	***28***	***120.40***	***Suboxone***	***RC***

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer $	Proprietary Name and Manufacturer	
	METHADONE HYDROCHLORIDE				
	CAUTION:				
	The risk of drug dependence is high.				
	Treatment of opiate dependence in accordance with the law of the relevant State or Territory.				
6171T	***Oral liquid 25 mg per 5 mL, 200 mL***	***1***	***7.40***	[a] ***Biodone Forte*** [a] ***SI***	***MW***
6172W	***Oral liquid 25 mg per 5 mL, 1 L***	***1***	***35.28***	[a] ***Biodone Forte*** [a] ***SI***	***MW***

SPECIAL AUTHORITY PROGRAM

TRASTUZUMAB

NOTE:

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

Written applications for authority to prescribe trastuzumab should be forwarded to:

Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

Further prescribing information is on the Medicare Australia website at www.medicareaustralia.gov.au.

Section 100 authority required

Initial treatment for HER2 positive early breast cancer commencing concurrently with adjuvant chemotherapy following surgery.

The total duration of PBS-subsidised treatment (initial plus continuing) that will be authorised is 52 weeks.

HER2 positivity must be demonstrated by in situ hybridisation (ISH).

Trastuzumab must not be used in patients with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure. Cardiac function must be tested by a suitable method including, for example, ECHO or MUGA, prior to seeking the initial authority approval and then at 3 monthly intervals during treatment.

Authority applications for initial treatment must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Early Breast Cancer - PBS Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes:
(i) a copy of the pathology report from an Approved Pathology Authority confirming the presence of HER2 gene amplification by in situ hybridisation (ISH); and
(ii) a copy of the signed patient acknowledgement form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].

The medical practitioner should request sufficient quantity based on the weight of the patient to provide for a maximum of 3 weeks' treatment (equivalent to the loading dose for the 3 weekly regimen, and the loading dose and 2 weekly doses for the once weekly regimen).

Section 100 authority required

Continuing treatment for HER2 positive early breast cancer where the patient has previously received treatment with PBS-subsidised trastuzumab.

The patient is eligible to receive sufficient trastuzumab to complete 52 weeks of combined PBS-subsidised and non-PBS-subsidised therapy.

Trastuzumab must not be used in patients with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure. Cardiac function must be tested by a suitable method including, for example, ECHO or MUGA, at 3 monthly intervals during treatment.

continued ☞

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer $	Proprietary Name and Manufacturer	
	Authority applications for continuing treatment may be made by telephone on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).				
	The medical practitioner should request sufficient quantity based on the weight of the patient for 3 weeks' supply (equivalent to 1 dose for the 3 weekly dosing regimen, or 3 doses for the once weekly dosing regimen). Up to a maximum of 3 repeats may be authorised.				
	Breaks in therapy. ***Where a patient has a break in trastuzumab therapy of more than 1 week but less than 6 weeks from when the last dose was due, authority approval will be granted for a new loading dose. Authority applications for new loading doses may be made by telephone on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).***				
6497Y	***Powder for I.V. infusion 150 mg***	***1***	***1030.21***	***Herceptin***	***RO***

Section 3

Container Prices, Fees, Standard Packs and Prices for Ready Prepared Pharmaceutical Benefits

CONTAINER PRICES FOR QUANTITIES OF READY PREPARED BENEFITS LESS THAN THE STANDARD PACK:

Injectables	**150 mL vial**	**$0.71**
Other Items	**25 mL vial**	**$0.28**

(The 25 mL is the most commonly used size)

FEES:

Dispensing Fee for Ready Prepared Benefits	**$5.99**
Dangerous Drug Fee	**$2.71**
Additional Fee for Agreed Price Ready Prepared Benefits	**$1.03**

NOTE -

Standard packs and prices (including mark-up, but without dispensing fee and dangerous drug fee) are for items against the price of which an asterisk (*) is shown in Section 2 of the Schedule.

(APPLY WASTAGE FACTOR IN CALCULATING BROKEN QUANTITY PRICES)

Code	Name	Form/Strength	Pack and Price $	Manufacturer

EMERGENCY DRUG (DOCTOR'S BAG) SUPPLIES

3486L	Benzylpenicillin	600 mg	1 @ 3.44	CS
3463G	Diphtheria and Tetanus Vaccine, Adsorbed, Diluted For Adult Use	0.5 mL	5 @ 67.15	CS
3470P	Hydrocortisone Sodium Succinate	100 mg with 2 mL solvent	1 @ 5.36	PH
3481F	Naloxone Hydrochloride	800 mcg in 2 mL	1 @ 20.94	CS
3482G		2 mg in 5 mL	1 @ 33.48	CS
3488N	Promethazine Hydrochloride	50 mg in 2 mL	5 @ 7.95	HH

SPECIAL PHARMACEUTICAL BENEFITS - FOR GENERAL USE

2315W	Bleomycin Sulfate	15,000 i.u.	1 @ 48.58 (for reimbursement price)	HH
			1 @ 92.28 (for total dispensed price)	HH
8298R	Naratriptan Hydrochloride	2.5 mg (base)	2 @ 9.74 (for reimbursement price)	GK
			2 @ 11.13 (for total dispensed price)	GK
9734H		2.5 mg (base)	2 @ 11.13 (for reimbursement price)	GK
			2 @ 11.13 (for total dispensed price)	GK
8266C	Zolmitriptan	2.5 mg	2 @ 9.71 (for reimbursement price)	AP
			2 @ 11.09 (for total dispensed price)	AP
9736K		2.5 mg	2 @ 11.09 (for reimbursement price)	AP
			2 @ 11.09 (for total dispensed price)	AP

GENERAL PHARMACEUTICAL BENEFITS

8048N	Abciximab	10 mg in 5 mL	1 @ 482.23	LY
8747J	Acetylcysteine	200 mg per mL, 5 mL	6 @ 28.11	BQ
1003T	Aciclovir	200 mg	25 @ 31.56	AF, GM, SZ
			25 @ 33.73	GK
2600W	Allopurinol	100 mg	100 @ 3.39	AF
2576N	Aluminium Hydroxide with Magnesium Hydroxide	200 mg-200 mg	100 @ 4.83	JT
2157M		200 mg-200 mg per 5 mL, 500 mL	1 @ 4.83	JT
2159P	Aluminium Hydroxide with Magnesium Trisilicate and Magnesium Hydroxide	250 mg-120 mg-120 mg per 5 mL, 500 mL	1 @ 4.01	FM
3109P	Amiloride Hydrochloride	5 mg	50 @ 2.28	AF
3079C	Amino Acid Formula without Methionine, Threonine and Valine and low in Isoleucine	200 g	1 @ 208.40	SB
8554F	Amino Acid Formula without Phenylalanine	500 mg, 200	1 @ 79.37	SB
8678R		1 g, 75	1 @ 59.19	SB
8706F		42 g, 20	1 @ 156.49	SB
2347M		20 g, 30	1 @ 208.07	SB
3072Q		250 g	1 @ 150.43	SB

(APPLY WASTAGE FACTOR IN CALCULATING BROKEN QUANTITY PRICES)

Code	Name	Form/Strength	Pack and Price $	Manufacturer
1411G	Amino Acid Formula without Phenylalanine, and Vitamins with Minerals	Pack containing 60 sachets/60 tablets	1 @ 544.55	SB
2379F	Amino Acid Formula without Phenylalanine, Tyrosine and Methionine	500 g	1 @ 666.39	SB
8479G	Amino Acid Formula with Vitamins, Minerals and Long Chain Polyunsaturated Fatty Acids without Phenylalanine	400 g	1 @ 87.15	SB
2650L	Amino Acid Formula with Vitamins and Minerals without Lysine and low in Tryptophan	400 g	1 @ 83.41	SB
2646G		500 g	1 @ 202.28	SB
8417B	Amino Acid Formula with Vitamins and Minerals without Methionine	400 g	1 @ 95.36	SB
8677Q		20 g, 30	1 @ 448.00	VF
8744F		25 g, 30	1 @ 772.99	VF
8328H		500 g	1 @ 222.29	SB
8416Y		500 g	1 @ 337.29	SB
9133Q		130 mL, 30	1 @ 772.99	VF
8058D	Amino Acid Formula with Vitamins and Minerals without Methionine, Threonine and Valine and low in Isoleucine	400 g	1 @ 77.88	SB
8059E		500 g	1 @ 192.04	SB
8061G		500 g	1 @ 240.69	SB
8555G	Amino Acid Formula with Vitamins and Minerals without Phenylalanine	20 g, 30	1 @ 221.15	VF
8591E		25 g, 30	1 @ 385.68	VF
8804J		27.8 g, 30	1 @ 514.34	SB
8613H		29 g, 30	1 @ 221.42	SB
8727H		50 g, 30	1 @ 501.88	SB
2737C		400 g	1 @ 75.00	SB
8467P		325 g	1 @ 85.54	AB
8545R		400 g	1 @ 105.27	AB
2738D		500 g	1 @ 109.70	SB
2739E		500 g	1 @ 168.25	SB
8746H		250 mL	18 @ 261.37	SB
2382J		87 mL, 30	1 @ 257.09	VF
9021T		125 mL, 30	1 @ 514.34	SB
8846N		130 mL, 30	1 @ 385.48	VF
2474F		174 mL, 30	1 @ 511.90	VF
8631G	Amino Acid Formula with Vitamins and Minerals without Phenylalanine and Tyrosine	20 g, 30	1 @ 448.00	VF
8667E		25 g, 30	1 @ 772.99	VF
8445L		400 g	1 @ 95.36	SB
8446M		500 g	1 @ 222.29	SB
3078B		500 g	1 @ 337.29	SB
9132P		130 mL, 30	1 @ 772.99	VF
8592F	Amino Acid Formula with Vitamins and Minerals without Valine, Leucine and Isoleucine	20 g, 30	1 @ 448.00	VF
8632H		25 g, 30	1 @ 772.99	VF
8745G		29 g, 30	1 @ 448.51	SB
2380G		400 g	1 @ 95.36	SB

(APPLY WASTAGE FACTOR IN CALCULATING BROKEN QUANTITY PRICES)

Code	Name	Form/Strength	Pack and Price $	Manufacturer
8310J		500 g	1 @ 666.39	SB
8260R		500 g	1 @ 222.29	SB
8057C		500 g	1 @ 337.29	SB
2375B		130 mL, 30	1 @ 772.99	VF
2250K	Amino Acids—Synthetic, Formula	400 g	1 @ 43.77	AB
8574G		400 g	1 @ 44.34	AB
8443J		400 g	1 @ 44.34	SB
8754R		400 g	1 @ 44.34	SB
2244D		400 g	1 @ 44.34	SB
8575H		400 g	1 @ 44.34	AB
3066J		400 g	1 @ 44.34	SB
8755T		400 g	1 @ 44.34	SB
2553J		400 g	1 @ 44.34	SB
2246F	Amino Acid Synthetic Formula supplemented with Long Chain Polyunsaturated Fatty Acids	400 g	1 @ 45.18	SB
2560R		400 g	1 @ 45.18	SB
8736T	Amisulpride	100 mg per mL, 60 mL	1 @ 71.16	SW
9386B	Amylopectin, Modified Long Chain	60 g, 30	1 @ 186.47	VF
9092M	Atomoxetine Hydrochloride	10 mg (base)	28 @ 107.38	LY
9093N		18 mg (base)	28 @ 107.38	LY
9094P		25 mg (base)	28 @ 107.38	LY
9095Q		40 mg (base)	28 @ 107.38	LY
9096R		60 mg (base)	28 @ 107.38	LY
1140B	Bcg Immunotherapeutic (bacillus Calmette-guérin/ Connaught Strain)	6.6 to 19.2 x 10^8 CFU set	1 @ 151.15	SW
1775K	Benzylpenicillin	600 mg	1 @ 3.44	CS
2647H		3 g	1 @ 5.65	CS
2812B	Betamethasone Valerate	200 mcg (base) per g, 100 g	1 @ 9.45	EX, FM, SH
			1 @ 12.54	SI
2820K		200 mcg (base) per g, 100 g	1 @ 9.45	EX, SH
8066M	Bifonazole	10 mg per g, 15 g	1 @ 9.69	BN
2544X	Biperiden Hydrochloride	2 mg	100 @ 7.23	LM
1260H	Bisacodyl	10 mg, 10	1 @ 5.15	PP
			1 @ 5.53	BY
1258F		10 mg, 12	1 @ 4.21	FL, PP
9117W	Bortezomib	3.5 mg	1 @ 1748.99	JC
9118X		3.5 mg	1 @ 1748.99	JC
8560M	Calcium	250 mg	120 @ 7.89	BN
3116B		500 mg	60 @ 4.91	IA
8740B	Calcium Folinate	equiv. to 50 mg folinic acid in 5 mL	1 @ 29.68	HH
			10 @ 234.55	PF
8812T		equiv. to 100 mg folinic acid in 10 mL	1 @ 26.70	IT
9041W		equiv. to 300 mg folinic acid in 30 mL	1 @ 77.31	HH
1153Q	Carbimazole	5 mg	100 @ 12.31	LM
8576J	Carbohydrate, Fat, Vitamins, Minerals and Trace Elements	400 g	1 @ 31.76	AB
8369L		400 g	1 @ 35.63	SB
8514D	Carbomer 974	3 mg per g, 0.5 g, 30	1 @ 9.88	AQ
8578L	Carbomer 980	2 mg per g, 0.6 mL, 30	1 @ 9.68	NV

(APPLY WASTAGE FACTOR IN CALCULATING BROKEN QUANTITY PRICES)

Code	Name	Form/Strength	Pack and Price $		Manufacturer
1160C	Carboplatin	50 mg in 5 mL	1 @	30.94	HH, IT, PU
1161D		150 mg in 15 mL	1 @	70.92	HH, IT, PU
1162E		450 mg in 45 mL	1 @	136.98	BX, HH, IT, PU
8823J	Carmellose Sodium	2.5 mg per mL, 0.6 mL, 24	1 @	8.50	CX
2338C		5 mg per mL, 0.4 mL, 30	1 @	9.88	AG
2324H		10 mg per mL, 0.4 mL, 30	1 @	9.88	AG
8824K		10 mg per mL, 0.6 mL, 28	1 @	9.22	CX
8315P	Cefepime	1 g	1 @	17.74	BQ
8316Q		2 g	1 @	32.52	BQ
1085D	Cefotaxime	1 g	1 @	4.64	SZ
1086E		2 g	1 @	8.51	SZ
1783W	Ceftriaxone	500 mg	1 @	4.07	IZ
1784X		1 g	1 @	6.36	HH, IZ, RO, SZ
1785Y		2 g	1 @	11.28	HH, IZ, RO, SZ
1256D	Cephazolin	500 mg	5 @	19.57	HH
1257E		1 g	5 @	30.05	HH
1163F	Chlorambucil	2 mg	25 @	32.89	GK
1585K	Chlorthalidone	25 mg	50 @	3.61	LM
2967E	Cholestyramine	4.7 g (equiv. to 4 g cholestyramine)	1 @	25.52	BQ
9249T		4.7 g (equivalent to 4 g cholestyramine)	1 @	25.52	BQ
1217C	Ciprofloxacin	3 mg per mL, 5 mL	1 @	9.96	IQ
			1 @	10.88	AQ
8800E	Cladribine	10 mg in 5 mL	1 @	660.45	OA
1211R	Clomiphene Citrate	50 mg	5 @	13.34	GX, HX, SI
1805B	Clonazepam	500 mcg	100 @	6.89	AF
			100 @	8.68	RO
1806C		2 mg	100 @	12.96	AF
			100 @	15.00	RO
1808E		2.5 mg per mL, 10 mL	1 @	4.31	RO
1027C	Clotrimazole	10 mg per mL, 20 mL	1 @	5.97	BN
8785J	Codeine Phosphate with Paracetamol	30 mg-500 mg	20 @	1.66	AL, AV, CO, FM, SZ
			20 @	4.46	SW
1228P	Copper Sulfate	Tablets, 36	1 @	32.53	BN
9251X		Tablets, 36	1 @	32.53	BN
1079T	Cyclophosphamide	500 mg	1 @	11.67	BX
8657P	Cyclosporin	10 mg	60 @	44.00	NV
8658Q		25 mg	30 @	48.25	SZ
			30 @	49.39	NV
8659R		50 mg	30 @	100.26	SZ
			30 @	101.38	NV
8660T		100 mg	30 @	194.94	SZ
			30 @	196.07	NV
8661W		100 mg per mL, 50 mL	1 @	353.12	NV
1798P	Cyproheptadine Hydrochloride	4 mg	50 @	3.89	AS
1270W	Cyproterone Acetate	50 mg	50 @	100.65	AF, GM, GX, SY, SZ
			50 @	102.15	SC
9164H	Cystine with Carbohydrate	4 g containing 500 mg cystine, 30	1 @	127.40	VF
2884T	Cytarabine	100 mg in 5 mL	5 @	44.55	PU
8641T	Dalteparin Sodium (low Molecular Weight Heparin Sodium—Porcine Mucous)	2,500 units (anti-Xa) in 0.2 mL	10 @	49.16	PH

(APPLY WASTAGE FACTOR IN CALCULATING BROKEN QUANTITY PRICES)

Code	Name	Form/Strength	Pack and Price $		Manufacturer
8642W		5,000 units (anti-Xa) in 0.2 mL	10 @	51.23	PH
8643X		7,500 units (anti-Xa) in 0.75 mL	10 @	77.23	PH
8662X	Desmopressin Acetate	200 mcg	30 @	57.83	FP
2129C		100 mcg per mL, 2.5 mL	1 @	30.95	FP
8711L		10 mcg per actuation, 60 actuations, 6 mL	1 @	77.31	FP
1302M	Diclofenac Sodium	100 mg	20 @	9.25	NV
1299J		25 mg (e.c.)	50 @	3.32	AW, CH, GM, GN, GX, SZ, TW
			50 @	4.30	NV
3164M	Digoxin	50 mcg per mL, 60 mL	1 @	11.13	SI
8461H	Disodium Pamidronate	15 mg in 5 mL	1 @	64.45	HH
8462J		30 mg in 10 mL	1 @	128.90	HH
8071T	Docetaxel	20 mg (anhydrous) set	1 @	327.33	SW
1336H	Doxorubicin Hydrochloride	10 mg in 5 mL	1 @	34.11	HH, IT, PH
1340M		20 mg in 10 mL	1 @	59.96	PH
1342P		50 mg in 25 mL	1 @	137.11	HH, IT, PH
9107H	Doxycycline	100 mg (as monohydrate)	7 @	2.05	CH, GX, SZ, TW
2702F		100 mg (as hydrochloride)	7 @	2.05	AF, GM, SI
			7 @	3.24	PF
2703G		100 mg (as hydrochloride)	7 @	2.05	FA
			7 @	3.20	HH
9108J		100 mg (as monohydrate)	7 @	2.05	CH, SZ, TW
2714W		100 mg (as hydrochloride)	7 @	2.05	AF, GM, SI
			7 @	3.24	PF
3199J	Electrolyte Replacement Solution	1 L	1 @	7.77	BX
8716R	Enoxaparin Sodium	20 mg (2,000 i.u. anti-Xa) in 0.2 mL	10 @	49.16	SW
8639Q		40 mg (4,000 i.u. anti-Xa) in 0.4 mL	10 @	51.23	SW
9196B		40 mg (4,000 i.u. anti-Xa) in 0.4 mL	10 @	51.23	SW
8640R		60 mg (6,000 i.u. anti-Xa) in 0.6 mL	10 @	73.26	SW
8367J	Entacapone	200 mg	100 @	137.70	NV
1375J	Epirubicin Hydrochloride	10 mg in 5 mL	1 @	53.34	IT, PH
1376K		20 mg in 10 mL	1 @	98.77	PH
1377L		50 mg in 25 mL	1 @	242.42	HH, IT, PH
8817C		100 mg in 50 mL	1 @	478.33	HH, IT
8397Y	Eprosartan Mesylate	400 mg (base)	28 @	13.09	SM
8951D		400 mg (base)	28 @	13.09	SM
8683B	Eptifibatide Acetate	20 mg (base) in 10 mL	1 @	128.06	SH
8684C		75 mg (base) in 100 mL	1 @	337.98	SH
1397M	Erythromycin Lactobionate	1 g (base)	1 @	8.99	LM
8001D	Essential Amino Acids Formula with Minerals and Vitamin C	200 g	1 @	62.77	SB
2027Q		400 g	1 @	125.55	SB
9385Y	Essential Amino Acids Formula with Vitamins and Minerals	12.5 g, 50	1 @	377.52	VF
8778B	Etanercept	25 mg and 1 mL solvent, 4	1 @	911.29	WX
8779C		25 mg and 1 mL solvent, 4	1 @	911.29	WX
9035M		25 mg and 1 mL solvent, 4	1 @	911.29	WX
9036N		25 mg and 1 mL solvent, 4	1 @	911.29	WX
8637N		25 mg and 1 mL solvent, 4	1 @	911.29	WX
8638P		25 mg and 1 mL solvent, 4	1 @	911.29	WX

(APPLY WASTAGE FACTOR IN CALCULATING BROKEN QUANTITY PRICES)

Code	Name	Form/Strength	Pack and Price $	Manufacturer
9037P		25 mg and 1 mL solvent, 4	1 @ 911.29	WX
8748K	Ethacrynic Acid	25 mg	100 @ 25.63	FK
1390E	Etoposide	100 mg in 5 mL	1 @ 33.37	HH
8120J	Etoposide Phosphate	113.6 mg (equiv. to 100 mg etoposide)	1 @ 33.37	BQ
8842J	Everolimus	0.75 mg	60 @ 786.10	NV
1473M	Fluconazole	100 mg in 50 mL	1 @ 22.75	PF, SZ
1474N		200 mg in 100 mL	1 @ 41.47	BX, PF, SZ
1433K	Fludrocortisone Acetate	100 mcg	100 @ 8.04	BQ
2528C	Fluorouracil	500 mg in 10 mL	1 @ 5.13	HH
			5 @ 25.65	IT
9005Y		1000 mg in 20 mL	1 @ 8.83	IT
2958Q	Folic Acid	500 mcg	100 @ 3.68	AF
1437P		5 mg	100 @ 3.80	AF
8672K	Follitropin Alfa	75 i.u.	1 @ 48.23	SG
8713N		300 i.u.	1 @ 185.67	SG
8675N		450 i.u.	1 @ 278.49	SG
8714P		450 i.u.	1 @ 278.50	SG
8715Q		900 i.u.	1 @ 554.41	SG
8565T	Follitropin Beta	300 i.u. in 0.36 mL	1 @ 185.67	SH
8566W		600 i.u. in 0.72 mL	1 @ 371.33	SH
8871X		900 i.u. in 1.08 mL	1 @ 554.40	SH
2414C	Frusemide	20 mg	50 @ 1.30	FM
			50 @ 2.25	SW
8444K	Gelatin - Succinylated	20 g per 500 mL, 500 mL	1 @ 13.11	BR
8049P	Gemcitabine Hydrochloride	200 mg (base)	1 @ 57.38	LY
8050Q		1 g (base)	1 @ 271.56	LY
2824P	Gentamicin Sulfate	80 mg (base) in 2 mL	5 @ 7.04	HH
2245E	Glucose	278 mmol per L, 1 L	1 @ 3.90	BX
3106L	Glucose and Ketone Indicator—Urine	Reagent strips, 50	1 @ 5.44	RD
3107M		Reagent strips, 50	1 @ 5.50	BN
9254C		Reagent strips, 50	1 @ 5.44	RD
9255D		Reagent strips, 50	1 @ 5.50	BN
9193W	Glucose Indicator—Blood	Electrode strips, 25	1 @ 11.69	PZ
2979T		Electrode strips, 50	1 @ 23.38	RD
2891E		Electrode strips, 50	1 @ 23.38	RD
9358M		Electrode strips, 50	1 @ 23.38	MS
8890X		Electrode strips, 50	1 @ 23.38	MS
1820T		Electrode strips, 50	1 @ 23.38	DB
9013J		Electrode strips, 50	1 @ 23.38	OZ
8766J		Electrode strips, 50	1 @ 23.38	OZ
8749L		Electrode strips, 50	1 @ 23.38	OZ
8682Y		Electrode strips, 50	1 @ 23.38	WF
8723D		Electrode strips, 50	1 @ 23.38	BR
9063B		Electrode strips, 50	1 @ 23.38	BR
2263D		Electrode strips, 50	1 @ 23.38	MS
8825L		Electrode strips, 50	1 @ 23.38	DB
8190C		Reagent strips, 50	1 @ 23.38	RD
8739Y		Reagent strips, 50	1 @ 23.38	RD
8806L		Reagent strips, 51	1 @ 23.38	RD
2890D		Reagent strips, 50	1 @ 23.38	NA
2860M		Reagent strips, 50	1 @ 23.38	NA
8759B		Reagent strips, 50	1 @ 23.38	LB
2914J		Reagent strips, 50	1 @ 19.74	NA

(APPLY WASTAGE FACTOR IN CALCULATING BROKEN QUANTITY PRICES)

Code	Name	Form/Strength	Pack and Price $	Manufacturer
2917M		Reagent strips, 50	1 @ 19.74	BN
8795X		Reagent strips, 50	1 @ 23.38	PX
9256E		Electrode strips, 25	1 @ 11.69	PZ
9257F		Electrode strips, 50	1 @ 23.38	RD
9258G		Electrode strips, 50	1 @ 23.38	RD
9359N		Electrode strips, 50	1 @ 23.38	MS
9259H		Electrode strips, 50	1 @ 23.38	MS
9260J		Electrode strips, 50	1 @ 23.38	DB
9261K		Electrode strips, 50	1 @ 23.38	OZ
9262L		Electrode strips, 50	1 @ 23.38	OZ
9263M		Electrode strips, 50	1 @ 23.38	OZ
9264N		Electrode strips, 50	1 @ 23.38	WF
9265P		Electrode strips, 50	1 @ 23.38	BR
9266Q		Electrode strips, 50	1 @ 23.38	BR
9267R		Electrode strips, 50	1 @ 23.38	MS
9268T		Electrode strips, 50	1 @ 23.38	DB
9273C		Reagent strips, 50	1 @ 23.38	RD
9274D		Reagent strips, 50	1 @ 23.38	RD
9275E		Reagent strips, 51	1 @ 23.38	RD
9276F		Reagent strips, 50	1 @ 23.38	NA
9277G		Reagent strips, 50	1 @ 23.38	NA
9278H		Reagent strips, 50	1 @ 23.38	LB
9279J		Reagent strips, 50	1 @ 19.74	NA
9280K		Reagent strips, 50	1 @ 19.74	BN
9281L		Reagent strips, 50	1 @ 23.38	PX
2352T	Glucose Indicator—Urine	Reagent strips, 50	1 @ 6.70	BN
3104J		Reagent strips, 50	1 @ 6.21	BN
9252Y		Reagent strips, 50	1 @ 6.70	BN
9253B		Reagent strips, 50	1 @ 6.21	BN
2555L	Glycerol	700 mg, 12	1 @ 3.83	PP
2556M		1.4 g, 12	1 @ 3.96	PP
2557N		2.8 g, 12	1 @ 4.11	PP
8728J	Granisetron Hydrochloride	2 mg (base)	1 @ 26.28	HH
1076P	Heparin Sodium	35,000 units in 35 mL	1 @ 22.68	HH
1583H	Human Chorionic Gonadotrophin	500 units set	1 @ 23.51	SH
1640H	Hydralazine Hydrochloride	25 mg	100 @ 4.54	AF
1639G		50 mg	100 @ 5.50	AF
1486F	Hydrochlorothiazide with Amiloride Hydrochloride	50 mg-5 mg	50 @ 3.73	MK
1502C	Hydrocortisone Acetate	21.1 g	1 @ 16.28	AS
1501B	Hydrocortisone Sodium Succinate	100 mg with 2 mL solvent	1 @ 5.36	PH
1510L		100 mg with 2 mL solvent	1 @ 5.36	PH
1511M		250 mg with 2 mL solvent	1 @ 9.27	PH
8299T	Hypromellose with Dextran	3 mg-1 mg per mL, 0.4 mL, 28	1 @ 9.22	AQ
3198H	Ibuprofen	200 mg	50 @ 2.82	AF
3190X		400 mg	30 @ 2.77	AB
2446R	Idarubicin Hydrochloride	5 mg	1 @ 80.23	PH
2448W		10 mg	1 @ 148.40	PH
8076C	Ifosfamide	1 g	1 @ 51.03	BX
8077D		2 g	1 @ 94.15	BX
2757D	Indomethacin	100 mg	20 @ 8.04	AS
2454E		25 mg	50 @ 2.83	AF
			50 @ 3.29	AS

(APPLY WASTAGE FACTOR IN CALCULATING BROKEN QUANTITY PRICES)

Code	Name	Form/Strength	Pack and Price $	Manufacturer
8571D	Insulin Aspart	100 units per mL, 10 mL	1 @ 30.57	NO
8435Y		100 units per mL, 3 mL, 5	1 @ 51.56	NF, NO
8609D	Insulin Aspart—Insulin Aspart Protamine Suspension	100 units (30 units-70 units) per mL, 3 mL, 5	1 @ 51.56	NF, NO
9040T	Insulin Detemir	100 units per mL, 3 mL, 5	1 @ 85.26	NF, NO
9039R	Insulin Glargine	100 units per mL, 3 mL, 5	1 @ 85.26	AV, SW
9224L	Insulin Glulisine	100 units per mL, 10 mL	1 @ 30.57	SW
1921D		100 units per mL, 3 mL, 5	1 @ 51.56	SW
1711C	Insulin Isophane (n.p.h.)	100 units per mL, 10 mL	1 @ 27.72	AS
1533Q		100 units per mL, 10 mL	1 @ 25.48	LY, NO
1761Q		100 units per mL, 3 mL, 5	1 @ 43.58	LY, NI, NL, NO
8084L	Insulin Lispro	100 units per mL, 10 mL	1 @ 30.57	LY
8212F		100 units per mL, 3 mL, 5	1 @ 51.56	LY
8390N	Insulin Lispro—Insulin Lispro Protamine Suspension	100 units (25 units-75 units) per mL, 3 mL, 5	1 @ 51.56	LY
8874C		100 units (50 units-50 units) per mL, 3 mL, 5	1 @ 51.56	LY
1713E	Insulin Neutral	100 units per mL, 10 mL	1 @ 27.72	AS
1531N		100 units per mL, 10 mL	1 @ 25.48	LY, NO
1762R		100 units per mL, 3 mL, 5	1 @ 43.58	LY, NO
1426C	Insulin Neutral—Insulin Isophane (n.p.h.), (mixed) (biphasic Isophane)	100 units (30 units-70 units) per mL, 10 mL	1 @ 25.48	LY
1763T		100 units (30 units-70 units) per mL, 3 mL, 5	1 @ 43.58	LY, NI, NO
2062M		100 units (50 units-50 units) per mL, 3 mL, 5	1 @ 43.58	NO
8180M	Interferon Alfa-2a	3,000,000 i.u. in 0.5 mL	1 @ 33.32	RO
8551C		4,500,000 i.u. in 0.5 mL	1 @ 51.66	RO
8552D		6,000,000 i.u. in 0.5 mL	1 @ 67.66	RO
8553E		9,000,000 i.u. in 0.5 mL	1 @ 99.94	RO
8181N		3,000,000 i.u. in 0.5 mL	1 @ 33.32	RO
8182P		4,500,000 i.u. in 0.5 mL	1 @ 51.66	RO
8183Q		6,000,000 i.u. in 0.5 mL	1 @ 67.66	RO
8184R		9,000,000 i.u. in 0.5 mL	1 @ 99.94	RO
8572E	Interferon Alfa-2b	18,000,000 i.u. in 1.2 mL	1 @ 199.87	SH
8348J		18,000,000 i.u. in 1.2 mL	1 @ 199.87	SH
8476D		30,000,000 i.u. in 1.2 mL	1 @ 333.11	SH
8671J	Ipratropium Bromide	21 mcg per dose (200 doses)	1 @ 14.43	BY
1542E		250 mcg (anhydrous) in 1 mL, 30	1 @ 15.43	AF, GM, PU, SI, TX
			1 @ 15.79	BY
8238N		500 mcg (anhydrous) in 1 mL, 30	1 @ 18.11	AF, GM, PU, SI, TX
			1 @ 18.42	BY
8415X	Irinotecan Hydrochloride Trihydrate	100 mg in 5 mL	1 @ 323.62	HH, PU, SZ
9134R	Isoleucine with Carbohydrate	4 g containing 50 mg isoleucine, 30	1 @ 127.40	VF
2587E	Isosorbide Dinitrate	10 mg	100 @ 3.86	AF
2588F		5 mg	100 @ 4.31	SI
1588N	Ketoprofen	100 mg	20 @ 9.44	SW
9148L	Lapatinib	250 mg (as ditosylate monohydrate)	70 @ 1690.52	GK
8797B	Levodopa with Carbidopa and Entacapone	50 mg-12.5 mg-200 mg	100 @ 152.73	NV
8798C		100 mg-25 mg-200 mg	100 @ 167.75	NV
8799D		150 mg-37.5 mg-200 mg	100 @ 182.77	NV

