



Australian Government

Department of Health and Ageing

**SCHEDULE OF PHARMACEUTICAL
BENEFITS FOR APPROVED
PHARMACISTS AND MEDICAL
PRACTITIONERS**

**OPERATIVE FROM 1 FEBRUARY 2007
(ALL PREVIOUS EDITIONS CANCELLED)**

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This Schedule provides information on the arrangements for the prescribing of pharmaceutical benefits by medical practitioners and participating dental practitioners, and the supply of pharmaceutical benefits by approved pharmacists, approved medical practitioners and approved hospital authorities. 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.

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PHARMACEUTICAL BENEFITS

This Schedule will take effect on 1 February 2007 and all previous issues are cancelled. New Schedules will take effect monthly on the first day of each month.

Internet

The Schedule of Pharmaceutical Benefits is also available on the Internet. The address of the Schedule is www.pbs.gov.au

Fees, Patient Contributions and Safety Net Thresholds

The following fees, patient contributions and safety net thresholds apply as at 1 February 2007 and are included, where applicable, in prices published in the Schedule —

Dispensing Fees:	Ready-prepared	\$5.15
	Dangerous drug fee	\$2.71
	Extemporaneously-prepared	\$7.19
Additional Fees (for safety net prices):	Ready-prepared	\$0.99
	Extemporaneously-prepared	\$1.38
Patient Co-payments:	General	\$30.70
	Concessional	\$4.90
Safety Net Thresholds:	General	\$1059.00
	Concessional	\$274.40
Safety Net Card Issue Fee:		\$7.72

SUMMARY OF CHANGES

ADDITIONS

Additions — Items

2480M **Ciprofloxacin**, ear drops 3 mg per mL (0.3%), 5 mL (*Ciloxan*)

Additions — Brands

8255L *GenRx Carvedilol, GX* — **Carvedilol**, tablet 3.125 mg
 8256M *GenRx Carvedilol, GX* — **Carvedilol**, tablet 6.25 mg
 8257N *GenRx Carvedilol, GX* — **Carvedilol**, tablet 12.5 mg
 8258P *GenRx Carvedilol, GX* — **Carvedilol**, tablet 25 mg
 8450R *Glimepiride Sandoz, SZ* — **Glimepiride**, tablet 1 mg
 8451T *Glimepiride Sandoz, SZ* — **Glimepiride**, tablet 2 mg
 8533D *Glimepiride Sandoz, SZ* — **Glimepiride**, tablet 3 mg
 8452W *Glimepiride Sandoz, SZ* — **Glimepiride**, tablet 4 mg
 8331L *Omeprazole Winthrop, SL* — **Omeprazole**, tablet 20 mg
 8333N *Omeprazole Winthrop, SL* — **Omeprazole**, tablet 20 mg (**Diff. Max. Rpts**)

1944H	<i>Ramipril Sandoz, QM; Ramipril Winthrop, WA</i> — Ramipril , tablet 1.25 mg
1945J	<i>Ramipril Sandoz, QM; Ramipril Winthrop, WA</i> — Ramipril , tablet 2.5 mg
1946K	<i>Ramipril Sandoz, QM; Ramipril Winthrop, WA</i> — Ramipril , tablet 5 mg
8470T	<i>Ramipril Sandoz, QM; Ramipril Winthrop, WA</i> — Ramipril , capsule 10 mg
1978D	<i>Ulcaid (RA)</i> — Ranitidine Hydrochloride , tablet 150 mg (base)
1977C	<i>Ulcaid (RA)</i> — Ranitidine Hydrochloride , tablet 300 mg (base)
1760P	<i>Roxide (HX)</i> — Roxithromycin , tablet 150 mg
8016X	<i>Roxide (HX)</i> — Roxithromycin , tablet 300 mg

DELETIONS

Deletions — Items

8742D	Carvedilol , pack containing 30 tablets 3.125 mg, 30 tablets 6.25 mg and 10 tablets 12.5 mg (<i>Dilatrend Titration Pack</i>)

Deletions — Brands

8511Y	<i>Chem mart Alendronate, CH; GenRx Alendronate, GX; Terry White Chemists Alendronate, TW</i> — Alendronate Sodium , tablet equivalent to 70 mg alendronic acid
1356J	<i>Nebcin, AS</i> — Tobramycin Sulfate , injection 80 mg (base) in 2 mL (with preservative)

Deletions — PBS Therapeutic Group Premium Exemption Codes

8945T	Ramipril , tablet 1.25 mg (<i>Ramace 1.25 mg, Tritace 1.25 mg</i>)
8946W	Ramipril , tablet 2.5 mg (<i>Ramace 2.5 mg, Tritace 2.5 mg</i>)
8947X	Ramipril , tablet 5 mg (<i>Ramace 5 mg, Tritace 5 mg</i>)
8937J	Ramipril , capsule 10 mg (<i>Ramace 10 mg, Tritace 10 mg</i>)

ALTERATIONS

Restriction Changes

8664B	Riluzole , tablet 50 mg (<i>Rilutek</i>)
8816B	Modafinil , tablet 100 mg (<i>Modavigil</i>)

Alterations — Notes

Notes have been amended in respect of the following:

Disodium Pamidronate **Epirubicin Hydrochloride**

Alterations — Item Description

From:	
2852D	Influenza Vaccine , injection (trivalent) 0.5 mL (containing A/New Caledonia/20/99, A/California/7/2004 and B/Malaysia/2506/2004 like strains)
To:	
2852D	Influenza Vaccine , injection (trivalent) 0.5 mL (containing A/New Caledonia/20/99, A/Wisconsin/67/2005 and B/Malaysia/2506/2004 like strains)

Alterations — Number of Repeats

		From	To
8506Q	Exemestane , tablet 25 mg (<i>Aromasin</i>)	2	5
8245Y	Letrozole , tablet 2.5 mg (<i>Femara 2.5 mg</i>)	2	5

Alterations — Manufacturer's Code

		From	To
1081X	Atenolol , tablet 50 mg (<i>Atehexal</i>)	HX	SZ
8220P	Citalopram Hydrobromide , tablet 20 mg (base) (<i>Talohexal</i>)	HX	SZ
8703C	Citalopram Hydrobromide , tablet 40 mg (base) (<i>Talohexal</i>)	HX	SZ
2711Q	Doxycycline , tablet 50 mg (<i>Doxyhexal</i>)	HX	SZ
2709N	Doxycycline , tablet 100 mg (<i>Doxyhexal</i>)	HX	SZ
2702F	Doxycycline , tablet 100 mg (<i>Doxyhexal</i>) (Diff. Max. Qty)	HX	SZ
2714W	Doxycycline , tablet 100 mg (<i>Doxyhexal</i>) (Diff. Max. Qty)	HX	SZ
3321T	Doxycycline , tablet 100 mg (<i>Doxyhexal</i>) (Dental)	HX	SZ
2242B	Paroxetine , tablet 20 mg (base) (<i>Oxetine</i>)	HX	SZ
2236Q	Sertraline Hydrochloride , tablet 50 mg (base) (<i>Concorz</i>)	HX	SZ
2237R	Sertraline Hydrochloride , tablet 100 mg (base) (<i>Concorz</i>)	HX	SZ
2804N	Terbinafine Hydrochloride , tablet 250 mg (base) (<i>Terbihexal</i>)	HX	SZ

SECTION 100 — HIGHLY SPECIALISED DRUGS PROGRAM

DELETIONS

Deletions — Items

9601H	Pegfilgrastim , injection 6 mg in 0.6 mL single-use pre-filled injection pen (<i>Neulasta SureClick</i>)

ALTERATIONS

Alterations — Notes

Notes have been amended in respect of the following:

Disodium Pamidronate

SECTION 100 — SPECIAL AUTHORITY PROGRAM

ALTERATIONS

Restriction Changes

6444E	Imatinib Mesylate , tablet 100 mg (base) (<i>Glivec</i>)
6445F	Imatinib Mesylate , tablet 400 mg (base) (<i>Glivec</i>)

ADVANCE NOTICES

Advance Notices — Deletion of Items

The following items will be deleted from the **Highly Specialised Drugs Program** on 1 **March** 2007:

Items discontinued by the manufacturer —

- 6248W **Saquinavir**, soft gelatin capsule 200 mg (*Fortovase*)
 6231Y **Nelfinavir Mesylate**, oral powder 50 mg (base) per g, 144 g (*Viracept*)

The following items will be deleted from the Schedule of Pharmaceutical Benefits on 1 **April** 2007:

Items discontinued by the manufacturer —

- 1508J **Hydroxocobalamin**, injection 1 mg in 1 mL (*Neo-Cytamen*)
 2545Y **Oxandrolone**, tablet 2.5 mg (*Oxandrin*)

Advance Notices — Deletion of Brands

The following brands will be deleted from the Schedule of Pharmaceutical Benefits on 1 **April** 2007:

Brands discontinued by the manufacturer —

- 1884E *Moxacin*, CS — **Amoxycillin**, capsule 250 mg
 3301R *Moxacin*, CS — **Amoxycillin**, capsule 250 mg (**Dental**)
 1886G *Moxacin*, CS — **Amoxycillin**, powder for syrup 125 mg per 5 mL, 100 mL
 3302T *Moxacin*, CS — **Amoxycillin**, powder for syrup 125 mg per 5 mL, 100 mL (**Dental**)
 1929M *Novantrone*, SI — **Mitozantrone**, injection 20 mg (base) in 10 mL
 1930N *Novantrone*, SI — **Mitozantrone**, injection 25 mg (base) in 12.5 mL

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 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 enquiries—

Tel: 132 290

IME enquiries—

Tel: 1300 302 122

Orange Service Centre
189 Anson Street
Orange NSW 2800

General enquiries—

Tel: 132 290

IME enquiries—

Tel: 1300 302 122

VICTORIA

Pharmaceutical Branch
Medibank House
460 Bourke Street
Melbourne Vic 3000

General enquiries—

Tel: 132 290

IME enquiries—

Tel: 1300 302 122

QUEENSLAND

Pharmaceutical Services Branch
444 Queen Street
Brisbane Qld 4000

General enquiries—

Tel: 132 290

IME enquiries

Tel: 1300 302 122

SOUTH AUSTRALIA and NORTHERN TERRITORY

Pharmaceutical Services Branch
209 Greenhill Road
Eastwood SA 5063

General enquiries—

Tel: 132 290

IME enquiries—

Tel: 1300 302 122

WESTERN AUSTRALIA

Pharmaceutical Benefits Branch
11th Floor, Bankwest Tower
108 St George's Terrace
Perth WA 6000

General enquiries—

Tel: 132 290

IME enquiries—

Tel: 1300 302 122

TASMANIA

Pharmaceutical Branch
242 Liverpool Street
Hobart Tas 7000

General enquiries—

Tel: 132 290

IME enquiries—

Tel: 1300 302 122

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

Prior approval is required for all “Authority required” items or requests for increased quantities and/or repeats. Authorisation 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 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 addresses and telephone numbers of the approving authorities within the State offices of 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

Royal Children's Hospital
Flemington Road
Parkville Vic 3052
Tel: (03) 9345 5680

QLD

Pharmacy Department
Royal Children's Hospital
Herston Qld 4029
Tel: see 24 hour contact above

WA

Sir Charles Gairdner Hospital
Hospital Avenue
Nedlands WA 6009
Tel: see 24 hour contact above

TAS

Tel: see 24 hour contact above

NT

Tel: see 24 hour contact above

ACT

Tel: see 24 hour contact above

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

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

QLD

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

SA

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

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

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

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 Services
PO Box 40596
Casuarina NT 0811

Ms H Stone (08) 8922 7035

Index of Manufacturers' Codes

<i>Code</i>	<i>Manufacturer</i>	<i>Code</i>	<i>Manufacturer</i>
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	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
AC	Alberto Culver Company 14 Loyalty Road North Rocks NSW 2151 Tel: (02) 9630 5099 Fax: (02) 9683 5026	AS	Aspen Pharmacare Australia Pty Ltd First Floor 34-36 Chandos Street St Leonards NSW 2065 Tel: (02) 8436 8300 Fax: (02) 9901 3540
AE	AFT Pharmaceuticals Pty Limited 9 Water Street Caringbah NSW 2229 Tel: 1800 097 639 Fax: 1800 097 810	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
AF	Alphapharm Pty Limited Chase Building 2 Wentworth Park Road Glebe NSW 2037 Tel: (02) 9298 3999 Fax: (02) 9566 4686	AV	Aventis Pharma Pty Limited Building D, Talavera Corporate Centre 12-24 Talavera Road Macquarie Park NSW 2113 Tel: (02) 8666 2000 Fax: (02) 8666 3000
AG	Allergan Australia Pty Ltd 77 Ridge Street Gordon NSW 2072 Tel: 1800 252 224 Fax: (02) 9498 0290	AW	Arrow Pharmaceuticals Pty Limited 24 Rothschild Avenue Rosebery NSW 2018 Tel: (02) 8344 8344 Fax: (02) 8344 8355
AH	Altana Pharma Pty Ltd Ground Floor, 2 Lyonpark Road North Ryde NSW 2113 Tel: (02) 9859 6900 Fax: (02) 9859 6950	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
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	BB	Blackmores Ltd 23 Roseberry Street Balgowlah NSW 2093 Tel: (02) 9951 0111 Fax: (02) 9949 1954
AN	Amgen Australia Pty Ltd Level 7, 123 Epping Road North Ryde NSW 2113 Tel: (02) 9870 1333 Fax: (02) 9870 1344	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
AP	AstraZeneca Pty Ltd Alma Road North Ryde NSW 2113 Tel: (02) 9978 3500 Fax: (02) 9978 3700		

<i>Code</i>	<i>Manufacturer</i>
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 54 Waterloo Road North Ryde NSW 2113 Tel: (02) 9888 8550 Fax: (02) 9888 8557
BI	Biotech Pharmaceuticals Pty Ltd 100 Antimony Street Carole Park Qld 4300 Tel: (07) 3271 9600 Fax: (07) 3271 1315
BK	Becton Dickinson Pty Ltd 80 Rushdale Street Knoxfield Vic 3180 Tel: (03) 9764 2444 Fax: (03) 9764 2550
BN	Bayer Australia Limited 875-893 Pacific Highway Pymble NSW 2073 Tel: (02) 9391 6000 Fax: (02) 9988 3311
BP	British Pharmaceuticals Unit A, 31-33 Sirius Road Lane Cove NSW 2066 Tel: (02) 9428 9411 Fax: (02) 9428 1732
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

<i>Code</i>	<i>Manufacturer</i>
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 4, Deutsche Bank Place Cnr Hunter and Phillip Streets Sydney NSW 2000 Tel: (02) 9629 0638 Fax: (02) 9629 0688
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 2801

<i>Code</i>	<i>Manufacturer</i>
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
DK	Dakota Pharmaceuticals A Division of Sanofi-Synthelabo Australia Pty Limited Building D, Talavera Corporate Centre 12-24 Talavera Road Macquarie Park NSW 2113 Tel: (02) 8666 2000 Fax: (02) 8666 3000
DN	Digiland Pty Ltd Paragon Building Suite 7, 799 Springvale Road Mulgrave Vic 3170 Tel: (03) 8545 0500 Fax: (03) 9561 7349
DR	DiaCare International Pty Ltd Unit 30, 10 Gladstone Road Castle Hill NSW 2154 Tel: (02) 8875 7909 Fax: (02) 8875 7777
DT	DermaTech Laboratories Pty Ltd Unit 17, 167 Prospect Highway Seven Hills NSW 2147 Tel: (02) 9624 5874 Fax: (02) 9624 8822
EG	Eagle Pharmaceuticals Pty Ltd 4/40 Carrington Road Castle Hill NSW 2154 Tel: (02) 9899 9099 Fax: (02) 9899 6564
EO	Ego Pharmaceuticals Pty Ltd 21-31 Malcolm Road Braeside Vic 3195 Tel: (03) 9587 1088 Fax: (03) 9580 7647

<i>Code</i>	<i>Manufacturer</i>
EP	EpiPharm Pty Ltd Level 13, 1 Collins Street Melbourne Vic 3000 Tel: 1800 028 880 Fax: (03) 9660 4999
ES	EBOS Group Pty Ltd Unit 2, 109 Vanessa Street Kingsgrove NSW 2208 Tel: (02) 9502 8410 Fax: (02) 9502 8411
EX	Essex Laboratories 11 Gibbon Road Baulkham Hills NSW 2153 Tel: (02) 9852 7444 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
FL	C. B. Fleet Co. (Aust.) Pty Ltd 25 Macbeth Street Braeside Vic 3195 Tel: (03) 9580 2755 Fax: (03) 9580 2899
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 2801
FP	Ferring Pharmaceuticals Pty Ltd Suite 2B, Level 2 802 Pacific Highway Gordon NSW 2072 Tel: (02) 9497 2300 Fax: (02) 9497 2399

<i>Code</i>	<i>Manufacturer</i>
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 9 Rodborough Road Frenchs Forest NSW 2086 Tel: 1800 800 765 Fax: (02) 9975 5374
GC	GlaxoSmithKline Consumer Healthcare 82 Hughes Avenue Ermington NSW 2115 Tel: (02) 9684 0888 Fax: (02) 9684 6958
GD	General Diabetes Services Rear, 137 Mt Alexander Road Flemington Vic 3031 Tel: (03) 9372 2389 Fax: (03) 9376 4158
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

<i>Code</i>	<i>Manufacturer</i>
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
GX	GenRx Pty Ltd Suite 2B, Level 3, Building A 11 Talavera Road North Ryde NSW 2113 Tel: 1800 195 055 Fax: 1800 133 300
HA	Hamilton Laboratories Pty Ltd 217 Flinders Street Adelaide SA 5000 Tel: (08) 8223 2957 Fax: (08) 8232 1480
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
HP	Hoechst Division of Aventis Pharma Pty Limited Building D, Talavera Corporate Centre 12-24 Talavera Road Macquarie Park NSW 2113 Tel: (02) 8666 2000 Fax: (02) 8666 3000
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 1-6 100 Harris Street Pyrmont NSW 2009 Tel: (02) 9566 1500 Fax: (02) 9566 1458
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

<i>Code</i>	<i>Manufacturer</i>
IS	Ipsen Pty Ltd Suite 6, 40 Montclair Avenue Glen Waverley Vic 3150 Tel: (03) 8544 8100 Fax: (03) 9562 5152
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
KR	Kenral Division of Pharmacia Australia Pty Limited 59 Kirby Street Rydalmere NSW 2116 Tel: (02) 9848 3000 Fax: (02) 9848 3333

<i>Code</i>	<i>Manufacturer</i>
KY	Key Pharmaceuticals Pty Ltd 9-11 Leeds Street Rhodes NSW 2138 Tel: (02) 9736 3811 Fax: (02) 9736 3316
LB	Life Bioscience Pty Ltd 80 Millewa Avenue Malvern East Vic 3145 Tel: 1800 114 610 Fax: (03) 8660 2785
LF	Laboratoires Fournier S.A. Level 1, Building 2 20 Bridge Street Pymble NSW 2073 Tel: (02) 9440 0977 Fax: (02) 9440 1382
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
ME	Menley & James Division of GlaxoSmithKline Australia Pty Ltd 1061 Mountain Highway Boronia Vic 3155 Tel: (03) 9721 6000 Fax: (03) 9729 5319

<i>Code</i>	<i>Manufacturer</i>
MF	Mundipharma Pty Ltd Level 26, 6 O'Connell 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
MK	Merck Sharp & Dohme (Australia) Pty Ltd 54-68 Ferndell Street South Granville NSW 2142 Tel: (02) 9795 9500 Fax: (02) 9795 9595
ML	Marion Division of Aventis Pharma Pty Limited Building D, Talavera Corporate Centre 12-24 Talavera Road Macquarie Park NSW 2113 Tel: (02) 8666 2000 Fax: (02) 8666 3000
MM	3M Pharmaceuticals Australia Pty Ltd 9-15 Chilvers Road Thornleigh NSW 2120 Tel: (02) 9875 6333 Fax: (02) 9875 6416
MQ	Merck Pharmaceuticals Chase Building 2 Wentworth Park Road Glebe NSW 2037 Tel: (02) 9298 3999 Fax: (02) 9566 4686
MS	Abbott Diagnostics Division (MediSense Products) 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
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

<i>Code</i>	<i>Manufacturer</i>
MX	Mayne Pharma Pty Ltd (David Bull Laboratories, Faulding Pharmaceuticals) Level 6, 390 St Kilda Road Melbourne Vic 3004 Tel: (03) 9868 0700 Fax: (03) 9868 0111
NA	National Diagnostic Products (Aust) Pty Limited 7-9 Merriwa Street Gordon NSW 2072 Tel: (02) 9418 1100 Fax: (02) 9418 1181
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
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

<i>Code</i>	<i>Manufacturer</i>
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
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
OR	Organon (Australia) Pty Limited 31-33 Sirius Road Lane Cove NSW 2066 Tel: (02) 9428 9411 Fax: (02) 9428 1732
PC	Pfizer Consumer Healthcare Pty Ltd 32 Cawarra Road Caringbah NSW 2229 Tel: (02) 9710 6500 Fax: (02) 9710 6644

<i>Code</i>	<i>Manufacturer</i>
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	Pharmalab 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

<i>Code</i>	<i>Manufacturer</i>	<i>Code</i>	<i>Manufacturer</i>
PX	Point of Care Diagnostics Australia Pty Ltd Unit 14, 76 Reserve Road Artarmon NSW 2064 Tel: (02) 9437 1355 Fax: (02) 9437 1399	SB	Scientific Hospital Supplies Australia Products c/- 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
PY	Procter & Gamble Pharmaceuticals Australia Pty Ltd 99 Phillip Street Parramatta NSW 2150 Tel: (02) 9685 4500 Fax: (02) 9685 4777	SC	Schering Pty Ltd Australian Subsidiary of Schering AG, Berlin 27-31 Doody Street Alexandria NSW 2015 Tel: (02) 9317 8666 Fax: (02) 9317 2138
QM	Qualimed Division of Aventis Pharma Pty Limited 27 Sirius Road Lane Cove NSW 2066 Tel: 1800 555 995 Fax: 1800 555 335	SE	Servier Laboratories (Aust.) Pty Ltd 8 Cato Street Hawthorn Vic 3122 Tel: (03) 8823 7333 Fax: (03) 9822 9790
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	SG	Serono Australia Pty Ltd Unit 3-4, 25 Frenchs Forest Road East Frenchs Forest NSW 2086 Tel: (02) 8977 4100 Fax: (02) 9975 1516
RC	Reckitt Benckiser (Australia) Pty Limited 44 Wharf Road West Ryde NSW 2114 Tel: (02) 9857 2000 Fax: (02) 9857 2004	SH	Schering-Plough Pty Ltd 11 Gibbon Road Baulkham Hills NSW 2153 Tel: (02) 9852 7444 Fax: (02) 9852 7500
RD	Roche Diagnostics Australia Pty Ltd 31 Victoria Avenue Castle Hill NSW 2154 Tel: (02) 9899 7999 Fax: (02) 9634 4696	SI	Sigma Pharmaceuticals Pty Ltd 96 Merrindale Drive Croydon Vic 3136 Tel: (03) 9839 2800 Fax: (03) 9839 2801
RE	Real-RL Division of GlaxoSmithKline Australia Pty Ltd 1061 Mountain Highway Boronia Vic 3155 Tel: (03) 9721 6000 Fax: (03) 9721 5319	SJ	Sharpe Laboratories Pty Ltd 12 Hope Street Ermington NSW 2115 Tel: (02) 9858 5622 Fax: (02) 9858 5957
RO	Roche Products Pty Ltd 4-10 Inman Road Dee Why NSW 2099 Tel: (02) 9454 9000 Fax: (02) 9971 7401	SL	SBPA A Division of Sandoz Pty Ltd 54 Waterloo Road North Ryde NSW 2113 Tel: (02) 9888 8550 Fax: (02) 9888 8557
SA	SciGen Pty Limited Level 7, 2 Bligh Street Sydney NSW 2000 Tel: (02) 9234 1700 Fax: (02) 9234 1777		

<i>Code</i>	<i>Manufacturer</i>
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-Synthelabo Australia Pty Limited 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 27-31 Doody Street Alexandria NSW 2015 Tel: (02) 9317 8666 Fax: (02) 9317 2138
SZ	Sandoz Pty Ltd 54 Waterloo Road North Ryde NSW 2113 Tel: (02) 9888 8550 Fax: (02) 9888 8557
TM	Technipro Marketing Pty Ltd Unit 10, 13 Berry Street Clyde NSW 2142 Tel: (02) 9897 5899 Fax: (02) 9897 5799

<i>Code</i>	<i>Manufacturer</i>
TW	Terry White Chemists Level 7, 5 Queens Road Melbourne Vic 3004 Tel: (03) 9918 2500 Fax: (03) 9918 2006
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 23-25 Pinto Way Highton Vic 3216 Tel: (03) 5244 5811 Fax: (03) 5244 5822
VT	Valeant Pharmaceuticals Australasia Pty Ltd Level 1, 85 St Hilliers Road Auburn NSW 2144 Tel: (02) 9648 4266 Fax: (02) 9648 4655
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
WW	Wm R. Warner 32 Cawarra Road Caringbah NSW 2229 Tel: (02) 9710 6500 Fax: (02) 9710 6644

<i>Code</i>	<i>Manufacturer</i>
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
ZT	Synthon AU Pty Ltd Level 28, 140 St Georges Terrace Perth WA 6000 Tel: (08) 9409 5200 Fax: (08) 9409 5211

<i>Code</i>	<i>Manufacturer</i>

Section 1 — Explanatory Notes

Introduction

These Explanatory Notes are provided to help doctors, dentists 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 of the medicines available under the PBS, and explains how they can be used in order to 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 and pharmacists remain up to date with information on which medicines are included in or excluded from the Schedule, 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 both doctors and dentists 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.)

A separate list at the end of Section 2 relates to items that can be prescribed by dentists who work within the PBS. This is 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 Doctors and Dentists

Eligible prescribers

Pharmaceutical benefits can only be prescribed by registered doctors and by dentists who are approved to work 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.

PBS prescription forms for both doctors and dentists 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.

PBS prescriptions should be provided to the patient in duplicate, as both copies make up a valid PBS prescription. The patient should be reminded to present both the original and the duplicate copy to their local 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 patient. Only a medical practitioner, in course of employment with the participating public hospital, may prescribe the subsidised medication. The States of Victoria, Queensland and Western Australia 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 or dentist.

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, but 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, in course of employment with the participating public hospital, may prescribe the subsidised medication. The States of Victoria, Queensland and Western Australia 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, but the patient is not suffering from one of the specified conditions, it cannot be prescribed as a pharmaceutical benefit. The prescriber should write the prescription either on a private prescription or on a standard prescription with 'PBS/RPBS' 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.

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 are required to, include their prescriber numbers 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, 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 specified; 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, in course of employment with the participating public hospital, may prescribe the subsidised medication. The States of Victoria, Queensland and Western Australia have agreed to implement these arrangements.

Restrictions

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

Unrestricted benefits – which have no restrictions on their therapeutic uses;

Restricted benefits – which can only be prescribed for specific therapeutic uses (they are noted as **restricted benefit**); and

Authority required benefits – which are restricted and require prior approval from Medicare Australia or the DVA (they are noted as **authority required**).

Authority PBS prescriptions

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

Approval of authority PBS prescriptions by Medicare Australia may be obtained by posting an Authority Prescription Form to Medicare Australia, by calling Medicare Australia's Authority Freecall service (1800 888 333), or by using Medicare Australia's 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's Authority Freecall service (1800 552 580).

An authority PBS prescription cannot have retrospective approval.

An authority PBS prescription is not valid until it has been approved by Medicare Australia or the DVA. Until then, a pharmacist must not supply the item as a PBS benefit.

The Authority PBS Prescription Form includes:

- the original copy, which records doctor, patient and pharmaceutical benefit item details. After approval, Medicare Australia will forward it with the duplicate to the patient or the doctor (if it is to be sent direct to the patient, the doctor should mark the box next to the patient's details).
- the duplicate copy, which is used for repeat supplies and is attached to repeat authorisations until the last supply is made. The duplicate is then retained by the pharmacist. In the new format, the duplicate ("Medicare Australia/DVA copy") is forwarded to Medicare Australia for processing and payment.
- the triplicate ("doctor or Medicare Australia/DVA") copy, which is kept by Medicare Australia or the DVA for record purposes when approval is sought in writing. Where approval is by telephone, the doctor must keep this copy for 12 months. This copy must record the daily dose, details of the disease, the 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, in course of employment with the participating public hospital, may prescribe the subsidised medication. The States of Victoria, Queensland and Western Australia 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 doctors in writing, unless otherwise approved by Medicare Australia;

- doctors should include their name, address, telephone number and **prescriber number** (not provider number);
- doctors must include the patient's name, address and entitlement status (i.e. whether they are a 'concessional' or 'general' patient);
- doctors 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 doctor must provide additional information to Medicare Australia with the authority application; and
- the PBS prescription must be signed by the doctor and dated.

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

In the case of authority PBS prescriptions approved by telephone, the doctor should ensure the approval number is 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.

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, in course of employment with the participating public hospital, may prescribe the subsidised medication. The States of Victoria, Queensland and Western Australia 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 come from the Repatriation Pharmaceutical Reference Committee (RPRC).

Only doctors (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 doctor feels the maximum quantity or number of repeats should be increased for a particular patient, he or she must complete an Authority Prescription Form (see procedures above under 'Authority 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 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 doctor.

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.

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 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.

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 original and duplicate of a valid PBS prescription which is not more than 12 months old; or
- the original and duplicate 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 duplicate PBS prescription (or in the new format, the "patient/pharmacist" copy) not more than 12 months after the date of the original PBS 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 supply is urgently needed to treat 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.

With the agreement of the patient, a pharmacist can supply an alternative brand of a benefit without reference to the prescriber, provided that:

- the PBS prescription does not indicate 'brand substitution not permitted';
- the Schedule shows the prescribed brand and the substitute brand are bioequivalent; and
- supply of the substitute brand does not contravene relevant State/Territory law.

A pharmacist cannot substitute one medicine for another – only an alternative brand of the medicine, as specified above.

Pharmacists must heed State/Territory laws when supplying drugs listed as narcotic, specified or restricted in the poisons 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 or a dentist.

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').

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 number;
- details of the original PBS prescription stating the item, brand, form, strength, quantity and directions;
- if brand substitution has occurred, the name of the brand actually supplied;
- for the first supply, the pharmacy 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 of the original PBS prescription number;
- 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.

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 2006, the pharmacist should write: "Certified supplied – mailed to patient 1 April 2006 (name of pharmacist) (signature of pharmacist) (date of certification)".

If an item is supplied in an urgent case (see above), 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 2006, the pharmacist should write: "Certified supplied 1 May 2006 – 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 \$30.70 for general patients and \$4.90 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 \$4.90.

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 \$24.60. 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 \$30.70 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 \$4.90.

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 from 1 January 2006 (see also details under '5. The Safety Net Scheme' and '7. How Pharmacists Claim Reimbursement').

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 \$4.90 – not free. For a general patient with a Safety Net Concession Card, the usual general patient amount (up to \$30.70) would apply – not the Safety Net concessional amount of \$4.90.

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 dispensed price for that benefit item. This extra charge is paid by all patients, 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 (see details under '9. Pricing Prescriptions').

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, in course of employment with the participating public hospital, may prescribe the subsidised medication. The States of Victoria, Queensland and Western Australia have agreed to implement these arrangements.

Solvents

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

Increased quantities

Where a doctor 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 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 PBS prescriptions through community pharmacies or 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, in course of employment with the participating public hospital, may prescribe the subsidised medication. The States of Victoria, Queensland and Western Australia 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 \$1059.00. When patients and/or their families reach this amount, they can apply for a Safety Net Concession Card and pay only \$4.90 per PBS prescription for the rest of the calendar year.

The concessional safety net threshold is \$274.40 (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 thresholds may be adjusted on 1 January each year in line with inflation.

Safety net cross-over arrangements

Some patients and/or members of their families will move in and out of concessional status 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 \$274.40. 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 \$4.90 per item.

General patients who were previously concessional patients can apply for a Safety Net Concession Card when they reach the general threshold of \$1059.00. In this case, any pharmaceutical benefits previously supplied at the concessional rate in that calendar year will be counted at the rate of \$4.90 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 \$4.90 per item until the \$274.40 threshold is reached. To receive a Safety Net Concession Card, general pharmaceutical benefits are counted at the general rate of up to \$30.70 per item and concessional pharmaceutical benefits at \$4.90 per item, until the threshold of \$1059.00 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 \$4.90 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 \$4.90 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 \$4.90 for each RPBS prescription item purchased.

Those with gold or orange cards receive all of their prescription items under the RPBS, and only pay \$4.90 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 \$1020.00 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 \$1059.00, 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. (see details under '4. Patient Charges') 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, in course of employment with the participating public hospital, may prescribe the subsidised medication. The States of Victoria, Queensland and Western Australia 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 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.

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) hotline (1300 302 122).

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 'DP No.' box on PBS dental 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 (see below)
- 'A' – (a) the price claimed for pricing elected PBS prescriptions, exceptional PBS prescriptions and RPBS non-scheduled prescriptions (see below 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 (see also '8. How Pharmacists Claim Reimbursement: Documents to be Submitted').

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 (see section 4 of this Schedule), 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 (see below).

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 under '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 (as detailed under '9. Pricing Prescriptions') 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.

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 (see below);
- 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 (blue pages). 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, in Section 4 of this Schedule.

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:

(a) determine the basic pricing unit relative to the quantity dispensed by referring to the following table:

<i>Quantity</i>	<i>Basic Pricing Unit</i>
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

(b) 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

(c) find the recovery price by multiplying the price of the basic pricing unit – as established in (b) – 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 <http://scaleplus.law.gov.au>.

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Section 2

Emergency Drug (Doctor's Bag) Supplies

Special Pharmaceutical Benefits

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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. 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 10 mL 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	
3451P	ADRENALINE Injection 1 mg in 1 mL (1 in 1,000)	5	18.46	AP	
3453R	ATROPINE SULFATE Injection 600 micrograms in 1 mL	10	13.39	AP	
3457Y	BENZTROPINE MESYLATE Injection 2 mg in 2 mL	5	20.86	Cogentin	MK
3486L or	BENZYL PENICILLIN Powder for injection 600 mg	10	*22.09	BenPen	CS
3485K	PROCAINE PENICILLIN Injection 1.5 g	5	51.35	Cilicaine	SI
3487M	BENZYL PENICILLIN Powder for injection 3 g	1	11.30	BenPen	CS
3455W or	CHLORPROMAZINE HYDROCHLORIDE Injection 50 mg in 2 mL	10	14.09	Largactil	AV
3456X	HALOPERIDOL Injection 5 mg in 1 mL	10	20.32	Serenace	SI
3472R or	DEXAMETHASONE SODIUM PHOSPHATE Injection equivalent to 4 mg dexamethasone phosphate in 1 mL	5	13.95	MX	
3470P or	HYDROCORTISONE SODIUM SUCCINATE Injection equivalent to 100 mg hydrocortisone with 2 mL solvent	2	*15.61	Solu-Cortef	PH
3471Q	HYDROCORTISONE SODIUM SUCCINATE Injection equivalent to 250 mg hydrocortisone with 2 mL solvent	1	14.61	Solu-Cortef	PH
3458B	DIAZEPAM Injection 10 mg in 2 mL	5	10.76	MX	
3460D	DIHYDROERGOTAMINE MESYLATE Injection 1 mg in 1 mL	5	15.33	Dihyergot	NV
3463G	DIPHTHERIA and TETANUS VACCINE, ADSORBED, DILUTED FOR ADULT USE Injection 0.5 mL in pre-filled syringe	20	*152.15	ADT	CS
3466K	FRUSEMIDE Injection 20 mg in 2 mL	5	10.33	^a Frusehexal ^a Lasix	HX AV

EMERGENCY DRUG (DOCTOR'S BAG) SUPPLIES

Code	Name, Manner of administration and form	Max. Qty	Dispensed Price for Max.Qty \$	Proprietary Name and Manufacturer	
3467L	GLUCAGON HYDROCHLORIDE Injection set containing 1 mg (1 i.u.) and 1 mL solvent in disposable syringe	1	39.38	GlucaGen Hypokit	NO
3475X	GLYCERYL TRINITRATE Buccal/sublingual spray (pump pack) 400 micrograms per dose (200 doses)	‡1	18.26	Nitrolingual Pumpspray	AV
3474W	LIGNOCAINE HYDROCHLORIDE Injection 100 mg in 5 mL	5	34.72	PF	
3476Y or	METOCLOPRAMIDE HYDROCHLORIDE Injection 10 mg in 2 mL	10	11.43	Maxolon	VT
3477B	PROCHLORPERAZINE Injection 12.5 mg in 1 mL	10	14.26	Stemetil	AV
3479D or	MORPHINE SULFATE Injection 15 mg in 1 mL	5	12.82	MX	
3480E	MORPHINE SULFATE Injection 30 mg in 1 mL	5	14.20	MX	
3481F or	NALOXONE HYDROCHLORIDE Injection 800 micrograms in 2 mL	5	*94.15	Naloxone Min-I-Jet	CS
3482G	NALOXONE HYDROCHLORIDE Injection 2 mg in 5 mL	2	*62.07	Naloxone Min-I-Jet	CS
3488N	PROMETHAZINE HYDROCHLORIDE Injection 50 mg in 2 mL	10	*18.27	MX	
3496B	SALBUTAMOL SULFATE Nebuliser solution single dose units 2.5 mg (base) in 2.5 mL, 30	‡1	14.27	^a Asmol 2.5 uni-dose ^a Butamol 2.5 ^a Chem mart Salbutamol ^a GenRx Salbutamol ^a Terry White Chemists Salbutamol ^a PU ^a Ventolin Nebules	AF AW CH GX TW GK
3495Y	SALBUTAMOL SULFATE Oral pressurised inhalation 100 micrograms (base) per dose (200 doses), CFC-free formulation	‡1	10.77 11.07 11.27	^a Asmol CFC-free ^a Epaq ^a Airomir ^a Ventolin CFC-free	AL AW MM GK

EMERGENCY DRUG (DOCTOR'S BAG) SUPPLIES

Code	Name, Manner of administration and form	Max. Qty	Dispensed Price for Max.Qty \$	Proprietary Name and Manufacturer	
3497C	SALBUTAMOL SULFATE Nebuliser solution single dose units 5 mg (base) in 2.5 mL, 30	1	14.79	^a Asmol 5 uni-dose	AF
				^a Butamol 5	AW
				^a Chem mart Salbutamol	CH
				^a GenRx Salbutamol	GX
				^a Terry White Chemists Salbutamol	TW
			15.85	^a Ventolin Nebules	GK
3491R	TERBUTALINE SULFATE Injection 500 micrograms in 1 mL	5	28.27	Bricanyl	AP
3484J	TRAMADOL HYDROCHLORIDE Injection 100 mg in 2 mL	5	10.53	^a Trama hexal	HX
				^a Tramal 100	CS
3494X	VERAPAMIL HYDROCHLORIDE Injection 5 mg in 2 mL	5	10.85	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 28.

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	
GENERAL PHARMACEUTICAL BENEFITS									
1888J	AMOXYCILLIN Powder for paediatric oral drops 100 mg per mL, 20 mL	‡1	1	§0.58	#11.65	#12.23	13.03	Amoxil	GK
AMOXYCILLIN									
Authority required									
<i>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.</i>									
9714G	Powder for paediatric oral drops 100 mg per mL, 20 mL	‡1	1	..	#12.23	#12.23	13.61	Amoxil	GK
BLEOMYCIN SULFATE									
Restricted benefit									
<i>Germ cell neoplasms; Lymphoma.</i>									
2315W	Powder for injection 15,000 i.u. (solvent required) (code 6896Y applies to above item with approved solvent)	10	..	§445.90 §445.90 §445.90 §76.86	*500.85 500.85 500.85	*946.75 946.75 1023.61	30.70 ^a MX 30.70 ^a Blenamax SI 30.70 ^a Blenoxane BQ		
ESCITALOPRAM OXALATE									
Restricted benefit									
<i>Major depressive disorders.</i>									
8849R	Oral solution 10 mg (base) per mL, 28 mL	‡1	5	§4.33	35.44	39.77	30.70	Lexapro	LU
Authority required									
<i>Major depressive disorders, where:</i>									
<i>(1) adverse events have occurred with other suitable PBS-listed drugs; or</i>									
<i>(2) drug interactions have occurred with other suitable PBS-listed drugs; or</i>									
<i>(3) drug interactions are expected to occur with other suitable PBS-listed drugs; or</i>									
<i>(4) transfer to another suitable PBS-listed drug would cause patient confusion resulting in problems with compliance; or</i>									
<i>(5) transfer to another suitable PBS-listed drug is likely to result in adverse clinical consequences.</i>									
9700M	Oral solution 10 mg (base) per mL, 28 mL	‡1	5	..	39.77	39.77	30.70	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. For eligible veterans under RPBS provisions, see RPBS EXPLANATORY NOTES, paragraph 31.

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	
LANSOPRAZOLE									
<u>Restricted benefit</u>									
<i>Initial treatment of peptic ulcer.</i>									
<u>NOTE:</u>									
<i>Helicobacter pylori eradication therapy should be considered.</i>									
8528W	Sachet containing granules for oral suspension, 30 mg per sachet	28	1	\$3.63	36.40	40.03	30.70	Zoton	WY
<u>NOTE:</u>									
<i>No applications for increased repeats will be authorised.</i>									
<u>Restricted benefit</u>									
<i>Gastro-oesophageal reflux disease; Scleroderma oesophagus.</i>									
8529X	Sachet containing granules for oral suspension, 30 mg per sachet	28	5	\$3.63	36.40	40.03	30.70	Zoton	WY
<u>Authority required</u>									
<i>Initial treatment of peptic ulcer, in patients unable to take a solid dose form of a proton pump inhibitor.</i>									
<u>NOTE:</u>									
<i>Helicobacter pylori eradication therapy should be considered.</i>									
9730D	Sachet containing granules for oral suspension, 30 mg per sachet	28	1	..	40.03	40.03	30.70	Zoton	WY
<u>NOTE:</u>									
<i>No applications for increased repeats will be authorised.</i>									
<u>Authority required</u>									
<i>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.</i>									
9731E	Sachet containing granules for oral suspension, 30 mg per sachet	28	5	..	40.03	40.03	30.70	Zoton	WY

SPECIAL PHARMACEUTICAL BENEFITS

The special patient contribution is payable by all patients in addition to the relevant patient contribution for concessional and general patients. For eligible veterans under RPBS provisions, see RPBS EXPLANATORY NOTES, paragraph 27.

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									
<i>Treatment of partial epileptic seizures which are not controlled satisfactorily by other anti-epileptic drugs.</i>									
8654L	Tablet 250 mg	60	5	\$7.13	55.15	62.28	30.70	Keppra	UC
8655M	Tablet 500 mg	60	5	\$11.91	88.53	100.44	30.70	Keppra	UC
8656N	Tablet 1 g	60	5	\$19.84	144.06	163.90	30.70	Keppra	UC

Authority required

Treatment of partial epileptic seizures which are not controlled satisfactorily by other anti-epileptic drugs, and where:

- (1) adverse events have occurred with other suitable PBS-listed drugs; or*
- (2) drug interactions have occurred with other suitable PBS-listed drugs; or*
- (3) drug interactions are expected to occur with other suitable PBS-listed drugs; or*
- (4) transfer to another suitable PBS-listed drug would cause patient confusion resulting in problems with compliance; or*
- (5) transfer to another suitable PBS-listed drug is likely to result in adverse clinical consequences.*

9708Y	Tablet 250 mg	60	5	..	62.28	62.28	30.70	Keppra	UC
9709B	Tablet 500 mg	60	5	..	100.44	100.44	30.70	Keppra	UC
9710C	Tablet 1 g	60	5	..	163.90	163.90	30.70	Keppra	UC

PEMETREXED DISODIUM

Authority required

Locally advanced or metastatic non-small cell lung cancer, after prior platinum-based chemotherapy.

8809P	Powder for I.V. infusion 500 mg (base)	2	2	\$398.72	*2906.27	*3304.99	30.70	Alimta	LY

Authority required

Locally advanced or metastatic non-small cell lung cancer, after prior platinum-based chemotherapy, where:

- (1) treatment with paclitaxel or docetaxel is contraindicated; or*
- (2) intolerance to treatment with either docetaxel or paclitaxel has developed; or*
- (3) treatment with either docetaxel or paclitaxel has been unsuccessful; or*
- (4) transfer to docetaxel or paclitaxel is likely to result in adverse clinical consequences.*

9713F	Powder for I.V. infusion 500 mg (base)	2	2	..	*3304.99	*3304.99	30.70	Alimta	LY

SPECIAL PHARMACEUTICAL BENEFITS

The special patient contribution is payable by all patients in addition to the relevant patient contribution for concessional and general patients. For eligible veterans under RPBS provisions, see RPBS EXPLANATORY NOTES, paragraph 31.

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
TOPIRAMATE								
<u>Authority required</u>								
<i>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.</i>								
8163P	Tablet 25 mg	60	5	\$2.32	38.49	40.81	30.70	Topamax JC
8164Q	Tablet 50 mg	60	5	\$2.32	60.73	63.05	30.70	Topamax JC
8165R	Tablet 100 mg	60	5	\$2.61	97.76	100.37	30.70	Topamax JC
8166T	Tablet 200 mg	60	5	\$2.62	160.72	163.34	30.70	Topamax JC
<u>Authority required</u>								
<i>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, and where:</i>								
<i>(1) adverse events have occurred with other suitable PBS-listed drugs; or</i>								
<i>(2) drug interactions have occurred with other suitable PBS-listed drugs; or</i>								
<i>(3) drug interactions are expected to occur with other suitable PBS-listed drugs; or</i>								
<i>(4) transfer to another suitable PBS-listed drug would cause patient confusion resulting in problems with compliance; or</i>								
<i>(5) transfer to another suitable PBS-listed drug is likely to result in adverse clinical consequences.</i>								
9704R	Tablet 25 mg	60	5	..	40.81	40.81	30.70	Topamax JC
9705T	Tablet 50 mg	60	5	..	63.05	63.05	30.70	Topamax JC
9706W	Tablet 100 mg	60	5	..	100.37	100.37	30.70	Topamax JC
9707X	Tablet 200 mg	60	5	..	163.34	163.34	30.70	Topamax JC
<u>Authority required</u>								
<i>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.</i>								
8371N	Capsule 15 mg	60	5	\$2.32	29.16	31.48	30.15	Topamax JC Sprinkle
8372P	Capsule 25 mg	60	5	\$2.32	38.49	40.81	30.70	Topamax JC Sprinkle
8520K	Capsule 50 mg	60	5	\$2.32	60.73	63.05	30.70	Topamax JC Sprinkle

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. For eligible veterans under RPBS provisions, see RPBS EXPLANATORY NOTES, paragraph 27.

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
<i>TOPIRAMATE—cont.</i>								
<u>Authority required</u>								
<i>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, and where:</i>								
<i>(1) adverse events have occurred with other suitable PBS-listed drugs; or</i>								
<i>(2) drug interactions have occurred with other suitable PBS-listed drugs; or</i>								
<i>(3) drug interactions are expected to occur with other suitable PBS-listed drugs; or</i>								
<i>(4) transfer to another suitable PBS-listed drug would cause patient confusion resulting in problems with compliance; or</i>								
<i>(5) transfer to another suitable PBS-listed drug is likely to result in adverse clinical consequences.</i>								
9701N	Capsule 15 mg	60	5	..	31.48	31.48	30.70	Topamax JC Sprinkle
9702P	Capsule 25 mg	60	5	..	40.81	40.81	30.70	Topamax JC Sprinkle
9703Q	Capsule 50 mg	60	5	..	63.05	63.05	30.70	Topamax JC Sprinkle

PHARMACEUTICAL BENEFITS FOR DENTAL USE

3310F	AMOXYCILLIN Powder for paediatric oral drops 100 mg per mL, 20 mL	‡1	..	§0.58	11.65	12.23	13.03	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								
2931G	AMPHOTERICIN Lozenge 10 mg	20	1	..	8.88	9.87	Fungilin	BQ
3033P	NYSTATIN Oral suspension 100,000 units per mL, 24 mL	‡1	1	..	9.39	10.38	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	..	18.50	19.49	Difflam	MM
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	..	*12.83	13.82	^a Gelusil	WW
				^B 0.40	*13.23	13.82	^a Mylanta P	PC
2157M	Oral suspension 200 mg-200 mg per 5 mL, 500 mL	2	5	..	*12.83	13.82	^a Gelusil	WW
				^B 0.30	*13.13	13.82	^a Mylanta P	PC
ALUMINIUM HYDROXIDE with MAGNESIUM TRISILICATE and MAGNESIUM HYDROXIDE								
2159P	Oral suspension 250 mg-120 mg- 120 mg per 5 mL, 500 mL	2	5	..	*12.83	13.82	Gastrogel	FM
Drugs for peptic ulcer and gastro-oesophageal reflux disease (GORD)								
• H₂-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:								
<i>Helicobacter pylori</i> eradication therapy should be considered prior to commencing initial treatment of peptic ulcer with this drug.								
1157X	Tablet 200 mg	120	5	..	24.24	25.23	^a Magicul 200	AF
				^B 2.49	26.73	25.23	^a Tagamet	GK
1158Y	Tablet 400 mg	60	5	..	24.24	25.23	^a GenRx Cimetidine	GX
				^B 2.49	26.73	25.23	^a Magicul 400	AF
							^a Tagamet	GK
1159B	Tablet 800 mg	30	5	..	24.24	25.23	^a GenRx Cimetidine	GX
							^a Magicul 800	AF

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	
FAMOTIDINE								
NOTE: <i>Helicobacter pylori</i> eradication therapy should be considered prior to commencing initial treatment of peptic ulcer with this drug.								
2487X	Tablet 20 mg	60	5	..	19.18	20.17	^a Ausfam 20 ^a Chem mart Famotidine ^a Famohexal ^a GenRx Famotidine ^a Pamacid 20 ^a Pepzan ^a Terry White Chemists Famotidine ^a Pepcidine M	AW CH HX GX AF GM TW MK
2488Y	Tablet 40 mg	30	5	..	19.18	20.17	^a Ausfam 40 ^a Chem mart Famotidine ^a Famohexal ^a GenRx Famotidine ^a Pamacid 40 ^a Pepzan ^a Terry White Chemists Famotidine ^B 5.41 24.59 20.17 ^a Pepcidine	AW CH HX GX AF GM TW MK
NIZATIDINE								
NOTE: <i>Helicobacter pylori</i> eradication therapy should be considered prior to commencing initial treatment of peptic ulcer with this drug.								
1505F	Capsule 150 mg	60	5	..	23.15	24.14	^a Nizac ^a Tacidine ^B 5.28 28.43 24.14 ^a Tazac	LN AF AS
1504E	Capsule 300 mg	30	5	..	23.15	24.14	^a Nizac ^a Tacidine ^B 5.28 28.43 24.14 ^a Tazac	LN AF 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	
RANITIDINE HYDROCHLORIDE								
NOTE: <i>Helicobacter pylori</i> eradication therapy should be considered prior to commencing initial treatment of peptic ulcer with this drug.								
1978D	Tablet 150 mg (base)	60	5	..	19.76	20.75	^a Ausran ^a Chem mart Ranitidine ^a GenRx Ranitidine ^a Rani 2 ^a Ranihexal ^a Ranoxyl ^a Terry White Chemists Ranitidine ^a Ulcaid ^a Zantac	SI CH GX AF HX GM TW RA GK
1937Y	Effervescent tablet 150 mg (base)	60	5	^B 2.17	^B 21.93	20.75	Zantac	GK
1977C	Tablet 300 mg (base)	30	5	..	19.76	20.75	^a Ausran ^a Chem mart Ranitidine ^a GenRx Ranitidine ^a Rani 2 ^a Ranihexal ^a Ranoxyl ^a Terry White Chemists Ranitidine ^a Ulcaid ^a Zantac	SI CH GX AF HX GM TW RA GK
8162N	Syrup 150 mg (base) per 10 mL, 300 mL	2	5	^B 2.10	^B 21.89	20.78	Zantac Syrup	GK
RANITIDINE HYDROCHLORIDE								
NOTE: <i>Helicobacter pylori</i> eradication therapy should be considered prior to commencing initial treatment of peptic ulcer with this drug.								
Authority required <i>Adverse effects occurring with all of the base-priced drugs;</i> <i>Drug interactions occurring with all of the base-priced drugs;</i> <i>Drug interactions expected to occur with all of the base-priced drugs;</i> <i>Transfer to a base-priced drug would cause patient confusion resulting in problems with compliance.</i>								
8903N	Effervescent tablet 150 mg (base)	60	5	..	*23.97	24.96	Zantac	GK
8905Q	Syrup 150 mg (base) per 10 mL, 300 mL	2	5	..	*21.89	22.88	Zantac Syrup	GK

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	
• Prostaglandins MISOPROSTOL CAUTION: <i>Misoprostol is a prostaglandin analogue. It should not be used in pregnant women.</i> Authority required <i>Reduction in the incidence of gastrointestinal complications in patients who have a history of peptic ulcer disease and in whom NSAID therapy is essential;</i> <i>Duodenal ulcer (including pyloric and stomal ulcers), proven by current or prior x-ray, endoscopy or surgery. The authority application must state the date and the method by which the ulcer was proven;</i> <i>Gastric ulcer, proven by x-ray, endoscopy or surgery within the previous 2 years. The authority application must state the date and the method by which the ulcer was proven.</i>								
1648R	Tablet 200 micrograms	120	2	..	50.47	30.70	Cytotec	PH
• Proton pump inhibitors ESOMEPRAZOLE MAGNESIUM TRIHYDRATE Restricted benefit <i>Initial treatment of gastric ulcer.</i> NOTE: <i>Helicobacter pylori eradication therapy should be considered.</i>								
8886Q	Tablet (enteric coated), equivalent to 20 mg esomeprazole	30	1	..	37.15	30.70	Nexium	AP
NOTE: <i>No applications for increased maximum quantities and/or repeats will be authorised.</i>								
Restricted benefit <i>Healing of gastro-oesophageal reflux disease.</i> NOTE: <i>No applications for increased maximum quantities and/or repeats will be authorised.</i>								
8601Q	Tablet (enteric coated), equivalent to 40 mg esomeprazole	30	1	..	59.58	30.70	Nexium	AP
Restricted benefit <i>Maintenance of healed gastro-oesophageal reflux disease.</i> NOTE: <i>No applications for increased maximum quantities will be authorised.</i>								
8600P	Tablet (enteric coated), equivalent to 20 mg esomeprazole	30	5	..	37.15	30.70	Nexium	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	
LANSOPRAZOLE								
<u>Restricted benefit</u>								
<i>Initial treatment of peptic ulcer.</i>								
<u>NOTE:</u>								
<i>Helicobacter pylori eradication therapy should be considered.</i>								
2240X	Capsule 30 mg	30	1	..	37.15	30.70	Zoton	WY
<u>NOTE:</u>								
<i>No applications for increased repeats will be authorised.</i>								
<u>Restricted benefit</u>								
<i>Gastro-oesophageal reflux disease;</i>								
<i>Scleroderma oesophagus.</i>								
8198L	Capsule 15 mg	30	5	..	23.45	24.44	Zoton	WY
2241Y	Capsule 30 mg	30	5	..	37.15	30.70	Zoton	WY
<i>See Special Pharmaceutical Benefits for listing for lansoprazole granules for oral suspension.</i>								
OMEPRAZOLE								
<u>Restricted benefit</u>								
<i>Initial treatment of peptic ulcer.</i>								
<u>NOTE:</u>								
<i>Helicobacter pylori eradication therapy should be considered.</i>								
8331L	Tablet 20 mg	30	1	..	34.38	30.70	^a Acimax Tablets	AL
							^a Meprazol	HX
							^a Omepral	PM
							^a Omeprazole	SL
							Winthrop	
				^B 2.75	37.13	30.70	^a Losec Tablets	AP
1326T	Capsule 20 mg	30	1	..	34.38	30.70	Probitor	SZ
<u>NOTE:</u>								
<i>No applications for increased repeats will be authorised.</i>								
<u>Restricted benefit</u>								
<i>Gastro-oesophageal reflux disease;</i>								
<i>Scleroderma oesophagus;</i>								
<i>Zollinger-Ellison syndrome.</i>								
8332M	Tablet 10 mg	30	5	..	25.75	26.74	Losec Tablets	AP
8333N	Tablet 20 mg	30	5	..	34.38	30.70	^a Acimax Tablets	AL
							^a Meprazol	HX
							^a Omepral	PM
							^a Omeprazole	SL
							Winthrop	
				^B 2.75	37.13	30.70	^a Losec Tablets	AP
1327W	Capsule 20 mg	30	5	..	34.38	30.70	Probitor	SZ

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	
PANTOPRAZOLE SODIUM SESQUIHYDRATE								
<u>Restricted benefit</u>								
<i>Initial treatment of peptic ulcer.</i>								
<u>NOTE:</u>								
<i>Helicobacter pylori eradication therapy should be considered.</i>								
8007K	Tablet (enteric coated), equivalent to 40 mg pantoprazole	30	2	..	38.27	30.70	Somac	PH
<u>NOTE:</u>								
<i>No applications for increased repeats will be authorised.</i>								
<u>Restricted benefit</u>								
<i>Gastro-oesophageal reflux disease.</i>								
8399C	Tablet (enteric coated), equivalent to 20 mg pantoprazole	30	5	..	22.89	23.88	Somac	PH
8008L	Tablet (enteric coated), equivalent to 40 mg pantoprazole	30	5	..	38.27	30.70	Somac	PH
<u>Restricted benefit</u>								
<i>Scleroderma oesophagus; Zollinger-Ellison syndrome.</i>								
8008L	Tablet (enteric coated), equivalent to 40 mg pantoprazole	30	5	..	38.27	30.70	Somac	PH
RABEPRAZOLE SODIUM								
<u>Restricted benefit</u>								
<i>Initial treatment of peptic ulcer.</i>								
<u>NOTE:</u>								
<i>Helicobacter pylori eradication therapy should be considered.</i>								
8509W	Tablet 20 mg (enteric coated)	30	2	..	37.05	30.70	Pariet	JC
<u>NOTE:</u>								
<i>No applications for increased repeats will be authorised.</i>								
<u>Restricted benefit</u>								
<i>Gastro-oesophageal reflux disease; Scleroderma oesophagus.</i>								
8507R	Tablet 10 mg (enteric coated)	28	5	..	37.05	30.70	Pariet	JC
8508T	Tablet 20 mg (enteric coated)	30	5	..	37.05	30.70	Pariet	JC

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	
• 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 amoxicillin 500 mg	‡1	..	..	95.26	30.70	Nexium Hp7	AP
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 amoxicillin 500 mg	‡1	..	..	95.49	30.70	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	..	*13.05	14.04	Gaviscon P	RC
SUCRALFATE								
2055E	Tablet equivalent to 1 g anhydrous sucralfate	120	2	.. B2.13	22.71 24.84	23.70 23.70	^a Ulcyte ^a 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	..	13.39	14.38	AP	
Propulsives								
• Propulsives								
DOMPERIDONE								
1347X	Tablet 10 mg	25	..	..	7.52	8.51	Motilium	JC
METOCLOPRAMIDE HYDROCHLORIDE								
1207M	Tablet 10 mg	25	..	.. B2.88	6.70 9.58	7.69 7.69	Pramin Maxolon	AF VT
1205K	Syrup 5 mg per 5 mL, 100 mL	‡1	..	..	7.66	8.65	Maxolon	VT
1206L	Injection 10 mg in 2 mL	10	..	..	11.43	12.42	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 (5HT₃) antagonists								
DOLASETRON MESYLATE								
Restricted benefit								
<i>Management of nausea and vomiting associated with cytotoxic chemotherapy being used to treat malignancy.</i>								
8191D	Tablet 200 mg	2	..	..	48.93	30.70	Anzemet	AV
8192E	I.V. injection 100 mg in 5 mL	1	..	..	27.03	28.02	Anzemet	AV
GRANISETRON HYDROCHLORIDE								
Restricted benefit								
<i>Management of nausea and vomiting associated with cytotoxic chemotherapy being used to treat malignancy.</i>								
8728J	Tablet 2 mg (base)	2	..	..	*57.71	30.70	Kytril	MX
8729K	Concentrated injection 3 mg (base) in 3 mL	1	..	..	35.21	30.70	Kytril	MX
Authority required								
<i>Management of nausea and vomiting associated with radiotherapy being used to treat malignancy.</i>								
8873B	Tablet 2 mg (base)	5	1	..	136.57	30.70	Kytril	MX
8730L	Concentrated injection 3 mg (base) in 3 mL	1	..	..	35.21	30.70	Kytril	MX
ONDANSETRON								
Restricted benefit								
<i>Management of nausea and vomiting associated with cytotoxic chemotherapy being used to treat malignancy.</i>								
8224W	Tablet 4 mg	4	..	..	38.71	30.70	^a Ondansetron- RL	RE
							^a Ondaz	HX
							^a Onsetron 4	AW
				^B 0.68	39.39	30.70	^a Zofran	GK
8225X	Tablet 8 mg	4	..	..	57.72	30.70	^a Ondansetron- RL	RE
							^a Ondaz	HX
				^B 0.69	58.41	30.70	^a Onsetron 8	AW
							^a Zofran	GK
8410P	Wafer 4 mg	4	..	..	38.71	30.70	^a Ondansetron- RL Zydys	RE
							^a Ondaz Zydys	HX
				^B 0.68	39.39	30.70	^a Zofran Zydys	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	
ONDANSETRON—cont.								
8411Q	Wafer 8 mg	4	..	..	57.72	30.70	^a Ondansetron- RL Zydis	RE
							^a Ondaz Zydis	HX
				^B 0.69	58.41	30.70	^a Zofran Zydis	GK
8226Y	I.V. injection 4 mg in 2 mL	1	..	..	24.07	25.06	^a Ondansetron- RL	RE
							^a Ondaz	HX
				^B 0.69	24.76	25.06	^a Zofran	GK
8227B	I.V. injection 8 mg in 4 mL	1	..	..	35.21	30.70	^a Ondansetron- RL	RE
							^a Ondaz	HX
				^B 0.67	35.88	30.70	^a Zofran	GK
Authority required								
<i>Management of nausea and vomiting associated with radiotherapy being used to treat malignancy.</i>								
1594X	Tablet 4 mg	10	1	..	89.04	30.70	^a Ondansetron- RL	RE
							^a Ondaz	HX
							^a Onsetron 4	AW
				^B 0.69	89.73	30.70	^a Zofran	GK
1595Y	Tablet 8 mg	10	1	..	136.57	30.70	^a Ondansetron- RL	RE
							^a Ondaz	HX
							^a Onsetron 8	AW
				^B 0.68	137.25	30.70	^a Zofran	GK
8412R	Wafer 4 mg	10	1	..	89.04	30.70	^a Ondansetron- RL Zydis	RE
							^a Ondaz Zydis	HX
				^B 0.69	89.73	30.70	^a Zofran Zydis	GK
8413T	Wafer 8 mg	10	1	..	136.57	30.70	^a Ondansetron- RL Zydis	RE
							^a Ondaz Zydis	HX
				^B 0.68	137.25	30.70	^a Zofran Zydis	GK
8233H	Syrup 4 mg per 5 mL, 50 mL	‡1	1	..	89.04	30.70	Zofran syrup 50 mL	GK
1596B	I.V. injection 4 mg in 2 mL	1	..	..	24.07	25.06	^a Ondansetron- RL	RE
							^a Ondaz	HX
				^B 0.69	24.76	25.06	^a Zofran	GK
1597C	I.V. injection 8 mg in 4 mL	1	..	..	35.21	30.70	^a Ondansetron- RL	RE
							^a Ondaz	HX
				^B 0.67	35.88	30.70	^a Zofran	GK

Code	Name, Restriction, Manner of administration and form	Max. No. of Qty Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Proprietary Name and Manufacturer	
TROPISETRON HYDROCHLORIDE							
<u>Restricted benefit</u>							
Management of nausea and vomiting associated with cytotoxic chemotherapy being used to treat malignancy.							
2745L	Capsule 5 mg (base)	2	..	..	48.93	30.70	Navoban NV
2746M	I.V. injection 5 mg (base) in 5 mL	1	..	..	27.03	28.02	Navoban NV
• Other antiemetics							
<u>APREPITANT</u>							
<u>NOTE:</u>							
Aprepitant is not PBS-subsidised for nausea and vomiting associated with radiotherapy being used to treat malignancy.							
<u>Authority required</u>							
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.							
<u>NOTE:</u>							
No applications for increased maximum quantities and/or repeats will be authorised.							
8808N	Pack containing 1 capsule 125 mg and 2 capsules 80 mg	‡1	..	..	147.07	30.70	Emend MK
PROCHLORPERAZINE							
<u>CAUTION:</u>							
Prochlorperazine may be associated with parkinsonism and tardive dyskinesia and should be used for short-term treatment only.							
2893G	Tablet 5 mg	25	..	.. B2.09	7.66 9.75	8.65 ^a Stemzine 8.65 ^a Stemetil	HP AV
2369Q	Injection 12.5 mg in 1 mL	10	..	..	14.26	15.25	Stemetil AV
2894H	Suppositories 5 mg, 5	‡1	2	..	15.42	16.41	Stemetil AV
2895J	Suppositories 25 mg, 5	‡1	2	..	16.92	17.91	Stemetil AV
<u>NOTE:</u>							
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.							

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	
BILE AND LIVER THERAPY								
	Bile therapy							
	• Bile acid preparations							
	URSODEOXYCHOLIC ACID							
	<u>Authority required</u>							
	<i>Primary biliary cirrhosis.</i>							
	<u>NOTE:</u>							
	<i>Not for use in the treatment of sclerosing cholangitis or cholelithiasis.</i>							
8448P	Capsule 250 mg	100	2	..	175.46	30.70	Ursofalk	OA
LAXATIVES								
	Laxatives							
	• Contact laxatives							
	BISACODYL							
	<u>Restricted benefit</u>							
	<i>Paraplegic and quadriplegic patients and others with severe neurogenic impairment of bowel function;</i>							
	<i>Patients who are receiving long-term nursing care on account of age, infirmity or other condition in hospitals, nursing homes or residential facilities;</i>							
	<i>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;</i>							
	<i>Patients receiving palliative care;</i>							
	<i>Terminal malignant neoplasia;</i>							
	<i>Anorectal congenital abnormalities;</i>							
	<i>Megacolon.</i>							
1259G	Tablet 5 mg	200	2	..	13.14	14.13	Bisalax Lax-Tab	AS AE
1260H	Suppositories 10 mg, 10	3	5	..	*20.24	21.23 ^a	Petrus Bisacodyl Suppositories	PP
				^B 1.11	*21.35	21.23 ^a	Durolax	BY
1258F	Suppositories 10 mg, 12	3	4	..	*17.45	18.44	Fleet Laxative Suppositories Petrus Bisacodyl Suppositories	FL PP
	DOCUSATE SODIUM with BISACODYL							
	<u>Restricted benefit</u>							
	<i>Paraplegic and quadriplegic patients and others with severe neurogenic impairment of bowel function;</i>							
	<i>Patients who are receiving long-term nursing care on account of age, infirmity or other condition in hospitals, nursing homes or residential facilities;</i>							
	<i>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;</i>							
	<i>Patients receiving palliative care;</i>							
	<i>Terminal malignant neoplasia;</i>							
	<i>Anorectal congenital abnormalities;</i>							
	<i>Megacolon.</i>							
1125F	Suppositories 100 mg-10 mg, 5	6	5	..	*20.27	21.26	Coloxyl	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	
• Bulk producers STERCULIA with FRANGULA BARK Restricted benefit <i>Paraplegic and quadriplegic patients and others with severe neurogenic impairment of bowel function;</i> <i>Patients who are receiving long-term nursing care on account of age, infirmity or other condition in hospitals, nursing homes or residential facilities;</i> <i>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;</i> <i>Patients receiving palliative care;</i> <i>Terminal malignant neoplasia;</i> <i>Anorectal congenital abnormalities;</i> <i>Megacolon.</i>								
1104D	Granules 620 mg-80 mg per g (62%-8%), 500 g	‡1	1	..	22.87	23.86	Normacol Plus	NE
• Osmotically acting laxatives LACTULOSE Restricted benefit <i>Hepatic coma or precoma (chronic porto-systemic encephalopathy);</i> <i>Constipation in patients with malignant neoplasia.</i>								
3064G	Mixture 3.34 g per 5 mL, 500 mL	‡1	5	..	15.11	16.10	^a Actilax ^a Genlac ^a GenRx Lactulose ^a Lac-Dol ^a Lactocur ^a Duphalac	AF AW GX GM HX SM
				B2.13	17.24	16.10		
MACROGOL 3350 Restricted benefit <i>Constipation in patients with malignant neoplasia.</i>								
8612G	Sachets containing powder for solution 13.125 g with electrolytes, 30	‡1	5	..	22.72	23.71	Movicol	NE
• Enemas BISACODYL Restricted benefit <i>Paraplegic and quadriplegic patients and others with severe neurogenic impairment of bowel function;</i> <i>Patients who are receiving long-term nursing care on account of age, infirmity or other condition in hospitals, nursing homes or residential facilities;</i> <i>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;</i> <i>Patients receiving palliative care;</i> <i>Terminal malignant neoplasia;</i> <i>Anorectal congenital abnormalities;</i> <i>Megacolon.</i>								
1263L	Enemas 10 mg in 5 mL, 25	‡1	2	..	35.17	30.70	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								
<u>Restricted benefit</u>								
<i>Paraplegic and quadriplegic patients and others with severe neurogenic impairment of bowel function;</i>								
<i>Patients who are receiving long-term nursing care on account of age, infirmity or other condition in hospitals, nursing homes or residential facilities;</i>								
<i>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;</i>								
<i>Patients receiving palliative care;</i>								
<i>Terminal malignant neoplasia;</i>								
<i>Anorectal congenital abnormalities;</i>								
<i>Megacolon.</i>								
2091C	Enemas 3.125 g-450 mg-45 mg in 5 mL, 12	2	2	..	*33.99	30.70	Microlax	PH
• Other laxatives								
GLYCEROL								
<u>Restricted benefit</u>								
<i>Paraplegic and quadriplegic patients and others with severe neurogenic impairment of bowel function;</i>								
<i>Patients who are receiving long-term nursing care on account of age, infirmity or other condition in hospitals, nursing homes or residential facilities;</i>								
<i>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;</i>								
<i>Patients receiving palliative care;</i>								
<i>Terminal malignant neoplasia;</i>								
<i>Anorectal congenital abnormalities;</i>								
<i>Megacolon.</i>								
2555L	Suppositories 700 mg (for infants), 12	3	5	..	*14.90	15.89	PP	
2556M	Suppositories 1.4 g (for children), 12	3	5	..	*15.23	16.22	PP	
2557N	Suppositories 2.8 g (for adults), 12	3	5	..	*15.56	16.55	PP	
ANTIDIARRHEALS, INTESTINAL ANTIINFLAMMATORY/ ANTIINFECTIVE AGENTS								
Intestinal antiinfectives								
• Antibiotics								
NEOMYCIN SULFATE								
2325J	Tablet 500 mg	25	1	..	13.40	14.39	Neosulf	AF
NYSTATIN								
1696G	Tablet 500,000 units	50	..	..	16.21	17.20	Nilstat	SI
1699K	Capsule 500,000 units	50	..	..	16.21	17.20	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								
<i>Antibiotic associated pseudomembranous colitis due to Clostridium difficile which is unresponsive to metronidazole;</i>								
<i>Antibiotic associated pseudomembranous colitis due to Clostridium difficile where there is intolerance to metronidazole.</i>								
NOTE:								
<i>Metronidazole has similar efficacy to vancomycin but may have less selective pressure to vancomycin resistant enterococci and is therefore the preferred treatment.</i>								
3113W	Capsule 125 mg (125,000 i.u.) vancomycin activity	40	..	..	*248.47	30.70	Vancocin	LY
3114X	Capsule 250 mg (250,000 i.u.) vancomycin activity	40	..	..	*473.81	30.70	Vancocin	LY
Electrolytes with carbohydrates								
• Oral rehydration salt formulations								
ELECTROLYTE REPLACEMENT (ORAL)								
3196F	Sachets containing powder for oral solution 4.9 g, 10	‡1	..	..	11.89	12.88	^a Chem mart Oral Rehydration Salts	CH
							^a O.R.S.	AS
							^a Repalyte New Formulation	AV
							^a restore O.R.S.	GM
							^a Terry White Chemists Oral Rehydration Salts	TW
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	..	..	7.03	8.02	^a Lofenoxal	KR
				^B 1.78	8.81	8.02	^a Lomotil	PH
LOPERAMIDE HYDROCHLORIDE								
1571Q	Capsule 2 mg	12	..	..	7.03	8.02	^a Gastro-Stop Loperamide	AS
				^B 0.90	7.93	8.02	^a Imodium	JC

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	..	*35.49	30.70	Colifoam	GC
[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	..	*132.71	30.70	Predsol	SI
PREDNISOLONE SODIUM PHOSPHATE								
Restricted benefit								
Proctitis;								
Ulcerative colitis.								
2554K	Suppositories equivalent to 5 mg prednisolone, 10	3	3	..	*31.19	30.70	Predsol	SI
• Aminosalicyclic acid and similar agents								
BALSALAZIDE SODIUM								
Authority required								
Ulcerative colitis where hypersensitivity to sulfonamides exists;								
Ulcerative colitis where intolerance to sulfasalazine exists.								
NOTE:								
Not for the treatment of Crohn's disease.								
8845M	Capsule 750 mg	180	5	..	123.58	30.70	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	..	..	126.45	30.70	Pentasa	FP
NOTE:								
No applications for increased maximum quantities and/or repeats will be authorised.								
Authority required								
Ulcerative colitis where hypersensitivity to sulfonamides exists;								
Ulcerative colitis where intolerance to sulfasalazine exists;								
Crohn's disease where hypersensitivity to sulfonamides exists;								
Crohn's disease where intolerance to sulfasalazine exists.								
1611T	Tablet 250 mg	100	5	..	72.06	30.70	Mesasal	GK
8731M	Tablet 500 mg (enteric coated)	100	5	..	135.25	30.70	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	
MESALAZINE—cont.								
Authority required								
<i>Ulcerative colitis where hypersensitivity to sulfonamides exists;</i>								
<i>Ulcerative colitis where intolerance to sulfasalazine exists.</i>								
NOTE:								
<i>Not for the treatment of Crohn's disease.</i>								
8598M	Sachet containing granules, 500 mg per sachet	100	5	..	139.00	30.70	Salofalk	OA
8599N	Sachet containing granules, 1 g per sachet	100	2	..	251.90	30.70	Salofalk	OA
Authority required								
<i>Acute episode of mild to moderate ulcerative colitis.</i>								
NOTE:								
<i>Not for the treatment of Crohn's disease.</i>								
8753Q	Enemas 1 g in 100 mL, 7	4	..	..	*334.95	30.70	Pentasa	FP
8616L	Enemas 2 g in 60 mL, 7	4	..	..	*334.95	30.70	Salofalk	OA
8617M	Enemas 4 g in 60 mL, 7	4	..	..	*444.63	30.70	Salofalk	OA
8768L	Rectal foam 1 g per applicatorful, 14 applications, aerosol 80 g	4	..	..	*334.95	30.70	Salofalk	OA
NOTE:								
<i>No applications for increased maximum quantities and/or repeats will be authorised.</i>								
OLSALAZINE SODIUM								
Authority required								
<i>Ulcerative colitis where hypersensitivity to sulfonamides exists;</i>								
<i>Ulcerative colitis where intolerance to sulfasalazine exists.</i>								
NOTE:								
<i>Not for the treatment of Crohn's disease.</i>								
1728Y	Capsule 250 mg	100	5	..	60.14	30.70	Dipentum	UC
8086N	Tablet 500 mg	100	5	..	102.02	30.70	Dipentum	UC
SULFASALAZINE								
2093E	Tablet 500 mg	200	5	..	*52.09	30.70	Salazopyrin	PH
2096H	Tablet 500 mg (enteric coated)	200	5	..	*56.81	30.70	^a Pyralin EN	KR
				^B 1.60	*58.41	30.70	^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	..	*117.95	30.70	Creon 5000	SM
8020D	Capsule (containing enteric coated minimicrospheres) providing not less than 10,000 BP units of lipase activity	500	10	..	*169.50	30.70	Creon	SM
8021E	Capsule (containing enteric coated minimicrospheres) providing not less than 25,000 BP units of lipase activity	200	10	..	*136.63	30.70	Creon Forte	SM
PANCRELIPASE								
2495H	Capsule (containing enteric coated microspheres) providing not less than 10,000 BP units of lipase activity	500	10	..	*172.31	30.70	Cotazym-S Forte	OR
8366H	Capsule (containing enteric coated microtablets) providing not less than 25,000 BP units of lipase activity	200	10	..	*136.63	30.70	Panzytrat 25000	TM
DRUGS USED IN DIABETES								
Insulins and analogues								
• Insulins and analogues, fast-acting								
INSULIN ASPART								
8571D	Injection (human analogue) 100 units per mL, 10 mL	5	2	..	*158.00	30.70	NovoRapid	NO
8435Y	Injections (human analogue) 100 units per mL, 3 mL, 5	5	1	..	*262.95	30.70	NovoRapid FlexPen NovoRapid Penfill 3 mL	NF NO
INSULIN LISPRO								
8084L	Injection (human analogue) 100 units per mL, 10 mL	5	2	..	*158.00	30.70	Humalog	LY
8212F	Injections (human analogue) 100 units per mL, 3 mL, 5	5	1	..	*262.95	30.70	Humalog	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	
INSULIN NEUTRAL								
1713E	Injection (bovine) 100 units per mL, 10 mL	5	2	..	*132.55	30.70	Hypurin Neutral	AS
1531N	Injection (human) 100 units per mL, 10 mL	5	2	..	*132.55	30.70	Actrapid Humulin R	NO LY
1762R	Injections (human) 100 units per mL, 3 mL, 5	5	1	..	*223.05	30.70	Actrapid Penfill 3 mL Humulin R	NO LY
• Insulins and analogues, intermediate-acting								
INSULIN ISOPHANE (N.P.H.)								
1711C	Injection (bovine) 100 units per mL, 10 mL	5	2	..	*132.55	30.70	Hypurin Isophane	AS
1533Q	Injection (human) 100 units per mL, 10 mL	5	2	..	*132.55	30.70	Humulin NPH Protaphane	LY NO
1761Q	Injections (human) 100 units per mL, 3 mL, 5	5	1	..	*223.05	30.70	Humulin NPH Protaphane InnoLet Protaphane NovoLet 3 mL Protaphane Penfill 3 mL	LY NI NL NO
• Insulins and analogues, 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	..	*262.95	30.70	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	..	*262.95	30.70	Humalog Mix25	LY
8874C	Injections (human analogue) 100 units (50 units-50 units) per mL, 3 mL, 5	5	1	..	*262.95	30.70	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	..	*132.55	30.70	Humulin 30/70 Mixtard 30/70	LY NO
1425B	Injection (human) 100 units (50 units-50 units) per mL, 10 mL	5	2	..	*132.55	30.70	Mixtard 50/50	NO
8006J	Injections (human) 100 units (20 units-80 units) per mL, 3 mL, 5	5	1	..	*223.05	30.70	Mixtard 20/80 Penfill 3 mL	NO

continued 

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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	
METFORMIN HYDROCHLORIDE—cont.								
1801T	Tablet 850 mg	60	5	..	13.65	14.64	^a Chem mart Metformin	CH
							^a Diaformin 850	AF
							^a Formet 850	AW
							^a GenRx Metformin	GX
							^a Glucohexal	HX
							^a Glucomet 850 mg	GM
							^a Metforbell	BF
							^a Terry White Chemists Metformin	TW
							^a GN	
				^B 1.41	15.06	14.64	^a Glucophage	MQ
				^B 2.09	15.74	14.64	^a Diabex 850	AL
8607B	Tablet 1 g	90	5	..	19.96	20.95	^a Diaformin 1000	AF
							^a Formet 1000	AW
				^B 1.80	21.76	20.95	^a Diabex 1000	AL
• Sulfonamides, urea derivatives								
GLIBENCLAMIDE								
CAUTION: Sulfonylureas may cause hypoglycaemia, particularly in the elderly.								
2939Q	Tablet 5 mg	100	5	..	10.30	11.29	^a Glimel	AF
				^B 1.19	11.49	11.29	^a Daonil	AV
GLICLAZIDE								
CAUTION: Sulfonylureas may cause hypoglycaemia, particularly in the elderly.								
8535F	Tablet 30 mg (modified release)	100	5	..	14.47	15.46	Diamicron MR	SE
2449X	Tablet 80 mg	100	5	..	14.20	15.19	^a Chem mart Gliclazide	CH
							^a GenRx Gliclazide	GX
							^a Glyade	AF
							^a Mellihexal	HX
							^a Nidem	AW
							^a Terry White Chemists Gliclazide	TW
				^B 2.60	16.80	15.19	^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	..	8.56	9.55	^a Aylide 1 AF ^a Diapride 1 AW ^a Dimirel ML ^a Glimepiride SZ Sandoz
				^B 2.41	10.97	9.55	^a Amaryl AV
8451T	Tablet 2 mg	30	5	..	11.68	12.67	^a Aylide 2 AF ^a Diapride 2 AW ^a Dimirel ML ^a Glimepiride SZ Sandoz
				^B 2.41	14.09	12.67	^a Amaryl AV
8533D	Tablet 3 mg	30	5	..	13.53	14.52	^a Aylide 3 AF ^a Diapride 3 AW ^a Dimirel ML ^a Glimepiride SZ Sandoz
				^B 2.43	15.96	14.52	^a Amaryl AV
8452W	Tablet 4 mg	30	5	..	15.40	16.39	^a Aylide 4 AF ^a Diapride 4 AW ^a Dimirel ML ^a Glimepiride SZ Sandoz
				^B 2.42	17.82	16.39	^a Amaryl AV
GLIPIZIDE							
CAUTION: Sulfonylureas may cause hypoglycaemia, particularly in the elderly.							
2440K	Tablet 5 mg	100	5	..	10.40	11.39	^a Melizide AF
				^B 3.97	14.37	11.39	^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	..	13.50	14.49	Glucovance 250mg/1.25mg AL
8810Q	Tablet 500 mg-2.5 mg	90	5	..	16.28	17.27	Glucovance 500mg/2.5mg AL
8811R	Tablet 500 mg-5 mg	90	5	..	17.44	18.43	Glucovance 500mg/5mg AL

ALIMENTARY TRACT AND METABOLISM —cont.

Code	Name, Restriction, Manner of administration and form	Max. No. of Qty Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Proprietary Name and Manufacturer
ROSIGLITAZONE MALEATE with METFORMIN HYDROCHLORIDE						
NOTE: <i>Rosiglitazone with metformin fixed dose combination tablet is not PBS-subsidised when used in combination with insulin.</i>						
Authority required <i>Patients requiring dual therapy of rosiglitazone and metformin</i> <i>Initiation of therapy in type 2 diabetes mellitus patients who have an HbA1c greater than 7% and in whom a combination with a sulfonylurea is contraindicated or not tolerated.</i> <i>The date of the HbA1c measurement, which must be no greater than 4 months old at the time of application, must be provided;</i> <i>Initiation of therapy in type 2 diabetes mellitus patients who are:</i> <i>(a) stabilised on PBS-subsidised rosiglitazone and metformin; or</i> <i>(b) stabilised on PBS-subsidised pioglitazone and metformin;</i> <i>Continuation of therapy in type 2 diabetes mellitus patients where the patient has previously been issued with an authority prescription for rosiglitazone maleate and metformin fixed dose combination tablet.</i>						
NOTE: <i>Blood glucose monitoring as an alternative assessment to HbA1c levels will be accepted in the following circumstances:</i> <i>(a) clinical conditions with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or</i> <i>(b) red cell transfusion within the previous 3 months.</i> <i>Patients 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 date of measurement of the most recent blood glucose level, which must be no greater than 4 months old at the time of application, must be provided.</i>						
Authority required <i>Triple combination therapy with a sulfonylurea</i> <i>Initiation of therapy, in combination with a sulfonylurea, in type 2 diabetes mellitus patients who have an HbA1c greater than 7% despite maximally tolerated doses of metformin and a sulfonylurea.</i> <i>The date of the HbA1c measurement, which must be no greater than 4 months old at the time of application, must be provided;</i> <i>Initiation of therapy, in combination with a sulfonylurea, in type 2 diabetes mellitus patients who are:</i> <i>(a) stabilised on PBS-subsidised rosiglitazone and metformin; or</i> <i>(b) stabilised on PBS-subsidised pioglitazone and metformin;</i> <i>Continuation of therapy, in combination with a sulfonylurea, in type 2 diabetes mellitus patients where the patient has previously been issued with an authority prescription for rosiglitazone maleate and metformin fixed dose combination tablet.</i>						
NOTE: <i>Blood glucose monitoring as an alternative assessment to HbA1c levels will be accepted in the following circumstances:</i> <i>(a) clinical conditions with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or</i> <i>(b) red cell transfusion within the previous 3 months.</i> <i>Patients 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 date of measurement of the most recent blood glucose level, which must be no greater than 4 months old at the time of application, must be provided.</i>						
9059T	Tablet 2 mg (base)-500 mg	56	5	..	65.01 30.70	Avandamet 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	
ROSIGLITAZONE MALEATE with METFORMIN HYDROCHLORIDE—cont.								
9060W	Tablet 2 mg (base)-1 g	56	5	..	69.47	30.70	Avandamet	GK
9061X	Tablet 4 mg (base)-500 mg	56	5	..	94.68	30.70	Avandamet	GK
9062Y	Tablet 4 mg (base)-1 g	56	5	..	99.13	30.70	Avandamet	GK
• Alpha glucosidase inhibitors								
ACARBOSE								
8188Y	Tablet 50 mg	90	5	..	28.57	29.56	Glucobay 50	BN
8189B	Tablet 100 mg	90	5	..	38.15	30.70	Glucobay 100	BN

• **Thiazolidinediones****PIOGLITAZONE HYDROCHLORIDE****Authority required**

Dual oral combination therapy with metformin or a sulfonylurea

Initiation of therapy, in combination with either metformin or a sulfonylurea, in type 2 diabetes mellitus patients who have an HbA1c greater than 7% and in whom a combination of metformin and a sulfonylurea is contraindicated or not tolerated.

The date of the HbA1c measurement, which must be no greater than 4 months old at the time of application, must be provided;

Continuation of therapy, in combination with either metformin or a sulfonylurea, in type 2 diabetes mellitus patients where the patient has previously been issued with an authority prescription for pioglitazone hydrochloride or rosiglitazone maleate.

NOTE:

Pioglitazone hydrochloride is not PBS-subsidised for use in combination with metformin and a sulfonylurea (triple oral therapy).

Pioglitazone hydrochloride is not PBS-subsidised as monotherapy.

Blood glucose monitoring as an alternative assessment to HbA1c levels will be accepted 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.

Patients 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 date of measurement of the most recent blood glucose level, which must be no greater than 4 months old at the time of application, must be provided.

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	
PIOGLITAZONE HYDROCHLORIDE—cont.								
Authority required								
<i>Combination therapy with insulin</i>								
<i>Initiation of therapy, in combination with insulin, in type 2 diabetes mellitus patients who have an HbA1c greater than 7% despite treatment with insulin and oral anti-diabetic agents, or insulin alone where metformin is contraindicated.</i>								
<i>The date of the HbA1c measurement, which must be no greater than 4 months old at the time of application, must be provided;</i>								
<i>Continuation of therapy, in combination with insulin, in type 2 diabetes mellitus patients where the patient has previously been issued with an authority prescription for pioglitazone hydrochloride or rosiglitazone maleate.</i>								
NOTE:								
<i>Pioglitazone hydrochloride is not PBS-subsidised as monotherapy.</i>								
<i>Blood glucose monitoring as an alternative assessment to HbA1c levels will be accepted in the following circumstances:</i>								
<i>(a) clinical conditions with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or</i>								
<i>(b) red cell transfusion within the previous 3 months.</i>								
<i>Patients 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 date of measurement of the most recent blood glucose level, which must be no greater than 4 months old at the time of application, must be provided.</i>								
8694N	Tablet 15 mg (base)	28	5	..	60.25	30.70	Actos	LY
8695P	Tablet 30 mg (base)	28	5	..	89.92	30.70	Actos	LY
8696Q	Tablet 45 mg (base)	28	5	..	115.37	30.70	Actos	LY

ROSIGLITAZONE MALEATE**Authority required***Dual oral combination therapy with metformin or a sulfonylurea**Initiation of therapy, in combination with either metformin or a sulfonylurea, in type 2 diabetes mellitus patients who have an HbA1c greater than 7% and in whom a combination of metformin and a sulfonylurea is contraindicated or not tolerated.**The date of the HbA1c measurement, which must be no greater than 4 months old at the time of application, must be provided;**Continuation of therapy, in combination with either metformin or a sulfonylurea, in type 2 diabetes mellitus patients where the patient has previously been issued with an authority prescription for rosiglitazone maleate or pioglitazone hydrochloride.***NOTE:***Rosiglitazone maleate is not PBS-subsidised as monotherapy.**Blood glucose monitoring as an alternative assessment to HbA1c levels will be accepted 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.**Patients 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 date of measurement of the most recent blood glucose level, which must be no greater than 4 months old at the time of application, must be provided.*

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—cont.							
Authority required							
<i>Triple oral combination therapy with metformin and a sulfonylurea</i>							
<i>Initiation of therapy, in combination with metformin and a sulfonylurea, in type 2 diabetes mellitus patients who have an HbA1c greater than 7% despite maximally tolerated doses of metformin and a sulfonylurea.</i>							
<i>The date of the HbA1c measurement, which must be no greater than 4 months old at the time of application, must be provided;</i>							
<i>Continuation of therapy, in combination with metformin and a sulfonylurea, in type 2 diabetes mellitus patients where the patient has previously been issued with an authority prescription for rosiglitazone maleate or pioglitazone hydrochloride.</i>							
NOTE:							
<i>Rosiglitazone maleate is not PBS-subsidised as monotherapy.</i>							
<i>Blood glucose monitoring as an alternative assessment to HbA1c levels will be accepted in the following circumstances:</i>							
<i>(a) clinical conditions with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or</i>							
<i>(b) red cell transfusion within the previous 3 months.</i>							
<i>Patients 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 date of measurement of the most recent blood glucose level, which must be no greater than 4 months old at the time of application, must be provided.</i>							
Authority required							
<i>Combination therapy with insulin</i>							
<i>Initiation of therapy, in combination with insulin, in type 2 diabetes mellitus patients who have an HbA1c greater than 7% despite treatment with insulin and oral anti-diabetic agents, or insulin alone where metformin is contraindicated.</i>							
<i>The date of the HbA1c measurement, which must be no greater than 4 months old at the time of application, must be provided;</i>							
<i>Continuation of therapy, in combination with insulin, in type 2 diabetes mellitus patients where the patient has previously been issued with an authority prescription for rosiglitazone maleate or pioglitazone hydrochloride.</i>							
NOTE:							
<i>Rosiglitazone maleate is not PBS-subsidised as monotherapy.</i>							
<i>Blood glucose monitoring as an alternative assessment to HbA1c levels will be accepted in the following circumstances:</i>							
<i>(a) clinical conditions with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or</i>							
<i>(b) red cell transfusion within the previous 3 months.</i>							
<i>Patients 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 date of measurement of the most recent blood glucose level, which must be no greater than 4 months old at the time of application, must be provided.</i>							
8689H	Tablet 4 mg (base)	28	5	..	60.25	30.70	Avandia GK
8690J	Tablet 8 mg (base)	28	5	..	89.92	30.70	Avandia GK

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						
	<i>Hypocalcaemia due to renal disease;</i>						
	<i>Hypoparathyroidism;</i>						
	<i>Hypophosphataemic rickets;</i>						
	<i>Vitamin D-resistant rickets;</i>						
	<i>Initial 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 included in the authority application.</i>						
	<i>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;</i>						
	<i>Continuing treatment for established osteoporosis in patients with fracture due to minimal trauma, where the patient has previously been issued with an authority prescription for this drug.</i>						
2502Q	Capsule 0.25 microgram	100	3	..	52.56	30.70	^a Calcitriol-DP GM ^a Citrihexal HX ^a GenRx GX Calcitriol ^a Kosteo AW ^a Rocaltrol RO ^a Sical AF ^a Sitriol AL
	Vitamin B₁, plain and in combination with vitamin B₆ and vitamin B₁₂						
	• Vitamin B₁, plain						
	THIAMINE HYDROCHLORIDE						
	Authority required						
	<i>Prophylaxis of thiamine deficiency in an Aboriginal or a Torres Strait Islander person.</i>						
1070H	Tablet 100 mg	100	2	..	9.36	10.35	Betamin AV
MINERAL SUPPLEMENTS							
	Calcium						
	• Calcium						
	CALCIUM						
	Authority required						
	<i>Hyperphosphataemia associated with chronic renal failure.</i>						
8560M	Tablet 250 mg (as citrate)	120	1	..	12.70	13.69	Citracal KY
3116B	Tablet (chewable) 500 mg (as carbonate)	120	1	..	*13.59	14.58	Cal-Sup MM
3117C	Tablet 600 mg (as carbonate)	120	1	..	12.70	13.69	Caltrate WT

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
Potassium							
• Potassium							
POTASSIUM CHLORIDE							
2642C	Tablet 600 mg (sustained release)	200	1	..	*10.93	11.92	^a Duro-K NM
				..	10.93	11.92	Span-K AS
				£2.78	*13.71	11.92	^a Slow-K NV
3012M	Effervescent tablet 14 mmol K ⁺ and 8 mmol Cl ⁻	60	1	..	11.06	12.05	^a K-Sol LN
				£2.54	13.60	12.05	^a Chlorvescent AS

ANABOLIC AGENTS FOR SYSTEMIC USE

Anabolic steroids• **Androstan derivatives****OXANDROLONE****Authority required**

Promotion of growth in girls with Turner syndrome (date of confirmation of diagnosis to be stated);

Promotion of growth in boys of short stature with delayed bone maturation (date of confirmation of diagnosis to be stated).

NOTE:

Oxandrolone should not be prescribed for promotion of growth in boys aged less than 11 years or boys who do not have a bone age of at least 9 years.