(APPLY WASTAGE FACTOR IN CALCULATING BROKEN QUANTITY PRICES)

Code	Name	Form/Strength	Pack and Price $	Manufacturer
9292C		200 mg-50 mg-200 mg	100 @ 196.60	NV
8290H	Lithium Carbonate	450 mg (s.r.)	100 @ 13.94	GK
1598D	Mercaptopurine	50 mg	25 @ 56.47	GK
8731M	Mesalazine	500 mg (e.c.)	100 @ 145.51	OA
2214M		500 mg (p.r.)	100 @ 145.51	FP
8598M		500 mg	100 @ 145.51	OA
8753Q		1 g in 100 mL, 7	1 @ 82.45	FP
8616L		2 g in 60 mL, 7	1 @ 82.45	OA
8617M		4 g in 60 mL, 7	1 @ 109.87	OA
8768L		80 g	1 @ 82.45	OA
1606M	Methadone Hydrochloride	10 mg in 1 mL	10 @ 46.94	SI
2826R	Methysergide	1 mg	50 @ 19.27	LM
1638F	Metronidazole	500 mg in 100 mL	1 @ 5.11	BX
			10 @ 39.34	HH, SZ
9026C	Miconazole Nitrate	20 mg per g, 15 g	1 @ 4.74	JT
8282X	Milk Powder—Lactose Free Formula	900 g	1 @ 18.15	WX
2350Q		900 g	1 @ 16.50	NU
8283Y		900 g	1 @ 18.15	WX
2349P		900 g	1 @ 16.50	NU
2358D	Milk Powder—Lactose Modified	900 g	1 @ 18.87	SJ
2357C		900 g	1 @ 18.87	SJ
3092R	Milk Powder—Synthetic	400 g	1 @ 46.87	NU
8630F	Milk Protein and Fat Formula with Vitamins and Minerals—Carbohydrate Free	225 g	1 @ 26.75	SB
8816B	Modafinil	100 mg	60 @ 170.28	CS
1674D	Naproxen	250 mg	50 @ 3.65	AF
			50 @ 4.82	RO
9285Q	Nilotinib	200 mg (as hydrochloride monohydrate)	28 @ 1371.00	NV
9171Q		200 mg (as hydrochloride monohydrate)	28 @ 1371.00	NV
2732T	Nitrazepam	5 mg	25 @ 1.47	AF
			25 @ 3.00	VT
1967M	Norethisterone	350 mcg	1 @ 2.67	JC
			1 @ 2.67	KR
			1 @ 3.67	PH
2772X	Norethisterone with Ethinyloestradiol	500 mcg-35 mcg	1 @ 4.65	PH
2774B		Tablet-Pack	1 @ 2.67	KR
			1 @ 4.65	PH
2773Y		1 mg-35 mcg	1 @ 4.65	PH
2775C		Tablet-Pack	1 @ 2.67	KR
			1 @ 4.65	PH
2776D		Tablet-Pack	1 @ 2.67	KR
			1 @ 4.65	PH
3176E	Norethisterone with Mestranol	1 mg-50 mcg	1 @ 2.67	PH
3179H		Tablet-Pack	1 @ 2.67	PH
1698J	Nystatin	100,000 units per g, 15 g	1 @ 6.07	BQ
1733F	Oestrogens—Conjugated	300 mcg	28 @ 4.58	WX
1734G		625 mcg	28 @ 4.84	WX
8383F	Ofloxacin	3 mg per mL, 5 mL	1 @ 12.86	AG
3134Y	Oxazepam	15 mg	25 @ 1.28	AF
			25 @ 3.06	SI

(APPLY WASTAGE FACTOR IN CALCULATING BROKEN QUANTITY PRICES)

Code	Name	Form/Strength	Pack and Price $		Manufacturer
3135B		30 mg	25 @	1.47	AF, FM
			25 @	3.37	SI
8588B	Oxcarbazepine	60 mg per mL, 250 mL	1 @	65.85	NV
3026G	Paclitaxel	30 mg in 5 mL	1 @	192.73	BQ, BX, HH
8018B		100 mg in 16.7 mL	1 @	639.29	BQ, BX, HH, IT
3017T		150 mg in 25 mL	1 @	931.01	BQ, HH, IT
8556H	Pancreatic Extract	not less than 5,000 BP units lipase activity	100 @	22.56	SM
8020D		not less than 10,000 BP units lipase activity	100 @	32.87	SM
8021E		not less than 25,000 BP units lipase activity	100 @	65.74	SM
9225M		not less than 5,000 BP units lipase activity	100 @	22.56	SM
9226N		not less than 10,000 BP units lipase activity	100 @	32.87	SM
9227P		not less than 25,000 BP units lipase activity	100 @	65.74	SM
8366H	Pancrelipase	not less than 25,000 BP units lipase activity	100 @	65.74	TM
9229R		not less than 25,000 BP units lipase activity	100 @	65.74	TM
8784H	Paracetamol	500 mg	100 @	2.00	CH, FM, GM, HX, PC, SI, SW, SZ, TW, YM
8814X		665 mg (m.r.)	96 @	5.11	GC
1754H	Paraffin	3.5 g	1 @	7.54	IQ
			1 @	8.57	AQ
9217D		3.5 g	1 @	7.54	IQ
			1 @	8.57	AQ
1166J	Phenoxybenzamine Hydrochloride	10 mg, 30	1 @	66.16	GH
1787C	Phenoxymethylpenicillin	250 mg	25 @	2.58	SI
3028J		500 mg	25 @	3.82	SI
9143F		150 mg per 5 mL, 100 mL	1 @	7.99	FM, SI
1703P		250 mg	25 @	2.58	SI
9384X	Phenylalanine with Carbohydrate	4 g containing 50 mg phenylalanine, 30	1 @	127.40	VF
9170P	Polyethylene Glycol 400 with Propylene Glycol	4 mg-3 mg per mL, single dose units 0.8 mL, 28	1 @	13.83	AQ
2334W	Polygeline	17.5 g per 500 mL, 500 mL	1 @	13.11	AE
2642C	Potassium Chloride	600 mg	100 @	3.44	NM
			100 @	4.84	NV
1920C	Prednisolone Sodium Phosphate	equiv. to 20 mg prednisolone in 100 mL	7 @	39.95	SI
2554K		equiv. to 5 mg prednisolone, 10	1 @	10.80	SI
1948M	Promethazine Hydrochloride	50 mg in 2 mL	5 @	7.95	HH
1953T	Propantheline Bromide	15 mg	100 @	10.02	SI
1955X	Propylthiouracil	50 mg	100 @	20.61	PL
2676W	Protein Hydrolysate Formula with Medium Chain Triglycerides	400 g	1 @	20.69	NT
8259Q		450 g	1 @	12.93	NU
8284B	Raltitrexed	2 mg	1 @	283.29	HH

(APPLY WASTAGE FACTOR IN CALCULATING BROKEN QUANTITY PRICES)

Code	Name	Form/Strength	Pack and Price $		Manufacturer
1937Y	Ranitidine Hydrochloride	150 mg (base), effervescent	30 @	7.37	GK
8162N		150 mg (base) per 10 mL, 300 mL	1 @	8.75	GK
8903N		150 mg (base), effervescent	30 @	7.37	GK
8905Q		150 mg (base) per 10 mL, 300 mL	1 @	8.75	GK
8787L	Risperidone	0.5 mg	20 @	10.17	JC, SI, TX
8788M		0.5 mg (orally disintegrating)	28 @	14.23	JC
8790P		1 mg (orally disintegrating)	28 @	27.21	JC
9080X		2 mg (orally disintegrating)	28 @	54.68	JC
8792R		1 mg (orally disintegrating)	28 @	27.21	JC
8794W		2 mg (orally disintegrating)	28 @	54.68	JC
9075P		3 mg (orally disintegrating)	28 @	81.28	JC
9076Q		4 mg (orally disintegrating)	28 @	107.47	JC
8869T		0.5 mg	20 @	10.17	JC, SI, TX
8870W		0.5 mg (orally disintegrating)	28 @	14.23	JC
8780D		25 mg	1 @	157.36	JC
8781E		37.5 mg	1 @	201.99	JC
8782F		50 mg	1 @	246.67	JC
1099W	Salbutamol Sulfate	200 mcg (base)	100 @	6.04	GK
8288F		100 mcg (base) per dose (200 doses)	1 @	4.40	AL, IA
			1 @	4.99	GK
8354Q		100 mcg (base) per dose (200 doses)	1 @	16.09	IA
2000G		2.5 mg (base) in 2.5 mL, 30	1 @	6.26	AF, CR, GM, GX, PU, SI, SZ
			1 @	6.99	GK
2001H		5 mg (base) in 2.5 mL, 30	1 @	6.61	AF, CR, GM, GX, SI, SZ
			1 @	7.34	GK
2003K		5 mg (base) per mL, 30 mL	1 @	2.30	PU
1103C		2 mg (base) per 5 mL, 150 mL	1 @	7.89	GK
2995P	Salcatonin	50 i.u. in 1 mL	5 @	33.54	NV
2997R		100 i.u. in 1 mL	5 @	51.57	NV
2014B	Sodium Alginate with Calcium Carbonate and Sodium Bicarbonate	1 g-320 mg-534 mg in 20 mL, 500 mL	1 @	4.13	RC
2264E	Sodium Chloride	154 mmol per L, 1 L	1 @	3.90	BX
2260Y		513 mmol per L, 1 L	1 @	5.90	BX
2266G	Sodium Chloride Compound	1 L	1 @	5.90	BX
2281C	Sodium Chloride with Glucose	31 mmol-222 mmol per L, 1 L	1 @	3.90	BX
2279Y		19 mmol-104 mmol per 500 mL, 500 mL	1 @	5.12	BX
2278X		39 mmol-69 mmol per 500 mL, 500 mL	1 @	5.12	BX
2286H	Sodium Lactate Compound	1 L	1 @	3.90	BX
2294R	Sodium Valproate	100 mg	100 @	12.79	SW
2289L		200 mg (e.c.)	100 @	13.72	AF, SZ, WA
			100 @	14.47	SW
2290M		500 mg (e.c.)	100 @	25.98	AF, SZ, WA
			100 @	26.73	SW
2293Q		200 mg per 5 mL, 300 mL	1 @	14.25	SW
2295T		200 mg per 5 mL, 300 mL	1 @	14.25	SW
9380Q	Sorafenib	200 mg (as tosylate)	60 @	3225.33	BN
2091C	Sorbitol with Sodium Citrate and Sodium Lauryl Sulfoacetate	3.125 g-450 mg-45 mg in 5 mL, 12	1 @	15.08	JT

(APPLY WASTAGE FACTOR IN CALCULATING BROKEN QUANTITY PRICES)

Code	Name	Form/Strength	Pack and Price $	Manufacturer
8577K	Soy Protein and Fat Formula with Vitamins and Minerals—Carbohydrate Free	384 mL	1 @ 5.53	AB
2093E	Sulfasalazine	500 mg	100 @ 23.16	PH
2096H		500 mg (e.c.)	100 @ 25.31	KR
			100 @ 26.10	PH
9208P		500 mg	100 @ 23.16	PH
9209Q		500 mg (e.c.)	100 @ 25.31	KR
			100 @ 26.10	PH
2047R	Sulindac	100 mg	50 @ 4.96	AF
8144P	Sumatriptan Succinate	50 mg (base)	2 @ 9.55	AF, GK
8885P		50 mg (base) (fast disintegrating)	2 @ 9.55	GK
2248H	Tamarindus Indica Seed Polysaccharide	10 mg per mL, 0.5 mL, 20	1 @ 9.88	JT
2110C	Tamoxifen Citrate	20 mg (base)	30 @ 28.83	AP
2088X	Temazepam	10 mg	25 @ 1.47	AF, FM
			25 @ 2.85	SI
8819E	Temozolomide	5 mg	5 @ 67.21	SH
8820F		20 mg	5 @ 187.17	SH
8821G		100 mg	5 @ 794.29	SH
9361Q		140 mg	5 @ 1086.56	SH
9160D	Terbinafine Hydrochloride	10 mg per g, 15 g	1 @ 15.47	NC
1251W	Terbutaline Sulfate	5 mg in 2 mL, 30	1 @ 17.19	AP
8098F	Testosterone	100 mg	1 @ 33.86	SH
8099G		200 mg	1 @ 67.71	SH
2670M	Testosterone Esters	100 mg	1 @ 4.75	SH
2101N		250 mg	1 @ 9.02	SH
2832C	Tetracosactrin	1 mg in 1 mL	1 @ 12.97	NV
2345K	Thiotepa	15 mg	1 @ 74.62	SI
8221Q	Tiagabine Hydrochloride	5 mg (base)	50 @ 33.11	OA
8222R		10 mg (base)	50 @ 66.21	OA
8223T		15 mg (base)	50 @ 95.23	OA
1356J	Tobramycin Sulfate	80 mg (base) in 2 mL	5 @ 29.30	HH
8872Y		80 mg (base) in 2 mL (without preservative)	5 @ 29.30	PU
2117K	Triamcinolone Acetonide	200 mcg per g, 100 g	1 @ 4.23	FM
			1 @ 5.88	SI
2118L		200 mcg per g, 100 g	1 @ 4.23	FM
			1 @ 5.88	SI
3128P	Triglycerides, Medium Chain	500 mL	1 @ 22.98	SB
3136C	Triglycerides, Medium Chain and Long Chain with Glucose Polymer	400 g	1 @ 36.14	SB
8478F	Triglycerides—Medium Chain, Formula	400 g	1 @ 51.86	SB
8629E		420 g	1 @ 57.63	SB
9383W		16 g, 25	1 @ 52.30	VF
9165J	Tyrosine with Carbohydrate	4 g containing 1 g tyrosine, 30	1 @ 127.40	VF
8448P	Ursodeoxycholic Acid	250 mg	100 @ 172.62	OA
8133C	Valaciclovir Hydrochloride	500 mg (base)	10 @ 49.68	GK
9135T	Valine with Carbohydrate	4 g containing 50 mg valine, 30	1 @ 127.40	VF
3113W	Vancomycin	125 mg	20 @ 119.41	AS
3114X		250 mg	20 @ 229.81	AS
3130R		500 mg	1 @ 20.05	AS, HH, SZ
3131T		500 mg	1 @ 19.58	AS, HH, SZ
2270L		1 g	1 @ 39.14	HH, SZ
9129L	Varenicline	1 mg (as tartrate)	56 @ 113.32	PF

(APPLY WASTAGE FACTOR IN CALCULATING BROKEN QUANTITY PRICES)

Code	Name	Form/Strength	Pack and Price $		Manufacturer
2374Y	Vincristine Sulfate	1 mg in 1 mL	5 @	77.46	HH, PU
9009E	Vinorelbine Tartrate	20 mg (base)	1 @	104.26	FB
9010F		30 mg (base)	1 @	154.70	FB
8280T		10 mg (base) in 1 mL	1 @	73.58	FB, HH, IT, LM
8281W		50 mg (base) in 5 mL	1 @	307.06	FB, HH, IT, LM
9382T	Whey Protein Formula supplemented with Amino Acids, Long Chain Polyunsaturated Fatty Acids, Vitamins and Minerals, and low in Protein, Phosphate, Potassium and Lactose	100 g, 10	1 @	165.36	VF
8587Y	Whey Protein Formula supplemented with Amino Acids, Vitamins and Minerals, and low in Protein, Phosphate, Potassium and Lactose	400 g	1 @	66.22	SB

PREPARATIONS WHICH MAY BE PRESCRIBED FOR PATIENTS RECEIVING PALLIATIVE CARE

5303D	Bisacodyl	10 mg, 10	1 @	5.15	PP
			1 @	5.53	BY
5304E		10 mg, 12	1 @	4.21	FL, PP
5307H		10 mg, 10	1 @	5.15	PP
			1 @	5.53	BY
5308J		10 mg, 12	1 @	4.21	FL, PP
5339B	Clonazepam	2.5 mg per mL, 10 mL	1 @	4.31	RO
5342E		2.5 mg per mL, 10 mL	1 @	4.31	RO
5361E	Diclofenac Sodium	25 mg (e.c.)	50 @	3.32	AW, CH, GM, GN, GX, SZ, TW
			50 @	4.30	NV
5363G		100 mg	20 @	9.25	NV
5364H		25 mg (e.c.)	50 @	3.32	AW, CH, GM, GN, GX, SZ, TW
			50 @	4.30	NV
5366K		100 mg	20 @	9.25	NV
5401G	Fentanyl	200 mcg, 3	1 @	35.49	OA
5402H		400 mcg, 3	1 @	35.49	OA
5403J		600 mcg, 3	1 @	35.49	OA
5404K		800 mcg, 3	1 @	35.49	OA
5405L		1200 mcg, 3	1 @	35.49	OA
5406M		1600 mcg, 3	1 @	35.49	OA
5407N		200 mcg, 3	1 @	33.55	OA
5408P		400 mcg, 3	1 @	33.55	OA
5409Q		600 mcg, 3	1 @	33.55	OA
5410R		800 mcg, 3	1 @	33.55	OA
5411T		1200 mcg, 3	1 @	33.55	OA
5412W		1600 mcg, 3	1 @	33.55	OA
5413X		200 mcg, 3	1 @	33.55	OA
5414Y		400 mcg, 3	1 @	33.55	OA
5415B		600 mcg, 3	1 @	33.55	OA
5416C		800 mcg, 3	1 @	33.55	OA
5417D		1200 mcg, 3	1 @	33.55	OA

(APPLY WASTAGE FACTOR IN CALCULATING BROKEN QUANTITY PRICES)

Code	Name	Form/Strength	Pack and Price $		Manufacturer
5418E		1600 mcg, 3	1 @	33.55	OA
5311M	Glycerol	700 mg, 12	1 @	3.83	PP
5312N		1.4 g, 12	1 @	3.96	PP
5313P		2.8 g, 12	1 @	4.11	PP
5314Q		700 mg, 12	1 @	3.83	PP
5315R		1.4 g, 12	1 @	3.96	PP
5316T		2.8 g, 12	1 @	4.11	PP
5367L	Ibuprofen	200 mg	50 @	2.82	AF
5368M		400 mg	30 @	2.77	AB
5369N		200 mg	50 @	2.82	AF
5370P		400 mg	30 @	2.77	AB
5377B	Indomethacin	25 mg	50 @	2.83	AF
			50 @	3.29	AS
5378C		100 mg	20 @	8.04	AS
5379D		25 mg	50 @	2.83	AF
			50 @	3.29	AS
5380E		100 mg	20 @	8.04	AS
5345H	Naproxen	250 mg	50 @	3.65	AF
			50 @	4.82	RO
5349M		250 mg	50 @	3.65	AF
			50 @	4.82	RO
5359C	Nitrazepam	5 mg	25 @	1.47	AF
			25 @	3.00	VT
5360D		5 mg	25 @	1.47	AF
			25 @	3.00	VT
5371Q	Oxazepam	15 mg	25 @	1.28	AF
			25 @	3.06	SI
5372R		30 mg	25 @	1.47	AF, FM
			25 @	3.37	SI
5373T		15 mg	25 @	1.28	AF
			25 @	3.06	SI
5374W		30 mg	25 @	1.47	AF, FM
			25 @	3.37	SI
5343F	Paracetamol	665 mg (m.r.)	96 @	5.11	GC
5344G		665 mg (m.r.)	96 @	5.11	GC
5331N	Sorbitol with Sodium Citrate and Sodium Lauryl Sulfoacetate	3.125 g-450 mg-45 mg in 5 mL, 12	1 @	15.08	JT
5332P		3.125 g-450 mg-45 mg in 5 mL, 12	1 @	15.08	JT
5381F	Sulindac	100 mg	50 @	4.96	AF
5383H		100 mg	50 @	4.96	AF
5375X	Temazepam	10 mg	25 @	1.47	AF, FM
			25 @	2.85	SI
5376Y		10 mg	25 @	1.47	AF, FM
			25 @	2.85	SI

PREPARATIONS WHICH MAY BE PRESCRIBED BY PARTICIPATING DENTAL PRACTITIONERS FOR DENTAL TREATMENT ONLY

3398W	Benzylpenicillin	600 mg	1 @	3.44	CS
3399X		3 g	1 @	5.65	CS
5048Q	Cefotaxime	1 g	1 @	4.64	SZ
5049R		2 g	1 @	8.51	SZ
5079H	Diclofenac Sodium	100 mg	20 @	9.25	NV

(APPLY WASTAGE FACTOR IN CALCULATING BROKEN QUANTITY PRICES)

Code	Name	Form/Strength	Pack and Price $		Manufacturer
5076E		25 mg (e.c.)	50 @	3.32	AW, CH, GM, GN, GX, SZ, TW
			50 @	4.30	NV
5088T	Erythromycin Lactobionate	1 g (base)	1 @	8.99	LM
5106R	Glucose	278 mmol per L, 1 L	1 @	3.90	BX
5118J	Hydrocortisone Sodium Succinate	100 mg with 2 mL solvent	1 @	5.36	PH
5119K		250 mg with 2 mL solvent	1 @	9.27	PH
5121M	Ibuprofen	200 mg	50 @	2.82	AF
5123P		400 mg	30 @	2.77	AB
5128X	Indomethacin	100 mg	20 @	8.04	AS
5126T		25 mg	50 @	2.83	AF
			50 @	3.29	AS
5139L	Ketoprofen	100 mg	20 @	9.44	SW
5154G	Metronidazole	500 mg in 100 mL	1 @	5.11	BX
			10 @	39.34	HH, SZ
5176K	Naproxen	250 mg	50 @	3.65	AF
			50 @	4.82	RO
5224Y	Paracetamol	500 mg	100 @	2.00	CH, FM, GM, HX, PC, SI, SW, SZ, TW, YM
3360W	Phenoxymethylpenicillin	250 mg	25 @	2.58	SI
3361X		500 mg	25 @	3.82	SI
5012T		150 mg per 5 mL, 100 mL	1 @	7.99	FM, SI
3374N	Promethazine Hydrochloride	50 mg in 2 mL	5 @	7.95	HH
5212H	Sodium Chloride	154 mmol per L, 1 L	1 @	3.90	BX
5213J		513 mmol per L, 1 L	1 @	5.90	BX
5214K	Sodium Chloride with Glucose	31 mmol-222 mmol per L, 1 L	1 @	3.90	BX
5215L		19 mmol-104 mmol per 500 mL, 500 mL	1 @	5.12	BX
5216M		39 mmol-69 mmol per 500 mL, 500 mL	1 @	5.12	BX
5217N	Sulindac	100 mg	50 @	4.96	AF
3323X	Vancomycin	500 mg	1 @	20.05	AS, HH, SZ

PREPARATIONS WHICH MAY BE PRESCRIBED BY AUTHORISED OPTOMETRISTS FOR OPTOMETRICAL TREATMENT ONLY

5502N	Carbomer 974	3 mg per g, 0.5 g, 30	1 @	9.88	AQ
5504Q	Carbomer 980	2 mg per g, 0.6 mL, 30	1 @	9.68	NV
5509Y	Carmellose Sodium	2.5 mg per mL, 0.6 mL, 24	1 @	8.50	CX
5506T		5 mg per mL, 0.4 mL, 30	1 @	9.88	AG
5505R		10 mg per mL, 0.4 mL, 30	1 @	9.88	AG
5510B		10 mg per mL, 0.6 mL, 28	1 @	9.22	CX
5521N	Hypromellose with Dextran	3 mg-1 mg per mL, 0.4 mL, 28	1 @	9.22	AQ
5523Q	Paraffin	3.5 g	1 @	7.54	IQ
			1 @	8.57	AQ
5532E	Polyethylene Glycol 400 with Propylene Glycol	4 mg-3 mg per mL, single dose units 0.8 mL, 28	1 @	13.83	AQ
5531D	Tamarindus Indica Seed Polysaccharide	10 mg per mL, 0.5 mL, 20	1 @	9.88	JT

Section 4

Drug Tariff

Container Prices

Standard Formulae Preparations

Table of Codes, Maximum Quantities, and Number of Repeats for Extemporaneously Prepared Pharmaceutical Benefits

Special Note:

Purified Water BP is the minimum requirement for water in all PBS extemporaneous preparations.

Drug Tariff

Drug	Standard	Recovery Prices 0.1 g/mL $	1 g/mL $	10 g/mL $	100 g/mL $
Acacia Mucilage (by weight)	APF 15	0.01	0.08	0.64	5.67
Acacia, powdered	BP	0.02	0.15	1.18	10.47
Acetic Acid (6 per cent)	BP	0.01	0.01	0.11	1.02
Acetic Acid (33 per cent)	BP	0.01	0.05	0.38	3.38
Acetone (use as additive only)	BP	0.01	0.08	0.60	5.30
Alum	BP	0.02	0.14	1.11	9.85
Aluminium Acetate Solution	BP	0.02	0.12	0.99	8.80
Anise Water Concentrated 1 in 40 (use as additive only)	BP	0.01	0.05	0.39	3.49
Aqueous Cream (for use only as a base combined with active ingredients)	APF	0.01	0.07	0.54	4.82
Ascorbic Acid (for use only as an ingredient of ferrous sulfate mixtures)	BP	0.05	0.36	2.91	25.86
Aspirin	BP	0.08	0.62	4.98	44.28
Belladonna Tincture	BP	0.05	0.36	2.85	25.30
Benzocaine	BP	0.08	0.63	5.07	45.08
Benzoic Acid	BP	0.06	0.47	3.78	33.58
Benzoic Acid Compound Ointment	APF	0.01	0.10	0.76	6.71
Benzoic Acid Solution	BP	0.01	0.09	0.74	6.62
Benzoin Compound Tincture	BP	0.02	0.17	1.38	12.23
Boric Acid (use as additive only)	BP	0.01	0.05	0.43	3.80
Boric Acid, Olive Oil and Zinc Oxide Ointment	QHF	0.01	0.06	0.45	3.99
Calcium Hydroxide	BP	0.02	0.16	1.29	11.50
Calcium Hydroxide Solution	BP	0.01	0.01	0.07	0.66
Castor Oil (use as additive only)	BP	0.01	0.06	0.44	3.90
Cetomacrogol Aqueous Cream (for use only as a base combined with active ingredients)	APF	0.01	0.02	0.19	1.73
Cetrimide Aqueous Cream (for use only as a base combined with active ingredients)	APF	0.02	0.12	0.94	8.40
Chlorhexidine Acetate (use as additive only)	BP	0.43	3.45	27.58	245.13
Chlorhexidine Aqueous Cream (for use only as a base combined with active ingredients)	APF	0.03	0.22	1.74	15.44
Chloroform (use as additive only)	BP	0.02	0.14	1.13	10.06
Chloroform Spirit	BP	0.01	0.03	0.25	2.26
Chloroform Water Concentrated 1 in 40	APF 15	0.01	0.03	0.25	2.26
Citric Acid Monohydrate	BP	0.01	0.06	0.49	4.38
Coal Tar	BP	0.10	0.79	6.30	56.00
Coal Tar Solution	BP	0.01	0.10	0.82	7.25
Cocaine Hydrochloride	BP	5.47	43.75	350.00	3111.11
Coconut Oil	BP	0.01	0.10	0.78	6.89

Drug	Standard	Recovery Prices 0.1 g/mL $	1 g/mL $	10 g/mL $	100 g/mL $
Codeine Linctus	APF	0.01	0.05	0.40	3.59
Codeine Phosphate (may only be prescribed in linctuses, mixtures or mixtures for children)	BP	1.34	10.73	85.87	763.26
Collodion Flexible	BP	0.05	0.38	3.02	26.83
Dithranol	BP	3.37	26.95	215.61	1916.57
Emulsifying Ointment (for use only as a base combined with active ingredients)	BP	0.01	0.06	0.49	4.36
Ephedrine Hydrochloride (may only be prescribed in nasal instillations)	BP	0.56	4.49	35.88	318.93
Ethanol (90 per cent) (use as additive only)	BP	0.01	0.02	0.18	1.63
Ethanol (96 per cent) (use as additive only)	BP	0.01	0.03	0.22	1.96
Ether Solvent (use as additive only)	BP	0.01	0.11	0.87	7.71
Eucalyptus Oil (use as additive only)	BP	0.01	0.11	0.84	7.49
Ferrous Sulfate	BP	0.10	0.78	6.21	55.20
Formaldehyde Solution	BP	0.02	0.19	1.51	13.42
Gentian Alkaline Mixture	APF	0.01	0.05	0.41	3.66
Glycerol	BP	0.01	0.05	0.38	3.39
Honey Purified (use as additive only)	BP 1993	0.01	0.02	0.15	1.37
Hydroxybenzoate Compound Solution	APF	0.06	0.48	3.87	34.43
Iodine	BP	0.38	3.02	24.15	214.67
Iodine Alcoholic Solution	BP	0.02	0.15	1.18	10.52
Iodine Aqueous Oral Solution	BP	0.02	0.18	1.44	12.76
Kaolin Mixture	BPC 1968	0.01	0.08	0.61	5.47
Kaolin and Opium Mixture	APF 14	0.01	0.08	0.66	5.83
Lactic Acid	BP	0.05	0.41	3.25	28.90
Lavender Spike Oil	BPC 1968	0.07	0.59	4.73	42.02
Liquorice Liquid Extract	BP	0.03	0.21	1.64	14.61
Magnesium Carbonate Light	BP	0.02	0.18	1.46	13.00
Magnesium Sulfate (may only be prescribed for other than oral use)	BP	0.01	0.01	0.09	0.77
Magnesium Trisilicate	BP	0.03	0.23	1.83	16.29
Menthol, Racemic or Levomenthol	BP	0.20	1.58	12.66	112.53
Methyl Hydroxybenzoate	BP	0.28	2.24	17.94	159.47
Methyl Hydroxybenzoate Solution	APF	0.03	0.23	1.81	16.09
Methylated Industrial Spirit (use as additive only)	BP	0.01	0.04	0.28	2.48
Olive Oil (use as additive only)	BP	0.01	0.10	0.76	6.79
Paraffin Hard	BP	0.01	0.06	0.46	4.13
Paraffin Liquid (may only be prescribed for other than oral use)	BP	0.01	0.03	0.22	1.98
Paraffin Light Liquid	BP	0.02	0.12	0.95	8.41
Paraffin Soft White	BP	0.01	0.03	0.25	2.19