2545Y	Tablet 2.5 mg	100	1	..	979.23	30.70	Oxandrin	CS

• **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	..	19.29	20.28	Deca-Durabolin	OR

BLOOD AND BLOOD FORMING ORGANS

Code	Name, Restriction, Manner of 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	..	7.89	8.88	Coumadin Marevan	SI FM
2209G	Tablet 2 mg	50	2	..	8.08	9.07	Coumadin	SI
2844Q	Tablet 3 mg	50	2	..	8.30	9.29	Marevan	FM
2211J	Tablet 5 mg	50	2	..	8.77	9.76	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	..	54.31	30.70	Fragmin	PH
2816F	Injection 5,000 units (anti-Xa) in 0.2 mL single dose pre-filled syringe	10	1	..	56.38	30.70	Fragmin	PH
8271H	Injection 7,500 units (anti-Xa) in 0.75 mL single dose pre-filled syringe	10	1	..	82.38	30.70	Fragmin	PH
8269F	Injection 10,000 units (anti-Xa) in 1 mL single dose pre-filled syringe	10	1	..	108.11	30.70	Fragmin	PH
DALTEPARIN SODIUM								
(Low Molecular Weight Heparin Sodium—porcine mucous)								
<u>Restricted benefit</u>								
<u>Haemodialysis.</u>								
8641T	Injection 2,500 units (anti-Xa) in 0.2 mL single dose pre- filled syringe	20	3	..	*103.47	30.70	Fragmin	PH
8642W	Injection 5,000 units (anti-Xa) in 0.2 mL single dose pre- filled syringe	20	3	..	*107.61	30.70	Fragmin	PH
8643X	Injection 7,500 units (anti-Xa) in 0.75 mL single dose pre- filled syringe	20	3	..	*159.61	30.70	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	..	54.31	30.70	Clexane	AV
8510X	Injection 40 mg (4,000 i.u. anti-Xa) in 0.4 mL pre-filled syringe	10	1	..	56.38	30.70	Clexane	AV
8262W	Injection 60 mg (6,000 i.u. anti-Xa) in 0.6 mL pre-filled syringe	10	1	..	78.41	30.70	Clexane	AV
8263X	Injection 80 mg (8,000 i.u. anti-Xa) in 0.8 mL pre-filled syringe	10	1	..	89.43	30.70	Clexane	AV
8264Y	Injection 100 mg (10,000 i.u. anti-Xa) in 1 mL pre-filled syringe	10	1	..	107.81	30.70	Clexane	AV
<u>ENOXAPARIN SODIUM</u>								
<u>Restricted benefit</u>								
<u>Haemodialysis.</u>								
8716R	Injection 20 mg (2,000 i.u. anti-Xa) in 0.2 mL pre-filled syringe	20	3	..	*103.47	30.70	Clexane	AV
8639Q	Injection 40 mg (4,000 i.u. anti-Xa) in 0.4 mL pre-filled syringe	20	3	..	*107.61	30.70	Clexane	AV
8640R	Injection 60 mg (6,000 i.u. anti-Xa) in 0.6 mL pre-filled syringe	20	3	..	*151.67	30.70	Clexane	AV
HEPARIN SODIUM								
1466E	Injection 5,000 units in 0.2 mL	5	5	..	11.48	12.47	MX	
1463B	Injection (preservative-free) 5,000 units in 5 mL	50	5	..	51.36	30.70	PU	
1076P	Injection 35,000 units in 35 mL	12	5	..	*144.23	30.70	MX	
• Platelet aggregation inhibitors excl. heparin								
<u>ABCIXIMAB</u>								
<u>Authority required</u>								
<i>Patients undergoing percutaneous coronary balloon angioplasty;</i>								
<i>Patients undergoing percutaneous coronary atherectomy;</i>								
<i>Patients undergoing percutaneous coronary stent placement.</i>								
8048N	I.V. injection 10 mg in 5 mL	3	..	..	*1436.18	30.70	ReoPro	LY
ASPIRIN								
8202Q	Tablet 100 mg	112	1	..	6.70	7.69	^a DBL Aspirin 100 mg	FA
				^b 1.32	8.02	7.69	^a Astrix	MX
1010E	Tablet 300 mg (dispersible)	96	1	..	7.32	8.31	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								
<u>Authority required</u>								
<i>Prevention of recurrence of ischaemic stroke or transient cerebral ischaemic events in patients:</i>								
<i>(1) with a history of symptomatic cerebrovascular ischaemic episodes while on therapy with low-dose aspirin; or</i>								
<i>(2) where low-dose aspirin poses an unacceptable risk of gastrointestinal bleeding; or</i>								
<i>(3) where there is a history of anaphylaxis, urticaria or asthma within 4 hours of ingestion of aspirin, other salicylates, or NSAIDs;</i>								
<i>Prevention of recurrence of myocardial infarction or unstable angina in patients:</i>								
<i>(1) with a history of symptomatic cardiac ischaemic events while on therapy with low-dose aspirin; or</i>								
<i>(2) where low-dose aspirin poses an unacceptable risk of gastrointestinal bleeding; or</i>								
<i>(3) where there is a history of anaphylaxis, urticaria or asthma within 4 hours of ingestion of aspirin, other salicylates, or NSAIDs.</i>								
<u>NOTE:</u>								
<i>Not for prophylaxis of DVT or peripheral arterial disease.</i>								
8358X	Tablet 75 mg (base)	28	5	..	81.95	30.70	^a Iscover ^a Plavix	BQ SW
DIPYRIDAMOLE								
<u>Restricted benefit</u>								
<i>Prevention of recurrence of ischaemic stroke or transient cerebral ischaemic events:</i>								
<i>(1) as adjunctive therapy with low-dose aspirin; or</i>								
<i>(2) where low-dose aspirin poses an unacceptable risk of gastrointestinal bleeding; or</i>								
<i>(3) where there is a history of anaphylaxis, urticaria or asthma within 4 hours of ingestion of aspirin, other salicylates, or NSAIDs.</i>								
8335Q	Capsule 200 mg (sustained release)	60	5	..	33.24	30.70	Persantin SR	BY
DIPYRIDAMOLE with ASPIRIN								
<u>Restricted benefit</u>								
<i>Prevention of recurrence of ischaemic stroke or transient cerebral ischaemic events.</i>								
8382E	Capsule 200 mg (sustained release)-25 mg	60	5	..	33.45	30.70	Asasantin SR	BY
EPTIFIBATIDE ACETATE								
<u>Authority required</u>								
<i>Patients undergoing non-urgent percutaneous intervention with intracoronary stenting.</i>								
8683B	Solution for I.V. injection 20 mg (base) in 10 mL	2	..	..	*261.27	30.70	Integrilin	SH
8684C	Solution for I.V. infusion 75 mg (base) in 100 mL	3	..	..	*1019.09	30.70	Integrilin	SH

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	
TICLOPIDINE HYDROCHLORIDE								
CAUTION:								
<i>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.</i>								
Authority required								
<i>Prevention of recurrence of ischaemic stroke or transient cerebral ischaemic events in patients:</i>								
<i>(1) with a history of symptomatic cerebrovascular ischaemic episodes while on therapy with low-dose aspirin; or</i>								
<i>(2) where low-dose aspirin poses an unacceptable risk of gastrointestinal bleeding; or</i>								
<i>(3) where there is a history of anaphylaxis, urticaria or asthma within 4 hours of ingestion of aspirin, other salicylates, or NSAIDs;</i>								
<i>Patients established on this drug as a pharmaceutical benefit prior to 1 November 1999.</i>								
2095G	Tablet 250 mg	60	5	..	148.07	30.70	^a Ticlopidine Hexal	HX
							^a Tilodene	AF
					^b 2.20	150.27	^a Ticlid	RO

TIROFIBAN HYDROCHLORIDE**Authority required**

Patients with high risk unstable angina who have new transient or persistent ST-T ischaemic changes and anginal pain lasting longer than 20 minutes;

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;

Patients with non-Q-wave myocardial infarction.

8350L	Solution concentrate for I.V. infusion 12.5 mg (base) in 50 mL	1	2	..	361.84	30.70	Aggrastat	MK

• **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:

- (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;*

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	
DROTRECOGIN ALFA (ACTIVATED)—cont.								
(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	..	..	465.87	30.70	Xigris	LY
8615K	Powder for I.V. infusion 20 mg	1	..	..	1762.15	30.70	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	..	..	2035.69	30.70	Rapilysin 10 U	RO
TENECTEPLASE								
Restricted benefit								
Treatment of acute myocardial infarction within 12 hours of onset of attack.								
8526R	Powder for injection 40 mg with solvent	1	..	..	1929.49	30.70	Metalyse	BY
8527T	Powder for injection 50 mg with solvent	1	..	..	2025.79	30.70	Metalyse	BY
• Direct thrombin inhibitors								
BIVALIRUDIN TRIFLUOROACETATE								
Authority required								
Patients undergoing non-emergency percutaneous coronary intervention.								
NOTE:								
Bivalirudin trifluoroacetate has not been evaluated in patients undergoing emergency percutaneous coronary intervention, i.e. as primary or salvage therapy for myocardial infarction.								
8844L	Powder for I.V. injection 250 mg (base)	1	..	..	670.48	30.70	Angiomax	CS
• Other antithrombotic agents								
FONDAPARINUX SODIUM								
Authority required								
Prevention of venous thromboembolic events in patients undergoing major hip surgery;								
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	..	..	116.92	30.70	Arixtra	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	
ANTIHEMORRHAGICS								
Antifibrinolytics								
• Amino acids								
TRANEXAMIC ACID								
2180R	Tablet 500 mg	100	2	..	49.99	30.70	Cyklokapron	PH
ANTIANEMIC PREPARATIONS								
Iron preparations								
• Iron bivalent, oral preparations								
FERROUS SULFATE								
8815Y	Oral liquid 30 mg per mL, 250 mL	‡1	2	..	17.15	18.14	Ferro-Liquid	AE
• Iron trivalent, parenteral preparations								
IRON POLYMALTOSE COMPLEX								
2593L	Injection 100 mg (iron) in 2 mL	5	..	..	51.24	30.70	^a Ferrosig	SI
				B1.19	52.43	30.70	^a Ferrum H	BX
IRON SUCROSE								
<u>Authority required</u>								
<i>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.</i>								
8807M	Concentrate for solution for infusion 2.7 g (equivalent to 100 mg iron (III)) in 5 mL	5	..	..	138.21	30.70	Venofer	BX
• Iron in combination with folic acid								
FERROUS FUMARATE with FOLIC ACID								
9011G	Tablet 310 mg (equivalent to 100 mg iron)-350 micrograms	60	1	..	10.60	11.59	Ferro-f-tab	AE
Vitamin B₁₂ and folic acid								
• Vitamin B₁₂ (cyanocobalamin and derivatives)								
HYDROXOCOBALAMIN								
<u>Restricted benefit</u>								
<i>Pernicious anaemia;</i>								
<i>Other proven vitamin B₁₂ deficiencies;</i>								
<i>Prophylaxis after gastrectomy.</i>								
1508J	Injection 1 mg in 1 mL	2	..	..	12.03	13.02	Neo-Cytamen	MX
9048F	Injection 1 mg in 1 mL	3	..	..	15.48	16.47	Neo-B12	MX
<u>NOTE:</u>								
<i>One injection of hydroxocobalamin 1 mg every three months provides appropriate maintenance therapy in vitamin B₁₂ deficiencies.</i>								

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	
• Folic acid and derivatives								
FOLIC ACID								
2958Q	Tablet 500 micrograms	200	..	..	*11.69	12.68	Megafol 0.5	AF
1437P	Tablet 5 mg	200	1	..	*12.03	13.02	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	..	..	*43.46	30.70	Gelofusine	BR
POLYGELENE								
2334W	I.V. infusion 17.5 g per 500 mL (3.5%) with electrolytes, 500 mL	3	..	..	*43.46	30.70	Haemaccel	AE

I.V. solutions**• Solutions for parenteral nutrition**

GLUCOSE								
2245E	I.V. infusion 278 mmol (anhydrous) per L (5%), 1 L	5	1	..	*23.80	24.79	BX	

• Solutions affecting the electrolyte balance

ELECTROLYTE REPLACEMENT SOLUTION								
3199J	I.V. infusion 1 L	2	1	..	*20.03	21.02	Plasma-Lyte 148	BX
SODIUM CHLORIDE								
2264E	I.V. infusion 154 mmol per L (0.9%), 1 L	5	1	..	*23.80	24.79	BX	
2260Y	I.V. infusion 513 mmol per L (3%), 1 L	2	1	..	*16.43	17.42	BX	
SODIUM CHLORIDE COMPOUND								
2266G	I.V. infusion 1 L	4	1	..	*27.71	28.70	BX	
SODIUM CHLORIDE with GLUCOSE								
2281C	I.V. infusion 31 mmol-222 mmol (anhydrous) per L (0.18%-4%), 1 L	5	1	..	*23.80	24.79	BX	
2279Y	I.V. infusion 19 mmol-104 mmol (anhydrous) per 500 mL (0.225%-3.75%), 500 mL	5	1	..	*29.65	30.64	BX	
2278X	I.V. infusion 39 mmol-69 mmol (anhydrous) per 500 mL (0.45%- 2.5%), 500 mL	5	1	..	*29.65	30.64	BX	
SODIUM LACTATE COMPOUND								
2286H	I.V. infusion 1 L	5	1	..	*23.80	24.79	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	..	8.79	9.78	^a Sigmaxin-PG	FM
				^B 1.74	10.53	9.78	^a Lanoxin-PG	SI
1322N	Tablet 250 micrograms	100	1	..	9.07	10.06	^a Sigmaxin	FM
				^B 1.75	10.82	10.06	^a Lanoxin	SI
3164M	Oral solution for children 50 micrograms per mL, 60 mL	2	3	..	*26.45	27.44	Lanoxin	SI
Antiarrhythmics, class I and III								
• Antiarrhythmics, class IA								
DISOPYRAMIDE								
2923W	Capsule 100 mg	100	5	..	24.98	25.97	Rythmodan	AV
2924X	Capsule 150 mg	100	5	..	33.62	30.70	Rythmodan	AV
• Antiarrhythmics, class IB								
LIGNOCAINE HYDROCHLORIDE								
2875H	Injection 100 mg in 5 mL	5	..	..	34.72	30.70	PF	
2876J	Infusion 500 mg in 5 mL	10	..	..	27.32	28.31	Xylocard 500	AP
MEXILETINE HYDROCHLORIDE								
1682M	Capsule 50 mg	100	5	..	28.84	29.83	Mexitil	BY
1683N	Capsule 200 mg	100	5	..	58.18	30.70	Mexitil	BY
• Antiarrhythmics, class IC								
FLECAINIDE ACETATE								
CAUTION:								
<i>Flecainide acetate should be avoided in patients with poor cardiac function.</i>								
Restricted benefit								
<i>Serious supra-ventricular cardiac arrhythmias;</i>								
<i>Serious ventricular cardiac arrhythmias where treatment is initiated in a hospital (in-patient or out-patient).</i>								
1088G	Tablet 50 mg	60	5	..	37.64	30.70	Tambocor	MM
1090J	Tablet 100 mg	60	5	..	45.43	30.70	^a Flecatab	AF
				^B 2.77	48.20	30.70	^a Tambocor	MM

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: <i>Amiodarone hydrochloride has been reported to cause frequent and potentially serious toxicity.</i> <i>Regular monitoring of hepatic and thyroid function is recommended.</i> Restricted benefit <i>Severe cardiac arrhythmias.</i>							
2344J	Tablet 100 mg	30	5	..	16.15	17.14	^a Aratac 100 AF ^a Cardinorm HX ^a GenRx GX <i>Amiodarone</i> ^a Rithmik 100 AW ^B 0.97 17.12 17.14 ^a Cordarone X SW 100
2343H	Tablet 200 mg	30	5	..	24.69	25.68	^a Aratac 200 AF ^a Cardinorm HX ^a Chem mart CH <i>Amiodarone</i> ^a GenRx GX <i>Amiodarone</i> ^a Rithmik 200 AW ^a Terry White TW Chemists <i>Amiodarone</i> ^B 0.96 25.65 25.68 ^a Cordarone X SW 200
SOTALOL HYDROCHLORIDE Restricted benefit <i>Severe cardiac arrhythmias.</i>							
8398B	Tablet 80 mg	60	5	..	17.09	18.08	^a GenRx Sotalol GX ^a Solavert AW ^a Sotahexal HX ^B 1.60 18.69 18.08 ^a Sotacor BQ
2043M	Tablet 160 mg	60	5	..	30.76	30.70	^a Cardol AF ^a Chem mart CH <i>Sotalol</i> ^a GenRx Sotalol GX ^a Solavert AW ^a Sotab GM ^a Sotahexal HX ^a Terry White TW Chemists <i>Sotalol</i> ^B 1.74 32.50 30.70 ^a Sotacor 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
Cardiac stimulants excl. cardiac glycosides							
• Adrenergic and dopaminergic agents							
ADRENALINE							
1016L	Injection 1 mg in 1 mL (1 in 1,000)	5	1	..	18.46	19.45	AP
ADRENALINE							
<u>Authority required</u>							
<i>Initial supply for anticipated emergency treatment of acute allergic reactions with anaphylaxis in a patient who:</i>							
<i>(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</i>							
<i>(b) has been discharged from hospital or an emergency department after treatment with adrenaline for acute allergic reaction with anaphylaxis;</i>							
<i>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.</i>							
<u>NOTE:</u>							
<i>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.)</i>							
8697R	I.M. injection 150 micrograms in 0.3 mL single dose syringe auto-injector	1	..	..	93.85	30.70	EpiPen Jr. CS
8698T	I.M. injection 300 micrograms in 0.3 mL single dose syringe auto-injector	1	..	..	93.85	30.70	EpiPen CS

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.

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	
Vasodilators used in cardiac diseases								
• Organic nitrates								
GLYCERYL TRINITRATE								
1459T	Tablets 600 micrograms, 100	‡1	5	.. B1.61	8.68 10.29	9.67 9.67	^a Lycinate ^a Anginine Stabilised	FM SI
8171C	Buccal/sublingual spray (pump pack) 400 micrograms per dose (200 doses)	‡1	5	..	18.26	19.25	Nitrolingual Pumpspray	AV
NOTE: The spray should not be inhaled.								
8027L	Transdermal patch releasing approximately 5 mg per 24 hours	30	5	..	26.82	27.81	Minitran 5	MM
1515R	Transdermal patch releasing approximately 5 mg per 24 hours	30	5	..	26.82	27.81	Transiderm- Nitro 25	NV
8010N	Transdermal patch releasing approximately 5 mg per 24 hours	30	5	..	26.82	27.81	Nitro-Dur 5	SH
8028M	Transdermal patch releasing approximately 10 mg per 24 hours	30	5	..	33.57	30.70	Minitran 10	MM
1516T	Transdermal patch releasing approximately 10 mg per 24 hours	30	5	..	33.57	30.70	Transiderm- Nitro 50	NV
8011P	Transdermal patch releasing approximately 10 mg per 24 hours	30	5	..	33.57	30.70	Nitro-Dur 10	SH
8119H	Transdermal patch releasing approximately 15 mg per 24 hours	30	5	..	33.57	30.70	Minitran 15	MM
8026K	Transdermal patch releasing approximately 15 mg per 24 hours	30	5	..	33.57	30.70	Nitro-Dur 15	SH
ISOSORBIDE DINITRATE								
2587E	Tablet 10 mg	200	2	.. B3.56	*12.39 *15.95	13.38 13.38	^a Sorbidin ^a Isordil	AF SI
2588F	Sublingual tablet 5 mg	200	2	..	*13.57	14.56	Isordil Sublingual	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	
ISOSORBIDE MONONITRATE								
1558B	Tablet 60 mg (sustained release)	30	5	..	13.39	14.38	^a Chem mart Isosorbide Mononitrate	CH
							^a Duride	AF
							^a GenRx Isosorbide Mononitrate	GX
							^a Imtrate 60 mg	GM
							^a Isomonit	HX
							^a Monodur 60 mg	PM
							^a Terry White Chemists Isosorbide Mononitrate	TW
				^B 2.84	16.23	14.38	^a Imdur Durule	AP
8273K	Tablet 120 mg (sustained release)	30	5	..	24.69	25.68	^a Monodur 120 mg	PM
				^B 3.00	27.69	25.68	^a Imdur 120 mg	AP
• Other vasodilators used in cardiac diseases								
NICORANDIL								
8228C	Tablets 10 mg, 60	‡1	5	..	20.75	21.74	Ikorel	AV
8229D	Tablets 20 mg, 60	‡1	5	..	27.24	28.23	Ikorel	AV
PERHEXILINE MALEATE								
CAUTION:								
Regular monitoring of drug serum levels is recommended.								
Authority required								
Angina not responding to other therapy.								
1822X	Tablet 100 mg	100	5	..	51.99	30.70	Pexsig	SI
ANTIHYPERTENSIVES								
Antiadrenergic agents, centrally acting								
• Methyldopa								
METHYLDOPA								
1629R	Tablet 250 mg	100	5	..	12.52	13.51	^a Hydopa	AF
				^B 2.85	15.37	13.51	^a Aldomet	MK
• Imidazoline receptor agonists								
CLONIDINE								
3145M	Tablet 100 micrograms	100	5	..	26.63	27.62	Catapres 100	BY
3141H	Tablet 150 micrograms	100	5	..	34.82	30.70	Catapres	BY
MOXONIDINE								
Restricted benefit								
Hypertension in patients receiving concurrent antihypertensive therapy.								
9019Q	Tablet 200 micrograms	30	5	..	17.69	18.68	Physiotens	SM
9020R	Tablet 400 micrograms	30	5	..	26.53	27.52	Physiotens	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	
Antiadrenergic agents, peripherally acting								
• Alpha-adrenoceptor antagonists								
PRAZOSIN HYDROCHLORIDE								
1479W	Tablet 1 mg (base)	100	5	..	13.06	14.05	^a Chem mart Prazosin	CH
							^a GenRx Prazosin	GX
							^a Pressin 1	AF
							^a Terry White Chemists Prazosin	TW
				^B 2.95	16.01	14.05	^a Minipress	PF
1480X	Tablet 2 mg (base)	100	5	..	16.00	16.99	^a Chem mart Prazosin	CH
							^a GenRx Prazosin	GX
							^a Pressin 2	AF
							^a Terry White Chemists Prazosin	TW
				^B 3.04	19.04	16.99	^a Minipress	PF
1478T	Tablet 5 mg (base)	100	5	..	23.55	24.54	^a Chem mart Prazosin	CH
							^a GenRx Prazosin	GX
							^a Pressin 5	AF
							^a Terry White Chemists Prazosin	TW
				^B 3.29	26.84	24.54	^a Minipress	PF
Arteriolar smooth muscle, agents acting on								
• Hydrazinophthalazine derivatives								
HYDRALAZINE HYDROCHLORIDE								
1640H	Tablet 25 mg	200	2	..	*13.85	14.84	Alphapress 25	AF
1639G	Tablet 50 mg	200	2	..	*15.67	16.66	Alphapress 50	AF
• Pyrimidine derivatives								
MINOXIDIL								
Authority required								
<i>Severe refractory hypertension where treatment with minoxidil was initiated in a hospital (in-patient or out-patient).</i>								
2313R	Tablet 10 mg	100	5	..	51.25	30.70	Loniten	PH
DIURETICS								
Low-ceiling diuretics, thiazides								
• Thiazides, plain								
HYDROCHLOROTHIAZIDE								
1484D	Tablet 25 mg	100	1	..	19.33	20.32	Dithiazide	PL
Low-ceiling diuretics, excl. thiazides								
• Sulfonamides, plain								
CHLORTHALIDONE								
1585K	Tablet 25 mg	100	1	..	*12.05	13.04	Hygroton 25	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	
INDAPAMIDE HEMIHYDRATE								
8532C	Tablet 1.5 mg (sustained release)	90	1	..	19.68	20.67	Natrilix SR	SE
2436F	Tablet 2.5 mg	90	1	..	19.26	20.25	^a Chem mart Indapamide	CH
							^a Dapa-Tabs	AF
							^a GenRx	GX
							Indapamide	
							^a Indahexal	HX
							^a Insig	SI
							^a Napamide 2.5 mg	GM
							^a Terry White Chemists	TW
							Indapamide	
				^B 3.26	22.52	20.25	^a Natrilix	SE
High-ceiling diuretics								
• Sulfonamides, plain								
FRUSEMIDE								
2414C	Tablet 20 mg	100	1	..	*8.47	9.46	^a Frusid Urex-M	GM FM
				..	8.47	9.46	^a Chem mart	CH
							Frusemide	
							^a GenRx	GX
							Frusemide	
							^a Terry White Chemists	TW
							Frusemide	
				^B 1.08	*9.55	9.46	^a Lasix-M	AV
2412Y	Tablet 40 mg	100	1	..	8.16	9.15	^a Chem mart	CH
							Frusemide	
							^a Frusehexal 40 mg	HX
							^a Frusid	GM
							^a GenRx	GX
							Frusemide	
							^a Terry White Chemists	TW
							Frusemide	
							^a Uremide	AF
							Urex	FM
				^B 1.08	9.24	9.15	^a Lasix	AV
2415D	Tablet 500 mg	50	3	..	20.86	21.85	Urex-Forte	FM
2411X	Oral solution 10 mg per mL, 30 mL	‡1	3	..	14.05	15.04	Lasix	AV
2413B	Injection 20 mg in 2 mL	5	..	..	10.33	11.32	^a Frusehexal	HX
							^a Lasix	AV
• Aryloxyacetic acid derivatives								
ETHACRYNIC ACID								
Restricted benefit								
Patients hypersensitive to other oral diuretics.								
8748K	Tablet 25 mg	200	1	..	*56.41	30.70	Edecrin	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	
Potassium-sparing agents								
• Aldosterone antagonists								
EPLERENONE								
CAUTION:								
<i>Serum electrolytes should be checked regularly.</i>								
Authority required								
<i>Initial PBS-subsidised therapy for heart failure with a left ventricular ejection fraction of 40% or less occurring within 3 to 14 days following an acute myocardial infarction. The date of the acute myocardial infarction must be provided at the time authority approval for initial treatment is sought. Treatment with eplerenone must be commenced within 14 days of an acute myocardial infarction;</i>								
<i>Continuation of therapy for heart failure with a left ventricular ejection fraction of 40% or less occurring following an acute myocardial infarction, where the patient has previously been issued with a PBS authority prescription for eplerenone.</i>								
NOTE:								
<i>Authorities for initial PBS-subsidised therapy will be granted where treatment for eligible patients was commenced in a hospital within 14 days of an acute myocardial infarction.</i>								
8879H	Tablet 25 mg	30	5	..	111.50	30.70	Inspira	PF
8880J	Tablet 50 mg	30	5	..	111.50	30.70	Inspira	PF
SPIRONOLACTONE								
CAUTION:								
<i>Serum electrolytes should be checked regularly.</i>								
CAUTION:								
<i>Appropriate contraceptive measures should be taken by women of child-bearing age in whom spironolactone therapy has been initiated.</i>								
2339D	Tablet 25 mg	100	5	..	12.89	13.88	^a Spiractin 25	AF
				^B 1.84	14.73	13.88	^a Aldactone	PH
2340E	Tablet 100 mg	100	5	..	35.63	30.70	^a Spiractin 100	AF
				^B 2.53	38.16	30.70	^a Aldactone	PH
• Other potassium-sparing agents								
AMILORIDE HYDROCHLORIDE								
CAUTION:								
<i>Serum electrolytes should be checked regularly.</i>								
3109P	Tablet 5 mg	100	1	..	*8.67	9.66	Kaluril	AF
Diuretics and potassium-sparing agents in combination								
• Low-ceiling diuretics and potassium-sparing agents								
HYDROCHLOROTHIAZIDE with AMILORIDE HYDROCHLORIDE								
CAUTION:								
<i>Serum electrolytes should be checked regularly.</i>								
1486F	Tablet 50 mg-5 mg	100	1	..	*11.35	12.34	^a Amizide	AF
				^B 3.30	*14.65	12.34	^a Moduretic	MK
HYDROCHLOROTHIAZIDE with TRIAMTERENE								
CAUTION:								
<i>Serum electrolytes should be checked regularly.</i>								
1280J	Tablet 25 mg-50 mg	100	1	..	11.34	12.33	Hydrene 25/50	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	
PERIPHERAL VASODILATORS								
Peripheral vasodilators								
• <i>Other peripheral vasodilators</i>								
PHENOXYBENZAMINE HYDROCHLORIDE								
Restricted benefit								
<i>Phaeochromocytoma; Neurogenic urinary retention.</i>								
1862B	Capsule 10 mg	100	5	..	51.13	30.70	Dibenyline	GH
BETA BLOCKING AGENTS								
Beta blocking agents								
• <i>Beta blocking agents, non-selective</i>								
OXPRENOLOL HYDROCHLORIDE								
2942W	Tablet 20 mg	100	5	..	8.57	9.56	Corbeton 20	AF
2961W	Tablet 40 mg	100	5	..	10.28	11.27	Corbeton 40	AF
PINDOLOL								
3062E	Tablet 5 mg	100	5	..	11.61	12.60	^a Barbloc 5	AF
				^B 2.71	14.32	12.60	^a Visken 5	NV
3065H	Tablet 15 mg	50	5	..	14.45	15.44	^a Barbloc 15	AF
				^B 2.69	17.14	15.44	^a Visken 15	NV
PROPRANOLOL HYDROCHLORIDE								
2565B	Tablet 10 mg	100	5	..	8.02	9.01	Deralin 10	AF
				^B 3.00	11.02	9.01	Inderal	AP
2566C	Tablet 40 mg	100	5	..	8.15	9.14	Deralin 40	AF
				^B 3.01	11.16	9.14	Inderal	AP
2899N	Tablet 160 mg	50	5	..	9.12	10.11	Deralin 160	AF
SOTALOL HYDROCHLORIDE								
<i>For listings see Generic/Proprietary Index</i>								
• <i>Beta blocking agents, selective</i>								
ATENOLOL								
1081X	Tablet 50 mg	30	5	..	10.06	11.05	^a Anselol 50 mg	GM
							^a Atehexal	SZ
							^a Chem mart	CH
							Atenolol	
							^a GenRx Atenolol	GX
							^a Noten	AF
							^a Tensig	SI
							^a Terry White	TW
							Chemists	
							Atenolol	
				^B 3.55	13.61	11.05	^a Tenormin	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	
BISOPROLOL FUMARATE								
Authority required								
<i>Moderate to severe heart failure in patients stabilised on conventional therapy which must include an ACE-inhibitor if tolerated.</i>								
8604W	Tablet 2.5 mg	28	5	..	54.20	30.70	Bicor	AL
8605X	Tablet 5 mg	28	5	..	66.48	30.70	Bicor	AL
8606Y	Tablet 10 mg	28	5	..	81.79	30.70	Bicor	AL
METOPROLOL SUCCINATE								
Authority required								
<i>Moderate to severe heart failure in patients stabilised on conventional therapy which must include an ACE-inhibitor if tolerated.</i>								
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	..	..	93.41	30.70	Toprol-XL Titration Pack	AP
8732N	Tablet 23.75 mg (controlled release)	15	..	..	19.13	20.12	Toprol-XL 23.75	AP
8733P	Tablet 47.5 mg (controlled release)	30	5	..	71.19	30.70	Toprol-XL 47.5	AP
8734Q	Tablet 95 mg (controlled release)	30	5	..	87.69	30.70	Toprol-XL 95	AP
8735R	Tablet 190 mg (controlled release)	30	5	..	108.33	30.70	Toprol-XL 190	AP
METOPROLOL TARTRATE								
1324Q	Tablet 50 mg	100	5	..	10.78	11.77	^a Chem mart Metoprolol	CH
							^a GenRx Metoprolol	GX
							^a Metohexal	HX
							^a Metolol	GM
							^a Metrol 50	AW
							^a Minax 50	AF
							^a Terry White Chemists Metoprolol	TW
				^B 2.75	13.53	11.77	Lopresor 50	NV
				^B 3.25	14.03	11.77	^a Betaloc	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	
METOPROLOL TARTRATE—cont.								
1325R	Tablet 100 mg	60	5	..	12.30	13.29	^a Chem mart Metoprolol	CH
							^a GenRx Metoprolol	GX
							^a Metohexal	HX
							^a Metolol	GM
							^a Metrol 100	AW
							^a Minax 100	AF
							^a Terry White Chemists Metoprolol	TW
				^B 2.76	15.06	13.29	Lopresor 100	NV
				^B 3.25	15.55	13.29	^a Betaloc	AP
• Alpha and beta blocking agents								
CARVEDILOL								
Authority required								
<i>Moderate to severe heart failure in patients stabilised on conventional therapy which must include an ACE-inhibitor if tolerated;</i>								
<i>Patients receiving this drug as a pharmaceutical benefit prior to 1 August 2002.</i>								
8255L	Tablet 3.125 mg	30	..	..	18.86	19.85	^a Dilatrend 3.125	RO
							^a GenRx Carvedilol	GX
							^a Kredex	MD
8256M	Tablet 6.25 mg	60	5	..	69.96	30.70	^a Dilatrend 6.25	RO
							^a GenRx Carvedilol	GX
							^a Kredex	MD
8257N	Tablet 12.5 mg	60	5	..	86.15	30.70	^a Dilatrend 12.5	RO
							^a GenRx Carvedilol	GX
							^a Kredex	MD
8258P	Tablet 25 mg	60	5	..	106.42	30.70	^a Dilatrend 25	RO
							^a GenRx Carvedilol	GX
							^a Kredex	MD
LABETALOL HYDROCHLORIDE								
1566K	Tablet 100 mg	100	5	..	13.79	14.78	^a Presolol 100	AF
				^B 2.73	16.52	14.78	^a Trandate	SI
1567L	Tablet 200 mg	100	5	..	20.15	21.14	^a Presolol 200	AF
				^B 2.89	23.04	21.14	^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 felodipine and nifedipine (except nifedipine controlled release tablet 20 mg).								
AMLODIPINE BESYLATE								
2751T	Tablet 5 mg (base)	30	5	T4.46	24.86	21.39	Norvasc	PF
2752W	Tablet 10 mg (base)	30	5	T6.48	38.46	30.70	Norvasc	PF
AMLODIPINE BESYLATE								
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.								
8923P	Tablet 5 mg (base)	30	5	..	24.86	25.85	Norvasc	PF
8924Q	Tablet 10 mg (base)	30	5	..	38.46	30.70	Norvasc	PF
FELODIPINE								
2361G	Tablet 2.5 mg (extended release)	30	5	..	15.44	16.43	^a Felodur ER 2.5 mg	AL
				^B 3.01	18.45	16.43	^a Plendil ER	AP
2366M	Tablet 5 mg (extended release)	30	5	..	19.31	20.30	^a Felodur ER 5 mg	AL
				^B 3.35	22.66	20.30	^a Plendil ER	AP
2367N	Tablet 10 mg (extended release)	30	5	..	30.49	30.70	^a Felodur ER 10 mg	AL
				^B 4.67	35.16	30.70	^a Plendil ER	AP
LERCANIDIPINE HYDROCHLORIDE								
8534E	Tablet 10 mg	30	5	T1.07	25.23	25.15	Zanidip	SM
8679T	Tablet 20 mg	30	5	T3.70	40.02	30.70	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	..	25.23	26.22	Zanidip	SM
8940M	Tablet 20 mg	30	5	..	40.02	30.70	Zanidip	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
NIFEDIPINE							
1694E	Tablet 10 mg	60	5	..	18.90	19.89	^a Adefin 10 AF ^a Nypine 10 AW ^a Adalat 10 BN
				^B 1.73	20.63	19.89	
1695F	Tablet 20 mg	60	5	..	22.29	23.28	^a Adefin 20 AF ^a Chem mart CH ^a Nifedipine ^a GenRx GX ^a Nifedipine ^a Nifehexal HX ^a Nyefax 20 mg GM ^a Nypine 20 AW ^a Terry White TW Chemists ^a Nifedipine
				^B 3.20	25.49	23.28	^a Adalat 20 BN
8610E	Tablet 20 mg (controlled release)	30	5	^T 3.30	25.53	23.22	Adalat Oros BN 20mg
1906H	Tablet 30 mg (controlled release)	30	5	..	23.58	24.57	^a Addos XR 30 AW ^a Adefin XL 30 AF ^a Adalat Oros 30 BN
				^B 3.70	27.28	24.57	
1907J	Tablet 60 mg (controlled release)	30	5	..	28.31	29.30	^a Addos XR 60 AW ^a Adefin XL 60 AF ^a Adalat Oros 60 BN
				^B 4.10	32.41	29.30	

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	..	25.53	26.52	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	..	11.64	12.63	^a Anpec 40 AF ^a Isoptin AB
				^B 0.97	12.61	12.63	
1250T	Tablet 80 mg	100	5	..	16.68	17.67	^a Anpec 80 AF ^a Isoptin AB
				^B 0.97	17.65	17.67	
1254B	Tablet 120 mg	100	5	..	21.86	22.85	Isoptin AB
1253Y	Tablet 160 mg	60	5	..	20.47	21.46	Isoptin AB
2208F	Tablet 180 mg (sustained release)	30	5	..	14.46	15.45	^a Cordilox 180 SR KN ^a Isoptin 180 SR AB
				^B 2.89	17.35	15.45	

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	
VERAPAMIL HYDROCHLORIDE—cont.								
1241H	Tablet 240 mg (sustained release)	30	5	..	17.56	18.55	^a Anpec SR	AF
				^B 2.89	20.45	18.55	^a Cordilox SR	KN
							^a Isoptin SR	AB
2206D	Capsule 160 mg (sustained release)	30	5	..	12.83	13.82	Veracaps SR	SI
2207E	Capsule 240 mg (sustained release)	30	5	..	17.68	18.67	Veracaps SR	SI
1060T	Injection 5 mg in 2 mL	5	..	..	10.85	11.84	Isoptin	AB
• 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	..	19.43	20.42	^a Chem mart Diltiazem	CH
							^a Coras	AF
							^a Diltahexal	HX
							^a Dilzem 60 mg	GM
							^a GenRx Diltiazem	GX
							^a Terry White Chemists Diltiazem	TW
				^B 2.55	21.98	20.42	^a Vasocardol	HP
							^a Cardizem	AV
1312C	Capsule 180 mg (controlled delivery)	30	5	..	20.99	21.98	^a Chem mart Diltiazem CD	CH
							^a Dilzem CD	GM
							^a GenRx Diltiazem CD	GX
							^a Terry White Chemists Diltiazem CD	TW
				^B 2.55	23.54	21.98	^a Vasocardol CD	HP
							^a Cardizem CD	AV
1313D	Capsule 240 mg (controlled delivery)	30	5	..	26.53	27.52	^a Chem mart Diltiazem CD	CH
							^a Dilzem CD	GM
							^a GenRx Diltiazem CD	GX
							^a Terry White Chemists Diltiazem CD	TW
				^B 2.56	29.09	27.52	^a Vasocardol CD	HP
							^a Cardizem CD	AV
8480H	Capsule 360 mg (controlled delivery)	30	5	..	33.19	30.70	^a Vasocardol CD	HP
				^B 3.10	36.29	30.70	^a Cardizem 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.						
	NOTE: The base-priced drugs in this therapeutic group are captopril, enalapril maleate, fosinopril sodium, lisinopril, perindopril, quinapril hydrochloride, ramipril (except ramipril pack containing 7 tablets 2.5 mg, 21 tablets 5 mg and 10 capsules 10 mg) and trandolapril.						
	CAPTOPRIL						
1147J	Tablet 12.5 mg	90	5	..	18.23	19.22	a Acenorm 12.5 mg AF a Captohexal HX a Chem mart CH Captopril a GenRx Captopril GX a Terry White TW Chemists Captopril a Topace FM a GM B2.46 20.69 19.22 a Capoten BQ
1148K	Tablet 25 mg	90	5	..	24.08	25.07	a Acenorm 25 mg AF a Captohexal HX a Chem mart CH Captopril a GenRx Captopril GX a Terry White TW Chemists Captopril a Topace FM a GM B2.47 26.55 25.07 a Capoten BQ
1149L	Tablet 50 mg	90	5	..	42.50	30.70	a Acenorm 50 mg AF a Captohexal HX a Chem mart CH Captopril a GenRx Captopril GX a Terry White TW Chemists Captopril a Topace FM a GM B2.46 44.96 30.70 a Capoten BQ
	CAPTOPRIL						
	Restricted benefit						
	<i>For patients unable to take a solid dose form of an ACE inhibitor.</i>						
8760C	Oral solution 5 mg per mL, 95 mL	1	5	..	53.30	30.70	Capoten 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
ENALAPRIL MALEATE							
1370D	Tablet 5 mg	30	5	..	13.71	14.70	^a Alphapril AF ^a Auspril SI ^a Chem mart CH Enalapril ^a Enahexal HX ^a Enalabell BF ^a Enalapril-DP GM 5mg ^a GenRx Enalapril GX ^a Terry White TW Chemists Enalapril
				^B 3.14	16.85	14.70	^a Renitec M MK
1368B	Tablet 10 mg	30	5	..	19.21	20.20	^a Alphapril AF ^a Auspril SI ^a Chem mart CH Enalapril ^a Enahexal HX ^a Enalabell BF ^a Enalapril-DP GM 10mg ^a GenRx Enalapril GX ^a Terry White TW Chemists Enalapril
				^B 3.14	22.35	20.20	^a Amprace 10 FR ^a Renitec MK
1369C	Tablet 20 mg	30	5	..	23.06	24.05	^a Alphapril AF ^a Auspril SI ^a Chem mart CH Enalapril ^a Enahexal HX ^a Enalabell BF ^a Enalapril-DP GM 20mg ^a GenRx Enalapril GX ^a Terry White TW Chemists Enalapril
				^B 3.14	26.20	24.05	^a Amprace 20 FR ^a Renitec 20 MK
FOSINOPRIL SODIUM							
1182F	Tablet 10 mg	30	5	..	17.23	18.22	^a Fosipril 10 AW ^a GenRx GX Fosinopril ^a Monace 10 AF ^a Monopril BQ
1183G	Tablet 20 mg	30	5	..	23.22	24.21	^a Fosipril 20 AW ^a GenRx GX Fosinopril ^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	..	14.97	15.96	^a Chem mart CH Lisinopril ^a Fibsol 5 AW ^a GenRx Lisinopril GX ^a Liprace GM ^a Lisinobell BF ^a Lisinopril Hexal HX ^a Lisodur AF ^a Terry White TW Chemists Lisinopril
				^B 1.95	16.92	15.96	^a Prinivil 5 MK
				^B 2.65	17.62	15.96	^a Zestril AP
2457H	Tablet 10 mg	30	5	..	19.90	20.89	^a Chem mart CH Lisinopril ^a Fibsol 10 AW ^a GenRx Lisinopril GX ^a Liprace GM ^a Lisinobell BF ^a Lisinopril Hexal HX ^a Lisodur AF ^a Terry White TW Chemists Lisinopril
				^B 1.95	21.85	20.89	^a Prinivil 10 MK
				^B 2.65	22.55	20.89	^a Zestril AP
2458J	Tablet 20 mg	30	5	..	23.73	24.72	^a Chem mart CH Lisinopril ^a Fibsol 20 AW ^a GenRx Lisinopril GX ^a Liprace GM ^a Lisinobell BF ^a Lisinopril Hexal HX ^a Lisodur AF ^a Terry White TW Chemists Lisinopril
				^B 1.95	25.68	24.72	^a Prinivil 20 MK
				^B 2.65	26.38	24.72	^a Zestril 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	
PERINDOPRIL								
3050M	Tablet containing 2 mg perindopril erbumine	30	5	..	14.59	15.58	^a Chem mart Perindopril	CH
							^a GenRx Perindopril	GX
							^a Terry White Chemists Perindopril	TW
9006B	Tablet containing 2.5 mg perindopril arginine	30	5	..	14.59	15.58	^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	..	22.13	23.12	^a Chem mart Perindopril	CH
							^a GenRx Perindopril	GX
							^a Terry White Chemists Perindopril	TW
9007C	Tablet containing 5 mg perindopril arginine	30	5	..	22.13	23.12	^a Coversyl 5mg	SE
NOTE: Bioequivalence has been demonstrated between perindopril erbumine 4 mg and perindopril arginine 5 mg.								
8704D	Tablet containing 8 mg perindopril erbumine	30	5	..	30.77	30.70	^a Chem mart Perindopril	CH
							^a GenRx Perindopril	GX
							^a Terry White Chemists Perindopril	TW
9008D	Tablet containing 10 mg perindopril arginine	30	5	..	30.77	30.70	^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	..	15.63	16.62	^a Acquin 5	AW
							^a Filpril	AF
				^B 0.49	16.12	16.62	^a Accupril	PF
1969P	Tablet 10 mg (base)	30	5	..	19.92	20.91	^a Acquin 10	AW
							^a Filpril	AF
				^B 0.66	20.58	20.91	^a Accupril	PF
1970Q	Tablet 20 mg (base)	30	5	..	23.37	24.36	^a Acquin 20	AW
							^a Filpril	AF
				^B 0.98	24.35	24.36	^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	..	12.14	13.13	^a Ramipril Sandoz	QM
							^a Ramipril	WA
							Winthrop	
				^B 1.00	13.14	13.13	^a Ramace 1.25 mg	ML
				^B 3.00	15.14	13.13	^a Tritace 1.25 mg	AV
1945J	Tablet 2.5 mg	30	5	..	15.36	16.35	^a Ramipril Sandoz	QM
							^a Ramipril	WA
							Winthrop	
				^B 1.46	16.82	16.35	^a Ramace 2.5 mg	ML
				^B 3.00	18.36	16.35	^a Tritace 2.5 mg	AV
1946K	Tablet 5 mg	30	5	..	17.95	18.94	^a Ramipril Sandoz	QM
							^a Ramipril	WA
							Winthrop	
				^B 1.83	19.78	18.94	^a Ramace 5 mg	ML
				^B 3.00	20.95	18.94	^a Tritace 5 mg	AV
8470T	Capsule 10 mg	30	5	..	27.74	28.73	^a Ramipril Sandoz	QM
							^a Ramipril	WA
							Winthrop	
				^B 3.23	30.97	28.73	^a Ramace 10 mg	ML
							^a Tritace 10 mg	AV
8668F	Pack containing 7 tablets 2.5 mg, 21 tablets 5 mg and 10 capsules 10 mg	‡1	..	‡2.84	27.89	26.04	Tritace Titration Pack	AV
RAMIPRIL								
Authority required								
<i>Adverse effects occurring with all of the base-priced drugs;</i>								
<i>Drug interactions occurring with all of the base-priced drugs;</i>								
<i>Drug interactions expected to occur with all of the base-priced drugs;</i>								
<i>Transfer to a base-priced drug would cause patient confusion resulting in problems with compliance.</i>								
8948Y	Pack containing 7 tablets 2.5 mg, 21 tablets 5 mg and 10 capsules 10 mg	‡1	..	..	27.89	28.88	Tritace Titration Pack	AV
TRANDOLAPRIL								
2791X	Capsule 500 micrograms	28	5	..	13.50	14.49	^a Odrik	KN
				^B 1.50	15.00	14.49	^a Gopten	AB
2792Y	Capsule 1 mg	28	5	..	18.42	19.41	^a Odrik	KN
				^B 1.50	19.92	19.41	^a Gopten	AB
2793B	Capsule 2 mg	28	5	..	19.52	20.51	^a Odrik	KN
				^B 1.50	21.02	20.51	^a Gopten	AB
8758Y	Capsule 4 mg	28	5	..	32.07	30.70	Gopten	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	
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 <i>Hypertension in patients who are not adequately controlled with 20 mg enalapril maleate.</i>								
8477E	Tablet 20 mg-6 mg	30	5	..	26.81	27.80	Renitec Plus 20/6	MK
FOSINOPRIL SODIUM with HYDROCHLOROTHIAZIDE								
Restricted benefit <i>Hypertension in patients who are not adequately controlled with either hydrochlorothiazide or fosinopril sodium monotherapy.</i>								
8400D	Tablet 10 mg-12.5 mg	30	5	..	20.87	21.86	Monoplus 10/12.5	BQ
8401E	Tablet 20 mg-12.5 mg	30	5	..	28.11	29.10	Monoplus 20/12.5	BQ
PERINDOPRIL ERBUMINE with INDAPAMIDE HEMIHYDRATE								
Restricted benefit <i>Hypertension in patients who are not adequately controlled with either indapamide hemihydrate or perindopril monotherapy.</i>								
8449Q	Tablet 4 mg-1.25 mg	30	5	..	29.28	30.27	Coversyl Plus 4/1.25	SE
QUINAPRIL HYDROCHLORIDE with HYDROCHLOROTHIAZIDE								
Restricted benefit <i>Hypertension in patients who are not adequately controlled with either hydrochlorothiazide or quinapril hydrochloride monotherapy.</i>								
8589C	Tablet 10 mg (base)-12.5 mg	30	5	..	22.05	23.04	Accuretic 10/12.5mg	PF
8590D	Tablet 20 mg (base)-12.5 mg	30	5	..	25.49	26.48	Accuretic 20/12.5mg	PF
Angiotensin II antagonists, plain								
• Angiotensin II antagonists, plain								
CANDESARTAN CILEXETIL								
8295N	Tablet 4 mg	30	5	..	19.13	20.12	Atacand	AP
8296P	Tablet 8 mg	30	5	..	22.79	23.78	Atacand	AP
8297Q	Tablet 16 mg	30	5	..	28.40	29.39	Atacand	AP
8889W	Tablet 32 mg	30	5	..	44.67	30.70	Atacand	AP
EPROSARTAN MESYLATE								
8397Y	Tablet 400 mg (base)	56	5	..	*27.27	28.26	Teveten	SM
8447N	Tablet 600 mg (base)	28	5	..	27.24	28.23	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	
8246B	IRBESARTAN Tablet 75 mg	30	5	..	19.20	20.19	^a Avapro ^a Karvea	BQ SW
8247C	Tablet 150 mg	30	5	..	23.07	24.06	^a Avapro ^a Karvea	BQ SW
8248D	Tablet 300 mg	30	5	..	27.93	28.92	^a Avapro ^a Karvea	BQ SW
8355R	TELMISARTAN Tablet 40 mg	28	5	..	19.52	20.51	Micardis	BY
8356T	Tablet 80 mg	28	5	..	26.37	27.36	Micardis	BY
Angiotensin II antagonists, combinations								
• Angiotensin II antagonists and diuretics								
CANDESARTAN CILEXETIL with HYDROCHLOROTHIAZIDE								
<u>Restricted benefit</u>								
<i>Hypertension in patients who are not adequately controlled with 16 mg candesartan cilexetil.</i>								
8504N	Tablet 16 mg-12.5 mg	30	5	..	30.53	30.70	Atacand Plus 16/12.5	AP
EPROSARTAN MESYLATE with HYDROCHLOROTHIAZIDE								
<u>Restricted benefit</u>								
<i>Hypertension in patients who are not adequately controlled with either hydrochlorothiazide or eprosartan mesylate monotherapy.</i>								
8624X	Tablet 600 mg (base)-12.5 mg	28	5	..	29.24	30.23	Teveten Plus 600/12.5	SM
IRBESARTAN with HYDROCHLOROTHIAZIDE								
<u>Restricted benefit</u>								
<i>Hypertension in patients who are not adequately controlled with either hydrochlorothiazide or irbesartan monotherapy.</i>								
8404H	Tablet 150 mg-12.5 mg	30	5	..	25.19	26.18	^a Avapro HCT 150/12.5 ^a Karvezide 150/12.5	BQ SW
8405J	Tablet 300 mg-12.5 mg	30	5	..	30.05	30.70	^a Avapro HCT 300/12.5 ^a Karvezide 300/12.5	BQ SW
TELMISARTAN with HYDROCHLOROTHIAZIDE								
<u>Restricted benefit</u>								
<i>Hypertension in patients who are not adequately controlled with either hydrochlorothiazide or telmisartan monotherapy.</i>								
8622T	Tablet 40 mg-12.5 mg	28	5	..	21.50	22.49	Micardis Plus 40/12.5 mg	BY
8623W	Tablet 80 mg-12.5 mg	28	5	..	28.34	29.33	Micardis Plus 80/12.5 mg	BY

CARDIOVASCULAR SYSTEM —cont.

Code	Name, Restriction, Manner of administration and form	Max. No.of			Dispensed Price for Max.Qty \$	Maximum Recordable Value for Safety Net \$	Proprietary Name and Manufacturer
		Qty	Rpts	Premium			
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 box below) may commence drug therapy with statins or fibrates immediately (ie simultaneously with an appropriate diet). For all other patients, dietary therapy should be trialled prior to initiation of drug therapy.

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

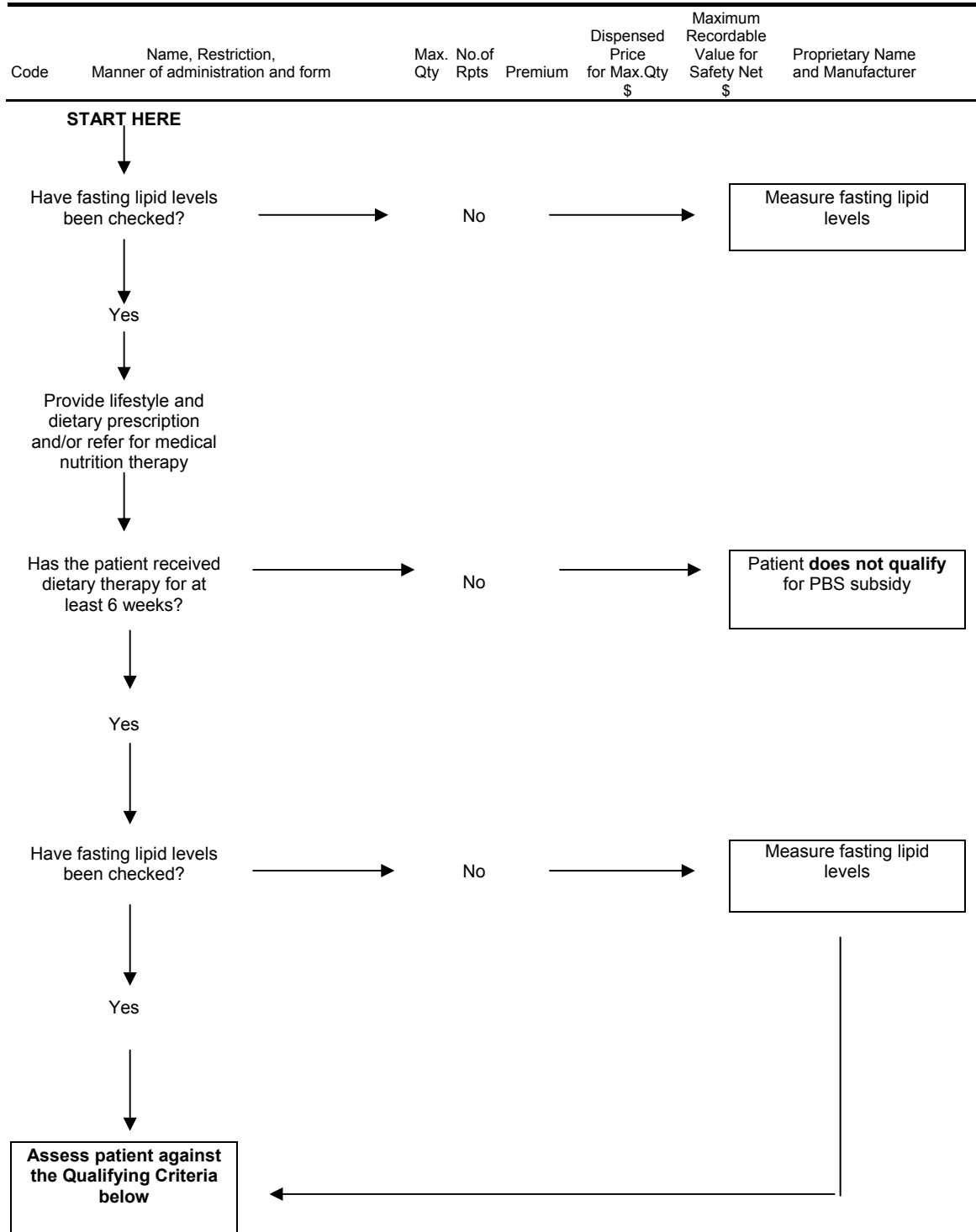
Patients identified as being in one of the following very high risk categories may commence drug therapy with statins or fibrates at any cholesterol level:

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

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

continued 

CARDIOVASCULAR SYSTEM —cont.



continued

CARDIOVASCULAR SYSTEM —cont.

Code	Name, Restriction, Manner of administration and form	Max. No. of Qty 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
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	..	41.19	30.70	Lipitor	PF
8214H	Tablet 20 mg (atorvastatin)	30	5	..	58.32	30.70	Lipitor	PF
8215J	Tablet 40 mg (atorvastatin)	30	5	..	80.03	30.70	Lipitor	PF
8521L	Tablet 80 mg (atorvastatin)	30	5	..	112.19	30.70	Lipitor	PF

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	..	25.50	26.49	^a Lescol	NV
				^B 1.00	26.50	26.49	^a Vastin	NM
8024H	Capsule 40 mg (fluvastatin)	28	5	..	30.10	30.70	^a Lescol	NV
				^B 0.99	31.09	30.70	^a Vastin	NM

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							
<u>Restricted benefit</u>							
<i>For use in patients that meet the criteria set out in the General Statement for Lipid-Lowering Drugs.</i>							
2833D	Tablet 10 mg	30	5	..	29.44	30.43	^a Chem mart CH
							^a Pravastatin
							^a Cholstat 10 AF
							^a GenRx GX
							^a Pravastatin
							^a Lipostat 10 AW
							^a Liprachol SZ
							^a Pravastatin-DP GM
							^a Pravastatin-RL RE
							^a Terry White TW
							Chemists
							^a Pravastatin
				^B 0.47	29.91	30.43	^a Pravachol BQ
2834E	Tablet 20 mg	30	5	..	43.74	30.70	^a Chem mart CH
							^a Pravastatin
							^a Cholstat 20 AF
							^a GenRx GX
							^a Pravastatin
							^a Lipostat 20 AW
							^a Liprachol SZ
							^a Pravastatin-DP GM
							^a Pravastatin-RL RE
							^a Terry White TW
							Chemists
							^a Pravastatin
				^B 0.48	44.22	30.70	^a Pravachol BQ
8197K	Tablet 40 mg	30	5	..	65.25	30.70	^a Chem mart CH
							^a Pravastatin
							^a Cholstat 40 AF
							^a GenRx GX
							^a Pravastatin
							^a Lipostat 40 AW
							^a Liprachol SZ
							^a Pravastatin-DP GM
							^a Pravastatin-RL RE
							^a Terry White TW
							Chemists
							^a Pravastatin
				^B 0.50	65.75	30.70	^a Pravachol BQ
8829Q	Tablet 80 mg	30	5	..	97.29	30.70	^a Lipostat 80 AW
				^B 0.49	97.78	30.70	^a Pravachol 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	
ROSUVASTATIN CALCIUM								
<u>Restricted benefit</u>								
<i>For use in patients that meet the criteria set out in the General Statement for Lipid-Lowering Drugs.</i>								
9042X	Tablet 5 mg (rosuvastatin)	30	5	..	50.81	30.70	Crestor	AP
9043Y	Tablet 10 mg (rosuvastatin)	30	5	..	70.61	30.70	Crestor	AP
9044B	Tablet 20 mg (rosuvastatin)	30	5	..	97.95	30.70	Crestor	AP
9045C	Tablet 40 mg (rosuvastatin)	30	5	..	137.13	30.70	Crestor	AP
SIMVASTATIN								
<u>Restricted benefit</u>								
<i>For use in patients that meet the criteria set out in the General Statement for Lipid-Lowering Drugs.</i>								
2013Y	Tablet 5 mg	30	5	..	26.67	27.66	^a Simvabell	BF
							^a Simvahexal	HX
							^a Simvastatin-RL	RE
							^a Zimstat	AF
				^B 0.68	27.35	27.66	^a Lipex 5	FR
							^a Zocor	MK
2011W	Tablet 10 mg	30	5	..	34.89	30.70	^a Chem mart	CH
							Simvastatin	
							^a GenRx	GX
							Simvastatin	
							^a Simvabell	BF
							^a Simvahexal	HX
							^a Simvar 10	AW
							^a Simvastatin-DP	GM
							^a Simvastatin-RL	RE
							^a Terry White	TW
							Chemists	
							Simvastatin	
							^a Zimstat	AF
							^a GN	
				^B 0.68	35.57	30.70	^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
SIMVASTATIN—cont.							
2012X	Tablet 20 mg	30	5	..	47.90	30.70	^a Chem mart CH Simvastatin ^a GenRx GX Simvastatin ^a Simvabell BF ^a Simvahexal HX ^a Simvar 20 AW ^a Simvastatin-DP GM ^a Simvastatin-RL RE ^a Terry White TW Chemists Simvastatin ^a Zimstat AF ^a GN ^b 0.68 48.58 30.70 ^a Lipex 20 FR ^a Zocor MK
8173E	Tablet 40 mg	30	5	..	66.67	30.70	^a Chem mart CH Simvastatin ^a GenRx GX Simvastatin ^a Simvabell BF ^a Simvahexal HX ^a Simvar 40 AW ^a Simvastatin-DP GM ^a Simvastatin-RL RE ^a Terry White TW Chemists Simvastatin ^a Zimstat AF ^a GN ^b 0.70 67.37 30.70 ^a Lipex 40 FR ^a Zocor MK
8313M	Tablet 80 mg	30	5	..	93.56	30.70	^a Chem mart CH Simvastatin ^a GenRx GX Simvastatin ^a Simvabell BF ^a Simvahexal HX ^a Simvar 80 AW ^a Simvastatin-DP GM ^a Simvastatin-RL RE ^a Terry White TW Chemists Simvastatin ^a Zimstat AF ^a GN ^b 0.67 94.23 30.70 ^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:								
<i>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.</i>								
Restricted benefit								
<i>For use in patients that meet the criteria set out in the General Statement for Lipid-Lowering Drugs.</i>								
9022W	Tablet 48 mg	60	5	..	27.76	28.75	Lipidil	LF
9023X	Tablet 145 mg	30	5	..	39.06	30.70	Lipidil	LF
GEMFIBROZIL								
NOTE:								
<i>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.</i>								
Restricted benefit								
<i>For use in patients that meet the criteria set out in the General Statement for Lipid-Lowering Drugs.</i>								
1453L	Tablet 600 mg	60	5	..	39.06	30.70	^a Ausgem	SI
							^a Chem mart	CH
							Gemfibrozil	
							^a Gemhexal	HX
							^a GenRx	GX
							Gemfibrozil	
							^a Jezil	AF
							^a Lipazil 600 mg	GM
							^a Terry White	TW
							Chemists	
							Gemfibrozil	
				^B 3.38	42.44	30.70	^a Lopid	PF
• Bile acid sequestrants								
CHOLESTYRAMINE								
2967E	Sachets 4.7 g (equivalent to 4 g cholestyramine), 50	2	5	..	*56.19	30.70	Questran Lite	BQ
2978R	Sachets 9.4 g (equivalent to 8 g cholestyramine), 50	‡1	5	..	53.17	30.70	Questran Lite	BQ
COLESTIPOL HYDROCHLORIDE								
1224K	Sachets 5 g, 120	‡1	5	..	66.42	30.70	Colestid	PH

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
• Other lipid modifying agents EZETIMIBE Authority required <i>Initial 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:</i> (a) coronary heart disease; or (b) diabetes mellitus; or (c) peripheral vascular disease; or (d) heterozygous familial hypercholesterolaemia; or (e) symptomatic cerebrovascular disease. <i>Inadequate control with a statin is defined as follows:</i> (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; 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. <i>The cholesterol level after 3 months of treatment with a statin and the dose of the statin must be provided at the time of application. The cholesterol level results provided must be no more than 2 months old at the time of application;</i> <i>Continuing treatment for co-administration with HMG CoA reductase inhibitors (statins) in patients with coronary heart disease or diabetes mellitus or peripheral vascular disease or heterozygous familial hypercholesterolaemia or symptomatic cerebrovascular disease whose cholesterol levels were inadequately controlled with a statin, where the patient has previously been issued with an authority prescription for this drug.</i>							
Authority required <i>Patients eligible for PBS-subsidised lipid-lowering medication (according to the criteria set out in the General Statement for Lipid-Lowering Drugs):</i> (a) where treatment with an HMG CoA reductase inhibitor (statin) is contraindicated; or (b) where treatment with an HMG CoA reductase inhibitor (statin) is unsuitable because the patient developed a clinically important product-related adverse event during treatment with a statin, and required discontinuation of all statin treatment. <i>A clinically important product-related adverse event is defined as follows:</i> (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 <i>Homozygous sitosterolaemia;</i> <i>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).</i>							
8757X	Tablet 10 mg	30	5	..	69.70	30.70	Ezetrol 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	
Lipid modifying agents, combinations								
• HMG CoA reductase inhibitors in combination with other lipid modifying agents								
EZETIMIBE with SIMVASTATIN								
<u>Authority required</u>								
<i>Initial 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:</i>								
<i>(a) coronary heart disease; or</i>								
<i>(b) diabetes mellitus; or</i>								
<i>(c) peripheral vascular disease; or</i>								
<i>(d) heterozygous familial hypercholesterolaemia; or</i>								
<i>(e) cerebrovascular disease which has become symptomatic.</i>								
<i>Inadequate control with a statin is defined as follows:</i>								
<i>(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; or</i>								
<i>(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.</i>								
<i>The cholesterol level after 3 months of treatment with a statin and the dose of the statin must be provided at the time of application. The cholesterol level results provided must be no more than 2 months old at the time of application;</i>								
<i>Continuing treatment in patients with coronary heart disease or diabetes mellitus or peripheral vascular disease or heterozygous familial hypercholesterolaemia or symptomatic cerebrovascular disease whose cholesterol levels were inadequately controlled with a statin, where the patient has previously been issued with an authority prescription for this item or the combination of ezetimibe and 40 mg or greater of a statin;</i>								
<i>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).</i>								
8881K	Tablet 10 mg-40 mg	30	5	..	131.23	30.70	Vytorin	MK
8882L	Tablet 10 mg-80 mg	30	5	..	158.12	30.70	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 <i>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:</i> <i>(a) who are currently receiving treatment with a dihydropyridine calcium channel blocker;</i> <i>OR</i> <i>(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</i> <i>(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.</i>								
9049G	Tablet 5 mg (base)-10 mg (base)	30	5	..	56.43	30.70	Caduet 5/10	PF
9050H	Tablet 5 mg (base)-20 mg (base)	30	5	..	73.57	30.70	Caduet 5/20	PF
9051J	Tablet 5 mg (base)-40 mg (base)	30	5	..	95.26	30.70	Caduet 5/40	PF
9052K	Tablet 5 mg (base)-80 mg (base)	30	5	..	127.43	30.70	Caduet 5/80	PF
9053L	Tablet 10 mg (base)-10 mg (base)	30	5	..	68.02	30.70	Caduet 10/10	PF
9054M	Tablet 10 mg (base)-20 mg (base)	30	5	..	85.15	30.70	Caduet 10/20	PF
9055N	Tablet 10 mg (base)-40 mg (base)	30	5	..	106.85	30.70	Caduet 10/40	PF
9056P	Tablet 10 mg (base)-80 mg (base)	30	5	..	139.01	30.70	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								
<u>Authority required</u>								
<i>Treatment of a fungal or a yeast infection in an Aboriginal or a Torres Strait Islander person.</i>								
1698J	Cream 100,000 units per g, 15 g	2	3	..	*13.85	14.84	Mycostatin	BQ
• Imidazole and triazole derivatives								
BIFONAZOLE								
<u>Authority required</u>								
<i>Treatment of a fungal or a yeast infection in an Aboriginal or a Torres Strait Islander person.</i>								
8066M	Cream 10 mg per g (1%), 15 g	2	3	..	*23.69	24.68	Mycospor	BN
CLOTRIMAZOLE								
<u>Authority required</u>								
<i>Treatment of a fungal or a yeast infection in an Aboriginal or a Torres Strait Islander person.</i>								
1027C	Lotion 10 mg per mL (1%), 20 mL	2	3	..	*16.57	17.56	Canesten	BN
KETOCONAZOLE								
<u>Authority required</u>								
<i>Treatment of a fungal or a yeast infection in an Aboriginal or a Torres Strait Islander person.</i>								
9024Y	Cream 20 mg per g (2%), 30 g	‡1	2	..	21.12	22.11	Nizoral 2% Cream	JC
9025B	Shampoo 10 mg per g (1%), 100 mL	‡1	1	..	15.84	16.83	Nizoral 1%	JC
1574W	Shampoo 20 mg per g (2%), 60 mL	‡1	1	..	16.52	17.51	Nizoral 2%	JC
MICONAZOLE								
<u>Authority required</u>								
<i>Treatment of a fungal or a yeast infection in an Aboriginal or a Torres Strait Islander person.</i>								
9031H	Tincture 20 mg per mL (2%), 30 mL	‡1	2	..	17.64	18.63	Daktarin	JC

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								
<i>Treatment of a fungal or a yeast infection in an Aboriginal or a Torres Strait Islander person.</i>								
9026C	Cream 20 mg per g (2%), 15 g	2	3	..	*14.21	15.20	Daktarin	JC
9027D	Cream 20 mg per g (2%), 30 g	‡1	2	..	13.16	14.15	Daktarin	JC
9028E	Cream 20 mg per g (2%), 70 g	‡1	1	..	15.07	16.06	Daktarin	JC
9029F	Powder 20 mg per g (2%), 30 g	‡1	2	..	13.90	14.89	Daktarin	JC
9030G	Lotion 20 mg per mL (2%), 30 g	‡1	2	..	15.01	16.00	Daktarin	JC
Antifungals for systemic use								
• Antifungals for systemic use								
GRISEOFULVIN								
1460W	Tablet 125 mg	100	2	..	20.61	21.60	Grisovin	SI
2982Y	Tablet 500 mg	28	2	..	19.44	20.43	Grisovin 500	SI
TERBINAFINE HYDROCHLORIDE								
Authority required								
<i>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.</i>								
NOTE:								
<i>No applications for increased maximum quantities and/or repeats will be authorised.</i>								
2804N	Tablet 250 mg (base)	42	1	..	133.69	30.70	^a GenRx Terbinafine	GX
							^a Tamsil	AW
							^a Terbihexal	SZ
							^a Terbinafine-DP	GM
							^a Zabel	AF
					^b 1.93	135.62	^a Lamisil	NV
ANTIPSORIATICS								
Antipsoriatics for topical use								
• Tars								
COAL TAR - PREPARED								
8864M	Gel 10 mg per g (1%), 100 mL	‡1	2	..	30.65	30.70	Exorex	EP
• Other antipsoriatics for topical use								
CALCIPOTRIOL								
Restricted benefit								
<i>Chronic stable plaque type psoriasis vulgaris.</i>								
8291J	Ointment 50 micrograms per g (0.005%), 30 g	‡1	1	..	21.84	22.83	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								
• <i>Retinoids for treatment of psoriasis</i>								
ACITRETIN								
CAUTION:								
<i>This drug is a potent teratogen—pregnancy should be avoided for at least two years after cessation of therapy.</i>								
NOTE:								
<i>Care must be taken to comply with the provisions of State/Territory law when prescribing acitretin.</i>								
Authority required								
<i>Severe intractable psoriasis;</i>								
<i>Severe forms of disorders of keratinisation.</i>								
2019G	Capsule 10 mg	100	2	..	204.50	30.70	Neotigason	RO
2020H	Capsule 25 mg	100	2	..	391.94	30.70	Neotigason	RO

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	..	..	15.88	16.87	Silvazine	SN
1997D	Cream 10 mg-2 mg per g (1%-0.2%), 100 g	‡1	..	..	19.04	20.03	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	..	7.37	8.36	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								
<u>Restricted benefit</u>								
<i>Treatment of corticosteroid-responsive dermatoses.</i>								
2887Y	Cream 10 mg per g (1%), 30 g	‡1	1	..	6.92	7.91 ^a	Cortic-DS 1%	FM
				^B 1.85	8.77	7.91 ^a	Sigmacort	SI
2881P	Cream 10 mg per g (1%), 50 g	‡1	1	..	7.37	8.36 ^a	Cortic-DS 1%	FM
				^B 0.08	7.45	8.36 ^a	Cortef	DT
				^B 1.86	9.23	8.36 ^a	Sigmacort	SI
2888B	Topical ointment 10 mg per g (1%), 30 g	‡1	1	..	6.92	7.91 ^a	Cortic-DS 1%	FM
				^B 1.85	8.77	7.91 ^a	Sigmacort	SI
2882Q	Topical ointment 10 mg per g (1%), 50 g	‡1	1	..	7.37	8.36 ^a	Cortic-DS 1%	FM
				^B 1.86	9.23	8.36 ^a	Sigmacort	SI
<i>[For other listings for this drug see Generic/Proprietary Index]</i>								
• Corticosteroids, moderately potent (group II)								
TRIAMCINOLONE ACETONIDE								
<u>Restricted benefit</u>								
<i>Treatment of corticosteroid-responsive dermatoses.</i>								
2117K	Cream 200 micrograms per g (0.02%), 100 g	2	..	..	*13.43	14.42 ^a	Tricortone	FM
				^B 3.18	*16.61	14.42 ^a	Aristocort 0.02%	SI
2118L	Ointment 200 micrograms per g (0.02%), 100 g	2	..	..	*13.43	14.42 ^a	Tricortone	FM
				^B 3.18	*16.61	14.42 ^a	Aristocort 0.02%	SI
• Corticosteroids, potent (group III)								
BETAMETHASONE DIPROPIONATE								
<u>Restricted benefit</u>								
<i>Treatment of corticosteroid-responsive dermatoses.</i>								
1115Q	Cream 500 micrograms (base) per g (0.05%), 15 g	‡1	1	..	7.88	8.87 ^a	Diprosone	SH
							Eleuphrat	EX
1119X	Ointment 500 micrograms (base) per g (0.05%), 15 g	‡1	1	..	7.88	8.87 ^a	Diprosone	SH
							Eleuphrat	EX
BETAMETHASONE VALERATE								
<u>Restricted benefit</u>								
<i>Treatment of corticosteroid-responsive dermatoses.</i>								
2812B	Cream 200 micrograms (base) per g (0.02%), 100 g	2	..	..	*13.43	14.42 ^a	Antroquoril	EX
							Celestone-M	SH
				^B 6.00	*19.43	14.42 ^b	Cortival 1/5	FM
							Betnovate 1/5	SI
2813C	Cream 500 micrograms (base) per g (0.05%), 15 g	‡1	1	..	7.23	8.22 ^b	Cortival 1/2	FM
				^B 1.86	9.09	8.22 ^b	Betnovate 1/2	SI
2820K	Ointment 200 micrograms (base) per g (0.02%), 100 g	2	..	..	*13.43	14.42 ^a	Antroquoril	EX
							Celestone-M	SH
2815E	Ointment 500 micrograms (base) per g (0.05%), 15 g	‡1	1	..	7.23	8.22 ^b	Cortival 1/2	FM
				^B 1.86	9.09	8.22 ^b	Betnovate 1/2	SI

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	
METHYLPREDNISOLONE ACEPONATE								
<u>Restricted benefit</u>								
<i>Treatment of corticosteroid-responsive dermatoses.</i>								
8054X	Cream 1 mg per g (0.1%), 15 g	‡1	..	..	10.63	11.62	Advantan	CS
8055Y	Ointment 1 mg per g (0.1%), 15 g	‡1	..	..	10.63	11.62	Advantan	CS
8128T	Fatty ointment 1 mg per g (0.1%), 15 g	‡1	..	..	10.63	11.62	Advantan	CS
<u>Restricted benefit</u>								
<i>Eczema.</i>								
8618N	Lotion 1 mg per g (0.1%), 20 g	‡1	..	..	11.35	12.34	Advantan	CS
MOMETASONE FUROATE								
<u>Restricted benefit</u>								
<i>Treatment of corticosteroid-responsive dermatoses.</i>								
1913Q	Cream 1 mg per g (0.1%), 15 g	‡1	..	..	10.63	11.62	^a Elocon ^a Novasone	SH EX
1915T	Ointment 1 mg per g (0.1%), 15 g	‡1	..	..	10.63	11.62	^a Elocon ^a Novasone	SH EX
8043H	Lotion 1 mg per g (0.1% w/w), 30 mL	‡1	..	..	14.52	15.51	^a Elocon ^a Novasone	SH 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:								
<i>This drug causes birth defects. Isotretinoin has been reported to cause other frequent and potentially serious toxicity.</i>								
NOTE:								
<i>Care must be taken to comply with the provisions of State/Territory law when prescribing isotretinoin.</i>								
Authority required								
<i>Severe cystic acne not responsive to other therapy.</i>								
NOTE:								
<i>No applications for increased maximum quantities and/or repeats will be authorised.</i>								
2591J	Capsule 10 mg	60	3	..	95.08	30.70	^a GenRx Isotretinoin	GX
							^a Oratane	GM
							^a Roaccutane	RO
2592K	Capsule 20 mg	60	3	..	145.32	30.70	^a Chem mart Isotretinoin	CH
							^a GenRx Isotretinoin	GX
							^a Isohexal	HX
							^a Oratane	GM
							^a Terry White Chemists Isotretinoin	TW
					^B 2.42 147.74	30.70	^a Roaccutane	RO
OTHER DERMATOLOGICAL PREPARATIONS								
Other dermatological preparations								
• Other dermatologicals								
DAPSONE								
8801F	Tablet 25 mg	100	1	..	99.31	30.70	LM	
1272Y	Tablet 100 mg	100	1	..	112.57	30.70	LM	
IMIQUIMOD								
Authority required								
<i>Treatment of biopsy confirmed primary (previously untreated) superficial basal cell carcinoma (sBCC) in immunocompetent patients who cannot have surgical excision, cryotherapy, or curettage with diathermy.</i>								
<i>The date of the pathology report and name of the Approved Pathology Authority must be provided at the time of application.</i>								
NOTE:								
<i>The patient or carer must be able to understand and administer the imiquimod dosing regimen.</i>								
<i>No applications for increased maximum quantities and/or repeats will be authorised.</i>								
<i>Treatment of recurrent (previously treated) lesions will not be authorised.</i>								
2546B	Cream 50 mg per g (5%), 250 mg single use sachets, 12	1	1	..	158.68	30.70	Aldara	MM

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
PIMECROLIMUS							
Authority required							
<i>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>							
<i>(i) perioral dermatitis;</i>							
<i>(ii) periorbital dermatitis;</i>							
<i>(iii) rosacea;</i>							
<i>(iv) epidermal atrophy;</i>							
<i>(v) dermal atrophy;</i>							
<i>(vi) allergy to topical corticosteroids;</i>							
<i>(vii) cataracts;</i>							
<i>(viii) glaucoma;</i>							
<i>(ix) raised intraocular pressure.</i>							
Authority required							
<i>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.</i>							
<i>Failure to achieve satisfactory disease control with intermittent topical corticosteroid therapy is manifest by:</i>							
<i>(i) failure of the facial skin to clear despite at least 2 weeks of topical hydrocortisone 1% applied every day; or</i>							
<i>(ii) failure of the facial skin to clear despite at least 1 week of a moderate or potent topical corticosteroid applied every day; or</i>							
<i>(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</i>							
<i>(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.</i>							
8802G	Cream 10 mg per g (1%), 15 g	1	1	..	31.33	30.70	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.

GENITO URINARY SYSTEM AND SEX HORMONES

Code	Name, Restriction, Manner of 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.								
8633J	Intrauterine drug delivery system 52 mg (releasing approximately 20 micrograms per 24 hours)	1	..	..	214.65	30.70	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	..	..	19.09	20.08	^a Krypton 2.5	AF
				^B 2.84	21.93	20.08	^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	..	33.00	30.70	^a Krypton 2.5	AF
				^B 2.92	35.92	30.70	^a Parlodel	NV
1446D	Capsule 5 mg (base)	60	5	..	59.92	30.70	^a Krypton 5	AF
				^B 2.91	62.83	30.70	^a Parlodel	NV
1445C	Capsule 10 mg (base)	100	5	..	201.31	30.70	^a Krypton 10	AF
				^B 3.08	204.39	30.70	^a Parlodel	NV
CABERGOLINE								
Restricted benefit								
Prevention of the onset of lactation in the puerperium for medical reasons.								
8115D	Tablet 500 micrograms	2	..	..	24.84	25.83	Dostinex	PH
Authority required								
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.								
8114C	Tablet 500 micrograms	8	5	..	74.95	30.70	Dostinex	PH

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	
QUINAGOLIDE HYDROCHLORIDE								
Authority required								
<i>Pathological hyperprolactinaemia where surgery is not indicated;</i>								
<i>Pathological hyperprolactinaemia where surgery has already been used with incomplete resolution;</i>								
<i>Pathological hyperprolactinaemia where radiotherapy is not indicated;</i>								
<i>Pathological hyperprolactinaemia where radiotherapy has already been used with incomplete resolution.</i>								
8860H	Pack containing 3 tablets 25 micrograms (base) and 3 tablets 50 micrograms (base)	1	..	..	9.98	10.97	Norprolac	FP
8822H	Tablet 75 micrograms (base)	30	5	..	53.41	30.70	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	..	*15.59	16.58	Microgynon 50 ED	SC
1393H	Tablets 150 micrograms- 30 micrograms, 21	4	2	^B 11.16	*26.75	16.58	^a Microgynon 30	SC
1394J	Pack containing 21 tablets 150 micrograms-30 micrograms and 7 inert tablets	4	2	..	15.58	16.57	^b Monofeme 28	WX
				..	*15.59	16.58	^a Levlen ED	SY
				^B 10.50	26.08	16.57	^b Nordette 28	WY
				^B 11.16	*26.75	16.58	^a Microgynon 30 ED	SC
NORETHISTERONE with ETHINYLOESTRADIOL								
2772X	Tablets 500 micrograms- 35 micrograms, 21	4	2	^B 7.68	*23.27	16.58	^a Brevinor	PH
2774B	Pack containing 21 tablets 500 micrograms-35 micrograms and 7 inert tablets	4	2	..	*15.59	16.58	^a Norimin 28 Day	KR
				^B 7.68	*23.27	16.58	^a Brevinor	PH
2773Y	Tablets 1 mg-35 micrograms, 21	4	2	^B 7.68	*23.27	16.58	^a Brevinor-1	PH
2775C	Pack containing 21 tablets 1 mg- 35 micrograms and 7 inert tablets	4	2	..	*15.59	16.58	^a Norimin-1 28 Day	KR
				^B 7.68	*23.27	16.58	^a Brevinor-1	PH
NORETHISTERONE with MESTRANOL								
3176E	Tablets 1 mg-50 micrograms, 21	4	2	..	*15.59	16.58	Norinyl-1	PH
3179H	Pack containing 21 tablets 1 mg- 50 micrograms and 7 inert tablets	4	2	..	*15.59	16.58	Norinyl-1/28	PH

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	
• Progestogens and estrogens, sequential preparations								
LEVONORGESTREL with ETHINYLOESTRADIOL								
1392G	Pack containing 6 tablets	4	2	..	15.58	16.57	^b Trifeme 28	WX
	50 micrograms-30 micrograms,			..	*15.59	16.58	^a Logynon ED	SY
	5 tablets 75 micrograms-			^B 10.50	26.08	16.57	^b Triphasil 28	WY
	40 micrograms, 10 tablets			^B 11.16	*26.75	16.58	^a Triquilar ED	SC
	125 micrograms-30 micrograms and 7 inert tablets							
NORETHISTERONE with ETHINYLOESTRADIOL								
2776D	Pack containing 12 tablets	4	2	..	*15.59	16.58	^a Improvil 28 Day	KR
	500 micrograms-35 micrograms,			^B 7.68	*23.27	16.58	^a Synphasic	PH
	9 tablets 1 mg-35 micrograms and 7 inert tablets							
• Progestogens								
ETONORGESTREL								
8487Q	Subcutaneous implant 68 mg	1	..	..	214.65	30.70	Implanon	OR
LEVONORGESTREL								
2913H	Tablets 30 micrograms, 28	4	2	..	15.58	16.57	Microval 28	WY
				..	*15.59	16.58	Microlut 28	SC
MEDROXYPROGESTERONE ACETATE								
3118D	Injection 150 mg in 1 mL	1	1	..	13.18	14.17	^a Depo-Ralovera	KR
				^B 3.25	16.43	14.17	^a Depo-Provera	PH
[For other listings for this drug see Generic/Proprietary Index]								
NORETHISTERONE								
1967M	Tablets 350 micrograms, 28	4	2	..	*15.59	16.58	^a Locilan 28 Day	KR
				^B 3.88	*19.47	16.58	Micronor	JC
							^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	..	..	*194.63	30.70	OR	
8099G	Subcutaneous implant 200 mg	3	..	..	*194.66	30.70	OR	
8830R	Transdermal gel 50 mg in 5 g sachet, 30	‡1	5	..	93.85	30.70	Testogel	SC
8460G	Transdermal patches 12.2 mg (releasing approximately 2.5 mg per 24 hours), 60	‡1	5	..	94.57	30.70	Androderm	MX

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	
TESTOSTERONE—cont.								
8619P	Transdermal patches 24.3 mg (releasing approximately 5 mg per 24 hours), 30	1	5	..	94.57	30.70	Androderm	MX
TESTOSTERONE ENANTHATE								
<u>Authority required</u> 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	..	31.03	30.70	Primoteston Depot	SC
TESTOSTERONE ESTERS								
<u>Authority required</u> 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	..	*18.77	19.76	Sustanon 100	OR
2101N	Injection 250 mg	3	3	..	*31.01	30.70	Sustanon 250	OR
TESTOSTERONE UNDECANOATE								
<u>Authority required</u> 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	..	34.91	30.70	Andriol Testocaps	OR
9004X	I.M. injection 1,000 mg in 4 mL	1	1	..	146.14	30.70	Reandron 1000	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	
Estrogens								
• Natural and semisynthetic estrogens, plain								
OESTRADIOL								
8274L	Tablet 2 mg	56	2	..	12.54	13.53	Zumenon	SM
1742Q	Vaginal tablets 25 micrograms, 15	‡1	2	..	20.32	21.31	Vagifem	NO
OESTRADIOL								
Restricted benefit								
<i>For use for post-menopausal symptoms where a trial of peri- or post-menopausal low-dose oestrogen therapy has demonstrated intolerance to oral estrogens.</i>								
NOTE:								
<i>Oestradiol should be used in conjunction with an oral progestogen in women with an intact uterus.</i>								
8286D	Transdermal gel 1 mg in 1 g sachet, 28	‡1	5	..	16.22	17.21	Sandrena	OR
8761D	Transdermal patches 390 micrograms (releasing approximately 25 micrograms per 24 hours), 8	‡1	5	..	16.22	17.21	Estradot 25	NV
8311K	Transdermal patches 750 micrograms (releasing approximately 25 micrograms per 24 hours), 8	‡1	5	..	16.22	17.21	Estraderm MX 25	NV
8485N	Transdermal patches 2 mg (releasing approximately 25 micrograms per 24 hours), 4	‡1	5	..	16.22	17.21	^a Climara 25 ^a Femtran 25	SC MM
1743R	Transdermal patches 2 mg (releasing approximately 25 micrograms per 24 hours), 8	‡1	5	..	16.22	17.21	Estraderm 25	NV
8762E	Transdermal patches 585 micrograms (releasing approximately 37.5 micrograms per 24 hours), 8	‡1	5	..	16.22	17.21	^b Estradot 37.5	NV
8012Q	Transdermal patches 3.28 mg (releasing approximately 37.5 micrograms per 24 hours), 8	‡1	5	^B 1.50	17.72	17.21	^b Menorest 37.5	NV
NOTE:								
<i>Bioequivalence has been demonstrated between Estradot 37.5 and Menorest 37.5 patches.</i>								

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—cont.								
8140K	Transdermal patches 1.5 mg (releasing approximately 50 micrograms per 24 hours), 8	‡1	5	..	16.22	17.21	Estraderm MX 50	NV
8125P	Transdermal patches 3.8 mg (releasing approximately 50 micrograms per 24 hours), 4	‡1	5	..	16.22	17.21	^a Climara 50 ^a Femtran 50	SC MM
1744T	Transdermal patches 4 mg (releasing approximately 50 micrograms per 24 hours), 8	‡1	5	..	16.22	17.21	Estraderm 50	NV
8763F	Transdermal patches 780 micrograms (releasing approximately 50 micrograms per 24 hours), 8	‡1	5	..	16.22	17.21	^b Estradot 50	NV
8013R	Transdermal patches 4.33 mg (releasing approximately 50 micrograms per 24 hours), 8	‡1	5	^B 1.50	17.72	17.21	^b Menorest 50	NV
NOTE: Bioequivalence has been demonstrated between Estradot 50 and Menorest 50 patches.								
8486P	Transdermal patches 5.7 mg (releasing approximately 75 micrograms per 24 hours), 4	‡1	5	..	18.33	19.32	Climara 75	SC
8764G	Transdermal patches 1.17 mg (releasing approximately 75 micrograms per 24 hours), 8	‡1	5	..	18.33	19.32	^b Estradot 75	NV
8014T	Transdermal patches 6.57 mg (releasing approximately 75 micrograms per 24 hours), 8	‡1	5	^B 1.49	19.82	19.32	^b Menorest 75	NV
NOTE: Bioequivalence has been demonstrated between Estradot 75 and Menorest 75 patches.								
8312L	Transdermal patches 3 mg (releasing approximately 100 micrograms per 24 hours), 8	‡1	5	..	18.33	19.32	Estraderm MX 100	NV
8126Q	Transdermal patches 7.6 mg (releasing approximately 100 micrograms per 24 hours), 4	‡1	5	..	18.33	19.32	^a Climara 100 ^a Femtran 100	SC MM

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—cont.								
1745W	Transdermal patches 8 mg (releasing approximately 100 micrograms per 24 hours), 8	‡1	5	..	18.33	19.32	Estraderm 100	NV
8765H	Transdermal patches 1.56 mg (releasing approximately 100 micrograms per 24 hours), 8	‡1	5	..	18.33	19.32	^b Estradot 100	NV
8041F	Transdermal patches 8.66 mg (releasing approximately 100 micrograms per 24 hours), 8	‡1	5	^B 1.49	19.82	19.32	^b Menorest 100	NV
NOTE: <i>Bioequivalence has been demonstrated between Estradot 100 and Menorest 100 patches.</i>								
OESTRADIOL HEMIHYDRATE								
Restricted benefit								
<i>For use for post-menopausal symptoms where a trial of peri- or post-menopausal low-dose oestrogen therapy has demonstrated intolerance to oral oestrogens.</i>								
NOTE: <i>Oestradiol should be used in conjunction with an oral progestogen in women with an intact uterus.</i>								
8645B	Nasal spray 150 micrograms per actuation, 60 actuations, 4.2 mL	‡1	5	..	19.47	20.46	Aerodiol	SE
OESTRADIOL VALERATE								
1663M	Tablet 1 mg	56	2	..	10.60	11.59	Progynova	SC
1664N	Tablet 2 mg	56	2	..	12.91	13.90	Progynova	SC
OESTRIOL								
1771F	Pessaries 500 micrograms, 15	‡1	2	..	19.34	20.33	Ovestin Ovula	OR
1781R	Vaginal cream 1 mg per g (0.1%), 15 g	‡1	1	..	16.17	17.16	Ovestin	OR
OESTROGENS—CONJUGATED								
1733F	Tablet 300 micrograms	56	2	..	*12.47	13.46	Premarin	WY
1734G	Tablet 625 micrograms	56	2	..	*12.93	13.92	Premarin	WY
PIPERAZINE OESTRONE SULFATE								
1777M	Tablet 730 micrograms (equivalent to 625 micrograms sodium oestrone sulfate)	56	2	.. ^B 1.43	10.60 12.03	11.59 11.59	^a Genoral 0.625 ^a Ogen .625	KR PH
1778N	Tablet 1.46 mg (equivalent to 1.25 mg sodium oestrone sulfate)	56	2	.. ^B 1.45	12.91 14.36	13.90 13.90	^a Genoral 1.25 ^a Ogen 1.25	KR PH

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	
Progestogens								
• Pregnen (4) derivatives								
MEDROXYPROGESTERONE ACETATE								
2323G	Tablet 5 mg	56	2	.. ^B 1.71	13.73 15.44	14.72 14.72	^a Ralovera ^a Provera	KR PH
2321E	Tablet 10 mg	30	2	.. ^B 1.70	14.36 16.06	15.35 15.35	^a Medroxyhexal ^a Ralovera ^a Provera	HX KR PH
2319C	Injection 50 mg in 1 mL	1	1	..	10.51	11.50	Depo-Provera	PH
MEDROXYPROGESTERONE ACETATE								
<u>Restricted benefit</u>								
<u>Endometriosis.</u>								
2722G	Tablet 10 mg	100	2	.. ^B 1.59	30.33 31.92	30.70 30.70	^a Ralovera ^a Provera	KR PH
[For other listings for this drug see Generic/Proprietary Index]								
• Pregnadien derivatives								
DYDROGESTERONE								
1350C	Tablet 10 mg	28	2	..	13.73	14.72	Duphaston	SM
• Estren derivatives								
NORETHISTERONE								
2993M	Tablet 5 mg	30	2	..	31.63	30.70	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	..	16.15	17.14	Kliovance	NO
8081H	Tablets 2 mg-1 mg, 28	‡1	5	..	16.15	17.14	Kliogest	NO
OESTRADIOL with NORETHISTERONE ACETATE								
<u>Restricted benefit</u>								
<i>For use for post-menopausal symptoms where a trial of peri- or post-menopausal low-dose oestrogen therapy has demonstrated intolerance to oral oestrogens.</i>								
8427M	Transdermal patches 620 micrograms-2.7 mg (releasing approximately 50 micrograms- 140 micrograms per 24 hours), 8	‡1	5	..	18.33	19.32	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	..	18.33	19.32	Estalis continuous 50/250	NV