Drug	Standard	Recovery Prices 0.1 g/mL $	1 g/mL $	10 g/mL $	100 g/mL $
Paraffin Soft Yellow	BP	0.01	0.05	0.41	3.67
Peppermint Oil (use as additive only)	BP	0.09	0.74	5.95	52.90
Peppermint Water Concentrated 1 in 40 (use as additive only)	APF 16	0.03	0.23	1.84	16.39
Phenobarbitone Sodium (may only be prescribed for the treatment of epilepsy)	BP	10.22	81.75	654.00	5813.33
Phenol Liquefied (not available for ear drops)	BP	0.05	0.42	3.36	29.90
Podophyllum Resin	BP	0.91	7.25	57.96	515.20
Potassium Citrate	BP	0.01	0.09	0.69	6.10
Potassium Iodide	BP	0.06	0.47	3.75	33.29
Potassium Permanganate	BP	0.02	0.15	1.16	10.32
Propyl Hydroxybenzoate	BP	0.24	1.90	15.18	134.93
Propylene Glycol	BP	0.01	0.07	0.55	4.88
Red Syrup	APF 15	0.01	0.11	0.88	7.87
Resorcinol	BP	0.12	0.93	7.44	66.10
Salicylic Acid	BP	0.02	0.18	1.47	13.09
Salicylic Acid Ointment	APF	0.01	0.09	0.71	6.34
Salicylic Acid Ointment	BP	0.01	0.09	0.71	6.34
Simple Ointment (white) (for use only as a base combined with active ingredients)	BP	0.02	0.14	1.09	9.68
Simple Ointment (yellow) (for use only as a base combined with active ingredients)	BP	0.02	0.16	1.29	11.44
Sodium Bicarbonate	BP	0.01	0.07	0.56	5.00
Sodium Chloride	BP	0.02	0.12	0.94	8.36
Sodium Chloride Solution	BP	0.01	0.01	0.07	0.61
Sodium Citrate	BP	0.01	0.11	0.91	8.07
Sodium Thiosulfate (use as additive only)	BP	0.02	0.19	1.54	13.68
Starch	BP	0.01	0.09	0.71	6.33
Sulfur Ointment (for use only as a base combined with active ingredients)	BP 1980	0.02	0.15	1.19	10.55
Sulfur Precipitated	BP 1980	0.03	0.23	1.83	16.27
Syrup	BP	0.01	0.03	0.23	2.09
Talc Purified, sterilised	BP	0.02	0.14	1.10	9.77
Thymol	BP	0.17	1.37	10.95	97.32
Thymol Compound Mouth Wash	APF 15	0.01	0.08	0.63	5.64
Tragacanth Compound Powder	BP 1980	0.07	0.52	4.16	36.95
Tragacanth Mucilage	APF 13	0.01	0.03	0.24	2.10
Tragacanth Mucilage	BPC 1973	0.01	0.02	0.17	1.55
Tragacanth, powdered	BP	0.10	0.76	6.05	53.82
Trichloroacetic Acid	BP 1980	0.25	1.99	15.88	141.12
Triethanolamine	BP	0.05	0.38	3.02	26.83
Water For Injections, sterilised (b) (extemporaneously prepared eye drops and eye lotions)	BP	0	0	0	8.09
Water Purified	BP	0.01	0.01	0.06	0.49
Wool Alcohols Ointment (white)	BP	0.02	0.13	1.00	8.93

Drug	Standard	Recovery Prices			
		0.1 g/mL $	1 g/mL $	10 g/mL $	100 g/mL $
(for use only as a base combined with active ingredients)					
Wool Alcohols Ointment (yellow)	BP	0.02	0.13	1.00	8.93
(for use only as a base combined with active ingredients)					
Wool Fat	BP	0.02	0.12	0.98	8.72
Wool Fat Hydrous	BP	0.01	0.10	0.79	7.00
Zinc Compound Paste	BP	0.02	0.15	1.17	10.36
Zinc Cream	BP	0.01	0.06	0.49	4.32
(for use only as a base combined with active ingredients)					
Zinc Oxide	BP	0.01	0.09	0.72	6.39
Zinc and Salicylic Acid Paste	BP	0.02	0.12	0.99	8.83
Zinc Sulfate	BP	0.02	0.19	1.48	13.17

Container Prices

	$
DISPENSING BOTTLES -	
25mL	0.47
50mL	0.47
100mL	0.46
200mL	0.72
500mL	1.02
POISON BOTTLES -	
25mL	0.43
50mL	0.41
100mL	0.45
200mL	0.63
500mL	1.15
SCREW CAP JARS -	
25g	0.57
50g	0.63
100g	0.72
200g	0.76
500g	1.15
DROPPER CONTAINERS -	
15mL polythene	0.73
15mL glass	0.75

Dispensing Fee for Extemporaneously Prepared Benefits	**8.03**
Additional Fee for Agreed Price Extemporaneously Prepared Benefits	**1.39**

Standard Formula Preparations

The following list is not intended to indicate in any way which particular formula an approved pharmacist should use in filling a prescription.

The prices shown in the column 'Dispensed Price for Max. Qty' are for the ingredients, the container and the dispensing fee. The prices shown in the column 'Maximum Recordable Value for Safety Net' are for the ingredients, the container and the dispensing fee and, where applicable, the additional fee for agreed price benefits.

KEY TO REFERENCES:

APF	**Australian Pharmaceutical Formulary**
BP	**British Pharmacopoeia**
BPC	**British Pharmaceutical Codex**
QHF	**Queensland Hospital Formulary**

Code	Item	Reference	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $
	CREAMS			
	(Maximum Quantity 100 g and 1 Repeat)			
7502W	Salicylic Acid and Sulfur Aqueous	APF	14.20	15.59
	DUSTING POWDERS			
	(Maximum Quantity 100 g and 1 Repeat)			
7458M	Zinc, Starch and Talc	APF 15 & BPC 1973	17.86	19.25
	EAR DROPS			
	(Maximum Quantity 15 mL and 2 Repeats)			
7642F	Aluminium Acetate	APF	9.76	11.15
7643G	Aluminium Acetate	BP	10.24	11.63
7314Y	Sodium Bicarbonate	APF & BP	9.10	10.49
7313X	Spirit	APF	10.19	11.58
	INHALATIONS			
	(Maximum Quantity 50 mL and 1 Repeat)			
7484X	Benzoin and Menthol	APF	16.90	18.29
7308P	Menthol	APF	10.94	12.33
7310R	Menthol and Eucalyptus	BP 1980	11.44	12.83
	LINCTUSES CONTAINING CODEINE PHOSPHATE			
	(Maximum Quantity 100 mL and 0 Repeats)			
7530H	Codeine	APF	12.08	13.47
	LOTIONS			
	(Maximum Quantity 200 mL and 2 Repeats)			
7709R	Aluminium Acetate Aqueous	APF	10.59	11.98
	MIXTURES, OTHER			
	(Maximum Quantity 200 mL and 4 Repeats)			
7604F	Gentian Alkaline	APF	16.07	17.46
7348R	Kaolin	BPC 1968	19.68	21.07
7301G	Kaolin and Opium	APF 14	20.41	21.80
7342K	Magnesium Trisilicate	BPC 1968	14.71	16.10
7343L	Magnesium Trisilicate and Belladonna	BPC 1968	17.46	18.85
	MOUTH WASHES			
	(Maximum Quantity 200 mL and 1 Repeat)			
7457L	Thymol Compound	APF 15	19.95	21.34
	OINTMENTS			
	(Maximum Quantity 100 g and 1 Repeat)			
7914M	Benzoic Acid Compound	APF	15.46	16.85
7914M	Benzoic Acid Compound (extemporaneous formula)	BP	15.46	16.85
7902X	Boric Acid, Olive Oil and Zinc Oxide	QHF	12.74	14.13

—CONTAINER RATES ARE INCLUDED—

Code	Item	Reference	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $
7926E	Salicylic Acid	APF	15.09	16.48
7928G	Salicylic Acid (extemporaneous formula)	BP	15.09	16.48
	PAINTS			
	(Maximum Quantity 25 mL and 1 Repeat)			
7567G	Podophyllin Compound	APF 16 & BP	39.07	32.90
7568H	Salicylic Acid	APF	16.47	17.86
	PASTES, OTHER			
	(Maximum Quantity 100 g and 1 Repeat)			
7558T	Zinc	APF	21.08	22.47
7558T	Zinc Compound (extemporaneous formula)	BP	21.08	22.47
	POWDER FOR INTERNAL USE			
	(Maximum Quantity 100 g and 2 Repeats)			
7545D	Magnesium Trisilicate	BP	25.08	26.47

Table of Codes, Maximum Quantities, and Number of Repeats for Extemporaneously Prepared Benefits

Code	Preparation	Maximum Quantity		Number of Repeats
13Q	Creams	100	g	1
48M	Dusting Powders	100	g	1
15T	Ear Drops	15	mL	2
19B	Eye Drops containing Cocaine Hydrochloride	15	mL	..
22E	Eye Drops, Other	15	mL	5
23F	Eye Lotions	200	mL	2
29M	Inhalations	50	mL	1
64J	Linctuses containing Codeine Phosphate	100	mL	..
34T	Linctuses, Other	100	mL	2
39C	Lotions	200	mL	2
65K	Mixtures containing Codeine Phosphate	200	mL	..
40D	Mixtures, Other	200	mL	4
66L	Mixtures for Children containing Codeine Phosphate	100	mL	..
41E	Mixtures for Children, Other	100	mL	4
30N	Mouth Washes	200	mL	1
42F	Nasal Instillations	15	mL	2
43G	Ointments, Waxes	100	g	1
44H	Paints	25	mL	1
63H	Pastes containing Cocaine Hydrochloride	25	g	..
45J	Pastes, Other	100	g	1
49N	Powders for Internal Use	100	g	2
52R	Solutions	200	mL	2

Australian Government

Department of Veterans' Affairs

REPATRIATION SCHEDULE OF PHARMACEUTICAL BENEFITS

1 MARCH 2009

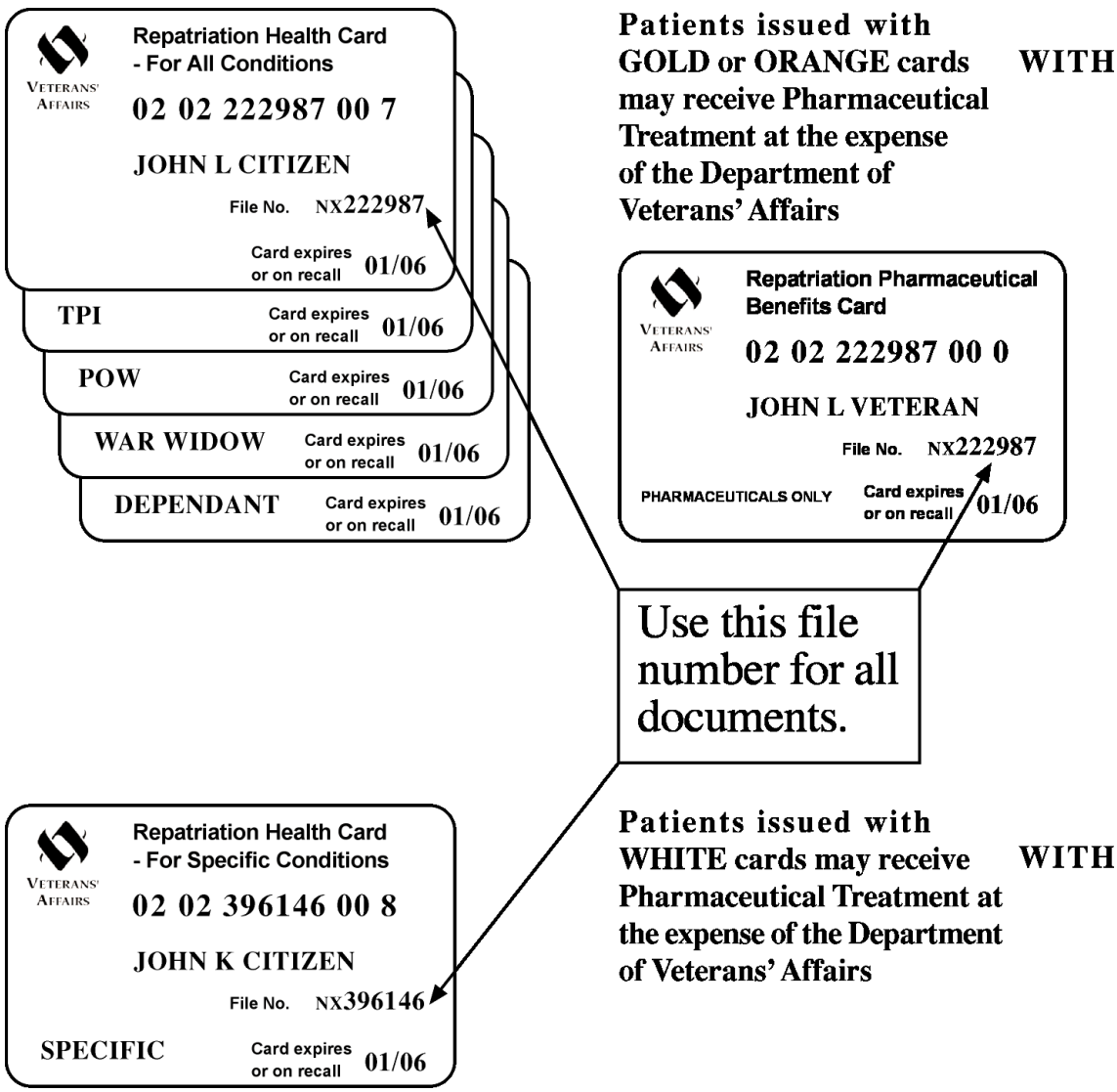
The benefits listed in this Schedule may only be prescribed to Department of Veterans' Affairs beneficiaries holding a:

- Repatriation Health Card For All Conditions (gold); or
- Repatriation Health Card For Specific Conditions (white); or
- Repatriation Pharmaceutical Benefits Card (orange);

BENEFICIARIES' ENTITLEMENT CARDS AND ELIGIBILITY

The diagram below outlines the drug eligibility of Department of Veterans' Affairs

REPATRIATION PHARMACEUTICAL BENEFITS



FOR REPATRIATION PHARMACEUTICAL BENEFITS

beneficiaries in accordance with their treatment entitlement.

PBS Schedule listings written on the common PBS/RPBS prescription form, ticked as 'RPBS' (restrictions apply)	+	Repatriation Schedule listings written on the common PBS/RPBS prescription form, ticked as 'RPBS'	+	Items for which prescribing approval has been authorised on the common PBS/RPBS authority prescription form for: (i) PBS and Repatriation Schedules 'Authority required' items; (ii) greater quantities/repeats of drugs listed in PBS and Repatriation Schedules; or (iii) items not listed in PBS or Repatriation Schedules.

Only for disabilities that have been accepted for treatment by the Department of Veterans' Affairs

PBS Schedule listings written on the common PBS/RPBS prescription form, ticked as 'RPBS' (restrictions apply)	+	Repatriation Schedule listings written on the common PBS/RPBS prescription form, ticked as 'RPBS'	+	Items for which prescribing approval has been authorised on a common PBS/RPBS authority prescription form for: (i) PBS and Repatriation Schedules 'Authority required' items; (ii) greater quantities/repeats of drugs listed in PBS and Repatriation Schedules; or (iii) items not listed in PBS or Repatriation Schedules.

RPBS Explanatory Notes

Introduction

The Australian Repatriation System

1. The Australian Repatriation system is based primarily on the principle of compensation to veterans and eligible dependants for injury or death related to war service. In certain cases, treatment is also provided for accepted injuries or conditions that are not service-related or have occurred as a result of other than war service.
2. Through the *Veterans' Entitlements Act 1986* the Department of Veterans' Affairs provides programs of compensation, income support and treatment for eligible veterans and their dependants. One of the defined benefits for eligible veterans is the Repatriation Pharmaceutical Benefits Scheme. This range of medications and dressings is more comprehensive than is available through the Pharmaceutical Benefits Scheme.

RPBS prescribing provisions

3. Unless otherwise stated, Repatriation Pharmaceutical Benefits Scheme (RPBS) prescriptions must conform with the requirements of Pharmaceutical Benefits Scheme (PBS) prescriptions, as detailed in Section 1 – Explanatory Notes in the *Schedule of Pharmaceutical Benefits* book. The prescriber shall ensure that a prescription contains the following details:
    - the category of benefit, i.e., RPBS, by placing a cross in the relevant box;
    - the patient's full name and address;
    - the prescription date;
    - the DVA file number of the patient as evidence of entitlement;
    - in the case of authority prescriptions, the Authority approval number or the four digit streamlined authority code;
    - the item, form, strength, quantity and directions;
    - the number of repeats, if applicable;
    - indicate when brand substitution is not permitted; and
    - the name, signature, the prescriber number and address of the prescriber.

Prior Approval Arrangements

4. The prior approval of the Department is required to prescribe the following:
    - ‘Authority required’ items (excluding ‘Authority required (STREAMLINED)’ items) listed in either the PBS or RPBS Schedule;
    - increased quantities and/or repeats of items listed in either the PBS or RPBS Schedule;
    - items listed under section 100 of the *National Health Act 1953*; and
    - other items not listed in either Schedule (non-Schedule items).
5. The above items are to be prescribed on the common PBS/RPBS authority prescription form in accordance with the directions stated in the Explanatory Notes in the *Schedule of Pharmaceutical Benefits* (See also information regarding dental prescribing and prescribing by optometrists under the RPBS in these Notes.)

6. All Authority required prescriptions and requests for non-Schedule items must receive prior approval from the Department. This can be achieved by either:
   - using the Department's national free call number 1800 552 580; or
   - by mailing the written authority prescription to the Veterans' Affairs Pharmaceutical Advisory Centre (VAPAC) at the reply paid address shown at the end of these RPBS Explanatory Notes.

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

7. Some requests for prior approval (including some non-Schedule items) need to be referred by VAPAC to the Repatriation Pharmaceutical Reference Committee for consideration. In such cases a VAPAC pharmacist will advise the prescriber to submit a request in writing that provides the following information:
   - A current clinical report on the patient's condition (such as age, co-morbidities, renal, liver failure) and clinical reports including pathology, biochemistry, diagnostic and other investigations if appropriate.
   - Details of past and current therapy for the condition. Include details of PBS, RPBS and non-Schedule items utilised, and the results of those therapies.
   - Details of the proposed treatment regimen. Include intended dose and duration of treatment and objective measures of response.
   - When the proposed use of the item is outside the TGA-approved indications for use in Australia, provide copies of articles from peer reviewed publications supporting the proposed treatment.
   - Signed, informed patient consent where the item is to be used for a non-TGA-approved indication.
   - For items without Australian marketing approval, a copy of the TGA Special Access Scheme approval to prescribe the drug.
8. Requests for prior approval to prescribe a non-Schedule (PBS or RPBS) item that is of the same therapeutic class (ATC level 3) as an item that is listed on the Schedule, will not be approved unless unequivocal clinical evidence is presented to demonstrate that the requested item is essential for effective treatment of the nominated patient.
9. A pharmacist should not supply an item prescribed on an RPBS Authority Prescription Form unless the form has been approved and stamped by VAPAC, or has been endorsed by the prescriber with a telephone Authority approval number provided by VAPAC. Medicare Australia will not accept RPBS Authority prescriptions that have not been approved by the Department of Veterans' Affairs for payment.

Palliative Care Drugs

10. The following medications may be available, or made available in increased quantities or doses under prior approval arrangements for use only in the palliative care of terminal disease:
    - clonazepam
    - cyclizine
    - dexamethasone
    - disodium pamidronate
    - fentanyl
    - glycopyrrolate
    - hyoscine butylbromide
    - hyoscine hydrobromide
    - ketamine
    - midazolam
    - octreotide

    For further information telephone VAPAC on 1800 552 580.

Dental Prescribing

11. Under Department of Veterans' Affairs arrangements, financial responsibility for pharmaceutical benefits prescribed by a Local Dental Officer (LDO) is limited to treatment to which holders of the following cards are entitled:
    - a Gold Repatriation Health Card – For All Conditions; or
    - a White Repatriation Health Card – For Specific Conditions; or
    - an Orange Repatriation Pharmaceutical Benefits Card.

    Where possible the LDO shall prescribe in accordance with the provisions governing dental prescribing under the Pharmaceutical Benefits Scheme (PBS).
12. Prescriptions for PBS Dental Schedule items for Gold, White and Orange Card holders are to be dispensed at the PBS concessional rate. Claims for payment by the dispensing pharmacist are to be included with other Repatriation prescriptions. The card holder is required to meet the cost of any applicable brand premium.
13. When a non-PBS Dental Schedule item is prescribed for an eligible card holder, the LDO's private prescription form should be used. The dispensing pharmacist may charge the patient the full cost of the prescription. The patient may claim a refund for the full cost of a non-Schedule item from the Department if an itemised receipt (not a cash register receipt) and a copy of the prescription are provided.

Prescribing by optometrists

14. Optometrists approved as ‘PBS prescribers’ may write RPBS prescriptions as outlined in Section 1 for medicines listed in Section 2 of the PBS Schedule as pharmaceutical benefits for optometrical use.
15. Medicines in the optometrist list include non-Authority and Authority required items. Procedures for obtaining VAPAC approval to prescribe ‘Authority required’ optometrist items or increased quantities and/or repeats of optometrist items under the RPBS are the same as indicated under prior approval arrangements above.

16. The list of medicines for prescribing by optometrists under the RPBS is the same as applies under the PBS. There are no optometrist listings in the RPBS Schedule for prescribing for veterans only. There is no provision for optometrist prescribers to request approval to prescribe items that are not included in the PBS optometrist list (non-Schedule items).
17. Optometrist PBS/RPBS prescription forms are for use for prescribing non-Authority or Authority required optometrist items under the RPBS with one item per form only.

Provisions governing pricing and payment for RPBS benefits

Introduction

18. Unless otherwise stated, the pricing and payment principles and arrangements for approved pharmacists supplying pharmaceutical benefits under the RPBS will be the same as those arrangements applying under the PBS.
19. Where a pharmaceutical benefit that is not listed on the PBS or RPBS Schedule is dispensed on an RPBS Authority prescription, a pharmacist will price the benefit and enter the serial number, prescription identifying number and price on the sticker or stamp imprint affixed to the prescription.

Pricing of Schedule Items

20. Items supplied under the RPBS from the PBS Schedule, both ready-prepared and extemporaneously-prepared, will be paid on the same basis as benefits supplied under the PBS. Items supplied under the RPBS from the Repatriation Schedule, including wound dressings, will be paid on the basis of the price as given in the Repatriation Pharmaceutical Benefits section (Section 1 – RPBS Schedule, Drugs, Medicines and Dressings) of the *Schedule of Pharmaceutical Benefits*.

Pricing of Non-Schedule Ready Prepared Items

21. Non-Schedule ready-prepared items are to be priced on the basis of the invoiced, GST-exclusive wholesale price to pharmacists plus the appropriate PBS mark-up and the PBS dispensing fee. Where the item price to pharmacists is greater than $100.00, a copy of the invoice pertaining to the supply of that item is to be submitted together with the appropriate copy of the authority prescription as part of the claim for payment.

Pricing of Non-Schedule Extemporaneously Prepared Items

22. When an ingredient drug is not listed in the PBS Drug Tariff, the recovery price will be based on the invoiced wholesale price to pharmacists, increased by a mark-up of 100%, calculated in accordance with the directions contained in the pricing instructions for pricing of PBS extemporaneously-prepared benefits in this Schedule. The price paid by the pharmacist for the commercial pack from which the ingredient is used shall be endorsed on the prescription form.

Miscellaneous Pricing Rules

23. The price to pharmacists used as the basis of pricing will be the invoiced, GST-exclusive price from the wholesaler.
24. If multiple quantities of a manufacturer's original pack are supplied, the PBS mark-up is applied to the price to pharmacist of each pack and then totalled. The PBS dispensing fee, and the PBS dangerous drug fee if applicable, are then added to the total of the marked-up prices.
25. When the quantity prescribed corresponds with the quantity of a manufacturer's original pack, in no circumstances will the price payable for one pack exceed that payable for multiples or combinations of packs to supply the quantity prescribed.
26. The list of ingredient drugs and prices included in the PBS Drug Tariff are common to both the PBS and RPBS. Certain restrictions apply regarding the prescribing and dispensing of some of these ingredient drugs as pharmaceutical benefits, e.g., use as additive only.

27. For items prescribed generically, including non-Schedule and wound dressings, the pharmacist should indicate on the prescription the quantity and brand supplied. If prescriptions are not endorsed, the Department will pay the lowest priced acceptable product available.

General

Packaging Material, Postage or Freight

28. Payment to a pharmacist for the costs of packaging materials, postage or freight required to supply a pharmaceutical benefit is to be paid by the patient, who may then claim reimbursement from the Department through the provision of a pharmacists itemised receipt.

Payment for Items Supplied at Short Intervals

29. For all items dispensed at specific short intervals of time, the Department will pay a separate PBS dispensing fee for each occasion that the drug is supplied and which is acknowledged on receipt by the patient or agent.

30. The price payable on the items supplied will be based on the individual dose quantity supplied. Where applicable, a PBS dangerous drug fee and a minimum container charge will be payable for each supply.

Receipts for Patient Charges

31. Where a charge is paid by a patient in any of the circumstances of paragraphs 13 or 24, the pharmacist is required to provide a printed receipt to the patient with the details of the items or services provided, the amount paid, date of supply and the patients name and address. The patient may apply for reimbursement from the Department.

Special Patient Contributions

32. The Special Patient Contribution for items listed as Special Pharmaceutical Benefits in the PBS Schedule is not payable by veterans entitled to pharmaceutical benefits under the RPBS. Eligible veterans receiving Special Pharmaceutical Benefits under the RPBS are required to pay only the concessional patient contribution and any applicable brand premium. If a Safety Net Entitlement card is held, the veteran should receive a Special Pharmaceutical Benefit free of charge, subject to any brand premium applicable. Medicare Australia will reimburse the dispensing pharmacist the total dispensed price, less the concessional patient contribution and/or brand premium if applicable.

Therapeutic Group Premiums — Authority Processing

33. Items attracting a therapeutic group premium are dual listed. Dispensing pharmacists are therefore required to select the appropriate code for those items that are dual listed as authority and non-authority items, in order to correctly charge the patient and claim from Medicare Australia. Those authority prescriptions that grant exemption from a therapeutic group premium will have the letters 'TPX' at the beginning of the telephone Authority approval number, or, in the case of a written approval, will be stamped with the words "This prescription does not attract a therapeutic group premium".

DEPARTMENT OF VETERANS' AFFAIRS

Authority Prescription Applications

Applications for authority to prescribe under the Repatriation Pharmaceutical Benefits Scheme (RPBS) should be sent to the Veterans' Affairs Pharmaceutical Advisory Centre (VAPAC) using the free postal service:

REPLY PAID 9998
VAPAC (Veterans' Affairs Pharmaceutical Advisory Centre)
Department of Veterens' Affairs
GPO Box 9998
BRISBANE QLD 4001

For RPBS enquiries and telephone approvals 24 hours a day the Freecall number is:

1800 552 580

Departmental pharmacists answer applications for prior approval for non-Schedule items and Authority application calls.

REPATRIATION PHARMACEUTICAL BENEFITS

This Schedule is effective from 1 March 2009 and all previous issues are cancelled.

New Schedules take effect on the first day of each month.

SUMMARY OF CHANGES

ALTERATIONS

Alteration — Note

(The note for Infliximab has been amended to reflect the change of address details for VAPAC)

4284L **Infliximab**, Powder for I.V. infusion 100 mg (*Remicade*)

Alteration — Proprietary Name

From:

4695D *(Tielle MT2440)* **Dressing—hydroactive (superficial wound—high exudate)**, Dressings, island, 11 cm x 11 cm, 10

To:

4695D *(Tielle MTL101E)* **Dressing—hydroactive (superficial wound—high exudate)**, Dressings, island, 11 cm x 11 cm, 10

Therapeutic Index for RPBS Schedule

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Section 1

Drugs, Medicines and Dressings

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
	ALIMENTARY TRACT AND METABOLISM							
	STOMATOLOGICAL PREPARATIONS							
	Stomatological preparations							
	• ***Antiinfectives and antiseptics for local oral treatment***							
	CHLORHEXIDINE GLUCONATE							
4161B	Mouth wash 2 mg per mL (0.2%), 250 mL	‡ 1	..	..	11.46	5.30	Plaqacide	OB
				..	11.98	5.30	Savacol Mouth and Throat Rinse	OM
4160Y	Mouth wash 2 mg per mL (0.2%), 250 mL	‡ 1	..	..	13.34	5.30	Periogard (Chlorohex) Mouth Rinse	OM
	• ***Other agents for local oral treatment***							
	CARMELLOSE SODIUM							
4568K	Mouth spray 10 mg per mL, 25 mL	‡ 1	1	..	9.77	5.30	Aquae	HA
4569L	Mouth spray 10 mg per mL, 100 mL	‡ 1	..	..	11.79	5.30	Aquae	HA
	DRUGS FOR ACID RELATED DISORDERS							
	Antacids							
	• ***Calcium compounds***							
	CALCIUM CARBONATE with GLYCINE							
	NOTE:							
	For patients with chronic renal failure.							
4055K	Tablet 420 mg-180 mg	200	5	..	* 22.75	5.30	Titralac	MM
	• ***Combinations and complexes of aluminium, calcium and magnesium compounds***							
	ALUMINIUM HYDROXIDE with MAGNESIUM HYDROXIDE and SIMETHICONE							
4453J	Tablet 400 mg-400 mg-40 mg	200	5	..	* 45.69	5.30	Mylanta Double Strength	JT
4118R	Oral suspension 400 mg-400 mg-30 mg per 5 mL, 500 mL	2	5	..	* 22.21	5.30	Mylanta Double Strength	JT
	DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS							
	Drugs for functional bowel disorders							
	• ***Synthetic anticholinergics, esters with tertiary amino group***							
	MEBEVERINE HYDROCHLORIDE							
4328T	Tablet 135 mg	90	..	..	27.69	5.30	[a] Colese	AF
				..	30.98	5.30	[a] Colofac	SM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
	Belladonna and derivatives, plain							
	• ***Belladonna alkaloids semisynthetic, quaternary ammonium compounds***							
	HYOSCINE BUTYLBROMIDE							
4279F	Injection 20 mg in 1 mL	5	..	..	20.95	5.30	Buscopan	BY
	LAXATIVES							
	Laxatives							
	• ***Softeners, emollients***							
	DOCUSATE SODIUM							
4200C	Tablet 50 mg	100	2	..	12.30	5.30	Coloxyl 50	FM
	• ***Contact laxatives***							
	DOCUSATE SODIUM with SENNA							
4198Y	Tablet 50 mg-8 mg	90	2	..	13.98	5.30	Coloxyl with Senna	FM
4028B	Tablet 50 mg-8 mg	100	2	..	13.98	5.30	Soflax	GM
	SENNA STANDARDISED							
4455L	Tablet 7.5 mg	100	1	..	13.43	5.30	Senokot	RC
	• ***Bulk producers***							
	ISPAGHULA HUSK							
4285M	Sachets 3.5 g, 30	‡ 1	1	..	17.21	5.30	Fybogel	RC
	PSYLLIUM HYDROPHILIC MUCILLOID							
4419N	Oral powder (orange-flavoured, sugar-free) 283 g	‡ 1	1	..	21.24	5.30	Metamucil Smooth Texture Orange	PY
4422R	Oral powder (non-flavoured) 336 g	‡ 1	1	..	21.24	5.30	Metamucil Regular	PY
	PSYLLIUM HYDROPHILIC MUCILLOID with HIGH AMYLOSE MAIZE STARCH							
4416K	Oral powder 2.7 g-0.7 g per 7.5 g, 440 g	‡ 1	1	..	20.84	5.30	Nucolox	SI
	STERCULIA with FRANGULA BARK							
4558X	Granules 620 mg-80 mg per g (62%-8%), 500 g	‡ 1	1	..	24.52	5.30	Normacol Plus	NE
	• ***Enemas***							
	SORBITOL with SODIUM CITRATE and SODIUM LAURYL SULFOACETATE							
4462W	Enemas 3.125 g-450 mg-45 mg in 5 mL, 4	‡ 1	..	..	11.67	5.30	Microlax	JT

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
	• ***Other laxatives***							
	GLYCEROL							
	Restricted Benefit							
	Short-term use when oral laxative therapy has failed or is inappropriate.							
4246L	***Suppositories 2.8 g (for adults), 12***	***3***	***..***	***..***	**** 18.32***	***5.30***	***PP***	

ANTIOBESITY PREPARATIONS, EXCL. DIET PRODUCTS

Antiobesity preparations, excl. diet products

• ***Peripherally acting antiobesity products***

ORLISTAT

Authority Required

For the treatment of obese patients.
Total treatment will not exceed 12 months from initial application.
Patients are eligible for 1 continuous treatment in a lifetime.
The patient must be receiving, or enrolled to receive, professional dietetic and weight management advice (where this is available).