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	
8168X	OESTROGENS—CONJUGATED with MEDROXYPROGESTERONE ACETATE Tablets 625 micrograms-2.5 mg, 28	1	5	..	16.15	17.14	Premia 2.5 Continuous	WY
8169Y	Tablets 625 micrograms-5 mg, 28	1	5	..	16.15	17.14	Premia 5 Continuous	WY
• Progestogens and estrogens, sequential preparations								
8244X	OESTRADIOL and OESTRADIOL with DYDROGESTERONE Pack containing 14 tablets oestradiol 2 mg and 14 tablets oestradiol 2 mg with dydrogesterone 10 mg	1	5	..	16.15	17.14	Femoston 2/10	SM
1764W	OESTRADIOL and OESTRADIOL with NORETHISTERONE ACETATE 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	..	16.15	17.14	Trisequens	NO
OESTRADIOL and OESTRADIOL with NORETHISTERONE ACETATE								
<u>Restricted benefit</u>								
<i>For use for post-menopausal symptoms where a trial of peri- or post-menopausal low-dose oestrogen therapy has demonstrated intolerance to oral oestrogens.</i>								
8425K	Pack containing 4 transdermal patches oestradiol 4.33 mg (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	..	18.33	19.32	Estalis sequi 50/140	NV
8426L	Pack containing 4 transdermal patches oestradiol 4.33 mg (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	..	18.33	19.32	Estalis sequi 50/250	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	
OESTRADIOL and OESTRADIOL with NORETHISTERONE ACETATE—cont.								
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	..	18.33	19.32	Estracombi	NV
Gonadotropins and other ovulation stimulants Gonadotropins FOLLITROPIN ALFA Restricted benefit Anovulatory infertility. NOTE: <i>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.</i> <i>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.</i> <i>Oligomenorrhoea should have been present for at least twelve months or amenorrhoea for at least six months prior to treatment.</i> <i>Patients with hyperprolactinaemia should have had appropriate surgical or medical treatment prior to treatment.</i>								
8672K	Injection set containing 1 vial powder for injection 75 i.u. and 1 pre-filled syringe solvent 1 mL	5	5	..	*246.30	30.70	Gonal-f 75	SG
8673L	Injection set containing 10 vials powder for injection 75 i.u. and 10 pre-filled syringes solvent 1 mL	1	5	..	469.41	30.70	Gonal-f 75	SG
8713N	Injection 300 i.u. in 0.5 mL multi-dose cartridge	3	5	..	*562.16	30.70	Gonal-f Pen	SG
8675N	Injection set containing 1 vial powder for injection 450 i.u. and 1 pre-filled syringe solvent 1 mL	3	5	..	*840.62	30.70	Gonal-f	SG
8714P	Injection 450 i.u. in 0.75 mL multi-dose cartridge	3	5	..	*840.65	30.70	Gonal-f Pen	SG
8715Q	Injection 900 i.u. in 1.5 mL multi-dose cartridge	2	5	..	*1111.33	30.70	Gonal-f Pen	SG

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	
FOLLITROPIN ALFA—cont.								
8674M	Injection set containing 1 vial powder for injection 1,050 i.u. and 1 pre-filled syringe solvent 2 mL	1	5	..	654.92	30.70	Gonal-f	SG
Restricted benefit <i>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.</i>								
8673L	Injection set containing 10 vials powder for injection 75 i.u. and 10 pre-filled syringes solvent 1 mL	1	5	..	469.41	30.70	Gonal-f 75	SG
8713N	Injection 300 i.u. in 0.5 mL multi-dose cartridge	3	5	..	*562.16	30.70	Gonal-f Pen	SG
8675N	Injection set containing 1 vial powder for injection 450 i.u. and 1 pre-filled syringe solvent 1 mL	3	5	..	*840.62	30.70	Gonal-f	SG
8714P	Injection 450 i.u. in 0.75 mL multi-dose cartridge	3	5	..	*840.65	30.70	Gonal-f Pen	SG
8715Q	Injection 900 i.u. in 1.5 mL multi-dose cartridge	2	5	..	*1111.33	30.70	Gonal-f Pen	SG
FOLLITROPIN BETA								
Restricted benefit <i>Anovulatory infertility.</i>								
NOTE: <i>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.</i>								
<i>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.</i>								
<i>Oligomenorrhoea should have been present for at least twelve months or amenorrhoea for at least six months prior to treatment.</i>								
<i>Patients with hyperprolactinaemia should have had appropriate surgical or medical treatment prior to treatment.</i>								
Restricted benefit <i>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.</i>								
8565T	Solution for injection 300 i.u. in 0.36 mL multi-dose cartridge	3	5	..	*562.16	30.70	Puregon 300 IU/0.36 mL	OR

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	
FOLLITROPIN BETA—cont.								
8566W	Solution for injection 600 i.u. in 0.72 mL multi-dose cartridge	2	5	..	*747.81	30.70	Puregon 600 IU/ 0.72 mL	OR
8871X	Solution for injection 900 i.u. in 1.08 mL multi-dose cartridge	2	5	..	*1111.31	30.70	Puregon 900 IU/ 1.08 mL	OR
HUMAN CHORIONIC GONADOTROPHIN								
<u>Restricted benefit</u>								
Anovulatory infertility.								
<u>NOTE:</u>								
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.								
<u>Restricted benefit</u>								
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.								
<u>Restricted benefit</u>								
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	..	28.54	29.53	Pregnyl	OR
1581F	Injection set containing 3 ampoules powder for injection 1,500 units and 3 ampoules solvent 1 mL	1	5	..	37.78	30.70	Pregnyl	OR
<u>Restricted benefit</u>								
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	..	*51.93	30.70	Pregnyl	OR

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
• Ovulation stimulants, synthetic CLOMIPHENE CITRATE NOTE: <i>Care must be taken to comply with the provisions of State/Territory law when prescribing clomiphene citrate.</i> Restricted benefit <i>Anovulatory infertility; Patients undergoing in-vitro fertilisation.</i>							
1211R	Tablet 50 mg	10	5	..	*39.17	30.70	^a Clomhexal HX ^a Fermil AW ^a GenRx GX Clomiphene ^a Serophene SG ^a Clomid AV
					^B 0.18 39.35	30.70	
					^B 3.61 42.78	30.70	
Antiandrogens • Antiandrogens, plain preparations CYPROTERONE ACETATE Authority required <i>Moderate to severe androgenisation in non-pregnant women (acne alone is not a sufficient indication of androgenisation).</i> CAUTION: <i>This drug should not be used during pregnancy as it may result in feminisation of the male foetus.</i>							
1269T	Tablet 50 mg	20	5	..	66.49	30.70	^a Cyprohexal HX ^a Cyprone AF ^a Cyprostat SY ^a GenRx GX Cyproterone Acetate ^a Procur GM ^a Androcur SC
					^B 4.58 71.07	30.70	
Authority required <i>Advanced carcinoma of the prostate; To reduce drive in sexual deviations in males.</i>							
1270W	Tablet 50 mg	100	5	..	*267.55	30.70	^a Cyprohexal HX ^a Cyprone AF ^a Cyprostat SY ^a GenRx GX Cyproterone Acetate ^a Procur GM ^a Androcur SC
					^B 4.00 *271.55	30.70	
8019C	Tablet 100 mg	50	5	..	221.13	30.70	^a Cyprohexal HX ^a Cyprostat-100 SY ^a GenRx GX Cyproterone Acetate ^a Procur 100 GM ^a Androcur-100 SC
					^B 2.01 223.14	30.70	

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:								
<i>Pregnancy must be excluded prior to administration of this drug.</i>								
Authority required								
<i>Endometriosis, visually proven;</i>								
<i>Hereditary angio-oedema;</i>								
<i>Short-term treatment (up to 6 months) of intractable primary menorrhagia (not more than 6 months' therapy will be authorised);</i>								
<i>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 (not more than 6 months' therapy will be authorised).</i>								
1285P	Capsule 100 mg	100	5	..	57.31	30.70	Azol 100	AF
1287R	Capsule 200 mg	100	5	..	85.70	30.70	Azol 200	AF
GESTRINONE								
Authority required								
<i>Short-term treatment (up to 6 months) of visually proven endometriosis (only 1 course of not more than 6 months' therapy will be authorised).</i>								
8015W	Capsule 2.5 mg	8	5	..	76.68	30.70	Dimetriose	AV
• Selective estrogen receptor modulators								
RALOXIFENE HYDROCHLORIDE								
<i>For listings see Generic/Proprietary Index</i>								
UROLOGICALS								
Other urologicals, incl. antispasmodics								
• Urinary antispasmodics								
OXYBUTYNIN HYDROCHLORIDE								
Restricted benefit								
<i>Detrusor overactivity where propantheline bromide has failed.</i>								
8039D	Tablet 5 mg	100	5	..	15.80	16.79	Ditropan	AV
PROPANTHELINE BROMIDE								
Restricted benefit								
<i>Detrusor overactivity.</i>								
1953T	Tablet 15 mg	200	5	..	*24.31	25.30	Pro-Banthine	SI
• Other urologicals								
PHENOXYBENZAMINE								
HYDROCHLORIDE								
Restricted benefit								
<i>Phaeochromocytoma;</i>								
<i>Neurogenic urinary retention.</i>								
1862B	Capsule 10 mg	100	5	..	51.13	30.70	Dibenyline	GH

SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS

Code	Name, Restriction, Manner of 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								
2832C	TETRACOSACTRIN Injection 1 mg in 1 mL	5	5	..	*70.00	30.70	Synacthen Depot 1 mg/1 mL	NV
Posterior pituitary lobe hormones								
• Vasopressin and analogues								
DESMOPRESSIN ACETATE								
Authority required								
<i>Cranial diabetes insipidus.</i>								
8662X	Tablet 200 micrograms	90	5	..	*150.08	30.70	Minirin	FP
2129C	Intranasal solution 100 micrograms per mL, 2.5 mL	5	5	..	*159.90	30.70	Minirin	FP
8711L	Nasal spray (pump pack) 10 micrograms per actuation, 60 actuations, 6 mL	2	5	..	*159.77	30.70	Minirin Nasal Spray	FP
Authority required								
<i>Primary nocturnal enuresis in patients aged 6 years or older:</i>								
<i>(1) who are refractory to an enuresis alarm; or</i>								
<i>(2) for whom an enuresis alarm is contraindicated. The reason that an alarm is</i>								
<i>contraindicated must be included in the authority application.</i>								
NOTE:								
<i>Not to be used in preference to enuresis alarms.</i>								
8663Y	Tablet 200 micrograms	30	5	..	53.46	30.70	Minirin	FP
NOTE:								
<i>Only one application per six months with no more than twice the maximum quantity will be</i>								
<i>authorised for the tablets.</i>								
8712M	Nasal spray (pump pack) 10 micrograms per actuation, 60 actuations, 6 mL	1	5	..	82.46	30.70	Minirin Nasal Spray	FP
Hypothalamic hormones								
• Gonadotropin-releasing hormones								
NAFARELIN ACETATE								
Authority required								
<i>Initial treatment (up to 6 months) of visually proven endometriosis;</i>								
<i>Subsequent treatment (up to 6 months) of visually proven endometriosis, where 2 years or</i>								
<i>more have elapsed since the end of the previous course and where a recent bone density</i>								
<i>assessment has been made. The date of the assessment must be provided.</i>								
2962X	Nasal spray (pump pack) 200 micrograms (base) per dose (60 doses)	1	5	..	94.24	30.70	Synarel	PH

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	
CORTICOSTEROIDS FOR SYSTEMIC USE								
Corticosteroids for systemic use, plain								
• Mineralocorticoids								
	FLUDROCORTISONE ACETATE							
1433K	Tablet 100 micrograms	200	1	..	*16.83	17.82	Florinef	BQ
• Glucocorticoids								
BETAMETHASONE ACETATE with BETAMETHASONE SODIUM PHOSPHATE								
<u>Restricted benefit</u>								
<i>Alopecia areata;</i>								
<i>For local intra-articular or peri-articular infiltration;</i>								
<i>Granulomata, dermal;</i>								
<i>Keloid;</i>								
<i>Lichen planus hypertrophic;</i>								
<i>Lichen simplex chronicus;</i>								
<i>Lupus erythematosus, chronic discoid;</i>								
<i>Necrobiosis lipoidica;</i>								
<i>Uveitis.</i>								
2694T	Injection 3 mg-3.9 mg (equivalent to 5.7 mg betamethasone) in 1 mL	5	..	..	24.42	25.41	Celestone Chronodose	SH
CORTISONE ACETATE								
1246N	Tablet 5 mg	50	4	..	13.04	14.03	Cortate	AS
1247P	Tablet 25 mg	60	4	..	14.79	15.78	Cortate	AS
DEXAMETHASONE								
1292B	Tablet 500 micrograms	30	4	..	7.32	8.31	Dexamethsone	AS
2507Y	Tablet 4 mg	30	4	..	10.65	11.64	Dexamethsone	AS
DEXAMETHASONE SODIUM PHOSPHATE								
2509C	Injection equivalent to 4 mg dexamethasone phosphate in 1 mL	5	..	..	13.95	14.94	MX	
1291Y	Injection equivalent to 8 mg dexamethasone phosphate in 2 mL	5	1	..	21.01	22.00	MX	
2508B	Injection equivalent to 120 mg dexamethasone phosphate in 5 mL	1	..	..	73.47	30.70	MX	
HYDROCORTISONE								
1499X	Tablet 4 mg	50	4	..	9.80	10.79	Hysone 4	AF
1500Y	Tablet 20 mg	60	4	..	13.36	14.35	Hysone 20	AF

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	
HYDROCORTISONE SODIUM SUCCINATE								
1501B	Injection equivalent to 100 mg hydrocortisone with 2 mL solvent	2	..	..	*15.61	16.60	Solu-Cortef	PH
3096Y	Injection equivalent to 250 mg hydrocortisone with 2 mL solvent	1	..	..	14.61	15.60	Solu-Cortef	PH
<i>HYDROCORTISONE SODIUM SUCCINATE</i>								
<i>Restricted benefit</i>								
<i>For use in a hospital.</i>								
1510L	Injection equivalent to 100 mg hydrocortisone with 2 mL solvent	6	..	..	*36.53	30.70	Solu-Cortef	PH
1511M	Injection equivalent to 250 mg hydrocortisone with 2 mL solvent	6	..	..	*61.91	30.70	Solu-Cortef	PH
<i>METHYLPREDNISOLONE ACETATE</i>								
<i>Restricted benefit</i>								
<i>For local intra-articular or peri-articular infiltration.</i>								
1928L	Injection 40 mg in 1 mL	5	..	..	23.10	24.09	<i>a Depo-Nisolone</i>	KR
				<i>B0.74</i>	23.84	24.09	<i>a Depo-Medrol</i>	PH
METHYLPREDNISOLONE SODIUM SUCCINATE								
2981X	Powder for injection equivalent to 40 mg methylprednisolone with diluent	5	..	..	31.66	30.70	Solu-Medrol	PF
8834Y	Powder for injection equivalent to 1 g methylprednisolone with diluent	1	..	..	99.72	30.70	Solu-Medrol	PF
PREDNISOLONE								
3152X	Tablet 1 mg	100	4	..	7.45	8.44	<i>a</i> Predsolone	LN
				<i>B0.59</i>	8.04	8.44	<i>a</i> Panafcortelone	AS
1917X	Tablet 5 mg	60	4	..	7.91	8.90	Panafcortelone Solone	AS FM
1916W	Tablet 25 mg	30	4	..	10.13	11.12	Panafcortelone Solone	AS FM
PREDNISOLONE SODIUM PHOSPHATE								
8285C	Oral solution equivalent to 5 mg prednisolone per mL, 30 mL	1	5	..	12.92	13.91	<i>a</i> PredMix	LN
				<i>B1.78</i>	14.70	13.91	<i>a</i> Redipred	AS

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	
1934T	PREDNISONE Tablet 1 mg	100	4	.. B0.59	7.45 8.04	8.44 8.44	^a Predsone ^a Panafcort	LN AS
1935W	Tablet 5 mg	60	4	..	7.91	8.90	Panafcort Sone	AS FM
1936X	Tablet 25 mg	30	4	..	10.13	11.12	Panafcort Sone	AS FM
TRIAMCINOLONE ACETONIDE								
<u>Restricted benefit</u>								
<i>Alopecia areata; For local intra-articular or peri-articular infiltration; Granulomata, dermal; Keloid; Lichen planus hypertrophic; Lichen simplex chronicus; Lupus erythematosus, chronic discoid; Necrobiosis lipidica; Psoriasis.</i>								
2990J	Injection 10 mg in 1 mL	5	..	..	24.42	25.41	Kenacort-A10	BQ
Antiadrenal preparations								
• Anticorticosteroids								
1036M	AMINOGLUTETHIMIDE Tablet 250 mg	100	5	..	158.33	30.70	Cytadren 250	NV
THYROID THERAPY								
Thyroid preparations								
• Thyroid hormones								
LIOTHYRONINE SODIUM								
<u>Authority required</u>								
<i>Management of patients with thyroid cancer; Replacement therapy for hypothyroid patients who have documented intolerance to thyroxine sodium; Replacement therapy for hypothyroid patients who have documented resistance to thyroxine sodium; Initiation of thyroid therapy in severely hypothyroid patients.</i>								
2318B	Tablet 20 micrograms	100	2	..	81.00	30.70	Tertroxin	SI
2174K	THYROXINE SODIUM Tablet equivalent to 50 micrograms anhydrous thyroxine sodium	200	1	.. B1.27	20.02 21.29	21.01 21.01	^a Eutroxsig ^a Oroxine	FM SI
2175L	Tablet equivalent to 100 micrograms anhydrous thyroxine sodium	200	1	.. B1.27	21.07 22.34	22.06 22.06	^a Eutroxsig ^a Oroxine	FM SI
2173J	Tablet equivalent to 200 micrograms anhydrous thyroxine sodium	200	1	.. B1.26	26.28 27.54	27.27 27.27	^a Eutroxsig ^a Oroxine	FM SI

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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	
Antithyroid preparations								
• Thiouracils								
1955X	PROPYLTHIOURACIL Tablet 50 mg	200	2	..	*45.55	30.70	PL	
• Sulfur-containing imidazole derivatives								
1153Q	CARBIMAZOLE Tablet 5 mg	200	2	..	*28.69	29.68	Neo-Mercazole	RO
PANCREATIC HORMONES								
Glycogenolytic hormones								
• Glycogenolytic hormones								
1449G	GLUCAGON HYDROCHLORIDE Injection set containing 1 mg (1 i.u.) and 1 mL solvent in disposable syringe	1	1	..	39.38	30.70	GlucaGen Hypokit	NO
CALCIUM HOMEOSTASIS								
Anti-parathyroid agents								
• Calcitonin preparations								
SALCATONIN								
NOTE:								
<i>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.</i>								
Authority required								
<i>Symptomatic Paget's disease of bone;</i>								
<i>Treatment initiated in a hospital (in-patient or out-patient) of hypercalcaemia.</i>								
2995P	Injection 50 i.u. in 1 mL	30	5	..	*206.39	30.70	Miacalcic 50	NV
2997R	Injection 100 i.u. in 1 mL	15	5	..	*159.86	30.70	Miacalcic 100	NV

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							
2709N	Tablet 100 mg	7	1	..	7.76	8.75	^a Chem mart CH Doxycycline ^a Doxsig SI ^a Doxy-100 GM ^a Doxyhexal SZ ^a Doxylin 100 AF ^a GenRx GX Doxycycline ^a Terry White TW Chemists Doxycycline ^a Vibramycin PF
2708M	Capsule 100 mg	7	1	..	7.76	8.75	^a DBL Doxycycline FA ^B 1.53 9.29 8.75 ^B 1.46 9.22 8.75 ^a Doryx MX
DOXYCYCLINE							
<u>Restricted benefit</u>							
<i>Bronchiectasis in patients aged 8 years or older; Chronic bronchitis in patients aged 8 years or older; Severe acne.</i>							
2711Q	Tablet 50 mg	25	5	..	9.80	10.79	^a Chem mart CH Doxycycline ^a Doxy-50 GM ^a Doxyhexal SZ ^a Doxylin 50 AF ^a Frakas AW ^a GenRx GX Doxycycline ^a Terry White TW Chemists Doxycycline ^B 1.60 11.40 10.79 ^a Vibra-Tabs PF
2707L	Capsule 50 mg	25	5	..	9.80	10.79	^a DBL FA Doxycycline ^B 1.66 11.46 10.79 ^a Doryx MX

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	
DOXYCYCLINE—cont.								
<u>Restricted benefit</u>								
<i>Pelvic inflammatory disease.</i>								
2702F	Tablet 100 mg	28	..	..	*15.59	16.58	^a Chem mart Doxycycline	CH
							^a Doxsig	SI
							^a Doxy-100	GM
							^a Doxyhexal	SZ
							^a Doxylin 100	AF
							^a GenRx	GX
							^a Doxycycline	
							^a Terry White Chemists	TW
							^a Doxycycline	
				^B 6.12	*21.71	16.58	^a Vibramycin	PF
2703G	Capsule 100 mg	28	..	..	*15.59	16.58	^a DBL	FA
							^a Doxycycline	
				^B 5.84	*21.43	16.58	^a Doryx	MX
<u>Restricted benefit</u>								
<i>Urethritis.</i>								
2714W	Tablet 100 mg	21	..	..	*12.98	13.97	^a Chem mart Doxycycline	CH
							^a Doxsig	SI
							^a Doxy-100	GM
							^a Doxyhexal	SZ
							^a Doxylin 100	AF
							^a Terry White Chemists	TW
							^a Doxycycline	
				..	12.98	13.97	^a GenRx	GX
				^B 4.59	*17.57	13.97	^a Doxycycline	
							^a Vibramycin	PF
2715X	Capsule 100 mg	21	..	..	12.93	13.92	^a DBL	FA
							^a Doxycycline	
				^B 2.66	15.59	13.92	^a Doryx	MX

MINOCYCLINE

CAUTION:

There are concerns about the incidence of benign intracranial hypertension associated with this drug.

3037W	Capsule 100 mg	11	..	..	9.28	10.27	Akamin 100	AF

NOTE:

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

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	
MINOCYCLINE—cont.								
CAUTION:								
<i>There are concerns about the incidence of benign intracranial hypertension associated with this drug.</i>								
Restricted benefit								
<i>Severe acne not responding to other tetracyclines.</i>								
NOTE:								
<i>No applications for increased maximum quantities and/or repeats will be authorised.</i>								
1616C	Tablet 50 mg	60	5	..	16.72	17.71	^a Akamin 50	AF
				^B 1.08	17.80	17.71	^a Minomycin-50	SI
Beta-lactam antibacterials, penicillins								
• Penicillins with extended spectrum								
AMOXYCILLIN								
1883D	Chewable tablet 250 mg	20	1	..	8.73	9.72	Amoxil	GK
1884E	Capsule 250 mg	20	1	..	7.87	8.86	^a Alphamox 250	AF
							^a Amohexal	HX
							^a Amoxycillin-DP	GM
							^a Chem mart	CH
							Amoxycillin	
							^a Cilamox	SI
							^a GenRx	GX
							Amoxycillin	
							^a Moxacin	CS
							^a Terry White	TW
							Chemists	
							Amoxycillin	
				^B 1.00	8.87	8.86	^a Amoxil	GK
1889K	Capsule 500 mg	20	1	..	10.55	11.54	^a Alphamox 500	AF
							^a Amohexal	HX
							^a Amoxycillin-DP	GM
							^a Chem mart	CH
							Amoxycillin	
							^a Cilamox	SI
							^a GenRx	GX
							Amoxycillin	
							^a Moxacin	CS
							^a Terry White	TW
							Chemists	
							Amoxycillin	
				^B 1.00	11.55	11.54	^a Amoxil	GK
1878W	Sachet containing oral powder 3 g	1	..	..	8.58	9.57	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
AMOXYCILLIN—cont.							
1886G	Powder for syrup 125 mg per 5 mL, 100 mL	‡1	1	..	#10.02	11.40	^a Alphamox 125 AF ^a Amohexal HX ^a Bgramin GM ^a Chem mart CH Amoxycillin ^a GenRx GX Amoxycillin ^a Moxacin CS ^a Terry White TW Chemists Amoxycillin
				^B 1.22	#11.24	11.40	^a Amoxil GK
1887H	Powder for syrup 250 mg per 5 mL, 100 mL	‡1	1	..	#11.09	12.47	^a Alphamox 250 AF ^a Amohexal HX ^a Bgramin GM ^a Chem mart CH Amoxycillin ^a Cilamox SI ^a GenRx GX Amoxycillin ^a Terry White TW Chemists Amoxycillin
				^B 1.01	#12.10	12.47	^a Amoxil Forte GK
8705E	Powder for oral suspension 500 mg per 5 mL, 100 mL	‡1	1	..	#13.80	15.18	Maxamox SZ

See Special Pharmaceutical Benefits for listing for amoxycillin powder for paediatric oral drops.

AMOXYCILLIN**Restricted benefit**

Acute exacerbations of chronic bronchitis.

8581P	Tablet 1 g	14	1	..	10.72	11.71	^a Amoxycillin Sandoz ^B 1.49 12.21 ^a 11.71 ^a Amoxil Duo ^a Maxamox	BG GK SZ
AMPICILLIN								
1048E	Capsule 250 mg	24	1	..	8.87	9.86	Alphacin 250	AF
2671N	Capsule 500 mg	24	..	..	12.12	13.11	Alphacin 500	AF
2390T	Powder for injection 500 mg	5	1	..	11.09	12.08	^a Austrapen ^a Ibimicyn	LN GM
2977Q	Powder for injection 1 g	5	1	..	14.90	15.89	^a Aspen Ampicyn ^a Austrapen ^a Ibimicyn	AS LN GM

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	
• Beta-lactamase sensitive penicillins								
BENZATHINE PENICILLIN								
8167W	Injection 900 mg in 2 mL cartridge-needle unit (for use with Tubex Injector)	1	..	..	25.43	26.42	Bicillin L-A Tubex	AS
9002T	Powder for injection 900 mg (1,200,000 i.u.)	1	..	..	*42.36	30.70	Pan Benzathine Benzyl- penicillin	AS
BENZATHINE PENICILLIN								
<u>Restricted benefit</u>								
<i>Syphilis.</i>								
8743E	Injection 900 mg in 2 mL cartridge-needle unit (for use with Tubex Injector)	2	..	..	*45.71	30.70	Bicillin L-A Tubex	AS
9003W	Powder for injection 900 mg (1,200,000 i.u.)	2	..	..	*70.74	30.70	Pan Benzathine Benzyl- penicillin	AS
BENZYL PENICILLIN								
1775K	Powder for injection 600 mg	10	1	..	*22.09	23.08	BenPen	CS
2647H	Powder for injection 3 g	10	..	..	*49.43	30.70	BenPen	CS
PHENOXYMETHYLPENICILLIN								
1787C	Tablet 250 mg	50	..	..	*11.71	12.70	Abbocillin-VK Filmtab	SI
3028J	Tablet 500 mg	50	..	..	*14.89	15.88	Abbocillin-VK Filmtab	SI
1789E	Capsule 250 mg	50	..	..	11.51	12.50	^a Cilicaine VK ^a Cilopen VK LPV ^a Penhexal VK	FM GM CS HX
2965C	Capsule 500 mg	50	..	..	14.61	15.60	^a Cilicaine VK ^a Cilopen VK LPV ^a Penhexal VK	FM GM CS HX
2356B	Paediatric oral suspension 125 mg per 5 mL, 100 mL	2	..	.. ^B 1.82	*12.49 *14.31	13.48 13.48	^a Cilicaine V ^a Abbocillin-V	FM SI
2354X	Oral suspension 250 mg per 5 mL, 100 mL	2	..	.. ^B 1.80	*15.19 *16.99	16.18 16.18	^a Cilicaine V ^a Abbocillin-V	FM SI
PHENOXYMETHYLPENICILLIN								
<u>Restricted benefit</u>								
<i>Prophylaxis of recurrent streptococcal infections (including rheumatic fever).</i>								
1703P	Tablet 250 mg	50	5	..	*11.71	12.70	Abbocillin-VK Filmtab	SI

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	
PHENOXYMETHYLPENICILLIN—cont.								
1705R	Capsule 250 mg	50	5	..	11.51	12.50	^a Cilicaine VK ^a Cilopen VK ^a LPV ^a Penhexal VK	FM GM CS HX
1794K	PROCAINE PENICILLIN Injection 1.5 g	5	..	..	51.35	30.70	Cilicaine	SI
• Beta-lactamase resistant penicillins								
DICLOXACILLIN								
8123M	Powder for injection 500 mg	5	..	..	16.83	17.82	Diclocil	BQ
8124N	Powder for injection 1 g	5	1	..	23.49	24.48	Diclocil	BQ
DICLOXACILLIN								
Restricted benefit								
Serious staphylococcal infections.								
8121K	Capsule 250 mg	24	..	..	11.56	12.55	^a Diclocil ^a Dicloxsig ^a Distaph 250	BQ SI AF
8122L	Capsule 500 mg	24	..	..	18.57	19.56	^a Diclocil ^a Dicloxsig ^a Distaph 500	BQ SI 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	..	..	16.72	17.71	^a Flopen ^a Flubiclox	CS GM
1525G	Powder for injection 1 g	5	1	..	23.30	24.29	^a Aspen Flucil ^a Flopen ^a Flubiclox ^a MX	AS CS GM
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	24	..	..	11.56	12.55	^a Flopen ^a Floxsig ^a Staphylex 250 ^a Floxapen	CS SI AF GK
				^b 0.45	12.01	12.55		
1527J	Capsule 500 mg	24	..	..	18.57	19.56	^a Flopen ^a Floxsig ^a Staphylex 500 ^a Floxapen	CS SI AF GK
				^b 0.57	19.14	19.56		

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—cont.								
1528K	Powder for syrup 125 mg per 5 mL, 100 mL	‡1	..	..	#13.38	14.76	Floxapen	GK
1529L	Powder for syrup 250 mg per 5 mL, 100 mL	‡1	..	..	#16.98	18.36	^a Flopen	CS
				^B 0.09	#17.07	18.36	^a Floxapen	GK
• Combinations of penicillins, incl. beta-lactamase inhibitors								
AMOXYCILLIN with CLAVULANIC ACID								
CAUTION:								
<i>Hepatotoxicity has been reported with this drug.</i>								
Restricted benefit								
<i>Infections where resistance to amoxycillin is suspected;</i>								
<i>Infections where resistance to amoxycillin is proven.</i>								
1891M	Tablet 500 mg-125 mg	10	1	..	12.47	13.46	^a Clamohexal Duo 500mg/125mg	HX
							^a Clamoxyl Duo	AL
							^a Clavulin Duo	ME
							^a Curam 500/125	SZ
							^a Muric 500/125	SL
				^B 0.99	13.46	13.46	^a Augmentin Duo	GK
8254K	Tablet 875 mg-125 mg	10	1	..	15.58	16.57	^a Chem mart Amoxycillin and Clavu- lanic Acid	CH
							^a Clamohexal Duo Forte 875mg/125mg	HX
							^a Clamoxyl Duo forte	AL
							^a Clavulin Duo Forte	ME
							^a Curam 875/125	SZ
							^a GenRx Amoxycillin and Clavu- lanic Acid	GX
							^a Muric 875/125	SL
							^a Terry White Chemists Amoxycillin and Clavu- lanic Acid	TW
				^B 1.30	16.88	16.57	^a Augmentin Duo forte	GK
1892N	Powder for syrup 125 mg- 31.25 mg per 5 mL, 75 mL	‡1	1	..	#12.10	13.48	^a Clamohexal 125mg/ 31.25mg/5mL	HX
							^a Clamoxyl	AL
							^a Clavulin	ME
				^B 0.96	#13.06	13.48	^a Augmentin	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	
AMOXYCILLIN with CLAVULANIC ACID—cont.								
8319W	Powder for syrup 400 mg- 57 mg per 5 mL, 60 mL	‡1	1	..	#14.02	15.40	^a Clamohexal Duo 400mg/57mg/ 5mL	HX
							^a Clamoxyl Duo 400	AL
							^a Clavulin Duo 400	ME
				^B 0.98	#15.00	15.40	^a Augmentin Duo 400	GK
TICARCILLIN with CLAVULANIC ACID								
Restricted benefit								
<i>Infections where positive bacteriological evidence confirms that this antibiotic is an appropriate therapeutic agent; Septicaemia, suspected; Septicaemia, proven.</i>								
2179Q	Powder for injection 3 g- 100 mg (solvent required) (code 6884H applies to above item with approved solvent)	10	..	..	147.79	30.70	Timentin	GK
Other beta-lactam antibacterials								
• First-generation cephalosporins								
CEPHALEXIN								
3058Y	Capsule 250 mg	20	1	..	8.24	9.23	^a Chem mart Cephalexin	CH
							^a Cilex	GM
							^a GenRx	GX
							Cephalexin	
							^a Ialex	LN
							^a Ibilex 250	AF
							^a Rancef	RA
							^a Sporahexal	HX
							^a Terry White Chemists	TW
							Cephalexin	
				^B 2.39	10.63	9.23	^a Keflex	AS
3119E	Capsule 500 mg	20	1	..	10.69	11.68	^a Chem mart Cephalexin	CH
							^a Cilex	GM
							^a GenRx	GX
							Cephalexin	
							^a Ialex	LN
							^a Ibilex 500	AF
							^a Rancef	RA
							^a Sporahexal	HX
							^a Terry White Chemists	TW
							Cephalexin	
				^B 2.84	13.53	11.68	^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	
CEPHALEXIN—cont.								
3094W	Granules for syrup 125 mg per 5 mL, 100 mL	‡1	1	..	#11.29	12.67	^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 2.47	#13.76	12.67	^a Keflex	AS
3095X	Granules for syrup 250 mg per 5 mL, 100 mL	‡1	1	..	#13.07	14.45	^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
				^B 2.82	#15.89	14.45	^a Keflex	AS
CEPHALOTHIN								
2964B	Powder for injection 1 g	10	1	..	42.72	30.70	^a MX	
				^B 0.28	43.00	30.70	^a Keflin Neutral	AS
CEPHAZOLIN								
<u>Restricted benefit</u>								
<i>Infections where positive bacteriological evidence confirms that this antibiotic is an appropriate therapeutic agent;</i>								
<i>Septicaemia, suspected;</i>								
<i>Septicaemia, proven.</i>								
1256D	Powder for injection 500 mg	10	..	..	*44.03	30.70	MX	
1257E	Powder for injection 1 g	10	..	..	*66.49	30.70	^a Cefazolin Sandoz	SZ
							^a MX	
				^B 2.42	68.91	30.70	^a Kefzol	AS

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
• 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	..	13.41	14.40	a Chem mart CH Cefaclor CD a Douglas GM Cefaclor-CD a GenRx Cefaclor GX CD a Karlor CD LN a Keflor CD AF a Ozcef RA a Terry White TW Chemists Cefaclor CD Ceclor CD AS
2460L	Powder for oral suspension 125 mg per 5 mL, 100 mL	‡1	1	..	#13.41	14.79	a Aclor 125 AW a Chem mart CH Cefaclor a GenRx Cefaclor GX a Keflor AF a Terry White TW Chemists Cefaclor Ceclor AS
2461M	Powder for oral suspension 250 mg per 5 mL, 75 mL	‡1	1	..	#13.82	15.20	a Aclor 250 AW a Chem mart CH Cefaclor a GenRx Cefaclor GX a Keflor AF a Terry White TW Chemists Cefaclor Ceclor AS
8292K	CEFUROXIME AXETIL Tablet 250 mg (base)	14	1	..	14.87	15.86	Zinnat GK
• Third-generation cephalosporins CEFOTAXIME Restricted benefit <i>Infections where positive bacteriological evidence confirms that this antibiotic is an appropriate therapeutic agent; Septicaemia, suspected; Septicaemia, proven.</i>							
1085D	Powder for injection 1 g	10	..	..	25.85	26.84	a MX Cefotaxime SZ Sandoz
1086E	Powder for injection 2 g	10	..	..	43.45	30.70	a MX Cefotaxime SZ Sandoz

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	
CEFTRIAXONE								
<u>Restricted benefit</u>								
<i>Gonorrhoea.</i>								
9058R	Powder for injection 500 mg	1	..	..	9.12	10.11	Ceftriaxone ICP	IZ
<u>Restricted benefit</u>								
<i>Infections where positive bacteriological evidence confirms that this antibiotic is an appropriate therapeutic agent;</i>								
<i>Septicaemia, suspected;</i>								
<i>Septicaemia, proven.</i>								
1783W	Powder for injection 500 mg	5	..	..	*25.00	25.99	Ceftriaxone ICP	IZ
1784X	Powder for injection 1 g	5	..	..	*36.15	30.70	^a Ceftriaxone ICP	IZ
							^a Ceftriaxone Sandoz	SZ
							^a Rocephin	RO
				..	36.15	30.70	^a DBL	MX
							Ceftriaxone	
1785Y	Powder for injection 2 g	5	..	..	*62.70	30.70	^a Ceftriaxone ICP	IZ
							^a Ceftriaxone Sandoz	SZ
							^a DBL	MX
							Ceftriaxone	
							^a Rocephin	RO
• Fourth-generation cephalosporins								
CEFEPIME								
<u>Authority required</u>								
<i>Treatment of febrile neutropenia.</i>								
8315P	Powder for injection 1 g (solvent required) (code 7079N applies to above item with approved solvent)	10	..	..	*182.55	30.70	Maxipime	BQ
8316Q	Powder for injection 2 g (solvent required) (code 7085X applies to above item with approved solvent)	10	..	..	*330.35	30.70	Maxipime	BQ
Sulfonamides and trimethoprim								
• Trimethoprim and derivatives								
TRIMETHOPRIM								
2922T	Tablet 300 mg	7	1	..	7.78	8.77	^a Alprim	AF
				^B 1.32	9.10	8.77	^a Triprim	SI
• Combinations of sulfonamides and trimethoprim, incl. derivatives								
TRIMETHOPRIM with SULFAMETHOXAZOLE								
<u>CAUTION:</u>								
There is an increased risk of severe adverse reactions with this combination in the elderly.								
2949F	Tablet 80 mg-400 mg	10	1	..	8.02	9.01	^a Resprim	AF
							^a Septrin	SI

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	
TRIMETHOPRIM with SULFAMETHOXAZOLE—cont.								
2951H	Tablet 160 mg-800 mg	10	1	..	8.93	9.92	^a Bactrim DS ^a Chem mart Trimethoprim with Sulfame- thoxazole DS ^a GenRx Trimethoprim with Sulfame- thoxazole DS ^a Resprim Forte ^a Terry White Chemists Trimethoprim with Sulfame- thoxazole DS	RO CH GX AF TW SI
				^B 1.41	10.34	9.92	^a Septrin Forte	SI
3103H	Oral suspension 40 mg-200 mg per 5 mL, 100 mL	‡1	1	..	8.51	9.50	^a Bactrim ^a Resprim	RO AF
				^B 1.85	10.36	9.50	^a 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	..	..	21.86	22.85	Zithromax	PF

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

8336R	Tablet 500 mg	2	2	..	21.86	22.85	Zithromax	PF
8201P	Powder for oral suspension 200 mg per 5 mL, 15 mL	‡1	..	..	#21.43	22.81	Zithromax	PF

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	
8318T	CLARITHROMYCIN Tablet 250 mg	14	1	..	13.13	14.12	^a Chem mart ^a Clarithromycin ^a Clarac ^a Clarihexal ^a Clarithro 250 ^a GenRx ^a Clarithromycin ^a Kalixocin ^a Terry White Chemists ^a Clarithromycin ^a Klacid	CH GM HX AW GX AF TW AB
				^B 2.50	15.63	14.12		
1404X	ERYTHROMYCIN Capsule 250 mg	25	1	..	8.99	9.98	^a DBL ^a Erythromycin ^a Eryc	FA MX
				^B 1.72	10.71	9.98		
2750R	ERYTHROMYCIN ETHYL SUCCLINATE Tablet 400 mg (base)	25	1	..	8.67	9.66	^a E-Mycin ^a E.E.S. 400 Filmtab	AF AB
				^B 2.81	11.48	9.66		
2424N	Powder for oral liquid 200 mg (base) per 5 mL, 100 mL	‡1	1	..	#10.77	12.15	^a E-Mycin 200 ^a E.E.S. 200	AF AB
				^B 2.12	#12.89	12.15		
2428T	Powder for oral liquid 400 mg (base) per 5 mL, 100 mL	‡1	1	..	#12.34	13.72	^a E-Mycin 400 ^a E.E.S. Granules	AF AB
				^B 1.71	#14.05	13.72		
1397M	ERYTHROMYCIN LACTOBIONATE Powder for I.V. infusion 1 g (base)	5	..	..	*49.65	30.70	Erythrocin-I.V.	AB
8129W	ROXITHROMYCIN Tablet for oral suspension 50 mg	10	1	..	10.44	11.43	Rulide D	AV
1760P	Tablet 150 mg	10	1	..	11.95	12.94	^a Biaxsig ^a Roxar 150 ^a Roxide ^a Roximycin ^a Rulide	HP AW HX AF AV
				^B 2.42	14.37	12.94		
8016X	Tablet 300 mg	5	1	..	11.95	12.94	^a Biaxsig ^a Roxar 300 ^a Roxide ^a Roximycin ^a Rulide	HP AW HX AF AV
				^B 2.42	14.37	12.94		
• Lincosamides CLINDAMYCIN <u>Restricted benefit</u> <i>Gram-positive coccal infections where these cannot be safely and effectively treated with a penicillin.</i>								
3138E	Capsule 150 mg	25	..	..	18.71	19.70	^a Cleocin ^a Dalacin C	KR PH
				^B 1.41	20.12	19.70		

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	
2530E	LINCOMYCIN Injection 600 mg in 2 mL	5	..	..	28.73	29.72	Lincocin	PH
Aminoglycoside antibacterials								
• Other aminoglycosides								
2824P	GENTAMICIN SULFATE Injection 80 mg (base) in 2 mL	10	1	..	*18.87 18.87	19.86 19.86	^a MX ^a PU	
TOBRAMYCIN SULFATE								
Restricted benefit								
<i>Infections where positive bacteriological evidence confirms that this antibiotic is an appropriate therapeutic agent; Septicaemia, suspected; Septicaemia, proven.</i>								
1356J	Injection 80 mg (base) in 2 mL (with preservative)	10	1	..	*63.75	30.70	MX	
8872Y	Injection 80 mg (base) in 2 mL (without preservative)	10	1	..	*63.75	30.70	PU	
Quinolone antibacterials								
• Fluoroquinolones								
CIPROFLOXACIN								
Restricted benefit								
<i>Gonorrhoea.</i>								
NOTE:								
<i>No applications for increased maximum quantities and/or repeats will be authorised.</i>								
1311B	Tablet 250 mg	2	..	..	12.39	13.38	Ciproxin 250	BN
Authority required								
<i>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.</i>								
1208N	Tablet 250 mg	14	..	..	30.54	30.70	^a C-Flox 250 ^a Ciprofloxacin-BC ^a Ciprol 250 ^a GenRx Ciprofloxacin ^a Profloxin ^a Ciproxin 250	AL BG AW GX HX BN
					^b 1.85	32.39	30.70	

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	
CIPROFLOXACIN—cont.								
1209P	Tablet 500 mg	14	..	..	54.76	30.70	^a C-Flox 500 ^a Ciprofloxacin- BC ^a Ciprol 500 ^a GenRx Ciprofloxacin ^a Profloxin ^a Proquin ^a GN	AL BG AW GX HX GM
				^B 1.85	56.61	30.70	^a Ciproxin 500	BN
1210Q	Tablet 750 mg	14	..	..	79.92	30.70	^a C-Flox 750 ^a Ciprol 750 ^a GenRx Ciprofloxacin ^a Profloxin ^a Proquin ^a GN	AL AW GX HX GM
				^B 1.83	81.75	30.70	^a Ciproxin 750	BN
NORFLOXACIN								
<u>Authority required</u>								
<i>Acute bacterial enterocolitis; Complicated urinary tract infection.</i>								
3010K	Tablet 400 mg	14	1	..	19.57	20.56	^a Chem mart Norfloxacin ^a GenRx Norfloxacin ^a Norflohexal ^a Nufloxib ^a Roxin ^a Terry White Chemists Norfloxacin ^a GM	CH GX HX AF AW TW
				^B 3.61	23.18	20.56	^a Noroxin	MK
Other antibacterials								
• Glycopeptide antibacterials								
VANCOMYCIN								
<u>Restricted benefit</u>								
<i>Prophylaxis of endocarditis in patients hypersensitive to penicillin.</i>								
3130R	Powder for injection 500 mg (500,000 i.u.) vancomycin activity	2	..	..	*50.81	30.70	^a Vancocin ^a MX	AS
<u>Restricted benefit</u>								
<i>Endophthalmitis; Use initiated in a hospital for infections where vancomycin is an appropriate antibiotic.</i>								
3131T	Powder for injection 500 mg (500,000 i.u.) vancomycin activity	5	..	..	*119.30	30.70	^a Vancocin ^a MX	AS

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 <i>For use in combination with another antibiotic in the treatment of proven serious staphylococcal infections.</i>								
2312Q	Tablet (sodium salt) 250 mg	36	1	..	73.60	30.70	Fucidin	CS
• Imidazole derivatives METRONIDAZOLE								
1636D	Tablet 200 mg	21	1	..	7.11	8.10	^a Metrogyl 200	AF
				^B 1.92	9.03	8.10	^a Metronide 200	HP
							^a Flagyl	AV
1626N	Tablet 400 mg	5	2	..	7.01	8.00	Metrogyl 400	AF
1642K	Suppositories 500 mg, 10	‡1	..	..	20.15	21.14	Flagyl	AV
METRONIDAZOLE Restricted benefit <i>Treatment of anaerobic infections.</i>								
1621H	Tablet 400 mg	21	1	..	9.75	10.74	^a Metrogyl 400	AF
				^B 2.00	11.75	10.74	^a Metronide 400	HP
							^a Flagyl	AV
Restricted benefit <i>Prophylaxis in large bowel surgery; Treatment, in a hospital, of acute anaerobic sepsis.</i>								
1638F	I.V. infusion 500 mg in 100 mL	5	1	..	*42.35	30.70	BX	
METRONIDAZOLE BENZOATE								
1630T	Oral suspension 320 mg per 5 mL (equivalent to 200 mg metronidazole in 5 mL), 100 mL	‡1	..	..	14.47	15.46	Flagyl S	AV
TINIDAZOLE								
1465D	Tablet 500 mg	4	..	..	7.87	8.86	^a Simplotan	GP
				^B 2.44	10.31	8.86	^a Fasigyn	PF
• Nitrofurantoin derivatives NITROFURANTOIN CAUTION: Nitrofurantoin may cause peripheral neuritis and severe pulmonary reactions.								
1692C	Capsule 50 mg	30	1	..	14.73	15.72	Macrochantin	PU
1693D	Capsule 100 mg	30	1	..	22.13	23.12	Macrochantin	PU
• Other antibacterials HEXAMINE HIPPURATE								
3124K	Tablet 1 g	100	5	..	32.01	30.70	Hiprex	MM

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	
ANTIMYCOTICS FOR SYSTEMIC USE								
Antimycotics for systemic use								
• Antibiotics								
AMPHOTERICIN								
1047D	Powder for injection 50 mg	1	..	..	27.34	28.33	Fungizone	BQ
• Imidazole derivatives								
KETOCONAZOLE								
<u>Authority required</u>								
<i>Symptomatic genital candidiasis recurring after treatment of at least 2 episodes with topical therapy.</i>								
<u>CAUTION:</u>								
<i>Hepatotoxicity has been reported with ketoconazole.</i>								
1573T	Tablet 200 mg	10	..	..	17.53	18.52	Nizoral	JC
<u>Authority required</u>								
<i>Oral candidiasis in severely immunocompromised persons where topical therapy has failed;</i>								
<i>Systemic or deep mycoses where other forms of therapy have failed.</i>								
<u>CAUTION:</u>								
<i>Hepatotoxicity has been reported with ketoconazole.</i>								
1572R	Tablet 200 mg	30	5	..	38.40	30.70	Nizoral	JC
• Triazole derivatives								
FLUCONAZOLE								
<u>Authority required</u>								
<i>Treatment of cryptococcal meningitis in patients unable to take or tolerate amphotericin;</i>								
<i>Maintenance therapy in patients with cryptococcal meningitis and immunosuppression;</i>								
<i>Treatment of oropharyngeal candidiasis in immunosuppressed patients;</i>								
<i>Treatment of oesophageal candidiasis in immunosuppressed patients;</i>								
<i>Secondary prophylaxis of oropharyngeal candidiasis in immunosuppressed patients;</i>								
<i>Treatment of serious and life-threatening candida infections in patients unable to tolerate amphotericin.</i>								
1471K	Capsule 50 mg	28	5	..	151.43	30.70	^a DBL Fluconazole	MX
							^a Diflucan	PF
							^a Dizole 50	AF
							^a Fluconazole Hexal	HX
							^a Fluzole 50	AW
							^a Ozole	RA
1472L	Capsule 100 mg	28	5	..	282.21	30.70	^a DBL Fluconazole	MX
							^a Diflucan	PF
							^a Dizole 100	AF
							^a Fluconazole Hexal	HX
							^a Ozole	RA

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
FLUCONAZOLE—cont.							
1475P	Capsule 200 mg	28	5	..	529.99	30.70	^a DBL MX Fluconazole ^a Diflucan PF ^a Dizole 200 AF ^a Fluconazole HX Hexal ^a Fluzole 200 AW ^a Ozole RA
1473M	Solution for I.V. infusion 100 mg in 50 mL	7	..	..	*190.79	30.70	Diflucan PF
1474N	Solution for I.V. infusion 200 mg in 100 mL	7	..	..	*340.66	30.70	Diflucan PF
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	..	207.51	30.70	Sporanox JC

ANTIMYCOBACTERIALS

Drugs for treatment of tuberculosis

• Hydrazides

ISONIAZID

1554T	Tablet 100 mg	100	2	..	9.68	10.67	FM

Drugs for treatment of lepra

• Drugs for treatment of lepra

DAPSONE

8801F	Tablet 25 mg	100	1	..	99.31	30.70	LM
1272Y	Tablet 100 mg	100	1	..	112.57	30.70	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	..	..	9.06	10.05	Rimycin 150 AF
1984K	Capsule 300 mg	10	..	..	11.97	12.96	Rimycin 300 AF
8025J	Syrup 100 mg per 5 mL, 60 mL	‡1	..	..	23.38	24.37	Rifadin AV

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	
RIFAMPICIN—cont.								
Authority required								
Leprosy in adults.								
1982H	Capsule 150 mg	100	..	..	34.41	30.70	Rimycin 150	AF
1983J	Capsule 300 mg	100	..	..	63.67	30.70	Rimycin 300	AF

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	..	..	*89.31	30.70	^a Acihexal	HX
							^a Acyclo-V 200	AF
							^a Lovir	GM
				..	89.31	30.70	^a GenRx Aciclovir	GX
				^B 5.78	*95.09	30.70	^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	..	159.12	30.70	^a Acihexal	HX
							^a Acyclo-V 200	AF
							^a Chem mart	CH
							Aciclovir	
							^a GenRx Aciclovir	GX
							^a Lovir	GM
							^a Ozvir	RA
							^a Terry White	TW
							Chemists	
							Aciclovir	
				^B 4.28	163.40	30.70	^a Zovirax 200 mg	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
ACICLOVIR—cont.							
Authority required							
<i>Treatment of patients with herpes zoster within 72 hours of the onset of the rash; Herpes zoster ophthalmicus.</i>							
NOTE:							
<i>Aciclovir is effective only if commenced within 72 hours of onset of rash.</i>							
<i>Aciclovir 800 mg is not PBS-subsidised for herpes simplex or chickenpox.</i>							
1052J	Tablet 800 mg	35	..	..	191.68	30.70	^a Acihexal HX
							^a Acyclo-V 800 AF
							^a GenRx Aciclovir GX
							^a Lovir GM
					^B 2.09 193.77	30.70	^a Zovirax 800 mg GK
NOTE:							
<i>No applications for repeats will be authorised.</i>							
Authority required							
<i>Patients with advanced HIV disease (CD4 cell counts of less than 150 million per litre).</i>							
8234J	Tablet 800 mg	120	5	..	590.20	30.70	^a Acihexal HX
							^a Acyclo-V 800 AF
							^a Lovir GM
					^B 7.19 597.39	30.70	^a Zovirax 800 mg GK
FAMCICLOVIR							
Authority required							
<i>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.</i>							
NOTE:							
<i>Famciclovir 125 mg is not PBS-subsidised for chickenpox, herpes zoster or herpes simplex infections other than genital herpes.</i>							
8092X	Tablet 125 mg	40	1	..	135.79	30.70	Famvir NV
Authority required							
<i>Treatment of patients with herpes zoster within 72 hours of the onset of the rash.</i>							
NOTE:							
<i>Famciclovir is effective only if commenced within 72 hours of onset of rash.</i>							
<i>Famciclovir 250 mg is not PBS-subsidised for chickenpox or herpes simplex infections other than genital herpes.</i>							
8002E	Tablet 250 mg	21	..	..	142.31	30.70	Famvir NV
NOTE:							
<i>No applications for repeats will be authorised.</i>							

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	
FAMCICLOVIR—cont.								
Authority required								
<i>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.</i>								
NOTE:								
<i>Famciclovir 250 mg is not PBS-subsidised for chickenpox or herpes simplex infections other than genital herpes.</i>								
8217L	Tablet 250 mg	56	5	..	355.66	30.70	Famvir	NV
Authority required								
<i>Treatment of immunocompromised patients with herpes zoster within 72 hours of the onset of the rash.</i>								
NOTE:								
<i>Famciclovir is effective only if commenced within 72 hours of onset of rash.</i>								
<i>Famciclovir 500 mg is not PBS-subsidised for chickenpox or herpes simplex infections other than genital herpes.</i>								
<i>Famciclovir 500 mg is not PBS-subsidised for genital herpes or herpes zoster in immunocompetent patients.</i>								
8897G	Tablet 500 mg	30	..	..	201.08	30.70	Famvir	NV
NOTE:								
<i>No applications for repeats will be authorised.</i>								
Authority required								
<i>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.</i>								
NOTE:								
<i>Famciclovir 500 mg is not PBS-subsidised for chickenpox or herpes simplex infections other than genital herpes.</i>								
<i>Famciclovir 500 mg is not PBS-subsidised for genital herpes or herpes zoster in immunocompetent patients.</i>								
8896F	Tablet 500 mg	56	5	..	355.66	30.70	Famvir	NV
VALACICLOVIR HYDROCHLORIDE								
Authority required								
<i>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.</i>								
NOTE:								
<i>Valaciclovir 500 mg is not PBS-subsidised for chickenpox or herpes simplex infections other than genital herpes.</i>								
8133C	Tablet 500 mg (base)	20	..	..	*104.51	30.70	Valtrex	GK
NOTE:								
<i>No applications for increased maximum quantities and/or repeats will be authorised.</i>								

continued

ANTIINFECTIVES FOR SYSTEMIC USE —cont.

Code	Name, Restriction, Manner of administration and form	Max. No. of Qty Rpts Premium	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Proprietary Name and Manufacturer	
VALACICLOVIR HYDROCHLORIDE—cont.						
Authority required						
<i>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.</i>						
NOTE:						
<i>Valaciclovir 500 mg is not PBS-subsidised for chickenpox or herpes simplex infections other than genital herpes.</i>						
8134D	Tablet 500 mg (base)	30 5 ..	154.16	30.70	Valtrex	GK
Authority required						
<i>Treatment of patients with herpes zoster within 72 hours of the onset of the rash; Herpes zoster ophthalmicus.</i>						
NOTE:						
<i>Valaciclovir is effective only if commenced within 72 hours of onset of rash.</i>						
<i>Valaciclovir 500 mg is not PBS-subsidised for chickenpox or herpes simplex infections other than genital herpes.</i>						
8064K	Tablet 500 mg (base)	42	212.79	30.70	Valtrex	GK
NOTE:						
<i>No applications for repeats will be authorised.</i>						
VACCINES						
Bacterial vaccines						
• Pneumococcal vaccines						
PNEUMOCOCCAL VACCINE, POLYVALENT						
Restricted benefit						
<i>Splenectomised persons over 2 years of age; Persons with Hodgkin's disease; Persons at high risk of pneumococcal infections.</i>						
1903E	Injection 0.5 mL (23 valent)	1	39.79	30.70	Pneumovax 23	CS
• Tetanus vaccines						
DIPHTHERIA and TETANUS VACCINE, ADSORBED						
NOTE:						
<i>For immunisation of children up to the age of eight years.</i>						
1341N	Injection 0.5 mL	3	*18.62	19.61	CS	
DIPHTHERIA and TETANUS VACCINE, ADSORBED, DILUTED FOR ADULT USE						
NOTE:						
<i>For immunisation of adults and children over the age of eight years.</i>						
8783G	Injection 0.5 mL in pre-filled syringe	3	*27.20	28.19	ADT	CS

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	
Viral vaccines								
• Influenza vaccines								
INFLUENZA VACCINE								
<u>Restricted benefit</u>								
<i>Persons at special risk of adverse consequences from infections of the lower respiratory tract.</i>								
2852D	Injection (trivalent) 0.5 mL (containing A/New Caledonia/20/99, A/Wisconsin/67/2005 and B/Malaysia/2506/2004 like strains)	1	..	..	17.79	18.78	Fluarix Fluvax Influvac Vaxigrip	GK 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								
1163F	CHLORAMBUCIL Tablet 2 mg	100	2	..	*80.31	30.70	Leukeran	GK
1266P	CYCLOPHOSPHAMIDE Tablet 50 mg	50	2	..	28.94	29.93	Cycloblastin	PH
1079T	Powder for injection 500 mg (solvent required) (code 6704W applies to above item with approved solvent)	2	..	..	*27.49	28.48	Endoxan	BX
1080W	Powder for injection 1 g (solvent required) (code 6710E applies to above item with approved solvent)	1	..	..	24.85	25.84	Endoxan	BX
1031G	Powder for injection 2 g (solvent required) (code 7055H applies to above item with approved solvent)	1	..	..	40.24	30.70	Endoxan	BX
IFOSFAMIDE								
Restricted benefit								
<i>Relapsed or refractory germ cell tumours following first-line chemotherapy; Relapsed or refractory sarcomas following first-line chemotherapy.</i>								
8076C	Powder for I.V. injection 1 g	5	5	..	*260.30	30.70	Holoxan	BX
8077D	Powder for I.V. injection 2 g	5	5	..	*475.90	30.70	Holoxan	BX
2547C	MELPHALAN Tablet 2 mg	25	1	..	27.13	28.12	Alkeran	GK
• Alkyl sulphonates								
1128J	BUSULFAN Tablet 2 mg	100	..	..	45.07	30.70	Myleran	GK
• Ethylene imines								
2345K	THIOTEPA Powder for injection 15 mg	2	1	..	*135.25	30.70	SI	
• Nitrosoureas								
CARMUSTINE								
Restricted benefit								
<i>Glioblastoma multiforme, suspected or confirmed, at the time of initial surgery.</i>								
NOTE:								
<i>Carmustine is not PBS-subsidised for use in conjunction with PBS-subsidised temozolomide.</i>								
8898H	Implants 7.7 mg, 8	£1	..	..	16013.5	30.70	Gliadel	OA

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	
FOTEMUSTINE								
Authority required								
<i>Metastatic malignant melanoma.</i>								
8786K	Powder for injection 208 mg with solvent	1	4	..	1001.47	30.70	Muphoran	SE
• Other alkylating agents								
TEMOZOLOMIDE								
Authority required								
<i>Glioblastoma multiforme concomitantly with radiotherapy.</i>								
NOTE:								
<i>Temozolomide is not PBS-subsidised for use in conjunction with PBS-subsidised carmustine.</i>								
8819E	Capsule 5 mg	15	2	..	*216.44	30.70	Temodal	SH
8820F	Capsule 20 mg	15	2	..	*596.21	30.70	Temodal	SH
8821G	Capsule 100 mg	15	2	..	*2479.76	30.70	Temodal	SH
NOTE:								
<i>Applications for doses above 150 mg per day will not be authorised. No applications for increased repeats will be authorised.</i>								
Authority required								
<i>Recurrence of anaplastic astrocytoma following standard therapy;</i>								
<i>Recurrence of glioblastoma multiforme following standard therapy;</i>								
<i>Glioblastoma multiforme following radiotherapy.</i>								
8378Y	Capsule 5 mg	5	5	..	76.02	30.70	Temodal	SH
8379B	Capsule 20 mg	5	5	..	212.59	30.70	Temodal	SH
8380C	Capsule 100 mg	5	5	..	849.15	30.70	Temodal	SH
8381D	Capsule 250 mg	5	5	..	1922.41	30.70	Temodal	SH
Antimetabolites								
• Folic acid analogues								
METHOTREXATE								
1622J	Tablet 2.5 mg	30	5	..	12.10	13.09	^a Methoblastin ^a MX	PH
1623K	Tablet 10 mg	50	2	..	46.14	30.70	Methoblastin	PH
2396D	Injection 5 mg in 2 mL	5	..	..	36.04	30.70	MX	
2395C	Injection 50 mg in 2 mL	5	..	..	35.35	30.70	MX PU	
8850T	Solution concentrate for I.V. infusion 500 mg in 5 mL	1	..	..	65.55	30.70	Methotrexate Ebewe	IT
8863L	Solution concentrate for I.V. infusion 500 mg in 20 mL	1	..	..	65.55	30.70	MX	
8851W	Solution concentrate for I.V. infusion 1000 mg in 10 mL	1	..	..	125.95	30.70	^a Methotrexate Ebewe ^a MX	IT
8852X	Solution concentrate for I.V. infusion 5000 mg in 50 mL	1	..	..	576.21	30.70	Methotrexate Ebewe	IT

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	
PEMETREXED DISODIUM								
<i>See Special Pharmaceutical Benefits</i>								
RALTITREXED								
Authority required								
<i>For use as a single agent in the treatment of advanced colorectal cancer.</i>								
8284B	Powder for I.V. infusion 2 mg	3	2	..	*855.02	30.70	Tomudex	AP
• Purine analogues								
CLADRIBINE								
Authority required								
<i>Hairy cell leukaemia.</i>								
8800E	Injection 10 mg in 5 mL	7	..	..	*4543.95	30.70	Litak	OA
1811H	Solution for I.V. infusion 10 mg in 10 mL	7	..	..	4544.12	30.70	Leustatin	JC
MERCAPTOPYRINE								
1598D	Tablet 50 mg	100	2	..	*100.43	30.70	Purinethol	GK
THIOGUANINE								
1233X	Tablet 40 mg	25	1	..	101.27	30.70	Lanvis	GK
• Pyrimidine analogues								
CAPECITABINE								
Authority required								
<i>Advanced breast cancer after failure of prior therapy which includes a taxane and an anthracycline;</i>								
<i>Advanced breast cancer where therapy with a taxane and/or an anthracycline is contraindicated;</i>								
<i>Advanced breast cancer in combination with docetaxel after failure of prior anthracycline-containing chemotherapy;</i>								
<i>Treatment of advanced or metastatic colorectal cancer;</i>								
<i>Adjuvant treatment of stage III (Dukes C) colon cancer, following complete resection of the primary tumour.</i>								
NOTE:								
<i>In the adjuvant setting, the recommended treatment duration is 24 weeks.</i>								
<i>Capecitabine is not PBS-subsidised for the treatment of patients with stage II (Dukes B) colon cancer.</i>								
<i>Capecitabine is not PBS-subsidised for the adjuvant treatment of patients with rectal cancer.</i>								
8361C	Tablet 150 mg	60	2	..	122.66	30.70	Xeloda	RO
8362D	Tablet 500 mg	120	2	..	693.90	30.70	Xeloda	RO
CYTARABINE								
2884T	Injection 100 mg in 5 mL	10	1	..	*66.67	30.70	PU	
FLUOROURACIL								
2528C	Injection 500 mg in 10 mL	10	..	..	*57.45	30.70	^a Fluorouracil Ebewe ^a MX	IT
9005Y	Injection 1000 mg in 20 mL	5	..	..	*49.65	30.70	Fluorouracil Ebewe	IT

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	
GEMCITABINE HYDROCHLORIDE								
Authority required								
<i>Advanced breast cancer in combination with paclitaxel after failure of prior therapy which includes an anthracycline;</i>								
<i>Advanced epithelial ovarian cancer, in combination with carboplatin, in patients who relapse more than 6 months after platinum-based therapy;</i>								
<i>Locally advanced or metastatic non-small cell lung cancer;</i>								
<i>Locally advanced or metastatic adenocarcinoma of the pancreas;</i>								
<i>Locally advanced or metastatic bladder cancer, in combination with cisplatin.</i>								
8049P	Powder for I.V. infusion 200 mg (base)	4	2	..	*234.67	30.70	Gemzar	LY
8050Q	Powder for I.V. infusion 1 g (base)	2	2	..	*548.27	30.70	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	..	..	104.57	30.70	MX	
VINCISTINE SULFATE								
2374Y	I.V. injection 1 mg in 1 mL	10	..	..	*163.25	30.70	^a MX ^a PU	
VINORELBINE TARTRATE								
Authority required								
<i>Locally advanced or metastatic non-small cell lung cancer.</i>								
9009E	Capsule 20 mg (base)	20	2	..	*2101.55	30.70	Navelbine	FB
9010F	Capsule 30 mg (base)	16	2	..	*2499.39	30.70	Navelbine	FB
Authority required								
<i>Advanced breast cancer after failure of prior therapy which includes an anthracycline;</i>								
<i>Locally advanced or metastatic non-small cell lung cancer.</i>								
8280T	Solution for I.V. infusion 10 mg (base) in 1 mL	16	2	..	*1200.19	30.70	^a Navelbine ^a Vinorelbine ^a Ebewe ^a MX	FB IT
8281W	Solution for I.V. infusion 50 mg (base) in 5 mL	4	2	..	*1250.27	30.70	^a Navelbine ^a Vinorelbine ^a Ebewe ^a MX	FB IT
• Podophyllotoxin derivatives								
ETOPOSIDE								
1396L	Capsule 50 mg	20	..	..	479.31	30.70	Vepesid	BQ
1389D	Capsule 100 mg	10	..	..	420.29	30.70	Vepesid	BQ
1390E	Solution for I.V. infusion 100 mg in 5 mL	5	..	..	*175.45	30.70	^a Etoposide ^a MX	Ebewe IT

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	
ETOPOSIDE PHOSPHATE								
8120J	Powder for I.V. infusion 113.6 mg (equivalent to 100 mg etoposide)	5	..	..	*175.45	30.70	Etopophos	BQ
8515E	Powder for I.V. infusion 1136 mg (equivalent to 1 g etoposide)	1	..	..	332.70	30.70	Etopophos	BQ
• Taxanes								
DOCETAXEL								
Authority required								
<i>Adjuvant treatment of node-positive breast cancer in combination with an anthracycline and cyclophosphamide;</i>								
<i>Advanced breast cancer after failure of prior therapy which includes an anthracycline;</i>								
<i>Advanced metastatic ovarian cancer after failure of prior therapy which includes a platinum compound;</i>								
<i>Locally advanced or metastatic non-small cell lung cancer;</i>								
<i>Treatment of HER2 positive early breast cancer in combination with trastuzumab.</i>								
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	..	..	*659.81	30.70	Taxotere	AV
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	..	..	1289.30	30.70	Taxotere	AV
PACLITAXEL								
Authority required								
<i>Adjuvant treatment of node-positive breast cancer administered sequentially to an anthracycline and cyclophosphamide;</i>								
<i>Advanced breast cancer after failure of prior therapy which includes an anthracycline;</i>								
<i>Advanced metastatic ovarian cancer after failure of prior therapy which includes a platinum compound;</i>								
<i>Primary treatment of ovarian cancer in combination with a platinum compound;</i>								
<i>Locally advanced or metastatic non-small cell lung cancer;</i>								
<i>Treatment of HER2 positive early breast cancer in combination with trastuzumab.</i>								
3026G	Solution concentrate for I.V. infusion 30 mg in 5 mL	5	..	..	*988.45	30.70	^a Anzatax ^a Paclitaxel Ebewe ^a Taxol	MX IT BQ
8018B	Solution concentrate for I.V. infusion 100 mg in 16.7 mL	2	..	..	*1299.63	30.70	^a Anzatax ^a Paclitaxel Ebewe ^a Taxol	MX IT BQ
3017T	Solution concentrate for I.V. infusion 150 mg in 25 mL	2	..	..	*1873.75	30.70	^a Anzatax ^a Paclitaxel Ebewe ^a Taxol	MX IT BQ
8360B	Solution concentrate for I.V. infusion 300 mg in 50 mL	1	..	..	1891.50	30.70	^a Anzatax ^a Paclitaxel Ebewe ^a Taxol	MX IT 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	
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	..	..	*144.35	30.70	^a Adriamycin Solution ^a Doxorubicin Ebewe ^a MX	PH IT
1340M	Solution for I.V. injection or intravesical administration 20 mg in 10 mL	4	..	..	*249.51	30.70	Adriamycin Solution	PH
1342P	Solution for I.V. injection or intravesical administration 50 mg in 25 mL	3	..	..	*424.52	30.70	^a Adriamycin Solution ^a Doxorubicin Ebewe ^a MX	PH IT
8827N	Solution for I.V. injection or intravesical administration 100 mg in 50 mL	1	..	..	290.71	30.70	Doxorubicin Ebewe	IT
8828P	Solution for I.V. injection or intravesical administration 200 mg in 100 mL	1	..	..	561.69	30.70	Doxorubicin Ebewe	IT
DOXORUBICIN HYDROCHLORIDE, PEGYLATED LIPOSOMAL								
Authority required								
<i>Advanced epithelial ovarian cancer in women who have failed a first-line platinum-based chemotherapy regimen;</i>								
<i>Metastatic breast cancer, as monotherapy, after failure of prior therapy which includes capecitabine and a taxane;</i>								
<i>Metastatic breast cancer, as monotherapy, where therapy with capecitabine and/or a taxane is contraindicated.</i>								
8569B	Suspension for I.V. infusion 20 mg in 10 mL	1	..	..	701.78	30.70	Caelyx	SH
8570C	Suspension for I.V. infusion 50 mg in 25 mL	1	..	..	1598.39	30.70	Caelyx	SH
EPIRUBICIN HYDROCHLORIDE								
1375J	Solution for injection 10 mg in 5 mL	4	..	..	*222.51	30.70	^a Epirubicin Ebewe ^a Pharmorubicin Solution	IT PH
1376K	Solution for injection 20 mg in 10 mL	4	..	..	*407.91	30.70	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	
EPIRUBICIN HYDROCHLORIDE—cont.								
1377L	Solution for injection 50 mg in 25 mL	3	..	..	*747.26	30.70	^a Epirubicin Ebewe ^a Pharmorubicin Solution	IT PH
9018P	Powder for injection 50 mg	3	..	..	*747.26	30.70	^a MX	
NOTE: The solution for injection 50 mg and powder for injection 50 mg (after reconstitution) are bioequivalent.								
8817C	Solution for injection 100 mg in 50 mL	2	..	..	*981.33	30.70	Epirubicin Ebewe	IT
8858F	Solution for injection 200 mg in 100 mL	1	..	..	966.71	30.70	Epirubicin Ebewe	IT
IDARUBICIN HYDROCHLORIDE Restricted benefit Acute myelogenous leukaemia.								
2446R	Capsule 5 mg	3	..	..	*245.84	30.70	Zavedos	PH
2448W	Capsule 10 mg	3	..	..	*450.35	30.70	Zavedos	PH
8530Y	Solution for I.V. injection 5 mg in 5 mL	3	..	..	567.61	30.70	Zavedos Solution	PH
8531B	Solution for I.V. injection 10 mg in 10 mL	6	..	..	2073.53	30.70	Zavedos Solution	PH
MITOZANTRONE HYDROCHLORIDE								
1932Q	Injection 10 mg (base) in 5 mL	1	..	..	160.16	30.70	PU	
1929M	Injection 20 mg (base) in 10 mL	1	..	..	304.98	30.70	^a Novantrone ^a Onkotrone ^a MX ^a PU	SI BX
1930N	Injection 25 mg (base) in 12.5 mL	1	..	..	375.22	30.70	^a Novantrone ^a Onkotrone ^a PU	SI BX
• Other cytotoxic antibiotics BLEOMYCIN SULFATE See Special Pharmaceutical Benefits								
Other antineoplastic agents								
• Platinum compounds								
CARBOPLATIN								
1160C	Solution for I.V. injection 50 mg in 5 mL	2	..	..	*68.29	30.70	^a Carboplatin Ebewe ^a MX ^a PU	IT
1161D	Solution for I.V. injection 150 mg in 15 mL	6	..	..	*439.01	30.70	^a Carboplatin Ebewe ^a MX ^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	
CARBOPLATIN—cont.								
1162E	Solution for I.V. injection 450 mg in 45 mL	2	..	..	*284.33	30.70	^a Carboplatin Ebewe ^a MX ^a PU	IT
CISPLATIN								
2578Q	I.V. injection 10 mg in 10 mL	1	..	..	13.38	14.37	PU	
2579R	I.V. injection 50 mg in 50 mL	1	..	..	27.22	28.21	^a MX ^a PU	
2580T	I.V. injection 100 mg in 100 mL	1	..	..	60.76	30.70	^a Cisplatin Ebewe ^a MX	IT

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	..	426.96	30.70	^a Eloxatin	SW
8539K	Powder for I.V. infusion 50 mg	1	2	..	376.48	30.70	^a Oxaliplatin Ebewe ^a Winthrop Oxaliplatin ^a MX	IT SW

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	..	816.35	30.70	^a Eloxatin	SW
8540L	Powder for I.V. infusion 100 mg	1	2	..	714.95	30.70	^a Oxaliplatin Ebewe ^a Winthrop Oxaliplatin ^a MX	IT SW

NOTE:

The solution concentrate for I.V. infusion 100 mg and powder for I.V. infusion 100 mg (after reconstitution) are bioequivalent.

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	
• Monoclonal antibodies RITUXIMAB Authority required <i>Relapsed or refractory low-grade B-cell non-Hodgkin's lymphoma;</i> <i>Relapsed or refractory follicular B-cell non-Hodgkin's lymphoma.</i>								
8293L	Solution for I.V. infusion 100 mg in 10 mL	2	3	..	946.80	30.70	Mabthera	RO
8294M	Solution for I.V. infusion 500 mg in 50 mL	1	3	..	2308.72	30.70	Mabthera	RO
Authority required <i>Treatment of previously untreated, CD20 positive, diffuse large B-cell non-Hodgkin's lymphoma, in combination with chemotherapy;</i> <i>Treatment of symptomatic patients with previously untreated, CD20 positive, Stage III or IV, follicular, B-cell non-Hodgkin's lymphoma, in combination with chemotherapy.</i>								
8665C	Solution for I.V. infusion 100 mg in 10 mL	2	7	..	946.80	30.70	Mabthera	RO
8666D	Solution for I.V. infusion 500 mg in 50 mL	1	7	..	2308.72	30.70	Mabthera	RO
• Other antineoplastic agents GEFITINIB NOTE: <i>Any queries concerning the arrangements to prescribe gefitinib may be directed to Medicare Australia on 1800 242 679.</i> <i>Written applications for authority to prescribe gefitinib should be forwarded to:</i> Medicare Australia Prior Written Approval of Specialised Drugs Reply Paid 9826 GPO Box 9826 HOBART TAS 7001 Authority required <i>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:</i> <i>(1) disease progression has occurred following treatment with at least 1 chemotherapy agent; and</i> <i>(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.</i> <i>The authority application must be made in writing and must include:</i> <i>(1) a completed authority prescription form; and</i> <i>(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 (visit www.medicareaustralia.gov.au/providers/forms/pbs.htm and click on 'Medical Practitioners'))]; and</i>								

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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	
GEFITINIB—cont.								
(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. Patients commenced on gefitinib therapy between 1 July 2004 and 1 December 2004 must demonstrate that they would have met the criteria for initial PBS-subsidised treatment at the time treatment with gefitinib was commenced. Medical practitioners who wish to apply for authority to prescribe gefitinib for patients who commenced on gefitinib therapy prior to 1 July 2004 should contact Medicare Australia on 1800 242 679.								
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 242 679.								
8769M	Tablet 250 mg	30	1	..	3820.09	30.70	Iressa	AP
NOTE:								
No applications for increased maximum quantities and/or repeats will be authorised.								
3093T	HYDROXYUREA Capsule 500 mg	100	..	..	75.19	30.70	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	..	144.86	30.70	^a Camptosar ^a MX	PU
8415X	I.V. injection 100 mg in 5 mL	2	3	..	*665.59	30.70	^a Camptosar ^a MX	PU
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	..	2095.09	30.70	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								
<u>Restricted benefit</u>								
<i>Hormone-dependent advanced breast cancer.</i>								
2728N	Tablet 500 mg	30	2	..	134.65	30.70	Provera	PH
<u>Restricted benefit</u>								
<i>Hormone-dependent breast cancer; Endometrial cancer.</i>								
2725K	Tablet 100 mg	100	2	..	96.19	30.70	Provera	PH
2316X	Tablet 200 mg	60	2	..	108.55	30.70	Provera	PH
2727M	Tablet 250 mg	60	2	..	134.41	30.70	Provera	PH
<i>[For other listings for this drug see Generic/Proprietary Index]</i>								
MEGESTROL ACETATE								
<u>Restricted benefit</u>								
<i>Hormone-dependent advanced breast cancer.</i>								
2734X	Tablet 160 mg	30	2	..	71.68	30.70	Megace	BQ
• Gonadotropin releasing hormone analogues								
GOSERELIN ACETATE								
<u>Authority required</u>								
<i>Locally advanced (equivalent to stage C) or metastatic (equivalent to stage D) carcinoma of the prostate;</i>								
<i>Hormone-dependent locally advanced (equivalent to stage III) or metastatic (equivalent to stage IV) breast cancer in pre-menopausal women;</i>								
<i>Short-term treatment (up to 6 months) of visually proven endometriosis (only 1 course of not more than 6 months' therapy will be authorised).</i>								
1454M	Subcutaneous implant 3.6 mg (base) in pre-filled injection syringe	1	5	..	331.73	30.70	Zoladex Implant	AP
<u>Authority required</u>								
<i>Locally advanced (equivalent to stage C) or metastatic (equivalent to stage D) carcinoma of the prostate.</i>								
8093Y	Subcutaneous implant (long acting) 10.8 mg (base) in pre-filled injection syringe	1	1	..	1105.09	30.70	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	
LEUPRORELIN ACETATE								
Authority required								
<i>Locally advanced (equivalent to stage C) or metastatic (equivalent to stage D) carcinoma of the prostate.</i>								
8875D	I.M. injection (modified release), powder for injection 7.5 mg with diluent in pre-filled dual-chamber syringe	1	5	..	418.93	30.70	Lucrin Depot 7.5mg PDS	AB
8707G	Suspension for subcutaneous injection (modified release), 7.5 mg injection set	1	5	..	418.93	30.70	Eligard 1 month	MX
8876E	I.M. injection (modified release), powder for injection 22.5 mg with diluent in pre-filled dual-chamber syringe	1	1	..	1105.09	30.70	Lucrin Depot 3 Month PDS	AB
8708H	Suspension for subcutaneous injection (modified release), 22.5 mg injection set	1	1	..	1105.09	30.70	Eligard 3 month	MX
8877F	I.M. injection (modified release), powder for injection 30 mg with diluent in pre-filled dual-chamber syringe	1	1	..	1434.49	30.70	Lucrin Depot 4 Month PDS	AB
8709J	Suspension for subcutaneous injection (modified release), 30 mg injection set	1	1	..	1434.49	30.70	Eligard 4 month	MX
8859G	Suspension for subcutaneous injection (modified release), 45 mg injection set	1	..	..	2092.71	30.70	Eligard 6 month	MX
Hormone antagonists and related agents								
• Anti-estrogens								
TAMOXIFEN CITRATE								
Restricted benefit								
<i>Treatment of hormone-dependent breast cancer.</i>								
NOTE:								
<i>This drug is not PBS-subsidised for primary prevention of breast cancer.</i>								
2109B	Tablet 10 mg (base)	60	5	..	46.55	30.70	^a Genox 10 ^a Tamoxen 10 mg	AF GM
				^B 2.12	*48.67	30.70	^a Nolvadex	AP

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	
TAMOXIFEN CITRATE—cont.								
2110C	Tablet 20 mg (base)	60	5	..	76.91	30.70	^a Chem mart Tamoxifen	CH
							^a Genox 20	AF
							^a GenRx Tamoxifen	GX
							^a Tamosin	SI
							^a Tamoxen 20 mg	GM
							^a Tamoxifen Hexal	HX
							^a Terry White Chemists Tamoxifen	TW
				^B 3.82	[*] 80.73	30.70	^a Nolvadex-D	AP
TOREMIFENE CITRATE								
Restricted benefit								
<i>Treatment of hormone-dependent metastatic breast cancer in post-menopausal patients.</i>								
NOTE:								
<i>This drug is not PBS-subsidised for primary prevention of breast cancer.</i>								
8216K	Tablet 60 mg (base)	30	5	..	67.84	30.70	Fareston	SH
• Anti-androgens								
BICALUTAMIDE								
Authority required								
<i>Metastatic (equivalent to stage D) prostatic carcinoma in combination with GnRH (LH-RH) agonist therapy.</i>								
NOTE:								
<i>No applications for increased maximum quantities and/or repeats will be authorised.</i>								
8094B	Tablet 50 mg	28	5	..	219.51	30.70	Cosudex	AP
CYPROTERONE ACETATE								
Authority required								
<i>Advanced carcinoma of the prostate;</i>								
<i>To reduce drive in sexual deviations in males.</i>								
1270W	Tablet 50 mg	100	5	..	[*] 267.55	30.70	^a Cyprohexal	HX
							^a Cyprone	AF
							^a Cyprostat	SY
							^a GenRx Cyproterone Acetate	GX
				^B 4.00	[*] 271.55	30.70	^a Procur	GM
							^a Androcur	SC
8019C	Tablet 100 mg	50	5	..	221.13	30.70	^a Cyprohexal	HX
							^a Cyprostat-100	SY
							^a GenRx Cyproterone Acetate	GX
				^B 2.01	223.14	30.70	^a Procur 100	GM
							^a Androcur-100	SC

[For other listings for this drug see Generic/Proprietary Index]

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS —cont.

Code	Name, Restriction, Manner of administration and form	Max. No. of Qty Rpts Premium	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Proprietary Name and Manufacturer	
FLUTAMIDE						
Authority required						
<i>Metastatic (equivalent to stage D) prostatic carcinoma in combination with GnRH (LH-RH) agonist therapy.</i>						
NOTE:						
<i>No applications for increased maximum quantities and/or repeats will be authorised.</i>						
1417N	Tablet 250 mg	100 5 ..	215.61	30.70	^a Eulexin ^a Flutamin	SH AF
NILUTAMIDE						
Authority required						
<i>Locally advanced (equivalent to stage C) or metastatic (equivalent to stage D) prostatic carcinoma, in combination with GnRH (LH-RH) agonist therapy;</i>						
<i>Locally advanced (equivalent to stage C) or metastatic (equivalent to stage D) prostatic carcinoma, in conjunction with surgical orchidectomy.</i>						
8131Y	Tablet 150 mg	30 5 ..	225.06	30.70	Anandron	AV
• Enzyme inhibitors						
AMINOGLUTETHIMIDE						
1036M	Tablet 250 mg	100 5 ..	158.33	30.70	Cytadren 250	NV
ANASTROZOLE						
Restricted benefit						
<i>Treatment of hormone-dependent breast cancer in post-menopausal women.</i>						
NOTE:						
<i>This drug is not PBS-subsidised for primary prevention of breast cancer.</i>						
<i>This drug is not PBS-subsidised for adjuvant hormonal treatment of early breast cancer extended beyond 5 years.</i>						
8179L	Tablet 1 mg	30 5 ..	187.19	30.70	Arimidex	AP
EXEMESTANE						
Restricted benefit						
<i>Treatment of hormone-dependent advanced breast cancer in post-menopausal women with disease progression following treatment with tamoxifen citrate;</i>						
<i>Treatment of hormone-dependent early breast cancer in post-menopausal women following a minimum of 2 years' treatment with tamoxifen citrate.</i>						
NOTE:						
<i>This drug is not PBS-subsidised for primary prevention of breast cancer.</i>						
<i>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.</i>						
8506Q	Tablet 25 mg	30 5 ..	187.19	30.70	Aromasin	PH
LETROZOLE						
Restricted benefit						
<i>Treatment of hormone-dependent breast cancer in post-menopausal women.</i>						
NOTE:						
<i>This drug is not PBS-subsidised for primary prevention of breast cancer.</i>						
<i>This drug is not PBS-subsidised for adjuvant hormonal treatment of early breast cancer extended beyond 5 years.</i>						
8245Y	Tablet 2.5 mg	30 5 ..	187.19	30.70	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								
Cytokines and immunomodulators								
• Interferons								
INTERFERON ALFA-2a								
CAUTION:								
<i>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.</i>								
Authority required								
<i>Hairy cell leukaemia; Myeloproliferative disease with excessive thrombocytosis.</i>								
8180M	Injection 3,000,000 i.u. in 0.5 mL single dose pre-filled syringe	15	4	..	*504.95	30.70	Roferon-A	RO
Authority required								
<i>Myeloproliferative disease with excessive thrombocytosis.</i>								
8551C	Injection 4,500,000 i.u. in 0.5 mL single dose pre-filled syringe	5	4	..	*263.45	30.70	Roferon-A	RO
8552D	Injection 6,000,000 i.u. in 0.5 mL single dose pre-filled syringe	5	4	..	*343.45	30.70	Roferon-A	RO
8553E	Injection 9,000,000 i.u. in 0.5 mL single dose pre-filled syringe	5	4	..	*504.85	30.70	Roferon-A	RO
Authority required								
<i>Low grade non-Hodgkin's lymphoma with clinical features suggestive of a poor prognosis, in combination with anthracycline-based chemotherapy.</i>								
8181N	Injection 3,000,000 i.u. in 0.5 mL single dose pre-filled syringe	15	5	..	*504.95	30.70	Roferon-A	RO
8182P	Injection 4,500,000 i.u. in 0.5 mL single dose pre-filled syringe	5	5	..	*263.45	30.70	Roferon-A	RO
8183Q	Injection 6,000,000 i.u. in 0.5 mL single dose pre-filled syringe	5	5	..	*343.45	30.70	Roferon-A	RO
8184R	Injection 9,000,000 i.u. in 0.5 mL single dose pre-filled syringe	5	5	..	*504.85	30.70	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: <i>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.</i>								
Authority required <i>Hairy cell leukaemia.</i>								
8572E	Solution for injection 18,000,000 i.u. in 1.2 mL multi-dose injection pen	3	4	..	*604.76	30.70	Intron A Redipen	SH
Authority required <i>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.</i>								
8348J	Solution for injection 18,000,000 i.u. in 1.2 mL multi-dose injection pen	3	5	..	*604.76	30.70	Intron A Redipen	SH
8476D	Solution for injection 30,000,000 i.u. in 1.2 mL multi-dose injection pen	3	5	..	*1004.48	30.70	Intron A Redipen	SH
INTERFERON BETA-1a								
Authority required <i>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.</i>								
8289G	Injection set comprising 1 vial powder for injection 30 micrograms (6,000,000 i.u.) with diluent	4	5	..	1055.10	30.70	Avonex	BD
8805K	Injection 30 micrograms (6,000,000 i.u.) in 0.5 mL single dose pre-filled syringe	4	5	..	1055.10	30.70	Avonex	BD
8403G	Injection 44 micrograms (12,000,000 i.u.) in 0.5 mL single dose pre-filled syringe	12	5	..	1055.10	30.70	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								
<u>Authority required</u>								
<i>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;</i>								
<i>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.</i>								
8101J	Injection set comprising 1 vial powder for injection 8,000,000 i.u. (250 micrograms) and solvent	15	5	..	1173.75	30.70	Betaferon	SC
• Other cytokines and immunomodulators								
BCG IMMUNOTHERAPEUTIC								
<i>(Bacillus Calmette-Guérin/ Connaught strain)</i>								
<u>Restricted benefit</u>								
<i>Treatment of carcinoma in situ of the urinary bladder.</i>								
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	..	*458.60	30.70	ImmuCyst	AV
BCG-TICE								
<i>(Bacillus Calmette-Guérin/ Tice strain)</i>								
<u>Restricted benefit</u>								
<i>Primary and relapsing superficial urothelial carcinoma of the bladder.</i>								
1131M	Vial containing powder for intravesical administration approximately 5 x 10 ⁸ CFU	3	1	..	531.79	30.70	OncoTICE	OR

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS —cont.

Code	Name, Restriction, Manner of administration and form	Max. No.of			Dispensed Price for Max.Qty \$	Maximum Recordable Value for Safety Net \$	Proprietary Name and Manufacturer
		Qty	Rpts	Premium			
<u>GLATIRAMER ACETATE</u>							
<u>Authority required</u>							
<i>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;</i>							
<i>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.</i>							
8726G	Injection 20 mg in 1 mL single dose pre-filled syringe	28	5	..	1089.60	30.70	Copaxone AV

IMMUNOSUPPRESSIVE AGENTS

Immunosuppressive agents

• Selective immunosuppressive agents

ADALIMUMAB**NOTE:**

Any queries concerning the arrangements to prescribe adalimumab may be directed to Medicare Australia on 1800 005 750 (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 tumour necrosis factor (TNF) alfa antagonists (adalimumab, etanercept and infliximab) and the interleukin-1 inhibitor (anakinra) for adult patients with severe rheumatoid arthritis.

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

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS —cont.

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

ADALIMUMAB—cont.**1. Patients who have received no prior PBS-subsidised bDMARD treatment at 1 December 2004.**

From 1 December 2004, the arrangements for prescribing the bDMARDs on the PBS have been amended to allow patients to commence a single cycle of bDMARD treatment that allows them to trial any number of bDMARDs without having to experience a disease flare when swapping between alternate bDMARDs. Within a single treatment cycle, patients may continue to receive long-term treatment with a bDMARD while they continue to show a response to therapy.

Once patients have either failed, or ceased to respond to, treatment with a maximum of 3 bDMARDs, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 5 year break in PBS-subsidised bDMARD therapy before they are eligible to commence the next cycle. The 5-year period will be measured from the date the last prescription for PBS-subsidised bDMARD treatment was approved in the most recent cycle to the date of the application for initial treatment with a bDMARD under the new cycle.

Patients who have failed treatment with fewer than 3 bDMARDs within a particular treatment cycle, and where a period of less than 5 years duration has elapsed since the patient's previous course of PBS-subsidised bDMARD treatment in that cycle, may commence a further course of bDMARD treatment within that same treatment cycle.

Patients who have failed treatment with fewer than 3 bDMARDs within a particular treatment cycle, and who have had a break in PBS-subsidised therapy of 5 years or more, are eligible to 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.

2. Patients who have received PBS-subsidised TNF- α antagonist treatment prior to 1 December 2004.

Patients who commenced PBS-subsidised TNF- α antagonist therapy prior to 1 December 2004 are considered to be in their first cycle of bDMARD treatment on 1 December 2004.

Patients who have failed to respond to prior PBS-subsidised treatment with fewer than 3 TNF- α antagonists at the time the first application for treatment is made on or after 1 December 2004, will be subject to the same conditions applying to new patients detailed above.

Therefore, patients who have failed:

- (a) 1 TNF- α antagonist will be eligible to trial further PBS-subsidised treatment with a bDMARD they have not failed in their first treatment cycle, until they fail to demonstrate a response to no more than another 2 bDMARDs;*
- (b) 2 TNF- α antagonists will be eligible to trial further PBS-subsidised treatment with a bDMARD they have not failed in their first treatment cycle, until they fail to demonstrate a response to no more than 1 other bDMARD.*

continued 

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS —cont.

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

ADALIMUMAB—cont.

Patients who have failed PBS-subsidised treatment with 3 TNF-alfa antagonists prior to 1 December 2004 or at the first assessment required after this date, will be eligible to trial PBS-subsidised treatment with anakinra if they wish. However, if they fail to demonstrate a response to anakinra, they will not be able to trial any further PBS-subsidised bDMARD treatment until a minimum of 5 years has elapsed from the date that the prescription for the last course of anakinra therapy was approved. Arrangements to allow these patients to fail 4 bDMARDs will only be in place for the first treatment cycle. For subsequent cycles, patients will cease to be eligible to receive PBS-subsidised bDMARD treatment once they have failed to demonstrate a response to a maximum of 3 bDMARDs.

Any queries on these arrangements should be forwarded to Medicare Australia.

3. Information relevant to all patients.

(a) Initial treatment.

Applications for initial treatment should be made where:

- (i) patients have received no prior PBS-subsidised bDMARD treatment and wish to commence such therapy; or*
- (ii) patients have received prior PBS-subsidised (initial or continuing) bDMARD therapy and wish to trial an alternate agent [further details are under 'Swapping therapy' below]; or*
- (iii) patients wish to re-commence treatment with a specific bDMARD following a break in PBS-subsidised therapy with that specific agent.*

All applications for initial treatment 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 bDMARD 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 bDMARD.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD, 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 bDMARD 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 bDMARD.

(c) Swapping therapy.

Once an authority for initial treatment with the first PBS-subsidised bDMARD is approved, patients may swap to an alternate bDMARD 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-bDMARD therapy requirements. However, the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS —cont.

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

ADALIMUMAB—cont.

Patients may swap to 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 or not.

Patients may alternate between therapy with any bDMARD of their choice (1 at a time) providing:

- (i) they have not received PBS-subsidised treatment with that particular bDMARD previously; or***
- (ii) they have demonstrated an adequate response to that particular bDMARD if they have previously trialled it on the PBS.***

Therefore, to maximise the choice of bDMARD patients may alternate between, it is important that patients 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 bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(d) 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 bDMARD. 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. more than 20 active joints), response will be determined according to a reduction in the total number of active joints.

(e) 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 bDMARD 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 at least 1 non-biological DMARD, 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.

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS —cont.

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

ADALIMUMAB—cont.**Authority required**

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, 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 that particular agent(s) only. Details of the contraindications or intolerance, including the degree of toxicity, must be provided at the time of application.

The following initiation criteria indicate failure to achieve an adequate response and must be demonstrable 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).*

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 Biological DMARD PBS Authority Application for Use in the Treatment of Rheumatoid Arthritis - Supporting Information Form [may be downloaded from the Medicare Australia website (visit www.medicareaustralia.gov.au/providers/forms/pbs.htm) and click on 'Medical Practitioners'] 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 may be downloaded from the Medicare Australia website (visit www.medicareaustralia.gov.au/providers/forms/pbs.htm) and click on 'Medical Practitioners'. Completion of this form declares that the patient understands and acknowledges that, within a single treatment cycle, PBS-subsidised treatment with any biological DMARD 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 

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS —cont.

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

ADALIMUMAB—cont.

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 005 750 (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 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

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 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.*

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.

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.

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

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

- (1) a completed authority prescription form; and*
- (2) a completed Biological DMARD PBS Authority Application for Use in the Treatment of Rheumatoid Arthritis - Supporting Information Form [may be downloaded from the Medicare Australia website (visit www.medicareaustralia.gov.au/providers/forms/pbs.htm) and click on 'Medical Practitioners']].*

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 005 750 (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 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.

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS —cont.

Code	Name, Restriction, Manner of administration and form	Max. Qty	No. of Rpts	Premium	Dispensed	Maximum	Proprietary Name and Manufacturer	
					Price for Max. Qty \$	Recordable Value for Safety Net \$		
ADALIMUMAB—cont.								
<i>Once patients fail to respond to treatment with 3 bDMARDs, they 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 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.</i>								
8737W	Injection 40 mg in 0.8 mL pre-filled syringe	2	3	..	1745.09	30.70	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 PBS-subsidised supply for continuing 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) were receiving treatment with adalimumab prior to 1 November 2004; and*
- (c) failed to qualify for PBS-subsidised therapy after 1 May 2004 due to an inability to receive concomitant methotrexate; and*
- (d) have demonstrated a response as specified in the criteria for continuing PBS-subsidised treatment with adalimumab.*

Medical practitioners who wish to apply for authority to prescribe a bDMARD for patients who commenced treatment with adalimumab prior to 1 November 2004 and who have not demonstrated a response to treatment should contact Medicare Australia on 1800 005 750.

The authority application must be in writing and must include sufficient information to determine the patient's eligibility. The date of assessment must be provided.

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.

Once patients fail to respond to treatment with 3 bDMARDs, they 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 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.

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS —cont.

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

ADALIMUMAB—cont.**Authority required**

Initial PBS-subsidised supply for continuing 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) were receiving treatment with adalimumab prior to 1 March 2005; and*
- (c) failed to qualify for PBS-subsidised therapy after 1 May 2004 due to testing negative for rheumatoid factor; and*
- (d) have demonstrated a response as specified in the criteria for continuing PBS-subsidised treatment with adalimumab.*

Medical practitioners who wish to apply for authority to prescribe a bDMARD for patients who commenced treatment with adalimumab prior to 1 March 2005 and who have not demonstrated a response to treatment should contact Medicare Australia on 1800 005 750.

The authority application must be in writing and must include sufficient information to determine the patient's eligibility. The date of assessment must be provided.

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.

Once patients fail to respond to treatment with 3 bDMARDs, they 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 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

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 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).*

continued ➤

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS —cont.

Code	Name, Restriction, Manner of administration and form	Max. No.of Qty Rpts Premium	Dispensed Price for Max.Qty \$	Maximum Recordable Value for Safety Net \$	Proprietary Name and Manufacturer
ADALIMUMAB—cont.					
<i>The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed Biological DMARD PBS Authority Application for Use in the Treatment of Rheumatoid Arthritis - Supporting Information Form [may be downloaded from the Medicare Australia website (visit www.medicareaustralia.gov.au/providers/forms/pbs.htm) and click on 'Medical Practitioners']].</i>					
<i>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.</i>					
<i>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 005 750 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).</i>					
<i>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.</i>					
<i>Once patients fail to respond to treatment with 3 bDMARDs, they 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 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.</i>					
8741C	Injection 40 mg in 0.8 mL pre-filled syringe	2 5 ..	1745.09	30.70	Humira AB
NOTE: <i>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.</i>					

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS —cont.

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

ADALIMUMAB—cont.**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.

continued ➞

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS —cont.

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

ADALIMUMAB—cont.

(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.

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS —cont.

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

ADALIMUMAB—cont.

(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.

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 either methotrexate or sulfasalazine, at an adequate dose, for a minimum of 3 months at the time the ESR or CRP levels and the active joint counts are measured.

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ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS—cont.

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

ADALIMUMAB—cont.**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 with a record of rheumatoid factor negative status within the last 12 months; 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.

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.*

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS —cont.

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

ADALIMUMAB—cont.

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 005 750 (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 with a record of rheumatoid factor negative status within the last 12 months; 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.

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 005 750 (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.

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	
ADALIMUMAB—cont.								
<i>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.</i>								
9033K	<i>Injection 40 mg in 0.8 mL pre-filled syringe</i>	2	3	..	1745.09	30.70	<i>Humira</i>	<i>AB</i>

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 with a record of rheumatoid factor negative status within the last 12 months; 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 005 750 (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.

Code	Name, Restriction, Manner of administration and form	Max. No.of		Premium	Dispensed	Maximum	Proprietary Name and Manufacturer
		Qty	Rpts		Price for Max.Qty \$	Recordable Value for Safety Net \$	
ADALIMUMAB—cont.							
<u>Authority required</u>							
<u>Continuing treatment</u>							
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 with a record of rheumatoid factor negative status; 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 005 750 (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	..	1745.09	30.70	Humira AB
<u>NOTE:</u>							
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.							

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS —cont.

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

ANAKINRA**NOTE:**

Any queries concerning the arrangements to prescribe anakinra may be directed to Medicare Australia on 1800 005 750 (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:

*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 tumour necrosis factor (TNF) alfa antagonists (adalimumab, etanercept and infliximab) and the interleukin-1 inhibitor (anakinra) for adult patients with severe rheumatoid arthritis.

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

1. Patients who have received no prior PBS-subsidised bDMARD treatment at 1 December 2004.

From 1 December 2004, the arrangements for prescribing the bDMARDs on the PBS have been amended to allow patients to commence a single cycle of bDMARD treatment that allows them to trial any number of bDMARDs without having to experience a disease flare when swapping between alternate bDMARDs. Within a single treatment cycle, patients may continue to receive long-term treatment with a bDMARD while they continue to show a response to therapy.

Once patients have either failed, or ceased to respond to, treatment with a maximum of 3 bDMARDs, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 5 year break in PBS-subsidised bDMARD therapy before they are eligible to commence the next cycle. The 5-year period will be measured from the date the last prescription for PBS-subsidised bDMARD treatment was approved in the most recent cycle to the date of the application for initial treatment with a bDMARD under the new cycle.

Patients who have failed treatment with fewer than 3 bDMARDs within a particular treatment cycle, and where a period of less than 5 years duration has elapsed since the patient's previous course of PBS-subsidised bDMARD treatment in that cycle, may commence a further course of bDMARD treatment within that same treatment cycle.

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS —cont.

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

ANAKINRA—cont.

Patients who have failed treatment with fewer than 3 bDMARDs within a particular treatment cycle, and who have had a break in PBS-subsidised therapy of 5 years or more, are eligible to 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.

2. Patients who have received PBS-subsidised TNF- α antagonist treatment prior to 1 December 2004.

Patients who commenced PBS-subsidised TNF- α antagonist therapy prior to 1 December 2004 are considered to be in their first cycle of bDMARD treatment on 1 December 2004.

Patients who have failed to respond to prior PBS-subsidised treatment with fewer than 3 TNF- α antagonists at the time the first application for treatment is made on or after 1 December 2004, will be subject to the same conditions applying to new patients detailed above.

Therefore, patients who have failed:

- (a) 1 TNF- α antagonist will be eligible to trial further PBS-subsidised treatment with a bDMARD they have not failed in their first treatment cycle, until they fail to demonstrate a response to no more than another 2 bDMARDs;*
- (b) 2 TNF- α antagonists will be eligible to trial further PBS-subsidised treatment with a bDMARD they have not failed in their first treatment cycle, until they fail to demonstrate a response to no more than 1 other bDMARD.*

Patients who have failed PBS-subsidised treatment with 3 TNF- α antagonists prior to 1 December 2004 or at the first assessment required after this date, will be eligible to trial PBS-subsidised treatment with anakinra if they wish. However, if they fail to demonstrate a response to anakinra, they will not be able to trial any further PBS-subsidised bDMARD treatment until a minimum of 5 years has elapsed from the date that the prescription for the last course of anakinra therapy was approved. Arrangements to allow these patients to fail 4 bDMARDs will only be in place for the first treatment cycle. For subsequent cycles, patients will cease to be eligible to receive PBS-subsidised bDMARD treatment once they have failed to demonstrate a response to a maximum of 3 bDMARDs.

Any queries on these arrangements should be forwarded to Medicare Australia.

3. Information relevant to all patients.

(a) Initial treatment.

Applications for initial treatment should be made where:

- (i) patients have received no prior PBS-subsidised bDMARD treatment and wish to commence such therapy; or*
- (ii) patients have received prior PBS-subsidised (initial or continuing) bDMARD therapy and wish to trial an alternate agent [further details are under 'Swapping therapy' below]; or*
- (iii) patients wish to re-commence treatment with a specific bDMARD following a break in PBS-subsidised therapy with that specific agent.*

continued ➞

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS —cont.

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

ANAKINRA—cont.

All applications for initial treatment 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 bDMARD 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 bDMARD.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD, 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 bDMARD 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 bDMARD.

(c) Swapping therapy.

Once an authority for initial treatment with the first PBS-subsidised bDMARD is approved, patients may swap to an alternate bDMARD 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-bDMARD therapy requirements. However, the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.

Patients may swap to 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 or not.

Patients may alternate between therapy with any bDMARD of their choice (1 at a time) providing:

- (i) they have not received PBS-subsidised treatment with that particular bDMARD previously; or*
- (ii) they have demonstrated an adequate response to that particular bDMARD if they have previously trialled it on the PBS.*

Therefore, to maximise the choice of bDMARD patients may alternate between, it is important that patients 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 bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS —cont.

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

ANAKINRA—cont.**(d) 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 bDMARD. 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. more than 20 active joints), response will be determined according to a reduction in the total number of active joints.

(e) 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 bDMARD 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 at least 1 non-biological DMARD, 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

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, 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 that particular agent(s) only. Details of the contraindications or intolerance, including the degree of toxicity, must be provided at the time of application.

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS —cont.

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

ANAKINRA—cont.

The following initiation criteria indicate failure to achieve an adequate response and must be demonstrable 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).

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 Biological DMARD PBS Authority Application for Use in the Treatment of Rheumatoid Arthritis - Supporting Information Form [may be downloaded from the Medicare Australia website (visit www.medicareaustralia.gov.au/providers/forms/pbs.htm) and click on 'Medical Practitioners']] 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 may be downloaded from the Medicare Australia website (visit www.medicareaustralia.gov.au/providers/forms/pbs.htm) and click on 'Medical Practitioners'). Completion of this form declares that the patient understands and acknowledges that, within a single treatment cycle, PBS-subsidised treatment with any biological DMARD 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 005 750 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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

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 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.

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS —cont.

Code	Name, Restriction, Manner of administration and form	Max. No. of Qty Rpts Premium	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Proprietary Name and Manufacturer
ANAKINRA—cont.					
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. 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. 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. For the first treatment cycle only, applications for anakinra will also be approved under this restriction for patients who have failed to demonstrate a response to treatment with 3 PBS-subsidised TNF-alfa antagonists prior to 1 December 2004. Once these patients fail to demonstrate a response to anakinra, they will not be able to trial further PBS-subsidised bDMARDs until a 5-year period has elapsed from the date that the last course of anakinra therapy was approved. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed Biological DMARD PBS Authority Application for Use in the Treatment of Rheumatoid Arthritis - Supporting Information Form [may be downloaded from the Medicare Australia website (visit www.medicareaustralia.gov.au/providers/forms/pbs.htm) and click on 'Medical Practitioners']]. 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 005 750 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). 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. Once patients fail to respond to treatment with 3 bDMARDs, they 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 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 ..	1351.36	30.70	Kineret AN

NOTE:

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

continued ➤

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS —cont.

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

ANAKINRA—cont.

Authority required

Initial PBS-subsidised supply for continuing 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) were receiving treatment with anakinra prior to 1 July 2004; and*
- (c) have demonstrated a response as specified in the criteria for continuing PBS-subsidised treatment with anakinra.*

Medical practitioners who wish to apply for authority to prescribe a bDMARD for patients who commenced treatment with anakinra prior to 1 July 2004 and who have not demonstrated a response to treatment should contact Medicare Australia on 1800 005 750.

The authority application must be in writing and must include sufficient information to determine the patient's eligibility. The date of assessment must be provided.

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.

Once patients fail to respond to treatment with 3 bDMARDs, they 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 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 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) were receiving treatment with anakinra prior to 1 March 2005; and*
- (c) failed to qualify for PBS-subsidised therapy after 1 December 2004 due to testing negative for rheumatoid factor; and*
- (d) have demonstrated a response as specified in the criteria for continuing PBS-subsidised treatment with anakinra.*

Medical practitioners who wish to apply for authority to prescribe a bDMARD for patients who commenced treatment with anakinra prior to 1 March 2005 and who have not demonstrated a response to treatment should contact Medicare Australia on 1800 005 750.

The authority application must be in writing and must include sufficient information to determine the patient's eligibility. The date of assessment must be provided.

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.

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS —cont.

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

ANAKINRA—cont.

Once patients fail to respond to treatment with 3 bDMARDs, they 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 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

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 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 Biological DMARD PBS Authority Application for Use in the Treatment of Rheumatoid Arthritis - Supporting Information Form [may be downloaded from the Medicare Australia website (visit www.medicareaustralia.gov.au/providers/forms/pbs.htm) and click on 'Medical Practitioners']].*

For the first treatment cycle only, applications for anakinra will also be approved under this restriction for patients who have failed to demonstrate a response to treatment with 3 PBS-subsidised TNF- α antagonists prior to 1 December 2004. Once these patients fail to demonstrate a response to anakinra, they will not be able to trial further PBS-subsidised bDMARDs until a 5-year period has elapsed from the date that the last course of anakinra therapy was approved.

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.

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS —cont.

Code	Name, Restriction, Manner of administration and form	Max. No.of			Dispensed	Maximum	Proprietary Name and Manufacturer
		Qty	Rpts	Premium	Price for Max.Qty \$	Recordable Value for Safety Net \$	
ANAKINRA—cont.							
<i>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 005 750 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).</i>							
<i>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.</i>							
<i>Once patients fail to respond to treatment with 3 bDMARDs, they 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 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.</i>							
8774T	Injection 100 mg in 0.67 mL single use pre-filled syringe	28	5	..	1351.36	30.70	Kineret AN

NOTE:

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

CYCLOSPORIN**CAUTION:**

Careful monitoring of patients is mandatory.

Authority required

Maintenance therapy, following initiation and stabilisation of treatment with cyclosporin, of:

- patients with organ or tissue transplants. Therapy must remain under the supervision and direction of the transplant unit reviewing the patient. The name of the specialised transplant unit reviewing treatment and the date of the latest review at the specialised transplant unit must be included in the authority application;
- 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;
- 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;
- 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;

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS —cont.

Code	Name, Restriction, Manner of administration and form	Max. No. of Qty Rpts Premium	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Proprietary Name and Manufacturer	
CYCLOSPORIN—cont.						
<i>(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;</i>						
<i>Management (which includes initiation, stabilisation and review of therapy) by:</i>						
<i>(a) dermatologists or clinical immunologists of patients with severe atopic dermatitis for whom other systemic therapies are ineffective or inappropriate;</i>						
<i>(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;</i>						
<i>(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.</i>						
8657P	Capsule 10 mg	120 3 ..	*93.15	30.70	Neoral 10	NV
8658Q	Capsule 25 mg	60 3 ..	*103.63	30.70	^a Cicloral	HX
			^B 2.32 *105.95	30.70	^a Neoral 25	NV
8659R	Capsule 50 mg	60 3 ..	*209.39	30.70	^a Cicloral	HX
			^B 2.30 *211.69	30.70	^a Neoral 50	NV
8660T	Capsule 100 mg	60 3 ..	*402.61	30.70	^a Cicloral	HX
			^B 2.32 *404.93	30.70	^a Neoral 100	NV
8661W	Oral liquid 100 mg per mL, 50 mL	2 3 ..	*711.39	30.70	Neoral	NV

EFALIZUMAB**NOTE:**

Any queries concerning the arrangements to prescribe efalizumab may be directed to Medicare Australia on 1800 242 679 (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 and etanercept, 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 and etanercept.

continued ➤

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS —cont.

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

EFALIZUMAB—cont.

From 1 August 2006, all patients will be able to commence a 'Biological Treatment Cycle' (Cycle), where they may trial both efalizumab and etanercept 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.

Patients are eligible for PBS-subsidised treatment with only 1 biological agent, as systemic monotherapy, at any 1 time.

Initial treatment with efalizumab consists of 16 weeks of therapy and response to treatment must be assessed after at least 12 weeks of treatment. Initial treatment with etanercept consists of 12 weeks of active therapy followed by a treatment-free period of at least 12 weeks. Response to treatment must be assessed at the completion of the 12 week active etanercept treatment course.

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, 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 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 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 '(6) 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 trial and fail, or cease to respond to, the same PBS-subsidised biological agent more than twice. Therefore once a patient fails to meet the response criteria for the same PBS-subsidised biological agent on 2 occasions, they must change to the alternate agent if they wish to continue PBS-subsidised biological treatment.

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.

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS —cont.

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

EFALIZUMAB—cont.

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 August 2006.

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 the alternate agent (Initial 2) [further details are under '(4) Swapping therapy' below]; and***
- (iii) patients have failed their most recent course of PBS-subsidised biological therapy and wish to trial a further course of treatment with the same agent [providing they have not failed that agent more than once] (Initial 2); and***
- (iv) 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 and 12 weeks of therapy in the case of etanercept. Approval will be based on the criteria included in the relevant initial treatment restriction.

Grandfather patients.

Applications for patients who commenced treatment with efalizumab or etanercept prior to 10 November 2005 or 16 March 2006 respectively, 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 either 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, consisting of 24 weeks of continuous treatment in the case of efalizumab and 12 weeks of active treatment followed by a treatment-free period of at least 12 weeks in the case of etanercept. Approval will be based on the criteria included in the relevant restriction.

(2) Assessment of response to initial treatment.

When prescribing efalizumab, where the initial treatment course is for 16 weeks, 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 16 week 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. Applications for continuing treatment with efalizumab must also be submitted to Medicare Australia prior to the completion of this initial 16 week course of therapy to ensure continuity of treatment for those patients who meet the continuation criterion and who wish to continue on treatment with efalizumab.

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS —cont.

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

EFALIZUMAB—cont.

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.

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 a 16 week initial treatment course of efalizumab, to which an adequate response has been demonstrated, patients may qualify to receive up to 24 weeks of continuing treatment with efalizumab. Patients are eligible to continue to receive continuous treatment with efalizumab in 24 week courses providing they continue to sustain a response.

Prescribers should ensure that applications for second and subsequent courses of efalizumab are submitted to Medicare Australia before patients complete their previous treatment course to ensure uninterrupted treatment.

At the completion of an initial 12 week treatment course of etanercept, to which an adequate response has been demonstrated, followed by a 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 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.

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS —cont.

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

EFALIZUMAB—cont.**NOTE:****(4) Swapping therapy.**

Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to the alternate agent within the same treatment Cycle without having to re-qualify with respect to disease severity (i.e. a PASI score of greater than 15), or prior treatment requirements. This also applies to patients who fail to achieve or sustain a response to the first PBS-subsidised biological agent approved and who wish to trial a further course of treatment with the same 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 drug on 2 occasions in the same Cycle.

Patients who commenced PBS-subsidised treatment with efalizumab prior to 1 August 2006 access these interchangeability arrangements in the same way as patients who have not. The response to treatment for these patients will be counted toward the allowable treatment failures under the interchangeability arrangements for the current Cycle.

PBS subsidy does not allow for patients to receive treatment with another biological agent during the required 12 week 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 biological therapy treatment-free period of at least 12 weeks, immediately following this course of treatment, before swapping to efalizumab. Patients who fail to respond to etanercept and who qualify and wish to try a course of efalizumab, or a further course of etanercept, 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.

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ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS —cont.

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

EFALIZUMAB—cont.

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 re-qualify 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 (i.e. not in conjunction with acitretin, methotrexate or cyclosporin) 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 form 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 (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.*

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS —cont.

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

EFALIZUMAB—cont.

Patients for whom a PASI assessment for any prior course of treatment, where that course of treatment was completed prior to 10 November 2005, is not available, may contact Medicare Australia on 1800 242 679 for advice.

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) a copy of the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets and whole body area diagrams including the dates of assessment of the patient's condition [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)];***
 - (ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy]; and***
 - (iii) a copy of the signed patient acknowledgement form.***

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 242 679 (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. Applications for continuing treatment should be made prior to the completion of this course of treatment to ensure continuity of treatment for those patients who meet the continuation criterion.

Authority required

- Initial or re-Treatment [Initial 2, Whole body (Received prior biological agent under PBS)] Treatment as systemic monotherapy (i.e. not in conjunction with acitretin, methotrexate or cyclosporin) 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 more than once in the current Treatment Cycle.***

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ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS —cont.

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

EFALIZUMAB—cont.

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) a copy of the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and whole body 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 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 a response to the patient's 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 242 679 (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. Applications for continuing treatment should be made prior to the completion of this course of treatment to ensure continuity of treatment for those patients who meet the continuation criterion.

Patients who fail to demonstrate a response to treatment with the biological agents, efalizumab and etanercept, on a total of 3 occasions 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.

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS —cont.

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

EFALIZUMAB—cont.

Authority required

Initial treatment [Initial 1, Face, hand, foot (New patients — No prior biological agent)]
Initial treatment as systemic monotherapy (i.e. not in conjunction with acitretin, methotrexate or cyclosporin) 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 form 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 (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.

Patients for whom a PASI assessment for any prior course of treatment, where that course of treatment was completed prior to 10 November 2005, is not available, may contact Medicare Australia on 1800 242 679 for advice.

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ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS —cont.

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

EFALIZUMAB—cont.

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) a copy of 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) a copy of the signed patient acknowledgement form.**

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 242 679 (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. Applications for continuing treatment should be made prior to the completion of this course of treatment to ensure continuity of treatment for those patients who meet the continuation criterion.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS —cont.

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

EFALIZUMAB—cont.

Authority required

Initial or re-Treatment [Initial 2, Face, hand, foot (Received prior biological agent under PBS)]

Treatment as systemic monotherapy (i.e. not in conjunction with acitretin, methotrexate or cyclosporin) 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 more than once 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) a copy of 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.**

The PASI assessment must be performed on the same affected area as assessed at baseline.

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 a response to the patient's 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 242 679 (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. Applications for continuing treatment should be made prior to the completion of this course of treatment to ensure continuity of treatment for those patients who meet the continuation criterion.

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ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS —cont.

Code	Name, Restriction, Manner of administration and form	Max. No. of			Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Proprietary Name and Manufacturer	
		Qty	Rpts	Premium				
<i>EFALIZUMAB—cont.</i>								
<i>Patients who fail to demonstrate a response to treatment with the biological agents, efalizumab and etanercept, on a total of 3 occasions 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.</i>								
9000Q	Injection set containing 4 vials powder for injection 125 mg and 4 pre-filled syringes diluent 1.3 mL	1	3	..	1028.30	30.70	Raptiva	SG

NOTE:

No applications for increased repeats will be authorised.

Authority required

Initial treatment [Initial 3, Whole body (Grandfather patients)]

Initial PBS-subsidised supply for continuing treatment as systemic monotherapy (i.e. not in conjunction with acitretin, methotrexate or cyclosporin) 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 efalizumab prior to 10 November 2005; and*
- (b) had a Psoriasis Area and Severity Index (PASI) score of greater than 15 prior to commencing treatment with efalizumab; and*
- (c) have signed a patient acknowledgement form 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 (whole body); and*
- (d) have demonstrated a response as specified in the criterion included in the restriction for continuing PBS-subsidised treatment with efalizumab (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) a copy of the completed Psoriasis Area and Severity Index (PASI) calculation sheet and whole body area diagrams including the date of the assessment of the patient's condition at baseline (prior to initiation of efalizumab 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) a copy of the signed patient acknowledgement form.*

The most recent PASI assessment must be no more than 1 month old at the time of application.

A maximum of 24 weeks of treatment with efalizumab will be authorised under this restriction.

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS —cont.

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

EFALIZUMAB—cont.

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 242 679 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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 efalizumab. Applications for continuing treatment should be made prior to the completion of this course of treatment in order to ensure continuity of treatment for those patients who meet the continuation criterion included in the restriction for continuing PBS-subsidised treatment with efalizumab.

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

Authority required

Continuing treatment (Whole body)

Continuing PBS-subsidised treatment as systemic monotherapy (i.e. not in conjunction with acitretin, methotrexate or cyclosporin) 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, after at least 12 weeks of efalizumab treatment, compared with the pre-biological treatment baseline value for this 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) a copy of the completed Psoriasis Area and Severity Index (PASI) calculation sheet and whole body 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)].*

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 242 679 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

continued ➤

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS —cont.

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

EFALIZUMAB—cont.

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. Applications for further continuing treatment should be made prior to the completion of this treatment course, to ensure continuity of treatment for those patients who meet the continuation criterion included in the restriction for continuing PBS-subsidised treatment with efalizumab.

Patients who fail to demonstrate a response to treatment with the biological agents, efalizumab and etanercept, on a total of 3 occasions 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 3, Face, hand, foot (Grandfather patients)]

Initial PBS-subsidised supply for continuing treatment as systemic monotherapy (i.e. not in conjunction with acitretin, methotrexate or cyclosporin) 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 efalizumab prior to 10 November 2005; and**
- (b) whose disease, prior to treatment with efalizumab, 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 form 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 (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 efalizumab (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) a copy of 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 efalizumab 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) a copy of the signed patient acknowledgement form.**

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS —cont.

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

EFALIZUMAB—cont.

The PASI assessment must be performed on the same affected area as assessed prior to initiation of efalizumab treatment.

The most recent PASI assessment must be no more than 1 month old at the time of application.

A maximum of 24 weeks of treatment with efalizumab will be authorised under this restriction.

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 242 679 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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 efalizumab. Applications for continuing treatment should be made prior to the completion of this course of treatment in order to ensure continuity of treatment for those patients who meet the continuation criterion included in the restriction for continuing PBS-subsidised treatment with efalizumab.

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

Authority required

Continuing treatment (Face, hand, foot)

Continuing PBS-subsidised treatment as systemic monotherapy (i.e. not in conjunction with acitretin, methotrexate or cyclosporin) 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 their most recent course of 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, after at least 12 weeks of efalizumab treatment, 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, after at least 12 weeks of efalizumab treatment, as compared to the pre-biological treatment baseline value.*

The PASI assessment for continuing treatment must be performed on the same affected area assessed at baseline.

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ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS —cont.

Code	Name, Restriction, Manner of administration and form	Max. No.of			Dispensed Price for Max.Qty \$	Maximum Recordable Value for Safety Net \$	Proprietary Name and Manufacturer
		Qty	Rpts	Premium			
EFALIZUMAB—cont.							
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) a copy of 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)].							
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 242 679 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).							
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. Applications for further continuing treatment should be made prior to the completion of this treatment course, to ensure continuity of treatment for those patients who meet the continuation criterion included in the restriction for continuing PBS-subsidised treatment with efalizumab.							
Patients who fail to demonstrate a response to treatment with the biological agents, efalizumab and etanercept, on a total of 3 occasions 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	..	1028.30	30.70	Raptiva SG

NOTE:

No applications for increased repeats will be authorised.

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS —cont.

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

ETANERCEPT

NOTE:

Any queries concerning the arrangements to prescribe etanercept may be directed to Medicare Australia (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) on the following numbers:

For rheumatoid arthritis, psoriatic arthritis or ankylosing spondylitis, please call 1800 005 750

For chronic plaque psoriasis, please call 1800 242 679

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Applications for authority to prescribe etanercept should be forwarded to:

Medicare Australia

Prior Written Approval of Specialised Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

NOTE:

TREATMENT OF ADULT PATIENTS WITH ACTIVE ANKYLOSING SPONDYLITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of etanercept and infliximab for adult patients with active ankylosing spondylitis only. It does not apply to the prescribing of adalimumab. Therefore, where the term 'tumour necrosis factor (TNF) alfa antagonists' appears in the following NOTES and restrictions, it only refers to etanercept and infliximab.

Patients are eligible for PBS-subsidised treatment with only 1 of the 2 TNF-alfa antagonists above at any 1 time.

From 1 August 2005, under the PBS, all patients will be able to commence a single treatment cycle where they may trial both of the PBS-subsidised TNF-alfa antagonists without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single treatment cycle, patients may continue to receive long-term treatment with a TNF-alfa antagonist while they continue to show a response to therapy.

Once patients have either failed or ceased to respond to treatment up to 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 5 year break in PBS-subsidised TNF-alfa antagonist therapy before they are eligible to commence the next cycle. Within the same treatment cycle, patients are not allowed to trial and fail, or cease to respond to, the same PBS-subsidised TNF-alfa antagonist more than twice. Patients who have failed the same PBS-subsidised TNF-alfa antagonist twice must change to the alternate PBS-subsidised agent if they wish to continue PBS-subsidised TNF-alfa antagonist treatment.

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ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS —cont.

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

ETANERCEPT—cont.

The 5-year break in therapy will be measured from the date the last approval for PBS-subsidised TNF-alfa antagonist treatment was granted in the most recent cycle to the date of the first application for initial treatment with a TNF-alfa antagonist under the new cycle.

Where a period of less than 5 years duration has elapsed since the patient's previous course of PBS-subsidised TNF-alfa antagonist treatment, patients who have failed TNF-alfa antagonist therapy less than 3 times within a particular treatment cycle, as defined in the restriction, may commence a further course of treatment within that cycle.

Where a break in PBS-subsidised therapy of 5 years or more has occurred, patients who have failed TNF-alfa antagonist therapy less than 3 times within a particular treatment cycle, as defined in the restriction, are eligible to commence a new treatment cycle.

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

1. Patients 'grandfathered' onto PBS-subsidised treatment with infliximab and etanercept.

Both the infliximab and etanercept restrictions allow patients who commenced treatment prior to 1 March 2004 and 1 July 2004 respectively to commence treatment under a different set of criteria than those patients who commenced treatment after these dates (i.e. new patients). This means such patients were 'grandfathered' onto PBS-subsidised treatment. Consequently, the criteria to enable 'grandfather' patients to continue on PBS-subsidised treatment are also different to those for new patients.

Where patients who were 'grandfathered' onto PBS-subsidised treatment with 1 TNF-alfa antagonist wish to swap to the alternate agent, they can only do so using the restrictions that apply to 'grandfather' patients.

'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, 'grandfather' patients must requalify for initial treatment under the criteria that apply to new patients. See 'Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' below for further details. Patients who commenced on PBS-subsidised etanercept or infliximab treatment prior to 1 August 2005 are deemed to be in their first cycle of therapy.

The first course of initial therapy for patients 'grandfathered' onto PBS-subsidised treatment with etanercept or infliximab will be limited to provide for 24 weeks of therapy. All subsequent initial treatment courses made under the 'grandfather' restriction will be limited to provide 6 weeks of therapy.

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS —cont.

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

ETANERCEPT—cont.

2. How to prescribe TNF-alfa antagonist therapy after 1 August 2005.

(a) Initial treatment.

Applications for initial treatment should be made where:

- (i) patients have received no prior PBS-subsidised TNF-alfa antagonist treatment and wish to commence such therapy; or*
- (ii) patients have received prior PBS-subsidised (initial or continuing) TNF-alfa antagonist therapy and wish to trial an alternate agent [further details are under 'Swapping therapy' below]; or*
- (iii) patients have failed their most recent course of PBS-subsidised TNF-alfa antagonist therapy but wish to trial a further course of treatment with the same TNF-alfa antagonist (providing they have not failed that TNF-alfa antagonist more than once); or*
- (iv) patients wish to re-commence treatment with a specific TNF-alfa antagonist following a break in PBS-subsidised therapy with that specific agent.*

All applications for initial treatment will be limited to provide for a maximum of 6 weeks of therapy except for the first application for 'grandfather' patients approved for PBS-subsidised treatment with etanercept and infliximab where up to 24 weeks of treatment will be approved.

In order to demonstrate a response to therapy, patients who have received an initial PBS-subsidised course of up to 6 weeks of treatment must be assessed no earlier than 4 weeks from the commencement of the initial therapy course. In order to demonstrate a response to therapy, patients who have received an initial PBS-subsidised course of up to 24 weeks must be assessed in the 4 weeks prior to treatment being ceased.

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, patients will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.

Prescribers should ensure that applications for second and subsequent courses of PBS-subsidised TNF-alfa antagonist treatment are submitted to Medicare Australia before patients complete their previous treatment course to ensure uninterrupted treatment. Applications where no provisions to fax the prescription and application are made in the restriction should be posted to Medicare Australia no later than 2 weeks prior to the patient completing their previous treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific TNF-alfa antagonist, 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 TNF-alfa antagonist treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS —cont.

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

ETANERCEPT—cont.

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, patients will be deemed to have failed to respond to treatment with that TNF- α antagonist.

(c) How to apply for TNF- α antagonist treatment on or after 1 August 2005. Patients for whom the first application for PBS-subsidised treatment with either etanercept or infliximab is made on or after 1 August 2005, will fall into 1 of the following categories:

(I) Patients who have not received any prior PBS-subsidised infliximab or PBS-subsidised etanercept treatment.

This includes the following:

(i) Patients who have not received any prior treatment with infliximab or etanercept for ankylosing spondylitis.

(ii) Patients who have received non-PBS-subsidised treatment with infliximab after 1 March 2004.

(iii) Patients who have received non-PBS-subsidised treatment with etanercept after 1 July 2004.

(iv) Patients who have received non-PBS-subsidised infliximab treatment prior to 1 March 2004.

(v) Patients who have received non-PBS-subsidised etanercept treatment prior to 1 July 2004.

To commence PBS-subsidised treatment with etanercept or infliximab, all patients who fall into groups (i)-(iii) must qualify under the first initial restriction for new patients (i.e. the patient must meet the criteria with respect to the indices of severity and prior treatment regimens specified in the 'new patient' restriction).

To commence PBS-subsidised treatment with infliximab, all patients who fall into group (iv) must qualify under the first initial restriction for 'grandfather' patients (i.e. the patient must meet the criteria with respect to the indices of severity and prior treatment regimens specified in the 'grandfather' restriction).

To commence PBS-subsidised treatment with etanercept, all patients who fall into group (v) must qualify under the first initial restriction for 'grandfather' patients (i.e. the patient must meet the criteria with respect to the indices of severity and prior treatment regimens specified in the 'grandfather' restriction).

Patients in groups (iv) and (v) can not be 'grandfathered' onto treatment with the alternate agent. If they wish to commence PBS-subsidised therapy with the alternate agent, they must qualify under the first initial restriction for new patients (i.e. the patient must meet the criteria with respect to the indices of severity and prior treatment regimens specified in the 'new patient' restriction).

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS —cont.

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

ETANERCEPT—cont.

(II) Patients who have received PBS-subsidised etanercept only.

(III) Patients who have received PBS-subsidised infliximab only.

(IV) Patients who have received PBS-subsidised etanercept and non-PBS-subsidised infliximab.

(V) Patients who have received PBS-subsidised infliximab and non-PBS-subsidised etanercept.

To receive PBS-subsidised treatment with etanercept or infliximab, the patients in groups (II)-(V) do not need to requalify with respect to the indices of severity or prior treatment requirements. They use the second initial restriction for either 'new' or 'grandfather' patients (i.e. whichever was applicable for their first course of PBS-subsidised treatment).

NOTE:

Patients who have responded to their most recent course of etanercept therapy as specified in the restriction may:

- continue on etanercept treatment under the 'grandfather' or new patient restriction, whichever is applicable [see 'Patients grandfathered' onto PBS-subsidised treatment with infliximab and etanercept]; or*
- swap to an initial course of infliximab treatment of up to 6 weeks under the 'grandfather' or new patient restriction, whichever is applicable [see 'Patients grandfathered' onto PBS-subsidised treatment with infliximab and etanercept].*

Patients who have failed to respond to their most recent course of etanercept treatment may:

- trial a further course of initial therapy of up to 6 weeks with etanercept; or*
- swap to an initial course of infliximab treatment of up to 6 weeks.*

Patients who have responded to their most recent course of infliximab therapy as specified in the restriction may:

- continue on infliximab treatment under the 'grandfather' or new patient restriction, whichever is applicable [see 'Patients grandfathered' onto PBS-subsidised treatment with infliximab and etanercept]; or*
- swap to an initial course of etanercept treatment of up to 6 weeks under the 'grandfather' or new patient restriction, whichever is applicable [see 'Patients grandfathered' onto PBS-subsidised treatment with infliximab and etanercept].*

Patients who have failed to respond to their most recent course of infliximab treatment may:

- trial a further course of initial therapy of up to 6 weeks with infliximab; or*
- swap to an initial course of etanercept treatment of up to 6 weeks.*

3. Swapping therapy.

Once an authority for initial treatment with the first PBS-subsidised TNF- α antagonist is approved, patients may swap to the alternate TNF- α 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. This also applies to patients who fail to achieve or sustain a response to the first PBS-subsidised TNF- α antagonist approved and who wish to trial a further course of treatment with the same TNF- α antagonist.

continued 

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS —cont.

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

ETANERCEPT—cont.

Patients 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 or not. However, they cannot swap to a particular TNF-alfa antagonist if they have failed to respond to prior treatment with that particular drug more than twice in the same cycle.

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

To avoid confusion, applications for patients who wish to swap to an alternate TNF-alfa antagonist should be accompanied by the approved authority prescription or remaining repeats for the TNF-alfa antagonist 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 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 is submitted within a treatment cycle and Medicare Australia will assess response according to these revised baseline measurements.

For new patients, the first BASDAI result used to determine baseline must be provided while the patient is still receiving NSAID therapy. However, this is not required for any subsequent BASDAI results provided for these patients nor for patients who were 'grandfathered' onto 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.

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 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.

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS —cont.

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

ETANERCEPT—cont.

Authority required

Initial 1 (new patients)

Application for the first course of initial PBS-subsidised treatment with etanercept, by a rheumatologist, of adults with active ankylosing spondylitis who have radiographically (plain X-ray) confirmed Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis, who have not received any PBS-subsidised treatment with either etanercept or infliximab;

AND

(a) have at least 2 of the following:

(i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; or

(ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI) [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 have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs) in combination with 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 reasons why a higher dose cannot be used.

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.

Patients who received treatment with etanercept prior to 1 July 2004 and wish to commence PBS-subsidised treatment with etanercept must qualify under the initial treatment restriction for 'grandfather' patients.

The following initiation criteria indicate failure to achieve an adequate response and must be demonstrable in all patients 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. No. of			Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Proprietary Name and Manufacturer
		Qty	Rpts	Premium			

ETANERCEPT—cont.

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 reasons why this criterion cannot be satisfied.

If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the patient is exempted from demonstrating an inadequate response to the above treatment regimen. Where appropriate, evidence to support a contraindication must be provided. If adverse events of a severity necessitating permanent withdrawal develop during the relevant period of use of 2 NSAIDs, the patient may be exempted from demonstrating an inadequate response to the above treatment regimen. For details of the adverse events, including the severity, which will be accepted for the purposes of administering this restriction, please refer to the Medicare Australia website at www.medicareaustralia.gov.au.

Authority applications must be made in writing and must include:

- (a) a completed authority prescription form; and**
- (b) a completed TNF- α antagonist PBS Authority Application for Use in the Treatment of Ankylosing Spondylitis - Supporting Information Form [may be downloaded from the Medicare Australia website (visit www.medicareaustralia.gov.au/providers/forms/pbs.htm) and click on 'Medical Practitioners']] which includes the following:**
 - (i) a copy of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and**
 - (ii) a copy of the completed BASDAI Assessment Form [may be downloaded from the Medicare Australia website (visit www.medicareaustralia.gov.au/providers/forms/pbs.htm) and click on 'Medical Practitioners']]; and**
 - (iii) a copy of the signed patient acknowledgment form [may be downloaded from the Medicare Australia website (visit www.medicareaustralia.gov.au/providers/forms/pbs.htm) and click on 'Medical Practitioners']]. Completion of this form declares that the patient understands and acknowledges that PBS-subsidised treatment with the TNF- α antagonists (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 no earlier than 4 weeks from the commencement 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 6 weeks of treatment with etanercept will be approved under this criterion.

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS —cont.

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

ETANERCEPT—cont.

Authority required

Initial 2 (new patients)

Application for an initial course of PBS-subsidised treatment with etanercept, by a rheumatologist, of adults with active ankylosing spondylitis who, in this treatment cycle, have received prior PBS-subsidised treatment with either etanercept or infliximab for this condition and have not failed PBS-subsidised therapy with etanercept more than once.

All applications for treatment must be accompanied by the results of the most recent course of TNF-alfa antagonist therapy within the timeframes specified below.

Where the most recent course of PBS-subsidised TNF-alfa antagonist treatment was approved under an initial treatment restriction for new patients, patients must have been assessed for response to that course no earlier than 4 weeks from the commencement of that course. 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 TNF-alfa antagonist treatment was approved under the continuing treatment criteria for new patients, patients must have been assessed for response to that course, and the assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

If the response assessments to the previous course of TNF-alfa antagonist treatment are not submitted as detailed above, patients 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 TNF-alfa antagonist PBS Authority Application for Use in the Treatment of Ankylosing Spondylitis - Supporting Information Form [may be downloaded from the Medicare Australia website (visit www.medicareaustralia.gov.au/providers/forms/pbs.htm) and click on 'Medical Practitioners']] which includes a copy of the completed BASDAI Assessment Form [may be downloaded from the Medicare Australia website (visit www.medicareaustralia.gov.au/providers/forms/pbs.htm) and click on 'Medical Practitioners']].***

A maximum of 6 weeks of treatment with etanercept will be approved under this criterion.

Authority required

Initial 2 ('grandfather' patients)

Application for an initial course of PBS-subsidised treatment with etanercept, by a rheumatologist, of adults with active ankylosing spondylitis who have radiographically (plain X-ray) confirmed Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis, who were 'grandfathered' onto PBS-subsidised treatment with etanercept or infliximab and who have not failed PBS-subsidised therapy with etanercept more than once.

Where the most recent course of PBS-subsidised TNF-alfa antagonist treatment was approved under an initial treatment restriction for 'grandfather' patients, patients must have been assessed for response to that course no earlier than 4 weeks from the commencement of that course. 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. No. of			Dispensed	Maximum	Proprietary Name and Manufacturer
		Qty	Rpts	Premium	Price for Max. Qty \$	Recordable Value for Safety Net \$	

ETANERCEPT—cont.

Where the most recent course of PBS-subsidised TNF- α antagonist treatment was approved under the continuing treatment criteria for 'grandfather' patients, patients must have been assessed for response to that course, and the assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

If the response assessments to the previous course of TNF- α antagonist treatment are not submitted as detailed above, patients will be deemed to have failed therapy with that particular course of TNF- α antagonist.

Authority applications must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed TNF- α antagonist PBS Authority Application for Use in the Treatment of Ankylosing Spondylitis - Supporting Information Form [may be downloaded from the Medicare Australia website (visit www.medicareaustralia.gov.au/providers/forms/pbs.htm and click on 'Medical Practitioners')) which includes a copy of the completed BASDAI Assessment Form [may be downloaded from the Medicare Australia website (visit www.medicareaustralia.gov.au/providers/forms/pbs.htm and click on 'Medical Practitioners'))].

A maximum of 6 weeks of treatment with etanercept will be approved under this criterion.

8778B	Injection set containing 4 vials powder for injection 25 mg and 4 pre-filled syringes solvent 1 mL	3	..	..	*2674.01	30.70	Enbrel	WY

NOTE:

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

Authority required

Continuing (new patients)

Continuing PBS-subsidised treatment, by a rheumatologist, of adults with active ankylosing spondylitis who:

- (a) have received 6 weeks or more of PBS-subsidised treatment with etanercept; and*
- (b) have demonstrated a response to treatment with etanercept; and*
- (c) 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.*

The same acute phase reactant measured at the relevant baseline must be measured in all subsequent continuing treatment applications.

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS —cont.

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

ETANERCEPT—cont.

The first application for continuing treatment following an initial treatment course must be made no earlier than 4 weeks from the commencement of the most recent initial treatment course with etanercept. This first authority application and a copy of the authority prescription may be faxed to Medicare Australia on (03) 6215 5640 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) in order to seek approval for a maximum of 4 weeks' supply. Medicare Australia will then contact the prescriber by telephone. The original document must then be posted to Medicare Australia with a second authority prescription for the balance of 24 weeks of treatment.

Second and subsequent 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 TNF- α antagonist PBS Authority Application for Continuing Use in the Treatment of Ankylosing Spondylitis - Supporting Information Form [may be downloaded from the Medicare Australia website (visit www.medicareaustralia.gov.au/providers/forms/pbs.htm and click on 'Medical Practitioners')) which includes the following:*
 - (i) a copy of the completed BASDAI Assessment Form [may be downloaded from the Medicare Australia website (visit www.medicareaustralia.gov.au/providers/forms/pbs.htm and click on 'Medical Practitioners')) including 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.

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS —cont.

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

ETANERCEPT—cont.

Authority required

Initial 1 ('grandfather' patients)

Application for an initial PBS-subsidised course of continuing treatment with etanercept, by a rheumatologist, of adults with active ankylosing spondylitis who have radiographically (plain X-ray) confirmed Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis, who were receiving treatment with etanercept prior to 1 July 2004;

AND

(a) are receiving treatment with etanercept at the time of application;

AND

(b) who have not received prior PBS-subsidised treatment with infliximab;

AND

(c) whose Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score is less than or equal to 5 on a 0-10 scale;

AND

(d) who have:

(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 must be no more than 1 month old at the time of application. The same acute phase reactant measured in the first application for PBS-subsidised treatment must be measured in all subsequent continuing treatment applications.

Authority applications must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed TNF- α antagonist PBS Authority Application for Use in the Treatment of Ankylosing Spondylitis - Supporting Information Form [may be downloaded from the Medicare Australia website (visit www.medicareaustralia.gov.au/providers/forms/pbs.htm) and click on 'Medical Practitioners']] which includes the following:

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

(ii) a copy of the completed BASDAI Assessment Form [may be downloaded from the Medicare Australia website (visit www.medicareaustralia.gov.au/providers/forms/pbs.htm) and click on 'Medical Practitioners']] and

(iii) a copy of the signed patient acknowledgment form [may be downloaded from the Medicare Australia website (visit www.medicareaustralia.gov.au/providers/forms/pbs.htm) and click on 'Medical Practitioners']]. Completion of this form declares that the patient understands and acknowledges that PBS-subsidised treatment with the TNF- α antagonists (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.

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS —cont.

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

ETANERCEPT—cont.

Those patients ceasing treatment or swapping to an alternate agent and wishing to demonstrate a response to treatment, must be assessed no earlier than 4 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 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.

Patients may only qualify for PBS-subsidised treatment under this criterion once.

Authority required

Continuing ('grandfather' patients)

Continuing PBS-subsidised treatment, by a rheumatologist, of adults with active ankylosing spondylitis who were 'grandfathered' onto PBS-subsidised treatment with a TNF-alfa antagonist and who:

- (a) have received 6 weeks or more of PBS-subsidised treatment with etanercept; and*
- (b) have demonstrated a response to treatment with etanercept; and*
- (c) whose most recent course of PBS-subsidised therapy in this treatment cycle was with etanercept.*

Response to treatment is defined as a BASDAI score no more than 20% greater than the score included in the initial application for PBS-subsidised treatment;

AND

- (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 pre-treatment baseline.*

The same acute phase reactant measured at the relevant baseline must be measured in all subsequent continuing treatment applications.

The first application for continuing treatment following an initial treatment course must be made no earlier than 4 weeks from the commencement of the most recent initial treatment course with etanercept. This first authority application and a copy of the authority prescription may be faxed to Medicare Australia on (03) 6215 5640 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) in order to seek approval for a maximum of 4 weeks' supply. Medicare Australia will then contact the prescriber by telephone. The original document must then be posted to Medicare Australia with a second authority prescription for the balance of 24 weeks of treatment.

Second and subsequent 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. No. of			Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Proprietary Name and Manufacturer
		Qty	Rpts	Premium			

ETANERCEPT—cont.

In order to demonstrate a response to treatment where the patient is ceasing or swapping to an alternate agent, the assessment must be provided to Medicare Australia no later than 4 weeks from the date that course was ceased.

Written applications for authorisation must include:

- (a) a completed authority prescription form; and*
- (b) a completed TNF- α antagonist PBS Authority Application for Continuing Use in the Treatment of Ankylosing Spondylitis - Supporting Information Form [may be downloaded from the Medicare Australia website (visit www.medicareaustralia.gov.au/providers/forms/pbs.htm and click on 'Medical Practitioners')] which includes the following:*
 - (i) a copy of the completed BASDAI Assessment Form [may be downloaded from the Medicare Australia website (visit www.medicareaustralia.gov.au/providers/forms/pbs.htm and click on 'Medical Practitioners')] including 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.

8779C	Injection set containing 4 vials powder for injection 25 mg and 4 pre-filled syringes solvent 1 mL	2	5	..	*1797.73	30.70	Enbrel	WY

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.

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS —cont.

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

ETANERCEPT—cont.

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.

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS —cont.

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

ETANERCEPT—cont.

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.

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS —cont.

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

ETANERCEPT—cont.

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 either methotrexate or sulfasalazine, 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.

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS —cont.

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

ETANERCEPT—cont.

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 with a record of rheumatoid factor negative status within the last 12 months; 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.

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*

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS —cont.

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

ETANERCEPT—cont.

(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 005 750 (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 with a record of rheumatoid factor negative status within the last 12 months; 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.

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)].**

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS —cont.

Code	Name, Restriction, Manner of administration and form	Max. No. of			Dispensed	Maximum	Proprietary Name and Manufacturer
		Qty	Rpts	Premium	Price for Max. Qty \$	Recordable Value for Safety Net \$	
ETANERCEPT—cont.							
<i>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 005 750 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).</i>							
<i>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.</i>							
<i>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.</i>							
9035M	Injection set containing 4 vials powder for injection 25 mg and 4 pre-filled syringes solvent 1 mL	2	3	..	*1797.73	30.70	Enbrel WY

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 with a record of rheumatoid factor negative status within the last 12 months; 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.

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS —cont.

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

ETANERCEPT—cont.

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 005 750 (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.

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 with a record of rheumatoid factor negative status; 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.

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS —cont.

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

ETANERCEPT—cont.

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 005 750 (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	..	*1797.73	30.70	Enbrel	WY

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 tumour necrosis factor (TNF) alfa antagonists (adalimumab, etanercept and infliximab) and the interleukin-1 inhibitor (anakinra) for adult patients with severe rheumatoid arthritis.

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

1. Patients who have received no prior PBS-subsidised bDMARD treatment at 1 December 2004.

From 1 December 2004, the arrangements for prescribing the bDMARDs on the PBS have been amended to allow patients to commence a single cycle of bDMARD treatment that allows them to trial any number of bDMARDs without having to experience a disease flare when swapping between alternate bDMARDs. Within a single treatment cycle, patients may continue to receive long-term treatment with a bDMARD while they continue to show a response to therapy.

Once patients have either failed, or ceased to respond to, treatment with a maximum of 3 bDMARDs, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 5 year break in PBS-subsidised bDMARD therapy before they are eligible to commence the next cycle. The 5-year period will be measured from the date the last prescription for PBS-subsidised bDMARD treatment was approved in the most recent cycle to the date of the application for initial treatment with a bDMARD under the new cycle.

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS —cont.

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

ETANERCEPT—cont.

Patients who have failed treatment with fewer than 3 bDMARDs within a particular treatment cycle, and where a period of less than 5 years duration has elapsed since the patient's previous course of PBS-subsidised bDMARD treatment in that cycle, may commence a further course of bDMARD treatment within that same treatment cycle.

Patients who have failed treatment with fewer than 3 bDMARDs within a particular treatment cycle, and who have had a break in PBS-subsidised therapy of 5 years or more, are eligible to 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.

2. Patients who have received PBS-subsidised TNF-alfa antagonist treatment prior to 1 December 2004.

Patients who commenced PBS-subsidised TNF-alfa antagonist therapy prior to 1 December 2004 are considered to be in their first cycle of bDMARD treatment on 1 December 2004.

Patients who have failed to respond to prior PBS-subsidised treatment with fewer than 3 TNF-alfa antagonists at the time the first application for treatment is made on or after 1 December 2004, will be subject to the same conditions applying to new patients detailed above.

Therefore, patients who have failed:

- (a) 1 TNF-alfa antagonist will be eligible to trial further PBS-subsidised treatment with a bDMARD they have not failed in their first treatment cycle, until they fail to demonstrate a response to no more than another 2 bDMARDs;*
- (b) 2 TNF-alfa antagonists will be eligible to trial further PBS-subsidised treatment with a bDMARD they have not failed in their first treatment cycle, until they fail to demonstrate a response to no more than 1 other bDMARD.*

Patients who have failed PBS-subsidised treatment with 3 TNF-alfa antagonists prior to 1 December 2004 or at the first assessment required after this date, will be eligible to trial PBS-subsidised treatment with anakinra if they wish. However, if they fail to demonstrate a response to anakinra, they will not be able to trial any further PBS-subsidised bDMARD treatment until a minimum of 5 years has elapsed from the date that the prescription for the last course of anakinra therapy was approved. Arrangements to allow these patients to fail 4 bDMARDs will only be in place for the first treatment cycle. For subsequent cycles, patients will cease to be eligible to receive PBS-subsidised bDMARD treatment once they have failed to demonstrate a response to a maximum of 3 bDMARDs.

Any queries on these arrangements should be forwarded to Medicare Australia.

continued ➤

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS —cont.

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

ETANERCEPT—cont.

3. Information relevant to all patients.

(a) Initial treatment.

Applications for initial treatment should be made where:

- (i) patients have received no prior PBS-subsidised bDMARD treatment and wish to commence such therapy; or*
- (ii) patients have received prior PBS-subsidised (initial or continuing) bDMARD therapy and wish to trial an alternate agent [further details are under 'Swapping therapy' below]; or*
- (iii) patients wish to re-commence treatment with a specific bDMARD following a break in PBS-subsidised therapy with that specific agent.*

All applications for initial treatment 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 bDMARD 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 bDMARD.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD, 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 bDMARD 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 bDMARD.

(c) Swapping therapy.

Once an authority for initial treatment with the first PBS-subsidised bDMARD is approved, patients may swap to an alternate bDMARD 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-bDMARD therapy requirements. However, the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.

Patients may swap to 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 or not.

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS —cont.

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

ETANERCEPT—cont.

Patients may alternate between therapy with any bDMARD of their choice (1 at a time) providing:

- (i) they have not received PBS-subsidised treatment with that particular bDMARD previously; or*
- (ii) they have demonstrated an adequate response to that particular bDMARD if they have previously trialled it on the PBS.*

Therefore, to maximise the choice of bDMARD patients may alternate between, it is important that patients 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 bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(d) 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 bDMARD. 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. more than 20 active joints), response will be determined according to a reduction in the total number of active joints.

(e) 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 bDMARD 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 at least 1 non-biological DMARD, 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.

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS —cont.

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

ETANERCEPT—cont.**Authority required**

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, 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 that particular agent(s) only. Details of the contraindications or intolerance, including the degree of toxicity, must be provided at the time of application.

The following initiation criteria indicate failure to achieve an adequate response and must be demonstrable 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).*

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 Biological DMARD PBS Authority Application for Use in the Treatment of Rheumatoid Arthritis - Supporting Information Form [may be downloaded from the Medicare Australia website (visit www.medicareaustralia.gov.au/providers/forms/pbs.htm) and click on 'Medical Practitioners'] 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*

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS —cont.

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

ETANERCEPT—cont.

(3) a copy of the signed patient acknowledgement form which may be downloaded from the Medicare Australia website (visit www.medicareaustralia.gov.au/providers/forms/pbs.htm and click on 'Medical Practitioners'). Completion of this form declares that the patient understands and acknowledges that, within a single treatment cycle, PBS-subsidised treatment with any biological DMARD 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 005 750 (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. 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

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 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.*

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.

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.

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.

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS —cont.

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

ETANERCEPT—cont.

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

- (1) a completed authority prescription form; and*
- (2) a completed Biological DMARD PBS Authority Application for Use in the Treatment of Rheumatoid Arthritis - Supporting Information Form [may be downloaded from the Medicare Australia website (visit www.medicareaustralia.gov.au/providers/forms/pbs.htm) and click on 'Medical Practitioners']].*

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 005 750 (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. 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.

Once patients fail to respond to treatment with 3 bDMARDs, they 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 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.*

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	
ETANERCEPT—cont.								
<i>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.</i> <i>The following criteria must be met in order to demonstrate failure to achieve an adequate response:</i> <i>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;</i> AND either <i>(i) an active joint count of at least 20 active (swollen and tender) joints; or</i> <i>(ii) at least 4 active joints from the following list:</i> <i>— elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or</i> <i>— 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).</i> <i>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.</i> <i>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.</i> <i>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.</i> <i>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.</i>								
8637N	Injection set containing 4 vials powder for injection 25 mg and 4 pre-filled syringes solvent 1 mL	2	3	..	*1797.73	30.70	Enbrel	WY
8861J	Injection set containing 4 vials powder for injection 50 mg and 4 pre-filled syringes solvent 1 mL	1	3	..	1745.10	30.70	Enbrel	WY

NOTE:

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

continued 

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS —cont.

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

ETANERCEPT—cont.**Authority required**

Initial PBS-subsidised supply for continuing 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) were receiving treatment with etanercept prior to 1 March 2005; and*
- (c) failed to qualify for PBS-subsidised therapy after 1 August 2003 due to testing negative for rheumatoid factor; and*
- (d) have demonstrated a response as specified in the criteria for continuing PBS-subsidised treatment with etanercept.*

Medical practitioners who wish to apply for authority to prescribe a bDMARD for patients who commenced treatment with etanercept prior to 1 March 2005 and who have not demonstrated a response to treatment should contact Medicare Australia on 1800 005 750.

The authority application must be in writing and must include sufficient information to determine the patient's eligibility. The date of assessment must be provided.

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.

Once patients fail to respond to treatment with 3 bDMARDs, they 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 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

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 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).*

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS —cont.

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

ETANERCEPT—cont.

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

- (1) a completed authority prescription form; and*
- (2) a completed Biological DMARD PBS Authority Application for Use in the Treatment of Rheumatoid Arthritis - Supporting Information Form [may be downloaded from the Medicare Australia website (visit www.medicareaustralia.gov.au/providers/forms/pbs.htm) and click on 'Medical Practitioners']].*

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.

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 005 750 (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. 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.

Once patients fail to respond to treatment with 3 bDMARDs, they 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 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.

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS —cont.

Code	Name, Restriction, Manner of administration and form	Max. No. of			Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Proprietary Name and Manufacturer	
		Qty	Rpts	Premium				
<i>ETANERCEPT—cont.</i>								
<i>Authority required</i>								
<i>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:</i>								
<i>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;</i>								
<i>AND 1 or more of the following:</i>								
<i>(i) an active joint count of fewer than 10 active (swollen and tender) joints; or</i>								
<i>(ii) a reduction in the active (swollen and tender) joint count by at least 50% from baseline;</i>								
<i>or</i>								
<i>(iii) a reduction in the number of the following active joints, from at least 4, by at least 50%:</i>								
<i>— elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or</i>								
<i>— 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).</i>								
<i>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.</i>								
<i>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.</i>								
<i>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.</i>								
8638P	Injection set containing 4 vials powder for injection 25 mg and 4 pre-filled syringes solvent 1 mL	2	5	..	*1797.73	30.70	Enbrel	WY
8862K	Injection set containing 4 vials powder for injection 50 mg and 4 pre-filled syringes solvent 1 mL	1	5	..	1745.10	30.70	Enbrel	WY

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. No. of Qty Rpts Premium	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Proprietary Name and Manufacturer

ETANERCEPT—cont.

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 and etanercept, 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 and etanercept.

From 1 August 2006, all patients will be able to commence a 'Biological Treatment Cycle' (Cycle), where they may trial both efalizumab and etanercept 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.

Patients are eligible for PBS-subsidised treatment with only 1 biological agent, as systemic monotherapy, at any 1 time.

Initial treatment with efalizumab consists of 16 weeks of therapy and response to treatment must be assessed after at least 12 weeks of treatment. Initial treatment with etanercept consists of 12 weeks of active therapy followed by a treatment-free period of at least 12 weeks. Response to treatment must be assessed at the completion of the 12 week active etanercept treatment course.

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, 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 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 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 '(6) 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 trial and fail, or cease to respond to, the same PBS-subsidised biological agent more than twice. Therefore once a patient fails to meet the response criteria for the same PBS-subsidised biological agent on 2 occasions, they must change to the alternate agent if they wish to continue PBS-subsidised biological treatment.

continued ➞

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS —cont.

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

ETANERCEPT—cont.

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 August 2006.

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 the alternate agent (Initial 2) [further details are under '(4) Swapping therapy' below]; and*
- (iii) patients have failed their most recent course of PBS-subsidised biological therapy and wish to trial a further course of treatment with the same agent [providing they have not failed that agent more than once] (Initial 2); and*
- (iv) 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 and 12 weeks of therapy in the case of etanercept. Approval will be based on the criteria included in the relevant initial treatment restriction.

Grandfather patients.

Applications for patients who commenced treatment with efalizumab or etanercept prior to 10 November 2005 or 16 March 2006 respectively, 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 either 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, consisting of 24 weeks of continuous treatment in the case of efalizumab and 12 weeks of active treatment followed by a treatment-free period of at least 12 weeks in the case of etanercept. Approval will be based on the criteria included in the relevant restriction.

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS —cont.

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

ETANERCEPT—cont.**(2) Assessment of response to initial treatment.**

When prescribing efalizumab, where the initial treatment course is for 16 weeks, 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 16 week 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. Applications for continuing treatment with efalizumab must also be submitted to Medicare Australia prior to the completion of this initial 16 week course of therapy to ensure continuity of treatment for those patients who meet the continuation criterion and who wish to continue on treatment with efalizumab.

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.

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 a 16 week initial treatment course of efalizumab, to which an adequate response has been demonstrated, patients may qualify to receive up to 24 weeks of continuing treatment with efalizumab. Patients are eligible to continue to receive continuous treatment with efalizumab in 24 week courses providing they continue to sustain a response.

Prescribers should ensure that applications for second and subsequent courses of efalizumab are submitted to Medicare Australia before patients complete their previous treatment course to ensure uninterrupted treatment.

At the completion of an initial 12 week treatment course of etanercept, to which an adequate response has been demonstrated, followed by a 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 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.

continued ➞

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS —cont.

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

ETANERCEPT—cont.

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.

NOTE:

(4) Swapping therapy.

Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to the alternate agent within the same treatment Cycle without having to re-qualify with respect to disease severity (i.e. a PASI score of greater than 15), or prior treatment requirements. This also applies to patients who fail to achieve or sustain a response to the first PBS-subsidised biological agent approved and who wish to trial a further course of treatment with the same 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 drug on 2 occasions in the same Cycle.

Patients who commenced PBS-subsidised treatment with efalizumab prior to 1 August 2006 access these interchangeability arrangements in the same way as patients who have not. The response to treatment for these patients will be counted toward the allowable treatment failures under the interchangeability arrangements for the current Cycle.

PBS subsidy does not allow for patients to receive treatment with another biological agent during the required 12 week 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 biological therapy treatment-free period of at least 12 weeks, immediately following this course of treatment, before swapping to efalizumab. Patients who fail to respond to etanercept and who qualify and wish to try a course of efalizumab, or a further course of etanercept, 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.

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS —cont.

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

ETANERCEPT—cont.

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 re-qualify 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 (i.e. not in conjunction with acitretin, methotrexate or cyclosporin) 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 form 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 (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.

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ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS —cont.

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

ETANERCEPT—cont.

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.*

Patients for whom a PASI assessment for any prior course of treatment, where that course of treatment was completed prior to 16 March 2006, is not available, may contact Medicare Australia on 1800 242 679 for advice.

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) a copy of the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets and whole body 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) a copy of the signed patient acknowledgement form.*

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 242 679 (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.

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS —cont.

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

ETANERCEPT—cont.

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 or a further course of etanercept 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 (i.e. not in conjunction with acitretin, methotrexate or cyclosporin) 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 more than once 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) a copy of the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and whole body 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 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.

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 242 679 (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. No. of			Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Proprietary Name and Manufacturer
		Qty	Rpts	Premium			

ETANERCEPT—cont.

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.

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 or a further course of etanercept 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 the biological agents, efalizumab and etanercept, on a total of 3 occasions 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 3, Whole body (Grandfather patients)]

Initial PBS-subsidised supply for continuing treatment as systemic monotherapy (i.e. not in conjunction with acitretin, methotrexate or cyclosporin) 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 etanercept prior to 16 March 2006; and

(b) had a Psoriasis Area and Severity Index (PASI) score of greater than 15 prior to commencing treatment with etanercept; and

(c) have signed a patient acknowledgement form 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 (whole body); and

(d) have demonstrated a response as specified in the criterion included in the restriction for continuing PBS-subsidised treatment with etanercept (whole body).

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS —cont.

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

ETANERCEPT—cont.

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) a copy of the completed Psoriasis Area and Severity Index (PASI) calculation sheet and whole body area diagrams including the date of the assessment of the patient's condition at baseline (prior to initiation of etanercept 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) a copy of the signed patient acknowledgement form.**

The most recent PASI assessment must be no more than 1 month old at the time of application.

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 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 242 679 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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.

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 or a further course of etanercept according to the interchangeability arrangements for biological agents for the treatment of severe chronic plaque psoriasis, without a 12 week treatment-free period before doing so.

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

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS —cont.

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

ETANERCEPT—cont.

Authority required

Continuing treatment (Whole body)

Continuing PBS-subsidised treatment as systemic monotherapy (i.e. not in conjunction with acitretin, methotrexate or cyclosporin) 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, after at least 12 weeks of etanercept treatment, compared with the pre-biological treatment baseline value for this 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) a copy of the completed Psoriasis Area and Severity Index (PASI) calculation sheet and whole body 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)].**

Approval will be based on the PASI assessment of response to the most recent course of active treatment with etanercept, which must have been undertaken at the completion of this course of active 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 242 679 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

A PASI assessment of the patient's response must be made at the completion of each 12 week active treatment course. 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 etanercept.

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.

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS —cont.

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

ETANERCEPT—cont.

Continuing treatment is available in the form of 12 weeks of active etanercept treatment followed by a 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 or a further initial course of etanercept 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 the biological agents, efalizumab and etanercept, on a total of 3 occasions 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 (i.e. not in conjunction with acitretin, methotrexate or cyclosporin) 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 form 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 (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).

continued ➞

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS —cont.

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

ETANERCEPT—cont.

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.*

Patients for whom a PASI assessment for any prior course of treatment, where that course of treatment was completed prior to 16 March 2006, is not available, may contact Medicare Australia on 1800 242 679 for advice.

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) a copy of 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)];*
 - (ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy]; and*
 - (iii) a copy of the signed patient acknowledgement form.*

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 242 679 (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.

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS —cont.

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

ETANERCEPT—cont.

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 or a further course of etanercept 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 (i.e. not in conjunction with acitretin, methotrexate or cyclosporin) 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 more than once 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) a copy of 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.*

The PASI assessment must be performed on the same affected area as assessed at baseline.

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 12 week 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.

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS —cont.

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

ETANERCEPT—cont.

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 242 679 (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 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.

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 or a further course of etanercept 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.

Patients who fail to demonstrate a response to treatment with the biological agents, efalizumab and etanercept, on a total of 3 occasions 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 3, Face, hand, foot (Grandfather patients)]

Initial PBS-subsidised supply for continuing treatment as systemic monotherapy (i.e. not in conjunction with acitretin, methotrexate or cyclosporin) 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 etanercept prior to 16 March 2006; and

(b) whose disease, prior to treatment with etanercept, 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 form 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 (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 etanercept (face, hand, foot).

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS —cont.

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

ETANERCEPT—cont.

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) a copy of 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 etanercept 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) a copy of the signed patient acknowledgement form.**

The PASI assessment must be performed on the same affected area as assessed prior to initiation of etanercept treatment.

The most recent PASI assessment must be no more than 1 month old at the time of application.

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 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 242 679 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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.

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 or a further course of etanercept 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.

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

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
ETANERCEPT—cont.							
Authority required							
Continuing treatment (Face, hand, foot)							
Continuing PBS-subsidised treatment as systemic monotherapy (i.e. not in conjunction with acitretin, methotrexate or cyclosporin) 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 their most recent course of 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, after at least 12 weeks of etanercept treatment, 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, after at least 12 weeks of etanercept treatment, as compared to the pre-biological treatment baseline value.							
The PASI assessment for continuing treatment must be performed on the same affected area assessed at baseline.							
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) a copy of 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)].							
Approval will be based on the PASI assessment of response to the most recent course of active treatment with etanercept, which must have been undertaken at the completion of this course of active 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 242 679 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).							

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	
ETANERCEPT—cont.								
<i>A PASI assessment of the patient's response must be made at the completion of each 12 week active treatment course. 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 etanercept.</i>								
<i>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.</i>								
<i>Continuing treatment is available in the form of 12 weeks of active etanercept treatment followed by a 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.</i>								
<i>Patients who fail to demonstrate such a response to etanercept treatment and who qualify to trial an alternate biological agent or a further initial course of etanercept 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.</i>								
<i>Patients who fail to demonstrate a response to treatment with the biological agents, efalizumab and etanercept, on a total of 3 occasions 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.</i>								
9037P	Injection set containing 4 vials powder for injection 25 mg and 4 pre-filled syringes solvent 1 mL	2	2	..	*1797.73	30.70	Enbrel	WY
9038Q	Injection set containing 4 vials powder for injection 50 mg and 4 pre-filled syringes solvent 1 mL	1	2	..	1745.10	30.70	Enbrel	WY

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. No. of Qty Rpts Premium	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Proprietary Name and Manufacturer	
EVEROLIMUS						
CAUTION:						
<i>Careful monitoring of patients is mandatory.</i>						
Authority required						
<i>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:</i>						
<i>(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;</i>						
<i>(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.</i>						
8840G	Tablet 0.25 mg	60 3 ..	281.52	30.70	Certican	NV
8841H	Tablet 0.5 mg	60 3 ..	542.56	30.70	Certican	NV
8842J	Tablet 0.75 mg	120 3 ..	*1556.89	30.70	Certican	NV
LEFLUNOMIDE						
CAUTION:						
<i>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.</i>						
Authority required						
<i>Initiation by consultant physicians for the treatment of severe active rheumatoid arthritis in patients for whom other disease modifying anti-rheumatic drugs (including methotrexate) are inappropriate and/or ineffective.</i>						
NOTE:						
<i>No applications for increased maximum quantities and/or repeats will be authorised.</i>						
8373Q	Pack containing 3 tablets leflunomide 100 mg and 30 tablets leflunomide 20 mg	£1	221.71	30.70	Arava	AV
Authority required						
<i>Initiation by consultant physicians for the treatment of severe active rheumatoid arthritis in patients for whom other disease modifying anti-rheumatic drugs (including methotrexate) are inappropriate and/or ineffective;</i>						
<i>Ongoing leflunomide therapy for severe active rheumatoid arthritis in patients for whom other disease modifying anti-rheumatic drugs (including methotrexate) are inappropriate and/or ineffective.</i>						
8374R	Tablet 10 mg	30 5 ..	96.01	30.70	^a Arabloc	HP
		^B 1.17	97.18	30.70	^a Arava	AV
8375T	Tablet 20 mg	30 5 ..	143.49	30.70	^a Arabloc	HP
		^B 1.17	144.66	30.70	^a Arava	AV

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:								
<i>Careful monitoring of patients is mandatory.</i>								
Authority required								
<i>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:</i>								
<i>(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;</i>								
<i>(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.</i>								
8649F	Capsule 250 mg	300	3	..	626.54	30.70	CellCept	RO
8650G	Tablet 500 mg	150	3	..	626.54	30.70	CellCept	RO
8651H	Powder for oral suspension 1 g per 5 mL, 165 mL	‡1	3	..	#288.50	30.70	CellCept	RO
MYCOPHENOLATE SODIUM								
CAUTION:								
<i>Careful monitoring of patients is mandatory.</i>								
Authority required								
<i>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.</i>								
8652J	Tablet (enteric coated) 180 mg (mycophenolic acid)	120	3	..	262.15	30.70	Myfortic	NV
8653K	Tablet (enteric coated) 360 mg (mycophenolic acid)	120	3	..	502.26	30.70	Myfortic	NV
SIROLIMUS								
CAUTION:								
<i>Careful monitoring of patients is mandatory.</i>								
Authority required								
<i>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.</i>								
8724E	Tablet 1 mg	100	3	..	813.98	30.70	Rapamune	WY
8833X	Tablet 2 mg	100	3	..	1561.76	30.70	Rapamune	WY
8725F	Oral solution 1 mg per mL, 60 mL	‡1	3	..	490.46	30.70	Rapamune	WY

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	
TACROLIMUS								
CAUTION:								
<i>Careful monitoring of patients is mandatory.</i>								
Authority required								
<i>Maintenance therapy, following initiation and stabilisation of treatment with tacrolimus and where therapy remains under the supervision and direction of the transplant unit reviewing that patient, of patients with:</i>								
<i>(a) liver 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;</i>								
<i>(b) 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.</i>								
8646C	Capsule 500 micrograms	100	3	..	224.58	30.70	Prograf	JC
8647D	Capsule 1 mg	100	3	..	426.00	30.70	Prograf	JC
8648E	Capsule 5 mg	50	3	..	1051.77	30.70	Prograf	JC
• Other immunosuppressive agents								
AZATHIOPRINE								
2688L	Tablet 25 mg	100	2	..	44.38	30.70	^a Azahexal	HX
				^B 1.51	45.89	30.70	^a Imuran	GK
2687K	Tablet 50 mg	100	2	..	71.93	30.70	^a Azahexal	HX
							^a Azamun	GM
							^a Azapin	AW
							^a GenRx	GX
							Azathioprine	
				^B 1.44	73.37	30.70	^a Thioprine	AF
							^a Imuran	GK
METHOTREXATE								
1622J	Tablet 2.5 mg	30	5	..	12.10	13.09	^a Methoblastin	PH
							^a MX	
1623K	Tablet 10 mg	50	2	..	46.14	30.70	Methoblastin	PH

MUSCULO-SKELETAL 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	
ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS								
Antiinflammatory and antirheumatic products, non-steroids								
• <i>Acetic acid derivatives and related substances</i>								
1302M	DICLOFENAC SODIUM Suppository 100 mg	40	3	..	*22.83	23.82	Voltaren 100	NV
DICLOFENAC SODIUM								
Restricted benefit								
<i>Chronic arthropathies (including osteoarthritis) with an inflammatory component; Bone pain due to malignant disease.</i>								
1299J	Tablet 25 mg (enteric coated)	100	3	..	*13.63	14.62	^a Chem mart Diclofenac	CH
							^a Clonac 25	AW
							^a Diclofenac-BC	BG
							^a Diclohexal	HX
							^a Dinac	GM
							^a GenRx	GX
							^a Diclofenac	
							^a Terry White Chemists	TW
							^a Diclofenac	
				..	13.63	14.62	^a Fenac 25	AF
				^B 3.18	*16.81	14.62	^a Voltaren 25	NV
1300K	Tablet 50 mg (enteric coated)	50	3	..	11.06	12.05	^a Chem mart Diclofenac	CH
							^a Clonac 50	AW
							^a Diclohexal	HX
							^a Dinac	GM
							^a Fenac	AF
							^a GenRx	GX
							^a Diclofenac	
							^a Terry White Chemists	TW
							^a Diclofenac	
				^B 3.09	14.15	12.05	^a Voltaren 50	NV
2757D	INDOMETHACIN Suppository 100 mg	40	3	..	*20.53	21.52	Indocid	MK
INDOMETHACIN								
Restricted benefit								
<i>Chronic arthropathies (including osteoarthritis) with an inflammatory component; Bone pain due to malignant disease.</i>								
2454E	Capsule 25 mg	100	3	..	*10.55	11.54	^a Arthrexin	AF
				^B 2.98	*13.53	11.54	^a Indocid	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	
SULINDAC								
Restricted benefit								
<i>Chronic arthropathies (including osteoarthritis) with an inflammatory component; Bone pain due to malignant disease.</i>								
2047R	Tablet 100 mg	100	3	..	*14.63	15.62	Aclin	AF
2048T	Tablet 200 mg	50	3	..	13.62	14.61	Aclin 200	AF
• Oxicams								
MELOXICAM								
NOTE:								
<i>The use of meloxicam for the treatment of the following conditions is not subsidised through the PBS:</i>								
<i>(a) acute pain;</i>								
<i>(b) soft tissue injury;</i>								
<i>(c) arthrosis without an inflammatory component.</i>								
Restricted benefit								
<i>Symptomatic treatment of osteoarthritis.</i>								
8561N	Tablet 7.5 mg	30	3	..	22.65	23.64	^a Movalis 7.5	AW
				^B 1.79	24.44	23.64	^a Mobic	BY
8562P	Tablet 15 mg	30	3	..	30.67	30.70	^a Movalis 15	AW
				^B 1.79	32.46	30.70	^a Mobic	BY
8887R	Capsule 7.5 mg	30	3	..	22.65	23.64	Mobic	BY
8888T	Capsule 15 mg	30	3	..	30.67	30.70	Mobic	BY
PIROXICAM								
Restricted benefit								
<i>Chronic arthropathies (including osteoarthritis) with an inflammatory component.</i>								
1895R	Dispersible tablet 10 mg	50	3	..	12.91	13.90	^a GenRx Piroxicam Dispersible	GX
							^a Mobilis D-10	AF
							^a Pirohexal-D	HX
				^B 2.66	15.57	13.90	^a Feldene-D	PF
1896T	Dispersible tablet 20 mg	25	3	..	12.52	13.51	^a Chem mart Piroxicam Dispersible	CH
							^a GenRx Piroxicam Dispersible	GX
							^a Mobilis D-20	AF
							^a Pirohexal-D	HX
							^a Terry White Chemists Piroxicam Dispersible	TW
				^B 2.64	15.16	13.51	^a Feldene-D	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	
PIROXICAM—cont.								
1897W	Capsule 10 mg	50	3	..	12.91	13.90	^a Chem mart Piroxicam	CH
							^a GenRx Piroxicam	GX
							^a Mobilis 10	AF
							^a Terry White Chemists Piroxicam	TW
				^B 2.66	15.57	13.90	^a Feldene	PF
1898X	Capsule 20 mg	25	3	..	12.52	13.51	^a Chem mart Piroxicam	CH
							^a GenRx Piroxicam	GX
							^a Mobilis 20	AF
							^a Terry White Chemists Piroxicam	TW
				^B 2.64	15.16	13.51	^a Feldene	PF
• Propionic acid derivatives								
IBUPROFEN								
3192B	Tablet 400 mg	30	..	..	7.80	8.79	Brufen	AB
IBUPROFEN								
Restricted benefit								
<i>Chronic arthropathies (including osteoarthritis) with an inflammatory component; Bone pain due to malignant disease.</i>								
3198H	Tablet 200 mg	100	3	..	*10.55	11.54	Rafen 200	AF
3190X	Tablet 400 mg	90	3	..	*13.10	14.09	Brufen	AB
KETOPROFEN								
1588N	Suppository 100 mg	40	3	..	*21.23	22.22	Orudis	AV
KETOPROFEN								
Restricted benefit								
<i>Chronic arthropathies (including osteoarthritis) with an inflammatory component.</i>								
1590Q	Capsule 200 mg (sustained release)	28	3	..	15.40	16.39	^a Oruvail SR	HP
				^B 1.95	17.35	16.39	^a Orudis SR 200	AV

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	
NAPROXEN								
<u>Restricted benefit</u>								
<i>Chronic arthropathies (including osteoarthritis) with an inflammatory component; Bone pain due to malignant disease.</i>								
1674D	Tablet 250 mg	100	3	..	*14.45	15.44	^a Inza 250	AF
				^B 3.00	*17.45	15.44	^a Naprosyn	RO
1659H	Tablet 500 mg	50	3	..	13.42	14.41	^a Inza 500	AF
				^B 1.75	15.17	14.41	^a Naprosyn	RO
1614Y	Tablet 750 mg (sustained release)	28	3	..	12.75	13.74	^a Proxen SR 750	MD
				^B 1.62	14.37	13.74	^a Naprosyn SR750	RO
1615B	Tablet 1 g (sustained release)	28	3	..	15.28	16.27	^a Proxen SR 1000	MD
				^B 1.72	17.00	16.27	^a Naprosyn SR1000	RO
<u>Authority required</u>								
<i>Chronic arthropathies (including osteoarthritis) with an inflammatory component in patients unable to take a solid dose form of a non-steroidal anti-inflammatory agent; Bone pain due to malignant disease in patients unable to take a solid dose form of a non- steroidal anti-inflammatory agent.</i>								
1658G	Oral suspension 125 mg per 5 mL, 474 mL	‡1	3	..	76.90	30.70	Naprosyn	RO
NAPROXEN SODIUM								
<u>Restricted benefit</u>								
<i>Chronic arthropathies (including osteoarthritis) with an inflammatory component; Bone pain due to malignant disease.</i>								
1795L	Tablet 550 mg	50	3	..	13.68	14.67	^a Crysanal	MD
				^B 2.91	16.59	14.67	^a Anaprox 550	RO
<u>NOTE:</u>								
<i>Naproxen sodium 550 mg is approximately equivalent to 500 mg of naproxen acid.</i>								
TIAPROFENIC ACID								
<u>CAUTION:</u>								
<i>Cystitis and other urinary disorders have been reported with this drug.</i>								
<u>NOTE:</u>								
<i>The recommended maximum dose is 600 mg per day.</i>								
<u>Restricted benefit</u>								
<i>Chronic arthropathies (including osteoarthritis) with an inflammatory component.</i>								
2103Q	Tablet 300 mg	60	3	..	15.82	16.81	Surgam	AV
• Fenamates								
MEFENAMIC ACID								
<u>Restricted benefit</u>								
<i>Dysmenorrhoea; Menorrhagia.</i>								
1824B	Capsule 250 mg	50	2	..	16.38	17.37	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: <i>The use of celecoxib for the treatment of the following conditions is not subsidised through the PBS:</i> <i>(a) acute pain;</i> <i>(b) soft tissue injury;</i> <i>(c) arthrosis without an inflammatory component.</i> Restricted benefit <i>Symptomatic treatment of osteoarthritis;</i> <i>Symptomatic treatment of rheumatoid arthritis.</i>								
8439E	Capsule 100 mg	60	3	..	29.91	30.70	Celebrex	PH
8440F	Capsule 200 mg	30	3	..	29.91	30.70	Celebrex	PH
LUMIRACOXIB NOTE: <i>The use of lumiracoxib for the treatment of the following conditions is not subsidised through the PBS:</i> <i>(a) acute pain;</i> <i>(b) soft tissue injury;</i> <i>(c) arthrosis without an inflammatory component.</i> Restricted benefit <i>Symptomatic treatment of osteoarthritis.</i> NOTE: <i>No applications for increased maximum quantities and/or repeats will be authorised.</i>								
9032J	Tablet 200 mg	30	3	..	29.91	30.70	Prexige	NV
Specific antirheumatic agents								
• Quinolines HYDROXYCHLOROQUINE SULFATE								
1512N	Tablet 200 mg	100	1	..	34.96	30.70	Plaquenil	SW
• Gold preparations AURANOFIN CAUTION: Regular blood and urine checks are essential.								
1095P	Tablet 3 mg	60	5	..	62.28	30.70	Ridaura	GH
SODIUM AUROTHIOMALATE CAUTION: Regular blood and urine checks are essential.								
2016D	Injection 10 mg	10	..	..	51.77	30.70	Myocrisin	AV
2017E	Injection 20 mg	10	1	..	79.19	30.70	Myocrisin	AV
2018F	Injection 50 mg	10	1	..	123.52	30.70	Myocrisin	AV

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	
• Penicillamine and similar agents PENICILLAMINE CAUTION: Regular blood and urine checks are essential.								
2721F	Tablet 125 mg	100	1	..	29.26	30.25	D-Penamine	AL
2838J	Tablet 250 mg	100	1	..	41.00	30.70	D-Penamine	AL
• Other specific antirheumatic agents LEFLUNOMIDE <i>For listings see Generic/Proprietary Index</i>								

MUSCLE RELAXANTS**Muscle relaxants, centrally acting agents****• Other centrally acting agents**

BACLOFEN								
2729P	Tablet 10 mg	100	5	..	37.86	30.70	a Baclo a Baclohexal a Chem mart Baclofen a Clofen 10 a GenRx Baclofen a Stelax 10 a Terry White Chemists Baclofen a Lioresal 10	GM HX CH AF GX AW TW NV
2730Q	Tablet 25 mg	100	5	..	76.71	30.70	a Baclo a Baclohexal a Chem mart Baclofen a Clofen 25 a GenRx Baclofen a Stelax 25 a Terry White Chemists Baclofen a Lioresal 25	GM HX CH AF GX AW TW NV
				^B 2.90	40.76	30.70	a Lioresal 10	NV
				^B 2.90	79.61	30.70	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	..	58.21	30.70	Dantrium	PU
1780Q	Capsule 50 mg	100	2	..	66.15	30.70	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							
• <i>Preparations inhibiting uric acid production</i>							
ALLOPURINOL							
NOTE:							
The dose should be adjusted in accordance with renal function.							
2600W	Tablet 100 mg	200	2	..	*13.79 13.79	14.78 14.78	^a Progout 100 AF ^a Allohexal HX ^a Allosig FM ^a Chem mart CH Allopurinol ^a GenRx GX Allopurinol ^a Terry White TW Chemists Allopurinol
				^B 2.43	16.22	14.78	^a Zyloprim SI
2604C	Tablet 300 mg	60	2	..	10.25	11.24	^a Allohexal HX ^a Allosig FM ^a Chem mart CH Allopurinol ^a GenRx GX Allopurinol ^a Progout 300 AF ^a Terry White TW Chemists Allopurinol
				^B 2.29	12.54	11.24	^a Zyloprim SI
• <i>Preparations increasing uric acid excretion</i>							
PROBENECID							
1940D	Tablet 500 mg	100	5	..	68.96	30.70	Pro-Cid PL
• <i>Preparations with no effect on uric acid metabolism</i>							
COLCHICINE							
1227N	Tablet 500 micrograms	100	2	..	9.55 ^B 0.89 10.44	10.54 10.54	^a Lengout LN ^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								
<i>Initial 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 included in the authority application.</i>								
<i>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;</i>								
<i>Continuing treatment as the sole PBS-subsidised anti-resorptive agent for established osteoporosis in patients with fracture due to minimal trauma, where the patient has previously been issued with an authority prescription for this drug.</i>								
8511Y	Tablet equivalent to 70 mg alendronic acid	4	5	..	52.29	30.70	^a Alendro Once Weekly	AW
				^B 0.82	53.11	30.70	^a Fosamax Once Weekly	MK
Authority required								
<i>Symptomatic Paget's disease of bone.</i>								
8090T	Tablet equivalent to 40 mg alendronic acid	30	5	..	159.26	30.70	Fosamax 40 mg	MK
DISODIUM ETIDRONATE								
Authority required								
<i>Symptomatic Paget's disease of bone when calcitonin has been found to be unsatisfactory due to:</i>								
<i>(a) lack of efficacy; or</i>								
<i>(b) unacceptable side effects;</i>								
<i>Heterotopic ossification.</i>								
2920Q	Tablet 200 mg	60	5	..	113.90	30.70	Didronel	PU
DISODIUM PAMIDRONATE								
Authority required								
<i>Symptomatic Paget's disease of bone.</i>								
8461H	Concentrated injection 15 mg in 5 mL	4	..	..	*267.83	30.70	^a Pamisol	MX
8208B	Injection set containing 4 vials powder for I.V. infusion 15 mg and 4 ampoules solvent 5 mL	1	..	..	267.83	30.70	^a Aredia 15 mg	NV
NOTE:								
<i>The concentrated injection 15 mg and powder for I.V. infusion 15 mg (after reconstitution) are bioequivalent.</i>								

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	
DISODIUM PAMIDRONATE—								
cont.								
8462J	Concentrated injection 30 mg in 10 mL	2	..	..	*267.85	30.70	^a Pamisol	MX
8209C	Injection set containing 2 vials powder for I.V. infusion 30 mg and 2 ampoules solvent 10 mL	1	..	..	267.83	30.70	^a Aredia 30 mg	NV
NOTE:								
<i>The concentrated injection 30 mg and powder for I.V. infusion 30 mg (after reconstitution) are bioequivalent.</i>								
8463K	Concentrated injection 60 mg in 10 mL	1	..	..	267.83	30.70	Pamisol	MX
RISEDRONATE SODIUM								
Authority required								
<i>Initial 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 included in the authority application.</i>								
<i>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;</i>								
<i>Continuing treatment as the sole PBS-subsidised anti-resorptive agent for established osteoporosis in patients with fracture due to minimal trauma, where the patient has previously been issued with an authority prescription for this drug.</i>								
8481J	Tablet 5 mg	28	5	..	52.29	30.70	Actonel	AV
8621R	Tablet 35 mg	4	5	..	52.29	30.70	Actonel Once-a-Week	AV
Authority required								
<i>Symptomatic Paget's disease of bone.</i>								
8482K	Tablet 30 mg	28	1	..	303.35	30.70	Actonel	AV
SODIUM CLODRONATE								
TETRAHYDRATE								
Restricted benefit								
<i>Maintenance treatment of hypercalcaemia of malignancy refractory to anti-neoplastic therapy;</i>								
<i>Multiple myeloma;</i>								
<i>Bone metastases from breast cancer.</i>								
8132B	Capsule equivalent to 400 mg sodium clodronate	100	2	..	332.81	30.70	Bonefos	SC
8265B	Tablet equivalent to 800 mg sodium clodronate	60	2	..	390.17	30.70	Bonefos 800 mg	SC

MUSCULO-SKELETAL SYSTEM —cont.

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

TILUDRONATE DISODIUM**Authority required***Symptomatic Paget's disease of bone.*

8267D	Tablet equivalent to 200 mg tiludronic acid	56	2	..	303.35	30.70	Skelid	MX

• **Bisphosphonates and calcium, sequential preparations****ALENDRONATE SODIUM with****COLECALCIFEROL****Authority required***Initial 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 included in the authority application.**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;**Continuing treatment as the sole PBS-subsidised anti-resorptive agent for established osteoporosis in patients with fracture due to minimal trauma, where the patient has previously been issued with an authority prescription for this drug.*

9012H	Tablet equivalent to 70 mg alendronic acid with 70 micrograms colecalciferol	4	5	..	52.29	30.70	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.***DISODIUM ETIDRONATE and****CALCIUM CARBONATE****Authority required***Initial 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 included in the authority application.**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;**Continuing treatment as the sole PBS-subsidised anti-resorptive agent for established osteoporosis in patients with fracture due to minimal trauma, where the patient has previously been issued with an authority prescription for this drug.*

8056B	Pack containing 28 tablets disodium etidronate 200 mg and 76 tablets calcium carbonate 1.25 g (equivalent to 500 mg calcium)	£1	1	..	69.42	30.70	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								
<u>Authority required</u>								
<i>Initial 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 included in the authority application.</i>								
<i>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;</i>								
<i>Continuing treatment as the sole PBS-subsidised anti-resorptive agent for established osteoporosis in patients with fracture due to minimal trauma, where the patient has previously been issued with an authority prescription for this drug.</i>								
8899J	Pack containing 4 tablets risedronate sodium 35 mg and 24 tablets calcium carbonate 1.25 g (equivalent to 500 mg calcium)	1	5	..	52.29	30.70	Actonel Combi	AV
• Other drugs affecting bone structure and mineralization								
CALCITRIOL								
<u>Authority required</u>								
<i>Hypocalcaemia due to renal disease;</i>								
<i>Hypoparathyroidism;</i>								
<i>Hypophosphataemic rickets;</i>								
<i>Vitamin D-resistant rickets;</i>								
<i>Initial 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 included in the authority application.</i>								
<i>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;</i>								
<i>Continuing treatment for established osteoporosis in patients with fracture due to minimal trauma, where the patient has previously been issued with an authority prescription for this drug.</i>								
2502Q	Capsule 0.25 microgram	100	3	..	52.56	30.70	^a Calcitriol-DP ^a Citrihexal ^a GenRx Calcitriol ^a Kosteol ^a Rocaltrol ^a Sical ^a Sitriol	GM HX GX AW RO AF AL

MUSCULO-SKELETAL SYSTEM —cont.