Initial treatment for patients who meet the following criteria to qualify:
(a) Body Mass Index (BMI) greater than or equal to 35 with no known co-morbidities; or
(b) BMI greater than or equal to 30 with 1 or more of the following co-morbidities:
(i) diabetes;
(ii) ischaemic heart disease;
(iii) psychiatric conditions;
(iv) hypertension.
The prescriber must provide the following:
(a) initial body weight; and
(b) BMI.

Continuing treatment for patients who have previously been issued with an authority prescription for orlistat. After 3 months and up to 6 months following commencement of orlistat treatment, patient's initial body weight must have been reduced by 2.5 kg or 2.5% (whichever is the lesser).

Continuing treatment for patients who have previously been issued with an authority prescription for orlistat. After 6 months and up to 12 months following commencement of orlistat treatment, patient's initial body weight must have been reduced by 5 kg or 5% (whichever is the lesser).

NOTE:
The patient should be ideally enrolled in an exercise program and be receiving supplemental vitamins.

4570M	***Capsule 120 mg***	***84***	***2***	***..***	***128.21***	***5.30***	***Xenical***	***RO***

VITAMINS

Vitamin B_1, plain and in combination with vitamin B_6 and vitamin B_{12}

• ***Vitamin B_1, plain***

THIAMINE HYDROCHLORIDE

4043T	Tablet 100 mg	100	2	..	10.39	5.30	Betamin	SW

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
	Vitamin B-complex, incl. combinations							
	• ***Vitamin B-complex, plain***							
	VITAMIN B GROUP COMPLEX							
4493L	Oral liquid 200 mL	‡ 1	2	..	12.91	5.30	Accomin Adult Tonic	WT
	MINERAL SUPPLEMENTS							
	Calcium							
	• ***Calcium***							
	CALCIUM							
	Restricted Benefit							
	Hypocalcaemia;							
	Osteoporosis;							
	Proven calcium malabsorption.							
4332B	***Tablet 250 mg (as citrate)***	***120***	***1***	***..***	***13.88***	***5.30***	***Citracal***	***BN***
4333C	***Tablet (chewable) 500 mg (as carbonate)***	***120***	***1***	***..***	**** 15.81***	***5.30***	***Cal-Sup***	***IA***
4082W	***Tablet 600 mg (as carbonate)***	***120***	***1***	***..***	***13.88***	***5.30***	***CAL-600***	***PP***
	Restricted Benefit							
	Hyperphosphataemia in chronic renal failure.							
4093K	***Tablet 250 mg (as citrate)***	***240***	***1***	***..***	**** 21.77***	***5.30***	***Citracal***	***BN***
4094L	***Tablet (chewable) 500 mg (as carbonate)***	***240***	***1***	***..***	**** 25.63***	***5.30***	***Cal-Sup***	***IA***
4142B	***Tablet 600 mg (as carbonate)***	***240***	***1***	***..***	**** 21.77***	***5.30***	***CAL-600***	***PP***
	Other mineral supplements							
	• ***Magnesium***							
	MAGNESIUM ASPARTATE							
	Restricted Benefit							
	Patients with documented hypomagnesaemia.							
4321K	***Tablet 500 mg***	***50***	***..***	***..***	***13.96***	***5.30***	***Magmin***	***BB***
							Mag-Sup	***PP***
	BLOOD AND BLOOD FORMING ORGANS							
	ANTITHROMBOTIC AGENTS							
	Antithrombotic agents							
	• ***Platelet aggregation inhibitors excl. heparin***							
	ASPIRIN							
4076M	Tablet 100 mg (with glycine)	90	1	..	15.24	5.30	Cardiprin 100	RC

continued ☞

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
4077N	Tablet 100 mg (enteric coated)	84	1	..	13.28	5.30	Cartia	GK
4078P	Capsule 100 mg (containing enteric coated pellets)	84	1	..	14.19	5.30	Astrix	HH

NOTE:
The enteric coated preparations are for patients with a significant risk of gastrointestinal bleeding.

CLOPIDOGREL HYDROGEN SULFATE

Authority Required
For use in patients pre- and post-angioplasty.

4179Y	***Tablet 75 mg (base)***	***28***	***3***	***..***	***80.49***	***5.30***	[a] ***Iscover***	***BQ***
							[a] ***Plavix***	***SW***

BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS

Irrigating solutions

- ***Salt solutions***

SODIUM CHLORIDE

4460R	Irrigation solution 9 mg per mL (0.9%), 500 mL	‡ 1	2	..	9.90	5.30	BX	
4461T	Irrigation solution 9 mg per mL (0.9%), 1 L	‡ 1	2	..	10.22	5.30	BX	

CARDIOVASCULAR SYSTEM

VASOPROTECTIVES

Agents for treatment of hemorrhoids and anal fissures for topical use

- ***Corticosteroids***

HYDROCORTISONE with CINCHOCAINE HYDROCHLORIDE

CAUTION:
Long-term use may lead to skin atrophy.

4036K	Ointment 5 mg-5 mg per g (0.5%-0.5%), 30 g	‡ 1	..	..	19.61	5.30	Proctosedyl	SW
4038M	Suppositories 5 mg-5 mg, 12	‡ 1	..	..	18.51	5.30	Proctosedyl	SW

- ***Other agents for treatment of hemorrhoids and anal fissures for topical use***

ZINC OXIDE

4039N	Compound ointment 50 g	‡ 1	1	..	14.01	5.30	Anusol	JT
4040P	Compound suppositories, 12	‡ 1	1	..	12.92	5.30	Anusol	JT

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
	DERMATOLOGICALS							
	ANTIFUNGALS FOR DERMATOLOGICAL USE							
	Antifungals for topical use							
	• ***Antibiotics***							
	NYSTATIN							
4001N	Cream 100,000 units per g, 15 g	‡ 1	1	..	12.06	5.30	Mycostatin	BQ
	• ***Imidazole and triazole derivatives***							
	BIFONAZOLE							
4003Q	Cream 10 mg per g (1%), 15 g	‡ 1	..	..	15.68	5.30	Mycospor	BN
	CLOTRIMAZOLE							
4004R	Cream 10 mg per g (1%), 20 g	‡ 1	1	..	8.54	5.30	Clonea	AF
4005T	Lotion 10 mg per mL (1%), 20 mL	‡ 1	1	..	11.96	5.30	Canesten	BN
	KETOCONAZOLE							
	Restricted Benefit ***Severe seborrhoeic dermatitis.***							
4008Y	***Shampoo 20 mg per g (2%), 60 mL***	***‡ 1***	***..***	***..***	***17.88***	***5.30***	***Nizoral 2%***	***JT***
4007X	***Shampoo 20 mg per g (2%), 100 mL***	***‡ 1***	***..***	***..***	***18.94***	***5.30***	***Sebizole***	***GM***
				..	***18.96***	***5.30***	***Hexal Konazol 2% Shampoo***	***HX***
	MICONAZOLE							
4341L	Tincture 20 mg per mL (2%), 30 mL	‡ 1	1	..	19.04	5.30	Daktarin	JT
	MICONAZOLE NITRATE							
4454K	Cream 20 mg per g (2%), 30 g	‡ 1	1	..	14.36	5.30	Daktarin	JT
	• ***Other antifungals for topical use***							
	AMOROLFINE HYDROCHLORIDE							
	Restricted Benefit ***Onychomycosis.***							
4010C	***Nail treatment kit containing nail lacquer 50 mg (base) per mL (5%), 5 mL, 60 isopropyl alcohol cleaning pads, 10 spatulas and 30 nail files***	***‡ 1***	***1***	***..***	***93.95***	***5.30***	***Loceryl***	***GA***

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Proprietary Name and Manufacturer	
	CICLOPIROX OLAMINE								
	Restricted Benefit ***Severe seborrhoeic dermatitis.***								
4106D	***Shampoo 15 mg per g (1.5%), 60 mL***	***‡ 1***	***..***	***..***	***16.13***	***5.30***		***Stieprox Liquid***	***SX***
	TERBINAFINE								
	Restricted Benefit ***Tinea pedis.***								
4463X	***Gel 10 mg per g (1%), 15 g***	***‡ 1***	***..***	***..***	***22.92***	***5.30***		***Lamisil DermGel***	***NC***
	TERBINAFINE HYDROCHLORIDE								
	Restricted Benefit ***Tinea pedis.***								
4473K	***Cream 10 mg per g (1%), 15 g***	***‡ 1***	***1***	***..***	***21.46***	***5.30***		***Lamisil***	***NC***
	TOLNAFTATE								
4481W	Spray aerosol 10 mg per g (1%), 100 g	‡ 1	..	..	14.25	5.30		Tinaderm	SH
	Antifungals for systemic use								
	• ***Antifungals for systemic use***								
	TERBINAFINE HYDROCHLORIDE								
	Authority Required ***Onychomycosis due to dermatophyte infection proven by microscopy or culture and confirmed by an approved pathology provider.***								
4011D	***Tablet 250 mg (base)***	***42***	***1***	***..***	***102.39***	***5.30***	[a]	***Tamsil***	***SI***
							[a]	***Terbihexal***	***SZ***
							[a]	***Terbinafine-DP***	***GM***
							[a]	***Zabel***	***AF***
				..	***103.85***	***5.30***	[a]	***Lamisil***	***NV***
	EMOLLIENTS AND PROTECTIVES								
	Emollients and protectives								
	• ***Silicone products***								
	DIMETHICONE with GLYCEROL								
	Restricted Benefit ***For colostomy and ileostomy use;*** ***For use by paraplegic and quadriplegic patients;*** ***For use with surgical appliances.***								
4556T	***Cream 150 mg-20 mg per g (15%-2%), 75 g***	***‡ 1***	***..***	***..***	***11.71***	***5.30***		***Silic 15***	***EO***

continued ☞

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
4551M	***Cream 150 mg-20 mg per g (15%-2%), 500 g***	***‡ 1***	***..***	***..***	***24.68***	***5.30***	***Silic 15***	***EO***
	• *Soft paraffin and fat products*							
	WOOL ALCOHOLS							
4041Q	Ointment 100 g	‡ 1	1	..	12.37	5.30	Eucerin	BE
	• *Carbamide products*							
	UREA							
4042R	Cream 100 mg per g (10%), 100 g	‡ 1	2	..	11.65	5.30	Aquacare H.P.	AG
				..	11.73	5.30	Urederm	HA
				..	12.34	5.30	Calmurid	OL
							Nutraplus	GA
	• *Other emollients and protectives*							
	CARMELLOSE SODIUM with PECTIN and GELATIN							
4518T	Paste 167 mg-167 mg-167 mg per g (16.7%-16.7%- 16.7%), 5 g	‡ 1	..	..	11.42	5.30	Orabase	BQ
	SKIN EMOLLIENT							
4122Y	Bath oil 500 mL	‡ 1	2	..	16.92	5.30	Alpha Keri Bath Oil	MT
				..	19.33	5.30	QV Bath Oil	EO
				..	19.42	5.30	Hamilton Skin Therapy Oil	HA
4107E	Lotion 500 mL	‡ 1	2	..	16.92	5.30	Alpha Keri Lotion	MT
	Protectives against UV-radiation							
	• *Protectives against UV-radiation for topical use*							
	SUNSCREENS							
4543D	Solid stick 4.5 g	‡ 1	2	..	11.68	5.30	Hamilton Solastick 30+	HA
4544E	Cream 100 g	‡ 1	2	..	15.09	5.30	Hamilton Sunscreen Family Sunscreen Cream SPF 15	HA
				..	16.69	5.30	SunSense Cream SPF 30+	EO

continued ☞

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
4546G	Lotion (non-alcoholic) 125 mL	‡ 1	2	..	15.09	5.30	Hamilton Sunscreen Family Sunscreen Milk SPF 15	HA
				..	15.55	5.30	Aquasun Lotion SPF 18	PF
				..	16.56	5.30	SunSense Ultra SPF 30+	EO

ANTIPRURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC.

Antipruritics, incl. antihistamines, anesthetics, etc.

- ***Anesthetics for topical use***

LIGNOCAINE HYDROCHLORIDE with CARBOXYMETHYLCELLULOSE

4308R	Mucilage 20 mg-25 mg per mL (2%-2.5%), 200 mL	‡ 1	..	..	78.92	5.30	Xylocaine Viscous	AP

- ***Other antipruritics***

PINE TAR with TRIETHANOLAMINE LAURYL SULFATE

NOTE:

For patients who have failed to respond to simple moisturising agents.

4408B	Solution 23 mg-60 mg per mL (2.3%-6%), 500 mL	‡ 1	2	..	19.87	5.30	Hamilton Pine Tar Solution	HA
				..	20.50	5.30	Pinetarsol	EO

ANTIPSORIATICS

Antipsoriatics for topical use

- ***Tars***

ALLANTOIN with SULFUR, PHENOL, COAL TAR SOLUTION and MENTHOL

4505D	Gel 25 mg-5 mg-5 mg-0.05 mL-7.5 mg per g (2.5%-0.5%-0.5%-5%-0.75%), 30 g	‡ 1	2	..	14.64	5.30	Egopsoryl-TA	EO

ANTIBIOTICS AND CHEMOTHERAPEUTICS FOR DERMATOLOGICAL USE

Antibiotics for topical use

- ***Other antibiotics for topical use***

MUPIROCIN

Restricted Benefit

For the topical treatment of secondarily infected traumatic skin lesions.

4348W	***Cream 20 mg (as calcium) per g (2%), 15 g***	***‡ 1***	***..***	***..***	***15.85***	***5.30***	***Bactroban***	***GK***

continued ☞

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
4350Y	***Ointment 20 mg per g (2%), 15 g***	***‡ 1***	***..***	***..***	***15.85***	***5.30***	***Bactroban***	***GK***
	Chemotherapeutics for topical use							
	• ***Antivirals***							
	PODOPHYLLOTOXIN							
	Authority Required							
	For the treatment of ano-genital warts.							
4566H	***Paint 5 mg per mL (0.5%), 3.5 mL (with 30 swabs)***	***‡ 1***	***..***	***..***	***38.03***	***5.30***	***Condyline Paint***	***HA***
	• ***Other chemotherapeutics***							
	METRONIDAZOLE							
4030D	Gel 7.5 mg per g (0.75%), 50 g	‡ 1	..	..	31.42	5.30	Rozex	GA
4340K	Cream 7.5 mg per g (0.75%), 30 g	‡ 1	1	..	22.23	5.30	Rozex	GA
	CORTICOSTEROIDS, DERMATOLOGICAL PREPARATIONS							
	Corticosteroids, plain							
	• ***Corticosteroids, potent (group III)***							
	BETAMETHASONE VALERATE							
4131K	Cream 1 mg (base) per g (0.1%), 30 g	‡ 1	2	..	22.00	5.30	Betnovate	SI
4132L	Ointment 1 mg (base) per g (0.1%), 30 g	‡ 1	2	..	22.00	5.30	Betnovate	SI
	MOMETASONE FUROATE							
4342M	Cream 1 mg per g (0.1%), 45 g	‡ 1	..	..	26.38	5.30	Elocon	SH
4343N	Ointment 1 mg per g (0.1%), 45 g	‡ 1	..	..	26.38	5.30	Elocon	SH
	NOTE: Application to large areas of skin for longer than four weeks is not recommended.							
	Corticosteroids, combinations with antibiotics							
	• ***Corticosteroids, moderately potent, combinations with antibiotics***							
	TRIAMCINOLONE ACETONIDE with NEOMYCIN SULFATE, GRAMICIDIN and NYSTATIN							
4482X	Ointment 1 mg-2.5 mg (base)-250 micrograms- 100,000 units per g (0.1%-0.25% (base)-0.025%-100,000 units in 1 g), 15 g	‡ 1	..	..	18.66	5.30	Kenacomb	BQ
	CAUTION: For the short-term treatment of localised infective eczema only.							

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
	ANTISEPTICS AND DISINFECTANTS							
	Antiseptics and disinfectants							
	• ***Iodine products***							
	POVIDONE-IODINE							
4411E	Solution 100 mg per mL (10%), 100 mL	‡ 1	..	..	20.39	5.30	Betadine Antiseptic Liquid	FH
	OTHER DERMATOLOGICAL PREPARATIONS							
	Other dermatological preparations							
	• ***Antihidrotics***							
	DIPHEMANIL METHYLSULFATE							
4191N	Dusting powder 20 mg per g (2%), 50 g	‡ 1	1	..	16.93	5.30	Prantal	SH
	• ***Medicated shampoos***							
	PINE TAR with CADE OIL, COAL TAR SOLUTION, ARACHIS OIL EXTRACT OF CRUDE COAL TAR and OLEYL ALCOHOL							
4405W	Scalp cleanser 3 mg-3 mg-1 mg-3 mg-10 mg per mL (0.3%-0.3%-0.1%-0.3%-1%), 300 mL	‡ 1	2	..	20.60	5.30	Polytar	SX
	SALICYLIC ACID with COAL TAR SOLUTION							
4560B	Scalp cleanser 20 mg-50 mg per mL (2%-5%), 200 mL	‡ 1	2	..	19.28	5.30	Ionil-T	GA
	SALICYLIC ACID with COAL TAR SOLUTION and PINE TAR							
4447C	Scalp cleanser 20 mg-10 mg-10 mg per mL (2%-1%-1%), 250 mL	‡ 1	2	..	17.28	5.30	Sebitar	EO
	SELENIUM SULFIDE							
4452H	Shampoo 25 mg per mL (2.5%), 125 mL	‡ 1	..	..	13.71	5.30	Selsun	AB
	• ***Wart and anti-corn preparations***							
	SALICYLIC ACID with PODOPHYLLIN RESIN							
4450F	Paint 100 mg-200 mg per mL (10%-20%), 6 mL	‡ 1	1	..	14.88	5.30	Posalfilin	NE

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
	• *Other dermatologicals*							
	ALLANTOIN with GLYCEROL and ICHTHAMMOL							
	NOTE:							
	For patients who have failed to respond to simple moisturising agents.							
4281H	Cream 5 mg-10 mg-10 mg per g (0.5%-1%-1%), 50 g	‡ 1	2	..	16.92	5.30	Egoderm Cream	EO
4280G	Ointment 5 mg-10 mg-10 mg per g (0.5%-1%-1%), 50 g	‡ 1	2	..	16.92	5.30	Egoderm Ointment	EO
	CATIONIC CONDITIONER with PANTHENOL							
	NOTE:							
	To be used in conjunction with the scalp cleanser salicylic acid with coal tar solution and pine tar (code 4447C).							
4510J	Cream 200 g	‡ 1	2	..	13.82	5.30	SebiRinse	EO
	IMIQUIMOD							
	Authority Required							
	Primary treatment of histopathologically confirmed superficial basal cell carcinoma where other standard treatments are inappropriate and topical drug therapy is required.							
4559Y	***Cream 50 mg per g (5%), 250 mg single use sachets, 12***	***1***	***1***	***..***	***159.52***	***5.30***	***Aldara***	***IA***
	Authority Required							
	Treatment of solar keratosis on the face and scalp in patients where other standard treatments are inappropriate and topical drug therapy is required as field treatment for clinically visible and subclinical lesions.							
4134N	***Cream 50 mg per g (5%), 250 mg single use sachets, 12***	***1***	***1***	***..***	***159.52***	***5.30***	***Aldara***	***IA***
	SKIN CLEANSER							
4549K	Lotion 500 mL	‡ 1	2	..	20.31	5.30	Hamilton Skin Therapy Wash	HA
	ZINC OXIDE with STARCH and CHLORPHENESIN							
4497Q	Dusting powder 100 g	‡ 1	1	..	11.83	5.30	Z.S.C.	SI

GENITO URINARY SYSTEM AND SEX HORMONES

GYNECOLOGICAL ANTIINFECTIVES AND ANTISEPTICS

Antiinfectives and antiseptics, excl. comb. with corticosteroids

	• *Antibiotics*							
	NYSTATIN							
4012E	Cream pessaries 100,000 units, 15	‡ 1	1	..	13.36	5.30	Nilstat	SI

continued ☞

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
4013F	Vaginal cream 100,000 units per dose, 15 doses, 75 g	‡ 1	1	..	13.36	5.30	Nilstat	SI
	• ***Imidazole derivatives***							
	CLOTRIMAZOLE							
4014G	Pessaries 100 mg, 6	‡ 1	..	..	14.65	5.30	Clofeme	HX
4015H	Pessary 500 mg	1	..	..	15.25	5.30	Clofeme	HX
4016J	Vaginal cream 50 mg per 5 g (1%), 35 g	‡ 1	..	..	14.65	5.30	Chem mart Clotrimazole 6 Day Cream	CH
							GenRx Clotrimazole 6 Day Cream	GX
							healthsense Clotrimazole 6 Day Cream	HS
							Terry White Chemists Clotrimazole 6 Day Cream	TW
				..	14.76	5.30	Hexal Clofeme 6 Day Cream	HX
4017K	Vaginal cream 100 mg per 5 g (2%), 20 g	‡ 1	..	..	14.65	5.30	Chem mart Clotrimazole 3 Day Cream	CH
							Femizol Vaginal Cream	GM
							GenRx Clotrimazole 3 Day Cream	GX
							healthsense Clotrimazole 3 Day Cream	HS
							Terry White Chemists Clotrimazole 3 Day Cream	TW
				..	14.76	5.30	Hexal Clofeme 3 Day Cream	HX
	MICONAZOLE NITRATE							
4020N	Pessaries 100 mg, 7	‡ 1	..	..	14.42	5.30	Monistat 7	JC
4021P	Vaginal cream 100 mg per 5 g (2%), 40 g	‡ 1	..	..	14.42	5.30	Monistat 7	JC

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
	OTHER GYNECOLOGICALS							
	Other gynecologicals							
	• ***Other gynecologicals***							
	RICINOLEIC ACID with ACETIC ACID and HYDROXYQUINOLINE SULFATE							
4434J	Vaginal jelly 7 mg-9.4 mg-250 micrograms per g (0.7%-0.94%-0.025%), 100 g	‡ 1	..	..	32.47	5.30	Aci-Jel	JC
	SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM							
	Estrogens							
	• ***Natural and semisynthetic estrogens, plain***							
	OESTRADIOL							
	Restricted Benefit ***Post-menopausal symptoms in women who have failed to respond using oral or topical oestrogens.***							
4365R	***Implant 50 mg***	***1***	..	..	***75.93***	***5.30***	***SH***	
4366T	***Implant 100 mg***	***1***	..	..	***115.66***	***5.30***	***SH***	
	UROLOGICALS							
	Other urologicals, incl. antispasmodics							
	• ***Drugs used in erectile dysfunction***							
	ALPROSTADIL							
	Authority Required ***Specific accepted war-caused or service-related disabilities for males with vasculogenic, psychogenic or neurogenic erectile dysfunction.*** ***Authorisation will not be given for any additional prescriptions within 6 months or for any increased quantities or repeats.***							
4579B	***Intracavernosal injection 10 micrograms with diluent in single use syringe***	***6***	***3***	..	**** 82.19***	***5.30***	***Caverject Impulse***	***PH***
4580C	***Intracavernosal injection 20 micrograms with diluent in single use syringe***	***6***	***3***	..	**** 103.19***	***5.30***	***Caverject Impulse***	***PH***
	SILDENAFIL CITRATE							
	Authority Required ***Specific accepted war-caused or service-related disabilities for males with vasculogenic, psychogenic or neurogenic erectile dysfunction.*** ***Authorisation will not be given for any additional prescriptions within 6 months or for any increased quantities or repeats.***							
4584G	***Tablet 25 mg (base)***	***4***	***5***	..	***57.67***	***5.30***	***Viagra***	***PF***
4585H	***Tablet 50 mg (base)***	***4***	***5***	..	***71.77***	***5.30***	***Viagra***	***PF***

continued ☞

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
4586J	***Tablet 100 mg (base)***	***4***	***5***	***..***	***77.14***	***5.30***	***Viagra***	***PF***
	TADALAFIL							
	Authority Required ***Specific accepted war-caused or service-related disabilities for males with vasculogenic, psychogenic or neurogenic erectile dysfunction.*** ***Authorisation will not be given for any additional prescriptions within 6 months or for any increased quantities or repeats.***							
4596X	***Tablet 10 mg***	***4***	***5***	***..***	***73.71***	***5.30***	***Cialis***	***LY***
4597Y	***Tablet 20 mg***	***4***	***5***	***..***	***79.23***	***5.30***	***Cialis***	***LY***
	• ***Other urologicals*** SODIUM BICARBONATE							
4458P	Capsule 840 mg **CAUTION:** For use in the treatment of renal disease.	100	2	..	13.57	5.30	Sodibic	AS
	SODIUM CITRO-TARTRATE							
	Restricted Benefit ***For relief of urinary symptoms when antibiotic or other therapy alone is inappropriate.***							
4049D	***Sachets containing oral effervescent powder 4 g, 28***	***‡ 1***	***4***	***..***	***13.12***	***5.30***	***Uracol Ural Sachets***	***GM SI***
	Drugs used in benign prostatic hypertrophy • ***Alpha-adrenoreceptor antagonists*** ***TAMSULOSIN HYDROCHLORIDE***							
	Authority Required ***Treatment of benign prostatic hyperplasia where surgery is inappropriate, or where other drug treatment has failed or is contraindicated.***							
4070F	***Tablet 400 micrograms (prolonged release)***	***30***	***5***	***..***	***62.93***	***5.30***	***Flomaxtra***	***CS***
	TERAZOSIN HYDROCHLORIDE							
	Authority Required ***Treatment of benign prostatic hyperplasia where surgery is inappropriate, or where other drug treatment has failed or is contraindicated.***							
4396J	***Starter pack containing 7 tablets 1 mg and 7 tablets 2 mg***	***‡ 1***	***..***	***..***	***19.62***	***5.30***	***Hytrin***	***AB***
4397K	***Tablet 2 mg***	***28***	***5***	***..***	***41.26***	***5.30***	***Hytrin***	***AB***
4398L	***Tablet 5 mg***	***28***	***5***	***..***	***57.76***	***5.30***	***Hytrin***	***AB***
4399M	***Tablet 10 mg***	***28***	***5***	***..***	***85.63***	***5.30***	***Hytrin***	***AB***

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Proprietary Name and Manufacturer	
	• ***Testosterone-5-alpha reductase inhibitors***								
	FINASTERIDE								
	Authority Required								
	Treatment of benign prostatic hyperplasia where surgery is inappropriate, or where other drug treatment has failed or is contraindicated.								
4233T	***Tablet 5 mg***	***30***	***5***	***..***	***101.69***	***5.30***	***a***	***Finasta***	***SZ***
				..	***111.26***	***5.30***	***a***	***Proscar***	***MK***

ANTIINFECTIVES FOR SYSTEMIC USE

ANTIBACTERIALS FOR SYSTEMIC USE

Macrolides, lincosamides and streptogramins

• ***Macrolides***

AZITHROMYCIN

Restricted Benefit

Upper and lower respiratory tract infections.

4115N	***Tablet 500 mg***	***3***	***..***	***..***	***34.67***	***5.30***		***Zithromax***	***PF***

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

ANTINEOPLASTIC AGENTS

Antimetabolites

• ***Pyrimidine analogues***

FLUOROURACIL

4222F	Cream 50 mg per g (5%), 20 g	‡ 1	..	..	50.45	5.30		Efudix	VT

IMMUNOSUPPRESSANTS

Immunosuppressants

• ***Tumor necrosis factor alpha (TNF-alpha) inhibitors***

INFLIXIMAB

NOTE:

Any queries concerning the arrangements to prescribe infliximab may be directed to the Veterans' Affairs Pharmaceutical Advisory Centre (VAPAC) on 1800 552 580.

Written applications for authority to prescribe infliximab should be forwarded to:

Reply Paid 9998
Veterans' Affairs Pharmaceutical Advisory Centre (VAPAC)
Department of Veterans' Affairs
GPO Box 9998
BRISBANE QLD 4001

continued ☞

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	

Authority Required

Initial treatment, in combination with methotrexate, of specific accepted war-caused or service-related disability of refractory rheumatoid arthritis. Initial treatment may be prescribed by rheumatologists or consultant physicians for the reduction of signs and symptoms and prevention of structural joint damage in adult patients with active rheumatoid arthritis who satisfy all of the following criteria:
(1) (a) Proven raised erythrocyte sedimentation rate (ESR) and/or C-reactive protein (CRP); and
(1) (b) Proven erosive rheumatoid arthritis without end-stage disease;
(2) Failure of an adequate trial of methotrexate and 2 other disease modifying anti-rheumatic drugs (such as sulfasalazine, hydroxychloroquine, leflunomide or cyclosporin) — unless these drugs were contraindicated or intolerance had developed;
(3) No history of active tuberculosis requiring treatment in the last 3 years;
(4) No history of opportunistic infection in the last 2 months;
(5) Female patients of child-bearing age are not pregnant, not breast-feeding, and are using an effective form of contraception.

Applications for authorisation must be in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Infliximab (Remicade) RPBS Authority Application - Supporting Information form (contact the VAPAC on 1800 552 580 for a copy of the form).

Authority Required

Continuing treatment, in combination with methotrexate, of specific accepted war-caused or service-related disability of refractory rheumatoid arthritis. Continuing treatment may be prescribed by rheumatologists or consultant physicians, following initial therapy of 3 doses, in patients who satisfy the following criteria:
(1) There is improvement in ESR and/or CRP; and
(2) An ACR20 (American College of Rheumatology) response is achieved by 14 weeks after the commencement of therapy.

Applications for authorisation must be in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Infliximab (Remicade) RPBS Authority Application - Supporting Information form (contact the VAPAC on 1800 552 580 for a copy of the form).