Code	Name, Restriction, Manner of administration and form	Max. No. of			Dispensed	Maximum	Proprietary Name and Manufacturer
		Qty	Rpts	Premium	Price for Max. Qty \$	Recordable Value for Safety Net \$	
<u>RALOXIFENE HYDROCHLORIDE</u>							
<u>Authority required</u>							
<i>Initial 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 included in the authority application.</i>							
<i>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;</i>							
<i>Continuing treatment as the sole PBS-subsidised anti-resorptive agent for established post-menopausal osteoporosis in patients with fracture due to minimal trauma, where the patient has previously been issued with an authority prescription for this drug.</i>							
8363E	Tablet 60 mg	28	5	..	57.65	30.70	Evista LY

NERVOUS 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
ANALGESICS							
Opioids							
• Natural opium alkaloids							
CODEINE PHOSPHATE							
1214X	Tablet 30 mg	20	..	..	10.92	11.91	FM
CODEINE PHOSPHATE with PARACETAMOL							
1215Y	Tablet 30 mg-500 mg	20	..	..	7.26	8.25	^a Codalgin Forte FM ^a Codapane Forte AL ^a Dolaforte CO ^a Dymadon Forte GK ^a Prodeine Forte DK
				^B 1.84	9.10	8.25	^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 <i>Severe disabling pain not responding to non-narcotic analgesics.</i>							
NOTE: <i>Each authority approval will be limited to no more than 240 tablets per month for no more than 6 months.</i>							
8785J	Tablet 30 mg-500 mg	60	..	..	*11.48	12.47	^a Codalgin Forte FM ^a Codapane Forte AL ^a Dolaforte CO ^a Dymadon Forte GK ^a Prodeine Forte DK
				^B 5.52	*17.00	12.47	^a Panadeine Forte SW
HYDROMORPHONE HYDROCHLORIDE							
CAUTION: The risk of drug dependence is high.							
8420E	Injection 2 mg in 1 mL	5	..	..	12.46	13.45	Dilaudid AB
8421F	Injection 10 mg in 1 mL	5	..	..	17.58	18.57	Dilaudid-HP AB
8422G	Injection 50 mg in 5 mL	5	..	..	45.12	30.70	Dilaudid-HP AB
8423H	Injection 500 mg in 50 mL	1	..	..	74.14	30.70	Dilaudid-HP AB

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	
HYDROMORPHONE HYDROCHLORIDE—cont.								
CAUTION: <i>The risk of drug dependence is high.</i>								
Restricted benefit <i>Severe disabling pain not responding to non-narcotic analgesics.</i>								
NOTE: <i>Authorities for increased maximum quantities and/or repeats will be granted only for:</i>								
<i>(i) severe disabling pain associated with proven malignant neoplasia; or</i>								
<i>(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</i>								
<i>(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</i>								
<i>(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.</i>								
8541M	Tablet 2 mg	20	..	..	12.73	13.72	Dilaudid	AB
8542N	Tablet 4 mg	20	..	..	17.57	18.56	Dilaudid	AB
8543P	Tablet 8 mg	20	..	..	26.90	27.89	Dilaudid	AB
8424J	Oral liquid 1 mg per mL, 473 mL	1	..	..	47.34	30.70	Dilaudid	AB
MORPHINE HYDROCHLORIDE								
CAUTION: <i>The risk of drug dependence is high.</i>								
Restricted benefit <i>Severe disabling pain not responding to non-narcotic analgesics.</i>								
NOTE: <i>Authorities for increased maximum quantities and/or repeats will be granted only for:</i>								
<i>(i) severe disabling pain associated with proven malignant neoplasia; or</i>								
<i>(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</i>								
<i>(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</i>								
<i>(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.</i>								
2122Q	Oral solution 2 mg per mL, 200 mL	1	..	..	17.45	18.44	Ordine 2	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	
MORPHINE HYDROCHLORIDE—cont.								
2123R	Oral solution 5 mg per mL, 200 mL	1	..	..	20.24	21.23	Ordine 5	MF
2124T	Oral solution 10 mg per mL, 200 mL	1	..	..	24.64	25.63	Ordine 10	MF
MORPHINE SULFATE								
CAUTION: The risk of drug dependence is high.								
1644M	Injection 10 mg in 1 mL	5	..	..	12.51	13.50	MX	
1645N	Injection 15 mg in 1 mL	5	..	..	12.82	13.81	MX	
1647Q	Injection 30 mg in 1 mL	5	..	..	14.20	15.19	MX	
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	..	..	13.75	14.74	Sevredol	MF
8670H	Tablet 20 mg	20	..	..	14.83	15.82	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	..	..	13.44	14.43	Anamorph	FM

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	
MORPHINE SULFATE—cont.								
Restricted benefit								
<i>Chronic severe disabling pain not responding to non-narcotic analgesics.</i>								
NOTE:								
<i>Authorities for increased maximum quantities and/or repeats will be granted only for:</i>								
<i>(i) chronic severe disabling pain associated with proven malignant neoplasia; or</i>								
<i>(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</i>								
<i>(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</i>								
<i>(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.</i>								
8035X	Tablet 5 mg (controlled release)	20	..	..	14.74	15.73	MS Contin	MF
1653B	Tablet 10 mg (controlled release)	20	..	..	15.87	16.86	MS Contin	MF
8489T	Tablet 15 mg (controlled release)	20	..	..	19.49	20.48	MS Contin	MF
1654C	Tablet 30 mg (controlled release)	20	..	..	28.27	29.26	MS Contin	MF
1655D	Tablet 60 mg (controlled release)	20	..	..	43.76	30.70	MS Contin	MF
1656E	Tablet 100 mg (controlled release)	20	..	..	59.99	30.70	MS Contin	MF
8349K	Capsule 10 mg (containing sustained release pellets)	20	..	..	15.87	16.86	Kapanol	GK
2839K	Capsule 20 mg (containing sustained release pellets)	20	..	..	20.77	21.76	Kapanol	GK
8491X	Capsule 30 mg (controlled release)	10	..	..	19.49	20.48	MS Mono	MF
2840L	Capsule 50 mg (containing sustained release pellets)	20	..	..	35.65	30.70	Kapanol	GK
8492Y	Capsule 60 mg (controlled release)	10	..	..	28.27	29.26	MS Mono	MF
8493B	Capsule 90 mg (controlled release)	10	..	..	34.12	30.70	MS Mono	MF
2841M	Capsule 100 mg (containing sustained release pellets)	20	..	..	59.99	30.70	Kapanol	GK
8494C	Capsule 120 mg (controlled release)	10	..	..	43.76	30.70	MS Mono	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	
MORPHINE SULFATE—cont.								
8490W	Sachet containing controlled release granules for oral suspension, 20 mg per sachet	20	..	..	20.77	21.76	MS Contin Suspension 20 mg	MF
8146R	Sachet containing controlled release granules for oral suspension, 30 mg per sachet	20	..	..	28.27	29.26	MS Contin Suspension 30 mg	MF
8305D	Sachet containing controlled release granules for oral suspension, 60 mg per sachet	20	..	..	43.76	30.70	MS Contin Suspension 60 mg	MF
8306E	Sachet containing controlled release granules for oral suspension, 100 mg per sachet	20	..	..	59.99	30.70	MS Contin Suspension 100 mg	MF
Authority required								
<i>Chronic severe disabling pain due to cancer.</i>								
8453X	Tablet 200 mg (controlled release)	20	..	..	103.66	30.70	MS Contin	MF
8454Y	Sachet containing controlled release granules for oral suspension, 200 mg per sachet	20	..	..	103.66	30.70	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	..	..	21.35	22.34	MX	
OXYCODONE								
CAUTION:								
The risk of drug dependence is high.								
Restricted benefit								
<i>Severe disabling pain not responding to non-narcotic analgesics.</i>								
NOTE:								
<i>Authorities for increased maximum quantities and/or repeats will be granted only for:</i>								
<i>(i) severe disabling pain associated with proven malignant neoplasia; or</i>								
<i>(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</i>								
<i>(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</i>								
<i>(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.</i>								
2481N	Suppository 30 mg	12	..	..	37.43	30.70	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: <i>The risk of drug dependence is high.</i>								
Restricted benefit <i>Severe disabling pain not responding to non-narcotic analgesics.</i>								
NOTE: <i>Authorities for increased maximum quantities and/or repeats will be granted only for:</i> <i>(i) severe disabling pain associated with proven malignant neoplasia; or</i> <i>(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</i> <i>(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</i> <i>(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.</i>								
2622B	Tablet 5 mg	20	..	..	10.90	11.89	Endone	SI
8464L	Capsule 5 mg	20	..	..	10.90	11.89	OxyNorm	MF
8501K	Capsule 10 mg	20	..	..	13.88	14.87	OxyNorm	MF
8502L	Capsule 20 mg	20	..	..	18.40	19.39	OxyNorm	MF
8644Y	Oral solution 5 mg per 5 mL, 250 mL	1	..	..	18.95	19.94	OxyNorm Liquid 5mg/5mL	MF
Restricted benefit <i>Chronic severe disabling pain not responding to non-narcotic analgesics.</i>								
NOTE: <i>Authorities for increased maximum quantities and/or repeats will be granted only for:</i> <i>(i) chronic severe disabling pain associated with proven malignant neoplasia; or</i> <i>(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</i> <i>(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</i> <i>(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.</i>								
8681X	Tablet 5 mg (controlled release)	20	..	..	19.39	20.38	OxyContin	MF
8385H	Tablet 10 mg (controlled release)	20	..	..	19.86	20.85	OxyContin	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	
OXYCODONE HYDROCHLORIDE—cont.								
8386J	Tablet 20 mg (controlled release)	20	..	..	28.27	29.26	OxyContin	MF
8387K	Tablet 40 mg (controlled release)	20	..	..	43.76	30.70	OxyContin	MF
8388L	Tablet 80 mg (controlled release)	20	..	..	70.43	30.70	OxyContin	MF
• Phenylpiperidine derivatives								
FENTANYL								
CAUTION:								
<i>The risk of drug dependence is high.</i>								
NOTE:								
<i>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).</i>								
Restricted benefit								
<i>Chronic severe disabling pain not responding to non-narcotic analgesics.</i>								
NOTE:								
<i>Authorities for increased maximum quantities and/or repeats will be granted only for:</i>								
<i>(i) chronic severe disabling pain associated with proven malignant neoplasia; or</i>								
<i>(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</i>								
<i>(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</i>								
<i>(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.</i>								
8878G	Transdermal patch 2.1 mg (releasing approximately 12 micrograms per hour)	5	..	..	44.74	30.70	Durogesic 12	JC
8891Y	Transdermal patch 4.2 mg (releasing approximately 25 micrograms per hour)	5	..	..	54.12	30.70	Durogesic 25	JC
8892B	Transdermal patch 8.4 mg (releasing approximately 50 micrograms per hour)	5	..	..	92.91	30.70	Durogesic 50	JC
8893C	Transdermal patch 12.6 mg (releasing approximately 75 micrograms per hour)	5	..	..	126.01	30.70	Durogesic 75	JC
8894D	Transdermal patch 16.8 mg (releasing approximately 100 micrograms per hour)	5	..	..	153.31	30.70	Durogesic 100	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
PETHIDINE HYDROCHLORIDE							
CAUTION:							
<i>The risk of drug dependence is high.</i>							
Restricted benefit							
<i>Short-term treatment of acute pain.</i>							
NOTE:							
<i>No applications for increased maximum quantities and/or repeats will be authorised.</i>							
1829G	Injection 100 mg in 2 mL	5	..	..	11.20	12.19	MX
• Diphenylpropylamine derivatives							
METHADONE HYDROCHLORIDE							
CAUTION:							
<i>The risk of drug dependence is high.</i>							
Restricted benefit							
<i>Severe disabling pain not responding to non-narcotic analgesics.</i>							
NOTE:							
<i>Authorities for increased maximum quantities and/or repeats will be granted only for:</i>							
<i>(i) severe disabling pain associated with proven malignant neoplasia; or</i>							
<i>(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</i>							
<i>(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</i>							
<i>(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.</i>							
1609Q	Tablet 10 mg	20	..	..	13.39	14.38	Physeptone GK
1606M	Injection 10 mg in 1 mL	5	..	..	28.61	29.60	Physeptone GK

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	
• Oripavine derivatives BUPRENORPHINE CAUTION: <i>The risk of drug dependence is high.</i> Restricted benefit <i>Chronic severe disabling pain not responding to non-narcotic analgesics.</i> NOTE: <i>Authorities for increased maximum quantities and/or repeats will be granted only for:</i> <i>(i) chronic severe disabling pain associated with proven malignant neoplasia; or</i> <i>(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</i> <i>(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</i> <i>(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.</i>								
8865N	Transdermal patch 5 mg (releasing approximately 5 micrograms per hour)	2	..	..	24.67	25.66	Norspan	MF
8866P	Transdermal patch 10 mg (releasing approximately 10 micrograms per hour)	2	..	..	35.12	30.70	Norspan	MF
8867Q	Transdermal patch 20 mg (releasing approximately 20 micrograms per hour)	2	..	..	54.56	30.70	Norspan	MF
• Other opioids TRAMADOL HYDROCHLORIDE Restricted benefit <i>For acute pain where aspirin and/or paracetamol alone are inappropriate or have failed.</i> NOTE: <i>No applications for increased maximum quantities and/or repeats will be authorised.</i>								
8455B	Capsule 50 mg	20	..	..	8.64	9.63	^a Chem mart Tramadol	CH
							^a GenRx Tramadol	GX
							^a Terry White Chemists Tramadol	TW
							^a Tramedo Tramadol	AF
							^a Zydol Tramadol	AW
					^b 1.45	10.09	^a Tramal Tramadol	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	
TRAMADOL HYDROCHLORIDE—cont.								
<u>Restricted benefit</u>								
<i>For dosage titration in chronic pain where aspirin and/or paracetamol alone are inappropriate or have failed.</i>								
<u>NOTE:</u>								
<i>No applications for increased maximum quantities and/or repeats will be authorised.</i>								
8611F	Capsule 50 mg	20	2	..	8.64	9.63	^a Chem mart Tramadol	CH
							^a GenRx Tramadol	GX
							^a Terry White Chemists Tramadol	TW
							^a Tramedo	AF
							^a Zydol	AW
				^B 1.45	10.09	9.63	^a Tramal	CS
<u>Restricted benefit</u>								
<i>For pain where aspirin and/or paracetamol alone are inappropriate or have failed.</i>								
<u>NOTE:</u>								
<i>Authorities for increased maximum quantities and/or repeats will be granted only for severe disabling pain not responding to non-narcotic analgesics.</i>								
2527B	Tablet 50 mg (sustained release)	20	..	..	11.79	12.78	Tramal SR 50	CS
8523N	Tablet 100 mg (sustained release)	20	..	..	14.64	15.63	^a Tramahexal SR	HX
							^a Zydol SR 100	AW
				^B 1.94	16.58	15.63	^a Tramal SR 100	CS
8524P	Tablet 150 mg (sustained release)	20	..	..	17.94	18.93	^a Tramahexal SR	HX
							^a Zydol SR 150	AW
				^B 1.94	19.88	18.93	^a Tramal SR 150	CS
8525Q	Tablet 200 mg (sustained release)	20	..	..	20.73	21.72	^a Tramahexal SR	HX
							^a Zydol SR 200	AW
				^B 1.92	22.65	21.72	^a Tramal SR 200	CS
8843K	Oral drops 100 mg per mL, 10 mL	‡1	..	..	8.64	9.63	Tramal	CS
<u>Restricted benefit</u>								
<i>Short-term treatment of acute pain.</i>								
<u>NOTE:</u>								
<i>No applications for increased maximum quantities and/or repeats will be authorised.</i>								
8582Q	Injection 100 mg in 2 mL	5	..	..	10.53	11.52	^a Tramahexal	HX
							^a Tramal 100	CS
Other analgesics and antipyretics								
• Salicylic acid and derivatives								
ASPIRIN								
1010E	Tablet 300 mg (dispersible)	96	1	..	7.32	8.31	Solprin	RC

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	
• Anilides								
PARACETAMOL								
1746X	Tablet 500 mg	100	1	..	7.70	8.69	a Chem mart Chemadol	CH
							a Dymadon P	PC
							a Febridol	GM
							a Panamax	SW
							b Parahexal	HX
							a Paralgin	FM
							b Parmol	AW
							a Terry White Chemists Paracetamol	TW
							b Tylenol	JT
1747Y	Oral liquid 120 mg per 5 mL, 100 mL	‡1	2	..	7.98	8.97	Panamax	SW
1770E	Oral liquid 240 mg per 5 mL, 200 mL	‡1	2	..	9.22	10.21	Panamax 240 Elixir	SW
PARACETAMOL								
<u>Restricted benefit</u>								
<i>Chronic arthropathies.</i>								
8784H	Tablet 500 mg	300	4	..	*12.80	13.79	a Chem mart Chemadol	CH
							a Dymadon P	PC
							a Febridol	GM
							a Panamax	SW
							b Parahexal	HX
							a Paralgin	FM
							b Parmol	AW
							a Terry White Chemists Paracetamol	TW
							b Tylenol	JT
<u>Restricted benefit</u>								
<i>Relief of persistent pain associated with osteoarthritis.</i>								
8814X	Tablet 665 mg (modified release)	192	5	..	*11.69	12.68	a Duatrol SR	ME
				B4.72	*16.41	12.68	a Panadol Osteo	GC
Antimigraine preparations								
• Ergot alkaloids								
DIHYDROERGOTAMINE MESYLATE								
1323P	Injection 1 mg in 1 mL	5	..	..	15.33	16.32	Dihydergot	NV
METHYSERGIDE								
2826R	Tablet 1 mg	100	2	..	*42.59	30.70	Deseril	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	
• Selective 5HT₁-receptor agonists NARATRIPTAN HYDROCHLORIDE CAUTION: <i>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.</i> Authority required <i>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.</i> NOTE: <i>No applications for increased maximum quantities and/or repeats will be authorised.</i>								
8298R	Tablet 2.5 mg (base)	4	5	..	*26.45	27.44	Naramig	GK
SUMATRIPTAN CAUTION: <i>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.</i> Authority required <i>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.</i> NOTE: <i>No applications for increased maximum quantities and/or repeats will be authorised.</i>								
8341B	Nasal spray 20 mg in 0.1 mL single dose unit	2	5	..	15.80	16.79	Imigran	GK
SUMATRIPTAN SUCCINATE CAUTION: <i>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.</i> Authority required <i>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.</i> NOTE: <i>No applications for increased maximum quantities and/or repeats will be authorised.</i>								
8144P	Tablet 50 mg (base)	4	5	..	*26.45	27.44	^a Imigran ^a Suvalan 50	GK ME
8885P	Tablet 50 mg (base) (fast disintegrating)	4	5	..	*26.45	27.44	Imigran FDT	GK

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	
ZOLMITRIPTAN								
CAUTION: <i>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.</i>								
Authority required <i>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.</i>								
NOTE: <i>No applications for increased maximum quantities and/or repeats will be authorised.</i>								
8266C	Tablet 2.5 mg	4	5	..	*26.35	27.34	Zomig	AP
• Other antimigraine preparations								
CYPROHEPTADINE								
HYDROCHLORIDE								
Restricted benefit								
<i>Prevention of migraine.</i>								
NOTE: <i>Cyproheptadine hydrochloride is not PBS-subsidised for use in hay fever or atopy.</i>								
1798P	Tablet 4 mg	100	2	..	*12.59	13.58	Periactin	FR
3074T	PIZOTIFEN MALATE Tablet 500 micrograms (base)	100	2	..	19.81	20.80	Sandomigran 0.5	NV
ANTIEPILEPTICS								
Antiepileptics								
• Barbiturates and derivatives								
PHENOBARBITONE								
Restricted benefit								
<i>Epilepsy.</i>								
1850J	Tablet 30 mg	200	4	..	10.10	11.09	SI	
PHENOBARBITONE SODIUM								
Restricted benefit								
<i>Epilepsy.</i>								
1853M	Injection 200 mg in 1 mL	5	..	..	17.57	18.56	FM	
1939C	PRIMIDONE Tablet 250 mg	200	2	..	50.94	30.70	Mysoline	LM
• Hydantoin derivatives								
1249R	PHENYTOIN Tablet 50 mg	200	2	..	27.82	28.81	Dilantin Infatabs	PF
2692Q	Paediatric oral suspension 30 mg per 5 mL, 500 mL	‡1	3	..	19.68	20.67	Dilantin	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	
	PHENYTOIN SODIUM							
1873N	Capsule 30 mg	200	2	..	26.92	27.91	Dilantin Sodium	PF
1874P	Capsule 100 mg	200	2	..	27.82	28.81	Dilantin Sodium	PF
	• Succinimide derivatives							
	ETHOSUXIMIDE							
1413J	Capsule 250 mg	200	2	..	52.65	30.70	Zarontin	PF
1414K	Paediatric syrup 250 mg per 5 mL, 200 mL	‡1	5	..	23.20	24.19	Zarontin	PF
	• Benzodiazepine derivatives							
	CLONAZEPAM							
	<u>Restricted benefit</u>							
	<u>Epilepsy.</u>							
1807D	Injection 1 mg in 2 mL (set containing solution 1 mg in 1 mL and 1 mL diluent)	5	..	..	16.78	17.77	Rivotril	RO
	<u>Authority required</u>							
	Neurologically proven epilepsy.							
	<u>CAUTION:</u>							
	Abuse of clonazepam has been reported. Refer to the current product information.							
1805B	Tablet 500 micrograms	200	2	..	*22.73	23.72	^a Paxam 0.5	AF
				^B 4.58	*27.31	23.72	^a Rivotril	RO
1806C	Tablet 2 mg	200	2	..	*38.19	30.70	^a Paxam 2	AF
				^B 5.20	*43.39	30.70	^a Rivotril	RO
1808E	Oral liquid 2.5 mg per mL, 10 mL	2	..	..	*13.41	14.40	Rivotril	RO
	NITRAZEPAM							
	<u>Authority required</u>							
	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	..	*8.89	9.88	^a Alodorm	AF
				^B 3.92	*12.81	9.88	^a Mogadon	VT

[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	
• Carboxamide derivatives								
CARBAMAZEPINE								
2422L	Tablet 100 mg	200	2	..	21.38	22.37	^a Carbamazepine-BC	BG
							^a Carbamazepine Sandoz	SZ
				^B 3.00	24.38	22.37	^a Tegretol 100	NV
2419H	Tablet 200 mg	200	2	..	35.48	30.70	^a Carbamazepine-BC	BG
							^a Carbamazepine Sandoz	SZ
				^B 3.30	38.78	30.70	^a Teril	AF
							^a Tegretol 200	NV
2426Q	Tablet 200 mg (controlled release)	200	2	..	36.09	30.70	Tegretol CR 200	NV
2431Y	Tablet 400 mg (controlled release)	200	2	..	63.96	30.70	Tegretol CR 400	NV
2427R	Oral suspension 100 mg per 5 mL, 300 mL	‡1	5	..	19.43	20.42	Tegretol Liquid	NV
OXCARBAZEPINE								
Authority required								
<i>Treatment of partial epileptic seizures and primary generalised tonic-clonic seizures, which are not controlled satisfactorily by other anti-epileptic drugs.</i>								
8584T	Tablet 150 mg	100	5	..	71.00	30.70	Trileptal	NV
8585W	Tablet 300 mg	100	5	..	113.81	30.70	Trileptal	NV
8586X	Tablet 600 mg	100	5	..	186.71	30.70	Trileptal	NV
8588B	Oral suspension 60 mg per mL, 250 mL	2	5	..	*136.85	30.70	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	..	*29.29	30.28	Epilim	SW
2289L	Tablet 200 mg (enteric coated)	200	2	..	*35.75	30.70	^a Valpro 200	AF
				^B 1.28	*37.03	30.70	^a Epilim EC	SW
2290M	Tablet 500 mg (enteric coated)	200	2	..	*65.73	30.70	^a Valpro 500	AF
				^B 1.60	*67.33	30.70	^a Epilim EC	SW
2293Q	Oral liquid 200 mg per 5 mL, 300 mL	2	2	..	*32.41	30.70	Epilim Liquid	SW
2295T	Syrup 200 mg per 5 mL, 300 mL	2	2	..	*32.41	30.70	Epilim Syrup	SW

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	
TIAGABINE HYDROCHLORIDE								
Authority required								
<i>Treatment of partial epileptic seizures which are not controlled satisfactorily by other anti-epileptic drugs.</i>								
8221Q	Tablet 5 mg (base)	100	5	..	71.37	30.70	Gabitril	MX
8222R	Tablet 10 mg (base)	100	5	..	137.57	30.70	Gabitril	MX
8223T	Tablet 15 mg (base)	100	5	..	*195.61	30.70	Gabitril	MX
VIGABATRIN								
CAUTION:								
<i>Visual field defects have been reported with this drug.</i>								
Authority required								
<i>Treatment of epileptic seizures which are not controlled satisfactorily by other anti-epileptic drugs.</i>								
2667J	Tablet 500 mg	100	5	..	90.05	30.70	Sabril	AV
2668K	Oral powder, sachet 500 mg	60	5	..	60.00	30.70	Sabril	AV
• Other antiepileptics								
GABAPENTIN								
Authority required								
<i>Treatment of partial epileptic seizures which are not controlled satisfactorily by other anti-epileptic drugs.</i>								
8505P	Capsule 100 mg	100	5	..	27.33	28.32	^a DBL Gabapentin	MX
							^a Gantin	AW
							^a Neurontin	PF
							^a Nupentin 100	AF
1834M	Capsule 300 mg	100	5	..	79.27	30.70	^a DBL Gabapentin	MX
							^a Douglas Gabapentin	GM
							^a Gabahexal 300mg	HX
							^a Gantin	AW
							^a GenRx	GX
							^a Gabapentin	
							^a Neurontin	PF
							^a Nupentin 300	AF
							^a Pendine 300	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
GABAPENTIN—cont.							
1835N	Capsule 400 mg	100	5	..	106.24	30.70	^a DBL MX ^a Gabapentin ^a Douglas GM ^a Gabapentin 400mg ^a GabaHexal HX 400mg ^a Gantin AW ^a GenRx GX ^a Gabapentin ^a Neurontin PF ^a Nupentin 400 AF ^a Pendine 400 AL
8559L	Tablet 600 mg	100	5	..	165.62	30.70	Neurontin PF
8389M	Tablet 800 mg	100	5	..	217.61	30.70	^a Gantin AW ^a Neurontin PF ^a Pendine 800 AF
LAMOTRIGINE							
Authority required							
<i>Treatment of epileptic seizures which are not controlled satisfactorily by other anti-epileptic drugs.</i>							
8063J	Tablet 5 mg	56	5	..	18.32	19.31	^a Elmendos ME ^a Lamitrin HX ^a Lamogine AF ^a Seaze 5 AW ^a Lamictal GK
2848X	Tablet 25 mg	56	5	..	34.45	30.70	^a Elmendos ME ^a GenRx GX ^a Lamotrigine ^a Lamidus RA ^a Lamitrin HX ^a Lamogine AF ^a Lamotrigine-DP GM ^a Seaze 25 AW ^a Lamictal GK
2849Y	Tablet 50 mg	56	5	..	54.02	30.70	^a Elmendos ME ^a GenRx GX ^a Lamotrigine ^a Lamidus RA ^a Lamitrin HX ^a Lamogine AF ^a Lamotrigine-DP GM ^a Seaze 50 AW ^a Lamictal GK
				^B 0.97	19.29	19.31	
				^B 0.98	35.43	30.70	
				^B 0.97	54.99	30.70	

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	
LAMOTRIGINE—cont.								
2850B	Tablet 100 mg	56	5	..	86.57	30.70	^a Elmendos ^a GenRx Lamotrigine ^a Lamidus ^a Lamitrin ^a Lamogine ^a Lamotrigine-DP ^a Seaze 100 ^a Lamictal	ME GX RA HX AF GM AW GK
				^B 0.97	87.54	30.70		
2851C	Tablet 200 mg	56	5	..	141.94	30.70	^a Elmendos ^a GenRx Lamotrigine ^a Lamidus ^a Lamitrin ^a Lamogine ^a Lamotrigine-DP ^a Seaze 200 ^a Lamictal	ME GX RA HX AF GM AW GK
				^B 0.96	142.90	30.70		
LEVETIRACETAM								
See Special Pharmaceutical Benefits								
SULTHIAMINE								
2099L	Tablet 50 mg	200	2	..	37.75	30.70	Ospolot	PL
2100M	Tablet 200 mg	200	2	..	85.58	30.70	Ospolot	PL
TOPIRAMATE								
See Special Pharmaceutical Benefits								
ANTI-PARKINSON DRUGS								
Anticholinergic agents								
• Tertiary amines								
BENZHEXOL HYDROCHLORIDE								
1109J	Tablet 2 mg	200	2	..	12.06	13.05	Artane	SI
1110K	Tablet 5 mg	200	1	..	14.09	15.08	Artane	SI
BIPERIDEN HYDROCHLORIDE								
2544X	Tablet 2 mg	200	2	..	*18.99	19.98	Akineton	AB
• Ethers of tropine or tropine derivatives								
BENZTROPINE MESYLATE								
2362H	Tablet 2 mg	60	2	..	11.21	12.20	Benztrop	PL
3038X	Injection 2 mg in 2 mL	5	..	..	20.86	21.85	Cogentin	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	
Dopaminergic agents								
• Dopa and dopa derivatives								
LEVODOPA with BENSERAZIDE								
8218M	Dispersible tablet 50 mg-12.5 mg	100	5	..	21.01	22.00	Madopar Rapid 62.5	RO
8219N	Dispersible tablet 100 mg-25 mg	100	5	..	36.24	30.70	Madopar Rapid 125	RO
2229H	Tablet 100 mg-25 mg	100	5	..	36.24	30.70	Madopar 125	RO
2228G	Tablet 200 mg-50 mg	100	5	..	48.15	30.70	Madopar	RO
2227F	Capsule 50 mg-12.5 mg	100	5	..	21.01	22.00	Madopar 62.5	RO
2225D	Capsule 100 mg-25 mg	100	5	..	36.24	30.70	Madopar 125	RO
2231K	Capsule 100 mg-25 mg (sustained release)	100	5	..	39.34	30.70	Madopar HBS	RO
2226E	Capsule 200 mg-50 mg	100	5	..	48.15	30.70	Madopar	RO
LEVODOPA with CARBIDOPA								
1242J	Tablet 100 mg-25 mg	100	5	..	38.21	30.70	^a Kinson	AF
				^B 5.22	43.43	30.70	^a Sinemet 100/25	MK
1245M	Tablet 250 mg-25 mg	100	5	..	45.91	30.70	^a Levohexal	HX
				^B 3.10	49.01	30.70	^a Sinemet	MK
LEVODOPA with CARBIDOPA								
Authority required								
<i>Parkinson's disease where fluctuations in motor function are not adequately controlled by frequent dosing with conventional formulations of levodopa with decarboxylase inhibitor.</i>								
1255C	Tablet 200 mg-50 mg (modified release)	100	5	..	63.69	30.70	Sinemet CR	MK
LEVODOPA with CARBIDOPA and ENTACAPONE								
Authority required								
<i>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; Parkinson's disease in patients stabilised on concomitant treatment with levodopa—decarboxylase inhibitor combinations and entacapone.</i>								
8797B	Tablet 50 mg-12.5 mg-200 mg	200	4	..	*310.61	30.70	Stalevo 50/12.5/200mg	NV
8798C	Tablet 100 mg-25 mg-200 mg	200	4	..	*340.65	30.70	Stalevo 100/25/200mg	NV
8799D	Tablet 150 mg-37.5 mg-200 mg	200	4	..	*370.69	30.70	Stalevo 150/37.5/200mg	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	
• Adamantane derivatives AMANTADINE HYDROCHLORIDE <u>Restricted benefit</u> <i>Parkinson's disease which is not drug induced.</i>								
3016R	Capsule 100 mg	100	5	..	41.87	30.70	Symmetrel 100	NV
• Dopamine agonists BROMOCRIPTINE MESYLATE <u>Restricted benefit</u> <i>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.</i>								
1443Y	Tablet 2.5 mg (base)	60	5	..	33.00	30.70	^a Krypton 2.5	AF
				^B 2.92	35.92	30.70	^a Parlodel	NV
1446D	Capsule 5 mg (base)	60	5	..	59.92	30.70	^a Krypton 5	AF
				^B 2.91	62.83	30.70	^a Parlodel	NV
1445C	Capsule 10 mg (base)	100	5	..	201.31	30.70	^a Krypton 10	AF
				^B 3.08	204.39	30.70	^a Parlodel	NV
[For other listings for this drug see Generic/Proprietary Index]								
CABERGOLINE <u>Restricted benefit</u> <i>Parkinson's disease.</i>								
8393R	Tablet 1 mg	30	5	..	68.65	30.70	Cabaser	PU
8394T	Tablet 2 mg	30	5	..	90.26	30.70	Cabaser	PU
8395W	Tablet 4 mg	30	5	..	111.75	30.70	Cabaser	PU
PERGOLIDE MESYLATE <u>Restricted benefit</u> <i>Parkinson's disease as adjunctive therapy in patients being treated with levodopa—decarboxylase inhibitor combinations.</i>								
2808T	Tablet 50 micrograms (base)	100	..	..	51.36	30.70	Permax	AS
2809W	Tablet 250 micrograms (base)	100	5	..	64.91	30.70	Permax	AS
2810X	Tablet 1 mg (base)	100	5	..	240.42	30.70	Permax	AS
• Monoamine oxidase type B inhibitors SELEGILINE HYDROCHLORIDE <u>Restricted benefit</u> <i>Late stage Parkinson's disease as adjunctive therapy in patients being treated with levodopa—decarboxylase inhibitor combinations.</i>								
1973W	Tablet 5 mg	100	5	..	55.29	30.70	^a Eldepryl ^a Selgene	GM AF

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	
• Other dopaminergic agents ENTACAPONE Authority required <i>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.</i>								
8367J	Tablet 200 mg	200	4	..	*280.55	30.70	Comtan	NV
PSYCHOLEPTICS								
Antipsychotics								
• Phenothiazine with aliphatic side-chain CHLORPROMAZINE HYDROCHLORIDE								
1196Y	Tablet 10 mg	100	5	..	8.18	9.17	Largactil	AV
1197B	Tablet 25 mg	100	5	..	9.62	10.61	Largactil	AV
1199D	Tablet 100 mg	100	5	..	13.31	14.30	Largactil	AV
1201F	Mixture 25 mg per 5 mL, 100 mL	‡1	5	..	9.41	10.40	Largactil	AV
1195X	Injection 50 mg in 2 mL	10	..	..	14.09	15.08	Largactil	AV
• Phenothiazine with piperazine structure FLUPHENAZINE DECANOATE								
1046C	Injection 12.5 mg in 0.5 mL	5	..	..	17.39	18.38	Modecate	BQ
3098C	Injection 25 mg in 1 mL	5	..	..	24.25	25.24	Modecate	BQ
1001Q	Injection 50 mg in 2 mL	5	..	..	35.03	30.70	Modecate	BQ
TRIFLUOPERAZINE HYDROCHLORIDE								
2185B	Tablet 1 mg (base)	100	5	..	8.24	9.23	Stelazine	GH
2386N	Tablet 2 mg (base)	100	5	..	9.09	10.08	Stelazine	GH
2186C	Tablet 5 mg (base)	100	5	..	9.89	10.88	Stelazine	GH
• Phenothiazines with piperidine structure PERICYAZINE								
3052P	Tablet 2.5 mg	100	5	..	8.77	9.76	Neulactil	AV
3053Q	Tablet 10 mg	100	5	..	12.84	13.83	Neulactil	AV
THIORIDAZINE HYDROCHLORIDE CAUTION: <i>Thioridazine may cause serious cardiac arrhythmias.</i>								
Authority required <i>Management of patients with schizophrenia who have failed to respond adequately to treatment with appropriate courses of at least 2 other antipsychotic drugs, at an adequate dose and for an adequate duration, because of:</i> <i>(a) insufficient effectiveness; or</i> <i>(b) the inability to achieve an effective dose due to intolerable adverse effects from those drugs.</i>								
2163W	Tablet 10 mg	100	5	..	8.88	9.87	Aldazine 10	AF
2359E	Tablet 25 mg	100	5	..	10.83	11.82	Aldazine 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	
THIORIDAZINE HYDROCHLORIDE—cont.								
2164X	Tablet 50 mg	100	5	..	14.06	15.05	Aldazine 50	AF
2165Y	Tablet 100 mg	100	5	..	20.77	21.76	Aldazine 100	AF
• Butyrophenone derivatives								
HALOPERIDOL								
2761H	Tablet 500 micrograms	100	5	..	8.63	9.62	Serenace	SI
2767P	Tablet 1.5 mg	100	5	..	9.08	10.07	Serenace	SI
2770T	Tablet 5 mg	50	5	..	9.09	10.08	Serenace	SI
2763K	Oral liquid 2 mg per mL, 100 mL	‡1	5	..	14.68	15.67	Serenace	SI
2768Q	Injection 5 mg in 1 mL	10	..	..	20.32	21.31	Serenace	SI
HALOPERIDOL DECANOATE								
2765M	I.M. injection equivalent to 50 mg haloperidol in 1 mL	5	..	..	24.25	25.24	Haldol decanoate	JC
2766N	I.M. injection equivalent to 150 mg haloperidol in 3 mL	5	..	..	43.44	30.70	Haldol decanoate	JC
• Thioxanthene derivatives								
FLUPENTHIXOL DECANOATE								
2255Q	Oily I.M. injection 20 mg in 1 mL	5	..	..	17.39	18.38	Fluanxol Depot	LU
2256R	Oily I.M. injection 40 mg in 2 mL	5	..	..	24.25	25.24	Fluanxol Depot	LU
2257T	Oily I.M. injection 100 mg in 1 mL	5	..	..	42.50	30.70	Fluanxol Concentrated Depot	LU
ZUCLOPENTHIXOL DECANOATE								
8097E	Oily I.M. injection 200 mg in 1 mL	5	..	..	23.25	24.24	Clopixol Depot	LU
• Diazepines, oxazepines and thiazepines								
OLANZAPINE								
<u>Authority required</u>								
<i>Schizophrenia;</i>								
<i>Maintenance treatment of bipolar I disorder.</i>								
8170B	Tablet 2.5 mg	30	5	..	56.84	30.70	Zyprexa	LY
8185T	Tablet 5 mg	30	5	..	107.51	30.70	Zyprexa	LY
8186W	Tablet 7.5 mg	30	5	..	160.23	30.70	Zyprexa	LY
8187X	Tablet 10 mg	30	5	..	211.13	30.70	Zyprexa	LY
8433W	Wafer 5 mg	28	5	..	100.67	30.70	Zyprexa Zydys	LY
8434X	Wafer 10 mg	28	5	..	198.13	30.70	Zyprexa Zydys	LY
QUETIAPINE FUMARATE								
<u>Authority required</u>								
<i>Schizophrenia.</i>								
8456C	Tablet 25 mg (base)	60	5	..	52.49	30.70	Seroquel	AP
8457D	Tablet 100 mg (base)	90	5	..	144.01	30.70	Seroquel	AP
8458E	Tablet 200 mg (base)	60	5	..	195.30	30.70	Seroquel	AP
8580N	Tablet 300 mg (base)	60	5	..	275.71	30.70	Seroquel	AP

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	
• Neuroleptics, in tardive dyskinesia TETRABENAZINE <u>Authority required</u> Hyperkinetic extrapyramidal disorders.								
1330B	Tablet 25 mg	112	5	..	328.91	30.70	OA	
• Benzamides AMISULPRIDE <u>Authority required</u> Schizophrenia.								
8594H	Tablet 100 mg	30	5	..	36.20	30.70	Solian 100	SW
8595J	Tablet 200 mg	60	5	..	138.99	30.70	Solian 200	SW
8596K	Tablet 400 mg	60	5	..	255.68	30.70	Solian 400	SW
8736T	Oral solution 100 mg per mL, 60 mL	2	5	..	*138.95	30.70	Solian Solution	SW
• Lithium LITHIUM CARBONATE For listings see Generic/Proprietary Index								
• Other antipsychotics ARIPIPRAZOLE <u>Authority required</u> Schizophrenia.								
8717T	Tablet 10 mg	30	5	..	155.18	30.70	Abilify	BQ
8718W	Tablet 15 mg	30	5	..	216.71	30.70	Abilify	BQ
8719X	Tablet 20 mg	30	5	..	258.76	30.70	Abilify	BQ
8720Y	Tablet 30 mg	30	5	..	310.26	30.70	Abilify	BQ
RISPERIDONE <u>Authority required</u> 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.								
8787L	Tablet 0.5 mg	60	2	..	*38.48	30.70	Risperdal	JC
8788M	Tablet 0.5 mg (orally disintegrating)	56	2	..	*36.25	30.70	Risperdal Quicklet	JC
8789N	Tablet 1 mg	60	2	..	71.79	30.70	Risperdal	JC
8790P	Tablet 1 mg (orally disintegrating)	56	2	..	*67.35	30.70	Risperdal Quicklet	JC
8791Q	Oral solution 1 mg per mL, 30 mL	‡1	2	..	38.63	30.70	Risperdal	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	
<u>RISPERIDONE—cont.</u>								
<u>Authority required</u>								
<u>Schizophrenia.</u>								
8869T	Tablet 0.5 mg	60	5	..	*38.48	30.70	Risperdal	JC
8870W	Tablet 0.5 mg (orally disintegrating)	56	5	..	*36.25	30.70	Risperdal Quicklet	JC
3169T	Tablet 1 mg	60	5	..	71.79	30.70	Risperdal	JC
8792R	Tablet 1 mg (orally disintegrating)	56	5	..	*67.35	30.70	Risperdal Quicklet	JC
3170W	Tablet 2 mg	60	5	..	139.05	30.70	Risperdal	JC
8794W	Tablet 2 mg (orally disintegrating)	56	5	..	*130.13	30.70	Risperdal Quicklet	JC
3171X	Tablet 3 mg	60	5	..	204.11	30.70	Risperdal	JC
3172Y	Tablet 4 mg	60	5	..	264.30	30.70	Risperdal	JC
8100H	Oral solution 1 mg per mL, 100 mL	‡1	5	..	116.76	30.70	Risperdal	JC
8780D	Powder for I.M. injection 25 mg (modified release) with 2 mL diluent in pre-filled syringe	2	5	..	*319.87	30.70	Risperdal Consta	JC
8781E	Powder for I.M. injection 37.5 mg (modified release) with 2 mL diluent in pre-filled syringe	2	5	..	*409.13	30.70	Risperdal Consta	JC
8782F	Powder for I.M. injection 50 mg (modified release) with 2 mL diluent in pre-filled syringe	2	5	..	*498.49	30.70	Risperdal Consta	JC
<u>Authority required</u>								
<u>Adjunctive therapy to mood stabilisers for up to 6 months, of an episode of acute mania associated with bipolar I disorder.</u>								
3169T	Tablet 1 mg	60	5	..	71.79	30.70	Risperdal	JC
8792R	Tablet 1 mg (orally disintegrating)	56	5	..	*67.35	30.70	Risperdal Quicklet	JC
3170W	Tablet 2 mg	60	5	..	139.05	30.70	Risperdal	JC
8794W	Tablet 2 mg (orally disintegrating)	56	5	..	*130.13	30.70	Risperdal Quicklet	JC
3171X	Tablet 3 mg	60	5	..	204.11	30.70	Risperdal	JC
3172Y	Tablet 4 mg	60	5	..	264.30	30.70	Risperdal	JC
8100H	Oral solution 1 mg per mL, 100 mL	‡1	5	..	116.76	30.70	Risperdal	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
Anxiolytics							
• Benzodiazepine derivatives							
ALPRAZOLAM							
Authority required							
<i>Panic disorder where other treatments have failed or are inappropriate.</i>							
2130D	Tablet 250 micrograms	50	..	..	9.13	10.12	^a Alprax 0.25 AW ^a Kalma 0.25 AF ^a Zamhexal HX 0.25mg
				^B 1.05	10.18	10.12	^a Xanax PH
2131E	Tablet 500 micrograms	50	..	..	11.60	12.59	^a Alprax 0.5 AW ^a Kalma 0.5 AF ^a Zamhexal HX 0.5mg
				^B 1.12	12.72	12.59	^a Xanax PH
2132F	Tablet 1 mg	50	2	..	16.38	17.37	^a Alprax 1 AW ^a Alprazolam-DP GM ^a Chem mart CH Alprazolam ^a GenRx GX Alprazolam ^a Kalma 1 AF ^a Terry White TW Chemists Alprazolam ^a Zamhexal HX 1.0mg
				^B 1.32	17.70	17.37	^a Xanax PH
8118G	Tablet 2 mg	50	2	..	22.54	23.53	^a Alprax 2 AW ^a Alprazolam-DP GM ^a Chem mart CH Alprazolam ^a GenRx GX Alprazolam ^a Kalma 2 AF ^a Terry White TW Chemists Alprazolam ^a Zamhexal 2mg HX
				^B 1.60	24.14	23.53	^a Xanax PH Tri-Score

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
DIAZEPAM							
3161J	Tablet 2 mg	50	..	..	7.13	8.12	^a Antenex 2 AF
				^B 0.87	8.00	8.12	^a Valpam 2 AW
				^B 1.27	8.40	8.12	Ducene SU
							^a Valium RO
3162K	Tablet 5 mg	50	..	..	7.35	8.34	^a Antenex 5 AF
							^a Diazepam-DP GM
							^a Valpam 5 AW
				^B 0.91	8.26	8.34	Ducene SU
				^B 1.28	8.63	8.34	^a Valium RO
2558P	Injection 10 mg in 2 mL	5	..	..	10.76	11.75	MX

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	..	..	6.39	7.38	^a Alepam 15 AF
				^B 1.74	8.13	7.38	^a Serepax SI
3133X	Tablet 30 mg	25	..	..	6.59	7.58	^a Alepam 30 AF
							^a Murelax FM
				^B 1.85	8.44	7.58	^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.

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	..	*7.63	8.62	^a Alepam 15 AF
				^B 3.48	*11.11	8.62	^a Serepax SI
3135B	Tablet 30 mg	50	5	..	*8.03	9.02	^a Alepam 30 AF
							^a Murelax FM
				^B 3.70	*11.73	9.02	^a Serepax 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
• Other anxiolytics CLOMIPRAMINE HYDROCHLORIDE Restricted benefit <i>Cataplexy associated with narcolepsy;</i> <i>Obsessive-compulsive disorder;</i> <i>Phobic disorders in adults.</i>							
1561E	Tablet 25 mg	50	2	..	18.43	19.42	^a Chem mart CH ^a Clomipramine GX ^a GenRx Clomipramine AF ^a Placil TW ^a Terry White Chemists Clomipramine NV ^B 3.26 21.69 19.42 ^a Anafranil 25
Hypnotics and sedatives • Benzodiazepine derivatives NITRAZEPAM							
2723H	Tablet 5 mg	25	..	..	7.02	8.01	^a Alodorm AF ^B 1.96 8.98 8.01 ^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.							
NITRAZEPAM Authority required <i>Myoclonic epilepsy;</i> <i>Malignant neoplasia (late stage);</i> <i>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;</i> <i>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.</i>							
2732T	Tablet 5 mg	50	5	..	*8.89	9.88	^a Alodorm AF ^B 3.92 *12.81 9.88 ^a Mogadon VT

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	
2089Y	TEMAZEPAM Tablet 10 mg	25	..	..	7.02	8.01	^a Temaze	AF
							^a Temtabs	FM
				^B 1.77	8.79	8.01	^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	..	*8.89	9.88	^a Temaze	AF
							^a Temtabs	FM
				^B 3.54	*12.43	9.88	^a Normison	SI

PSYCHOANALEPTICS

Antidepressants• **Non-selective monoamine reuptake inhibitors**AMITRIPTYLINE
HYDROCHLORIDE

2417F	Tablet 10 mg	50	2	..	7.09	8.08	Endep 10	AF
2418G	Tablet 25 mg	50	2	..	7.09	8.08	Endep 25	AF
2429W	Tablet 50 mg	50	2	..	7.52	8.51	Endep 50	AF

CLOMIPRAMINE
HYDROCHLORIDE**Restricted benefit**

Cataplexy associated with narcolepsy;

Obsessive-compulsive disorder;

Phobic disorders in adults.

1561E	Tablet 25 mg	50	2	..	18.43	19.42	^a Chem mart	CH
							Clomipramine	
							^a GenRx	GX
							Clomipramine	
							^a Placil	AF
							^a Terry White	TW
							Chemists	
							Clomipramine	
				^B 3.26	21.69	19.42	^a Anafranil 25	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	
DOTHIEPIN HYDROCHLORIDE								
1357K	Capsule 25 mg	50	2	.. B2.00	8.00 10.00	8.99 ^a 8.99 ^a	Dothep 25 Prothiaden	AF AB
1358L	Tablet 75 mg	30	2	.. B1.03	7.98 9.01	8.97 ^a 8.97 ^a	Dothep 75 Prothiaden	AF AB
DOXEPIN HYDROCHLORIDE								
1012G	Tablet 50 mg (base)	50	2	..	8.30	9.29	Deptran 50	AF
1011F	Capsule 10 mg (base)	50	2	.. B1.78	7.59 9.37	8.58 8.58	Deptran 10 Sinequan	AF PF
1013H	Capsule 25 mg (base)	50	2	.. B1.51	8.00 9.51	8.99 8.99	Deptran 25 Sinequan	AF PF
IMIPRAMINE HYDROCHLORIDE								
2420J	Tablet 10 mg	50	2	.. B1.70	7.09 8.79	8.08 ^a 8.08 ^a	Tolerade 10 Tofranil 10	LN NV
2421K	Tablet 25 mg	50	2	.. B1.70	7.09 8.79	8.08 ^a 8.08 ^a	Tolerade 25 Tofranil 25	LN NV
<u>NORTRIPTYLINE HYDROCHLORIDE</u>								
<u>Restricted benefit</u>								
<i>Major depression where other antidepressant therapy has failed; Major depression where other antidepressant therapy is contraindicated.</i>								
2522R	Tablet 10 mg (base)	50	2	..	11.08	12.07	Allegron	AS
2523T	Tablet 25 mg (base)	50	2	..	12.81	13.80	Allegron	AS
• Selective serotonin reuptake inhibitors								
<u>CITALOPRAM HYDROBROMIDE</u>								
<u>Restricted benefit</u>								
<i>Major depressive disorders.</i>								
8702B	Tablet 10 mg (base)	28	5	..	19.03	20.02	Celapram	AF
8220P	Tablet 20 mg (base)	28	5	..	26.23	27.22 ^a	Celapram Chem mart Citalopram Ciazil Citalopram-RL GenRx Citalopram Talam Talohehexal Terry White Chemists Citalopram Cipramil	AF CH GM RE GX AW SZ TW LU
8703C	Tablet 40 mg (base)	28	5	..	40.81	30.70	Celapram GenRx Citalopram Talohehexal	AF GX SZ

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	
ESCITALOPRAM OXALATE								
<u>Restricted benefit</u>								
<i>Major depressive disorders.</i>								
8700X	Tablet 10 mg (base)	28	5	..	27.59	28.58	^a Esipram	CF
				^B 3.20	30.79	28.58	^a Lexapro	LU
8701Y	Tablet 20 mg (base)	28	5	..	41.18	30.70	^a Esipram	CF
				^B 5.34	46.52	30.70	^a Lexapro	LU
<i>See Special Pharmaceutical Benefits for listing for escitalopram oxalate oral solution.</i>								
FLUOXETINE HYDROCHLORIDE								
<u>Restricted benefit</u>								
<i>Major depressive disorders; Obsessive-compulsive disorder.</i>								
8270G	Tablet 20 mg (base) (dispersible)	28	5	..	23.50	24.49	^a Lovan 20 Tab	AL
				^B 6.96	30.46	24.49	^a Prozac Tab	LY
1434L	Capsule 20 mg (base)	28	5	..	23.50	24.49	^a Auscap	SI
							^a Chem mart	CH
							Fluoxetine	
							^a Fluohexal	HX
							^a Fluoxebell	BF
							^a Fluoxetine-DP	GM
							^a GenRx	GX
							Fluoxetine	
							^a Lovan	AL
							^a Terry White Chemists	TW
							Fluoxetine	
							^a Zactin	AF
				^B 6.96	30.46	24.49	^a Prozac 20	LY
FLUVOXAMINE MALEATE								
<u>Restricted benefit</u>								
<i>Major depressive disorders; Obsessive-compulsive disorder.</i>								
8512B	Tablet 50 mg	30	5	..	22.94	23.93	^a Faverin 50	AW
							^a Movox 50	AL
							^a Voxam	HX
				^B 3.77	26.71	23.93	^a Luvox	SM
8174F	Tablet 100 mg	30	5	..	32.09	30.70	^a Faverin 100	AW
							^a Movox 100	AF
							^a Voxam	HX
				^B 3.77	35.86	30.70	^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 HYDROCHLORIDE							
<u>Restricted benefit</u>							
<i>Major depressive disorders; Obsessive-compulsive disorder; Panic disorder.</i>							
2242B	Tablet 20 mg (base)	30	5	..	29.45	30.44	^a Chem mart CH ^a Paroxetine ^a Extine 20 AW ^a GenRx GX ^a Paroxetine ^a Oxetine SZ ^a Paroxetine-DP GM ^a Paxtine AF ^a Terry White TW Chemists ^a Paroxetine Aropax GK
				^B 1.10	30.55	30.44	
SERTRALINE HYDROCHLORIDE							
<u>Restricted benefit</u>							
<i>Major depressive disorders.</i>							
2236Q	Tablet 50 mg (base)	30	5	..	28.40	29.39	^a Chem mart CH ^a Sertraline ^a Concorz SZ ^a Eleva 50 AF ^a GenRx GX ^a Sertraline ^a Sertraline-DP GM ^a Setrona RA ^a Terry White TW Chemists ^a Sertraline ^a Xydep 50 AW ^a Zoloft PF
				^B 0.54	28.94	29.39	
2237R	Tablet 100 mg (base)	30	5	..	28.40	29.39	^a Chem mart CH ^a Sertraline ^a Concorz SZ ^a Eleva 100 AF ^a GenRx GX ^a Sertraline ^a Sertraline-DP GM ^a Setrona RA ^a Terry White TW Chemists ^a Sertraline ^a Xydep 100 AW ^a Zoloft PF
				^B 0.54	28.94	29.39	

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	
SERTRALINE HYDROCHLORIDE—cont.								
<u>Restricted benefit</u>								
<i>Obsessive-compulsive disorder;</i>								
<i>Panic disorder where other treatments have failed or are inappropriate.</i>								
8836C	Tablet 50 mg (base)	30	5	..	28.40	29.39	^a Eleva 50	AF
							^a Xydep 50	AW
				^B 0.54	28.94	29.39	^a Zoloft	PF
8837D	Tablet 100 mg (base)	30	5	..	28.40	29.39	^a Eleva 100	AF
							^a Xydep 100	AW
				^B 0.54	28.94	29.39	^a Zoloft	PF
• Monoamine oxidase inhibitors, non-selective								
PHENELZINE SULFATE								
<u>CAUTION:</u>								
<i>This drug is an irreversible monoamine oxidase inhibitor.</i>								
<u>Restricted benefit</u>								
<i>Depression where all other anti-depressant therapy has failed or is inappropriate.</i>								
2856H	Tablet 15 mg (base)	100	1	..	98.83	30.70	Nardil	LM
TRANLYCYPROMINE SULFATE								
<u>CAUTION:</u>								
<i>This drug is an irreversible monoamine oxidase inhibitor.</i>								
2444P	Tablet 10 mg (base)	50	2	..	25.95	26.94	Parnate	GH
• Monoamine oxidase type A inhibitors								
MOCLOBEMIDE								
<u>Restricted benefit</u>								
<i>Major depressive disorders.</i>								
1900B	Tablet 150 mg	60	5	..	20.89	21.88	^a Amira 150	AF
							^a Arima	AL
							^a Chem mart	CH
							<i>Moclobemide</i>	
							^a Clobemix	GM
							^a GenRx	GX
							<i>Moclobemide</i>	
							^a Mohexal	HX
							^a Terry White	TW
							<i>Chemists</i>	
							<i>Moclobemide</i>	
				^B 0.93	21.82	21.88	^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	
MOCLOBEMIDE—cont.								
8003F	Tablet 300 mg	60	5	..	35.44	30.70	^a Amira 300	AF
							^a Arima 300	AL
							^a Chem mart	CH
							Moclobemide	
							^a Clobemix	GM
							^a GenRx	GX
							Moclobemide	
							^a Maosig	SI
							^a Mohexal	HX
							^a Terry White	TW
							Chemists	
							Moclobemide	
				^B 1.86	37.30	30.70	^a Aurorix 300 mg	RO
• Other antidepressants								
LITHIUM CARBONATE								
3059B	Tablet 250 mg	200	2	..	13.75	14.74	Lithicarb	AS
8290H	Tablet 450 mg (slow release)	200	2	..	*26.49	27.48	Quilonum SR	GK
MIANSERIN HYDROCHLORIDE								
CAUTION:								
<i>Neutropenia and agranulocytosis are more frequent in the elderly, especially in the early months of therapy.</i>								
Restricted benefit								
<i>Severe depression.</i>								
1627P	Tablet 10 mg	50	5	..	14.45	15.44	^a Lumin 10	AF
				^B 1.93	16.38	15.44	^a Tolvon	OR
1628Q	Tablet 20 mg	50	5	..	24.77	25.76	^a Lumin 20	AF
				^B 2.90	27.67	25.76	^a Tolvon	OR
MIRTAZAPINE								
Restricted benefit								
<i>Major depressive disorders.</i>								
8855C	Tablet 15 mg (orally disintegrating)	30	5	..	22.94	23.93	Avanza SolTab	BP
8513C	Tablet 30 mg	30	5	..	31.83	30.70	^a Axit 30	AF
							^a Mirtazapine-DP	GM
							^a Mirtazon	AW
				^B 2.17	34.00	30.70	^a Avanza	BP
				^B 25.83	57.66	30.70	^a Remeron	OR
8856D	Tablet 30 mg (orally disintegrating)	30	5	..	31.83	30.70	Avanza SolTab	BP
8883M	Tablet 45 mg	30	5	..	49.61	30.70	^a Mirtazon	AW
				^B 2.19	51.80	30.70	^a Avanza	BP
8857E	Tablet 45 mg (orally disintegrating)	30	5	..	49.61	30.70	Avanza SolTab	BP

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	
REBOXETINE MESILATE								
<u>Restricted benefit</u>								
<i>Major depressive disorders.</i>								
8583R	Tablet 4 mg (base)	60	5	..	36.08	30.70	Edronax	PH
VENLAFAXINE								
HYDROCHLORIDE								
<u>Restricted benefit</u>								
<i>Major depressive disorders.</i>								
8868R	Capsule 37.5 mg (base) (modified release)	28	..	..	23.86	24.85	Efexor-XR	WY
8301X	Capsule 75 mg (base) (modified release)	28	5	..	42.57	30.70	Efexor-XR	WY
8302Y	Capsule 150 mg (base) (modified release)	28	5	..	51.02	30.70	Efexor-XR	WY
Psychostimulants, agents used for ADHD and nootropics								
• Centrally acting sympathomimetics								
DEXAMPHETAMINE SULFATE								
<u>NOTE:</u>								
<i>Care must be taken to comply with the provisions of State/Territory law when prescribing dexamphetamine.</i>								
<u>Authority required</u>								
<i>Use in attention deficit hyperactivity disorder, in accordance with State/Territory law; Narcolepsy.</i>								
1165H	Tablet 5 mg	100	5	..	16.53	17.52	SI	
METHYLPHENIDATE								
HYDROCHLORIDE								
<u>NOTE:</u>								
<i>Care must be taken to comply with the provisions of State/Territory law when prescribing methylphenidate hydrochloride.</i>								
<u>Authority required</u>								
<i>Use in attention deficit hyperactivity disorder, in accordance with State/Territory law.</i>								
8839F	Tablet 10 mg	100	5	..	16.53	17.52	^a Attenta	AF
				^B 1.75	18.28	17.52	^a Ritalin 10	NV

NERVOUS SYSTEM —cont.

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

MODAFINIL**NOTE:**

Any queries concerning the arrangements to prescribe modafinil may be directed to Medicare Australia on 1800 005 750 (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:

*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.

NERVOUS SYSTEM —cont.

Code	Name, Restriction, Manner of administration and form	Max. No.of			Dispensed	Maximum	Proprietary Name and Manufacturer
		Qty	Rpts	Premium	Price for Max.Qty \$	Recordable Value for Safety Net \$	
MODAFINIL—cont.							
<i>The authority application must be made in writing and must include the following:</i>							
<i>(a) a completed authority prescription form; and</i>							
<i>(b) a completed Modafinil (Modavigil) PBS Authority Application for Use in the Treatment of Narcolepsy - Supporting Information Form [www.medicareaustralia.gov.au]; and</i>							
<i>(c) details of the contraindication or intolerance to dexamphetamine sulfate; and</i>							
<i>(d) either:</i>							
<i>(i) the result and date of the polysomnography test and MSLT conducted by, or under the supervision of, a qualified sleep medicine practitioner; or</i>							
<i>(ii) the result and date of the EEG, conducted by, or under the supervision of, a neurologist.</i>							
<i>The polysomnography, MSLT or EEG test reports must be provided with the authority application.</i>							
<u>Authority required</u>							
<i>Continuing treatment of narcolepsy, where the patient has previously been issued with an authority prescription for this drug.</i>							
8816B	Tablet 100 mg	120	5	..	*345.71	30.70	Modavigil CS

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 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.

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;

NERVOUS SYSTEM —cont.

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

DONEPEZIL HYDROCHLORIDE—cont.**CONTINUING TREATMENT — (S)MMSE or ADAS-Cog improvement.**

Continuing treatment, 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 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;*

continued ➡

NERVOUS SYSTEM —cont.

Code	Name, Restriction, Manner of administration and form	Max. No.of			Dispensed Price for Max.Qty \$	Maximum Recordable Value for Safety Net \$	Proprietary Name and Manufacturer	
		Qty	Rpts	Premium				
<i>DONEPEZIL HYDROCHLORIDE—cont.</i>								
<i>CONTINUING TREATMENT — Clinician assessed improvement.</i>								
<i>Continuing treatment, 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.</i>								
<i>The initial authority application for continuing treatment must state the improvement achieved on the CIBIC scale and must be in writing.</i>								
<i>Subsequent applications for continuing treatment can be made by telephone.</i>								
8495D	Tablet 5 mg	28	5	..	154.18	30.70	Aricept	PF
8496E	Tablet 10 mg	28	5	..	154.18	30.70	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 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.

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, 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.

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	
GALANTAMINE HYDROBROMIDE—cont.								
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.								
<i>Initial treatment 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).</i>								
<i>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.</i>								
<i>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.</i>								
<i>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.</i>								
<i>Patients who qualify under this criterion are from 1 or more of the following groups:</i>								
<i>(1) Unable to communicate adequately because of lack of competence in English, in people of non-English speaking background;</i>								
<i>(2) Limited education, as defined by less than 6 years of education, or who are illiterate or innumerate;</i>								
<i>(3) Aboriginal or Torres Strait Islanders who, by virtue of cultural factors, are unable to complete an (S)MMSE test;</i>								
<i>(4) Intellectual (developmental or acquired) disability, eg Down's syndrome;</i>								
<i>(5) Significant sensory impairment despite best correction, which precludes completion of an (S)MMSE test;</i>								
<i>(6) Prominent dysphasia, out of proportion to other cognitive and functional impairment;</i>								
CONTINUING TREATMENT — Clinician assessed improvement.								
<i>Continuing treatment, 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.</i>								
<i>The initial authority application for continuing treatment must state the improvement achieved on the CIBIC scale and must be in writing.</i>								
<i>Subsequent applications for continuing treatment can be made by telephone.</i>								
8770N	Capsule 8 mg (base) (prolonged release)	28	5	..	129.55	30.70	Reminyl	JC
8771P	Capsule 16 mg (base) (prolonged release)	28	5	..	157.32	30.70	Reminyl	JC
8772Q	Capsule 24 mg (base) (prolonged release)	28	5	..	186.50	30.70	Reminyl	JC

NERVOUS SYSTEM —cont.

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

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 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.

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, 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 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.

NERVOUS SYSTEM —cont.

Code	Name, Restriction, Manner of administration and form	Max. No. of Qty Rpts Premium	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Proprietary Name and Manufacturer	
RIVASTIGMINE HYDROGEN TARTRATE—cont.						
<i>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.</i> <i>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.</i> <i>Patients who qualify under this criterion are from 1 or more of the following groups:</i> <i>(1) Unable to communicate adequately because of lack of competence in English, in people of non-English speaking background;</i> <i>(2) Limited education, as defined by less than 6 years of education, or who are illiterate or innumerate;</i> <i>(3) Aboriginal or Torres Strait Islanders who, by virtue of cultural factors, are unable to complete an (S)MMSE test;</i> <i>(4) Intellectual (developmental or acquired) disability, eg Down's syndrome;</i> <i>(5) Significant sensory impairment despite best correction, which precludes completion of an (S)MMSE test;</i> <i>(6) Prominent dysphasia, out of proportion to other cognitive and functional impairment;</i> CONTINUING TREATMENT — Clinician assessed improvement. <i>Continuing treatment, 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.</i> <i>The initial authority application for continuing treatment must state the improvement achieved on the CIBIC scale and must be in writing.</i> <i>Subsequent applications for continuing treatment can be made by telephone.</i>						
8497F	Capsule 1.5 mg (base)	56 5 ..	154.18	30.70	Exelon	NV
8498G	Capsule 3 mg (base)	56 5 ..	154.18	30.70	Exelon	NV
8499H	Capsule 4.5 mg (base)	56 5 ..	154.18	30.70	Exelon	NV
8500J	Capsule 6 mg (base)	56 5 ..	154.18	30.70	Exelon	NV
8563Q	Oral solution 2 mg (base) per mL, 120 mL	£1 5 ..	154.18	30.70	Exelon	NV
OTHER NERVOUS SYSTEM DRUGS						
Parasympathomimetics						
• Anticholinesterases						
PYRIDOSTIGMINE BROMIDE						
2724J	Tablet 10 mg	100 5 ..	17.82	18.81	Mestinon	VT
1959D	Tablet 60 mg	150 5 ..	54.73	30.70	Mestinon	VT
2608G	Tablet 180 mg (modified release)	100 5 ..	113.20	30.70	Mestinon Timespan	VT
• Choline esters						
BETHANECHOL CHLORIDE						
1062X	Tablet 10 mg	100 2 ..	18.80	19.79	Uro-Carb	HA

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 addictive disorders								
• Drugs used in nicotine dependence								
BUPROPION HYDROCHLORIDE								
NOTE:								
<i>Only one treatment course per year with no increased maximum quantities or repeats will be authorised.</i>								
Authority required								
<i>Commencement of treatment as short-term adjunctive therapy for nicotine dependence to facilitate the goal of achieving abstinence in patients who have indicated that they are ready to cease smoking and:</i>								
<i>(a) who have entered a comprehensive support and counselling program; or</i>								
<i>(b) who are entering a comprehensive support and counselling program during the consultation at which this authority is requested.</i>								
<i>Details of the program must be specified in the authority application.</i>								
8465M	Tablet 150 mg (sustained release)	30	..	..	77.43	30.70	^a Bupropion-RL	RE
							^a Clorprax	HX
				^B 0.87	78.30	30.70	^a Zyban	GK
Authority required								
<i>Completion of treatment as short-term adjunctive therapy for nicotine dependence to facilitate the goal of achieving abstinence in patients who have indicated that they are ready to cease smoking and who have entered a comprehensive support and counselling program.</i>								
8710K	Tablet 150 mg (sustained release)	90	..	..	170.57	30.70	^a Bupropion-RL	RE
							^a Clorprax	HX
				^B 0.87	171.44	30.70	^a Zyban	GK
• Drugs used in alcohol dependence								
ACAMPROSATE CALCIUM								
Authority required								
<i>For use within a comprehensive treatment program for alcohol dependence with the goal of maintaining abstinence.</i>								
NOTE:								
<i>No applications for increased maximum quantities and/or repeats will be authorised.</i>								
8357W	Tablet 333 mg (enteric coated)	180	1	..	165.31	30.70	Campral	AF
NALTREXONE HYDROCHLORIDE								
CAUTION:								
<i>Naltrexone hydrochloride is contraindicated in patients receiving opioid drugs.</i>								
Authority required								
<i>For use within a comprehensive treatment program for alcohol dependence with the goal of maintaining abstinence.</i>								
NOTE:								
<i>No applications for increased maximum quantities and/or repeats will be authorised.</i>								
8370M	Tablet 50 mg	30	1	..	162.59	30.70	ReVia	BQ

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
Other nervous system drugs							
• Other nervous system drugs							
RILUZOLE							
Authority required							
➤ <i>Initial treatment of amyotrophic lateral sclerosis, as diagnosed by a neurologist, in patients with disease duration of 2 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:</i>							
<i>(1) are ambulatory, and</i>							
<i>(a) have not undergone tracheostomy, and</i>							
<i>(b) have not experienced respiratory failure;</i>							
OR							
<i>(2) are not ambulatory, and</i>							
<i>(a) have not undergone tracheostomy, and</i>							
<i>(b) have not experienced respiratory failure, and</i>							
<i>(c) are either able to use upper limbs or able to swallow.</i>							
<i>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.</i>							
Authority required							
<i>Continuing treatment of amyotrophic lateral sclerosis in patients who have previously been issued with an authority prescription for this drug and who:</i>							
<i>(1) are ambulatory, and</i>							
<i>(a) have not undergone tracheostomy, and</i>							
<i>(b) have not experienced respiratory failure;</i>							
OR							
<i>(2) are not ambulatory, and</i>							
<i>(a) have not undergone tracheostomy, and</i>							
<i>(b) have not experienced respiratory failure, and</i>							
<i>(c) are either able to use upper limbs or able to swallow.</i>							
8664B	Tablet 50 mg	56	5	..	660.73	30.70	Rilutek AV

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								
<i>For listings see Generic/Proprietary Index</i>								
METRONIDAZOLE BENZOATE								
<i>For listings see Generic/Proprietary Index</i>								
TINIDAZOLE								
<i>For listings see Generic/Proprietary Index</i>								
• Other agents against amoebiasis and other protozoal diseases								
ATOVAQUONE								
<u>Authority required</u>								
<i>Treatment of mild to moderate Pneumocystis carinii pneumonia in adult patients who are intolerant of trimethoprim/sulfamethoxazole therapy.</i>								
8300W	Oral suspension 750 mg per 5 mL, 210 mL	1	..	..	861.94	30.70	Wellvone	GK
1966L	PYRIMETHAMINE Tablet 25 mg	50	..	..	13.08	14.07	Daraprim	GK
Antimalarials								
• Methanolquinolines								
QUININE BISULFATE								
<u>CAUTION:</u>								
<i>Severe thrombocytopenia has been reported with this drug.</i>								
<u>Authority required</u>								
<i>Malaria.</i>								
1972T	Tablet 300 mg	50	2	..	10.67	11.66	Quinbisul	AS
QUININE SULFATE								
<u>CAUTION:</u>								
<i>Severe thrombocytopenia has been reported with this drug.</i>								
<u>Authority required</u>								
<i>Malaria.</i>								
1975Y	Tablet 300 mg	50	2	..	10.67	11.66	^a Quinsul	LN
				^B 2.13	12.80	11.66	^a Quinate	AS

ANTIPARASITIC PRODUCTS, INSECTICIDES AND REPELLENTS —cont.

Code	Name, Restriction, Manner of 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								
<i>Treatment of whipworm infestation in an Aboriginal or a Torres Strait Islander person.</i>								
9047E	Tablet 200 mg	6	..	..	26.41	27.40	Zentel	GK
Authority required								
<i>Treatment of tapeworm infestation.</i>								
8503M	Tablet 200 mg	6	1	..	26.41	27.40	Zentel	GK
Authority required								
<i>For the treatment of hydatid disease in conjunction with surgery or when a surgical cure cannot be achieved or where surgery cannot be used.</i>								
8459F	Tablet 400 mg	60	2	..	154.18	30.70	Eskazole	GK
• Tetrahydropyrimidine derivatives								
PYRANTEL EMBONATE								
3047J	Tablet 125 mg (base)	6	..	..	6.70	7.69	Anthel 125	AF
3048K	Tablet 250 mg (base)	6	..	..	8.08	9.07	Anthel 250	AF
• Avermectines								
IVERMECTIN								
Authority required								
<i>Onchocerciasis; Strongyloidiasis.</i>								
8359Y	Tablet 3 mg	4	..	..	28.95	29.94	Stromectol	MK
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	..	15.05	16.04	Lyclear	PC

RESPIRATORY 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	
DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES								
Adrenergics, inhalants								
• Selective beta-2-adrenoceptor agonists								
EFORMOTEROL FUMARATE DIHYDRATE								
Restricted benefit								
<i>Patients with frequent episodes of asthma who are currently receiving treatment with oral corticosteroids;</i>								
<i>Patients with frequent episodes of asthma who are currently receiving treatment with optimal doses of inhaled corticosteroids.</i>								
8136F	Capsule containing powder for oral inhalation 12 micrograms (for use in Foradile Aerolizer)	60	5	..	34.72	30.70	Foradile	NV
8239P	Powder for oral inhalation in breath actuated device 6 micrograms per dose (60 doses)	‡1	5	..	24.25	25.24	Oxis Turbuhaler	AP
8240Q	Powder for oral inhalation in breath actuated device 12 micrograms per dose (60 doses)	‡1	5	..	33.86	30.70	Oxis Turbuhaler	AP
SALBUTAMOL SULFATE								
1099W	Capsule containing powder for oral inhalation 200 micrograms (base) (for use in Ventolin Rotahaler)	200	5	..	*20.55	21.54	Ventolin Rotacaps	GK
8288F	Oral pressurised inhalation 100 micrograms (base) per dose (200 doses), CFC-free formulation	2	5	..	*16.39	17.38	^a Asmol CFC-free	AL
							^a Epaq	AW
				^B 0.60	*16.99	17.38	^a Airomir	MM
				^B 1.00	*17.39	17.38	^a Ventolin CFC-free	GK
SALBUTAMOL SULFATE								
Restricted benefit								
<i>Patients unable to achieve co-ordinated use of other metered dose inhalers containing this drug.</i>								
8354Q	Oral pressurised inhalation in breath actuated device 100 micrograms (base) per dose (200 doses), CFC-free formulation	2	5	..	*35.93	30.70	Airomir Autohaler	MM

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	
SALBUTAMOL SULFATE—cont.								
Restricted benefit								
<i>Asthma in patients unable to use this drug delivered from an oral pressurised inhalation device via a spacer;</i>								
<i>Chronic obstructive pulmonary disease in patients unable to use this drug delivered from an oral pressurised inhalation device via a spacer.</i>								
2000G	Nebuliser solution single dose units 2.5 mg (base) in 2.5 mL, 30	2	5	..	*23.39	24.38	^a Asmol 2.5 uni-dose	AF
							^a Butamol 2.5	AW
							^a Chem mart Salbutamol	CH
							^a GenRx Salbutamol	GX
							^a Terry White Chemists Salbutamol	TW
							^a PU	
				^B 2.14	*25.53	24.38	^a Ventolin Nebules	GK
2001H	Nebuliser solution single dose units 5 mg (base) in 2.5 mL, 30	2	5	..	*24.43	25.42	^a Asmol 5 uni-dose	AF
							^a Butamol 5	AW
							^a Chem mart Salbutamol	CH
							^a GenRx Salbutamol	GX
							^a Terry White Chemists Salbutamol	TW
							^a Ventolin Nebules	GK
				^B 2.12	*26.55	25.42		
2003K	Nebuliser solution 5 mg (base) per mL (0.5%), 30 mL	2	2	..	*11.83	12.82	PU	
SALMETEROL XINAFOATE								
Restricted benefit								
<i>Patients with frequent episodes of asthma who are currently receiving treatment with oral corticosteroids;</i>								
<i>Patients with frequent episodes of asthma who are currently receiving treatment with optimal doses of inhaled corticosteroids.</i>								
3027H	Oral pressurised inhalation 25 micrograms (base) per dose (120 doses)	‡1	5	..	33.86	30.70	Serevent	GK
8141L	Powder for oral inhalation in breath actuated device 50 micrograms (base) per dose (60 doses)	‡1	5	..	33.86	30.70	Serevent Accuhaler	GK
TERBUTALINE SULFATE								
1252X	Powder for oral inhalation in breath actuated device 500 micrograms per dose (200 doses)	‡1	5	..	16.06	17.05	Bricanyl Turbuhaler	AP

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	
TERBUTALINE SULFATE—cont.								
<u>Restricted benefit</u>								
<i>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.</i>								
1251W	Nebuliser solution single dose units 5 mg in 2 mL, 30	2	5	..	*26.55	27.54	Bricanyl Respules	AP
• Adrenergics and other drugs for obstructive airway diseases								
BUDESONIDE with EFORMOTEROL FUMARATE DIHYDRATE								
<u>Restricted benefit</u>								
<i>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.</i>								
8796Y	Powder for oral inhalation in breath actuated device 100 micrograms- 6 micrograms per dose (120 doses)	1	5	..	53.06	30.70	Symbicort Turbuhaler 100/6	AP
8625Y	Powder for oral inhalation in breath actuated device 200 micrograms- 6 micrograms per dose (120 doses)	1	5	..	57.50	30.70	Symbicort Turbuhaler 200/6	AP
8750M	Powder for oral inhalation in breath actuated devices 400 micrograms- 12 micrograms per dose (60 doses), 2	1	5	..	85.62	30.70	Symbicort Turbuhaler 400/12	AP
FLUTICASONE PROPIONATE with SALMETEROL XINAFOATE								
<u>Restricted benefit</u>								
<i>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.</i>								
8517G	Oral pressurised inhalation 50 micrograms- 25 micrograms (base) per dose (120 doses), CFC-free formulation	1	5	..	45.06	30.70	Seretide MDI 50/25	GK

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	
FLUTICASONE PROPIONATE with SALMETEROL XINAFOATE—cont.								
8518H	Oral pressurised inhalation 125 micrograms- 25 micrograms (base) per dose (120 doses), CFC-free formulation	₹1	5	..	58.04	30.70	Seretide MDI 125/25	GK
8519J	Oral pressurised inhalation 250 micrograms- 25 micrograms (base) per dose (120 doses), CFC-free formulation	₹1	5	..	77.53	30.70	Seretide MDI 250/25	GK
8430Q	Powder for oral inhalation in breath actuated device 100 micrograms- 50 micrograms (base) per dose (60 doses)	₹1	5	..	45.06	30.70	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	..	58.04	30.70	Seretide Accuhaler 250/50	GK
8432T	Powder for oral inhalation in breath actuated device 500 micrograms- 50 micrograms (base) per dose (60 doses)	₹1	5	..	77.53	30.70	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	..	17.46	18.45	Qvar 50	MM
8407L	Oral pressurised inhalation 100 micrograms per dose (200 doses), CFC-free formulation	₹1	5	..	31.01	30.70	Qvar 100	MM
BECLOMETHASONE DIPROPIONATE								
Restricted benefit								
<i>Patients unable to achieve co-ordinated use of other metered dose inhalers containing this drug.</i>								
8408M	Oral pressurised inhalation in breath actuated device 50 micrograms per dose (200 doses), CFC-free formulation	₹1	5	..	25.67	26.66	Qvar 50 Autohaler	MM
8409N	Oral pressurised inhalation in breath actuated device 100 micrograms per dose (200 doses), CFC-free formulation	₹1	5	..	36.43	30.70	Qvar 100 Autohaler	MM

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	
BUDESONIDE								
2070Y	Powder for oral inhalation in breath actuated device 100 micrograms per dose (200 doses)	‡1	5	..	21.33	22.32	Pulmicort Turbuhaler	AP
2071B	Powder for oral inhalation in breath actuated device 200 micrograms per dose (200 doses)	‡1	5	..	28.73	29.72	Pulmicort Turbuhaler	AP
2072C	Powder for oral inhalation in breath actuated device 400 micrograms per dose (200 doses)	‡1	5	..	43.56	30.70	Pulmicort Turbuhaler	AP
BUDESONIDE								
<u>Authority required</u>								
<i>Severe chronic asthma in patients who require long-term steroid therapy and who are unable to use other forms of inhaled steroid therapy.</i>								
2065Q	<i>Nebuliser suspension single dose units 500 micrograms in 2 mL, 30</i>	‡1	5	..	35.22	30.70	<i>Pulmicort Respules</i>	AP
2066R	<i>Nebuliser suspension single dose units 1 mg in 2 mL, 30</i>	‡1	5	..	47.04	30.70	<i>Pulmicort Respules</i>	AP
CICLESONIDE								
8853Y	Oral pressurised inhalation 80 micrograms per dose (120 doses), CFC-free formulation	‡1	5	..	23.71	24.70	Alvesco 80	AH
8854B	Oral pressurised inhalation 160 micrograms per dose (120 doses), CFC-free formulation	‡1	5	..	39.29	30.70	Alvesco 160	AH
FLUTICASONE PROPIONATE								
8516F	Oral pressurised inhalation 50 micrograms per dose (120 doses), CFC-free formulation	‡1	5	..	15.36	16.35	Flixotide Junior	GK
8345F	Oral pressurised inhalation 125 micrograms per dose (120 doses), CFC-free formulation	‡1	5	..	28.34	29.33	Flixotide	GK
8346G	Oral pressurised inhalation 250 micrograms per dose (120 doses), CFC-free formulation	‡1	1	..	47.83	30.70	Flixotide	GK
8147T	Powder for oral inhalation in breath actuated device 100 micrograms per dose (60 doses)	‡1	5	..	15.36	16.35	Flixotide Junior Accuhaler	GK

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	
FLUTICASONE PROPIONATE—cont.								
8148W	Powder for oral inhalation in breath actuated device 250 micrograms per dose (60 doses)	‡1	5	..	28.34	29.33	Flixotide Accuhaler	GK
8149X	Powder for oral inhalation in breath actuated device 500 micrograms per dose (60 doses)	‡1	1	..	47.83	30.70	Flixotide Accuhaler	GK
• Anticholinergics								
IPRATROPIUM BROMIDE								
8671J	Oral pressurised inhalation 21 micrograms per dose (200 doses), CFC-free formulation	2	5	..	*39.89	30.70	Atrovent	BY
IPRATROPIUM BROMIDE								
<u>Restricted benefit</u>								
<i>Asthma in patients unable to use this drug delivered from an oral pressurised inhalation device via a spacer;</i>								
<i>Chronic obstructive pulmonary disease in patients unable to use this drug delivered from an oral pressurised inhalation device via a spacer.</i>								
1542E	Nebuliser solution single dose units 250 micrograms (anhydrous) in 1 mL, 30	2	5	..	*44.51	30.70	^a Aeron 250 ^a Apoven 250 ^a Chem mart Ipratropium ^a GenRx Ipratropium ^a Ipratrin ^a Ipravent ^a Terry White Chemists Ipratropium Atrovent	AW GM CH GX AF PU TW BY
8238N	Nebuliser solution single dose units 500 micrograms (anhydrous) in 1 mL, 30	2	5	..	^B 0.92 *51.69	30.70	^a Aeron 500 ^a Apoven 500 ^a Chem mart Ipratropium ^a GenRx Ipratropium ^a Ipratrin Adult ^a Ipravent ^a Terry White Chemists Ipratropium Atrovent Adult	AW GM CH GX AF PU TW BY
1541D	Nebuliser solution 250 micrograms (anhydrous) per mL (0.025%), 20 mL	2	2	..	^B 0.90 *16.87	17.86	Atrovent	BY

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	
TIOTROPIUM BROMIDE MONOHYDRATE								
<u>Restricted benefit</u>								
<i>For the long-term maintenance treatment of bronchospasm and dyspnoea associated with chronic obstructive pulmonary disease.</i>								
8626B	<i>Capsule containing powder for oral inhalation 18 micrograms (base) (for use in HandiHaler)</i>	30	5	..	75.62	30.70	<i>Spiriva</i>	<i>BY</i>
• Antiallergic agents, excl. corticosteroids								
NEDOCROMIL SODIUM								
8365G	Oral pressurised inhalation 2 mg per dose (112 doses), CFC-free formulation	‡1	5	..	33.17	30.70	Tilade CFC-Free	AV
SODIUM CROMOGLYCAT								
2878L	Capsule containing powder for oral inhalation 20 mg (for use in Intal Spinhaler or Intal Halermatic)	100	5	..	31.06	30.70	Intal Spincaps	GM
1124E	Solution for inhalation 20 mg in 2 mL ampoule	120	3	..	*58.83	30.70	Intal	AV
2872E	Oral pressurised inhalation 1 mg per dose (200 doses)	‡1	5	..	27.76	28.75	Intal	AV
8767K	Oral pressurised inhalation 1 mg per dose (200 doses), CFC-free formulation	‡1	5	..	27.76	28.75	Intal CFC-Free	AV
8334P	Oral pressurised inhalation 5 mg per dose (112 doses), CFC-free formulation	‡1	5	..	33.17	30.70	Intal Forte CFC-Free	AV
• Adrenergics for systemic use								
• Alpha- and beta-adrenoceptor agonists								
ADRENALINE								
1016L	Injection 1 mg in 1 mL (1 in 1,000)	5	1	..	18.46	19.45	AP	

continued 

Code	Name, Restriction, Manner of administration and form	Max. No. of Qty Rpts Premium	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Proprietary Name and Manufacturer	
ADRENALINE—cont.						
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	93.85	30.70	EpiPen Jr.	CS
8698T	I.M. injection 300 micrograms in 0.3 mL single dose syringe auto-injector	1	93.85	30.70	EpiPen	CS
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 ..	*12.69	13.68	Ventolin	GK
TERBUTALINE SULFATE						
1034K	Injection 500 micrograms in 1 mL	5	28.27	29.26	Bricanyl	AP
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 ..	10.64	11.63	Nuelin-SR 200	MM
2634P	Tablet 250 mg (sustained release)	100 5 ..	11.75	12.74	Nuelin-SR 250	MM
8231F	Tablet 300 mg (sustained release)	100 5 ..	13.07	14.06	Nuelin-SR 300	MM

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	
2614N	THEOPHYLLINE—cont. Syrup 133.3 mg per 25 mL, 500 mL	‡1	5	..	9.36	10.35	Nuelin	MM
• Leukotriene receptor antagonists								
MONTELUKAST SODIUM								
NOTE:								
<i>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.</i>								
NOTE:								
<i>No applications for increased maximum quantities and/or repeats will be authorised.</i>								
Authority required								
<i>First-line preventer medication, as the single preventer agent for children aged 2 to 5 years with frequent episodic or mild persistent asthma, as an alternative to sodium cromoglycate or nedocromil sodium.</i>								
8627C	Chewable tablet 4 mg (base)	28	5	..	45.86	30.70	Singulair	MK
Authority required								
<i>First-line preventer medication, as the single preventer agent for children aged 6 to 14 years with frequent episodic or mild persistent asthma, as an alternative to sodium cromoglycate or nedocromil sodium.</i>								
8628D	Chewable tablet 5 mg (base)	28	5	..	45.86	30.70	Singulair	MK
COUGH AND COLD PREPARATIONS								
Expectorants, excl. combinations with cough suppressants								
• Mucolytics								
ACETYLCYSTEINE								
Restricted benefit								
<i>Bronchiectasis;</i>								
<i>Cystic fibrosis.</i>								
8747J	Sterile inhalation solution 200 mg per mL (20%), 5 mL	30	3	..	*145.70	30.70	Mucomyst	BQ
Cough suppressants, excl. combinations with expectorants								
• Opium alkaloids and derivatives								
CODEINE PHOSPHATE								
1214X	Tablet 30 mg	20	..	..	10.92	11.91	FM	
ANTI-HISTAMINES FOR SYSTEMIC USE								
Antihistamines for systemic use								
• Phenothiazine derivatives								
PROMETHAZINE								
HYDROCHLORIDE								
1948M	Injection 50 mg in 2 mL	10	..	..	*18.27	19.26	MX	

SENSORY ORGANS

Code	Name, Restriction, Manner of 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								
<u>Restricted benefit</u>								
<i>Trachoma.</i>								
<u>NOTE:</u>								
<i>No applications for increased maximum quantities and/or repeats will be authorised.</i>								
8336R	Tablet 500 mg	2	2	..	21.86	22.85	Zithromax	PF
8201P	Powder for oral suspension 200 mg per 5 mL, 15 mL	‡1	..	..	#21.43	22.81	Zithromax	PF
CHLORAMPHENICOL								
2360F	Eye drops 5 mg per mL (0.5%), 10 mL	‡1	2	..	7.91	8.90	Chloromycetin Chlorsig	PF SI
1171P	Eye ointment 10 mg per g (1%), 4 g	‡1	..	..	8.34	9.33	Chloromycetin Chlorsig	PF SI
GENTAMICIN SULFATE								
<u>Restricted benefit</u>								
<i>Invasive ocular infection;</i>								
<i>Perioperative use in ophthalmic surgery;</i>								
<i>Suspected pseudomonal eye infection.</i>								
1441W	Eye drops 3 mg (base) per mL (0.3%), 5 mL	‡1	2	..	17.13	18.12	Genoptic	AG
TOBRAMYCIN								
<u>Restricted benefit</u>								
<i>Invasive ocular infection;</i>								
<i>Perioperative use in ophthalmic surgery;</i>								
<i>Suspected pseudomonal eye infection.</i>								
2328M	Eye drops 3 mg per mL (0.3%), 5 mL	‡1	2	..	17.13	18.12	Tobrex	AQ
2329N	Eye ointment 3 mg per g (0.3%), 3.5 g	‡1	..	..	19.71	20.70	Tobrex	AQ
• Sulfonamides								
SULFACETAMIDE SODIUM								
2063N	Eye drops 100 mg per mL (10%), 15 mL	‡1	2	..	11.39	12.38	Bleph 10	AG
• Antivirals								
ACICLOVIR								
<u>Restricted benefit</u>								
<i>Herpes simplex keratitis.</i>								
1002R	Eye ointment 30 mg per g (3%), 4.5 g	‡1	..	..	22.82	23.81	Zovirax	GK

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	
• Other antiinfectives CIPROFLOXACIN <u>Authority required</u> <i>Bacterial keratitis.</i>								
1217C	Eye drops 3 mg per mL (0.3%), 5 mL	2	..	.. B2.42	*29.11 *31.53	30.10 ^a 30.10 ^a	CiloQuin Ciloxan	IQ AQ
OFLOXACIN <u>Authority required</u> <i>Bacterial keratitis.</i>								
8383F	Eye drops 3 mg per mL (0.3%), 5 mL	2	..	..	*29.11	30.10	Ocuflox	AG
Antiinflammatory agents • Corticosteroids, plain								
1288T	DEXAMETHASONE Eye drops 1 mg per mL (0.1%), 5 mL	‡1	2	..	8.82	9.81	Maxidex	AQ
1204J	FLUOROMETHOLONE Eye drops 1 mg per mL (0.1%), 5 mL	‡1	5	..	8.82	9.81	Flucon FML Liquifilm	AQ AG
1438Q	FLUOROMETHOLONE ACETATE Eye drops 1 mg per mL (0.1%), 5 mL	‡1	2	..	8.82	9.81	Flarex	AQ
1497T	HYDROCORTISONE ACETATE Eye ointment 5 mg per g (0.5%), 5 g	‡1	..	..	10.38	11.37	Hycor	SI
2441L	Eye ointment 10 mg per g (1%), 5 g	‡1	..	..	10.56	11.55	Hycor	SI
• Corticosteroids and mydriatics in combination PREDNISOLONE ACETATE with PHENYLEPHRINE HYDROCHLORIDE <u>Restricted benefit</u> <i>Corneal grafts;</i> <i>Uveitis.</i>								
3112T	Eye drops 10 mg-1.2 mg per mL (1%-0.12%), 10 mL	‡1	2	..	20.68	21.67	Prednefrin Forte	AG
• Antiinflammatory agents, non-steroids								
8699W	FLURBIPROFEN SODIUM Eye drops 300 micrograms per mL (0.03%), single dose units 0.4 mL, 5	1	..	..	12.72	13.71	Ocufen	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	
Antiglaucoma preparations and miotics								
• Sympathomimetics in glaucoma therapy								
APRACLOPIDINE HYDROCHLORIDE								
Restricted benefit								
<i>Short-term reduction of intra-ocular pressure in patients already on maximally tolerated anti-glaucoma therapy.</i>								
8083K	Eye drops 5 mg (base) per mL (0.5%), 10 mL	‡1	2	..	36.57	30.70	Iopidine 0.5%	AQ
BRIMONIDINE TARTRATE								
8351M	Eye drops 2 mg per mL (0.2%), 5 mL	‡1	5	.. B1.70	19.37 21.07	20.36 20.36	^a Enidin ^a Alphagan	PE AG
BRIMONIDINE TARTRATE with TIMOLOL MALEATE								
Restricted benefit								
<i>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.</i>								
8826M	Eye drops 2 mg-5 mg (base) per mL (0.2%-0.5%), 5 mL	‡1	5	..	27.29	28.28	Combigan	AG
DIPIVEFRINE HYDROCHLORIDE								
1351D	Eye drops 1 mg per mL (0.1%), 10 mL	‡1	5	..	21.05	22.04	Propine	AG
• Parasympathomimetics								
PILOCARPINE HYDROCHLORIDE								
2778F	Eye drops 5 mg per mL (0.5%), 15 mL	‡1	5	..	10.66	11.65	^a Piloft ^a P.V. Carpine	PE AG
2595N	Eye drops 10 mg per mL (1%), 15 mL	‡1	5	..	10.66	11.65	Isopto Carpine	AQ
				B2.53	13.19	11.65	^a Piloft ^a P.V. Carpine	PE AG
2596P	Eye drops 20 mg per mL (2%), 15 mL	‡1	5	..	11.78	12.77	Isopto Carpine	AQ
				B2.51	14.29	12.77	^a Piloft ^a P.V. Carpine	PE AG
2598R	Eye drops 40 mg per mL (4%), 15 mL	‡1	5	..	14.36	15.35	Isopto Carpine	AQ
				B2.49	16.85	15.35	^a Piloft ^a P.V. Carpine	PE AG
2779G	Eye drops 60 mg per mL (6%), 15 mL	‡1	5	..	18.41	19.40	^a Piloft	PE
				B2.43	20.84	19.40	^a P.V. Carpine	AG
• Carbonic anhydrase inhibitors								
ACETAZOLAMIDE								
1004W	Tablet 250 mg	100	3	..	21.76	22.75	Diamox	SI
BRINZOLAMIDE								
8483L	Eye drops 10 mg per mL (1%), 5 mL	‡1	5	.. B0.98	19.37 20.35	20.36 20.36	^a BrinzoQuin ^a Azopt	IQ 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	
8488R	DORZOLAMIDE HYDROCHLORIDE Eye drops 20 mg (base) per mL (2%), 5 mL	‡1	5	..	19.37	20.36	Trusopt	MK
8567X	DORZOLAMIDE HYDROCHLORIDE with TIMOLOL MALEATE Restricted benefit <i>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.</i> Eye drops 20 mg (base)-5 mg (base) per mL (2%-0.5%), 5 mL	‡1	5	..	27.29	28.28	Cosopt	MK
	• Beta blocking agents							
2811Y	BETAXOLOL HYDROCHLORIDE Eye drops, suspension, 2.5 mg (base) per mL (0.25%), 5 mL	‡1	5	..	13.06	14.05	Betoptic S	AQ
2825Q	Eye drops, solution, 5 mg (base) per mL (0.5%), 5 mL	‡1	5	.. B1.95	13.06 15.01	14.05 14.05	^a BetoQuin ^a Betoptic	IQ AQ
1819R	LEVOBUNOLOL HYDROCHLORIDE Eye drops 2.5 mg per mL (0.25%), 5 mL	‡1	5	..	12.01	13.00	Betagan	AG
8803H	TIMOLOL MALEATE Eye gel 1 mg (base) per g (0.1%), 5 g	‡1	5	..	12.01	13.00	Nyogel	NV
1278G	Eye drops 2.5 mg (base) per mL (0.25%), 5 mL	‡1	5	.. B1.05	12.01 13.06	13.00 13.00	^a Tenopt ^a Timoptol	SI FR
1279H	Eye drops 5 mg (base) per mL (0.5%), 5 mL	‡1	5	.. B1.10	13.06 14.16	14.05 14.05	^a Tenopt ^a Timoptol	SI FR
1925H	Eye drops (gellan gum solution) 2.5 mg (base) per mL (0.25%), 2.5 mL	‡1	5	..	12.01	13.00	Timoptol XE	MK
1926J	Eye drops (gellan gum solution) 5 mg (base) per mL (0.5%), 2.5 mL	‡1	5	..	13.06	14.05	Timoptol XE	MK
	• Prostaglandin analogues							
8620Q	BIMATOPROST Eye drops 300 micrograms per mL (0.03%), 3 mL	‡1	5	..	36.36	30.70	Lumigan	AG
8243W	LATANOPROST Eye drops 50 micrograms per mL (0.005%), 2.5 mL	‡1	5	..	36.36	30.70	Xalatan	PU