4284L	*Powder for I.V. infusion 100 mg*	*1*	*2*	*..*	*846.55*	*5.30*	*Remicade*	*SH*

MUSCULO-SKELETAL SYSTEM

ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS

Antiinflammatory and antirheumatic products, non-steroids

- ***Acetic acid derivatives and related substances***

DICLOFENAC SODIUM with MISOPROSTOL

Authority Required

Patients requiring an NSAID in whom a risk of upper gastrointestinal complications is high or with a history of peptic ulcer disease.

4190M	*Tablet 50 mg-200 micrograms*	*60*	*2*	*..*	*37.35*	*5.30*	*Arthrotec 50*	*PH*

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
	TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN							
	Topical products for joint and muscular pain							
	• ***Preparations with salicylic acid derivatives***							
	METHYL SALICYLATE							
4022Q	Compound cream APF, 100 g	‡ 1	1	..	13.59	5.30	Gold Cross	BI
4023R	Ointment BP, 100 g	‡ 1	1	..	11.74	5.30	Gold Cross	BI
4025W	Compound ointment APF 1934, 100 g	‡ 1	1	..	10.38	5.30	Gold Cross	BI
4026X	Liniment APF, 100 mL	‡ 1	1	..	9.51	5.30	Gold Cross	BI
4027Y	Compound liniment APF, 100 mL	‡ 1	1	..	11.08	5.30	Gold Cross	BI
	DRUGS FOR TREATMENT OF BONE DISEASES							
	Drugs affecting bone structure and mineralization							
	• ***Bisphosphonates***							
	RISEDRONATE SODIUM							
	Authority Required							
	For preservation of bone mineral density in patients on long-term glucocorticoid therapy where patients are undergoing continuous treatment with a dose equal to or greater than 7.5 mg of prednisone or equivalent per day. Prescribers need to demonstrate that the patient has been on continuous therapy for 3 months or more and demonstrate that the patient is osteopenic (bone mineral density t-score of less than -1.0).							
4443W	***Tablet 5 mg***	***28***	***5***	***..***	***52.91***	***5.30***	***Actonel***	***SW***
4444X	***Tablet 35 mg***	***4***	***5***	***..***	***52.91***	***5.30***	***Actonel Once-a-Week***	***SW***
	• ***Bisphosphonates, combinations***							
	RISEDRONATE SODIUM and CALCIUM CARBONATE							
	Authority Required							
	For preservation of bone mineral density in patients on long-term glucocorticoid therapy where patients are undergoing continuous treatment with a dose equal to or greater than 7.5 mg of prednisone or equivalent per day. Prescribers need to demonstrate that the patient has been on continuous therapy for 3 months or more and demonstrate that the patient is osteopenic (bone mineral density t-score of less than -1.0).							
4059P	***Pack containing 4 tablets risedronate sodium 35 mg and 24 tablets calcium carbonate 1.25 g (equivalent to 500 mg calcium)***	***‡ 1***	***5***	***..***	***52.91***	***5.30***	***Actonel Combi***	***SW***

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
	NERVOUS SYSTEM							
	ANALGESICS							
	Opioids							
	• ***Natural opium alkaloids***							
	MORPHINE SULFATE							
	CAUTION:							
	The risk of drug dependence is high.							
	Restricted Benefit							
	Chronic severe disabling pain not responding to non-narcotic analgesics.							
	NOTE:							
	Authorities for increased maximum quantities and/or repeats will be granted only for							
	(i) chronic severe disabling pain associated with proven malignant neoplasia; or							
	(ii) chronic severe disabling pain where treatment has been initiated by a specialist with appropriate expertise in pain management.							
4349X	***Tablet 200 mg (controlled release)***	***20***	***..***	***..***	***104.50***	***5.30***	***MS Contin***	***MF***
	• ***Diphenylpropylamine derivatives***							
	DEXTROPROPOXYPHENE NAPSYLATE							
	CAUTION:							
	Chronic use of this preparation is likely to cause drug dependence.							
4081T	Capsule 100 mg	50	..	..	* 18.19	5.30	Doloxene	AS
	Other analgesics and antipyretics							
	• ***Salicylic acid and derivatives***							
	CODEINE PHOSPHATE with ASPIRIN							
4061R	Tablet soluble 8 mg-300 mg	50	2	..	13.14	5.30	Aspalgin	FM
	• ***Anilides***							
	CODEINE PHOSPHATE with PARACETAMOL							
4171M	Tablet 8 mg-500 mg	50	2	..	11.31	5.30	Panamax Co.	SW
				..	12.43	5.30	Codalgin	FM
4170L	Tablet 15 mg-500 mg	20	2	..	8.80	5.30	Prodeine 15	SW
	• ***Other analgesics and antipyretics***							
	GABAPENTIN							
	Authority Required							
	To be approved for the treatment of refractory neuropathic pain not controlled by other drugs.							
4591P	***Capsule 100 mg***	***100***	***5***	***..***	***23.38***	***5.30***	[a] ***Gantin***	***AW***
							[a] ***Neurontin***	***PF***
							[a] ***Nupentin 100***	***AF***

continued ☞

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
4592Q	*Capsule 300 mg*	*100*	*5*	*..*	*61.58*	*5.30*	[a] *DBL Gabapentin*	*HH*
							[a] *Douglas Gabapentin 300mg*	*GM*
							[a] *Gabahexal 300mg*	*SZ*
							[a] *Gantin*	*AW*
							[a] *GenRx Gabapentin*	*GX*
							[a] *Neurontin*	*PF*
							[a] *Nupentin 300*	*AF*
4593R	*Capsule 400 mg*	*100*	*5*	*..*	*81.81*	*5.30*	[a] *DBL Gabapentin*	*HH*
							[a] *Douglas Gabapentin 400mg*	*GM*
							[a] *Gabahexal 400mg*	*SZ*
							[a] *Gantin*	*AW*
							[a] *GenRx Gabapentin*	*GX*
							[a] *Neurontin*	*PF*
							[a] *Nupentin 400*	*AF*
4594T	*Tablet 600 mg*	*100*	*5*	*..*	*126.34*	*5.30*	*Neurontin*	*PF*
4595W	*Tablet 800 mg*	*100*	*5*	*..*	*166.43*	*5.30*	[a] *Gantin*	*AW*
							[a] *Neurontin*	*PF*

PREGABALIN

Authority Required

For the treatment of refractory neuropathic pain not controlled by other drugs.

4322L	*Capsule 75 mg*	*56*	*5*	*..*	*84.53*	*5.30*	*Lyrica*	*PF*
4323M	*Capsule 150 mg*	*56*	*5*	*..*	*123.81*	*5.30*	*Lyrica*	*PF*
4324N	*Capsule 300 mg*	*56*	*5*	*..*	*182.71*	*5.30*	*Lyrica*	*PF*

PSYCHOLEPTICS

Anxiolytics

- ***Benzodiazepine derivatives***

BROMAZEPAM

Authority Required

Patients with terminal disease;

Patients with refractory phobic or anxiety states.

NOTE:

For short-term use and palliative care. This drug should not be used as the first line of treatment. Other PBS-listed benzodiazepines should have been adequately tried and found to be ineffective or inappropriate. Authorities for increased quantities and/or repeats may be granted to patients with terminal disease, and other patients who have been shown to be dependent on this item by an unsuccessful attempt at gradual withdrawal.

4150K	*Tablet 3 mg*	*60*	*..*	*..*	* *26.95*	*5.30*	*Lexotan*	*RO*
4151L	*Tablet 6 mg*	*60*	*..*	*..*	* *32.97*	*5.30*	*Lexotan*	*RO*

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Proprietary Name and Manufacturer	
	• ***Azaspirodecanedione derivatives***								
	BUSPIRONE HYDROCHLORIDE								
	Authority Required								
	For the short-term treatment of anxiety.								
4144D	***Tablet 5 mg***	***50***	***..***	***..***	***37.56***	***5.30***		***Buspar***	***BQ***
4145E	***Tablet 10 mg***	***50***	***..***	***..***	***54.41***	***5.30***		***Buspar***	***BQ***
	Hypnotics and sedatives								
	• ***Benzodiazepine derivatives***								
	FLUNITRAZEPAM								
	Authority Required								
	Patients with terminal disease;								
	Patients with refractory phobic or anxiety states.								
	NOTE:								
	For short-term use and palliative care. This drug should not be used as the first line of treatment. Other PBS-listed benzodiazepines should have been adequately tried and found to be ineffective or inappropriate. Authorities for increased quantities and/or repeats may be granted to patients with terminal disease, and other patients who have been shown to be dependent on this item by an unsuccessful attempt at gradual withdrawal.								
4216X	***Tablet 1 mg***	***30***	***..***	***..***	***13.08***	***5.30***		***Hypnodorm***	***AF***
	• ***Benzodiazepine related drugs***								
	ZOPICLONE								
	Restricted Benefit								
	For the short-term treatment of insomnia.								
4522B	***Tablet 7.5 mg***	***30***	***..***	***..***	***21.33***	***5.30***	[a]	***Imrest***	***AF***
				..	***22.91***	***5.30***	[a]	***Imovane***	***SW***
	OTHER NERVOUS SYSTEM DRUGS								
	Drugs used in addictive disorders								
	• ***Drugs used in nicotine dependence***								
	NICOTINE								
	Authority Required								
	Patients who have indicated that they are ready to cease smoking and who have entered a support and counselling program.								
	NOTE:								
	Studies have shown that successful therapy with this drug is enhanced by patient participation in a support and counselling program.								
4576W	***Transdermal patches releasing approximately 5 mg per 16 hours, 7***	***2***	***..***	***..***	**** 50.39***	***5.30***		***Nicorette Patch***	***JT***
4571N	***Transdermal patches releasing approximately 7 mg per 24 hours, 7***	***2***	***..***	***..***	**** 45.77***	***5.30***		***QuitX***	***AF***
				..	**** 73.89***	***5.30***		***Nicabate CQ 7***	***GK***

continued ☞

REPATRIATION

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
4577X	***Transdermal patches releasing approximately 10 mg per 16 hours, 7***	***2***	***..***	***..***	**** 54.35***	***5.30***	***Nicorette Patch***	***JT***
4572P	***Transdermal patches releasing approximately 14 mg per 24 hours, 7***	***2***	***..***	***..***	**** 49.09***	***5.30***	***QuitX***	***AF***
				..	**** 73.89***	***5.30***	***Nicabate CQ 14***	***GK***
4578Y	***Transdermal patches releasing approximately 15 mg per 16 hours, 7***	***2***	***2***	***..***	**** 59.53***	***5.30***	***Nicorette Patch***	***JT***
4573Q	***Transdermal patches releasing approximately 21 mg per 24 hours, 7***	***2***	***2***	***..***	**** 53.09***	***5.30***	***QuitX***	***AF***
				..	**** 73.89***	***5.30***	***Nicabate CQ 21***	***GK***

ANTIPARASITIC PRODUCTS, INSECTICIDES AND REPELLENTS

ANTHELMINTICS

Antinematodal agents

- ***Benzimidazole derivatives***

MEBENDAZOLE

4325P	Tablet 100 mg	6	..	..	19.62	5.30	Vermox	JC

RESPIRATORY SYSTEM

NASAL PREPARATIONS

Decongestants and other nasal preparations for topical use

- ***Sympathomimetics, plain***

OXYMETAZOLINE HYDROCHLORIDE

4378K	Nasal spray 500 micrograms per mL (0.05%), 15 mL	‡ 1	..	..	16.20	5.30	Drixine	SH
4379L	Nasal spray 500 micrograms per mL (0.05%), 18 mL	‡ 1	..	..	16.33	5.30	Logicin Rapid Relief	SI

- ***Antiallergic agents, excl. corticosteroids***

LEVOCABASTINE HYDROCHLORIDE

4311X	Nasal spray 500 micrograms per mL (0.05%), 10 mL (100 doses)	‡ 1	2	..	17.81	5.30	Livostin	JT

SODIUM CROMOGLYCATE

4468E	Nasal spray metered dose pump 20 mg per mL (2%), 26 mL	‡ 1	5	..	19.93	5.30	Rynacrom	SW

- ***Corticosteroids***

BUDESONIDE

Restricted Benefit
Severe intractable rhinitis.

4092J	***Aqueous nasal spray (pump pack) 64 micrograms per dose (120 doses)***	***‡ 1***	***..***	***..***	***31.30***	***5.30***	***Budamax Aqueous***	***PM***

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
	• ***Other nasal preparations***							
	IPRATROPIUM BROMIDE							
	Restricted Benefit							
	Severe intractable rhinorrhoea, associated with perennial rhinitis, unresponsive to insufflated nasal steroids.							
4089F	***Aqueous nasal spray (pump pack) 21 micrograms (anhydrous) per dose (180 doses)***	***‡ 1***	***5***	***..***	***22.03***	***5.30***	***Atrovent Nasal Aqueous***	***BY***
4090G	***Aqueous nasal spray (pump pack) 42 micrograms (anhydrous) per dose (180 doses)***	***‡ 1***	***5***	***..***	***28.46***	***5.30***	***Atrovent Nasal Forte***	***BY***
	Nasal decongestants for systemic use							
	• ***Sympathomimetics***							
	PSEUDOEPHEDRINE HYDROCHLORIDE							
4029C	Tablet 60 mg	12	..	..	10.59	5.30	Logicin Sinus	SI
	COUGH AND COLD PREPARATIONS							
	Expectorants, excl. combinations with cough suppressants							
	• ***Expectorants***							
	SENEGA and AMMONIA							
4074K	Mixture 200 mL	‡ 1	4	..	8.75	5.30	Gold Cross	BI
	Cough suppressants, excl. combinations with expectorants							
	• ***Opium alkaloids and derivatives***							
	PHOLCODINE							
4071G	Linctus 1 mg per mL (0.1%), 100 mL	‡ 1	2	..	8.59	5.30	Gold Cross	BI
				..	13.47	5.30	Duro-Tuss	IA
	ANTIHISTAMINES FOR SYSTEMIC USE							
	Antihistamines for systemic use							
	• ***Phenothiazine derivatives***							
	PROMETHAZINE HYDROCHLORIDE							
4072H	Tablet 10 mg	50	2	..	14.24	5.30	Phenergan	SW
4073J	Tablet 25 mg **CAUTION:** Significant side effects may occur.	50	2	..	16.33	5.30	Phenergan	SW
	• ***Piperazine derivatives***							
	CETIRIZINE HYDROCHLORIDE							
4175R	Tablet 10 mg	30	..	..	32.44	5.30	Alzene	AF
							Zilarex	SZ
				..	39.02	5.30	Zyrtec	JT

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
	• *Other antihistamines for systemic use*							
	FEXOFENADINE HYDROCHLORIDE							
4237B	Tablet 60 mg	60	..	..	* 40.70	5.30	[a] Fexal	SZ
							[a] Xergic	AF
				..	* 47.75	5.30	[a] Telfast	SW
4238C	Tablet 120 mg	30	..	..	34.28	5.30	[a] Fexal	SZ
							[a] Xergic	AF
				..	41.09	5.30	[a] Telfast 120	SW
	LORATADINE							
4313B	Tablet 10 mg	30	..	..	43.22	5.30	[a] Lorano	SZ
				..	44.31	5.30	[a] Allereze	AF
							[a] Claratyne	SH

SENSORY ORGANS

OPHTHALMOLOGICALS

Decongestants and antiallergics

• *Sympathomimetics used as decongestants*

ANTAZOLINE with NAPHAZOLINE

4031E	Eye drops 5 mg (sulfate)-250 micrograms (nitrate) per mL (0.5%-0.025%), 10 mL	‡ 1	1	..	13.43	5.30	Antistine-Privine	NV
4032F	Eye drops 5 mg (phosphate)-500 micrograms (hydrochloride) per mL (0.5%-0.05%), 15 mL	‡ 1	1	..	13.38	5.30	Albalon-A	AG
	NAPHAZOLINE HYDROCHLORIDE							
4035J	Eye drops 1 mg per mL (0.1%), 15 mL	‡ 1	1	..	12.59	5.30	Naphcon Forte	AQ
				..	13.44	5.30	Albalon Liquifilm	AG
	NAPHAZOLINE HYDROCHLORIDE with PHENIRAMINE MALEATE							
4355F	Eye drops 250 micrograms-3 mg per mL (0.025%-0.3%), 15 mL	‡ 1	1	..	13.71	5.30	Naphcon-A	AQ
	ZINC SULFATE with PHENYLEPHRINE HYDROCHLORIDE							
4034H	Eye drops 2.5 mg-1.2 mg per mL (0.25%-0.12%), 15 mL	‡ 1	5	..	12.59	5.30	Zincfrin	AQ

• *Other antiallergics*

LEVOCABASTINE HYDROCHLORIDE

4310W	Eye drops 500 micrograms per mL (0.05%), 4 mL (120 doses)	‡ 1	1	..	17.81	5.30	Livostin	JT

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	OTOLOGICALS							
	Corticosteroids and antiinfectives in combination							
	• ***Corticosteroids and antiinfectives in combination***							
	CIPROFLOXACIN HYDROCHLORIDE with HYDROCORTISONE							
	Authority Required							
	Indicated where first-line treatment has not been successful or is inappropriate.							
4528H	***Ear drops 2 mg (base)-10 mg per mL (0.2%-1%), 10 mL***	***‡ 1***	***2***	***..***	***29.37***	***5.30***	***Ciproxin HC***	***AQ***
	Other otologicals							
	• ***Indifferent preparations***							
	CARBAMIDE PEROXIDE							
4176T	Ear drops 65 mg per mL (6.5%), 12 mL	‡ 1	..	..	13.97	5.30	Ear Clear for Ear Wax Removal	KY
	DICHLOROBENZENE with CHLORBUTOL and TURPENTINE OIL							
4180B	Ear drops 20 mg-50 mg-0.1 mL per mL (2%-5%-10%), 11 mL	‡ 1	..	..	13.65	5.30	Cerumol	AC
	DOCUSATE SODIUM							
4199B	Ear drops 5 mg per mL (0.5%), 10 mL	‡ 1	..	..	14.04	5.30	Waxsol	NE
	VARIOUS							
	ALL OTHER THERAPEUTIC PRODUCTS							
	All other therapeutic products							
	• ***Drugs for treatment of hyperkalemia and hyperphosphatemia***							
	SODIUM POLYSTYRENE SULFONATE							
4470G	Oral powder 454 g	‡ 1	2	..	65.13	5.30	Resonium-A	SW

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ALL OTHER NON-THERAPEUTIC PRODUCTS

All other non-therapeutic products

- ***Other non-therapeutic auxiliary products***

REPATRIATION PHARMACEUTICAL BENEFITS SCHEME (RPBS) WOUND ASSESSMENT AND DRESSING IDENTIFICATION

It is essential to define the aetiology of the wound before selecting a dressing. Recommendations are based on wound type, colour of wound base, depth of wound, and amount of exudate.

This wound chart adheres to the MOIST WOUND concept of healing and wound dressings are described below as ABSORBING or MOISTURE DONATING.

Most wound healing products are designed to remain in situ for several days, with the exception of those for infected wounds which should be changed daily. The quantities and repeats listed in the Repatriation Schedule are considered to be adequate to manage the treatment of a wound for two weeks to one month, when an assessment of the wound's healing process should be undertaken.

DRESSINGS

PINK EPITHELIALISING WOUND

Aim: To protect and promote epithelialisation. Epithelialising wounds normally are superficial and only produce a light exudate.

(A) Covering	• Film; • Film Island	• Gauze—Paraffin; • Non-adherent
(B) Absorbing	• Foam (Light Exudate); • Hydroactive (Superficial Wound—Light Exudate)	• Hydrocolloid (Superficial Wound—Light Exudate)

continued ☞

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer

RED GRANULATING WOUND

Aims: (1) to protect the granulating tissue; (2) to encourage epithelialisation; (3) to absorb excess exudate.

LIGHT EXUDATE:	**Superficial**	**Cavity**
(A) Absorbing	• Foam (Light Exudate); • Hydroactive (Superficial Wound—Light Exudate); • Hydrocolloid (Superficial Wound—Light Exudate)	• Hydrocolloid (Cavity Wound)
(B) Moisture donating	• Hydrogel—Amorphous; • Hydrogel—Sheet	• Hydrogel—Amorphous
HIGH EXUDATE:	**Superficial**	**Cavity**
(A) Absorbing	• Alginate (Superficial Wound); • Foam—Heavy Exudate; • Hydroactive (Superficial Wound—Moderate Exudate); • Hydrocolloid (Superficial Wound—Moderate/High Exudate)	• Alginate (Cavity Wound); • Foam—Moderate Exudate (see “cavity conforming” product); • Hydroactive (Cavity Wound); • Hydrocolloid (Cavity Wound)
(B) Moisture donating	NOT APPROPRIATE	

continued ☞

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer

YELLOW SLOUGHY WOUND

Aims: (1) to remove slough; (2) to encourage granulation; (3) to absorb excess exudate.

LIGHT EXUDATE:	**Superficial**	**Cavity**
(A) Absorbing	• Cadexomer Iodine; • Foam—Light Exudate; • Foam with Charcoal; • Hydroactive (Superficial Wound—Moderate Exudate); • Hydrocolloid (Superficial Wound—Moderate Exudate)	• Cadexomer Iodine; • Hydrocolloid (Cavity Wound)
(B) Moisture Donating	• Hydrogel—Amorphous; • Hydrogel—Sheet	• Hydrogel—Amorphous
HIGH EXUDATE:	**Superficial**	**Cavity**
(A) Absorbing	• Alginate (Superficial Wound); • Cadexomer Iodine; • Foam—Heavy Exudate; • Hydroactive (Superficial Wound—Moderate/High Exudate); • Hydrocolloid (Superficial Wound—Moderate/High Exudate)	• Alginate (Cavity Wound); • Cadexomer Iodine; • Hydrocolloid (Cavity Wound)
(B) Moisture donating	NOT APPROPRIATE	

continued ☞

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	

BLACK NECROTIC WOUND

Aim: To remove eschar by — (1) sharp debridement, e.g., scissor/scalpel and/or (2) rehydration and autolytic debridement. (These wounds usually produce a LIGHT EXUDATE.)

DRY / LIGHT EXUDATE:	**Superficial**	**Cavity**
(A) Absorbing	• Hydroactive (Superficial Wound—Light Exudate); • Hydrocolloid (Superficial Wound—Light/Moderate Exudate)	• Hydrocolloid (Cavity Wound)
(B) Moisture donating	• Hydrogel—Amorphous; • Hydrogel—Sheet	• Hydrogel—Amorphous; • Hydrogel—Sheet

INFECTED WOUNDS

Aims: (1) to clear the infection with systemic antibiotics; (2) to absorb excess exudate; (3) to remove slough if present; (4) to decrease bacterial burden - by applying a Silver dressing or Cadexomer Iodine dressing.

MALODOROUS WOUNDS

Aims: (1) to clear infection if present; (2) to remove slough if present; (3) to clear colonising odour-producing bacteria **in** slough — by applying metronidazole gel, a Silver dressing or a Cadexomer Iodine dressing; (4) to absorb excess exudate.

Products: Activated Charcoal; Alginate with Charcoal; Foam with Charcoal; Silver dressing; Cadexomer Iodine dressing.

MINOR SKIN TRAUMA

Aims: (1) to stop bleeding; (2) to prevent infection; (3) to minimise the surface defect; (4) to promote epithelialisation.

ORDERING HARTMANN PRODUCTS

Hartmann wound dressings are available through the Hartmann Alliance only. If you would like to order Hartmann Wound Care products, please call Hartmann National Customer Care on 1800 805 839.

BANDAGE—ABSORBENT WOOL

4651T	Bandage (natural, non-sterile) 10 cm x 2.7 m	6	..	..	* 34.01	5.30	Soffban 7224	BV
4653X	Bandage 10 cm x 3 m	6	..	..	19.89	5.30	Surepress 650948	CC

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
	BANDAGE—CALICO							
4717G	Bandage, triangular, large	‡ 1	..	..	13.06	5.30	Handy 5608	BV
	BANDAGE—COMPRESSION **NOTE:** ***Treatment of varices and oedema associated with venous disease and lymphoedema; contraindicated in arterial disease.***							
4654Y	Bandage, short stretch, 8 cm x 5 m	5	..	..	* 70.29	5.30	Comprilan 1027	BV
4736G	Bandage, high stretch, 7.5 cm x 3 m	5	..	..	* 85.14	5.30	Tensopress 66004347	BV
4656C	Bandage, high stretch, 7.5 cm x 3.5 m	5	..	..	* 67.94	5.30	Setopress 3504	SS
4748X	Bandage, high stretch, 10 cm x 3 m	5	..	.. ..	* 72.49 * 110.79	5.30 5.30	Surepress 650947 Tensopress 66004348	CC BV
4657D	Bandage, high stretch, 10 cm x 3.5 m	5	..	.. ..	* 55.24 * 78.14	5.30 5.30	Eloflex 2480 Setopress 3505	BV SS
4658E	Bandage, four layer	5	..	..	* 199.79	5.30	Profore 66050016	SN
4598B	Bandage, four layer	5	..	..	* 134.74	5.30	Profore Lite 66050415	SN
	BANDAGE—COMPRESSION **NOTE:** ***Treatment of varices and oedema associated with venous disease and lymphoedema; contraindicated in arterial disease.***							
	Restricted Benefit ***Initial treatment of venous ulcers.***							
4938X	***Bandage, two layer, 18 cm-22 cm (red)***	***1***	..	..	***45.73***	***5.30***	***ProGuide 66000780***	***SN***
4939Y	***Bandage, two layer, 22 cm-28 cm (yellow)***	***1***	..	..	***45.73***	***5.30***	***ProGuide 66000781***	***SN***
4940B	***Bandage, two layer, 28 cm-32 cm (green)***	***1***	..	..	***45.73***	***5.30***	***ProGuide 66000782***	***SN***
	Restricted Benefit ***Continuation of treatment of venous ulcers where patient's ability to tolerate dressing has been demonstrated.***							
4941C	***Bandage, two layer, 18 cm-22 cm (red)***	***4***	..	..	**** 161.03***	***5.30***	***ProGuide 66000780***	***SN***

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Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
4942D	***Bandage, two layer, 22 cm-28 cm (yellow)***	***4***	***..***	***..***	**** 161.03***	***5.30***	***ProGuide 66000781***	***SN***
4943E	***Bandage, two layer, 28 cm-32 cm (green)***	***4***	***..***	***..***	**** 161.03***	***5.30***	***ProGuide 66000782***	***SN***
	BANDAGE—RETENTION—COHESIVE—HEAVY							
4811F	Bandage 5 cm x 1.3 m	2	..	..	* 13.59	5.30	Peg 7420	BK
4812G	Bandage 7.5 cm x 1.3 m	2	..	..	* 16.87	5.30	Peg 7422	BK
4659F	Bandage 7.5 cm x 3 m	2	..	..	* 19.63	5.30	Coplus 3629	BV
4813H	Bandage 10 cm x 1.3 m	2	..	..	* 20.61	5.30	Peg 7423	BK
4660G	Bandage 10 cm x 2 m	2	..	..	* 18.93	5.30	Coban 1584	MM
4814J	Bandage 15 cm x 1.3 m	2	..	..	* 27.75	5.30	Peg 7425	BK
	BANDAGE—RETENTION—COHESIVE—LIGHT							
4718H	Bandages 2.5 cm x 4 m, 2	‡ 1	..	..	12.09	5.30	Handygauze Cohesive 8631	BV
4719J	Bandage 6 cm x 4 m	2	..	..	* 14.27	5.30	Handygauze Cohesive 8633	BV
4662J	Bandage 10 cm x 4 m	2	..	..	* 16.71	5.30	Handygauze Cohesive 8635	BV
	BANDAGE—RETENTION—COTTON CREPE							
4727T	Bandage 5 cm x 2.3 m	2	..	..	* 17.01	5.30	Telfa 8252F	KE
				..	* 17.85	5.30	Elastocrepe 36102520	BV
4728W	Bandage 7.5 cm x 2.3 m	2	..	..	* 21.79	5.30	Telfa 8253F	KE
				..	* 21.97	5.30	Elastocrepe 36102420	BV
4729X	Bandage 10 cm x 2.3 m	2	..	..	* 24.95	5.30	Telfa 8254F	KE
				..	* 27.39	5.30	Elastocrepe 36102320	BV
	BANDAGE—TUBULAR							
4855M	Bandage 6.25 cm x 1 m	‡ 1	..	..	17.74	5.30	Tubigrip B 1520	SS
4856N	Bandage 6.75 cm x 1 m	‡ 1	..	..	17.74	5.30	Tubigrip C 1545	SS
4857P	Bandage 7.5 cm x 1 m	‡ 1	..	..	17.74	5.30	Tubigrip D 1546	SS
4858Q	Bandage 8.75 cm x 1 m	‡ 1	..	..	17.74	5.30	Tubigrip E 1547	SS
4859R	Bandage 10 cm x 1 m	‡ 1	..	..	17.74	5.30	Tubigrip F 1548	SS
4663K	Bandage, straight, size C	‡ 1	..	..	14.68	5.30	Elastoplast 2225	BE

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REPATRIATION

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
4664L	Bandage, straight, size D	‡ 1	..	..	14.68	5.30	Elastoplast 2226	BE
4665M	Bandage, straight, size E	‡ 1	..	..	14.68	5.30	Elastoplast 2227	BE
4667P	Bandage, lightweight, 8.75 cm x 1 m	‡ 1	..	..	16.64	5.30	Tensogrip 36361259	BV
	BANDAGE—TUBULAR (FINGER)							
4798M	Complete pack including applicator	‡ 1	..	..	17.34	5.30	Tubegauz 0501633	SS
4726R	Refill	‡ 1	..	..	13.30	5.30	Tubegauz 0501658	SS
	BANDAGE—TUBULAR (LIGHTWEIGHT)							
4671W	Bandage, small limb size (red), 10 m	‡ 1	..	..	27.93	5.30	Tubifast 2434	SS
4672X	Bandage, medium limb size (green), 10 m	‡ 1	..	..	31.59	5.30	Tubifast 2436	SS
4673Y	Bandage, large limb size (blue), 10 m	‡ 1	..	..	35.15	5.30	Tubifast 2438	SS
	BANDAGE—TUBULAR (LONG STOCKING)							
4674B	Bandage, small size	2	..	..	* 39.75	5.30	Tubigrip 1482	SS
4797L	Bandage, medium size	2	..	..	* 39.75	5.30	Tubigrip 1483	SS
4799N	Bandage, large size	2	..	..	* 39.75	5.30	Tubigrip 1484	SS
4675C	Bandage, XX/large size	2	..	..	* 39.75	5.30	Tubigrip 1486	SS
	BANDAGE—TUBULAR (SHORT STOCKING)							
4661H	Bandage, small B/C size	2	..	..	* 30.01	5.30	Tubigrip 1479	SS
4815K	Bandage, medium C/D size	2	..	..	* 30.01	5.30	Tubigrip 1480	SS
4816L	Bandage, large D/E size	2	..	..	* 30.01	5.30	Tubigrip 1481	SS
	BANDAGE—ZINC PASTE **NOTE:** Used as an adjunct in the management of leg ulceration and associated eczema and skin conditions.							
4668Q	Bandage 7.5 cm x 6 m	2	..	..	* 28.77	5.30	Zincaband 3604	SS
4669R	Bandage 7.5 cm x 6 m	2	3	..	* 29.23	5.30	Steripaste 3610	XP
4750B	Bandage 7.5 cm x 6 m	2	3	..	* 63.11	5.30	Viscopaste 4948	SN
4749Y	Bandage 8 cm x 5 m (compression)	2	3	..	* 38.13	5.30	Gelocast Elastic 1080	BV
4670T	Bandage 10 cm x 9.1 m	2	3	..	* 28.35	5.30	Flexidress 650941	CC
4760M	Bandages 80 cm (stockings), 4	‡ 1	3	..	72.69	5.30	ZipZoc 66051550	SN