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	
LATANOPROST with TIMOLOL MALEATE								
<u>Restricted benefit</u>								
<i>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;</i>								
<i>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.</i>								
8895E	Eye drops 50 micrograms-5 mg (base) per mL (0.005%-0.5%), 2.5 mL	₡1	5	..	43.21	30.70	Xalacom	PF
8597L	TRAVOPROST Eye drops 40 micrograms per mL (0.004%), 2.5 mL	₡1	5	..	36.36	30.70	Travatan	AQ
TRAVOPROST with TIMOLOL MALEATE								
<u>Restricted benefit</u>								
<i>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 travoprost eye drops;</i>								
<i>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 travoprost eye drops.</i>								
9057Q	Eye drops 40 micrograms-5 mg (base) per mL (0.004%-0.5%), 2.5 mL	₡1	5	..	43.21	30.70	Duotrav	AQ
Mydriatics and cycloplegics								
• Anticholinergics								
1093M	ATROPINE SULFATE Eye drops 10 mg per mL (1%), 15 mL	₡1	2	..	9.74	10.73	Atropt	SI
2541R	HOMATROPINE HYDROBROMIDE Eye drops 20 mg per mL (2%), 15 mL	₡1	2	..	15.96	16.95	Isopto Homatropine	AQ
Decongestants and antiallergics								
• Other antiallergics								
SODIUM CROMOGLYCATE								
<u>Restricted benefit</u>								
<i>Vernal kerato-conjunctivitis.</i>								
1127H	Eye drops 20 mg per mL (2%), 10 mL	₡1	5	..	13.22	14.21 ^a	Cromolux ^a Opticrom	AE AV

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	
Other ophthalmologicals								
• Other ophthalmologicals								
CARBOMER 974								
<u>Authority required</u>								
<i>Severe dry eye syndrome in patients who are sensitive to preservatives in multi-dose eye drops.</i>								
8514D	Ocular lubricating gel 3 mg per g (0.3%), single dose units 0.5 g, 30	3	5	..	*33.50	30.70	Poly Gel	AQ
CARBOMER 980								
<u>Restricted benefit</u>								
<i>Severe dry eye syndrome, including Sjogren's syndrome.</i>								
8384G	Ocular lubricating gel 2 mg per g (0.2%), 10 g	‡1	5	..	9.14	10.13	GelTears	BU
							^a PAA	NM
				^B 0.98	10.12	10.13	^a Viscotears Liquid Gel	NV
<u>Authority required</u>								
<i>Severe dry eye syndrome in patients who are sensitive to preservatives in multi-dose eye drops.</i>								
8578L	Eye drops 2 mg per g (0.2%), single dose units 0.6 mL, 30	3	5	..	*33.50	30.70	Viscotears	NV
CARMELLOSE SODIUM								
<u>Restricted benefit</u>								
<i>Severe dry eye syndrome, including Sjogren's syndrome.</i>								
8548X	Eye drops 5 mg per mL (0.5%), 15 mL	‡1	5	..	9.14	10.13	Refresh Tears Plus	AG
8593G	Eye drops 10 mg per mL (1%), 15 mL	‡1	5	..	9.14	10.13	Refresh Liquigel	AG
<u>Authority required</u>								
<i>Severe dry eye syndrome in patients who are sensitive to preservatives in multi-dose eye drops.</i>								
8823J	Eye drops 2.5 mg per mL (0.25%), single dose units 0.6 mL, 24	4	5	..	*35.39	30.70	TheraTears	CX
2338C	Eye drops 5 mg per mL (0.5%), single dose units 0.4 mL, 30	3	5	..	*33.50	30.70	Cellufresh	AG
2324H	Eye drops 10 mg per mL (1%), single dose units 0.4 mL, 30	3	5	..	*33.50	30.70	Celluvisc	AG
8824K	Ocular lubricating gel 10 mg per mL (1%), single dose units 0.6 mL, 28	3	5	..	*31.61	30.70	TheraTears	CX

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	
<u>HYPROMELLOSE</u>								
<u>Restricted benefit</u>								
<i>Severe dry eye syndrome, including Sjogren's syndrome.</i>								
8287E	Eye drops 3 mg per mL (0.3%), 15 mL (contains sodium perborate as preservative)	‡1	5	..	9.14	10.13	^a In a Wink Moisturising	NM
				^B 1.82	10.96	10.13	^a Genteal	NV
2956N	Eye drops 5 mg per mL (0.5%), 15 mL	‡1	5	..	9.14	10.13	Isopto Tears Methopt	AQ SI
<u>HYPROMELLOSE with CARBOMER 980</u>								
<u>Restricted benefit</u>								
<i>Severe dry eye syndrome, including Sjogren's syndrome.</i>								
8564R	Ocular lubricating gel 3 mg- 2 mg per g (0.3%-0.2%), 10 g	‡1	5	..	9.14	10.13	^a HPMC PAA	NM
				^B 1.82	10.96	10.13	^a Genteal gel	NV
<u>HYPROMELLOSE with DEXTRAN</u>								
<u>Restricted benefit</u>								
<i>Severe dry eye syndrome, including Sjogren's syndrome.</i>								
1509K	Eye drops 3 mg-1 mg per mL (0.3%-0.1%), 15 mL	‡1	5	..	9.14	10.13	^a Poly-Tears	IQ
				^B 1.63	10.77	10.13	^a Tears Naturale	AQ
<u>Authority required</u>								
<i>Severe dry eye syndrome in patients who are sensitive to preservatives in multi-dose eye drops.</i>								
8299T	Eye drops 3 mg-1 mg per mL (0.3%-0.1%), single dose units 0.4 mL, 28	3	5	..	*31.61	30.70	Bion Tears	AQ
<u>PARAFFIN</u>								
1754H	Compound eye ointment 3.5 g	2	5	..	*19.09	20.08	^a Poly Visc	IQ
				^B 1.92	*21.01	20.08	^a Duratears	AQ
1750D	Pack containing 2 tubes compound eye ointment 3.5 g	‡1	5	..	19.09	20.08	^a Ircal	PE
				^B 2.08	21.17	20.08	^a Poly Visc Lacri-Lube	IQ AG
<u>POLYETHYLENE GLYCOL 400 with PROPYLENE GLYCOL</u>								
<u>Restricted benefit</u>								
<i>Severe dry eye syndrome, including Sjogren's syndrome.</i>								
8676P	Eye drops 4 mg-3 mg per mL (0.4%-0.3%), 15 mL	‡1	5	..	9.14	10.13	Systane	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	
POLYVINYL ALCOHOL								
<u>Restricted benefit</u>								
<i>Severe dry eye syndrome, including Sjogren's syndrome.</i>								
2682E	Eye drops 14 mg per mL (1.4%), 15 mL	‡1	5	.. ^B 1.66	9.14 10.80	10.13 ^a 10.13 ^a	PVA Tears Liquifilm Tears	PE AG
8831T	Eye drops 14 mg per mL (1.4%), 15 mL (contains sodium chlorite/hydrogen peroxide as preservative)	‡1	5	..	9.14	10.13	Vistil	AE
2681D	Eye drops 30 mg per mL (3%), 15 mL	‡1	5	.. ^B 5.80	9.14 14.94	10.13 ^a 10.13 ^a	PVA Forte Liquifilm Forte	PE AG
8832W	Eye drops 30 mg per mL (3%), 15 mL (contains sodium chlorite/hydrogen peroxide as preservative)	‡1	5	..	9.14	10.13	Vistil Forte	AE
OTOLOGICALS								
Antiinfectives								
• Antiinfectives								
CHLORAMPHENICOL								
1172Q	Ear drops (aqueous) 5 mg per mL (0.5%), 5 mL	‡1	2	..	9.58	10.57	Chloromycetin	PF
CIPROFLOXACIN								
<u>Authority required</u>								
<i>Treatment of chronic suppurative otitis media in an Aboriginal or a Torres Strait Islander person aged 1 year and older.</i>								
2480M	Ear drops 3 mg per mL (0.3%), 5 mL	‡1	1	..	17.13	18.12	Ciloxan	AQ
NEOMYCIN UNDECENOATE with BACITRACIN ZINC								
2296W	Ear ointment 12 mg (3.5 mg base)-400 units per g, 10 g	‡1	..	..	7.28	8.27	Nemdyn	HA
Corticosteroids and antiinfectives in combination								
• Corticosteroids and antiinfectives in combination								
DEXAMETHASONE with FRAMYCETIN SULFATE and GRAMICIDIN								
2781J	Ear drops 500 micrograms-5 mg- 50 micrograms per mL, 8 mL	‡1	2	.. ^B 1.71	7.44 9.15	8.43 ^a 8.43 ^a	Otodex Sofradex	QM AV
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	.. ^B 1.05	7.44 8.49	8.43 ^a 8.43 ^a	Otocomb Otic Kenacomb Otic	BC 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	.. ^B 1.05	6.97 8.02	7.96 ^a 7.96 ^a	Otocomb Otic Kenacomb Otic	BC BQ

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	
OPHTHALMOLOGICAL AND OTOLOGICAL PREPARATIONS								
	Antiinfectives							
	• Antiinfectives							
	FRAMYCETIN SULFATE							
1440T	Eye and ear drops 5 mg per mL (0.5%), 8 mL	‡1	2	..	7.94	8.93	Soframycin	AV

VARIOUS

Code	Name, Restriction, Manner of 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	..	..	203.87	30.70	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	..	..	203.87	30.70	Albey Paper Wasp Venom	ES
INSECT ALLERGEN EXTRACT— YELLOW JACKET VENOM								
2883R	Injection set containing 550 micrograms	1	..	..	203.87	30.70	Albey Yellow Jacket Venom	ES
ALL OTHER THERAPEUTIC PRODUCTS								
All other therapeutic products								
• Antidotes								
NALOXONE HYDROCHLORIDE								
1752F	Injection 800 micrograms in 2 mL	1	..	..	22.95	23.94	Naloxone Min-I-Jet	CS
1753G	Injection 2 mg in 5 mL	1	..	..	33.61	30.70	Naloxone Min-I-Jet	CS
• Detoxifying agents for antineoplastic treatment								
CALCIUM FOLINATE								
8740B	Injection equivalent to 50 mg folinic acid in 5 mL	5	5	..	*156.55	30.70	^a Leucovorin Calcium	MX
							^a Leucovorin Calcium	PF
				..	156.55	30.70	^a Calcium Folate Ebewe	IT
8812T	Injection equivalent to 100 mg folinic acid in 10 mL	10	1	..	*277.25	30.70	^a Calcium Folate Ebewe	IT
				..	277.25	30.70	^a Leucovorin Calcium	PF
9041W	Injection equivalent to 300 mg folinic acid in 30 mL	4	1	..	*320.35	30.70	Leucovorin Calcium	MX
CALCIUM FOLINATE								
Restricted benefit								
Antidote to folic acid antagonists.								
2308L	Tablet equivalent to 15 mg folinic acid	10	..	..	95.72	30.70	Leucovorin Calcium	MX

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	
MESNA								
<u>Restricted benefit</u>								
<i>Adjunctive therapy for use with ifosfamide or high dose cyclophosphamide.</i>								
8078E	Solution for I.V. injection 400 mg in 4 mL	15	5	..	71.54	30.70	Uromitexan	BX
8079F	Solution for I.V. injection 1 g in 10 mL	15	5	..	156.90	30.70	Uromitexan	BX
• Drugs for treatment of hypercalcemia								
SODIUM ACID PHOSPHATE								
<u>Authority required</u>								
<i>Familial hypophosphataemia; Hypercalcaemia; Hypophosphataemic rickets; Vitamin D-resistant rickets.</i>								
2946C	Compound effervescent tablet containing elemental phosphorus 500 mg, sodium 469 mg (20.4 mmol), potassium 123 mg (3.1 mmol)	100	5	..	80.36	30.70	Phosphate Sandoz	NV
DIAGNOSTIC AGENTS								
Urine tests								
• Urine tests								
COPPER SULFATE								
1228P	Diagnostic compound tablets, 36	2	3	..	*70.21	30.70	Clinitest	BN
GLUCOSE INDICATOR—URINE								
2352T	Reagent strips, 50	2	2	..	*17.97	18.96	Clinistix	BN
3104J	Reagent strips, 50	2	2	..	*17.03	18.02	Diastix	BN
GLUCOSE and KETONE INDICATOR—URINE								
3106L	Reagent strips, 50	2	2	..	*15.55	16.54	Keto-Diabur- Test 5000	RD
3107M	Reagent strips, 50	2	2	..	*15.67	16.66	Keto-Diastix	BN
Other diagnostic agents								
• Tests for diabetes								
GLUCOSE INDICATOR—BLOOD								
2891E	Electrode strips, 50	2	5	..	*51.63	30.70	Advantage II	RD
8890X	Electrode strips, 50	2	5	..	*51.63	30.70	Freestyle Papillon	MS
9013J	Electrode strips, 50	2	5	..	*51.63	30.70	Glucocard 01 Sensor	DR
8749L	Electrode strips, 50	2	5	..	*51.63	30.70	GlucoCare	DR
8766J	Electrode strips, 50	2	5	..	*51.63	30.70	GlucoCare Super Sensor	DR

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	
GLUCOSE INDICATOR—BLOOD—cont.								
8557J	Electrode strips, 50	2	5	..	*51.63	30.70	GlucoMen Sensor	GD
8682Y	Electrode strips, 50	2	5	..	*51.63	30.70	MWD Pen Sensor Strips	WF
8723D	Electrode strips, 50	2	5	..	*51.63	30.70	Omnitest EZ	BR
9063B	Electrode strips, 50	2	5	..	*51.63	30.70	Omnitest Plus	BR
9046D	Electrode strips, 50	2	5	..	*51.63	30.70	Touch-In Plus	DN
8825L	Electrode strips, 50	2	5	..	*51.63	30.70	TrueTrack	DR
8176H	Discs containing electrode sensors, 10 sensors per disc, 5	2	5	..	*51.63	30.70	Ascensia Glucodisc	BN
8522M	Electrode strips, 100	‡1	5	..	51.61	30.70	Optium glucose	MS
8573F	Electrode strips, 100	‡1	5	..	51.61	30.70	SofTact	MS
8608C	Electrode strips, 100	‡1	5	..	51.61	30.70	TrueSense	MS
8190C	Reagent strips, 50	2	5	..	*51.63	30.70	Accu-Chek Active	RD
8739Y	Reagent strips, 50	2	5	..	*51.63	30.70	Accu-Chek Go	RD
8806L	Reagent strips, 51	2	5	..	*51.63	30.70	Accu-Chek Integra	RD
2890D	Reagent strips, 50	2	5	..	*51.63	30.70	Betachek	NA
8759B	Reagent strips, 50	2	5	..	*51.63	30.70	CareSens	LB
2914J	Reagent strips, 50	2	5	..	*43.63	30.70	Glucoflex-R	NA
2917M	Reagent strips, 50	2	5	..	*43.63	30.70	Glucostix	BN
8795X	Reagent strips, 50	2	5	..	*51.63	30.70	SensoCard	PX

GLUCOSE INDICATOR—BLOOD**Authority required***Patients who have previously received this product as a pharmaceutical benefit;**Patients who have purchased a meter to be used with this product prior to 1 August 2003.*

8634K	Electrode strips, 50	2	5	..	*59.03	30.70	Ascensia Elite	BN
2926B	Electrode strips, 100	‡1	5	..	53.26	30.70	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							
	TRIGLYCERIDES, MEDIUM CHAIN							
	NOTE:							
	<i>No applications for increased maximum quantities and/or repeats will be authorised.</i>							
	Authority required							
	<i>Chylous ascites;</i>							
	<i>Chylothorax;</i>							
	<i>Fat malabsorption due to liver disease, short gut syndrome, cystic fibrosis and gastrointestinal disorders;</i>							
	<i>Hyperlipoproteinaemia type 1;</i>							
	<i>Intractable childhood epilepsy or cerebrospinal fluid glucose transporter defect, requiring a ketogenic diet;</i>							
	<i>Long chain fatty acid oxidation disorders.</i>							
3128P	Oil 500 mL	2	5	..	*52.27	30.70	MCT Oil	SB
	• Fat/carbohydrates/proteins/minerals/vitamins, combinations							
	AMINO ACIDS—SYNTHETIC, FORMULA							
	Authority required							
	<i>Initial treatment, for up to 3 months, for combined intolerance (not infant colic) to cows' milk protein, soy protein and protein hydrolysate formulae in children 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.</i>							
	NOTE:							
	<i>No applications for increased maximum quantities and/or repeats will be authorised.</i>							
8574G	Compound powder 400 g	8	5	..	*359.87	30.70	EleCare	AB
8443J	Compound powder 400 g	8	5	..	*371.15	30.70	Neocate	SB
8754R	Compound powder 400 g	8	5	..	*371.15	30.70	Neocate Advance	SB

VARIOUS—cont.

Code	Name, Restriction, Manner of administration and form	Max. No.of			Dispensed	Maximum	Proprietary Name and Manufacturer
		Qty	Rpts	Premium	Price for Max.Qty \$	Recordable Value for Safety Net \$	
AMINO ACIDS—SYNTHETIC, FORMULA—cont.							
<u>Authority required</u>							
<i>Continuing treatment for combined intolerance (not infant colic) to cows' milk protein, soy protein and protein hydrolysate formulae in children 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;</i>							
<i>Treatment for combined intolerance (not infant colic) to cows' milk protein, soy protein and protein hydrolysate formulae in children 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;</i>							
<i>Severe intestinal malabsorption including short bowel syndrome where protein hydrolysate formulae have failed;</i>							
<i>Severe intestinal malabsorption including short bowel syndrome where the patient has been receiving parenteral nutrition.</i>							
<u>NOTE:</u>							
<i>Authorities for increased maximum quantities, up to a maximum of 20, may be authorised.</i>							
8575H	Compound powder 400 g	8	5	..	*359.87	30.70	EleCare AB
3066J	Compound powder 400 g	8	5	..	*371.15	30.70	Neocate SB
8755T	Compound powder 400 g	8	5	..	*371.15	30.70	Neocate SB
Advance							

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 children 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 children 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 children 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;

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 infants under the age of 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	..	*96.99	30.70	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	
PROTEIN HYDROLYSATE FORMULA with MEDIUM CHAIN TRIGLYCERIDES—								
cont.								
<u>Authority required</u>								
<i>Initial treatment, for up to 3 months, for intolerance (not infant colic) to both cows' milk protein and soy protein in children 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;</i>								
<i>Continuing treatment for intolerance (not infant colic) to both cows' milk protein and soy protein in children 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;</i>								
<i>Continuing treatment for intolerance (not infant colic) to both cows' milk protein and soy protein in children 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;</i>								
<i>Biliary atresia;</i>								
<i>Chronic liver failure with fat malabsorption;</i>								
<i>Chylous ascites;</i>								
<i>Cystic fibrosis;</i>								
<i>Enterokinase deficiency;</i>								
<i>Proven fat malabsorption;</i>								
<i>Severe diarrhoea of greater than 2 weeks' duration in infants under the age of 4 months. The date of birth of the patient must be included in the authority application;</i>								
<i>Severe intestinal malabsorption including short bowel syndrome.</i>								
8259Q	Compound powder 450 g	8	5	..	*108.59	30.70	Pepti-Junior	NU
TRIGLYCERIDES—MEDIUM CHAIN, FORMULA								
<u>NOTE:</u>								
<i>No applications for increased maximum quantities and/or repeats will be authorised.</i>								
<u>Restricted benefit</u>								
<i>Chylous ascites;</i>								
<i>Chylothorax;</i>								
<i>Fat malabsorption due to liver disease, short gut syndrome, cystic fibrosis and gastrointestinal disorders;</i>								
<i>Hyperlipoproteinaemia type 1;</i>								
<i>Long chain fatty acid oxidation disorders.</i>								
<u>NOTE:</u>								
<i>Monogen is not indicated for the treatment of intractable childhood epilepsy or cerebrospinal fluid glucose transporter defect requiring a ketogenic diet.</i>								
8478F	Compound powder 400 g	8	5	..	*321.07	30.70	Monogen	SB
<u>Restricted benefit</u>								
<i>Chylous ascites;</i>								
<i>Chylothorax;</i>								
<i>Fat malabsorption due to liver disease, short gut syndrome, cystic fibrosis and gastrointestinal disorders.</i>								
<u>NOTE:</u>								
<i>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.</i>								
8629E	Compound powder 420 g	8	5	..	*350.19	30.70	Caprilon	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	
• Milk substitutes MILK POWDER—LACTOSE FREE FORMULA Authority required <i>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.</i> NOTE: <i>No applications for increased maximum quantities and/or repeats will be authorised. No more than 1 application per patient will be authorised.</i>								
8282X	Infant formula powder 900 g	5	..	..	*87.65	30.70	S-26 LF	WY
2350Q	Lactose-predigested powder infant formula 900 g	5	..	..	*87.65	30.70	Karicare De-Lact	NU
Authority required <i>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:</i> <i>(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</i> <i>(b) not less than 0.5% reducing substance in stool exudate tested with copper sulfate diagnostic compound tablet.</i> NOTE: <i>No applications for increased maximum quantities and/or repeats will be authorised.</i>								
8283Y	Infant formula powder 900 g	5	5	..	*87.65	30.70	S-26 LF	WY
2349P	Lactose-predigested powder infant formula 900 g	5	5	..	*87.65	30.70	Karicare De-Lact	NU
MILK POWDER—LACTOSE MODIFIED Authority required <i>Acute lactose intolerance in children aged 1 year and over. The date of birth of the patient must be included in the authority application.</i> NOTE: <i>No applications for increased maximum quantities and/or repeats will be authorised. No more than 1 application per patient will be authorised.</i>								
2358D	Lactose-predigested powder 900 g	3	1	..	*56.15	30.70	Digestelact	SJ
Authority required <i>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:</i> <i>(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</i> <i>(b) not less than 0.5% reducing substance in stool exudate tested with copper sulfate diagnostic compound tablet.</i> NOTE: <i>No applications for increased maximum quantities and/or repeats will be authorised.</i>								
2357C	Lactose-predigested powder 900 g	3	10	..	*56.15	30.70	Digestelact	SJ

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	
MILK POWDER—SYNTHETIC								
NOTE:								
<i>No applications for increased maximum quantities and/or repeats will be authorised.</i>								
Authority required								
<i>Hypercalcaemia in children under the age of 4 years.</i>								
3092R	Low calcium compound powder 400 g	8	5	..	*296.35	30.70	Locasol	NU
• Other combinations of nutrients								
AMINO ACID FORMULA without METHIONINE, THREONINE and VALINE and low in ISOLEUCINE								
Restricted benefit								
<i>Methylmalonic acidemia; Propionic acidemia.</i>								
3079C	Powder 200 g	5	5	..	*1080.65	30.70	XMTVI Asadon	SB
AMINO ACID FORMULA without PHENYLALANINE								
Restricted benefit								
<i>Phenylketonuria.</i>								
8554F	Capsules 500 mg, 200	16	5	..	*1324.19	30.70	Phlexy-10	SB
8678R	Tablets 1 g, 75	24	5	..	*1485.23	30.70	Phlexy-10	SB
8706F	Bars 42 g, 20	10	5	..	*1639.35	30.70	Phlexy-10	SB
2347M	Sachets containing powder 20 g, 30	7	5	..	*1523.52	30.70	Phlexy-10 Drink Mix	SB
3072Q	Powder 250 g	8	5	..	*1253.15	30.70	PK AID II	SB
AMINO ACID FORMULA without PHENYLALANINE, TYROSINE and METHIONINE								
Restricted benefit								
<i>Tyrosinaemia.</i>								
2379F	Powder 500 g	4	5	..	*1453.15	30.70	XPTM Tyrosidon	SB
AMINO ACID FORMULA with VITAMINS, MINERALS and LONG CHAIN POLYUNSATURATED FATTY ACIDS without PHENYLALANINE								
Restricted benefit								
<i>Phenylketonuria.</i>								
8479G	Infant formula, powder 400 g	8	5	..	*725.63	30.70	XP Analog LCP	SB
AMINO ACID FORMULA with VITAMINS and MINERALS without METHIONINE								
Restricted benefit								
<i>For infants and very young children with pyridoxine non-responsive homocystinuria.</i>								
8417B	Infant formula, powder 400 g	8	5	..	*718.91	30.70	XMET Analog	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	
AMINO ACID FORMULA with VITAMINS and MINERALS without METHIONINE—cont.								
<u>Restricted benefit</u>								
<i>Pyridoxine non-responsive homocystinuria.</i>								
8677Q	Sachets 20 g, 30	4	5	..	*1348.91	30.70	HCU gel	VF
8744F	Sachets 25 g, 30	4	5	..	*1767.51	30.70	HCU express	VF
8328H	Powder 500 g	8	5	..	*1405.15	30.70	XMET Maxamaid	SB
8416Y	Powder 500 g	8	5	..	*1641.95	30.70	XMET Maxamum	SB
AMINO ACID FORMULA with VITAMINS and MINERALS without METHIONINE, THREONINE and VALINE and low in ISOLEUCINE								
<u>Restricted benefit</u>								
<i>Methylmalonic acidemia; Propionic acidemia.</i>								
8058D	Infant formula, powder 400 g	8	5	..	*648.99	30.70	XMTVI Analog	SB
8059E	Powder 500 g	8	5	..	*1608.83	30.70	XMTVI Maxamaid	SB
8061G	Powder 500 g	8	5	..	*2029.15	30.70	XMTVI Maxamum	SB
AMINO ACID FORMULA with VITAMINS and MINERALS without PHENYLALANINE								
<u>Restricted benefit</u>								
<i>Phenylketonuria.</i>								
8555G	Sachets 20 g, 30	4	5	..	*889.75	30.70	PKU-gel	VF
8591E	Sachets 25 g, 30	4	5	..	*1528.55	30.70	PKU-Express	VF
8804J	Sachets 27.8 g, 30	3	5	..	*1615.97	30.70	Lophlex	SB
8613H	Sachets 29 g, 30	4	5	..	*920.39	30.70	Minaphlex	SB
8727H	Sachets 50 g, 30	3	5	..	*1576.04	30.70	XP Maxamum	SB
8466N	Infant formula, powder 350 g	8	5	..	*496.27	30.70	Phenex-1	AB
2737C	Infant formula, powder 400 g	8	5	..	*507.87	30.70	XP Analog	SB
8467P	Powder 325 g	10	5	..	*860.55	30.70	Phenex-2	AB
8545R	Powder 400 g	8	5	..	*847.31	30.70	Phenex-2	AB
2738D	Powder 500 g	8	5	..	*912.03	30.70	XP Maxamaid	SB
2739E	Powder 500 g	8	5	..	*1405.47	30.70	XP Maxamum	SB
8746H	Oral liquid 250 mL	90	5	..	*1363.65	30.70	Easiphen	SB
9021T	Oral liquid 125 mL, 30	3	5	..	*1615.97	30.70	Lophlex LQ	SB
8846N	Oral liquid 130 mL, 30	4	5	..	*1527.75	30.70	PKU Express Liquid	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 PHENYLALANINE and TYROSINE								
<u>Restricted benefit</u> <i>Tyrosinaemia.</i>								
8631G	Sachets 20 g, 30	4	5	..	*1602.91	30.70	TYR gel	VF
8667E	Sachets 25 g, 30	4	5	..	*2333.27	30.70	TYR Express	VF
8445L	Infant formula, powder 400 g	8	5	..	*795.55	30.70	XPhen, Tyr Analog	SB
8446M	Powder 500 g	8	5	..	*1685.15	30.70	XPhen, Tyr Maxamaid	SB
3078B	Powder 500 g	8	5	..	*2181.15	30.70	XPhen, Tyr Maxamum	SB
AMINO ACID FORMULA with VITAMINS and MINERALS without VALINE, LEUCINE and ISOLEUCINE								
<u>Restricted benefit</u> <i>Maple syrup urine disease.</i>								
8592F	Sachets 20 g, 30	4	5	..	*889.75	30.70	MSUD-gel	VF
8632H	Sachets 25 g, 30	4	5	..	*1528.55	30.70	MSUD Express	VF
8745G	Sachets 29 g, 30	4	5	..	*920.39	30.70	Mapleflex	SB
8468Q	Infant formula, powder 350 g	8	5	..	*496.27	30.70	Ketonex-1	AB
2380G	Infant formula, powder 400 g	8	5	..	*507.87	30.70	MSUD Analog	SB
8469R	Powder 325 g	10	5	..	*860.55	30.70	Ketonex-2	AB
8310J	Powder 500 g	4	5	..	*1405.15	30.70	MSUD AID III	SB
8260R	Powder 500 g	8	5	..	*912.03	30.70	MSUD Maxamaid	SB
8057C	Powder 500 g	8	5	..	*1405.47	30.70	MSUD Maxamum	SB
CARBOHYDRATE, FAT, VITAMINS, MINERALS and TRACE ELEMENTS								
<u>Restricted benefit</u> <i>Patients with proven inborn errors of protein metabolism who are unable to meet their energy requirements with permitted food and formulae.</i>								
8576J	Powder 400 g	8	5	..	*259.23	30.70	Pro-Phree	AB
8369L	Powder 400 g	8	5	..	*299.15	30.70	Energivit	SB
ESSENTIAL AMINO ACIDS FORMULA with MINERALS and VITAMIN C								
<u>Restricted benefit</u> <i>Gyrate atrophy of the choroid and retina; Urea cycle disorders.</i>								
8001D	Powder 200 g	10	5	..	*653.95	30.70	Dialamine	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	
MILK PROTEIN and FAT FORMULA with VITAMINS and MINERALS—CARBOHYDRATE FREE								
<u>Restricted benefit</u>								
<i>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.</i>								
8630F	Powder 225 g	24	5	..	*668.51	30.70	Carbohydrate Free Mixture	SB
MINERAL MIXTURE								
<u>NOTE:</u>								
<i>For use with Amino Acid Formula without Phenylalanine.</i>								
<u>Restricted benefit</u>								
<i>Metabolic disorders.</i>								
1451J	Powder 250 g	1	5	..	50.47	30.70	Metabolic Mineral Mixture	SB
SOY PROTEIN and FAT FORMULA with VITAMINS and MINERALS—CARBOHYDRATE FREE								
<u>Restricted benefit</u>								
<i>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.</i>								
8577K	Liquid 384 mL	120	5	..	*668.75	30.70	RCF	AB
TRIGLYCERIDES, MEDIUM CHAIN and LONG CHAIN with GLUCOSE POLYMER								
<u>Restricted benefit</u>								
<i>Patients with proven inborn errors of protein metabolism who are unable to meet their energy requirements with permitted food and formulae.</i>								
3136C	Compound powder 400 g	8	5	..	*256.67	30.70	Duocal	SB
WHEY PROTEIN FORMULA supplemented with AMINO ACIDS, VITAMINS and MINERALS, and low in PROTEIN, PHOSPHATE, POTASSIUM and LACTOSE								
<u>Authority required</u>								
<i>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.</i>								
8587Y	Powder 400 g	16	5	..	*787.23	30.70	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	..	16.38	17.37	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.

PREPARATIONS WHICH MAY BE PRESCRIBED FOR PATIENTS RECEIVING PALLIATIVE CARE—cont.

Code	Name, Restriction, Manner of administration and form	Max. No. of Qty 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						
• <i>Other agents for local oral treatment</i>						
BENZYDAMINE HYDROCHLORIDE						
<u>Authority required</u>						
<i>Initial supply (for up to 4 months) for palliative care patients where a painful mouth is a problem;</i>						
<i>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.</i>						
<u>NOTE:</u>						
<i>No applications for increased repeats will be authorised.</i>						
5385K	Mouth and throat rinse 22.5 mg per 15 mL, 500 mL	£1 3 ..	18.50	19.49	Difflam	MM
<u>Authority required</u>						
<i>Continuing supply for palliative care patients where a painful mouth is a problem.</i>						
<u>NOTE:</u>						
<i>No applications for repeats will be authorised.</i>						
5386L	Mouth and throat rinse 22.5 mg per 15 mL, 500 mL	£1	18.50	19.49	Difflam	MM
CARMELLOSE SODIUM						
<u>Authority required</u>						
<i>Initial supply (for up to 4 months) for palliative care patients where dry mouth is a symptom;</i>						
<i>Continuing supply for palliative care patients where dry mouth is a symptom, and where consultation with a palliative care specialist or service has occurred.</i>						
<u>NOTE:</u>						
<i>No applications for increased repeats will be authorised.</i>						
5333Q	Mouth spray 10 mg per mL, 25 mL	£1 3 ..	8.57	9.56	Aquae	HA
5334R	Mouth spray 10 mg per mL, 100 mL	£1 3 ..	10.69	11.68	Aquae	HA
<u>Authority required</u>						
<i>Continuing supply for palliative care patients where dry mouth is a symptom.</i>						
<u>NOTE:</u>						
<i>No applications for repeats will be authorised.</i>						
5335T	Mouth spray 10 mg per mL, 25 mL	£1	8.57	9.56	Aquae	HA
5336W	Mouth spray 10 mg per mL, 100 mL	£1	10.69	11.68	Aquae	HA

PREPARATIONS WHICH MAY BE PRESCRIBED FOR PATIENTS RECEIVING PALLIATIVE CARE—cont.

Code	Name, Restriction, Manner of administration and form	Max. No. of Qty 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					
	• <i>Belladonna alkaloids semisynthetic, quaternary ammonium compounds</i>					
	HYOSCINE BUTYLBROMIDE					
	<u>Authority required</u>					
	<i>Initial supply (for up to 4 months) for palliative care patients where colicky pain is a symptom;</i>					
	<i>Continuing supply for palliative care patients where colicky pain is a symptom, and where consultation with a palliative care specialist or service has occurred.</i>					
	<u>NOTE:</u>					
	<i>No applications for increased repeats will be authorised.</i>					
5317W	Injection 20 mg in 1 mL	5 3 ..	16.98	17.97	Buscopan	BY
	<u>Authority required</u>					
	<i>Continuing supply for palliative care patients where colicky pain is a symptom.</i>					
	<u>NOTE:</u>					
	<i>No applications for repeats will be authorised.</i>					
5318X	Injection 20 mg in 1 mL	5	16.98	17.97	Buscopan	BY
ANTIEMETICS AND ANTINAUSEANTS						
	Antiemetics and antinauseants					
	• <i>Other antiemetics</i>					
	PROMETHAZINE					
	HYDROCHLORIDE					
	<u>Authority required</u>					
	<i>Initial supply (for up to 4 months) for palliative care patients where nausea and/or vomiting is a problem;</i>					
	<i>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.</i>					
	<u>NOTE:</u>					
	<i>No applications for increased repeats will be authorised.</i>					
5325G	Tablet 10 mg	50 3 ..	13.04	14.03	Phenergan	AV
5326H	Tablet 25 mg	50 3 ..	15.04	16.03	Phenergan	AV
5327J	Oral liquid 5 mg per 5 mL, 100 mL	£1 3 ..	13.04	14.03	Phenergan	AV
	<u>Authority required</u>					
	<i>Continuing supply for palliative care patients where nausea and/or vomiting is a problem.</i>					
	<u>NOTE:</u>					
	<i>No applications for repeats will be authorised.</i>					
5328K	Tablet 10 mg	50	13.04	14.03	Phenergan	AV
5329L	Tablet 25 mg	50	15.04	16.03	Phenergan	AV
5330M	Oral liquid 5 mg per 5 mL, 100 mL	£1	13.04	14.03	Phenergan	AV

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	
LAXATIVES								
Laxatives								
• Contact laxatives								
BISACODYL								
Authority required								
<i>Initial supply (for up to 4 months) for palliative care patients where constipation is a problem;</i>								
<i>Continuing supply for palliative care patients where constipation is a problem, and where consultation with a palliative care specialist or service has occurred.</i>								
NOTE:								
<i>No applications for increased repeats will be authorised.</i>								
5301B	Tablet 5 mg	200	3	..	13.14	14.13	Bisalax Lax-Tab	AS AE
5303D	Suppositories 10 mg, 10	3	3	..	*20.24	21.23	^a Petrus Bisacodyl Suppositories	PP
				^B 1.11	*21.35	21.23	^a Durolax	BY
5304E	Suppositories 10 mg, 12	3	3	..	*17.45	18.44	Fleet Laxative Suppositories Petrus Bisacodyl Suppositories	FL PP
Authority required								
<i>Continuing supply for palliative care patients where constipation is a problem.</i>								
NOTE:								
<i>No applications for repeats will be authorised.</i>								
5305F	Tablet 5 mg	200	..	..	13.14	14.13	Bisalax Lax-Tab	AS AE
5307H	Suppositories 10 mg, 10	3	..	..	*20.24	21.23	^a Petrus Bisacodyl Suppositories	PP
				^B 1.11	*21.35	21.23	^a Durolax	BY
5308J	Suppositories 10 mg, 12	3	..	..	*17.45	18.44	Fleet Laxative Suppositories Petrus Bisacodyl Suppositories	FL PP

PREPARATIONS WHICH MAY BE PRESCRIBED FOR PATIENTS RECEIVING PALLIATIVE CARE—cont.

Code	Name, Restriction, Manner of administration and form	Max. No. of Qty Rpts Premium	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Proprietary Name and Manufacturer	
DOCUSATE SODIUM with BISACODYL						
<u>Authority required</u>						
<i>Initial supply (for up to 4 months) for palliative care patients where constipation is a problem;</i>						
<i>Continuing supply for palliative care patients where constipation is a problem, and where consultation with a palliative care specialist or service has occurred.</i>						
<u>NOTE:</u>						
<i>No applications for increased repeats will be authorised.</i>						
5309K	Suppositories 100 mg-10 mg, 5	6 3 ..	*20.27	21.26	Coloxyl	FM
<u>Authority required</u>						
<i>Continuing supply for palliative care patients where constipation is a problem.</i>						
<u>NOTE:</u>						
<i>No applications for repeats will be authorised.</i>						
5310L	Suppositories 100 mg-10 mg, 5	6	*20.27	21.26	Coloxyl	FM
• Bulk producers						
STERCULIA with FRANGULA BARK						
<u>Authority required</u>						
<i>Initial supply (for up to 4 months) for palliative care patients where constipation is a problem;</i>						
<i>Continuing supply for palliative care patients where constipation is a problem, and where consultation with a palliative care specialist or service has occurred.</i>						
<u>NOTE:</u>						
<i>No applications for increased repeats will be authorised.</i>						
5322D	Granules 620 mg-80 mg per g (62%-8%), 500 g	£1 3 ..	22.87	23.86	Normacol Plus	NE
<u>Authority required</u>						
<i>Continuing supply for palliative care patients where constipation is a problem.</i>						
<u>NOTE:</u>						
<i>No applications for repeats will be authorised.</i>						
5324F	Granules 620 mg-80 mg per g (62%-8%), 500 g	£1	22.87	23.86	Normacol Plus	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	
• Osmotically acting laxatives LACTULOSE Authority required <i>Initial supply (for up to 4 months) for palliative care patients where constipation is a problem;</i> <i>Continuing supply for palliative care patients where constipation is a problem, and where consultation with a palliative care specialist or service has occurred.</i> NOTE: <i>No applications for increased repeats will be authorised.</i>								
5387M	Mixture 3.34 g per 5 mL, 500 mL	1	3	..	15.11	16.10	a Actilax a Genlac a GenRx Lactulose a Lac-Dol a Lactocur Duphalac	AF AW GX GM HX SM
					^B 2.13	17.24	16.10	
Authority required <i>Continuing supply for palliative care patients where constipation is a problem.</i> NOTE: <i>No applications for repeats will be authorised.</i>								
5388N	Mixture 3.34 g per 5 mL, 500 mL	1	..	..	15.11	16.10	a Actilax a Genlac a GenRx Lactulose a Lac-Dol a Lactocur Duphalac	AF AW GX GM HX SM
					^B 2.13	17.24	16.10	
MACROGOL 3350 Authority required <i>Initial supply (for up to 4 months) for palliative care patients where constipation is a problem;</i> <i>Continuing supply for palliative care patients where constipation is a problem, and where consultation with a palliative care specialist or service has occurred.</i> NOTE: <i>No applications for increased repeats will be authorised.</i>								
5389P	Sachets containing powder for solution 13.125 g with electrolytes, 30	1	3	..	22.72	23.71	Movicol	NE
Authority required <i>Continuing supply for palliative care patients where constipation is a problem.</i> NOTE: <i>No applications for repeats will be authorised.</i>								
5390Q	Sachets containing powder for solution 13.125 g with electrolytes, 30	1	..	..	22.72	23.71	Movicol	NE

PREPARATIONS WHICH MAY BE PRESCRIBED FOR PATIENTS RECEIVING PALLIATIVE CARE—cont.

Code	Name, Restriction, Manner of administration and form	Max. No. of Qty Rpts Premium	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Proprietary Name and Manufacturer	
• Enemas BISACODYL Authority required <i>Initial supply (for up to 4 months) for palliative care patients where constipation is a problem;</i> <i>Continuing supply for palliative care patients where constipation is a problem, and where consultation with a palliative care specialist or service has occurred.</i> NOTE: <i>No applications for increased repeats will be authorised.</i>						
5302C	Enemas 10 mg in 5 mL, 25	£1 3 ..	35.17	30.70	Bisalax	AS
Authority required <i>Continuing supply for palliative care patients where constipation is a problem.</i> NOTE: <i>No applications for repeats will be authorised.</i>						
5306G	Enemas 10 mg in 5 mL, 25	£1	35.17	30.70	Bisalax	AS
SORBITOL with SODIUM CITRATE and SODIUM LAURYL SULFOACETATE Authority required <i>Initial supply (for up to 4 months) for palliative care patients where constipation is a problem;</i> <i>Continuing supply for palliative care patients where constipation is a problem, and where consultation with a palliative care specialist or service has occurred.</i> NOTE: <i>No applications for increased repeats will be authorised.</i>						
5331N	Enemas 3.125 g-450 mg-45 mg in 5 mL, 12	2 3 ..	*33.99	30.70	Microlax	PH
Authority required <i>Continuing supply for palliative care patients where constipation is a problem.</i> NOTE: <i>No applications for repeats will be authorised.</i>						
5332P	Enemas 3.125 g-450 mg-45 mg in 5 mL, 12	2	*33.99	30.70	Microlax	PH

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 <i>Initial supply (for up to 4 months) for palliative care patients where constipation is a problem;</i> <i>Continuing supply for palliative care patients where constipation is a problem, and where consultation with a palliative care specialist or service has occurred.</i> NOTE: <i>No applications for increased repeats will be authorised.</i>							
5311M	Suppositories 700 mg (for infants), 12	3	3	..	*14.90	15.89	PP
5312N	Suppositories 1.4 g (for children), 12	3	3	..	*15.23	16.22	PP
5313P	Suppositories 2.8 g (for adults), 12	3	3	..	*15.56	16.55	PP
Authority required <i>Continuing supply for palliative care patients where constipation is a problem.</i> NOTE: <i>No applications for repeats will be authorised.</i>							
5314Q	Suppositories 700 mg (for infants), 12	3	..	..	*14.90	15.89	PP
5315R	Suppositories 1.4 g (for children), 12	3	..	..	*15.23	16.22	PP
5316T	Suppositories 2.8 g (for adults), 12	3	..	..	*15.56	16.55	PP

PREPARATIONS WHICH MAY BE PRESCRIBED FOR PATIENTS RECEIVING PALLIATIVE CARE—cont.

Code	Name, Restriction, Manner of administration and form	Max. No. of Qty 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					
• <i>Acetic acid derivatives and related substances</i>					
DICLOFENAC SODIUM					
Authority required					
<i>Initial supply (for up to 4 months) for palliative care patients where severe pain is a problem;</i>					
<i>Continuing supply for palliative care patients where severe pain is a problem, and where consultation with a palliative care specialist or service has occurred.</i>					
NOTE:					
<i>No applications for increased repeats will be authorised.</i>					
5361E	Tablet 25 mg (enteric coated)	100 3 ..	*13.63	14.62	a Chem mart CH Diclofenac a Clonac 25 AW a Diclofenac-BC BG a Diclohexal HX a Dinac GM a GenRx GX Diclofenac a Terry White TW Chemists Diclofenac .. 13.63 14.62 a Fenac 25 AF B3.18 *16.81 14.62 a Voltaren 25 NV
5362F	Tablet 50 mg (enteric coated)	50 3 ..	11.06	12.05	a Chem mart CH Diclofenac a Clonac 50 AW a Diclohexal HX a Dinac GM a Fenac AF a GenRx GX Diclofenac a Terry White TW Chemists Diclofenac B3.09 14.15 12.05 a Voltaren 50 NV
5363G	Suppository 100 mg	40 3 ..	*22.83	23.82	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	
DICLOFENAC SODIUM—cont.								
Authority required								
<i>Continuing supply for palliative care patients where severe pain is a problem.</i>								
NOTE:								
<i>No applications for repeats will be authorised.</i>								
5364H	Tablet 25 mg (enteric coated)	100	..	..	*13.63	14.62	^a Chem mart Diclofenac	CH
							^a Clonac 25	AW
							^a Diclofenac-BC	BG
							^a Diclohexal	HX
							^a Dinac	GM
							^a GenRx	GX
							^a Diclofenac	
							^a Terry White Chemists	TW
					.. 13.63	14.62	^a Fenac 25	AF
				^B 3.18	*16.81	14.62	^a Voltaren 25	NV
5365J	Tablet 50 mg (enteric coated)	50	..	..	11.06	12.05	^a Chem mart Diclofenac	CH
							^a Clonac 50	AW
							^a Diclohexal	HX
							^a Dinac	GM
							^a Fenac	AF
							^a GenRx	GX
							^a Diclofenac	
							^a Terry White Chemists	TW
					^B 3.09	14.15	^a Voltaren 50	NV
5366K	Suppository 100 mg	40	..	..	*22.83	23.82	Voltaren 100	NV
INDOMETHACIN								
Authority required								
<i>Initial supply (for up to 4 months) for palliative care patients where severe pain is a problem;</i>								
<i>Continuing supply for palliative care patients where severe pain is a problem, and where consultation with a palliative care specialist or service has occurred.</i>								
NOTE:								
<i>No applications for increased repeats will be authorised.</i>								
5377B	Capsule 25 mg	100	3	..	*10.55	11.54	^a Arthrexin	AF
				^B 2.98	*13.53	11.54	^a Indocid	MK
5378C	Suppository 100 mg	40	3	..	*20.53	21.52	Indocid	MK

continued

PREPARATIONS WHICH MAY BE PRESCRIBED FOR PATIENTS RECEIVING PALLIATIVE CARE—cont.

Code	Name, Restriction, Manner of administration and form	Max. No. of Qty Rpts Premium	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Proprietary Name and Manufacturer	
INDOMETHACIN—cont.						
Authority required						
<i>Continuing supply for palliative care patients where severe pain is a problem.</i>						
NOTE:						
<i>No applications for repeats will be authorised.</i>						
5379D	Capsule 25 mg	100	*10.55	11.54 ^a	Arthrexin	AF
			£2.98 *13.53	11.54 ^a	Indocid	MK
5380E	Suppository 100 mg	40	*20.53	21.52	Indocid	MK
SULINDAC						
Authority required						
<i>Initial supply (for up to 4 months) for palliative care patients where severe pain is a problem;</i>						
<i>Continuing supply for palliative care patients where severe pain is a problem, and where consultation with a palliative care specialist or service has occurred.</i>						
NOTE:						
<i>No applications for increased repeats will be authorised.</i>						
5381F	Tablet 100 mg	100 3 ..	*14.63	15.62	Aclin	AF
5382G	Tablet 200 mg	50 3 ..	13.62	14.61	Aclin 200	AF
Authority required						
<i>Continuing supply for palliative care patients where severe pain is a problem.</i>						
NOTE:						
<i>No applications for repeats will be authorised.</i>						
5383H	Tablet 100 mg	100	*14.63	15.62	Aclin	AF
5384J	Tablet 200 mg	50	13.62	14.61	Aclin 200	AF
• Propionic acid derivatives						
IBUPROFEN						
Authority required						
<i>Initial supply (for up to 4 months) for palliative care patients where severe pain is a problem;</i>						
<i>Continuing supply for palliative care patients where severe pain is a problem, and where consultation with a palliative care specialist or service has occurred.</i>						
NOTE:						
<i>No applications for increased repeats will be authorised.</i>						
5367L	Tablet 200 mg	100 3 ..	*10.55	11.54	Rafen 200	AF
5368M	Tablet 400 mg	90 3 ..	*13.10	14.09	Brufen	AB
Authority required						
<i>Continuing supply for palliative care patients where severe pain is a problem.</i>						
NOTE:						
<i>No applications for repeats will be authorised.</i>						
5369N	Tablet 200 mg	100	*10.55	11.54	Rafen 200	AF
5370P	Tablet 400 mg	90	*13.10	14.09	Brufen	AB

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	
NAPROXEN								
<u>Authority required</u>								
<i>Initial supply (for up to 4 months) for palliative care patients where severe pain is a problem;</i>								
<i>Continuing supply for palliative care patients where severe pain is a problem, and where consultation with a palliative care specialist or service has occurred.</i>								
<u>NOTE:</u>								
<i>No applications for increased repeats will be authorised.</i>								
5345H	Tablet 250 mg	100	3	..	*14.45	15.44	^a Inza 250	AF
				^B 3.00	*17.45	15.44	^a Naprosyn	RO
5346J	Tablet 500 mg	50	3	..	13.42	14.41	^a Inza 500	AF
				^B 1.75	15.17	14.41	^a Naprosyn	RO
5347K	Tablet 750 mg (sustained release)	28	3	..	12.75	13.74	^a Proxen SR 750	MD
				^B 1.62	14.37	13.74	^a Naprosyn SR750	RO
5348L	Tablet 1 g (sustained release)	28	3	..	15.28	16.27	^a Proxen SR 1000	MD
				^B 1.72	17.00	16.27	^a Naprosyn SR1000	RO
<u>Authority required</u>								
<i>Continuing supply for palliative care patients where severe pain is a problem.</i>								
<u>NOTE:</u>								
<i>No applications for repeats will be authorised.</i>								
5349M	Tablet 250 mg	100	..	..	*14.45	15.44	^a Inza 250	AF
				^B 3.00	*17.45	15.44	^a Naprosyn	RO
5350N	Tablet 500 mg	50	..	..	13.42	14.41	^a Inza 500	AF
				^B 1.75	15.17	14.41	^a Naprosyn	RO
5351P	Tablet 750 mg (sustained release)	28	..	..	12.75	13.74	^a Proxen SR 750	MD
				^B 1.62	14.37	13.74	^a Naprosyn SR750	RO
5352Q	Tablet 1 g (sustained release)	28	..	..	15.28	16.27	^a Proxen SR 1000	MD
				^B 1.72	17.00	16.27	^a Naprosyn SR1000	RO

continued

Code	Name, Restriction, Manner of administration and form	Max. No. of Qty Rpts Premium	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Proprietary Name and Manufacturer
NAPROXEN—cont.					
Authority required					
<i>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;</i>					
<i>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.</i>					
NOTE:					
<i>No applications for increased repeats will be authorised.</i>					
5397C	Oral suspension 125 mg per 5 mL, 474 mL	£1 3 ..	76.90	30.70	Naprosyn RO
Authority required					
<i>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.</i>					
NOTE:					
<i>No applications for repeats will be authorised.</i>					
5398D	Oral suspension 125 mg per 5 mL, 474 mL	£1	76.90	30.70	Naprosyn RO
NAPROXEN SODIUM					
Authority required					
<i>Initial supply (for up to 4 months) for palliative care patients where severe pain is a problem;</i>					
<i>Continuing supply for palliative care patients where severe pain is a problem, and where consultation with a palliative care specialist or service has occurred.</i>					
NOTE:					
<i>No applications for increased repeats will be authorised.</i>					
5353R	Tablet 550 mg	50 3 ..	13.68 B2.91	14.67 14.67	a Crysanal a Anaprox 550 MD RO
NOTE:					
<i>Naproxen sodium 550 mg is approximately equivalent to 500 mg of naproxen acid.</i>					
Authority required					
<i>Continuing supply for palliative care patients where severe pain is a problem.</i>					
NOTE:					
<i>No applications for repeats will be authorised.</i>					
5354T	Tablet 550 mg	50	13.68 B2.91	14.67 14.67	a Crysanal a Anaprox 550 MD RO
NOTE:					
<i>Naproxen sodium 550 mg is approximately equivalent to 500 mg of naproxen acid.</i>					

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								
• <i>Natural opium alkaloids</i>								
MORPHINE SULFATE								
CAUTION:								
<i>The risk of drug dependence is high.</i>								
Authority required								
<i>Initial supply (for up to 3 months) for palliative care patients with severe disabling pain not responding to non-narcotic analgesics;</i>								
<i>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.</i>								
NOTE:								
<i>Telephone approvals are limited to 1 month's therapy.</i>								
5393W	Tablet 10 mg	20	2	..	13.75	14.74	Sevredol	MF
5394X	Tablet 20 mg	20	2	..	14.83	15.82	Sevredol	MF
Authority required								
<i>Continuing supply (for up to 1 month) for palliative care patients with severe disabling pain not responding to non-narcotic analgesics.</i>								
NOTE:								
<i>No applications for repeats will be authorised.</i>								
5395Y	Tablet 10 mg	20	..	..	13.75	14.74	Sevredol	MF
5396B	Tablet 20 mg	20	..	..	14.83	15.82	Sevredol	MF
Authority required								
<i>Initial supply (for up to 3 months) for palliative care patients with chronic severe disabling pain not responding to non-narcotic analgesics;</i>								
<i>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.</i>								
NOTE:								
<i>Telephone approvals are limited to 1 month's therapy.</i>								
5391R	Tablet 200 mg (controlled release)	20	2	..	103.66	30.70	MS Contin	MF
Authority required								
<i>Continuing supply (for up to 1 month) for palliative care patients with chronic severe disabling pain not responding to non-narcotic analgesics.</i>								
NOTE:								
<i>No applications for repeats will be authorised.</i>								
5392T	Tablet 200 mg (controlled release)	20	..	..	103.66	30.70	MS Contin	MF

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	
Diphenylpropylamine derivatives METHADONE HYDROCHLORIDE CAUTION: <i>The risk of drug dependence is high.</i> Authority required <i>Initial supply (for up to 3 months) for palliative care patients with chronic severe disabling pain not responding to non-narcotic analgesics;</i> <i>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.</i> NOTE: <i>Telephone approvals are limited to 1 month's therapy.</i>								
5399E	Oral liquid 25 mg per 5 mL, 200 mL	1	2	..	16.62	17.61	GK	
Authority required <i>Continuing supply (for up to 1 month) for palliative care patients with chronic severe disabling pain not responding to non-narcotic analgesics.</i> NOTE: <i>No applications for repeats will be authorised.</i>								
5400F	Oral liquid 25 mg per 5 mL, 200 mL	1	..	..	16.62	17.61	GK	
Other analgesics and antipyretics Anilides PARACETAMOL Authority required <i>Initial supply (for up to 4 months) for palliative care patients for analgesia or fever where alternative therapy cannot be tolerated;</i> <i>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.</i> NOTE: <i>No applications for increased repeats will be authorised.</i>								
5343F	Tablet 665 mg (modified release)	192	3	..	*11.69 B4.72	12.68 ^a 12.68 ^a	Duatrol SR Panadol Osteo	ME GC
5319Y	Suppositories 500 mg, 24	‡1	3	..	24.66	25.65	Panadol	GC
Authority required <i>Continuing supply for palliative care patients for analgesia or fever where alternative therapy cannot be tolerated.</i> NOTE: <i>No applications for repeats will be authorised.</i>								
5344G	Tablet 665 mg (modified release)	192	..	..	*11.69 B4.72	12.68 ^a 12.68 ^a	Duatrol SR Panadol Osteo	ME GC
5320B	Suppositories 500 mg, 24	‡1	..	..	24.66	25.65	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								
<i>Initial supply (for up to 4 months) for palliative care patients for the prevention of epilepsy;</i>								
<i>Continuing supply for palliative care patients for the prevention of epilepsy, where</i>								
<i>consultation with a palliative care specialist or service has occurred.</i>								
NOTE:								
<i>No applications for increased repeats will be authorised.</i>								
5337X	Tablet 500 micrograms	100	3	..	13.94	14.93	^a Paxam 0.5	AF
				^B 2.29	16.23	14.93	^a Rivotril	RO
5338Y	Tablet 2 mg	100	3	..	21.67	22.66	^a Paxam 2	AF
				^B 2.60	24.27	22.66	^a Rivotril	RO
5339B	Oral liquid 2.5 mg per mL, 10 mL	2	3	..	*13.41	14.40	Rivotril	RO
Authority required								
<i>Continuing supply for palliative care patients for the prevention of epilepsy.</i>								
NOTE:								
<i>No applications for repeats will be authorised.</i>								
5340C	Tablet 500 micrograms	100	..	..	13.94	14.93	^a Paxam 0.5	AF
				^B 2.29	16.23	14.93	^a Rivotril	RO
5341D	Tablet 2 mg	100	..	..	21.67	22.66	^a Paxam 2	AF
				^B 2.60	24.27	22.66	^a Rivotril	RO
5342E	Oral liquid 2.5 mg per mL, 10 mL	2	..	..	*13.41	14.40	Rivotril	RO
PSYCHOLEPTICS								
Anxiolytics								
• Benzodiazepine derivatives								
DIAZEPAM								
Authority required								
<i>Initial supply (for up to 4 months) for palliative care patients where anxiety is a problem;</i>								
<i>Continuing supply for palliative care patients where anxiety is a problem, and where</i>								
<i>consultation with a palliative care specialist or service has occurred.</i>								
NOTE:								
<i>No applications for increased repeats will be authorised.</i>								
5355W	Tablet 2 mg	50	3	..	7.13	8.12	^a Antenex 2	AF
							^a Valpam 2	AW
				^B 0.87	8.00	8.12	Ducene	SU
				^B 1.27	8.40	8.12	^a Valium	RO

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
<u>DIAZEPAM—cont.</u>							
5356X	Tablet 5 mg	50	3	..	7.35	8.34	^a Antenex 5 AF ^a Diazepam-DP GM ^a Valpam 5 AW ^B 0.91 Ducene SU ^B 1.28 8.63 8.34 ^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	..	..	7.13	8.12	^a Antenex 2 AF ^a Valpam 2 AW ^B 0.87 8.00 8.12 Ducene SU ^B 1.27 8.40 8.12 ^a Valium RO
5358B	Tablet 5 mg	50	..	..	7.35	8.34	^a Antenex 5 AF ^a Diazepam-DP GM ^a Valpam 5 AW ^B 0.91 Ducene SU ^B 1.28 8.63 8.34 ^a Valium RO

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	..	*7.63	8.62	^a Alepam 15 AF ^B 3.48 *11.11 8.62 ^a Serepax SI
5372R	Tablet 30 mg	50	3	..	*8.03	9.02	^a Alepam 30 AF ^B 3.70 *11.73 9.02 ^a Murelax FM ^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	..	..	*7.63	8.62	^a Alepam 15 AF ^B 3.48 *11.11 8.62 ^a Serepax SI
5374W	Tablet 30 mg	50	..	..	*8.03	9.02	^a Alepam 30 AF ^B 3.70 *11.73 9.02 ^a Murelax FM ^a Serepax SI

PREPARATIONS WHICH MAY BE PRESCRIBED FOR PATIENTS RECEIVING PALLIATIVE CARE—cont.

Code	Name, Restriction, Manner of administration and form	Max. No. of Qty Rpts Premium	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Proprietary Name and Manufacturer	
Hypnotics and sedatives						
• Benzodiazepine derivatives						
NITRAZEPAM						
<u>Authority required</u>						
<i>Initial supply (for up to 4 months) for palliative care patients where insomnia is a problem;</i>						
<i>Continuing supply for palliative care patients where insomnia is a problem, and where consultation with a palliative care specialist or service has occurred.</i>						
<u>NOTE:</u>						
<i>No applications for increased repeats will be authorised.</i>						
5359C	Tablet 5 mg	50 3 ..	*8.89	9.88	^a Alodorm	AF
		^B 3.92	*12.81	9.88	^a Mogadon	VT
<u>Authority required</u>						
<i>Continuing supply for palliative care patients where insomnia is a problem.</i>						
<u>NOTE:</u>						
<i>No applications for repeats will be authorised.</i>						
5360D	Tablet 5 mg	50	*8.89	9.88	^a Alodorm	AF
		^B 3.92	*12.81	9.88	^a Mogadon	VT
TEMAZEPAM						
<u>Authority required</u>						
<i>Initial supply (for up to 4 months) for palliative care patients where insomnia is a problem;</i>						
<i>Continuing supply for palliative care patients where insomnia is a problem, and where consultation with a palliative care specialist or service has occurred.</i>						
<u>NOTE:</u>						
<i>No applications for increased repeats will be authorised.</i>						
5375X	Tablet 10 mg	50 3 ..	*8.89	9.88	^a Temaze	AF
		^B 3.54	*12.43	9.88	^a Temtabs	FM
				9.88	^a Normison	SI
<u>Authority required</u>						
<i>Continuing supply for palliative care patients where insomnia is a problem.</i>						
<u>NOTE:</u>						
<i>No applications for repeats will be authorised.</i>						
5376Y	Tablet 10 mg	50	*8.89	9.88	^a Temaze	AF
		^B 3.54	*12.43	9.88	^a Temtabs	FM
				9.88	^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. No. of Qty 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	8.88	9.87	Fungilin	BQ
NYSTATIN						
3343Y	Oral suspension 100,000 units per mL, 24 mL	‡1	9.39	10.38	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	18.50	19.49	Difflam	MM
DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS						
Belladonna and derivatives, plain						
• Belladonna alkaloids, tertiary amines						
ATROPINE SULFATE						
5022H	Injection 600 micrograms in 1 mL	10	13.39	14.38	AP	
Propulsives						
• Propulsives						
METOCLOPRAMIDE						
HYDROCHLORIDE						
5151D	Tablet 10 mg	25	6.70 B2.88 9.58	7.69 7.69	Pramin Maxolon	AF VT
5152E	Syrup 5 mg per 5 mL, 100 mL	‡1	7.66	8.65	Maxolon	VT
5153F	Injection 10 mg in 2 mL	10	11.43	12.42	Maxolon	VT
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 5 mg	25	7.66 B2.09 9.75	8.65 8.65	^a Stemizine ^a Stemetil	HP AV
5206B	Injection 12.5 mg in 1 mL	10	14.26	15.25	Stemetil	AV
5207C	Suppositories 5 mg, 5	‡1	15.42	16.41	Stemetil	AV
5208D	Suppositories 25 mg, 5	‡1	16.92	17.91	Stemetil	AV

**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	
3374N	PROMETHAZINE HYDROCHLORIDE Injection 50 mg in 2 mL	10	..	..	*18.27	19.26	MX	
ANTIDIARRHEALS, INTESTINAL ANTIINFLAMMATORY/ ANTIINFECTIVE AGENTS								
Intestinal antiinfectives								
• Antibiotics								
3342X	NYSTATIN Tablet 500,000 units	50	..	..	16.21	17.20	Nilstat	SI
3345C	Capsule 500,000 units	50	..	..	16.21	17.20	Nilstat	SI
BLOOD AND BLOOD FORMING ORGANS								
BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS								
I.V. solutions								
• Solutions for parenteral nutrition								
5106R	GLUCOSE I.V. infusion 278 mmol (anhydrous) per L (5%), 1 L	5	..	..	*23.80	24.79	BX	
• Solutions affecting the electrolyte balance								
5212H	SODIUM CHLORIDE I.V. infusion 154 mmol per L (0.9%), 1 L	5	..	..	*23.80	24.79	BX	
5213J	I.V. infusion 513 mmol per L (3%), 1 L	2	..	..	*16.43	17.42	BX	
5214K	SODIUM CHLORIDE with GLUCOSE I.V. infusion 31 mmol-222 mmol (anhydrous) per L (0.18%-4%), 1 L	5	..	..	*23.80	24.79	BX	
5215L	I.V. infusion 19 mmol-104 mmol (anhydrous) per 500 mL (0.225%-3.75%), 500 mL	5	..	..	*29.65	30.64	BX	
5216M	I.V. infusion 39 mmol-69 mmol (anhydrous) per 500 mL (0.45%- 2.5%), 500 mL	5	..	..	*29.65	30.64	BX	
CARDIOVASCULAR SYSTEM								
CARDIAC THERAPY								
Antiarrhythmics, class I and III								
• Antiarrhythmics, class IB								
5142P	LIGNOCAINE HYDROCHLORIDE Injection 100 mg in 5 mL	5	..	..	34.72	30.70	PF	

**PREPARATIONS WHICH MAY BE PRESCRIBED BY PARTICIPATING DENTAL
PRACTITIONERS FOR DENTAL TREATMENT ONLY—cont.**

Code	Name, Restriction, Manner of administration and form	Max. No. of Qty Rpts Premium	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Proprietary Name and Manufacturer
Cardiac stimulants excl. cardiac glycosides					
• Adrenergic and dopaminergic agents					
ADRENALINE					
5004J	Injection 1 mg in 1 mL (1 in 1,000)	5	18.46	19.45	AP
Vasodilators used in cardiac diseases					
• Organic nitrates					
GLYCERYL TRINITRATE					
5108W	Tablets 600 micrograms, 100	‡1	8.68	9.67	^a Lycinate FM
			^B 1.61 10.29	9.67	^a Anginine SI
					Stabilised

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	6.92	7.91	^a Cortic-DS 1% FM
			^B 1.85 8.77	7.91	^a Sigmacort SI
5113D	Cream 10 mg per g (1%), 50 g	‡1	7.37	8.36	^a Cortic-DS 1% FM
			^B 0.08 7.45	8.36	^a Cortef DT
			^B 1.86 9.23	8.36	^a Sigmacort SI
5112C	Topical ointment 10 mg per g (1%), 30 g	‡1	6.92	7.91	^a Cortic-DS 1% FM
			^B 1.85 8.77	7.91	^a Sigmacort SI
5114E	Topical ointment 10 mg per g (1%), 50 g	‡1	7.37	8.36	^a Cortic-DS 1% FM
			^B 1.86 9.23	8.36	^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	24.42	25.41	Celestone Chronodose SH

**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	
HYDROCORTISONE SODIUM SUCCINATE								
<u>Restricted benefit</u>								
<i>For use in a hospital.</i>								
5118J	Injection equivalent to 100 mg hydrocortisone with 2 mL solvent	6	..	..	*36.53	30.70	Solu-Cortef	PH
5119K	Injection equivalent to 250 mg hydrocortisone with 2 mL solvent	6	..	..	*61.91	30.70	Solu-Cortef	PH
METHYLPREDNISOLONE ACETATE								
<u>Restricted benefit</u>								
<i>For local intra-articular or peri-articular infiltration.</i>								
5148Y	Injection 40 mg in 1 mL	5	..	..	23.10	24.09	^a Depo-Nisolone	KR
				^B 0.74	23.84	24.09	^a Depo-Medrol	PH
TRIAMCINOLONE ACETONIDE								
<u>Restricted benefit</u>								
<i>For local intra-articular or peri-articular infiltration; Keloid; Lichen planus hypertrophic.</i>								
5233K	Injection 10 mg in 1 mL	5	..	..	24.42	25.41	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	..	..	39.38	30.70	GlucaGen Hypokit	NO
ANTIINFECTIVES FOR SYSTEMIC USE								
ANTIBACTERIALS FOR SYSTEMIC USE								
Tetracyclines								
• Tetracyclines								
DOXYCYCLINE								
3321T	Tablet 100 mg	7	..	..	7.76	8.75	^a Chem mart Doxycycline	CH
							^a Doxsig	SI
							^a Doxy-100	GM
							^a Doxyhexal	SZ
							^a Doxylin 100	AF
							^a GenRx	GX
							Doxycycline	
							^a Terry White Chemists	TW
							Doxycycline	
				^B 1.53	9.29	8.75	^a Vibramycin	PF
3322W	Capsule 100 mg	7	..	..	7.76	8.75	^a DBL Doxycycline	FA
				^B 1.46	9.22	8.75	^a Doryx	MX

**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								
• <i>Penicillins with extended spectrum</i>								
AMOXYCILLIN								
3303W	Chewable tablet 250 mg	20	..	..	8.73	9.72	Amoxil	GK
3301R	Capsule 250 mg	20	..	..	7.87	8.86	^a Alphamox 250	AF
							^a Amohexal	HX
							^a Amoxycillin-DP	GM
							^a Chem mart	CH
							Amoxycillin	
							^a Cilamox	SI
							^a GenRx	GX
							Amoxycillin	
							^a Moxacin	CS
							^a Terry White	TW
							Chemists	
							Amoxycillin	
				^B 1.00	8.87	8.86	^a Amoxil	GK
3300Q	Capsule 500 mg	20	..	..	10.55	11.54	^a Alphamox 500	AF
							^a Amohexal	HX
							^a Amoxycillin-DP	GM
							^a Chem mart	CH
							Amoxycillin	
							^a Cilamox	SI
							^a GenRx	GX
							Amoxycillin	
							^a Moxacin	CS
							^a Terry White	TW
							Chemists	
							Amoxycillin	
				^B 1.00	11.55	11.54	^a Amoxil	GK
3309E	Sachet containing oral powder 3 g	1	..	..	8.58	9.57	Amoxil	GK
3302T	Powder for syrup 125 mg per 5 mL, 100 mL	‡1	..	..	#10.02	11.40	^a Alphamox 125	AF
							^a Amohexal	HX
							^a Bgramin	GM
							^a Chem mart	CH
							Amoxycillin	
							^a GenRx	GX
							Amoxycillin	
							^a Moxacin	CS
							^a Terry White	TW
							Chemists	
							Amoxycillin	
				^B 1.22	#11.24	11.40	^a 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	
AMOXYCILLIN—cont.								
3393N	Powder for syrup 250 mg per 5 mL, 100 mL	‡1	..	..	#11.09	12.47	^a Alphamox 250 ^a Amohexal ^a Bgramin ^a Chem mart Amoxycillin ^a Cilamox ^a GenRx Amoxycillin ^a Terry White Chemists Amoxycillin	AF HX GM CH SI GX TW
				^B 1.01	#12.10	12.47	^a Amoxil Forte	GK
5225B	Powder for oral suspension 500 mg per 5 mL, 100 mL	‡1	..	..	#13.80	15.18	Maxamox	SZ
See Special Pharmaceutical Benefits for listing for amoxycillin powder for paediatric oral drops.								
AMPICILLIN								
5013W	Capsule 250 mg	24	..	..	8.87	9.86	Alphacin 250	AF
5014X	Capsule 500 mg	24	..	..	12.12	13.11	Alphacin 500	AF
3313J	Powder for injection 500 mg	5	..	..	11.09	12.08	^a Austrapen ^a Ibimicyn	LN GM
3314K	Powder for injection 1 g	5	..	..	14.90	15.89	^a Aspen Ampicyn ^a Austrapen ^a Ibimicyn	AS LN GM
• Beta-lactamase sensitive penicillins								
BENZATHINE PENICILLIN								
5025L	Injection 900 mg in 2 mL cartridge-needle unit (for use with Tubex Injector)	1	..	..	25.43	26.42	Bicillin L-A Tubex	AS
5252K	Powder for injection 900 mg (1,200,000 i.u.)	1	..	..	*42.36	30.70	Pan Benzathine Benzyl- penicillin	AS
BENZYL PENICILLIN								
3398W	Powder for injection 600 mg	10	..	..	*22.09	23.08	BenPen	CS
3399X	Powder for injection 3 g	10	..	..	*49.43	30.70	BenPen	CS

**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	
PHENOXYMETHYLPENICILLIN								
3360W	Tablet 250 mg	50	..	..	*11.71	12.70	Abbocillin-VK Filmtab	SI
3361X	Tablet 500 mg	50	..	..	*14.89	15.88	Abbocillin-VK Filmtab	SI
3363B	Capsule 250 mg	50	..	..	11.51	12.50	^a Cilicaine VK ^a Cilopen VK LPV ^a Penhexal VK	FM GM CS HX
3364C	Capsule 500 mg	50	..	..	14.61	15.60	^a Cilicaine VK ^a Cilopen VK LPV ^a Penhexal VK	FM GM CS HX
3365D	Paediatric oral suspension 125 mg per 5 mL, 100 mL	2	..	..	*12.49 ^B 1.82 *14.31	13.48 13.48	^a Cilicaine V ^a Abbocillin-V	FM SI
3366E	Oral suspension 250 mg per 5 mL, 100 mL	2	..	..	*15.19 ^B 1.80 *16.99	16.18 16.18	^a Cilicaine V ^a Abbocillin-V	FM SI
PROCAINE PENICILLIN								
3371K	Injection 1.5 g	5	..	..	51.35	30.70	Cilicaine	SI
• Beta-lactamase resistant penicillins								
DICLOXACILLIN								
5098H	Powder for injection 500 mg	5	..	..	16.83	17.82	Diclocil	BQ
5099J	Powder for injection 1 g	5	..	..	23.49	24.48	Diclocil	BQ
<u>DICLOXACILLIN</u>								
<u>Restricted benefit</u>								
<i>Serious staphylococcal infections.</i>								
5096F	Capsule 250 mg	24	..	..	11.56	12.55	^a Diclocil ^a Dicloxsig ^a Distaph 250	BQ SI AF
5097G	Capsule 500 mg	24	..	..	18.57	19.56	^a Diclocil ^a Dicloxsig ^a Distaph 500	BQ SI AF

**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	
FLUCLOXACILLIN								
<u>CAUTION:</u> 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	..	..	16.72	17.71	^a Flopen ^a Flubiclox	CS GM
5095E	Powder for injection 1 g	5	..	..	23.30	24.29	^a Aspen Flucil ^a Flopen ^a Flubiclox ^a MX	AS CS GM
FLUCLOXACILLIN								
<u>CAUTION:</u> 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.								
<u>Restricted benefit</u> Serious staphylococcal infections.								
5090X	Capsule 250 mg	24	..	..	11.56	12.55	^a Flopen ^a Floxsig ^a Staphylex 250	CS SI AF
				^B 0.45	12.01	12.55	^a Floxapen	GK
5091Y	Capsule 500 mg	24	..	..	18.57	19.56	^a Flopen ^a Floxsig ^a Staphylex 500	CS SI AF
				^B 0.57	19.14	19.56	^a Floxapen	GK
5092B	Powder for syrup 125 mg per 5 mL, 100 mL	#1	..	..	#13.38	14.76	Floxapen	GK
5093C	Powder for syrup 250 mg per 5 mL, 100 mL	#1	..	..	#16.98 ^B 0.09 #17.07	18.36 18.36	^a Flopen ^a Floxapen	CS GK
• Combinations of penicillins, incl. beta-lactamase inhibitors AMOXYCILLIN with CLAVULANIC ACID								
<u>CAUTION:</u> Hepatotoxicity has been reported with this drug.								
<u>Restricted benefit</u> Infections where resistance to amoxycillin is suspected; Infections where resistance to amoxycillin is proven.								
5008N	Tablet 500 mg-125 mg	10	..	..	12.47	13.46	^a Clamohexal Duo 500mg/125mg ^a Clamoxyl Duo ^a Clavulin Duo ^a Curam 500/125 ^a Muric 500/125	HX AL ME SZ SL
				^B 0.99	13.46	13.46	^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
AMOXYCILLIN with CLAVULANIC ACID—cont.							
5006L	Tablet 875 mg-125 mg	10	..	..	15.58	16.57	^a Chem mart Amoxycillin and Clavu- lanic Acid ^a Clamohexal Duo Forte 875mg/125mg ^a Clamoxyl Duo forte ^a Clavulin Duo Forte ^a Curam 875/125 ^a GenRx Amoxycillin and Clavu- lanic Acid ^a Muric 875/125 ^a Terry White Chemists Amoxycillin and Clavu- lanic Acid ^a Augmentin Duo forte
					^B 1.30	16.88	16.57
5009P	Powder for syrup 125 mg- 31.25 mg per 5 mL, 75 mL	‡1	..	..	#12.10	13.48	^a Clamohexal 125mg/ 31.25mg/5mL ^a Clamoxyl ^a Clavulin ^a Augmentin
					^B 0.96	#13.06	13.48
5011R	Powder for syrup 400 mg- 57 mg per 5 mL, 60 mL	‡1	..	..	#14.02	15.40	^a Clamohexal Duo 400mg/57mg/ 5mL ^a Clamoxyl Duo 400 ^a Clavulin Duo 400 ^a Augmentin Duo 400
					^B 0.98	#15.00	15.40
TICARCILLIN with CLAVULANIC ACID							
Restricted benefit							
<i>Infections where positive bacteriological evidence confirms that this antibiotic is an appropriate therapeutic agent.</i>							
5230G	Powder for injection 3 g- 100 mg (solvent required) (code 7043Q applies to above item with approved solvent)	10	..	..	147.79	30.70	Timentin GK

**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 beta-lactam antibacterials								
• <i>First-generation cephalosporins</i>								
CEPHALEXIN								
3317N	Capsule 250 mg	20	..	..	8.24	9.23	^a Chem mart Cephalexin	CH
							^a Cilex	GM
							^a GenRx	GX
							Cephalexin	
							^a Ialex	LN
							^a Ibilex 250	AF
							^a Rancef	RA
							^a Sporahexal	HX
							^a Terry White Chemists	TW
							Cephalexin	
				^B 2.39	10.63	9.23	^a Keflex	AS
3318P	Capsule 500 mg	20	..	..	10.69	11.68	^a Chem mart Cephalexin	CH
							^a Cilex	GM
							^a GenRx	GX
							Cephalexin	
							^a Ialex	LN
							^a Ibilex 500	AF
							^a Rancef	RA
							^a Sporahexal	HX
							^a Terry White Chemists	TW
							Cephalexin	
				^B 2.84	13.53	11.68	^a Keflex	AS
3319Q	Granules for syrup 125 mg per 5 mL, 100 mL	‡1	..	..	#11.29	12.67	^a Chem mart Cephalexin	CH
							^a Cilex	GM
							^a GenRx	GX
							Cephalexin	
							^a Ialex	LN
							^a Ibilex 125	AF
							^a Terry White Chemists	TW
							Cephalexin	
				^B 2.47	#13.76	12.67	^a Keflex	AS
3320R	Granules for syrup 250 mg per 5 mL, 100 mL	‡1	..	..	#13.07	14.45	^a Chem mart Cephalexin	CH
							^a Cilex	GM
							^a GenRx	GX
							Cephalexin	
							^a Ialex	LN
							^a Ibilex 250	AF
							^a Terry White Chemists	TW
							Cephalexin	
				^B 2.82	#15.89	14.45	^a Keflex	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	
CEPHALOTHIN								
3376Q	Powder for injection 1 g	10	..	.. B0.28	42.72 43.00	30.70 30.70	a MX a Keflin Neutral	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	..	..	13.41	14.40	a Chem mart Cefaclor CD a Douglas Cefaclor-CD a GenRx Cefaclor CD a Karlor CD a Keflor CD a Ozcef a Terry White Chemists Cefaclor CD	CH GM GX LN AF RA TW AS
				B2.91	16.32	14.40	a Ceclor CD	AS
5046N	Powder for oral suspension 125 mg per 5 mL, 100 mL	‡1	..	..	#13.41	14.79	a Aclor 125 a Chem mart Cefaclor a GenRx Cefaclor a Keflor a Terry White Chemists Cefaclor	AW CH GX AF TW AS
				B2.54	#15.95	14.79	a Ceclor	AS
5047P	Powder for oral suspension 250 mg per 5 mL, 75 mL	‡1	..	..	#13.82	15.20	a Aclor 250 a Chem mart Cefaclor a GenRx Cefaclor a Keflor a Terry White Chemists Cefaclor	AW CH GX AF TW AS
				B2.62	#16.44	15.20	a Ceclor	AS
CEFUROXIME AXETIL								
5052X	Tablet 250 mg (base)	14	..	..	14.87	15.86	Zinnat	GK

**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	
• Third-generation cephalosporins CEFOTAXIME Restricted benefit <i>Infections where positive bacteriological evidence confirms that this antibiotic is an appropriate therapeutic agent.</i>								
5048Q	Powder for injection 1 g	10	..	.. B26.40	25.85 *52.25	26.84 26.84	a MX a Cefotaxime Sandoz	SZ
5049R	Powder for injection 2 g	10	..	.. B48.60	43.45 *92.05	30.70 30.70	a MX 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	..	..	8.02	9.01	a Resprim a Septrin	AF SI
3390K	Tablet 160 mg-800 mg	10	..	..	8.93	9.92	a Bactrim DS a Chem mart Trimethoprim with Sulfame- thoxazole DS a GenRx Trimethoprim with Sulfame- thoxazole DS a Resprim Forte a Terry White Chemists Trimethoprim with Sulfame- thoxazole DS	RO CH GX AF TW
3391L	Oral suspension 40 mg-200 mg per 5 mL, 100 mL	‡1	..	.. B1.41 B1.85	10.34 8.51 10.36	9.92 9.50 9.50	a Septrin Forte a Bactrim a Resprim a Septrin	SI RO AF SI
Macrolides, lincosamides and streptogramins • Macrolides ERYTHROMYCIN								
3325B	Capsule 250 mg	25	..	.. B1.72	8.99 10.71	9.98 9.98	a DBL Erythromycin a Eryc	FA MX

**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	..	.. B2.81	8.67 11.48	9.66 9.66	^a E-Mycin ^a E.E.S. 400 Filmstab	AF AB
3334L	Powder for oral liquid 200 mg (base) per 5 mL, 100 mL	‡1	..	.. B2.12	#10.77 #12.89	12.15 12.15	^a E-Mycin 200 ^a E.E.S. 200	AF AB
3337P	Powder for oral liquid 400 mg (base) per 5 mL, 100 mL	‡1	..	.. B1.71	#12.34 #14.05	13.72 13.72	^a E-Mycin 400 ^a E.E.S. Granules	AF AB
ERYTHROMYCIN LACTOBIONATE								
5088T	Powder for I.V. infusion 1 g (base)	5	..	..	*49.65	30.70	Erythrocin-I.V.	AB
• Lincosamides								
CLINDAMYCIN								
Restricted benefit								
<i>Gram-positive coccal infections where these cannot be safely and effectively treated with a penicillin.</i>								
5057E	Capsule 150 mg	25	..	.. B1.41	18.71 20.12	19.70 19.70	^a Cleocin ^a Dalacin C	KR PH
LINCOMYCIN								
5144R	Injection 600 mg in 2 mL	5	..	..	28.73	29.72	Lincocin	PH
Other antibacterials								
• Glycopeptide antibacterials								
VANCOMYCIN								
Restricted benefit								
<i>Prophylaxis of endocarditis in patients hypersensitive to penicillin.</i>								
3323X	Powder for injection 500 mg (500,000 i.u.) vancomycin activity	2	..	..	*50.81	30.70	^a Vancocin ^a MX	AS
• Imidazole derivatives								
METRONIDAZOLE								
3339R	Tablet 200 mg	21	..	.. B1.92	7.11 9.03	8.10 8.10	^a Metrogyl 200 ^a Metronide 200 ^a Flagyl	AF HP AV
5159M	Tablet 400 mg	5	..	..	7.01	8.00	Metrogyl 400	AF
5157K	Suppositories 500 mg, 10	‡1	..	..	20.15	21.14	Flagyl	AV
METRONIDAZOLE								
Restricted benefit								
<i>Treatment of anaerobic infections.</i>								
5155H	Tablet 400 mg	21	..	.. B2.00	9.75 11.75	10.74 10.74	^a Metrogyl 400 ^a Metronide 400 ^a Flagyl	AF HP AV

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	
<i>METRONIDAZOLE—cont.</i>								
<u>Restricted benefit</u>								
<i>Treatment, in a hospital, of acute anaerobic sepsis.</i>								
5154G	<i>I.V. infusion 500 mg in 100 mL</i>	5	..	..	*42.35	30.70	BX	
3341W	METRONIDAZOLE BENZOATE Oral suspension 320 mg per 5 mL (equivalent to 200 mg metronidazole in 5 mL), 100 mL	‡1	..	..	14.47	15.46	Flagyl S	AV

MUSCULO-SKELETAL SYSTEM

ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS

Antiinflammatory and antirheumatic products, non-steroids

• ***Acetic acid derivatives and related substances***

5079H	DICLOFENAC SODIUM Suppository 100 mg	40	..	..	*22.83	23.82	Voltaren 100	NV

DICLOFENAC SODIUM

Restricted benefit

***Chronic arthropathies (including osteoarthritis) with an inflammatory component;
Bone pain due to malignant disease.***

5076E	<i>Tablet 25 mg (enteric coated)</i>	100	..	..	*13.63	14.62	^a Chem mart	CH
							<i>Diclofenac</i>	
							^a Clonac 25	AW
							^a Diclofenac-BC	BG
							^a Diclohexal	HX
							^a Dinac	GM
							^a GenRx	GX
							<i>Diclofenac</i>	
							^a Terry White	TW
							<i>Chemists</i>	
							<i>Diclofenac</i>	
				..	13.63	14.62	^a Fenac 25	AF
				^B3.18	*16.81	14.62	^a Voltaren 25	NV
5077F	<i>Tablet 50 mg (enteric coated)</i>	50	..	..	11.06	12.05	^a Chem mart	CH
							<i>Diclofenac</i>	
							^a Clonac 50	AW
							^a Diclohexal	HX
							^a Dinac	GM
							^a Fenac	AF
							^a GenRx	GX
							<i>Diclofenac</i>	
							^a Terry White	TW
							<i>Chemists</i>	
							<i>Diclofenac</i>	
				^B3.09	14.15	12.05	^a Voltaren 50	NV

**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	
5128X	INDOMETHACIN Suppository 100 mg	40	..	..	*20.53	21.52	Indocid	MK
INDOMETHACIN								
<u>Restricted benefit</u>								
<i>Chronic arthropathies (including osteoarthritis) with an inflammatory component; Bone pain due to malignant disease.</i>								
5126T	Capsule 25 mg	100	..	..	*10.55	11.54	^a Arthrexin	AF
				^B 2.98	*13.53	11.54	^a Indocid	MK
SULINDAC								
<u>Restricted benefit</u>								
<i>Chronic arthropathies (including osteoarthritis) with an inflammatory component; Bone pain due to malignant disease.</i>								
5217N	Tablet 100 mg	100	..	..	*14.63	15.62	Aclin	AF
5218P	Tablet 200 mg	50	..	..	13.62	14.61	Aclin 200	AF
• Oxicams								
PIROXICAM								
<u>Restricted benefit</u>								
<i>Chronic arthropathies (including osteoarthritis) with an inflammatory component.</i>								
5201R	Dispersible tablet 10 mg	50	..	..	12.91	13.90	^a GenRx	GX
							^a Piroxicam Dispersible	
							^a Mobilis D-10	AF
							^a Pirohexal-D	HX
				^B 2.66	15.57	13.90	^a Feldene-D	PF
5202T	Dispersible tablet 20 mg	25	..	..	12.52	13.51	^a Chem mart	CH
							^a Piroxicam Dispersible	
							^a GenRx	GX
							^a Piroxicam Dispersible	
							^a Mobilis D-20	AF
							^a Pirohexal-D	HX
							^a Terry White Chemists	TW
							^a Piroxicam Dispersible	
				^B 2.64	15.16	13.51	^a Feldene-D	PF
5203W	Capsule 10 mg	50	..	..	12.91	13.90	^a Chem mart	CH
							^a Piroxicam	
							^a GenRx	GX
							^a Piroxicam	
							^a Mobilis 10	AF
							^a Terry White Chemists	TW
							^a Piroxicam	
				^B 2.66	15.57	13.90	^a Feldene	PF

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	
PIROXICAM—cont.								
5204X	Capsule 20 mg	25	..	..	12.52	13.51	^a Chem mart	CH
							^a Piroxicam	
							^a GenRx	GX
							^a Piroxicam	
							^a Mobilis 20	AF
							^a Terry White	TW
							Chemists	
							Piroxicam	
				B2.64	15.16	13.51	^a Feldene	PF
• Propionic acid derivatives								
IBUPROFEN								
5124Q	Tablet 400 mg	30	..	..	7.80	8.79	Brufen	AB
IBUPROFEN								
Restricted benefit								
Chronic arthropathies (including osteoarthritis) with an inflammatory component; Bone pain due to malignant disease.								
5121M	Tablet 200 mg	100	..	..	*10.55	11.54	Rafen 200	AF
5123P	Tablet 400 mg	90	..	..	*13.10	14.09	Brufen	AB
KETOPROFEN								
5139L	Suppository 100 mg	40	..	..	*21.23	22.22	Orudis	AV
KETOPROFEN								
Restricted benefit								
Chronic arthropathies (including osteoarthritis) with an inflammatory component.								
5136H	Capsule 200 mg (sustained release)	28	..	..	15.40	16.39	^a Oruvail SR	HP
				B1.95	17.35	16.39	^a Orudis SR 200	AV
NAPROXEN								
Restricted benefit								
Chronic arthropathies (including osteoarthritis) with an inflammatory component; Bone pain due to malignant disease.								
5176K	Tablet 250 mg	100	..	..	*14.45	15.44	^a Inza 250	AF
				B3.00	*17.45	15.44	^a Naprosyn	RO
5177L	Tablet 500 mg	50	..	..	13.42	14.41	^a Inza 500	AF
				B1.75	15.17	14.41	^a Naprosyn	RO
5178M	Tablet 750 mg (sustained release)	28	..	..	12.75	13.74	^a Proxen SR 750	MD
				B1.62	14.37	13.74	^a Naprosyn SR750	RO
5179N	Tablet 1 g (sustained release)	28	..	..	15.28	16.27	^a Proxen SR 1000	MD
				B1.72	17.00	16.27	^a Naprosyn SR1000	RO

**PREPARATIONS WHICH MAY BE PRESCRIBED BY PARTICIPATING DENTAL
PRACTITIONERS FOR DENTAL TREATMENT ONLY—cont.**

Code	Name, Restriction, Manner of administration and form	Max. No. of Qty Rpts Premium	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Proprietary Name and Manufacturer	
NAPROXEN SODIUM						
Restricted benefit						
<i>Chronic arthropathies (including osteoarthritis) with an inflammatory component; Bone pain due to malignant disease.</i>						
5186Y	Tablet 550 mg	50	13.68 B2.91 16.59	14.67 14.67	^a Crysanal ^a Anaprox 550	MD RO

NOTE:

Naproxen sodium 550 mg is approximately equivalent to 500 mg of naproxen acid.

NERVOUS SYSTEM**ANALGESICS****Opioids**• **Natural opium alkaloids**

CODEINE PHOSPHATE						
5063L	Tablet 30 mg	20	10.92	11.91	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	7.26	8.25	^a Codalgin Forte ^a Codapane Forte ^a Dolaforte ^a Dymadon Forte ^a Prodeine Forte ^a Panadeine Forte	FM AL CO GK DK SW
			B1.84 9.10	8.25		

HYDROMORPHONE HYDROCHLORIDE**CAUTION:**

The risk of drug dependence is high.

5129Y	Injection 2 mg in 1 mL	5	12.46	13.45	Dilaudid	AB
5130B	Injection 10 mg in 1 mL	5	17.58	18.57	Dilaudid-HP	AB
5131C	Injection 50 mg in 5 mL	5	45.12	30.70	Dilaudid-HP	AB

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	12.73	13.72	Dilaudid	AB
5116G	Tablet 4 mg	20	17.57	18.56	Dilaudid	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	
HYDROMORPHONE HYDROCHLORIDE—cont.								
5117H	Tablet 8 mg	20	..	..	26.90	27.89	Dilaudid	AB
5132D	Oral liquid 1 mg per mL, 473 mL	1	..	..	47.34	30.70	Dilaudid	AB

NOTE:

Prescribing of drugs of addiction by dentists is not permitted in some States/Territories.