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
	COTTON WOOL ROLL							
4701K	Roll 100 g	‡ 1	2	..	10.08	5.30	JJ 02013	JJ
	DRESSING—ACTIVATED CHARCOAL (MALODOROUS WOUND)							
4742N	Dressings 10 cm x 10 cm, 10	‡ 1	..	..	78.55	5.30	CarboFLEX 403202	CC
4681J	Dressing 10.5 cm x 10.5 cm	10	..	..	* 84.79	5.30	Actisorb Plus MAC031	JJ
4743P	Dressings 15 cm x 20 cm, 5	‡ 1	..	..	89.44	5.30	CarboFLEX 403204	CC
	DRESSING—ALGINATE (CAVITY WOUND) **NOTE:** This dressing should be used only on moderately to heavily exuding wounds and should remain in place until saturated or for a maximum of 3 days.							
4832H	Rope 2 g	10	..	..	* 108.69	5.30	Sorbsan 1411	UM
				..	* 114.83	5.30	Kaltostat 168117	CC
4685N	Ropes 2 g (30 cm), 5	2	..	..	* 81.69	5.30	Restore CalciCare 9940	HO
4682K	Ropes 2 g (40 cm), 6	2	..	..	* 137.29	5.30	Comfeel SeaSorb Filler 3740	CT
	DRESSING—ALGINATE (SUPERFICIAL WOUND) **NOTE:** This dressing should be used only on moderately to heavily exuding wounds and should remain in place until saturated or for a maximum of 3 days.							
4699H	Dressings 5 cm x 5 cm, 10	‡ 1	1	..	40.09	5.30	Restore CalciCare 9938	HO
				..	44.68	5.30	Algisite M 66000519	SN
				..	48.97	5.30	Kaltostat 168210	CC
4684M	Dressing 5 cm x 5 cm	10	1	..	* 46.49	5.30	Comfeel SeaSorb Dressing 3705	CT
4683L	Dressings 7.5 cm x 12 cm, 10	‡ 1	1	..	90.65	5.30	Kaltostat 168212	CC
4831G	Dressing 10 cm x 10 cm	10	1	..	* 83.99	5.30	Sorbsan 1410	UM
				..	* 89.69	5.30	Comfeel SeaSorb Dressing 3710	CT
4700J	Dressings 10 cm x 10 cm, 10	‡ 1	1	..	71.21	5.30	Restore CalciCare 9937	HO
				..	83.93	5.30	Algisite M 66000520	SN

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REPATRIATION

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
4691X	Dressings 15 cm x 20 cm, 10	‡ 1	1	..	203.20	5.30	Algisite M 66000521	SN
	DRESSING—FILM							
4686P	Dressings 6 cm x 7 cm, 8	‡ 1	..	..	15.21	5.30	Nexcare Tegaderm Transparent H1624	MM
4687Q	Dressings 10 cm x 12 cm, 4	‡ 1	..	..	19.22	5.30	Nexcare Tegaderm Transparent H1626	MM
4893M	Dressings 10 cm x 12 cm, 10	‡ 1	..	..	27.71	5.30	Op-Site Flexigrid 4629	SN
4688R	Dressing 15 cm x 20 cm	6	..	..	* 30.23	5.30	Tegaderm Transparent 1628	MM
	DRESSING—FILM ISLAND							
4689T	Dressing 5 cm x 7 cm	10	..	..	* 15.79	5.30	Tegaderm Transparent Island 3582	MM
4898T	Dressings 5 cm x 7.2 cm, 5	2	..	..	* 24.19	5.30	Cutifilm Plus 76309	SN
4899W	Dressings 8 cm x 10 cm, 5	2	..	..	* 38.15	5.30	Cutifilm Plus 76308	SN
4690W	Dressing 9 cm x 10 cm	10	..	..	* 27.29	5.30	Tegaderm Transparent Island 3586	MM
	DRESSING—FOAM—HEAVY EXUDATE **NOTE:** This dressing should remain in place until saturated or up to a maximum of 7 days. Allow a minimum of 2 cm to 3 cm in excess of the wound size of the dressing around the wound.							
4795J	Dressings 10 cm x 10 cm, 10	‡ 1	1	..	74.63	5.30	Lyofoam Extra 603088	XP
				..	111.36	5.30	Allevyn 66007637	SN
4880W	Dressings 20 cm x 15 cm, 10	‡ 1	1	..	188.68	5.30	Lyofoam Extra 603090	XP
	DRESSING—FOAM—MODERATE EXUDATE **NOTE:** This dressing should remain in place until saturated or up to a maximum of 7 days. Allow a minimum of 2 cm to 3 cm in excess of the wound size of the dressing around the wound.							
4890J	Dressings 7.5 cm x 7.5 cm, 10	‡ 1	1	..	42.41	5.30	Lyofoam Flat 603092	XP

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Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
4891K	Dressings 10 cm x 10 cm, 10	‡ 1	1	..	49.05	5.30	Lyofoam Flat 603093	XP
4590N	Dressings 12.5 cm x 12.5 cm, 10	‡ 1	..	..	104.94	5.30	Allevyn Adhesive 66000044	SN
	NOTE: Care should be taken when changing *Allevyn Adhesive* dressings to avoid skin tears.							
4878R	Dressings 20 cm x 15 cm, 10	‡ 1	1	..	101.43	5.30	Lyofoam Flat 603095	XP
4694C	Dressing, cavity, conforming, 20 g	1	1	..	75.72	5.30	Cavicare 4563	SN
	DRESSING—FOAM with CHARCOAL (MALODOROUS WOUND) **NOTE:** This dressing should remain in place on wounds with odour until saturated or up to a maximum of 7 days. Allow a minimum of 2 cm to 3 cm in excess of the wound size of the dressing around the wound.							
4892L	Dressings 10 cm x 10 cm, 10	2	..	..	* 173.63	5.30	Lyofoam C 603025	SS
	DRESSING—FOAM with SILICONE—HEAVY EXUDATE							
4642H	Dressings 7.5 cm x 7.5 cm, 5	‡ 1	..	..	30.34	5.30	Mepilex Border 295200	MH
4643J	Dressings 10 cm x 10 cm, 5	‡ 1	..	..	42.25	5.30	Mepilex Border 295300	MH
	DRESSING—FOAM with SILICONE—LIGHT EXUDATE							
4644K	Dressings 6 cm x 8.5 cm, 5	‡ 1	..	..	27.63	5.30	Mepilex Lite 284000	MH
4645L	Dressings 10 cm x 10 cm, 5	‡ 1	..	..	37.78	5.30	Mepilex Lite 284100	MH
	DRESSING—FOAM with SILICONE—MODERATE EXUDATE							
4626L	Dressings 10 cm x 10 cm, 5	‡ 1	..	..	42.25	5.30	Mepilex 294100	MH
	DRESSING—GAUZE (ABSORBENT PAD)							
4707R	Pads 5 cm x 5 cm, 100	‡ 1	..	..	13.45	5.30	Handy 5672	BV
4708T	Pads 10 cm x 10 cm, 100	‡ 1	..	..	26.97	5.30	Handy 5674	BV
	DRESSING—GAUZE—EYE PAD							
4768Y	Pads, 12	‡ 1	..	..	12.40	5.30	Curity 4112	KE
	DRESSING—GAUZE—PARAFFIN							
4759L	Dressings 10 cm x 10 cm, 10	‡ 1	..	..	17.43	5.30	Jelonet 7404	SN

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
	DRESSING—GAUZE—PARAFFIN with CHLORHEXIDINE ACETATE							
4845B	Dressings 10 cm x 10 cm, 10	‡ 1	2	..	24.14	5.30	Bactigras 7457	SN
	DRESSING—GAUZE—POVIDONE-IODINE PAD							
4779M	Pads 22.5 cm x 7.5 cm, 12	‡ 1	2	..	33.11	5.30	Betadine	FH
	DRESSING—HYDROACTIVE (CAVITY WOUND)							
4918W	Dressings 5 cm x 6 cm, 10	‡ 1	1	..	75.52	5.30	Allevyn Plus Cavity 66047571	SN
4919X	Dressings 10 cm x 10 cm, 5	2	1	..	* 158.91	5.30	Allevyn Plus Cavity 66047573	SN
	DRESSING—HYDROACTIVE (DEBRIDEMENT)							
4949L	Dressings 4 cm, 8	‡ 1	..	..	67.47	5.30	TenderWet 24 Active	HR
4948K	Dressings 5.5 cm, 8	‡ 1	..	..	68.23	5.30	TenderWet Active Cavity	HR
4950M	Dressings 7.5 cm x 7.5 cm, 8	‡ 1	..	..	91.76	5.30	TenderWet 24 Active	HR
	NOTE: Hartmann products are not available through pharmacy wholesalers. To order please contact the Hartmann Alliance (refer to 'Ordering Hartmann Products' at the foot of the 'Wound Assessment and Dressing Identification' chart at the beginning of this section).							
	DRESSING—HYDROACTIVE (SUPERFICIAL WOUND—HIGH EXUDATE)							
4692Y	Dressings (foam alternative) 10 cm x 10 cm, 10	‡ 1	..	..	54.47	5.30	CombiDERM 651031	CC
4693B	Dressings (foam alternative) 15 cm x 18 cm, 5	‡ 1	..	..	71.29	5.30	CombiDERM 651027	CC
4695D	Dressings, island, 11 cm x 11 cm, 10	‡ 1	..	..	110.81	5.30	Tielle MTL101E	JJ
4696E	Dressings, island, 18 cm x 18 cm, 5	‡ 1	..	..	101.50	5.30	Tielle MT2442	JJ
4927H	Non-adhesive waterproof semi-permeable absorbent foam pads 10 cm x 10 cm, 10	‡ 1	1	..	87.50	5.30	Biatain Non-adhesive 3410	CT
4928J	Non-adhesive waterproof semi-permeable absorbent foam pads 15 cm x 15 cm, 5	‡ 1	2	..	86.02	5.30	Biatain Non-adhesive 3413	CT
4929K	Adhesive waterproof semi-permeable absorbent foam pads 12 cm x 12 cm, 10	‡ 1	1	..	96.52	5.30	Biatain Adhesive 3420	CT
4930L	Adhesive waterproof semi-permeable absorbent foam pads 18 cm x 18 cm, 5	‡ 1	2	..	93.39	5.30	Biatain Adhesive 3423	CT

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
	DRESSING—HYDROACTIVE (SUPERFICIAL WOUND—LIGHT EXUDATE)							
4905E	Dressings 5 cm x 6 cm, 10	‡ 1	1	..	52.74	5.30	Allevyn Thin 66047576	SN
4906F	Dressings 10 cm x 10 cm, 5	2	1	..	* 95.75	5.30	Allevyn Thin 66047578	SN
	DRESSING—HYDROACTIVE (SUPERFICIAL WOUND—MODERATE EXUDATE)							
4885D	Dressings 5 cm x 6 cm, 10	‡ 1	1	..	41.81	5.30	Cutinova Hydro 66047441	SN
4886E	Dressings 10 cm x 10 cm, 5	2	1	..	* 67.85	5.30	Cutinova Hydro 66047443	SN
	DRESSING—HYDROCOLLOID (CAVITY WOUND) **NOTE:** This dressing should remain in place until saturated or strike through occurs for a maximum of 7 days.							
4896Q	Paste 30 g	10	..	..	* 144.69	5.30	DuoDERM Paste H7930	CC
4895P	Paste 50 g	2	3	..	* 42.79	5.30	Comfeel Paste 4701	CT
4697F	Powder 6 g	5	2	..	* 46.99	5.30	Comfeel Powder 4706	CT
	DRESSING—HYDROCOLLOID (SUPERFICIAL WOUND—LIGHT EXUDATE) **NOTE:** This dressing should be applied to a thickness of 3 mm to 5 mm. It should be covered with a hydrocolloid dressing and may be left in place for up to 7 days.							
4888G	Dressings 5 cm x 7 cm, 10	‡ 1	1	..	41.29	5.30	Comfeel Plus Transparent 3530	CT
4889H	Dressings 9 cm x 14 cm, 10	‡ 1	1	..	84.09	5.30	Comfeel Plus Transparent 3536	CT
4908H	Dressings 10 cm x 10 cm, 5	2	1	..	* 52.85	5.30	Restore Extra Thin 9921	HO
4907G	Dressings 10 cm x 10 cm, 10	‡ 1	1	..	71.29	5.30	DuoDERM Extra Thin H7955	CC
4924E	Dressings 10 cm x 10 cm, 10	‡ 1	1	..	69.35	5.30	Comfeel Plus Transparent 3533	CT
4947J	Dressings 10 cm x 10 cm, 10	‡ 1	1	..	47.72	5.30	Hydrocoll Thin 900942/1	HR

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	NOTE: Hartmann products are not available through pharmacy wholesalers. To order please contact the Hartmann Alliance (refer to 'Ordering Hartmann Products' at the foot of the 'Wound Assessment and Dressing Identification' chart at the beginning of this section).							
	DRESSING—HYDROCOLLOID (SUPERFICIAL WOUND—MODERATE EXUDATE) **NOTE:** This dressing should remain in place until saturated or strike through occurs for a maximum of 7 days.							
4897R	Dressings 10 cm x 10 cm, 5	2	1	.. ..	* 58.39 * 80.97	5.30 5.30	Restore Plus 9956 DuoDERM CGF H7660	HO CC
4921B	Dressings 10 cm x 10 cm, 10	‡ 1	1	..	68.57	5.30	Replicare Ultra 66000434	SN
4945G	Dressings 10 cm x 10 cm, 10	‡ 1	1	..	47.72	5.30	Hydrocoll 900938/1	HR
	NOTE: Hartmann products are not available through pharmacy wholesalers. To order please contact the Hartmann Alliance (refer to 'Ordering Hartmann Products' at the foot of the 'Wound Assessment and Dressing Identification' chart at the beginning of this section).							
4678F	Butterfly shape 7 cm	5	..	..	* 54.74	5.30	Comfeel Plus Pressure Relieving 3350	CT
4679G	Round 10 cm	5	..	..	* 59.19	5.30	Comfeel Plus Pressure Relieving 3353	CT
4946H	Dressings 15 cm x 15 cm, 10	‡ 1	1	..	89.48	5.30	Hydrocoll 900939/1	HR
	NOTE: Hartmann products are not available through pharmacy wholesalers. To order please contact the Hartmann Alliance (refer to 'Ordering Hartmann Products' at the foot of the 'Wound Assessment and Dressing Identification' chart at the beginning of this section).							
4853K	Dressings 15 cm x 20 cm, 3	3	1	..	* 132.83	5.30	Restore Plus 9957	HO
4854L	Dressings 20 cm x 20 cm, 3	3	1	..	* 158.00	5.30	Restore Plus 9958	HO
4920Y	Dressings 20 cm x 20 cm, 5	2	1	..	* 221.89	5.30	DuoDERM CGF H7662	CC
4923D	Dressings with alginate 10 cm x 10 cm, 10	‡ 1	1	..	81.56	5.30	Comfeel Plus Ulcer Dressing 3110	CT
4842W	Dressings, sacral, 5	2	1	..	* 99.17	5.30	Restore Plus Sacral 9959	HO
	DRESSING—HYDROFIBRE (ALTERNATE TO ALGINATES)							
4698G	Ropes 2 g (30 cm), 5	‡ 1	1	..	83.28	5.30	Aquacel 177904	CC
4649Q	Dressings 10 cm x 10 cm, 10	‡ 1	1	..	100.55	5.30	Aquacel 177902	CC

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Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
4922C	Dressings 15 cm x 15 cm, 5	2	1	..	* 208.27	5.30	Aquacel 177903	CC
	DRESSING—HYDROGEL—AMORPHOUS **NOTE:** This dressing should be applied to a thickness of 3 mm to 5 mm and remain in situ in infected wounds for 24 hours and in clean wounds for up to 3 days. It should be covered with a secondary dressing such as foam or film. It should not be covered with gauze or combine.							
4912M	Tubes 15 g, 10	‡ 1	1	..	64.05	5.30	DuoDERM Gel H7990	CC
				..	71.66	5.30	Comfeel Purilon Gel 3900	CT
4894N	Tube 25 g	4	3	..	* 53.43	5.30	Intrasite Gel 7313	SN
4913N	Tubes 30 g, 3	3	1	..	* 96.68	5.30	DuoDERM Gel H7987	CC
4914P	Tube 50 g	3	3	..	* 32.69	5.30	Solugel 10336	JJ
4599C	Tube 50 g	3	3	..	* 26.30	5.30	SoloSite Gel 36361338	SN
	DRESSING—HYDROGEL—SHEET **NOTE:** This dressing should be applied to a thickness of 3 mm to 5 mm and remain in situ in infected wounds for 24 hours and in clean wounds for up to 3 days. It should be covered with a secondary dressing such as foam or film. It should not be covered with gauze or combine.							
4911L	Dressings 9.5 cm x 10.2 cm, 5	2	..	..	* 82.77	5.30	Nu-Gel 2497	JJ
4806Y	Dressings 10 cm x 10 cm, 5	2	..	..	* 52.85	5.30	Aquaclear 900796	HR
	NOTE: Hartmann products are not available through pharmacy wholesalers. To order please contact the Hartmann Alliance (refer to 'Ordering Hartmann Products' at the foot of the 'Wound Assessment and Dressing Identification' chart at the beginning of this section).							
	DRESSING—NON-ADHERENT							
4860T	Dressings 5 cm x 5 cm, 5	2	..	..	* 14.25	5.30	Melolin 36361357	SN
4819P	Dressings 5 cm x 5 cm, 5	2	..	..	* 13.59	5.30	Cutilin Non-Stick Wound Pad 76301	SN
4755G	Dressings 5 cm x 7.5 cm, 10	‡ 1	..	..	10.59	5.30	Telfa 1970C	KE
4758K	Dressings 7.5 cm x 10 cm, 6	‡ 1	..	..	10.80	5.30	Telfa 2140C	KE
4944F	Dressings 7.5 cm x 10 cm, 10	‡ 1	..	..	14.81	5.30	Atrauman 499513	HR
	NOTE: Hartmann products are not available through pharmacy wholesalers. To order please contact the Hartmann Alliance (refer to 'Ordering Hartmann Products' at the foot of the 'Wound Assessment and Dressing Identification' chart at the beginning of this section).							

continued ☞

REPATRIATION

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
4862X	Dressings 10 cm x 10 cm, 5	2	..	..	* 21.33	5.30	Cutilin Non-Stick Wound Pad 76300	SN
4861W	Dressings 10 cm x 10 cm, 10	‡ 1	..	..	29.09	5.30	Melolin 66974933	SN
4844Y	Dressings, self-adhesive, 7.5 cm x 10 cm, 6	‡ 1	2	..	11.59	5.30	Telfa 7650C	KE
	DRESSING—TULLE NON-GAUZE—PARAFFIN							
4909J	Dressing 7.6 cm x 7.6 cm	10	1	..	* 15.29	5.30	Adaptic 2012	JJ
	DRESSING with CADEXOMER IODINE **NOTE:** Suitable for yellow sloughy infected and malodorous wounds.							
4931M	Sachets 3 g, 7	‡ 1	2	..	59.67	5.30	Iodosorb Powder 66051070	SN
4932N	Tubes 10 g, 4	‡ 1	2	..	95.96	5.30	Iodosorb Ointment 66051240	SN
4933P	Tubes 20 g, 2	‡ 1	2	..	95.07	5.30	Iodosorb Ointment 66051230	SN
4935R	Sachets 5 g (6 cm x 4 cm), 5	‡ 1	2	..	90.71	5.30	Iodosorb 66051330	SN
4936T	Sachets 10 g (8 cm x 6 cm), 3	‡ 1	2	..	131.01	5.30	Iodosorb 66051340	SN
4937W	Sachets 17 g (10 cm x 8 cm), 2	‡ 1	..	..	137.36	5.30	Iodosorb 66051360	SN
	DRESSING with SILVER							
	Authority Required ***For wounds where there is evidence of critical colonisation and for well-assessed chronic wounds that have not responded to conventional dressings.***							
4646M	***Hydroactive dressings non-adhesive 10 cm x 10 cm, 5***	***‡ 1***	***..***	***..***	***175.46***	***5.30***	***Contreet Foam Non-Adhesive 9622***	***CT***
4647N	***Hydroactive dressings adhesive 12.5 cm x 12.5 cm, 5***	***‡ 1***	***..***	***..***	***190.86***	***5.30***	***Contreet Foam Adhesive 9632***	***CT***
4648P	***Tulle dressings 10 cm x 10 cm, 3***	***‡ 1***	***..***	***..***	***43.35***	***5.30***	***Atrauman Ag 499572***	***HR***
	NOTE: ***Hartmann products are not available through pharmacy wholesalers. To order please contact the Hartmann Alliance (refer to 'Ordering Hartmann Products' at the foot of the 'Wound Assessment and Dressing Identification' chart at the beginning of this section).***							
	GAUZE and COTTON TISSUE (COMBINE ROLL)							
4767X	Wrapped pack 9 cm x 10 m	‡ 1	..	..	14.96	5.30	BSN 2902165	BV

continued ☞

REPATRIATION

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
4761N	Wrapped pack 10 cm x 10 m	‡ 1	..	..	14.67	5.30	JJ 12010	JJ
	GLOVES PLASTIC (DISPOSABLE)							
4772E	Gloves, small, 100	‡ 1	..	..	11.77	5.30	Handy 4207	BV
4773F	Gloves, medium, 100	‡ 1	..	..	11.77	5.30	Handy 4208	BV
4774G	Gloves, large, 100	‡ 1	..	..	11.77	5.30	Handy 4209	BV
	LUBRICATING AGENT							
4318G	Jelly 60 g	‡ 1	..	..	10.48	5.30	Surgical Lubricating Gel	BI
	PRESSURE REDUCING PRODUCTS							
4676D	Sheet 10 cm x 10 cm x 3 mm	2	..	..	* 28.07	5.30	Spenco Dermal Pad 10-553	KC
4677E	Sheet 10 cm x 10 cm x 12 mm	2	..	..	* 48.89	5.30	Spenco Dermal Pad 10-561	KC
	TAPES—NON-WOVEN RETENTION (POLYACRYLATE)							
4915Q	Roll 2.5 cm x 9.1 m	‡ 1	..	..	12.44	5.30	Medipore 2961	MM
4863Y	Roll 2.5 cm x 10 m	‡ 1	..	..	15.93	5.30	Hypafix 71443-0	BV
4917T	Roll 2.5 cm x 10 m	‡ 1	..	..	10.61	5.30	Mefix 310250	MH
4916R	Roll 5 cm x 10 m	‡ 1	..	..	23.19	5.30	Hypafix 71443-1	BV
	TAPES—PLASTER ADHESIVE ELASTIC							
4780N	Roll 2.5 cm x 2.5 m	‡ 1	..	..	12.33	5.30	Leukoplast 1071	BV
4781P	Roll 5 cm x 2.5 m	‡ 1	..	..	18.13	5.30	Leukoplast 1072	BV
4782Q	Roll 7.5 cm x 2.5 m	‡ 1	..	..	21.70	5.30	Leukoplast 1073	BV
4735F	Roll 10 cm x 2.5 m	‡ 1	..	..	21.92	5.30	Elastoplast 1004	BV
	TAPES—PLASTER ADHESIVE HYPOALLERGENIC							
4783R	Roll 1.25 cm x 5 m	‡ 1	..	..	9.91	5.30	Leukopor 2471	BV
4785W	Roll 1.25 cm x 5 m	‡ 1	..	..	10.19	5.30	Leukosilk 1021	BV
4794H	Roll 2.5 cm x 5 m	‡ 1	..	..	12.30	5.30	Leukopor 2472	BV
4787Y	Roll 2.5 cm x 5 m	‡ 1	..	..	12.81	5.30	Leukosilk 1022	BV
4788B	Stretch roll 5 cm x 5 m	‡ 1	..	..	16.78	5.30	Leukoflex 1124	BV
4790D	Roll 5 cm x 5 m	‡ 1	..	..	15.78	5.30	Leukopor 2474	BV
4789C	Roll 5 cm x 5 m	‡ 1	..	..	16.62	5.30	Leukosilk 1024	BV

continued ☞

REPATRIATION

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Proprietary Name and Manufacturer	
4848E	Roll (dispenser) 1.9 cm x 5.4 m	‡ 1	..	..	10.62	5.30	Nexcare Durable Cloth First Aid Tape 799	MM
4849F	Roll (dispenser) 1.9 cm x 7.3 m	‡ 1	..	..	10.62	5.30	Nexcare Gentle Paper First Aid Tape 789	MM

Section 2

Standard Packs and Prices

NOTE—
Standard packs and prices (including mark-up, but without dispensing fee and dangerous drug fee) are for items against the price of which an asterisk (*) is shown in Section 1 of the Schedule.

(APPLY WASTAGE FACTOR IN CALCULATING BROKEN QUANTITY PRICES)

Code	Name	Form/Strength	Pack and Price $	Manufacturer
4579B	Alprostadil	10 mcg	2 @ 25.40	PH
4580C		20 mcg	2 @ 32.40	PH
4453J	Aluminium Hydroxide with Magnesium Hydroxide and Simethicone	400 mg-400 mg-40 mg	100 @ 19.85	JT
4118R		400 mg-400 mg-30 mg per 5 mL, 500 mL	1 @ 8.11	JT
4651T	Bandage—Absorbent Wool	10 cm x 2.7 m	1 @ 4.67	BV
4654Y	Bandage—Compression	8 cm x 5 m	1 @ 12.86	BV
4736G		7.5 cm x 3 m	1 @ 15.83	BV
4656C		7.5 cm x 3.5 m	1 @ 12.39	SS
4748X		10 cm x 3 m	1 @ 13.30	CC
			1 @ 20.96	BV
4657D		10 cm x 3.5 m	1 @ 9.85	BV
			1 @ 14.43	SS
4658E		Four layer	1 @ 38.76	SN
4598B		Four layer	1 @ 25.75	SN
4941C		Two layer, 18 cm-22 cm	1 @ 38.76	SN
4942D		Two layer, 22 cm-28 cm	1 @ 38.76	SN
4943E		Two layer, 28 cm-32 cm	1 @ 38.76	SN
4811F	Bandage—Retention—Cohesive—Heavy	5 cm x 1.3 m	1 @ 3.80	BK
4812G		7.5 cm x 1.3 m	1 @ 5.44	BK
4659F		7.5 cm x 3 m	1 @ 6.82	BV
4813H		10 cm x 1.3 m	1 @ 7.31	BK
4660G		10 cm x 2 m	1 @ 6.47	MM
4814J		15 cm x 1.3 m	1 @ 10.88	BK
4719J	Bandage—Retention—Cohesive—Light	6 cm x 4 m	1 @ 4.14	BV
4662J		10 cm x 4 m	1 @ 5.36	BV
4727T	Bandage—Retention—Cotton Crepe	5 cm x 2.3 m	1 @ 5.51	KE
			1 @ 5.93	BV
4728W		7.5 cm x 2.3 m	1 @ 7.90	KE
			1 @ 7.99	BV
4729X		10 cm x 2.3 m	1 @ 9.48	KE
			1 @ 10.70	BV
4674B	Bandage—Tubular (long Stocking)	Small	1 @ 16.88	SS
4797L		Medium	1 @ 16.88	SS
4799N		Large	1 @ 16.88	SS
4675C		XX/large	1 @ 16.88	SS
4661H	Bandage—Tubular (short Stocking)	Small B/C	1 @ 12.01	SS
4815K		Medium C/D	1 @ 12.01	SS
4816L		Large D/E	1 @ 12.01	SS
4668Q	Bandage—Zinc Paste	7.5 cm x 6 m	1 @ 11.39	SS
4669R		7.5 cm x 6 m	1 @ 11.62	XP
4750B		7.5 cm x 6 m	1 @ 28.56	SN
4749Y		8 cm x 5 m	1 @ 16.07	BV
4670T		10 cm x 9.1 m	1 @ 11.18	CC
4150K	Bromazepam	3 mg	30 @ 10.48	RO
4151L		6 mg	30 @ 13.49	RO
4333C	Calcium	500 mg	60 @ 4.91	IA
4093K		250 mg	120 @ 7.89	BN
4094L		500 mg	60 @ 4.91	IA
4142B		600 mg	120 @ 7.89	PP
4055K	Calcium Carbonate with Glycine	420 mg-180 mg	100 @ 8.38	MM
4081T	Dextropropoxyphene Napsylate	100 mg	10 @ 2.44	AS

(APPLY WASTAGE FACTOR IN CALCULATING BROKEN QUANTITY PRICES)

Code	Name	Form/Strength	Pack and Price $		Manufacturer
4681J	Dressing—Activated Charcoal (malodorous Wound)	10.5 cm x 10.5 cm	1 @	7.88	JJ
4832H	Dressing—Alginate (cavity Wound)	2 g	1 @	10.27	UM
			5 @	54.42	CC
4685N		2 g (30 cm), 5	1 @	37.85	HO
4682K		2 g (40 cm), 6	1 @	65.65	CT
4684M	Dressing—Alginate (superficial Wound)	5 cm x 5 cm	1 @	4.05	CT
4831G		10 cm x 10 cm	1 @	7.80	UM
			1 @	8.37	CT
4688R	Dressing—Film	15 cm x 20 cm	1 @	4.04	MM
4689T	Dressing—Film Island	5 cm x 7 cm	1 @	0.98	MM
4898T		5 cm x 7.2 cm, 5	1 @	9.10	SN
4899W		8 cm x 10 cm, 5	1 @	16.08	SN
4690W		9 cm x 10 cm	1 @	2.13	MM
4892L	Dressing—Foam with Charcoal (malodorous Wound)	10 cm x 10 cm, 10	1 @	83.82	SS
4919X	Dressing—Hydroactive (cavity Wound)	10 cm x 10 cm, 5	1 @	76.46	SN
4906F	Dressing—Hydroactive (superficial Wound—Light Exudate)	10 cm x 10 cm, 5	1 @	44.88	SN
4886E	Dressing—Hydroactive (superficial Wound—Moderate Exudate)	10 cm x 10 cm, 5	1 @	30.93	SN
4896Q	Dressing—Hydrocolloid (cavity Wound)	30 g	1 @	13.87	CC
4895P		50 g	1 @	18.40	CT
4697F		6 g	1 @	8.20	CT
4908H	Dressing—Hydrocolloid (superficial Wound—Light Exudate)	10 cm x 10 cm, 5	1 @	23.43	HO
4897R	Dressing—Hydrocolloid (superficial Wound—Moderate Exudate)	10 cm x 10 cm, 5	1 @	26.20	HO
			1 @	37.49	CC
4678F		7 cm	1 @	9.75	CT
4679G		10 cm	1 @	10.64	CT
4853K		15 cm x 20 cm, 3	1 @	42.28	HO
4854L		20 cm x 20 cm, 3	1 @	50.67	HO
4920Y		20 cm x 20 cm, 5	1 @	107.95	CC
4842W		5	1 @	46.59	HO
4922C	Dressing—Hydrofibre (alternate To Alginates)	15 cm x 15 cm, 5	1 @	101.14	CC
4894N	Dressing—Hydrogel—Amorphous	25 g	1 @	11.86	SN
4913N		30 g, 3	1 @	30.23	CC
4914P		50 g	1 @	8.90	JJ
4599C		50 g	1 @	6.77	SN
4911L	Dressing—Hydrogel—Sheet	9.5 cm x 10.2 cm, 5	1 @	38.39	JJ
4806Y		10 cm x 10 cm, 5	1 @	23.43	HR
4860T	Dressing—Non-adherent	5 cm x 5 cm, 5	1 @	4.13	SN
4819P		5 cm x 5 cm, 5	1 @	3.80	SN
4862X		10 cm x 10 cm, 5	1 @	7.67	SN
4909J	Dressing—Tulle Non-gauze—Paraffin	7.6 cm x 7.6 cm	1 @	0.93	JJ
4237B	Fexofenadine Hydrochloride	60 mg	20 @	11.57	AF, SZ
			20 @	13.92	SW
4246L	Glycerol	2.8 g, 12	1 @	4.11	PP
4576W	Nicotine	Approx. 5 mg per 16 hours, 7	1 @	22.20	JT
4571N		Approx. 7 mg per 24 hours, 7	1 @	19.89	AF
			1 @	33.95	GK

(APPLY WASTAGE FACTOR IN CALCULATING BROKEN QUANTITY PRICES)

Code	Name	Form/Strength	Pack and Price $	Manufacturer
4577X		Approx. 10 mg per 16 hours, 7	1 @ 24.18	JT
4572P		Approx. 14 mg per 24 hours, 7	1 @ 21.55	AF
			1 @ 33.95	GK
4578Y		Approx. 15 mg per 16 hours, 7	1 @ 26.77	JT
4573Q		Approx. 21 mg per 24 hours, 7	1 @ 23.55	AF
			1 @ 33.95	GK
4676D	Pressure Reducing Products	10 cm x 10 cm x 3 mm	1 @ 11.04	KC
4677E		10 cm x 10 cm x 12 mm	1 @ 21.45	KC

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A

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THERAPEUTIC GROUP PREMIUM POLICY

PHARMACEUTICAL BENEFIT ITEMS WHICH HAVE A THERAPEUTIC GROUP PREMIUM WITH EFFECT FROM 1 MARCH 2009

The Schedule of Pharmaceutical Benefits shows differences in price in some therapeutic groups where alternative drugs may have a therapeutic group premium.