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	..	..	17.45	18.44	Ordine 2	MF
5238Q	Oral solution 5 mg per mL, 200 mL	1	..	..	20.24	21.23	Ordine 5	MF
5239R	Oral solution 10 mg per mL, 200 mL	1	..	..	24.64	25.63	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	..	..	12.51	13.50	MX	
5169C	Injection 15 mg in 1 mL	5	..	..	12.82	13.81	MX	
5170D	Injection 30 mg in 1 mL	5	..	..	14.20	15.19	MX	

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	..	..	13.44	14.43	Anamorph	FM

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 SULFATE—cont.								
Restricted benefit								
<i>Chronic severe disabling pain not responding to non-narcotic analgesics.</i>								
5162Q	Tablet 5 mg (controlled release)	20	..	..	14.74	15.73	MS Contin	MF
5164T	Tablet 10 mg (controlled release)	20	..	..	15.87	16.86	MS Contin	MF
5161P	Tablet 15 mg (controlled release)	20	..	..	19.49	20.48	MS Contin	MF
5165W	Tablet 30 mg (controlled release)	20	..	..	28.27	29.26	MS Contin	MF
5166X	Tablet 60 mg (controlled release)	20	..	..	43.76	30.70	MS Contin	MF
5167Y	Tablet 100 mg (controlled release)	20	..	..	59.99	30.70	MS Contin	MF
5246D	Capsule 10 mg (containing sustained release pellets)	20	..	..	15.87	16.86	Kapanol	GK
5240T	Capsule 20 mg (containing sustained release pellets)	20	..	..	20.77	21.76	Kapanol	GK
5064M	Capsule 30 mg (controlled release)	10	..	..	19.49	20.48	MS Mono	MF
5241W	Capsule 50 mg (containing sustained release pellets)	20	..	..	35.65	30.70	Kapanol	GK
5065N	Capsule 60 mg (controlled release)	10	..	..	28.27	29.26	MS Mono	MF
5066P	Capsule 90 mg (controlled release)	10	..	..	34.12	30.70	MS Mono	MF
5242X	Capsule 100 mg (containing sustained release pellets)	20	..	..	59.99	30.70	Kapanol	GK
5067Q	Capsule 120 mg (controlled release)	10	..	..	43.76	30.70	MS Mono	MF
5171E	Sachet containing controlled release granules for oral suspension, 20 mg per sachet	20	..	..	20.77	21.76	MS Contin Suspension 20 mg	MF
5243Y	Sachet containing controlled release granules for oral suspension, 30 mg per sachet	20	..	..	28.27	29.26	MS Contin Suspension 30 mg	MF
5244B	Sachet containing controlled release granules for oral suspension, 60 mg per sachet	20	..	..	43.76	30.70	MS Contin Suspension 60 mg	MF
5245C	Sachet containing controlled release granules for oral suspension, 100 mg per sachet	20	..	..	59.99	30.70	MS Contin Suspension 100 mg	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
• Phenylpiperidine derivatives PETHIDINE HYDROCHLORIDE CAUTION: <i>The risk of drug dependence is high.</i> Restricted benefit <i>Short-term treatment of acute pain.</i>							
5200Q	Injection 100 mg in 2 mL	5	..	..	11.20	12.19	MX
NOTE: <i>Prescribing of drugs of addiction by dentists is not permitted in some States/Territories.</i>							
• Other opioids TRAMADOL HYDROCHLORIDE Restricted benefit <i>For acute pain where aspirin and/or paracetamol alone are inappropriate or have failed;</i> <i>For dosage titration in chronic pain where aspirin and/or paracetamol alone are</i> <i>inappropriate or have failed.</i>							
5232J	Capsule 50 mg	20	..	..	8.64	9.63	^a Chem mart CH ^a Tramadol ^a GenRx GX ^a Tramadol ^a Terry White TW ^a Chemists ^a Tramadol ^a Tramedo AF ^a Zydol AW ^B 1.45 10.09 9.63 ^a Tramal CS
Restricted benefit <i>For pain where aspirin and/or paracetamol alone are inappropriate or have failed.</i>							
3338Q	Tablet 50 mg (sustained release)	20	..	..	11.79	12.78	Tramal SR 50 CS
5234L	Tablet 100 mg (sustained release)	20	..	..	14.64	15.63	^a Tramahexal SR HX ^a Zydol SR 100 AW ^B 1.94 16.58 15.63 ^a Tramal SR 100 CS
5235M	Tablet 150 mg (sustained release)	20	..	..	17.94	18.93	^a Tramahexal SR HX ^a Zydol SR 150 AW ^B 1.94 19.88 18.93 ^a Tramal SR 150 CS
5236N	Tablet 200 mg (sustained release)	20	..	..	20.73	21.72	^a Tramahexal SR HX ^a Zydol SR 200 AW ^B 1.92 22.65 21.72 ^a Tramal SR 200 CS
5150C	Oral drops 100 mg per mL, 10 mL	‡1	..	..	8.64	9.63	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. No. of Qty Rpts Premium	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Proprietary Name and Manufacturer
TRAMADOL HYDROCHLORIDE—cont.					
<u>Restricted benefit</u>					
<i>Short-term treatment of acute pain.</i>					
5231H	Injection 100 mg in 2 mL	5	10.53	11.52	^a Tramahexal ^a Tramal 100 HX CS
Other analgesics and antipyretics					
• Salicylic acid and derivatives					
ASPIRIN					
5018D	Tablet 300 mg (dispersible)	96	7.32	8.31	Solprin RC
• Anilides					
PARACETAMOL					
5196L	Tablet 500 mg	100	7.70	8.69	^a Chem mart CH Chemadol ^a Dymadon P PC ^a Febridol GM ^a Panamax SW ^b Parahexal HX ^a Paralgin FM ^b Parmol AW ^a Terry White TW Chemists Paracetamol ^b Tylenol JT
3348F	Oral liquid 120 mg per 5 mL, 100 mL	‡1	7.98	8.97	Panamax SW
3349G	Oral liquid 240 mg per 5 mL, 200 mL	‡1	9.22	10.21	Panamax 240 Elixir SW
PARACETAMOL					
<u>Restricted benefit</u>					
<i>Chronic arthropathies.</i>					
5224Y	Tablet 500 mg	300	*12.80	13.79	^a Chem mart CH Chemadol ^a Dymadon P PC ^a Febridol GM ^a Panamax SW ^b Parahexal HX ^a Paralgin FM ^b Parmol AW ^a Terry White TW Chemists Paracetamol ^b Tylenol JT

**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	
ANTIEPILEPTICS								
Antiepileptics								
• Carboxamide derivatives								
CARBAMAZEPINE								
5039F	Tablet 100 mg	200	..	..	21.38	22.37	^a Carbamazepine-BC	BG
							^a Carbamazepine Sandoz	SZ
				^B 3.00	24.38	22.37	^a Tegretol 100	NV
5040G	Tablet 200 mg	200	..	..	35.48	30.70	^a Carbamazepine-BC	BG
							^a Carbamazepine Sandoz	SZ
				^B 3.30	38.78	30.70	^a Teril	AF
							^a Tegretol 200	NV
5038E	Tablet 200 mg (controlled release)	200	..	..	36.09	30.70	Tegretol CR 200	NV
5037D	Tablet 400 mg (controlled release)	200	..	..	63.96	30.70	Tegretol CR 400	NV
5041H	Oral suspension 100 mg per 5 mL, 300 mL	‡1	..	..	19.43	20.42	Tegretol Liquid	NV
ANTI-PARKINSON DRUGS								
Anticholinergic agents								
• Ethers of tropine or tropine derivatives								
BENZTROPINE MESYLATE								
5031T	Injection 2 mg in 2 mL	5	..	..	20.86	21.85	Cogentin	MK
PSYCHOLEPTICS								
Anxiolytics								
• Benzodiazepine derivatives								
DIAZEPAM								
5071X	Tablet 2 mg	50	..	..	7.13	8.12	^a Antenex 2	AF
							^a Valpam 2	AW
				^B 0.87	8.00	8.12	Ducene	SU
				^B 1.27	8.40	8.12	^a Valium	RO
5072Y	Tablet 5 mg	50	..	..	7.35	8.34	^a Antenex 5	AF
							^a Diazepam-DP	GM
							^a Valpam 5	AW
				^B 0.91	8.26	8.34	Ducene	SU
				^B 1.28	8.63	8.34	^a Valium	RO
5073B	Injection 10 mg in 2 mL	5	..	..	10.76	11.75	MX	
OXAZEPAM								
5192G	Tablet 15 mg	25	..	..	6.39	7.38	^a Alepam 15	AF
				^B 1.74	8.13	7.38	^a Serepax	SI
5193H	Tablet 30 mg	25	..	..	6.59	7.58	^a Alepam 30	AF
							^a Murelax	FM
				^B 1.85	8.44	7.58	^a Serepax	SI

**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	
Hypnotics and sedatives								
• Benzodiazepine derivatives								
NITRAZEPAM								
5189D	Tablet 5 mg	25	..	.. B1.96	7.02 8.98	8.01 ^a 8.01 ^a	Alodorm Mogadon	AF VT
TEMAZEPAM								
5221T	Tablet 10 mg	25	..	.. B1.77	7.02 8.79	8.01 ^a 8.01 ^a	Temaze Temtabs Normison	AF FM 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	..	..	18.46	19.45	AP	

SENSORY ORGANS

OPHTHALMOLOGICALS

Antiinfectives

• **Antibiotics**

CHLORAMPHENICOL

5055C	Eye drops 5 mg per mL (0.5%), 10 mL	‡1	..	..	7.91	8.90	Chloromycetin Chlorsig	PF SI

VARIOUS

ALL OTHER THERAPEUTIC PRODUCTS

All other therapeutic products

• **Antidotes**

NALOXONE HYDROCHLORIDE

5174H	Injection 800 micrograms in 2 mL	1	..	..	22.95	23.94	Naloxone Min-I-Jet	CS
5175J	Injection 2 mg in 5 mL	1	..	..	33.61	30.70	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	..	..	16.38	17.37	PF	

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.

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; and
- \$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 (telephone 132 290) or the Australian Government adviser below:

Highly Specialised Drugs Working Party Secretariat (02) 6289 7238

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	
ABACAVIR SULFATE					
<u>Private hospital authority required</u>					
<i>Treatment of HIV infection in patients with:</i>					
<i>(a) CD4 cell counts of less than 500 per cubic millimetre; or</i>					
<i>(b) viral load of greater than 10,000 copies per mL.</i>					
6264Q	Tablet 300 mg (base)	60	423.00	Ziagen	GK
6265R	Oral solution 20 mg (base) per mL, 240 mL	1	75.20	Ziagen	GK
<u>NOTE:</u>					
<i>These prices are based on special supply arrangements—see Pharmaceutical Benefits Pricing Authority relativity sheet for full details.</i>					
ABACAVIR SULFATE with LAMIVUDINE					
<u>Private hospital authority required</u>					
<i>Treatment of HIV infection in patients over 12 years of age, weighing 40 kg or more, with:</i>					
<i>(a) CD4 cell counts of less than 500 per cubic millimetre; or</i>					
<i>(b) viral load of greater than 10,000 copies per mL.</i>					
6458X	Tablet 600 mg (base)-300 mg	30	564.00	Kivexa	GK
ABACAVIR SULFATE with LAMIVUDINE and ZIDOVUDINE					
<u>Private hospital authority required</u>					
<i>Treatment of HIV infection in patients over 12 years of age, weighing 40 kg or more, with:</i>					
<i>(a) CD4 cell counts of less than 500 per cubic millimetre; or</i>					
<i>(b) viral load of greater than 10,000 copies per mL.</i>					
6327B	Tablet 300 mg (base)-150 mg-300 mg	60	852.00	Trizivir	GK
ADEFOVIR DIPVOXIL					
<u>Private hospital authority required</u>					
<i>Patients with chronic hepatitis B who have failed lamivudine therapy and who satisfy all of the following criteria:</i>					
<i>(1) Repeatedly elevated (greater than 1.2 times the upper limit of normal) 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 (HBe antigen positive and/or serum HBV DNA positive);</i>					
<i>(2) Female patients of child-bearing age are not pregnant, not breast-feeding, and are using an effective form of contraception.</i>					
<i>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.</i>					
<u>NOTE:</u>					
<i>Patients should have undergone a liver biopsy at some point since initial diagnosis to obtain histological evidence of chronic hepatitis.</i>					
<i>Patients may receive treatment in combination with lamivudine for the initial 3 months only of PBS-subsidised adefovir dipivoxil therapy. Patients who are immunocompromised may receive treatment in combination with lamivudine for the initial 12 months of PBS-subsidised adefovir dipivoxil therapy. Thereafter, PBS-subsidised adefovir dipivoxil must be used as monotherapy.</i>					
6450L	Tablet 10 mg	30	625.00	Hepsera	GI

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer \$	Proprietary Name and Manufacturer	
AMPRENAVIR					
<u>Private hospital authority required</u>					
<i>Treatment of HIV infection in patients who have:</i>					
<i>(a) failed treatment with other protease inhibitors; or</i>					
<i>(b) experienced treatment-limiting toxicity with other protease inhibitors.</i>					
6333H	Capsule 150 mg	240	227.50	Agenerase	GK
6334J	Oral solution 15 mg per mL, 240 mL	1	19.50	Agenerase	GK
APOMORPHINE					
HYDROCHLORIDE					
<u>Private hospital authority required</u>					
<i>Parkinson's disease in patients severely disabled by motor fluctuations which do not respond to other therapy.</i>					
6104G	Injection 10 mg in 1 mL	5	33.47	Apomine	MX
ATAZANAVIR SULFATE					
<u>Private hospital authority required</u>					
<i>Treatment, in combination with 2 or more other antiretroviral drugs, of HIV infection in patients with:</i>					
<i>(a) CD4 cell counts of less than 500 per cubic millimetre; or</i>					
<i>(b) viral load of greater than 10,000 copies per mL.</i>					
6451M	Capsule 150 mg (base)	60	521.91	Reyataz	BQ
6452N	Capsule 200 mg (base)	60	695.88	Reyataz	BQ
AZITHROMYCIN					
<u>Private hospital authority required</u>					
<i>Prophylaxis against Mycobacterium avium complex infections in HIV-positive patients with CD4 cell counts of less than 75 per cubic millimetre.</i>					
6221K	Tablet 600 mg	8	67.82	Zithromax	PF
BACLOFEN					
<u>Private hospital authority required</u>					
<i>Severe chronic spasticity, where oral antispastic agents have failed or have caused unacceptable side effects, in patients with chronic spasticity:</i>					
<i>(1) of cerebral origin; or</i>					
<i>(2) due to multiple sclerosis; or</i>					
<i>(3) due to spinal cord injury; or</i>					
<i>(4) due to spinal cord disease.</i>					
6284R	Intrathecal injection 10 mg in 5 mL	1	148.37	Lioresal Intrathecal	NV
6285T	Intrathecal injection 10 mg in 20 mL	1	148.37	Lioresal Intrathecal	NV

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer \$	Proprietary Name and Manufacturer

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 or PBS-subsidised epoprostenol 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 adult 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.*

Adult patients:

From 1 August 2006, adult patients with primary pulmonary hypertension will be able to access, through the PBS, either bosentan monohydrate, iloprost trometamol or epoprostenol sodium. Once these patients are approved initial treatment with 1 of these 3 drugs, they may swap between bosentan monohydrate, iloprost trometamol and epoprostenol 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 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 (unless the prescriber wishes to submit new baselines).

Patients may only swap to bosentan monohydrate, iloprost trometamol or epoprostenol sodium if they have not failed prior PBS-subsidised treatment with that drug.

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer \$	Proprietary Name and Manufacturer

BOSENTAN MONOHYDRATE—cont.

Adult patients with pulmonary arterial hypertension secondary to scleroderma will be able to access, through the PBS, either bosentan monohydrate or iloprost trometamol. Once these patients are approved initial treatment with 1 of these 2 drugs, they may swap between bosentan monohydrate and iloprost trometamol 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 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 (unless the prescriber wishes to submit new baselines).

Patients may only swap to bosentan monohydrate or iloprost trometamol if they have not failed prior PBS-subsidised treatment with that drug.

Patients with pulmonary arterial hypertension secondary to connective tissue disease other than scleroderma are only eligible for treatment with iloprost trometamol. They may not swap to bosentan monohydrate or epoprostenol sodium.

Patients with drug-induced pulmonary arterial hypertension are only eligible for treatment with iloprost trometamol. They may not swap to bosentan monohydrate or epoprostenol sodium.

Patients under 18 years of age:

From 1 August 2006, patients aged less than 18 years with primary pulmonary hypertension are eligible to receive PBS-subsidised treatment with either bosentan monohydrate or epoprostenol sodium. Once these patients are approved initial treatment with 1 of these 2 drugs, they may swap between bosentan monohydrate and epoprostenol 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 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 (unless the prescriber wishes to submit new baselines). They may qualify for treatment with iloprost trometamol when they are aged 18 years or older.

Patients may only swap to bosentan monohydrate or epoprostenol 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.*

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer \$	Proprietary Name and Manufacturer

BOSENTAN MONOHYDRATE—cont.

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 or epoprostenol 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.

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 or with epoprostenol sodium on or after 1 August 2006, 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.

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer \$	Proprietary Name and Manufacturer

BOSENTAN MONOHYDRATE—cont.

Where patients received treatment with either bosentan monohydrate, iloprost trometamol or epoprostenol sodium prior to being commenced on PBS-subsidised treatment with the first of either bosentan monohydrate, iloprost trometamol or epoprostenol 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 or epoprostenol sodium, whichever of the 3 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.

NOTE:

5. Definition of response to 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.

Code	Item and Section 100 Restriction	Pack Size	Price ex	Proprietary
			Manufacturer \$	Name and Manufacturer

BOSENTAN MONOHYDRATE—cont.

6. Authority approval requirements. *[The following 2 sections are only relevant to the PBS listing of bosentan monohydrate. The requirements specific to iloprost trometamol or epoprostenol sodium are given in parts 6 and 7 of the NOTE included in the iloprost trometamol or epoprostenol 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 or epoprostenol 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.

(c) Swapping between bosentan monohydrate, iloprost trometamol and epoprostenol sodium.

For eligible patients, applications to swap between these 3 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.

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer \$	Proprietary Name and Manufacturer

BOSENTAN MONOHYDRATE—cont.

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 diagrammatical 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

Application for initial PBS-subsidised treatment with bosentan monohydrate of adult patients who have not received prior PBS-subsidised treatment with iloprost trometamol or epoprostenol 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.

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer \$	Proprietary Name and Manufacturer

BOSENTAN MONOHYDRATE—cont.

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 [may be downloaded from the Medicare Australia website (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 copy of a signed patient acknowledgment form indicating that the patient understands and acknowledges that PBS-subsidised treatment with bosentan monohydrate for primary pulmonary hypertension or pulmonary arterial hypertension secondary to scleroderma, 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, 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 is commenced on bosentan monohydrate treatment due to an adverse event or a contraindication to vasodilator treatment, 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

Application for initial PBS-subsidised treatment with bosentan monohydrate of adult patients who have not received prior PBS-subsidised treatment with iloprost trometamol or epoprostenol 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.*

continued ➤

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer \$	Proprietary Name and Manufacturer

BOSENTAN MONOHYDRATE—cont.

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) two completed authority prescription forms [see Note for authority approval requirements]; and*
- (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form [may be downloaded from the Medicare Australia website (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 copy of a signed patient acknowledgment form indicating that the patient understands and acknowledges that PBS-subsidised treatment with bosentan monohydrate for primary pulmonary hypertension or pulmonary arterial hypertension secondary to scleroderma, 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, 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

Application for initial PBS-subsidised treatment of patients aged less than 18 years who have not received prior PBS-subsidised treatment with epoprostenol sodium and who have been assessed by a physician from a designated hospital and who 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.

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer \$	Proprietary Name and Manufacturer

BOSENTAN MONOHYDRATE—cont.

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 [may be downloaded from the Medicare Australia website (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 copy of a patient acknowledgment form, signed by the parent or authorised guardian, indicating that they understand and acknowledge that PBS-subsidised treatment with bosentan monohydrate or epoprostenol sodium 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 is commenced on bosentan monohydrate treatment due to an adverse event or a contraindication to vasodilator treatment, 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

Application for initial PBS-subsidised treatment of patients aged less than 18 years who have not received prior PBS-subsidised treatment with epoprostenol sodium 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.*

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer \$	Proprietary Name and Manufacturer

BOSENTAN MONOHYDRATE—cont.

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 [may be downloaded from the Medicare Australia website (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 copy of a patient acknowledgment form, signed by the parent or authorised guardian, indicating that they understand and acknowledge that PBS-subsidised treatment with bosentan monohydrate or epoprostenol sodium 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

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; 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 [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the results on which approval for the first application for PBS-subsidised bosentan monohydrate, iloprost trometamol or epoprostenol sodium, whichever was initiated first, was granted; and*

Code	Item and Section 100 Restriction	Pack Size	Price ex	Proprietary
			Manufacturer \$	Name and Manufacturer

BOSENTAN MONOHYDRATE—cont.

(3) the date of the first application for PBS-subsidised treatment with bosentan monohydrate, iloprost trometamol or epoprostenol 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 or epoprostenol 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. 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

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.

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 [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the results on which approval for the first application for PBS-subsidised bosentan monohydrate or epoprostenol sodium, whichever was initiated first, was granted; and

(3) the date of the first application for PBS-subsidised treatment with bosentan monohydrate or epoprostenol 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 or epoprostenol 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. 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).

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer \$	Proprietary Name and Manufacturer
BOSENTAN MONOHYDRATE—cont. <u>Public and private hospital authority required</u> <i>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].</i> <i>Applications for authorisation must be in writing and must include:</i> <i>(1) a completed authority prescription form; and</i> <i>(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes results from the 3 tests below, where available:</i> <i>(i) RHC composite assessment; and</i> <i>(ii) ECHO composite assessment; and</i> <i>(iii) 6MWT.</i> <i>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].</i> <i>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.</i> <i>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).</i> <u>Public and private hospital authority required</u> <i>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 who have not responded to bosentan monohydrate therapy [see Note for definition of response], to allow for gradual cessation of treatment.</i> <i>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].</i> <i>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.</i> <i>Under no circumstances will telephone approvals be granted for treatment that would extend the final treatment period beyond 1 month.</i>				
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.

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer \$	Proprietary Name and Manufacturer	
CIDOFOVIR					
<u>Private hospital authority required</u>					
<i>Treatment of cytomegalovirus retinitis in patients with AIDS.</i>					
6247T	Solution for I.V. infusion 375 mg (anhydrous) in 5 mL single use vial	1	900.00	Vistide	PU
CLARITHROMYCIN					
<u>Private hospital authority required</u>					
<i>Treatment of Mycobacterium avium complex infections.</i>					
6151R	Tablet 250 mg	100	48.16	Klacid	AB
6152T	Tablet 500 mg	100	96.32	Klacid	AB
CLOZAPINE					
<u>Private hospital authority required</u>					
<i>Schizophrenia in patients who are:</i>					
<i>(a) non-responsive to other neuroleptic agents; or</i>					
<i>(b) intolerant of other neuroleptic agents.</i>					
6101D	Tablet 25 mg	100	72.00	a Clopine 25 a CloSyn a Clozaril 25	MX ZT NV
6417R	Tablet 50 mg	100	144.00	Clopine 50	MX
6102E	Tablet 100 mg	100	270.00	a Clopine 100 a CloSyn a Clozaril 100	MX ZT NV
6418T	Tablet 200 mg	100	540.00	Clopine 200	MX
CYCLOSPORIN					
<u>CAUTION:</u>					
<i>Careful monitoring of patients is mandatory.</i>					
<u>Private hospital authority required</u>					
<i>For use by organ or tissue transplant recipients.</i>					
6109M	Solution concentrate for I.V. infusion 50 mg in 1 mL ampoule	10	54.10	Sandimmun	NV
6110N	Solution concentrate for I.V. infusion 250 mg in 5 mL ampoule	10	257.95	Sandimmun	NV

continued 

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer \$	Proprietary Name and Manufacturer	
CYCLOSPORIN—cont.					
<u>Private hospital authority required</u>					
<i>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;</i>					
<i>Management (which includes initiation, stabilisation and review of therapy) by:</i>					
<i>(1) dermatologists or clinical immunologists of patients with severe atopic dermatitis for whom other systemic therapies are ineffective or inappropriate;</i>					
<i>(2) 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;</i>					
<i>(3) 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;</i>					
<i>(4) 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.</i>					
6232B	Capsule 10 mg	60	37.20	Neoral 10	NV
6352H	Capsule 25 mg	30	41.63	^a Cicloral	HX
				^a Neoral 25	NV
<u>NOTE:</u>					
<i>A brand premium of \$0.99 applies to Neoral 25 brand. Both brands may not be available in all hospitals.</i>					
6353J	Capsule 50 mg	30	86.60	^a Cicloral	HX
				^a Neoral 50	NV
<u>NOTE:</u>					
<i>A brand premium of \$1.07 applies to Neoral 50 brand. Both brands may not be available in all hospitals.</i>					
6354K	Capsule 100 mg	30	176.45	^a Cicloral	HX
				^a Neoral 100	NV
<u>NOTE:</u>					
<i>A brand premium of \$1.08 applies to Neoral 100 brand. Both brands may not be available in all hospitals.</i>					
6125J	Oral liquid 100 mg per mL, 50 mL	1	315.79	Neoral	NV
DARBEPOETIN ALFA					
<u>Private hospital authority required</u>					
<i>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.</i>					
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

continued

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer \$	Proprietary Name and Manufacturer	
DARBEPOETIN ALFA—cont.					
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
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
DEFERASIROX					
<u>Private hospital authority required</u>					
<i>Chronic iron overload in adults, adolescents and children 6 years and older associated with disorders of erythropoiesis;</i>					
<i>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.</i>					
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:					
<i>These prices are based on special supply arrangements—see Pharmaceutical Benefits Pricing Authority relativity sheet for full details.</i>					
DEFERIPRONE					
<u>Private hospital authority required</u>					
<i>Iron overload in patients with thalassaemia major who are unable to take desferrioxamine therapy;</i>					
<i>Iron overload in patients with thalassaemia major in whom desferrioxamine therapy has proven ineffective.</i>					
6416Q	Tablet 500 mg	100	440.00	Ferriprox	OA

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer \$	Proprietary Name and Manufacturer	
DELAVIDINE MESYLATE					
Private hospital authority required					
<i>Treatment of HIV infection in patients with:</i>					
<i>(a) CD4 cell counts of less than 500 per cubic millimetre; or</i>					
<i>(b) viral load of greater than 10,000 copies per mL.</i>					
6243N	Tablet 100 mg	360	271.58	Rescriptor	PF
DESFERRIOXAMINE MESYLATE					
Private hospital authority required					
<i>Disorders of erythropoiesis associated with treatment-related chronic iron overload.</i>					
6113R	Powder for injection 500 mg vial	10	99.00	^a Desferal 500 mg ^a MX	NV
NOTE:					
<i>A brand premium of \$8.19 applies to Desferal 500 mg brand. Both brands may not be available in all hospitals.</i>					
6270B	Powder for injection 2 g vial	1	39.60	^a Desferal 2 g ^a MX	NV
NOTE:					
<i>A brand premium of \$0.40 applies to Desferal 2 g brand. Both brands may not be available in all hospitals.</i>					
DIDANOSINE					
Private hospital authority required					
<i>Treatment of HIV infection in patients with:</i>					
<i>(a) CD4 cell counts of less than 500 per cubic millimetre; or</i>					
<i>(b) viral load of greater than 10,000 copies per mL.</i>					
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					
<i>Treatment of hypercalcaemia of malignancy refractory to anti-neoplastic therapy.</i>					
6286W	Concentrated injection 15 mg in 5 mL	1	56.89	^a Pamisol	MX
6290C	Injection set containing 4 vials powder for I.V. infusion 15 mg and 4 ampoules solvent 5 mL	1	227.57	^a Aredia 15 mg	NV
NOTE:					
<i>The concentrated injection 15 mg and powder for I.V. infusion 15 mg (after reconstitution) are bioequivalent.</i>					

continued ↗

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer \$	Proprietary Name and Manufacturer	

**DISODIUM PAMIDRONATE—
cont.**

6287X	Concentrated injection 30 mg in 10 mL	1	113.79	^a Pamisol	MX
6279L	Injection set containing 2 vials powder for I.V. infusion 30 mg and 2 ampoules solvent 10 mL	1	227.57	^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	227.57	Pamisol	MX
6289B	Concentrated injection 90 mg in 10 mL	1	341.36	^a Pamisol	MX
6223M	Injection set containing 1 vial powder for I.V. infusion 90 mg and 1 ampoule solvent 10 mL	1	341.36	^a Aredia 90 mg	NV

Private hospital authority required

Multiple myeloma;
Bone metastases from breast cancer.

6289B	Concentrated injection 90 mg in 10 mL	1	341.36	^a Pamisol	MX
6223M	Injection set containing 1 vial powder for I.V. infusion 90 mg and 1 ampoule solvent 10 mL	1	341.36	^a Aredia 90 mg	NV

NOTE:

The concentrated injection 90 mg and powder for I.V. infusion 90 mg (after reconstitution) are bioequivalent.

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;

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer \$	Proprietary Name and Manufacturer	
DORNASE ALFA—cont. (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 ampoule	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 vial	1	622.99	Caelyx	SH
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.					
6283Q	Capsule 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.					

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer \$	Proprietary Name and Manufacturer	
	EMTRICITABINE				
	<u>Private hospital authority required</u>				
	<i>Treatment of HIV infection in patients with:</i>				
	<i>(a) CD4 cell counts of less than 500 per cubic millimetre; or</i>				
	<i>(b) viral load of greater than 10,000 copies per mL.</i>				
6137B	Capsule 200 mg	30	282.00	Emtriva	GI
	ENFUVIRTIDE				
	<u>Private hospital authority required</u>				
	<i>Treatment, in combination with other antiretroviral agents, of HIV infection in antiretroviral experienced patients with treatment failure characterised by:</i>				
	<i>(a) evidence of HIV replication, despite ongoing therapy; or</i>				
	<i>(b) treatment-limiting toxicity to previous antiretroviral agents.</i>				
	<i>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>				
	<i>(i) at least 1 non-nucleoside reverse transcriptase inhibitor; and</i>				
	<i>(ii) at least 1 nucleoside reverse transcriptase inhibitor; and</i>				
	<i>(iii) at least 1 protease inhibitor.</i>				
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				
	<u>Private hospital authority required</u>				
	<i>Patients aged 16 years or older with chronic hepatitis B who satisfy all of the following criteria:</i>				
	<i>(1) Histological evidence of chronic hepatitis on liver biopsy (except in patients with coagulation disorders considered severe enough to prevent liver biopsy);</i>				
	<i>(2) Abnormal serum ALT levels in conjunction with documented chronic hepatitis B infection (HBe antigen positive and/or HBV DNA positive);</i>				
	<i>(3) Female patients of child-bearing age are not pregnant, not breast-feeding, and are using an effective form of contraception.</i>				
	<i>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.</i>				
	<u>NOTE:</u>				
	<i>PBS-subsidised entecavir monohydrate must be used as monotherapy.</i>				
9602J	Tablet 0.5 mg	30	384.30	Baraclude	BQ

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer \$	Proprietary Name and Manufacturer

ENTECAVIR MONOHYDRATE—cont.**Private hospital authority required**

Patients aged 16 years or older with chronic hepatitis B who have failed lamivudine therapy and who satisfy all of the following criteria:

(1) Repeatedly elevated (greater than 1.2 times the upper limit of normal) 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 (HBe antigen positive and/or serum HBV DNA positive);

(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
6339P	Injection 40,000 units in 1 mL pre-filled syringe	1	660.00	Eprex 40,000	JC

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer \$	Proprietary Name and Manufacturer	
EPOETIN BETA					
<u>Private hospital authority required</u>					
<i>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.</i>					
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
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 or PBS-subsidised iloprost trometamol.

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 adult 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.*

continued ➞

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer \$	Proprietary Name and Manufacturer

EPOPROSTENOL SODIUM—cont.**Adult patients:**

From 1 August 2006, adult patients with primary pulmonary hypertension will be able to access, through the PBS, either bosentan monohydrate, iloprost trometamol or epoprostenol sodium. Once these patients are approved initial treatment with 1 of these 3 drugs, they may swap between bosentan monohydrate, iloprost trometamol and epoprostenol 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 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 (unless the prescriber wishes to submit new baselines).

Patients may only swap to bosentan monohydrate, iloprost trometamol or epoprostenol 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, either bosentan monohydrate or iloprost trometamol. Once these patients are approved initial treatment with 1 of these 2 drugs, they may swap between bosentan monohydrate and iloprost trometamol 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 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 (unless the prescriber wishes to submit new baselines).

Patients may only swap to bosentan monohydrate or iloprost trometamol if they have not failed prior PBS-subsidised treatment with that drug.

Patients with pulmonary arterial hypertension secondary to connective tissue disease other than scleroderma are only eligible for treatment with iloprost trometamol. They may not swap to bosentan monohydrate or epoprostenol sodium.

Patients with drug-induced pulmonary arterial hypertension are only eligible for treatment with iloprost trometamol. They may not swap to bosentan monohydrate or epoprostenol sodium.

Patients under 18 years of age:

From 1 August 2006, patients aged less than 18 years with primary pulmonary hypertension are eligible to receive PBS-subsidised treatment with either bosentan monohydrate or epoprostenol sodium. Once these patients are approved initial treatment with 1 of these 2 drugs, they may swap between bosentan monohydrate and epoprostenol 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 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 (unless the prescriber wishes to submit new baselines). They may qualify for treatment with iloprost trometamol when they are aged 18 years or older.

Patients may only swap to bosentan monohydrate or epoprostenol sodium if they have not failed prior PBS-subsidised treatment with that drug.

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer \$	Proprietary Name and Manufacturer

EPOPROSTENOL SODIUM—cont.

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 or epoprostenol 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.**

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer \$	Proprietary Name and Manufacturer

EPOPROSTENOL SODIUM—cont.

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.

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 or with epoprostenol sodium on or after 1 August 2006, 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 or epoprostenol sodium prior to being commenced on PBS-subsidised treatment with the first of either bosentan monohydrate, iloprost trometamol or epoprostenol 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 or epoprostenol sodium, whichever of the 3 drugs the patient received first.

(ii) Patients who received non-PBS-subsidised treatment with epoprostenol sodium prior to 1 August 2006.

For patients with primary pulmonary hypertension who were commenced on epoprostenol sodium treatment prior to 1 August 2006 and who have received less than 6 months of treatment with epoprostenol 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 epoprostenol sodium, bosentan monohydrate, or iloprost trometamol, whichever was initiated first.

For patients with primary pulmonary hypertension who were commenced on epoprostenol sodium treatment prior to 1 August 2006 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 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.

NOTE:

(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.*

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer \$	Proprietary Name and Manufacturer

EPOPROSTENOL SODIUM—cont.

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 epoprostenol sodium, bosentan monohydrate, iloprost trometamol 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 and iloprost trometamol are given in parts 6 and 7 of the NOTE included in the bosentan monohydrate and iloprost trometamol 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 or iloprost trometamol.

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 epoprostenol sodium treatment after 1 August 2006 and patients who received 6 or more months of epoprostenol sodium treatment prior to 1 August 2006 are eligible to receive up to 6 months of treatment per authority application.

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer \$	Proprietary Name and Manufacturer

EPOPROSTENOL SODIUM—cont.

Patients who commenced treatment with epoprostenol sodium prior to 1 August 2006 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 who commenced treatment with epoprostenol sodium prior to 1 August 2006 will be eligible to commence PBS-subsidised treatment with epoprostenol sodium. Thereafter, to be eligible for further PBS-subsidised supply, these patients must demonstrate a response to epoprostenol 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 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 and epoprostenol sodium.

For eligible patients, applications to swap between these 3 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.

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer \$	Proprietary Name and Manufacturer

EPOPROSTENOL SODIUM—cont.**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 diagrammatical 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

Application for initial PBS-subsidised treatment with epoprostenol sodium of adult patients who have not received prior PBS-subsidised treatment with bosentan monohydrate or iloprost trometamol 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 [may be downloaded from the Medicare Australia website (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 copy of a signed patient acknowledgment form 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, 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 is commenced on epoprostenol sodium treatment due to an adverse event or a contraindication to vasodilator treatment, details on the nature of the adverse event or contraindication according to the TGA-approved Product Information must also be provided with the application.

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer \$	Proprietary Name and Manufacturer

EPOPROSTENOL SODIUM—cont.

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

Application for initial PBS-subsidised treatment with epoprostenol sodium of adult patients who have not received prior PBS-subsidised treatment with bosentan monohydrate or iloprost trometamol 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.

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 [may be downloaded from the Medicare Australia website (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 copy of a signed patient acknowledgment form 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, 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].

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer \$	Proprietary Name and Manufacturer

EPOPROSTENOL SODIUM—cont.

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

Application for initial PBS-subsidised treatment with epoprostenol sodium of adult patients who were receiving treatment with epoprostenol sodium prior to 1 August 2006, who have not received prior PBS-subsidised treatment with bosentan monohydrate or iloprost trometamol and who have been assessed by a physician from a designated hospital to have WHO Functional Class III or 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) for patients who have received less than 6 months of epoprostenol sodium treatment at the time of application — a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes results of the following 3 tests, where available, at the time treatment with epoprostenol 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 epoprostenol sodium treatment at the time of application — a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes results of the following 3 tests, both at the time treatment with epoprostenol 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 epoprostenol sodium treatment; and

(4) a copy of a signed patient acknowledgment form 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, 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].

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer \$	Proprietary Name and Manufacturer

EPOPROSTENOL SODIUM—cont.

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 epoprostenol sodium therapy. Where patients have received less than 6 months of non-PBS-subsidised treatment with epoprostenol 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 epoprostenol 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

Application for initial PBS-subsidised treatment with epoprostenol sodium of patients aged less than 18 years who were receiving treatment with epoprostenol sodium prior to 1 August 2006, who have not received prior PBS-subsidised treatment with bosentan monohydrate and who have been assessed by a physician from a designated hospital to have WHO Functional Class III or 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) for patients who have received less than 6 months of epoprostenol sodium treatment at the time of application — a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes results of the following 3 tests, where available, at the time treatment with epoprostenol 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 epoprostenol sodium treatment at the time of application — a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes results of the following 3 tests, both at the time treatment with epoprostenol 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 epoprostenol sodium treatment; and*
- (4) a copy of a patient acknowledgment form, signed by the parent or authorised guardian, indicating that they understand and acknowledge that PBS-subsidised treatment with epoprostenol sodium or bosentan monohydrate 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].

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer \$	Proprietary Name and Manufacturer

EPOPROSTENOL SODIUM—cont.

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 epoprostenol sodium therapy. Where patients have received less than 6 months of non-PBS-subsidised treatment with epoprostenol 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 epoprostenol 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

Application for initial PBS-subsidised treatment of patients aged less than 18 years who have not received prior PBS-subsidised treatment with bosentan monohydrate 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 [may be downloaded from the Medicare Australia website (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 copy of a patient acknowledgment form, signed by the parent or authorised guardian, indicating that they understand and acknowledge that PBS-subsidised treatment with epoprostenol sodium or bosentan monohydrate 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 is commenced on epoprostenol sodium treatment due to an adverse event or a contraindication to vasodilator treatment, 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].

Code	Item and Section 100 Restriction	Pack Size	Price ex	Proprietary Name and Manufacturer
			Manufacturer \$	

EPOPROSTENOL SODIUM—cont.

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

Application for initial PBS-subsidised treatment of patients aged less than 18 years who have not received prior PBS-subsidised treatment with bosentan monohydrate 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 [may be downloaded from the Medicare Australia website (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 copy of a patient acknowledgment form, signed by the parent or authorised guardian, indicating that they understand and acknowledge that PBS-subsidised treatment with epoprostenol sodium or bosentan monohydrate 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).

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer \$	Proprietary Name and Manufacturer

EPOPROSTENOL SODIUM—cont.**Public and private hospital authority required**

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 or iloprost trometamol.*

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 [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the results on which approval for the first application for PBS-subsidised 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 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 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

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.*

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 [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the results on which approval for the first application for PBS-subsidised epoprostenol sodium or bosentan monohydrate, whichever was initiated first, was granted; and*

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer \$	Proprietary Name and Manufacturer	
EPOPROSTENOL SODIUM—cont. (3) the date of the first application for PBS-subsidised treatment with epoprostenol sodium 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 epoprostenol sodium 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 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 [may be downloaded from the Medicare Australia website (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).					
6477X	Powder for I.V. infusion 500 micrograms (base) with 1 vial diluent 50 mL	1	41.69	Flolan	GK
6478Y	Powder for I.V. infusion 1.5 mg (base) with 2 vials diluent 50 mL	1	83.37	Flolan	GK

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer \$	Proprietary Name and Manufacturer

ETANERCEPT**NOTE:**

Any queries concerning the arrangements to prescribe etanercept may be directed to Medicare Australia on 1800 005 750 (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.

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer \$	Proprietary Name and Manufacturer

ETANERCEPT—cont.

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.

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.

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer \$	Proprietary Name and Manufacturer	
ETANERCEPT—cont.					
<u>Public and private hospital authority required</u>					
<i>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:</i>					
<i>(a) an active joint count of fewer than 10 active (swollen and tender) joints;</i>					
OR					
<i>(b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline;</i>					
OR					
<i>(c) a reduction in the number of the following active joints, from at least 4, by at least 50%:</i>					
<i>(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or</i>					
<i>(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).</i>					
<i>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.</i>					
<i>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.</i>					
<i>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.</i>					
<i>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.</i>					
<i>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.</i>					
6367D	Injection set containing 4 vials powder for injection 25 mg and 4 pre-filled syringes solvent 1 mL	1	815.00	Enbrel	WY
EVEROLIMUS					
<u>CAUTION:</u>					
<i>Careful monitoring of patients is mandatory.</i>					
<u>Private hospital authority required</u>					
<i>Management of rejection, under the supervision and direction of a transplant unit, in patients receiving this drug for:</i>					
<i>(a) Prophylaxis of renal allograft rejection. Management includes initiation, stabilisation and review of therapy as required;</i>					
<i>(b) Prophylaxis of cardiac allograft rejection. Management includes initiation, stabilisation and review of therapy as required.</i>					
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 <i>For use in patients undergoing induction and consolidation therapy for acute myeloid leukaemia;</i> <i>Mobilisation of peripheral blood progenitor cells to facilitate harvest of such cells for autologous transplantation into patients with non-myeloid malignancies who have had myeloablative or myelosuppressive therapy;</i> <i>Mobilisation of peripheral blood progenitor cells, in normal volunteers, for use in allogeneic transplantation;</i> <i>Patients receiving marrow-ablative chemotherapy and subsequent bone marrow transplantation;</i> <i>Patients with non-myeloid malignancies receiving marrow-ablative chemotherapy and subsequent autologous peripheral blood progenitor cell transplantation;</i> <i>Patients being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in:</i> <i>Acute lymphoblastic leukaemia;</i> <i>Ewing's sarcoma;</i> <i>Germ cell tumours;</i> <i>Infants and children with CNS tumours;</i> <i>Neuroblastoma;</i> <i>Non-Hodgkin's lymphoma (intermediate or high grade);</i> <i>Osteosarcoma;</i> <i>Relapsed Hodgkin's disease;</i> <i>Rhabdomyosarcoma;</i> <i>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;</i> <i>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;</i> <i>Patients receiving chemotherapy for myeloma who have 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;</i> <i>Patients 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);</i> <i>Patients 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));</i>			

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer \$	Proprietary Name and Manufacturer	
FILGRASTIM—cont.					
<i>Patients 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)).</i>					
6126K	Injection 300 micrograms in 1 mL vial	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 vial	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					
<u>Private hospital authority required</u>					
<i>Treatment, in combination with 2 or more other antiretroviral drugs, of HIV infection in patients with:</i>					
<i>(a) CD4 cell counts of less than 500 per cubic millimetre; or</i>					
<i>(b) viral load of greater than 10,000 copies per mL.</i>					
6453P	Tablet 700 mg (base)	60	568.74	Telzir	GK
NOTE:					
<i>This price is based on special supply arrangements—see Pharmaceutical Benefits Pricing Authority relativity sheet for full details.</i>					
6454Q	Oral liquid 50 mg (base) per mL, 225 mL	1	101.56	Telzir	GK
FOSCARNET SODIUM					
<u>Private hospital authority required</u>					
<i>Treatment of cytomegalovirus retinitis in patients with AIDS;</i>					
<i>Treatment of aciclovir-resistant herpes simplex virus infection in immunocompromised patients with HIV infection.</i>					
6134W	I.V. infusion 24 mg per mL, 250 mL bottle	6	395.00	Foscavir	AP
GANCICLOVIR					
<u>Private hospital authority required</u>					
<i>Cytomegalovirus retinitis in severely immunocompromised patients.</i>					
6256G	Intravitreal implant 4.5 mg	1	6000.00	Vitrasert	BU
GANCICLOVIR SODIUM					
<u>Private hospital authority required</u>					
<i>Cytomegalovirus retinitis in severely immunocompromised patients;</i>					
<i>Prophylaxis of cytomegalovirus disease in bone marrow transplant patients at risk of cytomegalovirus disease;</i>					
<i>Prophylaxis of cytomegalovirus disease in solid organ transplant patients at risk of cytomegalovirus disease.</i>					
6136Y	Powder for I.V. infusion equivalent to 500 mg ganciclovir, vial	5	280.00	Cymevene	RO

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 or PBS-subsidised epoprostenol 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 adult 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.*

Adult patients:

From 1 August 2006, adult patients with primary pulmonary hypertension will be able to access, through the PBS, either bosentan monohydrate, iloprost trometamol or epoprostenol sodium. Once these patients are approved initial treatment with 1 of these 3 drugs, they may swap between bosentan monohydrate, iloprost trometamol and epoprostenol 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 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 (unless the prescriber wishes to submit new baselines).

Patients may only swap to bosentan monohydrate, iloprost trometamol or epoprostenol sodium if they have not failed prior PBS-subsidised treatment with that drug.

Code	Item and Section 100 Restriction	Pack Size	Price ex	Proprietary Name and Manufacturer
			Manufacturer \$	

ILOPROST TROMETAMOL—cont.

Adult patients with pulmonary arterial hypertension secondary to scleroderma will be able to access, through the PBS, either bosentan monohydrate or iloprost trometamol. Once these patients are approved initial treatment with 1 of these 2 drugs, they may swap between bosentan monohydrate and iloprost trometamol 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 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 (unless the prescriber wishes to submit new baselines).

Patients may only swap to bosentan monohydrate or iloprost trometamol if they have not failed prior PBS-subsidised treatment with that drug.

Patients with pulmonary arterial hypertension secondary to connective tissue disease other than scleroderma are only eligible for treatment with iloprost trometamol. They may not swap to bosentan monohydrate or epoprostenol sodium.

Patients with drug-induced pulmonary arterial hypertension are only eligible for treatment with iloprost trometamol. They may not swap to bosentan monohydrate or epoprostenol sodium.

Patients under 18 years of age:

From 1 August 2006, patients aged less than 18 years with primary pulmonary hypertension are eligible to receive PBS-subsidised treatment with either bosentan monohydrate or epoprostenol sodium. Once these patients are approved initial treatment with 1 of these 2 drugs, they may swap between bosentan monohydrate and epoprostenol 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 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 (unless the prescriber wishes to submit new baselines). They may qualify for treatment with iloprost trometamol when they are aged 18 years or older.

Patients may only swap to bosentan monohydrate or epoprostenol 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.*

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer \$	Proprietary Name and Manufacturer

ILOPROST TROMETAMOL—cont.**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 or epoprostenol 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.

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 or with epoprostenol sodium on or after 1 August 2006, 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.

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer \$	Proprietary Name and Manufacturer

ILOPROST TROMETAMOL—cont.

Where patients received treatment with either bosentan monohydrate, iloprost trometamol or epoprostenol sodium prior to being commenced on PBS-subsidised treatment with the first of either bosentan monohydrate, iloprost trometamol or epoprostenol 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 or epoprostenol sodium, whichever of the 3 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.

NOTE:

5. Definition of response to iloprost trometamol, bosentan monohydrate, 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.

6. Authority approval requirements. *[The following 2 sections are only relevant to the PBS listing of iloprost trometamol. The requirements specific to bosentan monohydrate and epoprostenol sodium are given in parts 6 and 7 of the NOTE included in the bosentan monohydrate and epoprostenol sodium Schedule entry respectively.]*

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer \$	Proprietary Name and Manufacturer

ILOPROST TROMETAMOL—cont.

(a) Initiation of PBS-subsidised treatment with iloprost trometamol, where the patient has not received prior PBS-subsidised treatment with bosentan monohydrate or epoprostenol 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 and epoprostenol sodium.

For eligible patients, applications to swap between these 3 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.

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer \$	Proprietary Name and Manufacturer

ILOPROST TROMETAMOL—cont.

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 diagrammatical 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

Application for initial PBS-subsidised treatment with iloprost trometamol of adult patients who have not received prior PBS-subsidised treatment with bosentan monohydrate or epoprostenol 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 [may be downloaded from the Medicare Australia website (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 copy of a signed patient acknowledgment form 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, will cease if the treating physician determines that the patient has not achieved a response to treatment [see Note for definition of response].*

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer \$	Proprietary Name and Manufacturer

ILOPROST TROMETAMOL—cont.

Details of prior vasodilator treatment, including the dose and duration of treatment, must be provided at the time of application. Where the patient is commenced on iloprost trometamol treatment due to an adverse event or a contraindication to vasodilator treatment, 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

Application for initial PBS-subsidised treatment with iloprost trometamol of adult patients who have not received prior PBS-subsidised treatment with bosentan monohydrate or epoprostenol 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 [may be downloaded from the Medicare Australia website (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*

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer \$	Proprietary Name and Manufacturer

ILOPROST TROMETAMOL—cont.

(3) a copy of a signed patient acknowledgment form 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, 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

Application for initial treatment with iloprost trometamol of adult 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 recommence 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.*

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 [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the results on which approval for the first application for PBS-subsidised iloprost trometamol, bosentan monohydrate or epoprostenol sodium, whichever was initiated first, was granted; and*
- (3) the date of the first application for PBS-subsidised treatment with iloprost trometamol, bosentan monohydrate or epoprostenol 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 or epoprostenol sodium.*

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer \$	Proprietary Name and Manufacturer	
ILOPROST TROMETAMOL—cont. <i>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).</i>					
Public and private hospital authority required <i>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].</i> <i>Applications for authorisation must be in writing and must include:</i> <i>(1) a completed authority prescription form; and</i> <i>(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes results from the 3 tests below, where available:</i> <i>(i) RHC composite assessment; and</i> <i>(ii) ECHO composite assessment; and</i> <i>(iii) 6MWT.</i> <i>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].</i> <i>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).</i>					
6456T	Solution for inhalation 20 micrograms (base) in 2 mL	30	1076.00	Ventavis	SC
NOTE: <i>This price is based on special supply arrangements—see Pharmaceutical Benefits Pricing Authority relativity sheet for full details.</i>					
INDINAVIR SULFATE Private hospital authority required <i>Treatment of HIV infection in patients with:</i> <i>(a) CD4 cell counts of less than 500 per cubic millimetre; or</i> <i>(b) viral load of greater than 10,000 copies per mL.</i>					
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

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer \$	Proprietary Name and Manufacturer

INFLIXIMAB**NOTE:**

Any queries concerning the arrangements to prescribe infliximab may be directed to Medicare Australia on 1800 005 750 (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 etanercept and infliximab for adult patients with active ankylosing spondylitis only. It does not apply to the prescribing of adalimumab. Therefore, where the term 'tumour necrosis factor (TNF) alfa antagonists' appears in the following NOTES and restrictions, it only refers to etanercept and infliximab.

Patients are eligible for PBS-subsidised treatment with only 1 of the 2 TNF-alfa antagonists above at any 1 time.

From 1 August 2005, under the PBS, all patients will be able to commence a single treatment cycle where they may trial both of the PBS-subsidised TNF-alfa antagonists without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single treatment cycle, patients may continue to receive long-term treatment with a TNF-alfa antagonist while they continue to show a response to therapy.

Once patients have either failed or ceased to respond to treatment up to 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 5 year break in PBS-subsidised TNF-alfa antagonist therapy before they are eligible to commence the next cycle. Within the same treatment cycle, patients are not allowed to trial and fail, or cease to respond to, the same PBS-subsidised TNF-alfa antagonist more than twice. Patients who have failed the same PBS-subsidised TNF-alfa antagonist twice must change to the alternate PBS-subsidised agent if they wish to continue PBS-subsidised TNF-alfa antagonist treatment.

The 5-year break in therapy will be measured from the date the last approval for PBS-subsidised TNF-alfa antagonist treatment was granted in the most recent cycle to the date of the first application for initial treatment with a TNF-alfa antagonist under the new cycle.

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer \$	Proprietary Name and Manufacturer

INFLIXIMAB—cont.

Where a period of less than 5 years duration has elapsed since the patient's previous course of PBS-subsidised TNF- α antagonist treatment, patients who have failed TNF- α antagonist therapy less than 3 times within a particular treatment cycle, as defined in the restriction, may commence a further course of treatment within that cycle.

Where a break in PBS-subsidised therapy of 5 years or more has occurred, patients who have failed TNF- α antagonist therapy less than 3 times within a particular treatment cycle, as defined in the restriction, are eligible to commence a new treatment cycle.

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

1. Patients 'grandfathered' onto PBS-subsidised treatment with infliximab and etanercept.

Both the infliximab and etanercept restrictions allow patients who commenced treatment prior to 1 March 2004 and 1 July 2004 respectively to commence treatment under a different set of criteria than those patients who commenced treatment after these dates (i.e. new patients). This means such patients were 'grandfathered' onto PBS-subsidised treatment. Consequently, the criteria to enable 'grandfather' patients to continue on PBS-subsidised treatment are also different to those for new patients.

Where patients who were 'grandfathered' onto PBS-subsidised treatment with 1 TNF- α antagonist wish to swap to the alternate agent, they can only do so using the restrictions that apply to 'grandfather' patients.

'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, 'grandfather' patients must requalify for initial treatment under the criteria that apply to new patients. See 'Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' below for further details. Patients who commenced on PBS-subsidised etanercept or infliximab treatment prior to 1 August 2005 are deemed to be in their first cycle of therapy.

The first course of initial therapy for patients 'grandfathered' onto PBS-subsidised treatment with etanercept or infliximab will be limited to provide for 24 weeks of therapy. All subsequent initial treatment courses made under the 'grandfather' restriction will be limited to provide 6 weeks of therapy.

2. How to prescribe TNF- α antagonist therapy after 1 August 2005.**(a) Initial treatment.**

Applications for initial treatment should be made where:

- (i) patients have received no prior PBS-subsidised TNF- α antagonist treatment and wish to commence such therapy; or*
- (ii) patients have received prior PBS-subsidised (initial or continuing) TNF- α antagonist therapy and wish to trial an alternate agent [further details are under 'Swapping therapy' below]; or*
- (iii) patients have failed their most recent course of PBS-subsidised TNF- α antagonist therapy but wish to trial a further course of treatment with the same TNF- α antagonist (providing they have not failed that TNF- α antagonist more than once); or*
- (iv) patients wish to re-commence treatment with a specific TNF- α antagonist following a break in PBS-subsidised therapy with that specific agent.*

Code	Item and Section 100 Restriction	Pack Size	Price ex	Proprietary Name and Manufacturer
			Manufacturer \$	

INFLIXIMAB—cont.

All applications for initial treatment will be limited to provide for a maximum of 6 weeks of therapy except for the first application for 'grandfather' patients approved for PBS-subsidised treatment with etanercept and infliximab where up to 24 weeks of treatment will be approved.

In order to demonstrate a response to therapy, patients who have received an initial PBS-subsidised course of up to 6 weeks of treatment must be assessed no earlier than 4 weeks from the commencement of the initial therapy course. In order to demonstrate a response to therapy, patients who have received an initial PBS-subsidised course of up to 24 weeks must be assessed in the 4 weeks prior to treatment being ceased.

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, patients will be deemed to have failed to respond to treatment with that TNF- α antagonist.

Prescribers should ensure that applications for second and subsequent courses of PBS-subsidised TNF- α antagonist treatment are submitted to Medicare Australia before patients complete their previous treatment course to ensure uninterrupted treatment. Applications where no provisions to fax the prescription and application are made in the restriction should be posted to Medicare Australia no later than 2 weeks prior to the patient completing their previous treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific TNF- α antagonist, 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 TNF- α antagonist treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

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, patients will be deemed to have failed to respond to treatment with that TNF- α antagonist.

(c) How to apply for TNF- α antagonist treatment on or after 1 August 2005.

Patients for whom the first application for PBS-subsidised treatment with either etanercept or infliximab is made on or after 1 August 2005, will fall into 1 of the following categories:

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer \$	Proprietary Name and Manufacturer

INFLIXIMAB—cont.

(I) Patients who have not received any prior PBS-subsidised infliximab or PBS-subsidised etanercept treatment.

This includes the following:

(i) Patients who have not received any prior treatment with infliximab or etanercept for ankylosing spondylitis.

(ii) Patients who have received non-PBS-subsidised treatment with infliximab after 1 March 2004.

(iii) Patients who have received non-PBS-subsidised treatment with etanercept after 1 July 2004.

(iv) Patients who have received non-PBS-subsidised infliximab treatment prior to 1 March 2004.

(v) Patients who have received non-PBS-subsidised etanercept treatment prior to 1 July 2004.

To commence PBS-subsidised treatment with etanercept or infliximab, all patients who fall into groups (i)-(iii) must qualify under the first initial restriction for new patients (i.e. the patient must meet the criteria with respect to the indices of severity and prior treatment regimens specified in the 'new patient' restriction).

To commence PBS-subsidised treatment with infliximab, all patients who fall into group (iv) must qualify under the first initial restriction for 'grandfather' patients (i.e. the patient must meet the criteria with respect to the indices of severity and prior treatment regimens specified in the 'grandfather' restriction).

To commence PBS-subsidised treatment with etanercept, all patients who fall into group (v) must qualify under the first initial restriction for 'grandfather' patients (i.e. the patient must meet the criteria with respect to the indices of severity and prior treatment regimens specified in the 'grandfather' restriction).

Patients in groups (iv) and (v) can not be 'grandfathered' onto treatment with the alternate agent. If they wish to commence PBS-subsidised therapy with the alternate agent, they must qualify under the first initial restriction for new patients (i.e. the patient must meet the criteria with respect to the indices of severity and prior treatment regimens specified in the 'new patient' restriction).

(II) Patients who have received PBS-subsidised etanercept only.

(III) Patients who have received PBS-subsidised infliximab only.

(IV) Patients who have received PBS-subsidised etanercept and non-PBS-subsidised infliximab.

(V) Patients who have received PBS-subsidised infliximab and non-PBS-subsidised etanercept.

To receive PBS-subsidised treatment with etanercept or infliximab, the patients in groups (II)-(V) do not need to requalify with respect to the indices of severity or prior treatment requirements. They use the second initial restriction for either 'new' or 'grandfather' patients (i.e. whichever was applicable for their first course of PBS-subsidised treatment).

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer \$	Proprietary Name and Manufacturer

INFLIXIMAB—cont.**NOTE:**

Patients who have responded to their most recent course of etanercept therapy as specified in the restriction may:

- *continue on etanercept treatment under the 'grandfather' or new patient restriction, whichever is applicable [see 'Patients grandfathered' onto PBS-subsidised treatment with infliximab and etanercept]; or*
- *swap to an initial course of infliximab treatment of up to 6 weeks under the 'grandfather' or new patient restriction, whichever is applicable [see 'Patients grandfathered' onto PBS-subsidised treatment with infliximab and etanercept].*

Patients who have failed to respond to their most recent course of etanercept treatment may:

- *trial a further course of initial therapy of up to 6 weeks with etanercept; or*
- *swap to an initial course of infliximab treatment of up to 6 weeks.*

Patients who have responded to their most recent course of infliximab therapy as specified in the restriction may:

- *continue on infliximab treatment under the 'grandfather' or new patient restriction, whichever is applicable [see 'Patients grandfathered' onto PBS-subsidised treatment with infliximab and etanercept]; or*
- *swap to an initial course of etanercept treatment of up to 6 weeks under the 'grandfather' or new patient restriction, whichever is applicable [see 'Patients grandfathered' onto PBS-subsidised treatment with infliximab and etanercept].*

Patients who have failed to respond to their most recent course of infliximab treatment may:

- *trial a further course of initial therapy of up to 6 weeks with infliximab; or*
- *swap to an initial course of etanercept treatment of up to 6 weeks.*

3. Swapping therapy.

Once an authority for initial treatment with the first PBS-subsidised TNF- α antagonist is approved, patients may swap to the alternate TNF- α 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. This also applies to patients who fail to achieve or sustain a response to the first PBS-subsidised TNF- α antagonist approved and who wish to trial a further course of treatment with the same TNF- α antagonist.

Patients may trial an alternate TNF- α antagonist at any time, regardless of whether they are receiving therapy (initial or continuing) with a TNF- α antagonist at the time of the application or not. However, they cannot swap to a particular TNF- α antagonist if they have failed to respond to prior treatment with that particular drug more than twice in the same cycle.

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

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer \$	Proprietary Name and Manufacturer

INFLIXIMAB—cont.

To avoid confusion, applications for patients who wish 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.

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 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 is submitted within a treatment cycle and Medicare Australia will assess response according to these revised baseline measurements.

For new patients, the first BASDAI result used to determine baseline must be provided while the patient is still receiving NSAID therapy. However, this is not required for any subsequent BASDAI results provided for these patients nor for patients who were 'grandfathered' onto 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.

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 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.

Public and private hospital authority required***Initial 1 (new patients)***

Application for the first course of initial PBS-subsidised treatment with infliximab, by a rheumatologist, of adults with active ankylosing spondylitis who have radiographically (plain X-ray) confirmed Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis, who have not received any PBS-subsidised treatment with either etanercept or infliximab;

AND

(a) have at least 2 of the following:

(i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; or

(ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI) [for further information on the BASMI please refer to the Medicare Australia website at www.medicareaustralia.gov.au]; or

Code	Item and Section 100 Restriction	Pack Size	Price ex	Proprietary Name and Manufacturer
			Manufacturer \$	

INFLIXIMAB—cont.

(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 have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs) in combination with 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 reasons why a higher dose cannot be used.

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.

Patients who received treatment with infliximab prior to 1 March 2004 and wish to commence PBS-subsidised treatment with infliximab must qualify under the initial treatment restriction for 'grandfather' patients.

The following initiation criteria indicate failure to achieve an adequate response and must be demonstrable in all patients 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 reasons why this criterion cannot be satisfied.

If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the patient is exempted from demonstrating an inadequate response to the above treatment regimen. Where appropriate, evidence to support a contraindication must be provided. If adverse events of a severity necessitating permanent withdrawal develop during the relevant period of use of 2 NSAIDs, the patient may be exempted from demonstrating an inadequate response to the above treatment regimen. For details of the adverse events, including the severity, which will be accepted for the purposes of administering this restriction, please refer to the Medicare Australia website at www.medicareaustralia.gov.au.

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer \$	Proprietary Name and Manufacturer

INFLIXIMAB—cont.

Authority applications must be made in writing and must include:

- (a) a completed authority prescription form; and**
- (b) a completed TNF-alfa antagonist PBS Authority Application for Use in the Treatment of Ankylosing Spondylitis - Supporting Information Form [may be downloaded from the Medicare Australia website (visit www.medicareaustralia.gov.au/providers/forms/pbs.htm) and click on 'Medical Practitioners']] which includes the following:**
 - (i) a copy of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and**
 - (ii) a copy of the completed BASDAI Assessment Form [may be downloaded from the Medicare Australia website (visit www.medicareaustralia.gov.au/providers/forms/pbs.htm) and click on 'Medical Practitioners']]; and**
 - (iii) a copy of the signed patient acknowledgment form [may be downloaded from the Medicare Australia website (visit www.medicareaustralia.gov.au/providers/forms/pbs.htm) and click on 'Medical Practitioners']]. Completion of this form declares that the patient understands and acknowledges that PBS-subsidised treatment with the TNF-alfa antagonists (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 no earlier than 4 weeks from the commencement 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 6 weeks of treatment with infliximab will be approved under this criterion.

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 2 infusions at a dose of 5 mg per kg. No repeats will be authorised.

Public and private hospital authority required**Initial 2 (new patients)**

Application for an initial course of PBS-subsidised treatment with infliximab, by a rheumatologist, of adults with active ankylosing spondylitis who, in this treatment cycle, have received prior PBS-subsidised treatment with either etanercept or infliximab for this condition and have not failed PBS-subsidised therapy with infliximab more than once.

All applications for treatment must be accompanied by the results of the most recent course of TNF-alfa antagonist therapy within the timeframes specified below.

Where the most recent course of PBS-subsidised TNF-alfa antagonist treatment was approved under an initial treatment restriction for new patients, patients must have been assessed for response to that course no earlier than 4 weeks from the commencement of that course. 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 TNF-alfa antagonist treatment was approved under the continuing treatment criteria for new patients, patients must have been assessed for response to that course, and the assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer \$	Proprietary Name and Manufacturer

INFLIXIMAB—cont.

If the response assessments to the previous course of TNF-alfa antagonist treatment are not submitted as detailed above, patients 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 TNF-alfa antagonist PBS Authority Application for Use in the Treatment of Ankylosing Spondylitis - Supporting Information Form [may be downloaded from the Medicare Australia website (visit www.medicareaustralia.gov.au/providers/forms/pbs.htm) and click on 'Medical Practitioners']] which includes a copy of the completed BASDAI Assessment Form [may be downloaded from the Medicare Australia website (visit www.medicareaustralia.gov.au/providers/forms/pbs.htm) and click on 'Medical Practitioners']].*

A maximum of 6 weeks of treatment with infliximab will be approved under this criterion.

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 2 infusions at a dose of 5 mg per kg. No repeats will be authorised.

Public and private hospital authority required

Continuing (new patients)

Continuing PBS-subsidised treatment, by a rheumatologist, of adults with active ankylosing spondylitis who:

- (a) have received 6 weeks or more of PBS-subsidised treatment with infliximab; and*
- (b) have demonstrated a response to treatment with infliximab; and*
- (c) 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.*

The same acute phase reactant measured at the relevant baseline must be measured in all subsequent continuing treatment applications.

The first application for continuing treatment following an initial treatment course must be made no earlier than 4 weeks from the commencement of the most recent initial treatment course with infliximab. This first authority application and a copy of the authority prescription may be faxed to Medicare Australia on (03) 6215 5640 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) in order to seek approval for a maximum of 4 weeks' supply. Medicare Australia will then contact the prescriber by telephone. The original document must then be posted to Medicare Australia with a second authority prescription for the balance of 24 weeks of treatment.

Second and subsequent 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.

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer \$	Proprietary Name and Manufacturer

INFLIXIMAB—cont.

Written applications for authorisation must include:

(a) a completed authority prescription form; and

(b) a completed TNF-alfa antagonist PBS Authority Application for Continuing Use in the Treatment of Ankylosing Spondylitis - Supporting Information Form [may be downloaded from the Medicare Australia website (visit www.medicareaustralia.gov.au/providers/forms/pbs.htm and click on 'Medical Practitioners')] which includes the following:

(i) a copy of the completed BASDAI Assessment Form [may be downloaded from the Medicare Australia website (visit www.medicareaustralia.gov.au/providers/forms/pbs.htm and click on 'Medical Practitioners')] including 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, 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. No applications for increased 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.

Public and private hospital authority required

Initial 1 ('grandfather' patients)

Application for an initial PBS-subsidised course of continuing treatment with infliximab, by a rheumatologist, of adults with active ankylosing spondylitis who have radiographically (plain X-ray) confirmed Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis, who were receiving treatment with infliximab prior to 1 March 2004;

AND

(a) are receiving treatment with infliximab at the time of application;

AND

(b) who have not received prior PBS-subsidised treatment with etanercept;

AND

(c) whose Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score is less than or equal to 5 on a 0-10 scale;

AND

(d) who have:

(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.

Code	Item and Section 100 Restriction	Pack Size	Price ex	Proprietary
			Manufacturer \$	Name and Manufacturer

INFLIXIMAB—cont.

The BASDAI assessment and ESR and/or CRP measurements must be no more than 1 month old at the time of application. The same acute phase reactant measured in the first application for PBS-subsidised treatment must be measured in all subsequent continuing treatment applications.

Authority applications must be made in writing and must include:

- (a) a completed authority prescription form; and*
- (b) a completed TNF-alfa antagonist PBS Authority Application for Use in the Treatment of Ankylosing Spondylitis - Supporting Information Form [may be downloaded from the Medicare Australia website (visit www.medicareaustralia.gov.au/providers/forms/pbs.htm) and click on 'Medical Practitioners']] which includes the following:*
 - (i) a copy of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and*
 - (ii) a copy of the completed BASDAI Assessment Form [may be downloaded from the Medicare Australia website (visit www.medicareaustralia.gov.au/providers/forms/pbs.htm) and click on 'Medical Practitioners']]; and*
 - (iii) a copy of the signed patient acknowledgment form [may be downloaded from the Medicare Australia website (visit www.medicareaustralia.gov.au/providers/forms/pbs.htm) and click on 'Medical Practitioners']]. Completion of this form declares that the patient understands and acknowledges that PBS-subsidised treatment with the TNF-alfa antagonists (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.

Those patients ceasing treatment or swapping to an alternate agent and wishing to demonstrate a response to treatment, must be assessed no earlier than 4 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 infliximab will be authorised under this criterion.

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. No applications for increased 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.

Patients may only qualify for PBS-subsidised treatment under this criterion once.

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer \$	Proprietary Name and Manufacturer

INFLIXIMAB—cont.**Public and private hospital authority required*****Initial 2 ('grandfather' patients)***

Application for an initial course of PBS-subsidised treatment with infliximab, by a rheumatologist, of adults with active ankylosing spondylitis who have radiographically (plain X-ray) confirmed Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis, who were 'grandfathered' onto PBS-subsidised treatment with etanercept or infliximab and who have not failed PBS-subsidised therapy with infliximab more than once.

Where the most recent course of PBS-subsidised TNF-alfa antagonist treatment was approved under an initial treatment restriction for 'grandfather' patients, patients must have been assessed for response to that course no earlier than 4 weeks from the commencement of that course. 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 TNF-alfa antagonist treatment was approved under the continuing treatment criteria for 'grandfather' patients, patients must have been assessed for response to that course, and the assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

If the response assessments to the previous course of TNF-alfa antagonist treatment are not submitted as detailed above, patients 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 TNF-alfa antagonist PBS Authority Application for Use in the Treatment of Ankylosing Spondylitis - Supporting Information Form [may be downloaded from the Medicare Australia website (visit www.medicareaustralia.gov.au/providers/forms/pbs.htm) and click on 'Medical Practitioners']] which includes a copy of the completed BASDAI Assessment Form [may be downloaded from the Medicare Australia website (visit www.medicareaustralia.gov.au/providers/forms/pbs.htm) and click on 'Medical Practitioners']].

A maximum of 6 weeks of treatment with infliximab will be approved under this criterion.

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 2 infusions at a dose of 5 mg per kg. No repeats will be authorised.

Public and private hospital authority required***Continuing ('grandfather' patients)***

Continuing PBS-subsidised treatment, by a rheumatologist, of adults with active ankylosing spondylitis who were 'grandfathered' onto PBS-subsidised treatment with a TNF-alfa antagonist and who:

(a) have received 6 weeks or more of PBS-subsidised treatment with infliximab; and

(b) have demonstrated a response to treatment with infliximab; and

(c) whose most recent course of PBS-subsidised therapy in this treatment cycle was with infliximab.

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer \$	Proprietary Name and Manufacturer

INFLIXIMAB—cont.

Response to treatment is defined as a BASDAI score no more than 20% greater than the score included in the initial application for PBS-subsidised treatment;

AND

(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 pre-treatment baseline.

The same acute phase reactant measured at the relevant baseline must be measured in all subsequent continuing treatment applications.

The first application for continuing treatment following an initial treatment course must be made no earlier than 4 weeks from the commencement of the most recent initial treatment course with infliximab. This first authority application and a copy of the authority prescription may be faxed to Medicare Australia on (03) 6215 5640 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) in order to seek approval for a maximum of 4 weeks' supply. Medicare Australia will then contact the prescriber by telephone. The original document must then be posted to Medicare Australia with a second authority prescription for the balance of 24 weeks of treatment.

Second and subsequent 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.

In order to demonstrate a response to treatment where the patient is ceasing or swapping to an alternate agent, the assessment must be provided to Medicare Australia no later than 4 weeks from the date that course was ceased.

Written applications for authorisation must include:

(a) a completed authority prescription form; and

(b) a completed TNF-alfa antagonist PBS Authority Application for Continuing Use in the Treatment of Ankylosing Spondylitis - Supporting Information Form [may be downloaded from the Medicare Australia website (visit

www.medicareaustralia.gov.au/providers/forms/pbs.htm and click on 'Medical Practitioners')] which includes the following:

(i) a copy of the completed BASDAI Assessment Form [may be downloaded from the Medicare Australia website (visit www.medicareaustralia.gov.au/providers/forms/pbs.htm and click on 'Medical Practitioners')] including 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, 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. No applications for increased repeats will be authorised.

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer \$	Proprietary Name and Manufacturer

INFLIXIMAB—cont.

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	875.00	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 tumour necrosis factor (TNF) alfa antagonists (adalimumab, etanercept and infliximab) and the interleukin-1 inhibitor (anakinra) for adult patients with severe rheumatoid arthritis.

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

1. Patients who have received no prior PBS-subsidised bDMARD treatment at 1 December 2004.

From 1 December 2004, the arrangements for prescribing the bDMARDs on the PBS have been amended to allow patients to commence a single cycle of bDMARD treatment that allows them to trial any number of bDMARDs without having to experience a disease flare when swapping between alternate bDMARDs. Within a single treatment cycle, patients may continue to receive long-term treatment with a bDMARD while they continue to show a response to therapy.

Once patients have either failed, or ceased to respond to, treatment with a maximum of 3 bDMARDs, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 5 year break in PBS-subsidised bDMARD therapy before they are eligible to commence the next cycle. The 5-year period will be measured from the date the last prescription for PBS-subsidised bDMARD treatment was approved in the most recent cycle to the date of the application for initial treatment with a bDMARD under the new cycle.

Patients who have failed treatment with fewer than 3 bDMARDs within a particular treatment cycle, and where a period of less than 5 years duration has elapsed since the patient's previous course of PBS-subsidised bDMARD treatment in that cycle, may commence a further course of bDMARD treatment within that same treatment cycle.

Patients who have failed treatment with fewer than 3 bDMARDs within a particular treatment cycle, and who have had a break in PBS-subsidised therapy of 5 years or more, are eligible to 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.

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer \$	Proprietary Name and Manufacturer

INFLIXIMAB—cont.

2. Patients who have received PBS-subsidised TNF-alfa antagonist treatment prior to 1 December 2004.

Patients who commenced PBS-subsidised TNF-alfa antagonist therapy prior to 1 December 2004 are considered to be in their first cycle of bDMARD treatment on 1 December 2004.

Patients who have failed to respond to prior PBS-subsidised treatment with fewer than 3 TNF-alfa antagonists at the time the first application for treatment is made on or after 1 December 2004, will be subject to the same conditions applying to new patients detailed above.

Therefore, patients who have failed:

- (a) 1 TNF-alfa antagonist will be eligible to trial further PBS-subsidised treatment with a bDMARD they have not failed in their first treatment cycle, until they fail to demonstrate a response to no more than another 2 bDMARDs;*
- (b) 2 TNF-alfa antagonists will be eligible to trial further PBS-subsidised treatment with a bDMARD they have not failed in their first treatment cycle, until they fail to demonstrate a response to no more than 1 other bDMARD.*

Patients who have failed PBS-subsidised treatment with 3 TNF-alfa antagonists prior to 1 December 2004 or at the first assessment required after this date, will be eligible to trial PBS-subsidised treatment with anakinra if they wish. However, if they fail to demonstrate a response to anakinra, they will not be able to trial any further PBS-subsidised bDMARD treatment until a minimum of 5 years has elapsed from the date that the prescription for the last course of anakinra therapy was approved. Arrangements to allow these patients to fail 4 bDMARDs will only be in place for the first treatment cycle. For subsequent cycles, patients will cease to be eligible to receive PBS-subsidised bDMARD treatment once they have failed to demonstrate a response to a maximum of 3 bDMARDs.

Any queries on these arrangements should be forwarded to Medicare Australia.

3. Information relevant to all patients.

(a) Initial treatment.

Applications for initial treatment should be made where:

- (i) patients have received no prior PBS-subsidised bDMARD treatment and wish to commence such therapy; or*
- (ii) patients have received prior PBS-subsidised (initial or continuing) bDMARD therapy and wish to trial an alternate agent [further details are under 'Swapping therapy' below]; or*
- (iii) patients wish to re-commence treatment with a specific bDMARD following a break in PBS-subsidised therapy with that specific agent.*

All applications for initial treatment 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 bDMARD 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 bDMARD.

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer \$	Proprietary Name and Manufacturer

INFLIXIMAB—cont.**(b) Continuing treatment.**

Following the completion of an initial treatment course with a specific bDMARD, 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 bDMARD 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 bDMARD.

(c) Swapping therapy.

Once an authority for initial treatment with the first PBS-subsidised bDMARD is approved, patients may swap to an alternate bDMARD 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-bDMARD therapy requirements. However, the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.

Patients may swap to 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 or not.

Patients may alternate between therapy with any bDMARD of their choice (1 at a time) providing:

- (i) they have not received PBS-subsidised treatment with that particular bDMARD previously; or*
- (ii) they have demonstrated an adequate response to that particular bDMARD if they have previously trialled it on the PBS.*

Therefore, to maximise the choice of bDMARD patients may alternate between, it is important that patients 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 bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(d) 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 bDMARD. 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.

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer \$	Proprietary Name and Manufacturer

INFLIXIMAB—cont.

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 a reduction in the total number of active joints.

(e) 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 bDMARD 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 at least 1 non-biological DMARD, 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

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, 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 that particular agent(s) only. Details of the contraindications or intolerance, including the degree of toxicity, must be provided at the time of application.

The following initiation criteria indicate failure to achieve an adequate response and must be demonstrable 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).*

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer \$	Proprietary Name and Manufacturer

INFLIXIMAB—cont.

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 Biological DMARD PBS Authority Application for Use in the Treatment of Rheumatoid Arthritis - Supporting Information Form [may be downloaded from the Medicare Australia website (visit www.medicareaustralia.gov.au/providers/forms/pbs.htm) and click on 'Medical Practitioners']] 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 may be downloaded from the Medicare Australia website (visit www.medicareaustralia.gov.au/providers/forms/pbs.htm) and click on 'Medical Practitioners'. Completion of this form declares that the patient understands and acknowledges that, within a single treatment cycle, PBS-subsidised treatment with any biological DMARD 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 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 005 750 (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 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

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 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.*

Patients who were commenced on treatment with infliximab prior to 1 December 2004 and who have received methotrexate at a dose of less than 7.5 mg per week will be able to continue to receive PBS-subsidised treatment with infliximab in combination with methotrexate at this lower dose for the duration of the first bDMARD treatment cycle. For subsequent treatment cycles, patients must receive concomitant methotrexate at a dose of at least 7.5 mg weekly.

Code	Item and Section 100 Restriction	Pack Size	Price ex	Proprietary Name and Manufacturer
			Manufacturer \$	

INFLIXIMAB—cont.

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.

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.

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

- (1) a completed authority prescription form; and**
- (2) a completed Biological DMARD PBS Authority Application for Use in the Treatment of Rheumatoid Arthritis - Supporting Information Form [may be downloaded from the Medicare Australia website (visit www.medicareaustralia.gov.au/providers/forms/pbs.htm) and click on 'Medical Practitioners']].**

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 005 750 (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 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.

Once patients fail to respond to treatment with 3 bDMARDs, they 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 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.

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer \$	Proprietary Name and Manufacturer

INFLIXIMAB—cont.**Public and private hospital authority required**

Initial PBS-subsidised supply for continuing 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) were receiving treatment with infliximab prior to 1 March 2005 and*
- (c) failed to qualify for PBS-subsidised therapy after 1 November 2003 due to testing negative for rheumatoid factor; and*
- (d) have demonstrated a response as specified in the criteria for continuing PBS-subsidised treatment with infliximab.*

Medical practitioners who wish to apply for authority to prescribe a bDMARD for patients who commenced treatment with infliximab prior to 1 March 2005 and who have not demonstrated a response to treatment should contact Medicare Australia on 1800 005 750.

The authority application must be in writing and must include sufficient information to determine the patient's eligibility. The date of assessment must be provided.

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.

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.

Once patients fail to respond to treatment with 3 bDMARDs, they 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 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 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 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.*

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer \$	Proprietary Name and Manufacturer

INFLIXIMAB—cont.

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).

Patients who were commenced on treatment with infliximab prior to 1 December 2004 and who have received methotrexate at a dose of less than 7.5 mg per week will be able to continue to receive PBS-subsidised treatment with infliximab in combination with methotrexate at this lower dose for the duration of the first bDMARD treatment cycle. For subsequent treatment cycles, patients must receive concomitant methotrexate at a dose of at least 7.5 mg weekly.

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

(1) a completed authority prescription form; and

(2) a completed Biological DMARD PBS Authority Application for Use in the Treatment of Rheumatoid Arthritis - Supporting Information Form [may be downloaded from the Medicare Australia website (visit www.medicareaustralia.gov.au/providers/forms/pbs.htm) and click on 'Medical Practitioners']].

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.

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 005 750 (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 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.

Code	Item and Section 100 Restriction	Pack Size	Price ex	Proprietary	
			Manufacturer \$	Name and Manufacturer	
<i>INFLIXIMAB—cont.</i>					
<i>Once patients fail to respond to treatment with 3 bDMARDs, they 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 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.</i>					
6397Q	Powder for I.V. infusion 100 mg	1	875.00	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.

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer \$	Proprietary Name and Manufacturer

INFLIXIMAB—cont.

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.

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer \$	Proprietary Name and Manufacturer

INFLIXIMAB—cont.**(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.

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer \$	Proprietary Name and Manufacturer

INFLIXIMAB—cont.

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 either methotrexate or sulfasalazine, 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 with a record of rheumatoid factor negative status within the last 12 months; 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.

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).

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer \$	Proprietary Name and Manufacturer

INFLIXIMAB—cont.

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.

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 005 750 (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 with a record of rheumatoid factor negative status within the last 12 months; 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.

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer \$	Proprietary Name and Manufacturer

INFLIXIMAB—cont.

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 005 750 (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 with a record of rheumatoid factor negative status within the last 12 months; 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.*

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.*

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer \$	Proprietary Name and Manufacturer

INFLIXIMAB—cont.

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 005 750 (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 with a record of rheumatoid factor negative status; 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)].***

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer \$	Proprietary Name and Manufacturer	
INFLIXIMAB—cont.					
<i>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.</i>					
<i>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.</i>					
<i>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 005 750 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).</i>					
<i>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.</i>					
<i>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.</i>					
6496X	Powder for I.V. infusion 100 mg	1	875.00	Remicade	SH
INTERFERON ALFA-2a					
CAUTION:					
<i>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.</i>					
Private hospital authority required					
<i>Use in the treatment of Philadelphia chromosome positive myelogenous leukaemia in the chronic phase;</i>					
<i>Patients with chronic hepatitis B who satisfy all of the following criteria:</i>					
<i>(1) Histological evidence of chronic hepatitis on liver biopsy (except in patients with coagulation disorders considered severe enough to prevent liver biopsy);</i>					
<i>(2) Abnormal serum ALT levels in conjunction with documented chronic hepatitis B infection (HBe antigen positive and/or HBV DNA positive);</i>					
<i>(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);</i>					
<i>(4) Female patients of child-bearing age are not pregnant, not breast-feeding, and are using an effective form of contraception.</i>					
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

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer \$	Proprietary Name and Manufacturer	
INTERFERON ALFA-2b					
CAUTION:					
<i>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.</i>					
Private hospital authority required					
<i>Adjunctive therapy of malignant melanoma following surgery in patients with nodal involvement;</i>					
<i>Use in the treatment of Philadelphia chromosome positive myelogenous leukaemia in the chronic phase;</i>					
<i>Patients with chronic hepatitis B who satisfy all of the following criteria:</i>					
<i>(1) Histological evidence of chronic hepatitis on liver biopsy (except in patients with coagulation disorders considered severe enough to prevent liver biopsy);</i>					
<i>(2) Abnormal serum ALT levels in conjunction with documented chronic hepatitis B infection (HBe antigen positive and/or HBV DNA positive);</i>					
<i>(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);</i>					
<i>(4) Female patients of child-bearing age are not pregnant, not breast-feeding, and are using an effective form of contraception.</i>					
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					
<i>Treatment of chronic granulomatous disease in patients with frequent and severe infections despite adequate prophylaxis with antimicrobial agents.</i>					
6148N	Injection 2,000,000 i.u. in 0.5 mL vial	6	1260.09	Imukin	BY
LAMIVUDINE					
Private hospital authority required					
<i>Patients with chronic hepatitis B who satisfy all of the following criteria:</i>					
<i>(1) Histological evidence of chronic hepatitis on liver biopsy (except in patients with coagulation disorders considered severe enough to prevent liver biopsy);</i>					
<i>(2) Abnormal serum ALT levels in conjunction with documented chronic hepatitis B infection (HBe antigen positive and/or HBV DNA positive);</i>					
<i>(3) Female patients of child-bearing age are not pregnant, not breast-feeding, and are using an effective form of contraception.</i>					
<i>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.</i>					
6257H	Tablet 100 mg	28	119.50	Zeffix	GK

continued

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer \$	Proprietary Name and Manufacturer	
6271C	LAMIVUDINE—cont. Oral solution 5 mg per mL, 240 mL	1	51.21	Zeffix	GK
	<u>Private hospital authority required</u> <i>Treatment of HIV infection in patients with:</i> <i>(a) CD4 cell counts of less than 500 per cubic millimetre; or</i> <i>(b) viral load of greater than 10,000 copies per mL.</i>				
6193Y	Tablet 150 mg	60	282.00	3TC	GK
6435Q	Tablet 300 mg	30	282.00	3TC	GK
6194B	Oral solution 10 mg per mL, 240 mL	1	75.20	3TC	GK
	LAMIVUDINE with ZIDOVUDINE <u>Private hospital authority required</u> <i>Treatment of HIV infection in patients with:</i> <i>(a) CD4 cell counts of less than 500 per cubic millimetre; or</i> <i>(b) viral load of greater than 10,000 copies per mL.</i>				
6234D	Tablet 150 mg-300 mg	60	578.60	Combivir	GK
	LANREOTIDE ACETATE <u>Private hospital authority required</u> <i>Active acromegaly in patients with persistent elevation of mean growth hormone levels of greater than 2.5 micrograms per litre AND</i> <i>(a) after failure of other therapy including dopamine agonists; or</i> <i>(b) as interim treatment in patients awaiting the effects of radiotherapy and where treatment with dopamine agonists has failed; or</i> <i>(c) where surgery and radiotherapy are contraindicated.</i> <i>Treatment is to cease in patients previously treated with radiotherapy where there is biochemical evidence of remission (normal IGF1) after lanreotide acetate withdrawal for at least 4 weeks (6 weeks after the last dose). Lanreotide acetate should be withdrawn for assessment of remission every 2 years in the 10 years after radiotherapy.</i> <i>Treatment is to cease if there has been failure to lower IGF1 after 3 months treatment.</i>				
6332G	Powder for suspension for injection 30 mg (base) with diluent ampoule	1	750.00	Somatuline LA	IS

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer \$	Proprietary Name and Manufacturer	
LANREOTIDE ACETATE—cont.					
<u>Private hospital authority required</u>					
<i>Active acromegaly in patients with persistent elevation of mean growth hormone levels of greater than 2.5 micrograms per litre AND</i>					
<i>(a) after failure of other therapy including dopamine agonists; or</i>					
<i>(b) as interim treatment in patients awaiting the effects of radiotherapy and where treatment with dopamine agonists has failed; or</i>					
<i>(c) where surgery and radiotherapy are contraindicated.</i>					
<i>Treatment is to cease in patients previously treated with radiotherapy where there is biochemical evidence of remission (normal IGF1) after lanreotide acetate withdrawal for at least 4 weeks (8 weeks after the last dose). Lanreotide acetate should be withdrawn for assessment of remission every 2 years in the 10 years after radiotherapy.</i>					
<i>Treatment is to cease if there has been failure to lower IGF1 after 3 months treatment; Patients with a histologically-confirmed diagnosis of a functional carcinoid tumour, experiencing on average over 1 week, 3 or more episodes per day of diarrhoea and/or flushing, which persists despite the use of anti-histamines, anti-serotonin agents and anti-diarrhoea agents, and for whom surgery or antineoplastic therapy has failed or is inappropriate.</i>					
<i>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.</i>					
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:

Acute lymphoblastic leukaemia;

Ewing's sarcoma;

Germ cell tumours;

Infants and children with CNS tumours;

Neuroblastoma;

Non-Hodgkin's lymphoma (intermediate or high grade);

Osteosarcoma;

Relapsed Hodgkin's disease;

Rhabdomyosarcoma;

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer \$	Proprietary Name and Manufacturer	
LENOGRASTIM—cont.					
<i>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;</i>					
<i>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.</i>					
6337M	Powder for injection 13,400,000 i.u. (105 micrograms) vial	10	512.50	Granocyte 13	MX
6338N	Powder for injection 33,600,000 i.u. (263 micrograms) vial	10	1283.60	Granocyte 34	MX
LOPINAVIR with RITONAVIR					
<u>Private hospital authority required</u>					
<i>Treatment, in combination with 2 or more other antiretroviral drugs, of HIV infection in patients with:</i>					
<i>(a) CD4 cell counts of less than 500 per cubic millimetre; or</i>					
<i>(b) viral load of greater than 10,000 copies per mL.</i>					
6340Q	Capsule 133.3 mg-33.3 mg	90	322.50	Kaletra	AB
6495W	Tablet 200 mg-50 mg	120	645.00	Kaletra	AB
6341R	Oral liquid 400 mg-100 mg per 5 mL, 60 mL	1	129.00	Kaletra	AB
MYCOPHENOLATE MOFETIL					
<u>CAUTION:</u>					
<i>Careful monitoring of patients is mandatory.</i>					
<u>Private hospital authority required</u>					
<i>Management of rejection, under the supervision and direction of a transplant unit, in patients receiving this drug for:</i>					
<i>(a) Prophylaxis of renal allograft rejection. Management includes initiation, stabilisation and review of therapy as required;</i>					
<i>(b) Prophylaxis of cardiac allograft rejection. Management includes initiation, stabilisation and review of therapy as required.</i>					
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

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer \$	Proprietary Name and Manufacturer	
MYCOPHENOLATE SODIUM					
CAUTION:					
<i>Careful monitoring of patients is mandatory.</i>					
Private hospital authority required					
<i>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.</i>					
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
NELFINAVIR MESYLATE					
Private hospital authority required					
<i>Treatment of HIV infection in patients with:</i>					
<i>(a) CD4 cell counts of less than 500 per cubic millimetre; or</i>					
<i>(b) viral load of greater than 10,000 copies per mL.</i>					
6331F	Tablet 250 mg (base)	300	505.56	Viracept	RO
6231Y	Oral powder 50 mg (base) per g, 144 g	1	48.53	Viracept	RO
NEVIRAPINE					
Private hospital authority required					
<i>Treatment of HIV infection in patients with:</i>					
<i>(a) CD4 cell counts of less than 500 per cubic millimetre; or</i>					
<i>(b) viral load of greater than 10,000 copies per mL.</i>					
6215D	Tablet 200 mg	60	271.58	Viramune	BY
OCTREOTIDE ACETATE					
Private hospital authority required					
<i>Active acromegaly in patients with persistent elevation of mean growth hormone levels of greater than 2.5 micrograms per litre AND</i>					
<i>(a) after failure of other therapy including dopamine agonists; or</i>					
<i>(b) as interim treatment in patients awaiting the effects of radiotherapy and where treatment with dopamine agonists has failed; or</i>					
<i>(c) where surgery and radiotherapy are contraindicated.</i>					
<i>Treatment is to cease in patients previously treated with radiotherapy where there is biochemical evidence of remission (normal IGF1) after octreotide withdrawal for at least 4 weeks. Octreotide should be withdrawn for assessment of remission every 2 years in the 10 years after radiotherapy.</i>					
<i>Treatment is to cease if there has been failure to lower IGF1 after 3 months treatment at a dose of 100 micrograms 3 times daily;</i>					
<i>Patients with a histologically-confirmed diagnosis of a functional carcinoid tumour or vasoactive intestinal peptide secreting tumour (VIPoma), experiencing on average over 1 week, 3 or more episodes per day of diarrhoea and/or flushing, which persists despite the use of anti-histamines, anti-serotonin agents and anti-diarrhoea agents, and for whom surgery or antineoplastic therapy has failed or is inappropriate.</i>					

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer \$	Proprietary Name and Manufacturer	
OCTREOTIDE ACETATE—cont.					
<i>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.</i>					
6227R	Injection 50 micrograms (base) in 1 mL	5	41.76	Sandostatin 0.05	NV
6228T	Injection 100 micrograms (base) in 1 mL	5	83.50	Sandostatin 0.1	NV
6229W	Injection 500 micrograms (base) in 1 mL	5	417.96	Sandostatin 0.5	NV

Private hospital authority required

Patients with acromegaly who are controlled on Sandostatin subcutaneous injections. Treatment is to cease in patients previously treated with radiotherapy where there is biochemical evidence of remission (normal IGF1) after octreotide acetate withdrawal for at least 4 weeks (8 weeks after the last dose). Octreotide acetate should be withdrawn for assessment of remission every 2 years in the 10 years after radiotherapy.

Treatment is to cease if there has been failure to lower IGF1 after 3 months of treatment; Patients with a histologically-confirmed diagnosis of a functional carcinoid tumour or vasoactive intestinal peptide secreting tumour (VIPoma) and who are controlled 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	1390.00	Sandostatin LAR	NV
6427G	Injection (modified release) 20 mg (base) vial and diluent syringe	1	1850.00	Sandostatin LAR	NV
6428H	Injection (modified release) 30 mg (base) vial and diluent syringe	1	2315.00	Sandostatin LAR	NV

PEGFILGRASTIM**Private hospital authority required**

For use in patients undergoing induction and consolidation therapy for acute myeloid leukaemia;

Patients being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in:

- Acute lymphoblastic leukaemia;*
- Ewing's sarcoma;*
- Germ cell tumours;*
- Infants and children with CNS tumours;*
- Neuroblastoma;*
- Non-Hodgkin's lymphoma (intermediate or high grade);*
- Osteosarcoma;*
- Relapsed Hodgkin's disease;*
- Rhabdomyosarcoma;*

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer \$	Proprietary Name and Manufacturer	
	PEGFILGRASTIM—cont. <i>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;</i> <i>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;</i> <i>Patients receiving chemotherapy for myeloma who have 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.</i>				
6363X	Injection 6 mg in 0.6 mL single use pre-filled syringe	1	1925.00	Neulasta	AN

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) Abnormal serum ALT levels in conjunction with documented chronic hepatitis B infection (HBe antigen positive and/or HBV DNA positive);*
- (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.