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

The Australian Government, through the PBS, subsidises up to the price of the lowest priced drug in the group. This means that consumers may have to pay for more expensive drugs (those with a therapeutic group premium). This extra amount does not count towards their PBS safety net threshold.

Therapeutic group premiums apply where a prescriber has prescribed a drug within a therapeutic group that attracts a therapeutic group premium and has not sought an exemption from Medicare Australia on clinical grounds.

The exemption provisions are:

- adverse effects occurring with all of the base-priced drugs; or
- drug interactions occurring with all of the base-priced drugs; or
- drug interactions expected to occur with all of the base-priced drugs; or
- transfer to a base-priced drug would cause patient confusion resulting in problems with compliance.

The premiums are not a Government charge but reflect the fact that the supplier(s) of the drug charge a price higher than the Government is willing to subsidise.

Under the Therapeutic Group Premium Policy drug substitution by pharmacists is not permitted.

For ease of prescribing and dispensing, and in the interests of your patients, the following list shows those PBS drugs that attract a therapeutic group premium.

Premium Priced Brand	Form and Strength	Max. Qty	Therapeutic Group Premium $
H_2-RECEPTOR ANTAGONISTS			
Zantac	Effervescent tablet 150 mg (base)	60	3.26
Zantac Syrup	Syrup 150 mg (base) per 10 mL, 300 mL	2	2.20

The base-priced drugs in this therapeutic group are cimetidine, famotidine, nizatidine, and ranitidine hydrochloride (except ranitidine hydrochloride effervescent tablet 150 mg (base) and syrup 150 mg (base) per 10 mL, 300 mL).

DIHYDROPYRIDINE-DERIVATIVE CALCIUM CHANNEL BLOCKERS			
Adalat Oros 20mg	Tablet 20 mg (controlled release)	30	2.26
Zanidip	Tablet 10 mg	30	2.01
Zanidip	Tablet 20 mg	30	4.02

The base-priced drugs in this therapeutic group are amlodipine, felodipine and nifedipine (except nifedipine controlled release tablet 20 mg).

PROTON PUMP INHIBITORS			
Zoton	Sachet containing granules for oral suspension, 30 mg per sachet	28	3.62

The base-priced drugs in this therapeutic group are esomeprazole magnesium trihydrate, omeprazole, pantoprazole sodium sesquihydrate, rabeprazole sodium and lansoprazole (except lansoprazole sachet containing granules for oral suspension, 30 mg per sachet).

ANGIOTENSIN II ANTAGONISTS			
Teveten	Tablet 400 mg (base)	56	1.52

The base-priced drugs in this therapeutic group are candesartan cilexetil, irbesartan, olmesartan medoxomil, telmisartan, valsartan and eprosartan mesylate (except eprosartan mesylate tablet 400 mg (base)).

BRAND PREMIUM POLICY

BRANDS OF PHARMACEUTICAL BENEFIT ITEMS WHICH HAVE A BRAND PREMIUM AND THAT MAY BE SUBSTITUTED WITH EFFECT FROM 1 MARCH 2009

The Schedule of Pharmaceutical Benefits shows differences in price between some alternative brands of the same drug product.

Manufacturers can develop generic equivalents and apply to have them listed on the PBS. In doing this, manufacturers need to ensure that they comply with the relevant legislation applicable to patents. These brands are clinically equivalent and must undergo the same strict quality controls. Although these brands are designed to act on the body in exactly the same way, they are usually cheaper than the originator brands.

The Australian Government, through the PBS, subsidises up to the price of the lowest priced brand (except in those instances where the lowest priced brand has, as part of its price, a therapeutic group premium). This means that consumers may have to pay extra for more expensive brands (those with a brand premium). This extra amount does not count towards their PBS safety net threshold.

Brand substitution by pharmacists without reference to the prescriber is permitted for PBS prescriptions where:

- the patient agrees to the substitution;
- the brands are identified in the Schedule of Pharmaceutical Benefits as being interchangeable;
- the prescriber has not indicated on the prescription form that substitution is not to occur; and
- substitution is permitted under the relevant State or Territory legislation.

Prescription forms supplied by Medicare Australia contain a box to be ticked where brand substitution is not to take place.

Prescribers not using these prescription forms should endorse the prescription if brand substitution is not permitted. Where a stamp is used for this purpose, the prescriber will be required to initial the stamped statement.

For ease of prescribing and dispensing, and in the interests of your patients, the following list shows those PBS drugs that attract a brand premium and that can be substituted where permitted. They are listed alphabetically, by brand name, with the brand premium and benchmark brand(s) cited in the last column.

Premium Priced Brand	Form and Strength	Max. Qty	Brand Premium $	Benchmark Priced Brands
Accupril	Tablet 5 mg (base)	30	0.38	*Acquin 5*; *APO-Quinapril*; *Filpril*; *Pharmacor Quinapril 5*; *Quinapril-DP*; *Quinapril generichealth*; *Quinapril Sandoz*
	Tablet 10 mg (base)	30	0.52	*Acquin 10*; *APO-Quinapril*; *Filpril*; *Pharmacor Quinapril 10*; *Quinapril-DP*; *Quinapril generichealth*
	Tablet 20 mg (base)	30	0.77	*Acquin 20*; *APO-Quinapril*; *Filpril*; *Pharmacor Quinapril 20*; *Quinapril-DP*; *Quinapril generichealth*; *Quinapril Sandoz*
Adalat Oros 30	Tablet 30 mg (controlled release)	30	2.54	*Addos XR 30*; *Adefin XL 30*
Adalat Oros 60	Tablet 60 mg (controlled release)	30	2.81	*Addos XR 60*; *Adefin XL 60*
Adalat 10	Tablet 10 mg	60	1.17	*Adefin 10*; *Nypine 10*
Adalat 20	Tablet 20 mg	60	2.21	*Adefin 20*; *GenRx Nifedipine*; *Nifehexal*; *Nyefax 20 mg*; *Nypine 20*
Aldactone	Tablet 25 mg	100	1.44	*Spiractin 25*
	Tablet 100 mg	100	1.99	*Spiractin 100*
Aldomet	Tablet 250 mg	100	2.24	*Hydopa*
Alphagan	Eye drops 2 mg per mL (0.2%), 5 mL	1	1.74	*Enidin*
Amaryl	Tablet 1 mg	30	2.81	*Aylide 1*; *Diapride 1*; *Dimirel*; *Glimepiride Sandoz*
	Tablet 2 mg	30	2.81	*Aylide 2*; *Diapride 2*; *Dimirel*; *Glimepiride Sandoz*
	Tablet 3 mg	30	2.80	*Aylide 3*; *Diapride 3*; *Dimirel*; *Glimepiride Sandoz*
	Tablet 4 mg	30	2.80	*Aylide 4*; *Diapride 4*; *Dimirel*; *Glimepiride Sandoz*
Amoxil	Capsule 250 mg	20	0.79	*Alphamox 250*; *Amohexal*; *Amoxycillin-DP*; *APO-Amoxycillin*; *Chem mart Amoxycillin*; *Cilamox*; *GenRx Amoxycillin*; *Terry White Chemists Amoxycillin*
	Capsule 500 mg	20	0.80	*Alphamox 500*; *Amohexal*; *Amoxycillin-DP*; *Amoxycillin Sandoz*; *APO-Amoxycillin*; *Chem mart Amoxycillin*; *Cilamox*; *GenRx Amoxycillin*; *Moxacin*; *Terry White Chemists Amoxycillin*
	Powder for syrup 125 mg per 5 mL, 100 mL	1	0.95	*Alphamox 125*; *Amoxycillin Sandoz*; *Bgramin*; *Chem mart Amoxycillin*; *GenRx Amoxycillin*; *Ranmoxy*; *Terry White Chemists Amoxycillin*
Amoxil Forte	Powder for syrup 250 mg per 5 mL, 100 mL	1	0.79	*Alphamox 250*; *Amohexal*; *Amoxycillin Sandoz*; *Bgramin*; *Chem mart Amoxycillin*; *Cilamox*; *GenRx Amoxycillin*; *Ranmoxy*; *Terry White Chemists Amoxycillin*
Amprace 10	Tablet 10 mg	30	2.46	*Alphapril*; *Auspril*; *Chem mart Enalapril*; *Enahexal*; *Enalabell*; *Enalapril-DP 10mg*; *Enalapril Winthrop*; *GenRx Enalapril*; *Terry White Chemists Enalapril*

Premium Priced Brand	Form and Strength	Max. Qty	Brand Premium $	Benchmark Priced Brands
Amprace 20	Tablet 20 mg	30	2.47	*Alphapril*; *Auspril*; *Chem mart Enalapril*; *Enahexal*; *Enalabell*; *Enalapril-DP 20mg*; *Enalapril Winthrop*; *GenRx Enalapril*; *Terry White Chemists Enalapril*
Anafranil 25	Tablet 25 mg	50	3.26	*Chem mart Clomipramine*; *GenRx Clomipramine*; *Placil*; *Terry White Chemists Clomipramine*
Anaprox 550	Tablet 550 mg	50	2.29	*Crysanal*
Androcur	Tablet 50 mg	20	3.13	*Cyprohexal*; *Cyprone*; *Cyprostat*; *GenRx Cyproterone Acetate*; *Procur*
	Tablet 50 mg	100	3.00	*Cyprohexal*; *Cyprone*; *Cyprostat*; *GenRx Cyproterone Acetate*; *Procur*
Androcur-100	Tablet 100 mg	50	1.65	*Cyprohexal*; *Cyprostat-100*; *GenRx Cyproterone Acetate*; *Procur 100*
Anginine Stabilised	Tablets 600 micrograms, 100	1	1.64	*Lycinate*
Aristocort 0.02%	Cream 200 micrograms per g (0.02%), 100 g	2	3.30	*Tricortone*
	Ointment 200 micrograms per g (0.02%), 100 g	2	3.30	*Tricortone*
Aropax	Tablet 20 mg (as hydrochloride)	30	0.86	*Chem mart Paroxetine*; *Extine 20*; *GenRx Paroxetine*; *Paroxetine 20*; *Paroxetine-DP*; *Paroxetine generichealth*; *Paroxetine Sandoz*; *Paroxetine Winthrop*; *Paxtine*; *Terry White Chemists Paroxetine*
Astrix	Tablet 100 mg	112	1.36	*DBL Aspirin 100 mg*
Atrovent	Nebuliser solution single dose units 250 micrograms (anhydrous) in 1 mL, 30	2	0.72	*Aeron 250*; *APO-Ipratropium*; *Apoven 250*; *Ipratrin*; *Ipravent*
Atrovent Adult	Nebuliser solution single dose units 500 micrograms (anhydrous) in 1 mL, 30	2	0.62	*Aeron 500*; *APO-Ipratropium*; *Apoven 500*; *Ipratrin Adult*; *Ipravent*
Augmentin	Powder for syrup 125 mg-31.25 mg per 5 mL, 75 mL	1	1.51	*Clamoxyl*
Augmentin Duo	Tablet 500 mg-125 mg	10	1.55	*Clamoxyl Duo*; *Curam 500/125*; *GA-Amclav 500/125*; *Moxiclav Duo 500/125*
Augmentin Duo forte	Tablet 875 mg-125 mg	10	2.04	*Chem mart Amoxycillin and Clavulanic Acid*; *Clamoxyl Duo forte*; *Clavycillin 875/125*; *Curam 875/125*; *GA-Amclav Forte 875/125*; *GenRx Amoxycillin and Clavulanic Acid*; *Moxiclav Duo Forte 875/125*; *Terry White Chemists Amoxycillin and Clavulanic Acid*
Augmentin Duo 400	Powder for syrup 400 mg-57 mg per 5 mL, 60 mL	1	1.54	*Clamoxyl Duo 400*
Aurorix	Tablet 150 mg	60	0.72	*Amira 150*; *Chem mart Moclobemide*; *Clobemix*; *GenRx Moclobemide*; *Mohexal*; *Terry White Chemists Moclobemide*
Aurorix 300 mg	Tablet 300 mg	60	1.45	*Amira 300*; *Chem mart Moclobemide*; *Clobemix*; *GenRx Moclobemide*; *Maosig*; *Mohexal*; *Terry White Chemists Moclobemide*
Avanza	Tablet 30 mg	30	1.70	*Axit 30*; *Chem mart Mirtazapine*; *GenRx Mirtazapine*; *Mirtazapine-DP*; *Mirtazapine Sandoz*; *Mirtazon*; *Terry White Chemists Mirtazapine*

Premium Priced Brand	Form and Strength	Max. Qty	Brand Premium $	Benchmark Priced Brands
	Tablet 45 mg	30	1.49	*APO-Mirtazapine*; *Chem mart Mirtazapine*; *Mirtazapine Sandoz*; *Mirtazon*; *Terry White Chemists Mirtazapine*
Azopt	Eye drops 10 mg per mL (1%), 5 mL	1	1.03	*BrinzoQuin*
Betaloc	Tablet 100 mg	60	3.25	*Chem mart Metoprolol*; *GenRx Metoprolol*; *Metohexal*; *Metolol*; *Metrol 100*; *Minax 100*; *Terry White Chemists Metoprolol*
	Tablet 50 mg	100	3.25	*Chem mart Metoprolol*; *GenRx Metoprolol*; *Metohexal*; *Metolol*; *Metrol 50*; *Minax 50*; *Terry White Chemists Metoprolol*
Betnovate 1/2	Cream 500 micrograms (base) per g (0.05%), 15 g	1	1.91	*Cortival 1/2*
	Ointment 500 micrograms (base) per g (0.05%), 15 g	1	1.91	*Cortival 1/2*
Betnovate 1/5	Cream 200 micrograms (base) per g (0.02%), 100 g	2	6.18	*Cortival 1/5*
Betoptic	Eye drops, solution, 5 mg (base) per mL (0.5%), 5 mL	1	1.99	*BetoQuin*
Blenoxane	Powder for injection 15,000 i.u. (solvent required)	10	75.30	*Blenamax*; HH brand
Brevinor	Tablets 500 micrograms-35 micrograms, 21	4	7.92	*Norimin 28 Day*
	Pack containing 21 tablets 500 micrograms-35 micrograms and 7 inert tablets	4	7.92	*Norimin 28 Day*
Brevinor-1	Tablets 1 mg-35 micrograms, 21	4	7.92	*Norimin-1 28 Day*
	Pack containing 21 tablets 1 mg-35 micrograms and 7 inert tablets	4	7.92	*Norimin-1 28 Day*
Capoten	Tablet 25 mg	90	3.67	*Acenorm 25 mg*; *Captohexal*; *GenRx Captopril*; GM brand
	Tablet 50 mg	90	3.66	*Acenorm 50 mg*; *Captohexal*; *GenRx Captopril*; GM brand
Carafate	Tablet equivalent to 1 g anhydrous sucralfate	120	2.18	*Ulcyte*
Ceclor	Powder for oral suspension 125 mg per 5 mL, 100 mL	1	4.18	*Aclor 125*; *Cefaclor Sandoz*; *Chem mart Cefaclor*; *GenRx Cefaclor*; *Keflor*; *Ozcef*; *Terry White Chemists Cefaclor*
	Powder for oral suspension 250 mg per 5 mL, 75 mL	1	4.37	*Aclor 250*; *Cefaclor Sandoz*; *Chem mart Cefaclor*; *GenRx Cefaclor*; *Keflor*; *Ozcef*; *Terry White Chemists Cefaclor*
Ceclor CD	Tablet 375 mg (sustained release)	10	5.20	*Cefaclor-GA*; *Chem mart Cefaclor CD*; *Douglas Cefaclor-CD*; *GenRx Cefaclor CD*; *Karlor CD*; *Keflor CD*; *Ozcef*; *Terry White Chemists Cefaclor CD*
Cefotaxime Sandoz	Powder for injection 1 g	10	25.10	HH brand
	Powder for injection 2 g	10	46.50	HH brand
Chlorvescent	Effervescent tablet 14 mmol potassium and 8 mmol chloride	60	2.61	*K-Sol*
Ciloxan	Eye drops 3 mg per mL (0.3%), 5 mL	2	1.84	*CiloQuin*
Cipramil	Tablet 20 mg (base)	28	4.45	*Celapram*; *Celica*; *Chem mart Citalopram*; *Ciazil*; *Citalobell*; *Citalopram 20*; *Citalopram Winthrop*; *GenRx Citalopram*; *Talam*; *Talohexal*; *Terry White Chemists Citalopram*
Ciproxin 250	Tablet 250 mg	14	1.45	*C-Flox 250*; *Cifran*; *Ciprol 250*; *GenRx Ciprofloxacin*; *Profloxin*

Premium Priced Brand	Form and Strength	Max. Qty	Brand Premium $	Benchmark Priced Brands
Ciproxin 500	Tablet 500 mg	14	1.26	*C-Flox 500*; *Cifran*; *Ciprofloxacin 500*; *Ciprofloxacin-BW*; *Ciprol 500*; *GenRx Ciprofloxacin*; *Profloxin*; *Proquin*; GN brand
Ciproxin 750	Tablet 750 mg	14	1.37	*C-Flox 750*; *Cifran*; *Ciprofloxacin 750*; *Ciprofloxacin-BW*; *Ciprol 750*; *GenRx Ciprofloxacin*; *Profloxin*; *Proquin*; GN brand
Clomid	Tablet 50 mg	10	3.90	*Clomhexal*; *Fermil*; *GenRx Clomiphene*
Colgout	Tablet 500 micrograms	100	0.91	*Lengout*
Dalacin C	Capsule 150 mg	24	1.45	*Cleocin*
Daonil	Tablet 5 mg	100	1.51	*Glimel*
Depo-Medrol	Injection 40 mg in 1 mL	5	0.76	*Depo-Nisolone*
Depo-Provera	Injection 150 mg in 1 mL	1	3.34	*Depo-Ralovera*
Diabex	Tablet 500 mg	100	1.40	*Chem mart Metformin*; *Diaformin*; *Formet 500*; *GenRx Metformin*; *Glucohexal*; *Glucomet 500 mg*; *Metforbell*; *Metformin 500*; *Metformin generichealth*; *Metformin Ranbaxy*; *Terry White Chemists Metformin*; GN brand
Diabex 850	Tablet 850 mg	60	1.40	*Chem mart Metformin*; *Diaformin 850*; *Formet 850*; *GenRx Metformin*; *Glucohexal*; *Glucomet 850 mg*; *Metforbell*; *Metformin 850*; *Metformin generichealth*; *Metformin Ranbaxy*; *Terry White Chemists Metformin*; GN brand
Diabex 1000	Tablet 1 g	90	1.41	*Diaformin 1000*; *Formet 1000*; *Glucohexal*
Diamicron	Tablet 80 mg	100	2.03	*Chem mart Gliclazide*; *GenRx Gliclazide*; *Glyade*; *Mellihexal*; *Nidem*; *Terry White Chemists Gliclazide*
Doryx	Capsule 100 mg (as hydrochloride)	7	1.15	*DBL Doxycycline*
	Capsule 50 mg (as hydrochloride)	25	1.31	*DBL Doxycycline*
	Capsule 100 mg (as hydrochloride)	28	4.60	*DBL Doxycycline*
	Capsule 100 mg (as hydrochloride)	21	2.09	*DBL Doxycycline*
Dulcolax	Suppositories 10 mg, 10	3	1.14	*Petrus Bisacodyl Suppositories*
Duphalac	Mixture 3.34 g per 5 mL, 500 mL	1	1.67	*Actilax*; *Genlac*; *GenRx Lactulose*; *Lac-Dol*; *Lactocur*
Duratears	Compound eye ointment 3.5 g	2	2.06	*Poly Visc*
E.E.S. Granules	Powder for oral liquid 400 mg (base) per 5 mL, 100 mL	1	1.35	*E-Mycin 400*
E.E.S. 200	Powder for oral liquid 200 mg (base) per 5 mL, 100 mL	1	1.67	*E-Mycin 200*
E.E.S. 400 Filmtab	Tablet 400 mg (base)	25	2.36	*E-Mycin*
Epilim EC	Tablet 200 mg (enteric coated)	200	1.50	*Sodium Valproate Sandoz*; *Valpro 200*; *Valproate Winthrop EC 200*
	Tablet 500 mg (enteric coated)	200	1.50	*Sodium Valproate Sandoz*; *Valpro 500*; *Valproate Winthrop EC 500*
Eryc	Capsule 250 mg	25	1.35	*DBL Erythromycin*
Fasigyn	Tablet 500 mg	4	2.51	*Simplotan*

Premium Priced Brand	Form and Strength	Max. Qty	Brand Premium $	Benchmark Priced Brands
Feldene	Capsule 10 mg	50	2.09	*Chem mart Piroxicam*; *GenRx Piroxicam*; *Mobilis 10*; *Terry White Chemists Piroxicam*
	Capsule 20 mg	25	2.07	*Chem mart Piroxicam*; *GenRx Piroxicam*; *Mobilis 20*; *Terry White Chemists Piroxicam*
Feldene-D	Dispersible tablet 10 mg	50	2.09	*Mobilis D-10*
	Dispersible tablet 20 mg	25	2.07	*Mobilis D-20*
Flagyl	Tablet 200 mg	21	2.30	*Metrogyl 200*; *Metronide 200*
	Tablet 400 mg	21	2.30	*Metrogyl 400*; *Metronide 400*
Fosamax Once Weekly	Tablet equivalent to 70 mg alendronic acid	4	1.42	*Adronat*; *Alendrobell 70mg*; *Alendronate-GA*; *Alendronate Sandoz*; *Alendro Once Weekly*; *APO-Alendronate*; *Chem mart Alendronate 70mg*; *Ossmax 70mg*; *Terry White Chemists Alendronate 70mg*
Genteal	Eye drops 3 mg per mL (0.3%), 15 mL (contains sodium perborate as preservative)	1	1.86	*In a Wink Moisturising*
Genteal gel	Ocular lubricating gel 3 mg-2 mg per g (0.3%-0.2%), 10 g	1	1.86	*HPMC PAA*
Glucophage	Tablet 500 mg	100	1.10	*Chem mart Metformin*; *Diaformin*; *Formet 500*; *GenRx Metformin*; *Glucohexal*; *Glucomet 500 mg*; *Metforbell*; *Metformin 500*; *Metformin generichealth*; *Metformin Ranbaxy*; *Terry White Chemists Metformin*; GN brand
	Tablet 850 mg	60	1.10	*Chem mart Metformin*; *Diaformin 850*; *Formet 850*; *GenRx Metformin*; *Glucohexal*; *Glucomet 850 mg*; *Metforbell*; *Metformin 850*; *Metformin generichealth*; *Metformin Ranbaxy*; *Terry White Chemists Metformin*; GN brand
Gopten	Capsule 500 micrograms	28	1.57	*APO-Trandolapril*; *Dolapril 0.5*; *Tranalpha*; *Trandolapril-DP*
	Capsule 1 mg	28	1.57	*APO-Trandolapril*; *Dolapril 1*; *Tranalpha*; *Trandolapril-DP*
	Capsule 2 mg	28	1.58	*APO-Trandolapril*; *Dolapril 2*; *Tranalpha*; *Trandolapril-DP*
	Capsule 4 mg	28	1.57	*APO-Trandolapril*; *Dolapril 4*; *Tranalpha*; *Trandolapril-DP*
Imdur 120 mg	Tablet 120 mg (sustained release)	30	3.00	*Monodur 120 mg*
Imdur Durule	Tablet 60 mg (sustained release)	30	2.84	*Chem mart Isosorbide Mononitrate*; *Duride*; *GenRx Isosorbide Mononitrate*; *Imtrate 60 mg*; *Isomonit*; *Monodur 60 mg*; *Terry White Chemists Isosorbide Mononitrate*
Imodium	Capsule 2 mg	12	0.94	*Gastro-Stop Loperamide*
Imuran	Tablet 25 mg	100	1.19	*Azahexal*
	Tablet 50 mg	100	1.09	*Azahexal*; *Azamun*; *Azapin*; *GenRx Azathioprine*; *Thioprine*
Indocid	Capsule 25 mg	100	0.92	*Arthrexin*
Isoptin	Tablet 40 mg	100	0.76	*Anpec 40*

Premium Priced Brand	Form and Strength	Max. Qty	Brand Premium $	Benchmark Priced Brands
	Tablet 80 mg	100	0.76	*Anpec 80*
Isoptin SR	Tablet 240 mg (sustained release)	30	2.26	*Anpec SR*; *Cordilox SR*
Isoptin 180 SR	Tablet 180 mg (sustained release)	30	2.27	*Cordilox 180 SR*
Keflex	Capsule 250 mg	20	3.30	*Cefalexin Sandoz*; *Cephabell*; *Cephalexin Max*; *Cephatrust 250*; *Chem mart Cephalexin*; *Cilex*; *GenRx Cephalexin*; *Ialex*; *Ibilex 250*; *Rancef*; *Sporahexal*; *Terry White Chemists Cephalexin*
	Capsule 500 mg	20	4.41	*Cefalexin Sandoz*; *Cephabell*; *Cephalexin Max*; *Cephatrust 500*; *Chem mart Cephalexin*; *Cilex*; *GenRx Cephalexin*; *Ialex*; *Ibilex 500*; *Rancef*; *Sporahexal*; *Terry White Chemists Cephalexin*
	Granules for syrup 125 mg per 5 mL, 100 mL	1	3.55	*Cefalexin Sandoz*; *Chem mart Cephalexin*; *Cilex*; *GenRx Cephalexin*; *Ialex*; *Ibilex 125*; *Terry White Chemists Cephalexin*
	Granules for syrup 250 mg per 5 mL, 100 mL	1	4.38	*Cefalexin Sandoz*; *Chem mart Cephalexin*; *Cilex*; *GenRx Cephalexin*; *Ialex*; *Ibilex 250*; *Terry White Chemists Cephalexin*
Kenacomb Otic	Ear drops 1 mg-2.5 mg (base)-250 micrograms-100,000 units per g (0.1%-0.25%-0.025%-100,000 units per g), 7.5 mL	1	1.07	*Otocomb Otic*
	Ear ointment 1 mg-2.5 mg (base)-250 micrograms-100,000 units per g (0.1%-0.25%-0.025%-100,000 units per g), 5 g	1	1.08	*Otocomb Otic*
Klacid	Tablet 250 mg	14	1.96	*APO-Clarithromycin*; *Chem mart Clarithromycin*; *Clarac*; *Clarihexal*; *Clarithro 250*; *GenRx Clarithromycin*; *Kalixocin*; *Terry White Chemists Clarithromycin*
Lacri-Lube	Pack containing 2 tubes compound eye ointment 3.5 g	1	2.24	*Ircal*
Lamictal	Tablet 5 mg	56	0.76	*Lamogine*; *Seaze 5*
	Tablet 25 mg	56	0.77	*GenRx Lamotrigine*; *Lamidus*; *Lamogine*; *Lamotrigine-DP*; *Lamotrigine-GA*; *Lamotrigine generichealth*; *Lamotrigine Sandoz*; *Seaze 25*
	Tablet 50 mg	56	0.66	*GenRx Lamotrigine*; *Lamidus*; *Lamogine*; *Lamotrigine-DP*; *Lamotrigine-GA*; *Lamotrigine generichealth*; *Lamotrigine Sandoz*; *Seaze 50*
	Tablet 100 mg	56	0.73	*GenRx Lamotrigine*; *Lamidus*; *Lamogine*; *Lamotrigine-DP*; *Lamotrigine-GA*; *Lamotrigine generichealth*; *Lamotrigine Sandoz*; *Seaze 100*

Premium Priced Brand	Form and Strength	Max. Qty	Brand Premium $	Benchmark Priced Brands
	Tablet 200 mg	56	0.72	*GenRx Lamotrigine*; *Lamidus*; *Lamogine*; *Lamotrigine-DP*; *Lamotrigine-GA*; *Lamotrigine generichealth*; *Lamotrigine Sandoz*; *Seaze 200*
Lamisil	Tablet 250 mg (base)	42	1.46	*GenRx Terbinafine*; *Tamsil*; *Terbihexal*; *Terbinafine 250*; *Terbinafine-DP*; *Zabel*
Lanoxin	Tablet 250 micrograms	100	1.80	*Sigmaxin*
Lanoxin-PG	Tablet 62.5 micrograms	200	1.79	*Sigmaxin-PG*
Lasix	Tablet 40 mg	100	2.40	*Chem mart Frusemide*; *Frusehexal 40 mg*; *Frusid*; *GenRx Frusemide*; *Terry White Chemists Frusemide*; *Uremide*
Lasix-M	Tablet 20 mg	100	1.90	*Chem mart Frusemide*; *Frusid*; *GenRx Frusemide*; *Terry White Chemists Frusemide*
Lexapro	Tablet 10 mg (base)	28	4.89	*Esipram*
	Tablet 20 mg (base)	28	7.16	*Esipram*
Lioresal 10	Tablet 10 mg	100	2.26	*Baclo*; *Chem mart Baclofen*; *Clofen 10*; *GenRx Baclofen*; *Stelax 10*; *Terry White Chemists Baclofen*
Lioresal 25	Tablet 25 mg	100	2.18	*Baclo*; *Chem mart Baclofen*; *Clofen 25*; *GenRx Baclofen*; *Stelax 25*; *Terry White Chemists Baclofen*
Lipex 10	Tablet 10 mg	30	1.08	*Chem mart Simvastatin*; *GenRx Simvastatin*; *Ransim*; *Simvabell*; *Simvahexal*; *Simvar 10*; *Simvastatin-DP*; *Simvastatin generichealth*; *Simvastatin-Spirit 10*; *Simvastatin Winthrop*; *Simvasyn*; *Terry White Chemists Simvastatin*; *Zimstat*; GN brand
Lipex 20	Tablet 20 mg	30	1.08	*Chem mart Simvastatin*; *GenRx Simvastatin*; *Ransim*; *Simvabell*; *Simvahexal*; *Simvar 20*; *Simvastatin-DP*; *Simvastatin generichealth*; *Simvastatin-Spirit 20*; *Simvastatin Winthrop*; *Simvasyn*; *Terry White Chemists Simvastatin*; *Zimstat*; GN brand
Lipex 40	Tablet 40 mg	30	0.93	*Chem mart Simvastatin*; *GenRx Simvastatin*; *Ransim*; *Simvabell*; *Simvahexal*; *Simvar 40*; *Simvastatin-DP*; *Simvastatin generichealth*; *Simvastatin-Spirit 40*; *Simvastatin Winthrop*; *Simvasyn*; *Terry White Chemists Simvastatin*; *Zimstat*; GN brand

Premium Priced Brand	Form and Strength	Max. Qty	Brand Premium $	Benchmark Priced Brands
Lipex 80	Tablet 80 mg	30	1.04	*Chem mart Simvastatin*; *GenRx Simvastatin*; *Ransim*; *Simvabell*; *Simvahexal*; *Simvar 80*; *Simvastatin-DP*; *Simvastatin generichealth*; *Simvastatin-Spirit 80*; *Simvastatin Winthrop*; *Simvasyn*; *Terry White Chemists Simvastatin*; *Zimstat*; GN brand
Liquifilm Forte	Eye drops 30 mg per mL (3%), 15 mL	1	5.94	*PVA Forte*
Liquifilm Tears	Eye drops 14 mg per mL (1.4%), 15 mL	1	1.71	*PVA Tears*
Lomotil	Tablet 2.5 mg-25 micrograms	20	1.83	*Lofenoxal*
Lopid	Tablet 600 mg	60	2.31	*Ausgem*; *Chem mart Gemfibrozil*; *Gemhexal*; *GenRx Gemfibrozil*; *Jezil*; *Lipazil 600 mg*; *Pharmacor Gemfibrozil 600*; *Terry White Chemists Gemfibrozil*
Losec Tablets	Tablet 20 mg (as magnesium)	30	2.75	*Acimax Tablets; Chemmart Omeprazole; GenRx Omeprazole; Meprazol; Omepral; Omeprazole-GA; Omeprazole Ranbaxy; Omeprazole Winthrop; Terry White Chemists Omeprazole*
Luvox	Tablet 50 mg	30	2.96	*Faverin 50*; *Movox 50*; *Voxam*
	Tablet 100 mg	30	2.95	*Faverin 100*; *Movox 100*; *Voxam*
Maxamox	Tablet 1 g	14	1.17	*Amoxycillin Sandoz*
Microgynon 30	Tablets 150 micrograms-30 micrograms, 21	4	11.45	*Levlen ED*
Microgynon 30 ED	Pack containing 21 tablets 150 micrograms-30 micrograms and 7 inert tablets	4	11.45	*Levlen ED*
Minidiab	Tablet 5 mg	100	4.07	*Melizide*
Minipress	Tablet 1 mg (base)	100	2.31	*Chem mart Prazosin*; *GenRx Prazosin*; *Pressin 1*; *Terry White Chemists Prazosin*
	Tablet 2 mg (base)	100	2.38	*Chem mart Prazosin*; *GenRx Prazosin*; *Pressin 2*; *Terry White Chemists Prazosin*
	Tablet 5 mg (base)	100	2.58	*Chem mart Prazosin*; *GenRx Prazosin*; *Pressin 5*; *Terry White Chemists Prazosin*
Minomycin-50	Tablet 50 mg	60	0.85	*Akamin 50*
Mobic	Tablet 7.5 mg	30	1.61	*Chem mart Meloxicam 7.5 mg*; *GenRx Meloxicam*; *Meloxibell*; *Meloxicam-GA*; *Meloxicam Ranbaxy*; *Meloxicam Sandoz*; *Meloxicam Winthrop*; *Movalis 7.5*; *Moxicam 7.5*; *Pharmacor Meloxicam 7.5*; *Terry White Chemists Meloxicam 7.5 mg*
	Tablet 15 mg	30	1.63	*Chem mart Meloxicam 15 mg*; *GenRx Meloxicam*; *Meloxibell*; *Meloxicam-GA*; *Meloxicam Ranbaxy*; *Meloxicam Sandoz*; *Meloxicam Winthrop*; *Movalis 15*; *Moxicam 15*; *Pharmacor Meloxicam 15*; *Terry White Chemists Meloxicam 15 mg*
Mogadon	Tablet 5 mg	50	3.06	*Alodorm*
	Tablet 5 mg	25	1.53	*Alodorm*

Premium Priced Brand	Form and Strength	Max. Qty	Brand Premium $	Benchmark Priced Brands
Naprosyn	Tablet 250 mg	100	2.34	*Inza 250*
	Tablet 500 mg	50	1.36	*Inza 500*
Naprosyn SR1000	Tablet 1 g (sustained release)	28	1.34	*Proxen SR 1000*
Naprosyn SR750	Tablet 750 mg (sustained release)	28	1.27	*Proxen SR 750*
Natrilix	Tablet 2.5 mg	90	2.56	*Chem mart Indapamide*; *Dapa-Tabs*; *GenRx Indapamide*; *Indahexal*; *Insig*; *Napamide 2.5 mg*; *Terry White Chemists Indapamide*
Neoral 25	Capsule 25 mg	60	2.28	*Cicloral*
Neoral 50	Capsule 50 mg	60	2.24	*Cicloral*
Neoral 100	Capsule 100 mg	60	2.26	*Cicloral*
Nolvadex-D	Tablet 20 mg (base)	60	3.82	*Chem mart Tamoxifen*; *Genox 20*; *GenRx Tamoxifen*; *Tamosin*; *Tamoxen 20 mg*; *Tamoxifen Sandoz*; *Terry White Chemists Tamoxifen*
Nordette 28	Pack containing 21 tablets 150 micrograms-30 micrograms and 7 inert tablets	4	11.78	*Monofeme 28*
Noriday 28 Day	Tablets 350 micrograms, 28	4	4.00	*Locilan 28 Day*
Normison	Tablet 10 mg	25	1.38	*Temaze*; *Temtabs*
	Tablet 10 mg	50	2.76	*Temaze*; *Temtabs*
Noroxin	Tablet 400 mg	14	3.62	*Chem mart Norfloxacin*; *GenRx Norfloxacin*; *Norflohexal*; *Nufloxib*; *Roxin*; *Terry White Chemists Norfloxacin*; GM brand
Norvasc	Tablet 5 mg (as besylate)	30	3.05	*Amlo 5* ; *Amlodipine-GA*; *Amlodipine generichealth*; *Amlodipine Sandoz*; *APO-Amlodipine*; *Chem mart Amlodipine*; *Ozlodip*; *Perivasc*; *Pharmacor Amlodipine 5*; *Terry White Chemists Amlodipine*
	Tablet 10 mg (as besylate)	30	4.45	*Amlo 10* ; *Amlodipine-GA*; *Amlodipine generichealth*; *Amlodipine Sandoz*; *APO-Amlodipine*; *Chem mart Amlodipine*; *Ozlodip*; *Perivasc*; *Pharmacor Amlodipine 10*; *Terry White Chemists Amlodipine*
Oroxine	Tablet equivalent to 50 micrograms anhydrous thyroxine sodium	200	1.30	*Eutroxsig*
	Tablet equivalent to 75 micrograms anhydrous thyroxine sodium	200	1.46	*Eutroxsig*
	Tablet equivalent to 100 micrograms anhydrous thyroxine sodium	200	1.31	*Eutroxsig*
	Tablet equivalent to 200 micrograms anhydrous thyroxine sodium	200	1.29	*Eutroxsig*
Orudis SR 200	Capsule 200 mg (sustained release)	28	2.30	*Oruvail SR*
P.V. Carpine	Eye drops 10 mg per mL (1%), 15 mL	1	2.97	*Pilopt*
	Eye drops 20 mg per mL (2%), 15 mL	1	2.96	*Pilopt*
	Eye drops 40 mg per mL (4%), 15 mL	1	2.83	*Pilopt*
	Eye drops 60 mg per mL (6%), 15 mL	1	2.86	*Pilopt*
Panadeine Forte	Tablet 30 mg-500 mg	20	2.80	*Codalgin Forte*; *Codapane Forte*; *Comfarol Forte*; *Dolaforte*; *Prodeine Forte*
	Tablet 30 mg-500 mg	60	8.40	*Codalgin Forte*; *Codapane Forte*; *Comfarol Forte*; *Dolaforte*; *Prodeine Forte*

Premium Priced Brand	Form and Strength	Max. Qty	Brand Premium $	Benchmark Priced Brands
Panafcort	Tablet 1 mg	100	0.65	*Predsone*
Panafcortelone	Tablet 1 mg	100	0.46	*Predsolone*
Parlodel	Tablet 2.5 mg (base)	30	2.84	*Kripton 2.5*
	Tablet 2.5 mg (base)	60	2.92	*Kripton 2.5*
	Capsule 5 mg (base)	60	2.91	*Kripton 5*
	Capsule 10 mg (base)	100	3.08	*Kripton 10*
Pepcidine	Tablet 40 mg	30	5.41	*Ausfam 40*; *Chem mart Famotidine*; *Famohexal*; *GenRx Famotidine*; *Pamacid 40*; *Pepzan*; *Terry White Chemists Famotidine*
Pepcidine M	Tablet 20 mg	60	4.25	*Ausfam 20*; *Chem mart Famotidine*; *Famohexal*; *GenRx Famotidine*; *Pamacid 20*; *Pepzan*; *Terry White Chemists Famotidine*
Plendil ER	Tablet 2.5 mg (extended release)	30	5.00	*Felodur ER 2.5 mg*
	Tablet 5 mg (extended release)	30	5.00	*Felodil XR 5*; *Felodur ER 5 mg*
	Tablet 10 mg (extended release)	30	5.00	*Felodil XR 10*; *Felodur ER 10 mg*
Pravachol	Tablet 10 mg	30	3.52	*Chem mart Pravastatin*; *Cholstat 10*; *GenRx Pravastatin*; *Lipostat 10*; *Liprachol*; *Pravastatin 10*; *Pravastatin-DP*; *Pravastatin-GA 10*; *Pravastatin generichealth*; *Pravastatin Winthrop*; *Terry White Chemists Pravastatin*
	Tablet 20 mg	30	3.52	*Chem mart Pravastatin*; *Cholstat 20*; *GenRx Pravastatin*; *Lipostat 20*; *Liprachol*; *Pravastatin 20*; *Pravastatin-DP*; *Pravastatin-GA 20*; *Pravastatin generichealth*; *Pravastatin Winthrop*; *Terry White Chemists Pravastatin*; *Vastoran*
	Tablet 40 mg	30	3.07	*Chem mart Pravastatin*; *Cholstat 40*; *GenRx Pravastatin*; *Lipostat 40*; *Liprachol*; *Pravastatin 40*; *Pravastatin-DP*; *Pravastatin-GA 40*; *Pravastatin generichealth*; *Pravastatin Winthrop*; *Terry White Chemists Pravastatin*; *Vastoran*
	Tablet 80 mg	30	3.37	*APO-Pravastatin*; *Chem mart Pravastatin*; *Lipostat 80*; *Pravastatin-GA 80*; *Pravastatin generichealth*; *Terry White Chemists Pravastatin*
Prinivil 5	Tablet 5 mg	30	1.52	*APO-Lisinopril*; *Chem mart Lisinopril*; *Fibsol 5*; *GenRx Lisinopril*; *Liprace*; *Lisinobell*; *Lisinopril 5*; *Lisinopril generichealth*; *Lisinopril Hexal*; *Lisinopril Winthrop*; *Lisodur*; *Terry White Chemists Lisinopril*
Prinivil 10	Tablet 10 mg	30	1.53	*Chem mart Lisinopril*; *Fibsol 10*; *GenRx Lisinopril*; *Liprace*; *Lisinobell*; *Lisinopril 10*; *Lisinopril generichealth*; *Lisinopril Hexal*; *Lisinopril Winthrop*; *Lisodur*; *Terry White Chemists Lisinopril*

Premium Priced Brand	Form and Strength	Max. Qty	Brand Premium $	Benchmark Priced Brands
Prinivil 20	Tablet 20 mg	30	1.53	*APO-Lisinopril*; *Chem mart Lisinopril*; *Fibsol 20*; *GenRx Lisinopril*; *Liprace*; *Lisinobell*; *Lisinopril 20*; *Lisinopril generichealth*; *Lisinopril Hexal*; *Lisinopril Winthrop*; *Lisodur*; *Terry White Chemists Lisinopril*
Prothiaden	Capsule 25 mg	50	1.58	*Dothep 25*
	Tablet 75 mg	30	0.81	*Dothep 75*
Provera	Tablet 5 mg	56	1.74	*Ralovera*
	Tablet 10 mg	30	1.75	*Medroxyhexal*; *Ralovera*
	Tablet 10 mg	100	1.64	*Ralovera*
Prozac Tab	Tablet 20 mg (base) (dispersible)	28	4.13	*Lovan 20 Tab*
Prozac 20	Capsule 20 mg (base)	28	4.13	*Auscap*; *Chem mart Fluoxetine*; *Fluohexal*; *Fluoxebell*; *Fluoxetine 20*; *Fluoxetine-DP*; *GenRx Fluoxetine*; *Lovan*; *Terry White Chemists Fluoxetine*; *Zactin*
Quinate	Tablet 300 mg	50	2.17	*Quinsul*
Redipred	Oral solution equivalent to 5 mg prednisolone per mL, 30 mL	1	1.86	*PredMix*
Renitec	Tablet 10 mg	30	2.46	*Alphapril*; *Auspril*; *Chem mart Enalapril*; *Enahexal*; *Enalabell*; *Enalapril-DP 10mg*; *Enalapril Winthrop*; *GenRx Enalapril*; *Terry White Chemists Enalapril*
Renitec M	Tablet 5 mg	30	2.46	*Alphapril*; *Auspril*; *Chem mart Enalapril*; *Enahexal*; *Enalabell*; *Enalapril-DP 5mg*; *Enalapril Winthrop*; *GenRx Enalapril*; *Terry White Chemists Enalapril*
Renitec 20	Tablet 20 mg	30	2.47	*Alphapril*; *Auspril*; *Chem mart Enalapril*; *Enahexal*; *Enalabell*; *Enalapril-DP 20mg*; *Enalapril Winthrop*; *GenRx Enalapril*; *Terry White Chemists Enalapril*
Ritalin 10	Tablet 10 mg	100	1.37	*Attenta*
Rivotril	Tablet 500 micrograms	200	3.58	*Paxam 0.5*
	Tablet 2 mg	200	4.08	*Paxam 2*
	Tablet 500 micrograms	100	1.79	*Paxam 0.5*
	Tablet 2 mg	100	2.04	*Paxam 2*
Roaccutane	Capsule 20 mg	60	2.37	*Chem mart Isotretinoin*; *GenRx Isotretinoin*; *Oratane*; *Terry White Chemists Isotretinoin*
Rulide	Tablet 150 mg	10	2.60	*Biaxsig*; *Roxar 150*; *Roxide*; *Roximycin*
	Tablet 300 mg	5	2.60	*Biaxsig*; *Roxar 300*; *Roxide*; *Roximycin*
Salazopyrin-EN	Tablet 500 mg (enteric coated)	200	1.58	*Pyralin EN*
Septrin Forte	Tablet 160 mg-800 mg	10	1.10	*Bactrim DS*; *Resprim Forte*
Serepax	Tablet 15 mg	25	1.78	*Alepam 15*
	Tablet 30 mg	25	1.90	*Alepam 30*; *Murelax*
	Tablet 15 mg	50	3.56	*Alepam 15*
	Tablet 30 mg	50	3.80	*Alepam 30*; *Murelax*
Serophene	Tablet 50 mg	10	0.14	*Clomhexal*; *Fermil*; *GenRx Clomiphene*

Premium Priced Brand	Form and Strength	Max. Qty	Brand Premium $	Benchmark Priced Brands
Sigmacort	Cream 10 mg per g (1%), 50 g	1	1.91	*Cortic-DS 1%*
	Cream 10 mg per g (1%), 50 g	1	1.91	*Cortic-DS 1%*
	Cream 10 mg per g (1%), 30 g	1	1.90	*Cortic-DS 1%*
	Topical ointment 10 mg per g (1%), 30 g	1	1.90	*Cortic-DS 1%*
	Topical ointment 10 mg per g (1%), 50 g	1	1.91	*Cortic-DS 1%*
Sinemet	Tablet 250 mg-25 mg	100	3.10	*Levohexal*
Sinemet 100/25	Tablet 100 mg-25 mg	100	5.22	*Kinson*
Slow-K	Tablet 600 mg (sustained release)	200	2.80	*Duro-K*
Sofradex	Ear drops 500 micrograms-5 mg-50 micrograms per mL, 8 mL	1	2.00	*Otodex*
Sotacor	Tablet 80 mg	60	4.50	*GenRx Sotalol*; *Solavert*; *Sotahexal*
	Tablet 160 mg	60	4.50	*Cardol*; *Chem mart Sotalol*; *GenRx Sotalol*; *Solavert*; *Sotab*; *Sotahexal*; *Terry White Chemists Sotalol*
Stemetil	Tablet containing prochlorperazine maleate 5 mg	25	2.50	*Stemzine*
Synphasic	Pack containing 12 tablets 500 micrograms-35 micrograms, 9 tablets 1 mg-35 micrograms and 7 inert tablets	4	7.92	*Improvil 28 Day*
Tagamet	Tablet 200 mg	120	1.94	*Magicul 200*
	Tablet 400 mg	60	1.94	*GenRx Cimetidine*; *Magicul 400*
Tazac	Capsule 150 mg	60	5.60	*Nizac*; *Tacidine*
	Capsule 300 mg	30	5.60	*Nizac*; *Tacidine*
Tears Naturale	Eye drops 3 mg-1 mg per mL (0.3%-0.1%), 15 mL	1	1.67	*Poly-Tears*
Tegretol 100	Tablet 100 mg	200	2.55	*Carbamazepine Sandoz*
Tegretol 200	Tablet 200 mg	200	2.74	*Carbamazepine Sandoz*; *Teril*
Tenormin	Tablet 50 mg	30	3.54	*Atehexal*; *Atenolol-GA*; *Chem mart Atenolol*; *GenRx Atenolol*; *Noten*; *Tensig*; *Terry White Chemists Atenolol*
Timoptol	Eye drops 2.5 mg (base) per mL (0.25%), 5 mL	1	1.18	*Tenopt*
	Eye drops 5 mg (base) per mL (0.5%), 5 mL	1	1.17	*Tenopt*
Tofranil 10	Tablet 10 mg	50	2.97	*Tolerade 10*
Tofranil 25	Tablet 25 mg	50	2.97	*Tolerade 25*
Tolvon	Tablet 10 mg	50	1.99	*Lumin 10*
	Tablet 20 mg	50	2.97	*Lumin 20*
Tramal	Capsule 50 mg	20	2.42	*Chem mart Tramadol*; *GenRx Tramadol*; *Terry White Chemists Tramadol*; *Tramedo*; *Zydol*
Tramal SR 100	Tablet 100 mg (twice daily sustained release)	20	4.51	*Tramahexal SR*; *Tramedo SR 100*; *Zydol SR 100*
Tramal SR 150	Tablet 150 mg (twice daily sustained release)	20	5.37	*Tramahexal SR*; *Tramedo SR 150*; *Zydol SR 150*
Tramal SR 200	Tablet 200 mg (twice daily sustained release)	20	6.09	*Tramahexal SR*; *Tramedo SR 200*; *Zydol SR 200*
Trandate	Tablet 100 mg	100	2.99	*Presolol 100*
	Tablet 200 mg	100	2.97	*Presolol 200*
Triphasil 28	Pack containing 6 tablets 50 micrograms-30 micrograms, 5 tablets 75 micrograms-40 micrograms, 10 tablets 125 micrograms-30 micrograms and 7 inert tablets	4	11.78	*Trifeme 28*
Triprim	Tablet 300 mg	7	1.03	*Alprim*
Triquilar ED	Pack containing 6 tablets 50 micrograms-30 micrograms, 5 tablets 75 micrograms-40 micrograms, 10 tablets 125 micrograms-30 micrograms and 7 inert tablets	4	11.45	*Logynon ED*
Valium	Tablet 2 mg	50	0.86	*Antenex 2*; *Valpam 2*

Premium Priced Brand	Form and Strength	Max. Qty	Brand Premium $	Benchmark Priced Brands
	Tablet 5 mg	50	0.88	*Antenex 5*; *Diazepam-DP*; *Ranzepam*; *Valpam 5*
Vastin	Capsule 20 mg (fluvastatin)	28	3.28	*Lescol*
	Capsule 40 mg (fluvastatin)	28	3.58	*Lescol*
Ventolin CFC-free	Oral pressurised inhalation 100 micrograms (base) per dose (200 doses), CFC-free formulation	2	1.18	*Airomir*; *Asmol CFC-free*
Ventolin Nebules	Nebuliser solution single dose units 2.5 mg (base) in 2.5 mL, 30	2	1.46	*Asmol 2.5 uni-dose*; *Butamol 2.5*; *GenRx Salbutamol*; *Pharmacor Salbutamol 2.5*; *Salbutamol-GA*; *Salbutamol Sandoz*; PU brand
	Nebuliser solution single dose units 5 mg (base) in 2.5 mL, 30	2	1.46	*Asmol 5 uni-dose*; *Butamol 5*; *GenRx Salbutamol*; *Pharmacor Salbutamol 5*; *Salbutamol-GA*; *Salbutamol Sandoz*
Vibramycin	Tablet 100 mg (as hydrochloride)	7	1.19	*Chem mart Doxycycline; Doxsig; Doxy-100; Doxyhexal; Doxylin 100; GenRx Doxycycline; Terry White Chemists Doxycycline*
	Tablet 100 mg (as hydrochloride)	28	4.76	*Chem mart Doxycycline; Doxsig; Doxy-100; Doxyhexal; Doxylin 100; GenRx Doxycycline; Terry White Chemists Doxycycline*
	Tablet 100 mg (as hydrochloride)	21	3.57	*Chem mart Doxycycline; Doxsig; Doxy-100; Doxyhexal; Doxylin 100; GenRx Doxycycline; Terry White Chemists Doxycycline*
Vibra-Tabs	Tablet 50 mg (as hydrochloride)	25	1.25	*Chem mart Doxycycline; Doxy-50; Doxyhexal; Doxylin 50; Frakas; GenRx Doxycycline; Terry White Chemists Doxycycline*
Viscotears Liquid Gel	Ocular lubricating gel 2 mg per g (0.2%), 10 g	1	1.00	*PAA*
Visken 5	Tablet 5 mg	100	2.71	*Barbloc 5*
Visken 15	Tablet 15 mg	50	2.69	*Barbloc 15*
Voltaren 25	Tablet 25 mg (enteric coated)	100	1.96	*Chem mart Diclofenac*; *Clonac 25*; *Diclofenac-GA*; *Diclohexal*; *Dinac*; *Fenac 25*; *GenRx Diclofenac*; *Terry White Chemists Diclofenac*
Voltaren 50	Tablet 50 mg (enteric coated)	50	1.96	*Chem mart Diclofenac*; *Clonac 50*; *Diclohexal*; *Dinac*; *Fenac*; *GenRx Diclofenac*; *Terry White Chemists Diclofenac*
Xanax	Tablet 250 micrograms	50	0.81	*Alprax 0.25*; *Kalma 0.25*; *Zamhexal 0.25mg*
	Tablet 500 micrograms	50	0.87	*Alprax 0.5*; *Kalma 0.5*; *Zamhexal 0.5mg*
	Tablet 1 mg	50	1.03	*Alprax 1*; *Alprazolam-DP*; *Chem mart Alprazolam*; *GenRx Alprazolam*; *Kalma 1*; *Terry White Chemists Alprazolam*; *Zamhexal 1.0mg*
Xanax Tri-Score	Tablet 2 mg	50	1.25	*Alprax 2*; *Alprazolam-DP*; *Chem mart Alprazolam*; *GenRx Alprazolam*; *Kalma 2*; *Terry White Chemists Alprazolam*; *Zamhexal 2mg*

Premium Priced Brand	Form and Strength	Max. Qty	Brand Premium $	Benchmark Priced Brands
Zantac	Tablet 150 mg (base)	60	1.71	*Ausran*; *Chem mart Ranitidine*; *GenRx Ranitidine*; *Rani 2*; *Ranihexal*; *Ranoxyl*; *Terry White Chemists Ranitidine*; *Ulcaid*
	Tablet 300 mg (base)	30	1.71	*Ausran*; *Chem mart Ranitidine*; *GenRx Ranitidine*; *Rani 2*; *Ranihexal*; *Ranoxyl*; *Terry White Chemists Ranitidine*; *Ulcaid*
Zestril	Tablet 10 mg	30	2.08	*Chem mart Lisinopril*; *Fibsol 10*; *GenRx Lisinopril*; *Liprace*; *Lisinobell*; *Lisinopril 10*; *Lisinopril generichealth*; *Lisinopril Hexal*; *Lisinopril Winthrop*; *Lisodur*; *Terry White Chemists Lisinopril*
	Tablet 20 mg	30	2.08	*APO-Lisinopril*; *Chem mart Lisinopril*; *Fibsol 20*; *GenRx Lisinopril*; *Liprace*; *Lisinobell*; *Lisinopril 20*; *Lisinopril generichealth*; *Lisinopril Hexal*; *Lisinopril Winthrop*; *Lisodur*; *Terry White Chemists Lisinopril*
	Tablet 5 mg	30	2.08	*APO-Lisinopril*; *Chem mart Lisinopril*; *Fibsol 5*; *GenRx Lisinopril*; *Liprace*; *Lisinobell*; *Lisinopril 5*; *Lisinopril generichealth*; *Lisinopril Hexal*; *Lisinopril Winthrop*; *Lisodur*; *Terry White Chemists Lisinopril*
Zocor	Tablet 10 mg	30	1.08	*Chem mart Simvastatin*; *GenRx Simvastatin*; *Ransim*; *Simvabell*; *Simvahexal*; *Simvar 10*; *Simvastatin-DP*; *Simvastatin generichealth*; *Simvastatin-Spirit 10*; *Simvastatin Winthrop*; *Simvasyn*; *Terry White Chemists Simvastatin*; *Zimstat*; GN brand
	Tablet 20 mg	30	1.08	*Chem mart Simvastatin*; *GenRx Simvastatin*; *Ransim*; *Simvabell*; *Simvahexal*; *Simvar 20*; *Simvastatin-DP*; *Simvastatin generichealth*; *Simvastatin-Spirit 20*; *Simvastatin Winthrop*; *Simvasyn*; *Terry White Chemists Simvastatin*; *Zimstat*; GN brand
	Tablet 40 mg	30	0.93	*Chem mart Simvastatin*; *GenRx Simvastatin*; *Ransim*; *Simvabell*; *Simvahexal*; *Simvar 40*; *Simvastatin-DP*; *Simvastatin generichealth*; *Simvastatin-Spirit 40*; *Simvastatin Winthrop*; *Simvasyn*; *Terry White Chemists Simvastatin*; *Zimstat*; GN brand

Premium Priced Brand	Form and Strength	Max. Qty	Brand Premium $	Benchmark Priced Brands
	Tablet 80 mg	30	1.04	*Chem mart Simvastatin*; *GenRx Simvastatin*; *Ransim*; *Simvabell*; *Simvahexal*; *Simvar 80*; *Simvastatin-DP*; *Simvastatin generichealth*; *Simvastatin-Spirit 80*; *Simvastatin Winthrop*; *Simvasyn*; *Terry White Chemists Simvastatin*; *Zimstat*; GN brand
	Tablet 5 mg	30	1.08	*Simvabell*; *Simvahexal*; *Simvasyn*; *Zimstat*
Zofran	Tablet 4 mg	4	0.62	*Ondansetron-RL*; *Ondaz*; *Onsetron 4*
	Tablet 8 mg	4	0.69	*Ondansetron-RL*; *Ondaz*; *Onsetron 8*
	I.V. injection 4 mg in 2 mL	1	0.70	*Ondansetron-RL*; *Ondaz*; *Onsetron*; PF brand
	I.V. injection 8 mg in 4 mL	1	0.69	*Ondansetron-RL*; *Ondaz*; *Onsetron*; PF brand
	Tablet 4 mg	10	0.69	*Ondansetron-RL*; *Ondaz*; *Onsetron 4*
	Tablet 8 mg	10	0.67	*Ondansetron-RL*; *Ondaz*; *Onsetron 8*
Zofran Zydis	Wafer 4 mg	4	0.62	*Ondansetron-RL Zydis*; *Ondaz Zydis*
	Wafer 8 mg	4	0.69	*Ondansetron-RL Zydis*; *Ondaz Zydis*
	Wafer 4 mg	10	0.69	*Ondansetron-RL Zydis*; *Ondaz Zydis*
	Wafer 8 mg	10	0.67	*Ondansetron-RL Zydis*; *Ondaz Zydis*
Zoloft	Tablet 50 mg (base)	30	0.41	*Chem mart Sertraline*; *Concorz*; *Eleva 50*; *GenRx Sertraline*; *Sertra 50*; *Sertraline 50*; *Sertraline-GA*; *Sertraline generichealth*; *Sertraline Winthrop*; *Setrona*; *Terry White Chemists Sertraline*; *Xydep 50*
	Tablet 100 mg (base)	30	0.41	*Chem mart Sertraline*; *Concorz*; *Eleva 100*; *GenRx Sertraline*; *Sertra 100*; *Sertraline 100*; *Sertraline-GA*; *Sertraline generichealth*; *Sertraline Winthrop*; *Setrona*; *Terry White Chemists Sertraline*; *Xydep 100*
Zovirax 200 mg	Tablet 200 mg	50	4.34	*Acihexal*; *Acyclo-V 200*; *GenRx Aciclovir*; *Lovir*
	Tablet 200 mg	90	3.21	*Aciclovir 200*; *Acihexal*; *Acyclo-V 200*; *Chem mart Aciclovir*; *GenRx Aciclovir*; *Lovir*; *Ozvir*; *Terry White Chemists Aciclovir*
Zovirax 800 mg	Tablet 800 mg	35	1.56	*Aciclovir 800*; *Acihexal*; *Acyclo-V 800*; *GenRx Aciclovir*; *Lovir*
	Tablet 800 mg	120	5.19	*Acihexal*; *Acyclo-V 800*; *Lovir*
Zyban	Tablet 150 mg (sustained release)	30	0.85	*Clorprax*; *Prexaton*
	Tablet 150 mg (sustained release)	90	0.86	*Clorprax*; *Prexaton*
Zyloprim	Tablet 100 mg	200	1.91	*Allohexal*; *Allosig*; *Chem mart Allopurinol*; *GenRx Allopurinol*; *Progout 100*; *Terry White Chemists Allopurinol*
	Tablet 300 mg	60	1.80	*Allohexal*; *Allosig*; *Chem mart Allopurinol*; *GenRx Allopurinol*; *Progout 300*; *Terry White Chemists Allopurinol*