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer \$	Proprietary Name and Manufacturer	
PEGINTERFERON ALFA-2a—cont.					
NOTE:					
<i>Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C:</i>					
<i>(a) a nurse educator/counsellor for patients; and</i>					
<i>(b) 24 hour access by patients to medical advice; and</i>					
<i>(c) an established liver clinic; and</i>					
<i>(d) facilities for safe liver biopsy.</i>					
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
PEGINTERFERON ALFA-2b					
CAUTION:					
<i>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.</i>					
Private hospital authority required					
<i>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:</i>					
<i>(1) Documented chronic hepatitis C infection (repeatedly anti-HCV positive and HCV RNA positive);</i>					
<i>(2) Female patients of child-bearing age are not pregnant, not breast-feeding, and are using an effective form of contraception.</i>					
<i>The treatment course is limited to up to 48 weeks.</i>					
<i>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.</i>					
NOTE:					
<i>Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C:</i>					
<i>(a) a nurse educator/counsellor for patients; and</i>					
<i>(b) 24 hour access by patients to medical advice; and</i>					
<i>(c) an established liver clinic; and</i>					
<i>(d) facilities for safe liver biopsy.</i>					
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

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer \$	Proprietary Name and Manufacturer	
RIBAVIRIN and PEGINTERFERON ALFA-2a					
CAUTION:					
<i>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.</i>					
CAUTION:					
<i>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.</i>					
Private hospital authority required					
<i>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:</i>					
<i>(1) Documented chronic hepatitis C infection (repeatedly anti-HCV positive and HCV RNA positive);</i>					
<i>(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.</i>					
<i>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.</i>					
<i>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).</i>					
<i>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.</i>					
NOTE:					
<i>Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C:</i>					
<i>(a) a nurse educator/counsellor for patients; and</i>					
<i>(b) 24 hour access by patients to medical advice; and</i>					
<i>(c) an established liver clinic; and</i>					
<i>(d) facilities for safe liver biopsy.</i>					
6389G	Pack containing 84 tablets ribavirin 200 mg and 4 pre-filled syringes peginterferon alfa-2a injection 135 micrograms	£1	1432.08	Pegasys RBV	RO
6390H	Pack containing 112 tablets ribavirin 200 mg and 4 pre-filled syringes peginterferon alfa-2a injection 135 micrograms	£1	1520.81	Pegasys RBV	RO

continued ➤

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer \$	Proprietary Name and Manufacturer	
6391J	RIBAVIRIN and PEGINTERFERON ALFA-2a—cont. <i>Pack containing 140 tablets ribavirin 200 mg and 4 pre-filled syringes peginterferon alfa-2a injection 135 micrograms</i>	‡1	1609.53	Pegasys RBV	RO
6392K	<i>Pack containing 168 tablets ribavirin 200 mg and 4 pre-filled syringes peginterferon alfa-2a injection 135 micrograms</i>	‡1	1698.26	Pegasys RBV	RO
6393L	<i>Pack containing 84 tablets ribavirin 200 mg and 4 pre-filled syringes peginterferon alfa-2a injection 180 micrograms</i>	‡1	1616.41	Pegasys RBV	RO
6394M	<i>Pack containing 112 tablets ribavirin 200 mg and 4 pre-filled syringes peginterferon alfa-2a injection 180 micrograms</i>	‡1	1705.14	Pegasys RBV	RO
6395N	<i>Pack containing 140 tablets ribavirin 200 mg and 4 pre-filled syringes peginterferon alfa-2a injection 180 micrograms</i>	‡1	1793.86	Pegasys RBV	RO
6396P	<i>Pack containing 168 tablets ribavirin 200 mg and 4 pre-filled syringes peginterferon alfa-2a injection 180 micrograms</i>	‡1	1882.59	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

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).*

continued ➤

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer \$	Proprietary Name and Manufacturer	
RIBAVIRIN and PEGINTERFERON ALFA-2b—cont.					
<i>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.</i>					
NOTE:					
<i>Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C:</i>					
<i>(a) a nurse educator/counsellor for patients; and</i>					
<i>(b) 24 hour access by patients to medical advice; and</i>					
<i>(c) an established liver clinic; and</i>					
<i>(d) facilities for safe liver biopsy.</i>					
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	1014.02	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	1171.51	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	1338.96	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	1496.44	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	1496.44	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	1555.58	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	1713.07	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	1772.20	Pegatron	SH

continued

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer \$	Proprietary Name and Manufacturer	
6407F	<i>RIBAVIRIN and PEGINTERFERON ALFA-2b—cont.</i> <i>Pack containing 140 capsules ribavirin 200 mg</i> <i>and 4 single use injection pens containing</i> <i>peginterferon alfa-2b powder for injection</i> <i>120 micrograms with diluent</i>	‡1	1929.69	<i>Pegatron</i>	<i>SH</i>
6408G	<i>Pack containing 84 capsules ribavirin 200 mg</i> <i>and 4 single use injection pens containing</i> <i>peginterferon alfa-2b powder for injection</i> <i>150 micrograms with diluent</i>	‡1	2097.14	<i>Pegatron</i>	<i>SH</i>
6409H	<i>Pack containing 140 capsules ribavirin 200 mg</i> <i>and 4 single use injection pens containing</i> <i>peginterferon alfa-2b powder for injection</i> <i>150 micrograms with diluent</i>	‡1	2254.63	<i>Pegatron</i>	<i>SH</i>
6410J	<i>Pack containing 168 capsules ribavirin 200 mg</i> <i>and 4 single use injection pens containing</i> <i>peginterferon alfa-2b powder for injection</i> <i>150 micrograms with diluent</i>	‡1	2254.63	<i>Pegatron</i>	<i>SH</i>
<i>RIFABUTIN</i>					
<u>Private hospital authority required</u>					
<i>Treatment of Mycobacterium avium complex infections in HIV-positive patients;</i> <i>Prophylaxis against Mycobacterium avium complex infections in HIV-positive patients with</i> <i>CD4 cell counts of less than 75 per cubic millimetre.</i>					
6195C	<i>Capsule 150 mg</i>	30	147.00	<i>Mycobutin</i>	<i>PH</i>
<i>RITONAVIR</i>					
<u>Private hospital authority required</u>					
<i>Treatment of HIV infection in patients with:</i> <i>(a) CD4 cell counts of less than 500 per cubic millimetre; or</i> <i>(b) viral load of greater than 10,000 copies per mL.</i>					
6203L	<i>Capsule 100 mg</i>	84	106.17	<i>Norvir</i>	<i>AB</i>
6494T	<i>Oral solution 600 mg per 7.5 mL (80 mg per mL),</i> <i>90 mL</i>	1	91.00	<i>Norvir</i>	<i>AB</i>
<i>SAQUINAVIR</i>					
<u>Private hospital authority required</u>					
<i>Treatment of HIV infection in patients with:</i> <i>(a) CD4 cell counts of less than 500 per cubic millimetre; or</i> <i>(b) viral load of greater than 10,000 copies per mL.</i>					
6248W	<i>Soft gelatin capsule 200 mg</i>	180	227.55	<i>Fortovase</i>	<i>RO</i>
<i>SAQUINAVIR MESYLATE</i>					
<u>Private hospital authority required</u>					
<i>Treatment of HIV infection in patients with:</i> <i>(a) CD4 cell counts of less than 500 per cubic millimetre; or</i> <i>(b) viral load of greater than 10,000 copies per mL.</i>					
6199G	<i>Capsule 200 mg (base)</i>	270	455.00	<i>Invirase</i>	<i>RO</i>
6498B	<i>Tablet 500 mg (base)</i>	120	505.56	<i>Invirase</i>	<i>RO</i>

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer \$	Proprietary Name and Manufacturer	
SIROLIMUS					
CAUTION:					
<i>Careful monitoring of patients is mandatory.</i>					
Private hospital authority required					
<i>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.</i>					
6436R	Tablet 1 mg	100	723.33	Rapamune	WY
6457W	Tablet 2 mg	100	1446.67	Rapamune	WY
6437T	Oral solution 1 mg per mL, 60 mL	1	434.00	Rapamune	WY
STAVUDINE					
Private hospital authority required					
<i>Treatment of HIV infection in patients with:</i>					
<i>(a) CD4 cell counts of less than 500 per cubic millimetre; or</i>					
<i>(b) viral load of greater than 10,000 copies per mL.</i>					
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	55.56	Zerit	BQ
TACROLIMUS					
CAUTION:					
<i>Careful monitoring of patients is mandatory.</i>					
Private hospital authority required					
<i>Management of rejection, under the supervision and direction of a transplant unit, in patients receiving this drug for:</i>					
<i>(a) Prophylaxis and treatment of liver allograft rejection. Management includes initiation, stabilisation and review of therapy as required;</i>					
<i>(b) Prophylaxis and treatment of renal allograft rejection. Management includes initiation, stabilisation and review of therapy as required.</i>					
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
TENOFOVIR DISOPROXIL FUMARATE					
Private hospital authority required					
<i>Treatment of HIV infection in patients with:</i>					
<i>(a) CD4 cell counts of less than 500 per cubic millimetre; or</i>					
<i>(b) viral load of greater than 10,000 copies per mL.</i>					
6358P	Tablet 300 mg	30	499.00	Viread	GI
TENOFOVIR DISOPROXIL FUMARATE with EMTRICITABINE					
Private hospital authority required					
<i>Treatment of HIV infection in patients with:</i>					
<i>(a) CD4 cell counts of less than 500 per cubic millimetre; or</i>					
<i>(b) viral load of greater than 10,000 copies per mL.</i>					
6468K	Tablet 300 mg-200 mg	30	781.00	Truvada	GI

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer \$	Proprietary Name and Manufacturer	
	THALIDOMIDE CAUTION: <i>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.</i>				
	Private hospital authority required <i>Relapsed or refractory multiple myeloma in patients who have failed at least 1 other treatment.</i>				
	NOTE: <i>Patients receiving thalidomide under the PBS listing must be registered in the Pharmion Risk Management Program.</i>				
6469L	Capsule 50 mg	28	420.00	Thalidomide Pharmion	PI
	VALACICLOVIR HYDROCHLORIDE Private hospital authority required <i>Prophylaxis of cytomegalovirus (CMV) infection and disease following renal transplantation in patients at risk of CMV disease.</i>				
6280M	Tablet 500 mg (base)	100	423.18	Valtrex	GK
	VALGANCICLOVIR HYDROCHLORIDE Private hospital authority required <i>Cytomegalovirus retinitis in patients with acquired immunodeficiency syndrome; Prophylaxis of cytomegalovirus infection and disease in solid organ transplant patients at risk of cytomegalovirus disease.</i>				
6357N	Tablet 450 mg (base)	60	2245.80	Valcyte	RO
	ZIDOVUDINE Private hospital authority required <i>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.</i>				
6153W	Capsule 100 mg	100	205.46	Retrovir	GK
6154X	Capsule 250 mg	60	308.19	Retrovir	GK
6155Y	Syrup 10 mg per mL, 200 mL bottle	1	41.09	Retrovir	GK
	ZOLEDRONIC ACID Private hospital authority required <i>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.</i>				
6371H	Injection concentrate for I.V. infusion 4 mg in 5 mL	1	450.00	Zometa	NV
	NOTE: <i>This price is based on special supply arrangements—see Pharmaceutical Benefits Pricing Authority relativity sheet for full details.</i>				

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer \$	Proprietary Name and Manufacturer	
BOTULINUM TOXIN PROGRAM					
BOTULINUM TOXIN TYPE A PURIFIED NEUROTOXIN COMPLEX					
NOTE: <i>Arrangements to prescribe this item should be made by medical practitioners with Medicare Australia, contact telephone number 1800 819 296.</i>					
<i>Treatment of blepharospasm associated with dystonia, including benign blepharospasm and VIIth nerve disorders (hemifacial spasm) in patients 12 years and older;</i>					
<i>Treatment of dynamic equinus foot deformity due to spasticity in ambulant paediatric cerebral palsy patients 2 years of age or older;</i>					
<i>Treatment of spasmodic torticollis, either as monotherapy or as adjunctive therapy to current standard care.</i>					
6103F	Lyophilised powder for I.M. injection 100 units vial	1	415.50	Botox	AG
NOTE: <i>The units used to express the potency of botulinum toxin preparations currently available for PBS subsidy are not equivalent.</i>					
CLOSTRIDIUM BOTULINUM TYPE A TOXIN—HAEMAGGLUTININ COMPLEX					
NOTE: <i>Arrangements to prescribe this item should be made by medical practitioners with Medicare Australia, contact telephone number 1800 819 296.</i>					
<i>Treatment of dynamic equinus foot deformity due to spasticity in ambulant paediatric cerebral palsy patients 2 years of age or older;</i>					
<i>Treatment of spasmodic torticollis, either as monotherapy or as adjunctive therapy to current standard care.</i>					
6293F	Lyophilised powder for I.M. injection 500 units vial	1	650.00	Dysport	IS
NOTE: <i>The units used to express the potency of botulinum toxin preparations currently available for PBS subsidy are not equivalent.</i>					
HUMAN GROWTH HORMONE PROGRAM					
SOMATROPIN <i>(Recombinant human growth hormone)</i>					
<i>Short stature in accordance with the 'Guidelines for the Availability of Human Growth Hormone (hGH) as a Pharmaceutical Benefit'.</i>					
NOTE: <i>These guidelines may be obtained from the Department of Health and Ageing's internet site at http://www.health.gov.au/internet/wcms/publishing.nsf/Content/pbs-hghguidelines-contents, or from:</i>					
<i>Growth Hormone Program Pharmaceutical Benefits Branch Department of Health and Ageing GPO Box 9848 CANBERRA ACT 2601 Contact telephone number (02) 6289 7274</i>					
6266T	Injection 4 mg (12 i.u.) vial with 3.5 mL diluent (with preservative)	1	198.00	SciTropin	SA
6330E	Injection 5 mg (15 i.u.) in 1 mL cartridge (with preservative)	1	247.50	Genotropin	PH

continued

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer \$	Proprietary Name and Manufacturer	
SOMATROPIN					
<i>(Recombinant human growth hormone)—cont.</i>					
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:					
<i>This price is based on special supply arrangements—see Pharmaceutical Benefits Pricing Authority relativity sheet for full details.</i>					
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
NOTE:					
<i>This price is based on special supply arrangements—see Pharmaceutical Benefits Pricing Authority relativity sheet for full details.</i>					
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:					
<i>This price is based on special supply arrangements—see Pharmaceutical Benefits Pricing Authority relativity sheet for full details.</i>					
6345Y	Injection 72 i.u. (24 mg) cartridge with 3.15 mL diluent (with preservative)	1	1188.00	Humatrope	LY
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

continued ➞

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer \$	Proprietary Name and Manufacturer	
SOMATROPIN					
<i>(Recombinant human growth hormone)—cont.</i>					
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					
FOLLITROPIN ALFA					
<i>Patients who are receiving medical treatment as described in items 13200 or 13203 of the Medicare Benefits Schedule.</i>					
NOTE:					
<i>Arrangements to prescribe this item should be made by medical practitioners with Medicare Australia, contact telephone number 1800 700 270.</i>					
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					
<i>Patients who are receiving medical treatment as described in items 13200 or 13203 of the Medicare Benefits Schedule.</i>					
NOTE:					
<i>Arrangements to prescribe this item should be made by medical practitioners with Medicare Australia, contact telephone number 1800 700 270.</i>					
6335K	Solution for injection 300 i.u. in 0.36 mL multi-dose cartridge	1	144.04	Puregon 300 IU/ 0.36 mL	OR
6336L	Solution for injection 600 i.u. in 0.72 mL multi-dose cartridge	1	288.09	Puregon 600 IU/ 0.72 mL	OR
6464F	Solution for injection 900 i.u. in 1.08 mL multi-dose cartridge	1	432.11	Puregon 900 IU/ 1.08 mL	OR

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer \$	Proprietary Name and Manufacturer	
HUMAN CHORIONIC GONADOTROPHIN					
<i>Patients who are receiving medical treatment as described in items 13200 or 13203 of the Medicare Benefits Schedule.</i>					
NOTE:					
<i>Arrangements to prescribe this item should be made by medical practitioners with Medicare Australia, contact telephone number 1800 700 270.</i>					
6176C	Injection set containing 3 ampoules powder for injection 500 units and 3 ampoules solvent 1 mL	1	19.77	Pregnyl	OR
6178E	Injection set containing 3 ampoules powder for injection 1,500 units and 3 ampoules solvent 1 mL	1	27.59	Pregnyl	OR
6181H	Injection set containing 3 ampoules powder for injection 5,000 units and 3 ampoules solvent 1 mL	1	32.00	Pregnyl	OR
PROGESTERONE					
<i>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.</i>					
NOTE:					
<i>Arrangements to prescribe this item should be made by medical practitioners with Medicare Australia, contact telephone number 1800 700 270.</i>					
6366C	Vaginal gel (prolonged release) 90 mg in single dose pre-filled applicator	15	148.50	Crinone 8%	SG
NOTE:					
<i>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').</i>					
OPIATE DEPENDENCE TREATMENT PROGRAM					
<i>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.</i>					
BUPRENORPHINE HYDROCHLORIDE					
<i>Treatment of opiate dependence, including maintenance and detoxification (withdrawal), within a framework of medical, social and psychological treatment.</i>					
NOTE:					
<i>Treatment must be in accordance with the law of the relevant State or Territory.</i>					
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

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer \$	Proprietary Name and Manufacturer	
BUPRENORPHINE HYDROCHLORIDE with NALOXONE HYDROCHLORIDE					
<i>Treatment of opiate dependence within a framework of medical, social and psychological treatment.</i>					
NOTE:					
<i>Treatment must be in accordance with the law of the relevant State or Territory.</i>					
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
METHADONE HYDROCHLORIDE					
CAUTION:					
<i>The risk of drug dependence is high.</i>					
<i>Treatment of opiate dependence in accordance with the law of the relevant State or Territory.</i>					
6171T	Oral liquid 25 mg per 5 mL, 200 mL	1	7.40	^a Biodone Forte ^a GK	MW
6172W	Oral liquid 25 mg per 5 mL, 1 L	1	36.00	^a Biodone Forte ^a GK	MW
6174Y	Powder 1 g (for preparation of other dosage forms)	1	3.50	GK	

SPECIAL AUTHORITY PROGRAM

IMATINIB MESYLATE

NOTE:

Any queries concerning the arrangements to prescribe imatinib mesylate may be directed to Medicare Australia on 1800 242 679.

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*

NOTE:

Imatinib mesylate is not PBS-subsidised for the treatment of patients with resectable malignant gastrointestinal stromal tumours.

Section 100 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.

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer \$	Proprietary Name and Manufacturer

IMATINIB MESYLATE—cont.

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.*

Section 100 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 242 679, 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.)*

6440Y	Tablet 100 mg (base)	60	1886.17	Glivec	NV
6441B	Tablet 400 mg (base)	30	3772.33	Glivec	NV

NOTE:

No applications for increased maximum quantities will be authorised. Up to 2 repeats may be authorised for item 6440Y or 6441B.

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer \$	Proprietary Name and Manufacturer

IMATINIB MESYLATE—cont.**Section 100 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].*

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.

Section 100 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.*

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer \$	Proprietary Name and Manufacturer

IMATINIB MESYLATE—cont.

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;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.

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer \$	Proprietary Name and Manufacturer	
IMATINIB MESYLATE—cont.					
<i>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.</i>					
6444E	Tablet 100 mg (base)	60	1886.17	Glivec	NV
6445F	Tablet 400 mg (base)	30	3772.33	Glivec	NV

NOTE:

Up to 5 repeats may be authorised for item 6444E or 6445F.

Section 100 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.*

Section 100 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.*

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer \$	Proprietary Name and Manufacturer

IMATINIB MESYLATE—cont.

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.*

Section 100 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:

- (i) the accelerated phase of chronic myeloid leukaemia; or*
- (ii) the blast phase of chronic myeloid leukaemia.*

6446G	Tablet 100 mg (base)	60	1886.17	Glivec	NV
6447H	Tablet 400 mg (base)	30	3772.33	Glivec	NV

NOTE:

Up to 2 repeats may be authorised for item 6446G or 6447H.

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.

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer \$	Proprietary Name and Manufacturer

TRASTUZUMAB—cont.

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

Initial treatment for HER2 positive early breast cancer in patients receiving treatment with adjuvant chemotherapy following surgery at 1 October 2006.

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).

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer \$	Proprietary Name and Manufacturer	
	TRASTUZUMAB—cont. <u>Section 100 authority required</u> <i>Initial PBS-subsidised treatment for HER2 positive early breast cancer where the patient was receiving treatment with trastuzumab at 1 October 2006.</i> <i>The patient is eligible to receive sufficient trastuzumab to complete 52 weeks of combined PBS-subsidised and non-PBS-subsidised therapy.</i> <i>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.</i> <i>Authority applications for initial PBS-subsidised treatment must be made in writing and must include:</i> <i>(a) a completed authority prescription form; and</i> <i>(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> <i>(i) the date upon which the patient commenced non-PBS-subsidised treatment with trastuzumab and the number of weeks of treatment received; and</i> <i>(ii) a copy of the signed patient acknowledgement form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].</i> <i>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 regimen, or 3 doses for the once weekly regimen). Up to a maximum of 3 repeats may be authorised.</i>				
	<u>Section 100 authority required</u> <i>Continuing treatment for HER2 positive early breast cancer where the patient has previously received treatment with PBS-subsidised trastuzumab.</i> <i>The patient is eligible to receive sufficient trastuzumab to complete 52 weeks of combined PBS-subsidised and non-PBS-subsidised therapy.</i> <i>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.</i> <i>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).</i> <i>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.</i>				
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	\$0.73
Other Items	25 mL vial	\$0.28

(The 25 mL is the most commonly used size)

FEES:

Dispensing Fee for Ready Prepared Benefits	\$5.15
Dangerous Drug Fee	\$2.71
Additional Fee for Agreed Price Ready Prepared Benefits	\$0.99

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	5 @ 8.47	CS
3463G	Diphtheria and Tetanus Vaccine, Adsorbed, Diluted For Adult Use	0.5 mL	1 @ 7.35	CS
3470P	Hydrocortisone Sodium Succinate	100 mg with 2 mL solvent	1 @ 5.23	PH
3481F	Naloxone Hydrochloride	800 mcg in 2 mL	1 @ 17.80	CS
3482G		2 mg in 5 mL	1 @ 28.46	CS
3488N	Promethazine Hydrochloride	50 mg in 2 mL	5 @ 6.56	MX
SPECIAL PHARMACEUTICAL BENEFITS				
General				
2315W	Bleomycin Sulfate	15,000 i.u.	1 @ 49.57	MX
			(for reimbursement price)	
			1 @ 94.16	MX
			(for total dispensed price)	
8809P	Pemetrexed Disodium	500 mg (base)	1 @ 1450.56	LY
			(for reimbursement price)	
			1 @ 1649.92	LY
			(for total dispensed price)	
9713F		500 mg (base)	1 @ 1649.92	LY
			(for reimbursement price)	
			1 @ 1649.92	LY
			(for total dispensed price)	
GENERAL PHARMACEUTICAL BENEFITS				
8048N	Abciximab	10 mg in 5 mL	1 @ 477.01	LY
8747J	Acetylcysteine	200 mg per mL, 5 mL	6 @ 28.11	BQ
1003T	Aciclovir	200 mg	25 @ 42.08	AF,GM,HX
			25 @ 44.97	GK
2600W	Allopurinol	100 mg	100 @ 4.32	AF
2576N	Aluminium Hydroxide with Magnesium Hydroxide	200 mg-200 mg	100 @ 3.84	WW
			100 @ 4.04	PC
2157M		200 mg-200 mg per 5 mL, 500 mL	1 @ 3.84	WW
			1 @ 3.99	PC
2159P	Aluminium Hydroxide with Magnesium Trisilicate and Magnesium Hydroxide	250 mg-120 mg-120 mg per 5 mL, 500 mL	1 @ 3.84	FM
3109P	Amiloride Hydrochloride	5 mg	50 @ 1.76	AF
3079C	Amino Acid Formula without Methionine, Threonine and Valine and low in Isoleucine	200 g	1 @ 215.10	SB
8554F	Amino Acid Formula without Phenylalanine	500 mg, 200	1 @ 82.44	SB
8678R		1 g, 75	1 @ 61.67	SB
8706F		42 g, 20	1 @ 163.42	SB
2347M		20 g, 30	1 @ 216.91	SB
3072Q		250 g	1 @ 156.00	SB
2379F	Amino Acid Formula without Phenylalanine, Tyrosine and Methionine	500 g	1 @ 362.00	SB

(APPLY WASTAGE FACTOR IN CALCULATING BROKEN QUANTITY PRICES)

Code	Approved Name	Form/Strength	Pack and Price \$	Manufacturer
8479G	Amino Acid Formula with Vitamins, Minerals and Long Chain Polyunsaturated Fatty Acids without Phenylalanine	400 g	1 @ 90.06	SB
8417B	Amino Acid Formula with Vitamins and Minerals without Methionine	400 g	1 @ 89.22	SB
8677Q		20 g, 30	1 @ 335.94	VF
8744F		25 g, 30	1 @ 440.59	VF
8328H		500 g	1 @ 175.00	SB
8416Y		500 g	1 @ 204.60	SB
8058D	Amino Acid Formula with Vitamins and Minerals without Methionine, Threonine and Valine and low in Isoleucine	400 g	1 @ 80.48	SB
8059E		500 g	1 @ 200.46	SB
8061G		500 g	1 @ 253.00	SB
8555G	Amino Acid Formula with Vitamins and Minerals without Phenylalanine	20 g, 30	1 @ 221.15	VF
8591E		25 g, 30	1 @ 380.85	VF
8804J		27.8 g, 30	1 @ 536.94	SB
8613H		29 g, 30	1 @ 228.81	SB
8727H		50 g, 30	1 @ 523.63	SB
8466N		350 g	1 @ 61.39	AB
2737C		400 g	1 @ 62.84	SB
8467P		325 g	1 @ 85.54	AB
8545R		400 g	1 @ 105.27	AB
2738D		500 g	1 @ 113.36	SB
2739E		500 g	1 @ 175.04	SB
8746H		250 mL	18 @ 271.70	SB
9021T		125 mL, 30	1 @ 536.94	SB
8846N		130 mL, 30	1 @ 380.65	VF
8631G	Amino Acid Formula with Vitamins and Minerals without Phenylalanine and Tyrosine	20 g, 30	1 @ 399.44	VF
8667E		25 g, 30	1 @ 582.03	VF
8445L		400 g	1 @ 98.80	SB
8446M		500 g	1 @ 210.00	SB
3078B		500 g	1 @ 272.00	SB
8592F	Amino Acid Formula with Vitamins and Minerals without Valine, Leucine and Isoleucine	20 g, 30	1 @ 221.15	VF
8632H		25 g, 30	1 @ 380.85	VF
8745G		29 g, 30	1 @ 228.81	SB
8468Q		350 g	1 @ 61.39	AB
2380G		400 g	1 @ 62.84	SB
8469R		325 g	1 @ 85.54	AB
8310J		500 g	1 @ 350.00	SB
8260R		500 g	1 @ 113.36	SB
8057C		500 g	1 @ 175.04	SB
8574G	Amino Acids—Synthetic, Formula	400 g	1 @ 44.34	AB
8443J		400 g	1 @ 45.75	SB
8754R		400 g	1 @ 45.75	SB
8575H		400 g	1 @ 44.34	AB
3066J		400 g	1 @ 45.75	SB
8755T		400 g	1 @ 45.75	SB
8736T	Amisulpride	100 mg per mL, 60 mL	1 @ 66.90	SW

(APPLY WASTAGE FACTOR IN CALCULATING BROKEN QUANTITY PRICES)

Code	Name	Form/Strength	Pack and Price \$	Manufacturer
1140B	BCG Immunotherapeutic (Bacillus Calmette-Guérin/ Connaught strain)	6.6 to 19.2 x 10 ⁸ CFU set	1 @ 151.15	AV
9002T	Benzathine Penicillin	900 mg (1,200,000 i.u.)	10 @ 202.25	AS
8743E		900 mg in 2 mL	1 @ 20.28	AS
9003W		900 mg (1,200,000 i.u.)	10 @ 202.25	AS
1775K	Benzylpenicillin	600 mg	5 @ 8.47	CS
2647H		3 g	5 @ 22.14	CS
2812B	Betamethasone Valerate	200 mcg (base) per g, 100 g	1 @ 4.14	EX,FM,SH
			1 @ 7.14	SI
2820K		200 mcg (base) per g, 100 g	1 @ 4.14	EX,SH
8066M	Bifonazole	10 mg per g, 15 g	1 @ 9.27	BN
2544X	Biperiden Hydrochloride	2 mg	100 @ 6.92	AB
1260H	Bisacodyl	10 mg, 10	1 @ 5.03	PP
			1 @ 5.40	BY
1258F		10 mg, 12	1 @ 4.10	FL,PP
3116B	Calcium	500 mg	60 @ 4.22	MM
8740B	Calcium Folate	equiv. to 50 mg folic acid in 5 mL	1 @ 30.28	MX
			10 @ 238.93	PF
8812T		equiv. to 100 mg folic acid in 10 mL	1 @ 27.21	IT
9041W		equiv. to 300 mg folic acid in 30 mL	1 @ 78.80	MX
1153Q	Carbimazole	5 mg	100 @ 11.77	RO
8576J	Carbohydrate, Fat, Vitamins, Minerals and Trace Elements	400 g	1 @ 31.76	AB
8369L		400 g	1 @ 36.75	SB
8514D	Carbomer 974	3 mg per g, 0.5 g, 30	1 @ 9.45	AQ
8578L	Carbomer 980	2 mg per g, 0.6 mL, 30	1 @ 9.45	NV
1160C	Carboplatin	50 mg in 5 mL	1 @ 31.57	IT,MX,PU
1161D		150 mg in 15 mL	1 @ 72.31	IT,MX,PU
1162E		450 mg in 45 mL	1 @ 139.59	IT,MX,PU
8823J	Carmellose Sodium	2.5 mg per mL, 0.6 mL, 24	1 @ 7.56	CX
2338C		5 mg per mL, 0.4 mL, 30	1 @ 9.45	AG
2324H		10 mg per mL, 0.4 mL, 30	1 @ 9.45	AG
8824K		10 mg per mL, 0.6 mL, 28	1 @ 8.82	CX
8315P	Cefepime	1 g	1 @ 17.74	BQ
8316Q		2 g	1 @ 32.52	BQ
1085D	Cefotaxime	1 g	1 @ 4.71	SZ
1086E		2 g	1 @ 8.69	SZ
1783W	Ceftriaxone	500 mg	1 @ 3.97	IZ
1784X		1 g	1 @ 6.20	IZ,RO,SZ
1785Y		2 g	1 @ 11.51	IZ,MX,RO, SZ
1256D	Cephazolin	500 mg	5 @ 19.44	MX
1257E		1 g	5 @ 30.67	MX,SZ
1163F	Chlorambucil	2 mg	25 @ 18.79	GK
1585K	Chlorthalidone	25 mg	50 @ 3.45	NV
2967E	Cholestyramine	4.7 g (equiv. to 4 g cholestyramine)	1 @ 25.52	BQ
1217C	Ciprofloxacin	3 mg per mL, 5 mL	1 @ 11.98	IQ
			1 @ 13.19	AQ
8800E	Cladribine	10 mg in 5 mL	1 @ 648.40	OA
1211R	Clomiphene Citrate	50 mg	5 @ 17.01	AW,GX,HX

(APPLY WASTAGE FACTOR IN CALCULATING BROKEN QUANTITY PRICES)

Code	Approved Name	Form/Strength	Pack and Price \$	Manufacturer
1805B	Clonazepam	500 mcg	100 @ 8.79	AF
			100 @ 11.08	RO
1806C		2 mg	100 @ 16.52	AF
			100 @ 19.12	RO
1808E		2.5 mg per mL, 10 mL	1 @ 4.13	RO
1027C	Clotrimazole	10 mg per mL, 20 mL	1 @ 5.71	BN
8785J	Codeine Phosphate with Paracetamol	30 mg-500 mg	20 @ 2.11	AL,CO,DK, FM,GK
			20 @ 3.95	SW
1228P	Copper Sulfate	Tablets, 36	1 @ 32.53	BN
1079T	Cyclophosphamide	500 mg	1 @ 11.17	BX
8657P	Cyclosporin	10 mg	60 @ 44.00	NV
8658Q		25 mg	30 @ 49.24	HX
			30 @ 50.40	NV
8659R		50 mg	30 @ 102.12	HX
			30 @ 103.27	NV
8660T		100 mg	30 @ 198.73	HX
			30 @ 199.89	NV
8661W		100 mg per mL, 50 mL	1 @ 353.12	NV
1798P	Cyproheptadine Hydrochloride	4 mg	50 @ 3.72	FR
1270W	Cyproterone Acetate	50 mg	50 @ 131.20	AF,GM,GX, HX,SY
			50 @ 133.20	SC
2884T	Cytarabine	100 mg in 5 mL	5 @ 30.76	PU
8641T	Dalteparin Sodium (Low Molecular Weight Heparin Sodium—porcine mucous)	2,500 units (anti-Xa) in 0.2 mL	10 @ 49.16	PH
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 @ 48.31	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
1299J	Diclofenac Sodium	25 mg (e.c.)	50 @ 4.24	AW,BG,CH, GM,GX, HX,TW
			50 @ 5.83	NV
1302M		100 mg	20 @ 8.84	NV
3164M	Digoxin	50 mcg per mL, 60 mL	1 @ 10.65	SI
1341N	Diphtheria and Tetanus Vaccine, Adsorbed	0.5 mL	1 @ 4.49	CS
8783G	Diphtheria and Tetanus Vaccine, Adsorbed, Diluted For Adult Use	0.5 mL	1 @ 7.35	CS
8461H	Disodium Pamidronate	15 mg in 5 mL	1 @ 65.67	MX
8462J		30 mg in 10 mL	1 @ 131.35	MX
8071T	Docetaxel	20 mg (anhydrous) set	1 @ 327.33	AV
1125F	Docusate Sodium with Bisacodyl	100 mg-10 mg, 5	1 @ 2.52	FM
1336H	Doxorubicin Hydrochloride	10 mg in 5 mL	1 @ 34.80	IT,MX,PH
1340M		20 mg in 10 mL	1 @ 61.09	PH
1342P		50 mg in 25 mL	1 @ 139.79	IT,MX,PH

(APPLY WASTAGE FACTOR IN CALCULATING BROKEN QUANTITY PRICES)

Code	Name	Form/Strength	Pack and Price \$	Manufacturer
2702F	Doxycycline	100 mg	7 @ 2.61	AF,CH,GM, GX,SI,SZ, TW
			7 @ 4.14	PF
2703G		100 mg	7 @ 2.61	FA
			7 @ 4.07	MX
2714W		100 mg	7 @ 2.61	AF,CH,GM, SI,SZ,TW
			7 @ 4.14	PF
3199J	Electrolyte Replacement Solution	1 L	1 @ 7.44	BX
8716R	Enoxaparin Sodium	20 mg (2,000 i.u. anti-Xa) in 0.2 mL	10 @ 49.16	AV
8639Q		40 mg (4,000 i.u. anti-Xa) in 0.4 mL	10 @ 51.23	AV
8640R		60 mg (6,000 i.u. anti-Xa) in 0.6 mL	10 @ 73.26	AV
8367J	Entacapone	200 mg	100 @ 137.70	NV
1375J	Epirubicin Hydrochloride	10 mg in 5 mL	1 @ 54.34	IT,PH
1376K		20 mg in 10 mL	1 @ 100.69	PH
1377L		50 mg in 25 mL	1 @ 247.37	IT,PH
9018P		50 mg	1 @ 247.37	MX
8817C		100 mg in 50 mL	1 @ 488.09	IT
8397Y	Eprosartan Mesylate	400 mg (base)	28 @ 11.06	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 @ 8.90	AB
8001D	Essential Amino Acids Formula with Minerals and Vitamin C	200 g	1 @ 64.88	SB
8778B	Etanercept	25 mg and 1 mL solvent, 4	1 @ 889.62	WY
8779C		25 mg and 1 mL solvent, 4	1 @ 896.29	WY
9035M		25 mg and 1 mL solvent, 4	1 @ 896.29	WY
9036N		25 mg and 1 mL solvent, 4	1 @ 896.29	WY
8637N		25 mg and 1 mL solvent, 4	1 @ 896.29	WY
8638P		25 mg and 1 mL solvent, 4	1 @ 896.29	WY
9037P		25 mg and 1 mL solvent, 4	1 @ 896.29	WY
8748K	Ethacrynic Acid	25 mg	100 @ 25.63	MK
1390E	Etoposide	100 mg in 5 mL	1 @ 34.06	IT,MX
8120J	Etoposide Phosphate	113.6 mg (equiv. to 100 mg etoposide)	1 @ 34.06	BQ
8842J	Everolimus	0.75 mg	60 @ 775.87	NV
1473M	Fluconazole	100 mg in 50 mL	1 @ 26.52	PF
1474N		200 mg in 100 mL	1 @ 47.93	PF
1433K	Fludrocortisone Acetate	100 mcg	100 @ 5.84	BQ
2528C	Fluorouracil	500 mg in 10 mL	1 @ 5.23	IT,MX
9005Y		1000 mg in 20 mL	1 @ 8.90	IT
2958Q	Folic Acid	500 mcg	100 @ 3.27	AF
1437P		5 mg	100 @ 3.44	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 @ 553.09	SG
8565T	Follitropin Beta	300 i.u. in 0.36 mL	1 @ 185.67	OR
8566W		600 i.u. in 0.72 mL	1 @ 371.33	OR
8871X		900 i.u. in 1.08 mL	1 @ 553.08	OR
2414C	Frusemide	20 mg	50 @ 1.66	FM,GM
			50 @ 2.20	AV
8444K	Gelatin - Succinylated	20 g per 500 mL, 500 mL	1 @ 12.77	BR

(APPLY WASTAGE FACTOR IN CALCULATING BROKEN QUANTITY PRICES)

Code	Approved Name	Form/Strength	Pack and Price \$	Manufacturer
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 @ 6.86	MX
2245E	Glucose	278 mmol per L, 1 L	1 @ 3.73	BX
2891E	Glucose Indicator—Blood	Electrode strips, 50	1 @ 23.24	RD
8634K		Electrode strips, 50	1 @ 26.94	BN
8890X		Electrode strips, 50	1 @ 23.24	MS
9013J		Electrode strips, 50	1 @ 23.24	DR
8749L		Electrode strips, 50	1 @ 23.24	DR
8766J		Electrode strips, 50	1 @ 23.24	DR
8557J		Electrode strips, 50	1 @ 23.24	GD
8682Y		Electrode strips, 50	1 @ 23.24	WF
8723D		Electrode strips, 50	1 @ 23.24	BR
9063B		Electrode strips, 50	1 @ 23.24	BR
9046D		Electrode strips, 50	1 @ 23.24	DN
8825L		Electrode strips, 50	1 @ 23.24	DR
8176H		Discs containing electrode sensors, 10 sensors per disc, 5	1 @ 23.24	BN
8190C		Reagent strips, 50	1 @ 23.24	RD
8739Y		Reagent strips, 50	1 @ 23.24	RD
8806L		Reagent strips, 51	1 @ 23.24	RD
2890D		Reagent strips, 50	1 @ 23.24	NA
8759B		Reagent strips, 50	1 @ 23.24	LB
2914J		Reagent strips, 50	1 @ 19.24	NA
2917M		Reagent strips, 50	1 @ 19.24	BN
8795X		Reagent strips, 50	1 @ 23.24	PX
2352T	Glucose Indicator—Urine	Reagent strips, 50	1 @ 6.41	BN
3104J		Reagent strips, 50	1 @ 5.94	BN
3106L	Glucose and Ketone Indicator— Urine	Reagent strips, 50	1 @ 5.20	RD
3107M		Reagent strips, 50	1 @ 5.26	BN
2555L	Glycerol	700 mg, 12	1 @ 3.25	PP
2556M		1.4 g, 12	1 @ 3.36	PP
2557N		2.8 g, 12	1 @ 3.47	PP
8728J	Granisetron Hydrochloride	2 mg (base)	1 @ 26.28	MX
1076P	Heparin Sodium	35,000 units in 35 mL	1 @ 11.59	MX
1583H	Human Chorionic Gonadotrophin	500 units set	1 @ 23.39	OR
1640H	Hydralazine Hydrochloride	25 mg	100 @ 4.35	AF
1639G		50 mg	100 @ 5.26	AF
1486F	Hydrochlorothiazide with Amiloride Hydrochloride	50 mg-5 mg	50 @ 3.10 50 @ 4.75	AF MK
1502C	Hydrocortisone Acetate	21.1 g	1 @ 15.17	GC
1510L	Hydrocortisone Sodium Succinate	100 mg with 2 mL solvent	1 @ 5.23	PH
1511M		250 mg with 2 mL solvent	1 @ 9.46	PH
1501B		100 mg with 2 mL solvent	1 @ 5.23	PH
8299T	Hypromellose with Dextran	3 mg-1 mg per mL, 0.4 mL, 28	1 @ 8.82	AQ
3198H	Ibuprofen	200 mg	50 @ 2.70	AF
3190X		400 mg	30 @ 2.65	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
2454E	Indomethacin	25 mg	50 @ 2.70 50 @ 4.19	AF MK
2757D		100 mg	20 @ 7.69	MK

(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
9039R	Insulin Glargine	100 units per mL, 3 mL, 5	1 @ 85.26	AV
1711C	Insulin Isophane (N.P.H.)	100 units per mL, 10 mL	1 @ 25.48	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 @ 25.48	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,NO
1425B		100 units (50 units- 50 units) per mL, 10 mL	1 @ 25.48	NO
8006J		100 units (20 units- 80 units) per mL, 3 mL, 5	1 @ 43.58	NO
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 @ 17.37	BY
1542E		250 mcg (anhydrous) in 1 mL, 30	1 @ 19.68	AF,AW,CH, GM,GX,PU, TW
			1 @ 20.14	BY
8238N		500 mcg (anhydrous) in 1 mL, 30	1 @ 23.27	AF,AW,CH, GM,GX,PU, TW
			1 @ 23.72	BY
1541D		250 mcg (anhydrous) per mL, 20 mL	1 @ 5.86	BY
8415X	Irinotecan Hydrochloride Trihydrate	100 mg in 5 mL	1 @ 330.22	MX,PU
2587E	Isosorbide Dinitrate	10 mg	100 @ 3.62	AF
			100 @ 5.40	SI
2588F		5 mg	100 @ 4.21	SI
1588N	Ketoprofen	100 mg	20 @ 8.04	AV

(APPLY WASTAGE FACTOR IN CALCULATING BROKEN QUANTITY PRICES)

Code	Approved Name	Form/Strength	Pack and Price \$	Manufacturer
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
2913H	Levonorgestrel	30 mcg	1 @ 2.61	SC
1456P	Levonorgestrel with Ethinyloestradiol	Tablet-Pack	1 @ 2.61	SC
1393H		150 mcg-30 mcg	1 @ 5.40	SC
1394J		Tablet-Pack	1 @ 2.61	SY
			1 @ 5.40	SC
1392G		Tablet-Pack	1 @ 2.61	SY
			1 @ 5.40	SC
8290H	Lithium Carbonate	450 mg (s.r.)	100 @ 10.67	GK
1598D	Mercaptopurine	50 mg	25 @ 23.82	GK
8753Q	Mesalazine	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
2826R	Methysergide	1 mg	50 @ 18.72	NV
1638F	Metronidazole	500 mg in 100 mL	1 @ 7.44	BX
9026C	Miconazole Nitrate	20 mg per g, 15 g	1 @ 4.53	JC
8282X	Milk Powder—Lactose Free Formula	900 g	1 @ 16.50	WY
2350Q		900 g	1 @ 16.50	NU
8283Y		900 g	1 @ 16.50	WY
2349P		900 g	1 @ 16.50	NU
2358D	Milk Powder—Lactose Modified	900 g	1 @ 17.00	SJ
2357C		900 g	1 @ 17.00	SJ
3092R	Milk Powder—Synthetic	400 g	1 @ 36.40	NU
8630F	Milk Protein and Fat Formula with Vitamins and Minerals—Carbohydrate Free	225 g	1 @ 27.64	SB
8816B	Modafinil	100 mg	60 @ 170.28	CS
1674D	Naproxen	250 mg	50 @ 4.65	AF
			50 @ 6.15	RO
8298R	Naratriptan Hydrochloride	2.5 mg (base)	2 @ 10.65	GK
2732T	Nitrazepam	5 mg	25 @ 1.87	AF
			25 @ 3.83	VT
1967M	Norethisterone	350 mcg	1 @ 2.61	JC,KR
			1 @ 3.58	PH
2772X	Norethisterone with Ethinyloestradiol	500 mcg-35 mcg	1 @ 4.53	PH
2774B		Tablet-Pack	1 @ 2.61	KR
			1 @ 4.53	PH
2773Y		1 mg-35 mcg	1 @ 4.53	PH
2775C		Tablet-Pack	1 @ 2.61	KR
			1 @ 4.53	PH
2776D		Tablet-Pack	1 @ 2.61	KR
			1 @ 4.53	PH
3176E	Norethisterone with Mestranol	1 mg-50 mcg	1 @ 2.61	PH
3179H		Tablet-Pack	1 @ 2.61	PH
1698J	Nystatin	100,000 units per g, 15 g	1 @ 4.35	BQ
1733F	Oestrogens—Conjugated	300 mcg	28 @ 3.66	WY
1734G		625 mcg	28 @ 3.89	WY
8383F	Ofloxacin	3 mg per mL, 5 mL	1 @ 11.98	AG

(APPLY WASTAGE FACTOR IN CALCULATING BROKEN QUANTITY PRICES)

Code	Name	Form/Strength	Pack and Price \$		Manufacturer
3134Y	Oxazepam	15 mg	25 @	1.24	AF
			25 @	2.98	SI
3135B		30 mg	25 @	1.44	AF,FM
			25 @	3.29	SI
8588B	Oxcarbazepine	60 mg per mL, 250 mL	1 @	65.85	NV
3026G	Paclitaxel	30 mg in 5 mL	1 @	196.66	BQ,IT,MX
8018B		100 mg in 16.7 mL	1 @	647.24	BQ,IT,MX
3017T		150 mg in 25 mL	1 @	934.30	BQ,IT,MX
8556H		not less than 5,000 BP units	100 @	22.56	SM
	Pancreatic Extract	lipase activity			
8020D		not less than 10,000 BP	100 @	32.87	SM
		units lipase activity			
8021E		not less than 25,000 BP	100 @	65.74	SM
	Pancrelipase	units lipase activity			
2495H		not less than 10,000 BP	250 @	83.58	OR
		units lipase activity			
8366H		not less than 25,000 BP	100 @	65.74	TM
	Paracetamol	units lipase activity			
8784H		500 mg	100 @	2.55	AW,CH,FM, GM,HX,JT, PC,SW,TW
8814X		665 mg (m.r.)	96 @	3.27	ME
	Paraffin		96 @	5.63	GC
1754H		3.5 g	1 @	6.97	IQ
			1 @	7.93	AQ
1703P	Phenoxymethylpenicillin	250 mg	25 @	3.28	SI
1787C		250 mg	25 @	3.28	SI
3028J		500 mg	25 @	4.87	SI
2356B		125 mg per 5 mL, 100 mL	1 @	3.67	FM
	2354X		1 @	4.58	SI
		250 mg per 5 mL, 100 mL	1 @	5.02	FM
			1 @	5.92	SI
2334W	Polygeline	17.5 g per 500 mL, 500 mL	1 @	12.77	AE
2642C	Potassium Chloride	600 mg	100 @	2.89	NM
			100 @	4.28	NV
1920C		Prednisolone Sodium Phosphate	7 @	31.89	SI
		equiv. to 20 mg prednisolone			
	2554K	in 100 mL			
		equiv. to 5 mg prednisolone,	1 @	8.68	SI
		10			
1948M	Promethazine Hydrochloride	50 mg in 2 mL	5 @	6.56	MX
1953T	Propantheline Bromide	15 mg	100 @	9.58	SI
1955X	Propylthiouracil	50 mg	100 @	20.20	PL
2676W	Protein Hydrolysate Formula with Medium Chain Triglycerides	400 g	1 @	11.48	NT
8259Q		450 g	1 @	12.93	NU
8284B		2 mg	1 @	283.29	AP
1937Y	Ranitidine Hydrochloride	150 mg (base), effervescent	30 @	9.41	GK
8903N		150 mg (base), effervescent	30 @	9.41	GK
8162N		150 mg (base) per 10 mL,	1 @	8.37	GK
		300 mL			
8905Q		150 mg (base) per 10 mL,	1 @	8.37	GK
		300 mL			

(APPLY WASTAGE FACTOR IN CALCULATING BROKEN QUANTITY PRICES)

Code	Approved Name	Form/Strength	Pack and Price		Manufacturer
			\$		
8787L	Risperidone	0.5 mg	20 @	11.11	JC
8788M		0.5 mg (orally disintegrating)	28 @	15.55	JC
8790P		1 mg (orally disintegrating)	28 @	31.10	JC
8869T		0.5 mg	20 @	11.11	JC
8870W		0.5 mg (orally disintegrating)	28 @	15.55	JC
8792R		1 mg (orally disintegrating)	28 @	31.10	JC
8794W		2 mg (orally disintegrating)	28 @	62.49	JC
8780D		25 mg	1 @	157.36	JC
8781E		37.5 mg	1 @	201.99	JC
8782F		50 mg	1 @	246.67	JC
1103C	Salbutamol Sulfate	2 mg (base) per 5 mL, 150 mL	1 @	3.77	GK
1099W		200 mcg (base)	100 @	7.70	GK
8288F		100 mcg (base) per dose (200 doses)	1 @	5.62	AL,AW
			1 @	5.92	MM
			1 @	6.12	GK
8354Q		100 mcg (base) per dose (200 doses)	1 @	15.39	MM
2000G		2.5 mg (base) in 2.5 mL, 30	1 @	9.12	AF,AW,CH, GX,PU,TW
2001H		5 mg (base) in 2.5 mL, 30	1 @	10.19	GK
			1 @	9.64	AF,AW,CH, GX,TW
			1 @	10.70	GK
2003K	Salcatonin	5 mg (base) per mL, 30 mL	1 @	3.34	PU
2995P		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 @	3.95	RC
2264E	Sodium Chloride	154 mmol per L, 1 L	1 @	3.73	BX
2260Y		513 mmol per L, 1 L	1 @	5.64	BX
2266G	Sodium Chloride Compound	1 L	1 @	5.64	BX
2281C	Sodium Chloride with Glucose	31 mmol-222 mmol per L, 1 L	1 @	3.73	BX
2279Y		19 mmol-104 mmol per 500 mL, 500 mL	1 @	4.90	BX
2278X		39 mmol-69 mmol per 500 mL, 500 mL	1 @	4.90	BX
1124E	Sodium Cromoglycate	20 mg in 2 mL	60 @	26.84	AV
2286H	Sodium Lactate Compound	1 L	1 @	3.73	BX
2294R	Sodium Valproate	100 mg	100 @	12.07	SW
2289L		200 mg (e.c.)	100 @	15.30	AF
			100 @	15.94	SW
			100 @	30.29	AF
2290M		500 mg (e.c.)	100 @	31.09	SW
2293Q		200 mg per 5 mL, 300 mL	1 @	13.63	SW
2295T		200 mg per 5 mL, 300 mL	1 @	13.63	SW
2091C	Sorbitol with Sodium Citrate and Sodium Lauryl Sulfoacetate	3.125 g-450 mg-45 mg in 5 mL, 12	1 @	14.42	PH
8577K	Soy Protein and Fat Formula with Vitamins and Minerals— Carbohydrate Free	384 mL	1 @	5.53	AB
2093E	Sulfasalazine	500 mg	100 @	23.47	PH
2096H		500 mg (e.c.)	100 @	25.83	KR
			100 @	26.63	PH
2047R	Sulindac	100 mg	50 @	4.74	AF

(APPLY WASTAGE FACTOR IN CALCULATING BROKEN QUANTITY PRICES)

Code	Name	Form/Strength	Pack and Price \$	Manufacturer
8144P	Sumatriptan Succinate	50 mg (base)	2 @ 10.65	GK,ME
8885P		50 mg (base) (fast disintegrating)	2 @ 10.65	GK
2109B	Tamoxifen Citrate	10 mg (base)	30 @ 21.76	AP
2110C		20 mg (base)	30 @ 37.79	AP
2088X	Temazepam	10 mg	25 @ 1.87	AF,FM
			25 @ 3.64	SI
8819E	Temozolomide	5 mg	5 @ 70.43	SH
8820F		20 mg	5 @ 197.02	SH
8821G		100 mg	5 @ 824.87	SH
1251W	Terbutaline Sulfate	5 mg in 2 mL, 30	1 @ 10.70	AP
8098F	Testosterone	100 mg	1 @ 31.58	OR
8099G		200 mg	1 @ 63.17	OR
2670M	Testosterone Esters	100 mg	1 @ 4.54	OR
2101N		250 mg	1 @ 8.62	OR
2832C	Tetracosactrin	1 mg in 1 mL	1 @ 12.97	NV
2345K	Thiotepa	15 mg	1 @ 65.05	SI
8223T	Tiagabine Hydrochloride	15 mg (base)	50 @ 95.23	MX
1356J	Tobramycin Sulfate	80 mg (base) in 2 mL (with preservative)	5 @ 29.30	MX
8872Y		80 mg (base) in 2 mL (without preservative)	5 @ 29.30	PU
2117K	Triamcinolone Acetonide	200 mcg per g, 100 g	1 @ 4.14	FM
			1 @ 5.73	SI
2118L		200 mcg per g, 100 g	1 @ 4.14	FM
			1 @ 5.73	SI
3128P	Triglycerides, Medium Chain	500 mL	1 @ 23.56	SB
8478F	Triglycerides—Medium Chain, Formula	400 g	1 @ 39.49	SB
8629E	Triglycerides, Medium Chain and Long Chain with Glucose Polymer	420 g	1 @ 43.13	SB
3136C		400 g	1 @ 31.44	SB
8133C	Valaciclovir Hydrochloride	500 mg (base)	10 @ 49.68	GK
3113W	Vancomycin	125 mg	20 @ 121.66	LY
3114X		250 mg	20 @ 234.33	LY
3130R		500 mg	1 @ 22.83	AS,MX
3131T		500 mg	1 @ 22.83	AS,MX
2374Y	Vincristine Sulfate	1 mg in 1 mL	5 @ 79.05	MX,PU
9009E	Vinorelbine Tartrate	20 mg (base)	1 @ 104.82	FB
9010F		30 mg (base)	1 @ 155.89	FB
8280T		10 mg (base) in 1 mL	1 @ 74.69	FB,IT,MX
8281W		50 mg (base) in 5 mL	1 @ 311.28	FB,IT,MX
8587Y	Whey Protein Formula supplemented with Amino Acids, Vitamins and Minerals, and low in Protein, Phosphate, Potassium and Lactose	400 g	1 @ 48.88	SB
8266C	Zolmitriptan	2.5 mg	2 @ 10.60	AP

PREPARATIONS WHICH MAY BE PRESCRIBED FOR PATIENTS RECEIVING PALLIATIVE CARE

5303D	Bisacodyl	10 mg, 10	1 @ 5.03	PP
			1 @ 5.40	BY
5304E		10 mg, 12	1 @ 4.10	FL,PP
5307H		10 mg, 10	1 @ 5.03	PP
		10 mg, 12	1 @ 5.40	BY
5308J			1 @ 4.10	FL,PP

(APPLY WASTAGE FACTOR IN CALCULATING BROKEN QUANTITY PRICES)

Code	Approved Name	Form/Strength	Pack and Price \$	Manufacturer
5339B	Clonazepam	2.5 mg per mL, 10 mL	1 @ 4.13	RO
5342E		2.5 mg per mL, 10 mL	1 @ 4.13	RO
5361E	Diclofenac Sodium	25 mg (e.c.)	50 @ 4.24	AW,BG,CH, GM,GX, HX,TW
			50 @ 5.83	NV
5364H		25 mg (e.c.)	50 @ 4.24	AW,BG,CH, GM,GX, HX,TW
			50 @ 5.83	NV
5363G		100 mg	20 @ 8.84	NV
5366K		100 mg	20 @ 8.84	NV
5309K	Docusate Sodium with Bisacodyl	100 mg-10 mg, 5	1 @ 2.52	FM
5310L		100 mg-10 mg, 5	1 @ 2.52	FM
5311M	Glycerol	700 mg, 12	1 @ 3.25	PP
5312N		1.4 g, 12	1 @ 3.36	PP
5313P		2.8 g, 12	1 @ 3.47	PP
5314Q		700 mg, 12	1 @ 3.25	PP
5315R		1.4 g, 12	1 @ 3.36	PP
5316T		2.8 g, 12	1 @ 3.47	PP
5367L	Ibuprofen	200 mg	50 @ 2.70	AF
5368M		400 mg	30 @ 2.65	AB
5369N		200 mg	50 @ 2.70	AF
5370P		400 mg	30 @ 2.65	AB
5377B	Indomethacin	25 mg	50 @ 2.70	AF
			50 @ 4.19	MK
5379D		25 mg	50 @ 2.70	AF
			50 @ 4.19	MK
5378C		100 mg	20 @ 7.69	MK
5380E		100 mg	20 @ 7.69	MK
5345H	Naproxen	250 mg	50 @ 4.65	AF
			50 @ 6.15	RO
5349M		250 mg	50 @ 4.65	AF
			50 @ 6.15	RO
5359C	Nitrazepam	5 mg	25 @ 1.87	AF
			25 @ 3.83	VT
5360D		5 mg	25 @ 1.87	AF
			25 @ 3.83	VT
5371Q	Oxazepam	15 mg	25 @ 1.24	AF
			25 @ 2.98	SI
5372R		30 mg	25 @ 1.44	AF,FM
			25 @ 3.29	SI
5373T		15 mg	25 @ 1.24	AF
			25 @ 2.98	SI
5374W		30 mg	25 @ 1.44	AF,FM
			25 @ 3.29	SI
5343F	Paracetamol	665 mg (m.r.)	96 @ 3.27	ME
			96 @ 5.63	GC
5344G		665 mg (m.r.)	96 @ 3.27	ME
			96 @ 5.63	GC
5331N	Sorbitol with Sodium Citrate and Sodium Lauryl Sulfoacetate	3.125 g-450 mg-45 mg in 5 mL, 12	1 @ 14.42	PH
5332P		3.125 g-450 mg-45 mg in 5 mL, 12	1 @ 14.42	PH
5381F	Sulindac	100 mg	50 @ 4.74	AF
5383H		100 mg	50 @ 4.74	AF

(APPLY WASTAGE FACTOR IN CALCULATING BROKEN QUANTITY PRICES)

Code	Name	Form/Strength	Pack and Price \$		Manufacturer
5375X	Temazepam	10 mg	25 @	1.87	AF,FM
			25 @	3.64	SI
5376Y		10 mg	25 @	1.87	AF,FM
			25 @	3.64	SI

**PREPARATIONS WHICH MAY BE PRESCRIBED BY PARTICIPATING DENTAL PRACTITIONERS
FOR DENTAL TREATMENT ONLY**

5252K	Benzathine Penicillin	900 mg (1,200,000 i.u.)	10 @	202.25	AS
3398W	Benzylpenicillin	600 mg	5 @	8.47	CS
3399X		3 g	5 @	22.14	CS
5048Q	Cefotaxime	1 g	1 @	4.71	SZ
5049R		2 g	1 @	8.69	SZ
5076E	Diclofenac Sodium	25 mg (e.c.)	50 @	4.24	AW,BG,CH, GM,GX, HX,TW
			50 @	5.83	NV
5079H		100 mg	20 @	8.84	NV
5088T		1 g (base)	1 @	8.90	AB
5106R	Glucose	278 mmol per L, 1 L	1 @	3.73	BX
5118J	Hydrocortisone Sodium Succinate	100 mg with 2 mL solvent	1 @	5.23	PH
5119K		250 mg with 2 mL solvent	1 @	9.46	PH
5121M	Ibuprofen	200 mg	50 @	2.70	AF
5123P		400 mg	30 @	2.65	AB
5126T	Indomethacin	25 mg	50 @	2.70	AF
			50 @	4.19	MK
5128X		100 mg	20 @	7.69	MK
5139L		100 mg	20 @	8.04	AV
5154G	Metronidazole	500 mg in 100 mL	1 @	7.44	BX
5176K	Naproxen	250 mg	50 @	4.65	AF
			50 @	6.15	RO
5224Y	Paracetamol	500 mg	100 @	2.55	AW,CH,FM, GM,HX,JT, PC,SW,TW
			25 @	3.28	SI
3360W	Phenoxymethylpenicillin	250 mg	25 @	4.87	SI
3361X		500 mg	1 @	3.67	FM
3365D		125 mg per 5 mL, 100 mL	1 @	4.58	SI
			1 @	5.02	FM
3366E		250 mg per 5 mL, 100 mL	1 @	5.92	SI
			5 @	6.56	MX
3374N	Promethazine Hydrochloride	50 mg in 2 mL	1 @	3.73	BX
5212H	Sodium Chloride	154 mmol per L, 1 L	1 @	5.64	BX
5213J		513 mmol per L, 1 L	1 @	3.73	BX
5214K	Sodium Chloride with Glucose	31 mmol-222 mmol per L, 1 L	1 @	4.90	BX
5215L		19 mmol-104 mmol per 500 mL, 500 mL	1 @	4.90	BX
5216M		39 mmol-69 mmol per 500 mL, 500 mL	50 @	4.74	AF
5217N		100 mg	1 @	22.83	AS,MX
3323X	Vancomycin	500 mg			

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	0.61	5.39
Acacia, powdered	BP	0.02	0.13	1.02	9.10
Acetic Acid (6 per cent)	BP	0.01	0.01	0.11	0.99
Acetic Acid (33 per cent)	BP	0.01	0.05	0.41	3.61
Acetone	BP	0.01	0.07	0.59	5.24
(use as additive only)					
Alum	BP	0.02	0.12	0.98	8.72
Aluminium Acetate Solution	BP	0.02	0.15	1.16	10.28
Anise Water Concentrated 1 in 40	BP	0.01	0.06	0.44	3.95
(use as additive only)					
Aqueous Cream	APF	0.01	0.02	0.17	1.48
(for use only as a base combined with active ingredients)					
Ascorbic Acid	BP	0.05	0.43	3.46	30.79
(use as ingredient of Mixtures of Ferrous Sulfate APF)					
Aspirin	BP	0.07	0.54	4.33	38.50
Belladonna Tincture	BP	0.04	0.31	2.48	22.00
Benzocaine	BP	0.07	0.55	4.41	39.20
Benzoic Acid	BP	0.03	0.22	1.73	15.33
Benzoic Acid Compound Ointment	APF	0.01	0.08	0.65	5.82
Benzoic Acid Solution	BP	0.01	0.09	0.68	6.03
Benzoïn Compound Tincture	BP	0.02	0.18	1.40	12.48
Boric Acid	BP	0.01	0.07	0.54	4.84
(use as additive only)					
Boric Acid, Olive Oil and Zinc Oxide Ointment	QHF	0.01	0.06	0.47	4.17
Calcium Hydroxide	BP	0.02	0.15	1.19	10.57
Calcium Hydroxide Solution	BP	0.01	0.01	0.06	0.56
Castor Oil	BP	0.01	0.05	0.43	3.84
(use as additive only)					
Cetomacrogol Aqueous Cream	APF	0.01	0.03	0.20	1.74
(for use only as a base combined with active ingredients)					
Cetrimide Aqueous Cream	APF	0.02	0.14	1.08	9.63
(for use only as a base combined with active ingredients)					
Chlorhexidine Acetate	BP	0.36	2.84	22.74	202.13
(use as additive only)					
Chlorhexidine Aqueous Cream	APF	0.03	0.20	1.61	14.32
(for use only as a base combined with active ingredients)					
Chloroform	BP	0.02	0.12	0.95	8.40
(use as additive only)					
Chloroform Spirit	BP	0.01	0.03	0.23	2.03
Chloroform Water Concentrated 1 in 40	APF 15	0.01	0.03	0.22	1.97
Citric Acid Monohydrate	BP	0.01	0.06	0.46	4.11
Coal Tar	BP	0.10	0.79	6.30	56.00

Drug	Standard	Recovery Prices			
		0.1 g/mL	1 g/mL	10 g/mL	100 g/mL
		\$	\$	\$	\$
Coal Tar Solution	BP	0.01	0.09	0.75	6.64
Cocaine Hydrochloride	BP	4.51	36.11	288.89	2567.94
Coconut Oil	BP	0.01	0.10	0.78	6.89
Codeine Linctus	APF	0.01	0.05	0.42	3.78
Codeine Phosphate (may only be prescribed in linctuses, mixtures or mixtures for children)	BP	1.17	9.39	75.11	667.62
Collodion Flexible	BP	0.04	0.33	2.63	23.33
Dithranol	BP	2.96	23.69	189.51	1684.53
Emulsifying Ointment (for use only as a base combined with active ingredients)	BP	0.01	0.06	0.49	4.35
Ephedrine Hydrochloride (may only be prescribed in nasal instillations)	BP	0.49	3.90	31.20	277.33
Ethanol (90 per cent) (use as additive only)	BP	0.01	0.02	0.17	1.50
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	0.02	0.12	0.92	8.21
Ferrous Sulfate	BP	0.09	0.68	5.40	48.00
Formaldehyde Solution	BP	0.02	0.16	1.26	11.20
Gentian Alkaline Mixture	APF	0.01	0.07	0.58	5.14
Glycerol	BP	0.01	0.04	0.33	2.97
Honey Purified (use as additive only)	BP 1993	0.01	0.02	0.17	1.50
Hydroxybenzoate Compound Solution	APF	0.11	0.85	6.82	60.61
Iodine	BP	0.33	2.63	21.00	186.67
Iodine Alcoholic Solution	BP	0.01	0.11	0.86	7.69
Iodine Aqueous Oral Solution	BP	0.02	0.18	1.46	12.94
Kaolin Mixture	BPC 1968	0.03	0.24	1.91	17.00
Kaolin and Opium Mixture	APF 14	0.01	0.06	0.45	4.00
Lactic Acid	BP	0.06	0.45	3.61	32.08
Lavender Spike Oil	BPC 1968	0.12	0.98	7.82	69.51
Liquorice Liquid Extract	BP	0.02	0.12	0.99	8.82
Magnesium Carbonate Light	BP	0.02	0.15	1.20	10.66
Magnesium Sulfate (may only be prescribed for other than oral use)	BP	0.01	0.01	0.09	0.81
Magnesium Trisilicate	BP	0.03	0.25	1.97	17.53
Menthol, Racemic or Levomenthol	BP	0.16	1.31	10.49	93.24
Methyl Hydroxybenzoate	BP	0.24	1.95	15.60	138.67
Methyl Hydroxybenzoate Solution	APF	0.03	0.22	1.73	15.42

Drug	Standard	Recovery Prices			
		0.1 g/mL \$	1 g/mL \$	10 g/mL \$	100 g/mL \$
Methylated Industrial Spirit (use as additive only)	BP	0.01	0.02	0.12	1.04
Olive Oil (use as additive only)	BP	0.01	0.09	0.70	6.25
Paraffin Hard	BP	0.01	0.06	0.46	4.09
Paraffin Liquid (may only be prescribed for other than oral use)	BP	0.01	0.02	0.16	1.45
Paraffin Light Liquid	BP	0.01	0.10	0.82	7.31
Paraffin Soft White	BP	0.01	0.04	0.35	3.14
Paraffin Soft Yellow	BP	0.01	0.05	0.42	3.75
Peppermint Oil (use as additive only)	BP	0.09	0.68	5.42	48.21
Peppermint Water Concentrated 1 in 40 (use as additive only)	APF 16	0.02	0.18	1.44	12.80
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	0.37	2.93	26.00
Pholcodine Citrate Syrup (use as additive only)	BPC 1959	0.01	0.09	0.73	6.47
Podophyllum Resin	BP	0.79	6.30	50.40	448.00
Potassium Citrate	BP	0.01	0.09	0.71	6.34
Potassium Iodide	BP	0.06	0.46	3.64	32.37
Potassium Permanganate	BP	0.02	0.14	1.10	9.82
Propyl Hydroxybenzoate	BP	0.21	1.65	13.20	117.33
Propylene Glycol	BP	0.01	0.08	0.64	5.67
Red Syrup	APF 15	0.02	0.13	1.07	9.52
Resorcinol	BP	0.10	0.83	6.64	58.98
Salicylic Acid	BP	0.04	0.28	2.21	19.66
Salicylic Acid Ointment	APF	0.01	0.11	0.87	7.70
Salicylic Acid Ointment	BP	0.01	0.09	0.68	6.01
Simple Ointment (white) (for use only as a base combined with active ingredients)	BP	0.01	0.11	0.84	7.45
Simple Ointment (yellow) (for use only as a base combined with active ingredients)	BP	0.01	0.11	0.84	7.45
Sodium Bicarbonate	BP	0.01	0.04	0.28	2.47
Sodium Chloride	BP	0.01	0.10	0.82	7.27
Sodium Chloride Solution	BP	0.01	0.01	0.06	0.51
Sodium Citrate	BP	0.01	0.11	0.86	7.66
Sodium Thiosulfate (use as additive only)	BP	0.02	0.17	1.34	11.89
Starch	BP	0.01	0.07	0.54	4.84
Sulfur Ointment (for use only as a base combined with active ingredients)	BP 1980	0.01	0.11	0.86	7.63
Sulfur Precipitated	BP 1980	0.02	0.12	0.93	8.28
Syrup	BP	0.01	0.03	0.21	1.86

Drug	Standard	Recovery Prices			
		0.1 g/mL	1 g/mL	10 g/mL	100 g/mL
		\$	\$	\$	\$
Talc Purified, sterilised	BP	0.02	0.13	1.05	9.33
Thymol	BP	0.17	1.33	10.64	94.58
Thymol Compound Mouth Wash	APF 15	0.01	0.09	0.73	6.46
Tragacanth Compound Powder	BP 1980	0.06	0.45	3.61	32.13
Tragacanth Mucilage	APF 13	0.01	0.03	0.26	2.27
Tragacanth Mucilage	BPC 1973	0.01	0.02	0.15	1.34
Tragacanth, powdered	BP	0.08	0.66	5.27	46.80
Trichloroacetic Acid	BP 1980	0.23	1.80	14.36	127.63
Triethanolamine	BP	0.04	0.33	2.63	23.33
Water For Injections, sterilised (b) (extemporaneously prepared eye drops and eye lotions)	BP	..	..	..	8.09
Water Purified	BP	0.01	0.01	0.05	0.41
Wool Alcohols Ointment (white) (for use only as a base combined with active ingredients)	BP	0.02	0.12	0.97	8.62
Wool Alcohols Ointment (yellow) (for use only as a base combined with active ingredients)	BP	0.02	0.12	0.97	8.62
Wool Fat	BP	0.01	0.08	0.65	5.75
Wool Fat Hydrous	BP	0.01	0.10	0.82	7.29
Zinc Compound Paste	BP	0.02	0.15	1.19	10.57
Zinc Cream (for use only as a base combined with active ingredients)	BP	0.01	0.06	0.50	4.43
Zinc Oxide	BP	0.01	0.07	0.59	5.26
Zinc and Salicylic Acid Paste	BP	0.02	0.19	1.50	13.38
Zinc Sulfate	BP	0.02	0.16	1.29	11.45

Container Prices

	\$
DISPENSING BOTTLES—	
25 mL	0.43
50 mL	0.43
100 mL	0.40
200 mL	0.48
500 mL	0.92
POISON BOTTLES—	
25 mL	0.36
50 mL	0.41
100 mL	0.45
200 mL	0.60
500 mL	1.16
SCREW CAP JARS—	
25 g	0.51
50 g	0.61
100 g	0.65
200 g	0.57
500 g	1.07
DROPPER CONTAINERS—	
15 mL polythene	0.62
15 mL glass	0.72

Dispensing Fee for Extemporaneously Prepared Benefits	\$7.19
Additional Fee for Agreed Price Extemporaneously Prepared Benefits	\$1.38

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	10.06	11.44
	DUSTING POWDERS (Maximum Quantity 100 g and 1 Repeat)			
7458M	Zinc, Starch and Talc	APF 15 & BPC 1973	15.84	17.22
	EAR DROPS (Maximum Quantity 15 mL and 2 Repeats)			
7642F	Aluminium Acetate	APF	9.02	10.40
7643G	Aluminium Acetate	BP	9.55	10.93
7314Y	Sodium Bicarbonate	APF & BP	8.08	9.46
7313X	Spirit	APF	8.03	9.41

—CONTAINER RATES ARE INCLUDED—

Code	Item	Reference	Dispensed Price for Max.Qty \$	Maximum Recordable Value for Safety Net \$
	INHALATIONS (Maximum Quantity 50 mL and 1 Repeat)			
7484X	Benzoin and Menthol	APF	15.91	17.29
7308P	Menthol	APF	9.76	11.14
7310R	Menthol and Eucalyptus	BP 1980	10.27	11.65
	LINCTUSES CONTAINING CODEINE PHOSPHATE (Maximum Quantity 100 mL and no Repeats)			
7530H	Codeine	APF	11.37	12.75
	LOTIONS (Maximum Quantity 200 mL and 2 Repeats)			
7709R	Aluminium Acetate Aqueous	APF	9.73	11.11
	MIXTURES, OTHER (Maximum Quantity 200 mL and 4 Repeats)			
7604F	Gentian Alkaline	APF	17.95	19.33
7348R	Kaolin	BPC 1968	41.67	30.70
7301G	Kaolin and Opium	APF 14	15.67	17.05
7342K	Magnesium Trisilicate	BPC 1968	12.82	14.20
7343L	Magnesium Trisilicate and Belladonna	BPC 1968	15.22	16.60
	MOUTH WASHES (Maximum Quantity 200 mL and 1 Repeat)			
7457L	Thymol Compound	APF 15	20.49	21.87
	OINTMENTS (Maximum Quantity 100 g and 1 Repeat)			
7914M	Benzoic Acid Compound	APF	13.66	15.04
7914M	Benzoic Acid Compound (extemporaneous formula)	BP	13.66	15.04
7902X	Boric Acid, Olive Oil and Zinc Oxide	QHF	12.01	13.39
7926E	Salicylic Acid	APF	15.54	16.92
7928G	Salicylic Acid (extemporaneous formula)	BP	13.85	15.23
	PAINTS (Maximum Quantity 25 mL and 1 Repeat)			
7567G	Podophyllin Compound	APF 16 & BP	34.68	30.70
7568H	Salicylic Acid	APF	14.83	16.21
	PASTES, OTHER (Maximum Quantity 100 g and 1 Repeat)			
7558T	Zinc	APF	18.41	19.79
7558T	Zinc Compound (extemporaneous formula)	BP	18.41	19.79
	POWDER FOR INTERNAL USE (Maximum Quantity 100 g and 2 Repeats)			
7545D	Magnesium Trisilicate	BP	25.29	26.67

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 FEBRUARY 2007

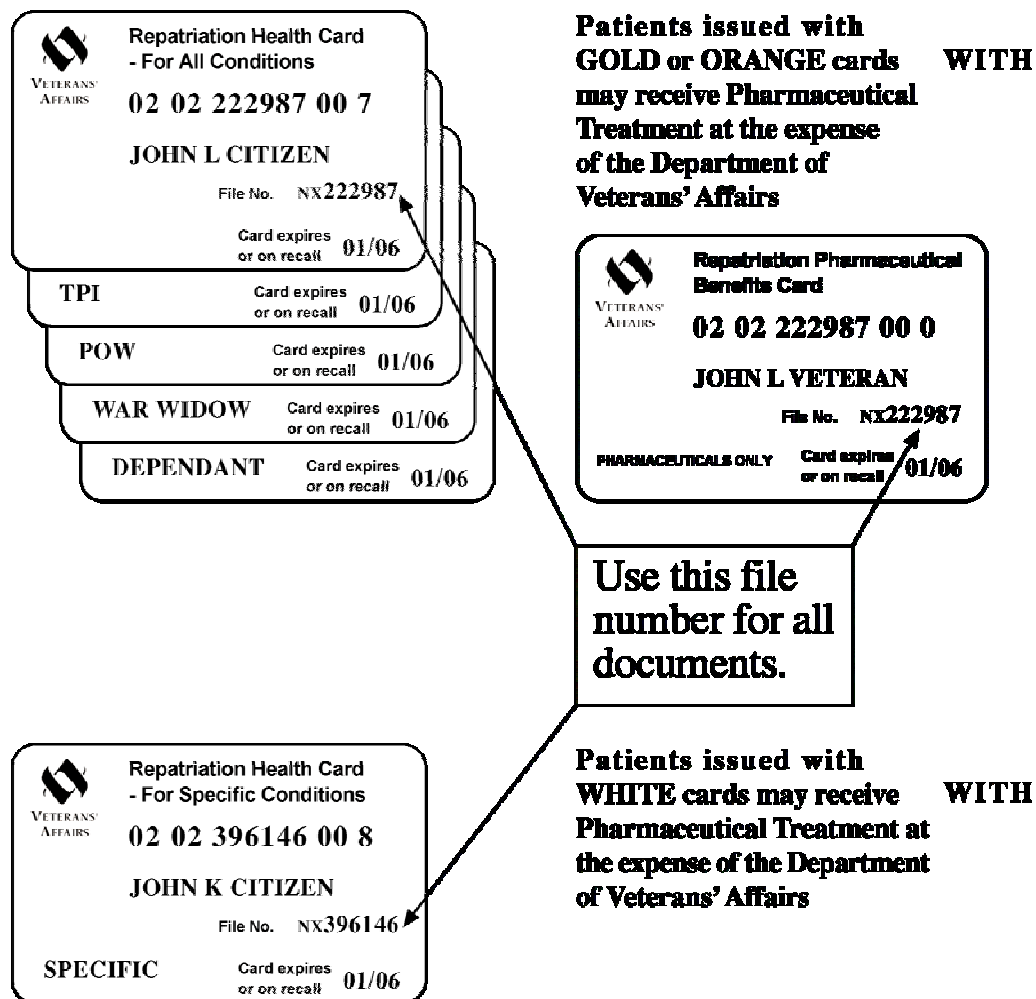
The benefits listed in this Schedule may only be prescribed to Department of Veterans' Affairs beneficiaries holding a:

- 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;
 - 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 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 Section 1 - Explanatory Notes in the *Schedule of Pharmaceutical Benefits* book.

6. All authority 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 Approvals Centre (VAPAC) at the reply paid address shown at the end of these RPBS Explanatory Notes.
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.

Provisions governing pricing and payment for RPBS benefits**Introduction**

14. 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.
15. 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

16. 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* book.

Pricing of Non-Schedule Ready Prepared Items

17. 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

18. When an ingredient drug is not listed in the PBS Drug Tariff (Section 4, PBS Schedule), 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 (Section 1 –, PBS Schedule Part 9, Pricing Prescriptions). 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

19. The price to pharmacists used as the basis of pricing will be the invoiced, GST-exclusive price from the wholesaler.
20. 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.
21. 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.
22. 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.
23. 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**

24. 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 pharmacist's itemised receipt.

Payment for Items Supplied at Short Intervals

25. 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.
26. 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

27. 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 patient's name and address. The patient may apply for reimbursement from the Department.

Special Patient Contributions

28. 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

29. 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 Approvals Centre (VAPAC) using the free postal service:

REPLY PAID No. 372
VAPAC (Veterans' Affairs Pharmaceutical Approvals Centre)
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 will take effect on 1 February 2007 and all previous issues are cancelled.

SUMMARY OF CHANGES

DELETIONS

Deletions — RPBS Therapeutic Group Premium Exemption Codes

4985J	Amlodipine Besylate , tablet 5 mg (base) (<i>Norvasc</i>)
4986K	Amlodipine Besylate , tablet 10 mg (base) (<i>Norvasc</i>)
4960C	Lercanidipine Hydrochloride , tablet 10 mg (<i>Zanidip</i>)
4959B	Lercanidipine Hydrochloride , tablet 20 mg (<i>Zanidip</i>)
4961D	Nifedipine , tablet 20 mg (controlled release) (<i>Adalat Oros 20 mg</i>)
4951N	Ramipril , tablet 1.25 mg (<i>Ramace 1.25 mg, Tritace 1.25 mg</i>)
4952P	Ramipril , tablet 2.5 mg (<i>Ramace 2.5 mg, Tritace 2.5 mg</i>)
4953Q	Ramipril , tablet 5 mg (<i>Ramace 5 mg, Tritace 5 mg</i>)
4962E	Ramipril , capsule 10 mg (<i>Ramace 10 mg, Tritace 10 mg</i>)
4954R	Ramipril , pack containing 7 tablets 2.5 mg, 21 tablets 5 mg and 10 capsules 10 mg (<i>Tritace Titration Pack</i>)
4978B	Ranitidine Hydrochloride , effervescent tablet 150 mg (base) (<i>Zantac</i>)
4980D	Ranitidine Hydrochloride , syrup 150 mg (base) per 10 mL, 300 mL (<i>Zantac Syrup</i>)

ALTERATIONS

Alterations — Manufacturer's Code

		<i>From</i>	<i>To</i>
4462W	Sorbitol with Sodium Citrate and Sodium Lauryl Sulfoacetate , enemas 3.125 g-450 mg-45 mg in 5 mL, 4 (<i>Microlax</i>)	PH	PC
4576W	Nicotine , transdermal patches releasing approximately 5 mg per 16 hours, 7 (<i>Nicorette Patch</i>)	PH	PC
4577X	Nicotine , transdermal patches releasing approximately 10 mg per 16 hours, 7 (<i>Nicorette Patch</i>)	PH	PC
4578Y	Nicotine , transdermal patches releasing approximately 15 mg per 16 hours, 7 (<i>Nicorette Patch</i>)	PH	PC

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Section 1

Drugs, Medicines and Dressings

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	
ALIMENTARY TRACT AND METABOLISM								
STOMATOLOGICAL PREPARATIONS								
Stomatological preparations								
• <i>Antifungals and antiseptics for local oral treatment</i>								
CHLORHEXIDINE GLUCONATE								
4161B	Mouth wash 2 mg per mL (0.2%), 250 mL	‡1	..	..	10.39 10.88	4.90 4.90	Plaqacide Savacol Mouth and Throat Rinse	OB OM
4160Y	Mouth wash 2 mg per mL (0.2%), 250 mL	‡1	..	..	12.18	4.90	Periogard (Chlorohex) Mouth Rinse	OM
• <i>Other agents for local oral treatment</i>								
CARMELLOSE SODIUM								
4568K	Mouth spray 10 mg per mL, 25 mL	‡1	1	..	8.57	4.90	Aquae	HA
4569L	Mouth spray 10 mg per mL, 100 mL	‡1	..	..	10.69	4.90	Aquae	HA
DRUGS FOR ACID RELATED DISORDERS								
Antacids								
• <i>Calcium compounds</i>								
CALCIUM CARBONATE with GLYCINE								
NOTE: For patients with chronic renal failure.								
4055K	Tablet 420 mg-180 mg	200	5	..	*21.19	4.90	Titralac	MM
• <i>Combinations and complexes of aluminium, calcium and magnesium compounds</i>								
ALUMINIUM HYDROXIDE with MAGNESIUM HYDROXIDE and SIMETHICONE								
4453J	Tablet 400 mg-400 mg-40 mg	200	5	..	*43.87	4.90	Mylanta Double Strength	PC
4118R	Oral suspension 400 mg-400 mg- 30 mg per 5 mL, 500 mL	2	5	..	*20.67	4.90	Mylanta Double Strength	PC
DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS								
Drugs for functional bowel disorders								
• <i>Synthetic anticholinergics, esters with tertiary amino group</i>								
MEBEVERINE HYDROCHLORIDE								
4328T	Tablet 135 mg	90	..	..	25.91 29.05	4.90 4.90	^a Colese ^a Colofac	AF SM

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	
Belladonna and derivatives, plain								
• Belladonna alkaloids semisynthetic, quaternary ammonium compounds								
4279F	HYOSCINE BUTYLBROMIDE Injection 20 mg in 1 mL	5	..	..	16.98	4.90	Buscopan	BY
LAXATIVES								
Laxatives								
• Softeners, emollients								
4200C	DOCUSATE SODIUM Tablet 50 mg	100	2	..	11.19	4.90	Coloxyl 50	FM
• Contact laxatives								
4198Y	DOCUSATE SODIUM with SENNA Tablet 50 mg-8 mg	90	2	..	12.80	4.90	Coloxyl with Senna	FM
4455L	SENNA STANDARDISED Tablet 7.5 mg	100	1	..	11.09	4.90	Senokot	RC
• Bulk producers								
4285M	ISPAGHULA HUSK Sachets 3.5 g, 30	‡1	1	..	14.10	4.90	Fybogel	RC
4419N	PSYLLIUM HYDROPHILIC MUCILLOID Oral powder (orange-flavoured, sugar-free) 283 g	‡1	1	..	19.74	4.90	Metamucil Smooth Texture Orange	PY
4422R	Oral powder (non-flavoured) 336 g	‡1	1	..	19.74	4.90	Metamucil Regular	PY
4416K	PSYLLIUM HYDROPHILIC MUCILLOID with HIGH AMYLOSE MAIZE STARCH Oral powder 2.7 g-0.7 g per 7.5 g, 440 g	‡1	1	..	19.35	4.90	Nucolox	SI
4558X	STERCULIA with FRANGULA BARK Granules 620 mg-80 mg per g (62%-8%), 500 g	‡1	1	..	22.87	4.90	Normacol Plus	NE
• Enemas								
4462W	SORBITOL with SODIUM CITRATE and SODIUM LAURYL SULFOACETATE Enemas 3.125 g-450 mg-45 mg in 5 mL, 4	‡1	..	..	10.58	4.90	Microlax	PC

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
• Other laxatives							
GLYCEROL							
Restricted benefit							
<i>Short-term use when oral laxative therapy has failed or is inappropriate.</i>							
4246L	Suppositories 2.8 g (for adults), 12	3	..	..	*15.56	4.90	PP

ANTIOBESITY PREPARATIONS, EXCL. DIET PRODUCTS

Antibesity 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	..	127.37	4.90	Xenical	RO

VITAMINS

Vitamin B₁, plain and in combination with vitamin B₆ and vitamin B₁₂

- **Vitamin B₁, plain**

THIAMINE HYDROCHLORIDE

4043T	Tablet 100 mg	100	2	..	9.36	4.90	Betamin	AV

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	
Vitamin B-complex, incl. combinations								
• Vitamin B-complex, plain								
VITAMIN B GROUP COMPLEX								
4493L	Oral liquid 200 mL	‡1	2	..	11.77	4.90	Accomin Adult Tonic	WT

MINERAL SUPPLEMENTS

Calcium

• Calcium

CALCIUM

Restricted benefit

Hyperphosphataemia in chronic renal failure;

Hypocalcaemia;

Osteoporosis;

Proven calcium malabsorption.

4332B	Tablet 250 mg (as citrate)	120	1	..	12.70	4.90	Citracal	KY
4333C	Tablet (chewable) 500 mg (as carbonate)	120	1	..	*13.59	4.90	Cal-Sup	MM
4334D	Tablet 600 mg (as carbonate)	120	1	..	12.70	4.90	Caltrate	WT

Other mineral supplements

• Magnesium

MAGNESIUM ASPARTATE

Restricted benefit

Patients with documented hypomagnesaemia.

4321K	Tablet 500 mg	50	..	..	12.77	4.90	Magmin	BB

BLOOD AND BLOOD FORMING ORGANS

ANTITHROMBOTIC AGENTS

Antithrombotic agents

• Platelet aggregation inhibitors excl. heparin

ASPIRIN

4076M	Tablet 100 mg (with glycine)	90	1	..	12.58	4.90	Cardiprin 100	RC
4077N	Tablet 100 mg (enteric coated)	84	1	..	11.94	4.90	Cartia	GK
4078P	Capsule 100 mg (containing enteric coated pellets)	84	1	..	12.99	4.90	Astrix	MX

NOTE:

The enteric coated preparations are for patients with a significant risk of gastrointestinal bleeding.

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	
CLOPIDOGREL HYDROGEN SULFATE								
Authority required								
For use in patients pre- and post-angioplasty.								
4179Y	Tablet 75 mg (base)	28	3	..	81.95	4.90	^a Iscover ^a Plavix	BQ 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	..	8.89	4.90	BX	
4461T	Irrigation solution 9 mg per mL (0.9%), 1 L	⌘1	2	..	9.20	4.90	BX	

CARDIOVASCULAR SYSTEM

VASOPROTECTIVES

Antihemorrhoids for topical use

• **Products containing 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	..	..	18.17	4.90	Proctosedyl	AV
4038M	Suppositories 5 mg-5 mg, 12	⌘1	..	..	17.13	4.90	Proctosedyl	AV

• **Other antihemorrhoids for topical use**

ZINC OXIDE

4039N	Compound ointment 50 g	⌘1	1	..	12.82	4.90	Anusol	PC
4040P	Compound suppositories, 12	⌘1	1	..	11.78	4.90	Anusol	PC

DERMATOLOGICALS

ANTIFUNGALS FOR DERMATOLOGICAL USE

Antifungals for topical use

• **Antibiotics**

NYSTATIN

4001N	Cream 100,000 units per g, 15 g	⌘1	1	..	9.50	4.90	Mycostatin	BQ

• **Imidazole and triazole derivatives**

BIFONAZOLE

4003Q	Cream 10 mg per g (1%), 15 g	⌘1	..	..	14.42	4.90	Mycospor	BN

CLOTRIMAZOLE

4004R	Cream 10 mg per g (1%), 20 g	⌘1	1	..	7.59	4.90	Clonea	AF
4005T	Lotion 10 mg per mL (1%), 20 mL	⌘1	1	..	10.86	4.90	Canesten	BN

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	
KETOCONAZOLE								
<u>Restricted benefit</u>								
<i>Severe seborrhoeic dermatitis.</i>								
4008Y	Shampoo 20 mg per g (2%), 60 mL	‡1	..	..	16.52	4.90	Nizoral 2%	JC
4007X	Shampoo 20 mg per g (2%), 100 mL	‡1	..	..	17.54 17.56	4.90 4.90	Sebizole Hexal Konazol 2% Shampoo	GM HX
4341L	MICONAZOLE Tincture 20 mg per mL (2%), 30 mL	‡1	1	..	17.64	4.90	Daktarin	JC
4454K	MICONAZOLE NITRATE Cream 20 mg per g (2%), 30 g	‡1	1	..	13.16	4.90	Daktarin	JC
• Other antifungals for topical use								
<u>AMOROLFINE HYDROCHLORIDE</u>								
<u>Restricted benefit</u>								
<i>Onychomycosis.</i>								
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	..	91.39	4.90	Loceryl	GA
<u>CICLOPIROX OLAMINE</u>								
<u>Restricted benefit</u>								
<i>Severe seborrhoeic dermatitis.</i>								
4106D	Shampoo 15 mg per g (1.5%), 60 mL	‡1	..	..	14.85	4.90	Stieprox Liquid	SX
<u>TERBINAFINE</u>								
<u>Restricted benefit</u>								
<i>Tinea pedis.</i>								
4463X	Gel 10 mg per g (1%), 15 g	‡1	..	..	21.34	4.90	Lamisil DermGel	NC
<u>TERBINAFINE HYDROCHLORIDE</u>								
<u>Restricted benefit</u>								
<i>Tinea pedis.</i>								
4473K	Cream 10 mg per g (1%), 15 g	‡1	1	..	21.34	4.90	Lamisil	NC
4481W	TOLNAFTATE Spray aerosol 10 mg per g (1%), 100 g	‡1	..	..	13.05	4.90	Tinaderm	SH

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	
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	..	133.69	4.90	^a Tamsil	AW
							^a Terbinafine-DP	GM
							^a Zabel	AF
				..	135.62	4.90	^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	..	..	9.97	4.90	Silic 15	EO
4551M	Cream 150 mg-20 mg per g (15%-2%), 500 g	‡1	..	..	20.91	4.90	Silic 15	EO
• Soft paraffin and fat products								
WOOL ALCOHOLS								
4041Q	Ointment 100 g	‡1	1	..	11.26	4.90	Eucerin	BE
• Carbamide products								
UREA								
4042R	Cream 100 mg per g (10%), 100 g	‡1	2	..	10.29	4.90	Urederm	HA
				..	10.56	4.90	Aquacare H.P.	AG
				..	10.82	4.90	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	..	..	9.42	4.90	Orabase	BQ
SKIN EMOLLIENT								
4122Y	Bath oil 500 mL	‡1	2	..	15.60	4.90	Alpha Keri Bath Oil	MT
				..	16.33	4.90	QV Bath Oil	EO
				..	17.67	4.90	Hamilton Bath Oil	HA
4107E	Lotion 500 mL	‡1	2	..	15.60	4.90	Alpha Keri Lotion	MT

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	
Protectives against UV-radiation								
• Protectives against UV-radiation for topical use								
SUNSCREENS								
4543D	Solid stick 4.5 g	‡1	2	..	10.35	4.90	Hamilton Solastick 30+	HA
4544E	Cream 100 g	‡1	2	..	13.46	4.90	Hamilton Sunscreen Broad Spectrum Cream 15+	HA
				..	15.01	4.90	SunSense Cream SPF 30+	EO
4546G	Lotion (non-alcoholic) 125 mL	‡1	2	..	13.46	4.90	Hamilton Broad Spectrum Milky Lotion 15+	HA
				..	14.29	4.90	Aquasun Lotion SPF 18	PF
				..	15.26	4.90	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	..	..	68.05	4.90	Xylocaine Viscous	AP
• Other antipruritics								
PINE TAR with TRIETHANOLAMINE LAURYL SULFATE								
NOTE: For patients who have failed to respond to simple moisturising agents.								
4408B	Solution 23 mg-60 mg per mL (2.3%-6%), 500 mL	‡1	2	..	17.81	4.90	Hamilton Pine Tar Solution	HA
				..	17.95	4.90	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	..	13.22	4.90	Egopsoryl-TA	EO

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	
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	..	..	14.58	4.90	Bactroban	GK
4350Y	Ointment 20 mg per g (2%), 15 g	‡1	..	..	14.58	4.90	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	..	..	35.64	4.90	Condyline Paint	HA
• Other chemotherapeutics								
METRONIDAZOLE								
4030D	Gel 7.5 mg per g (0.75%), 50 g	‡1	..	..	27.85	4.90	Rozex	GA
4340K	Cream 7.5 mg per g (0.75%), 30 g	‡1	1	..	19.66	4.90	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	..	20.46	4.90	Betnovate	SI
4132L	Ointment 1 mg (base) per g (0.1%), 30 g	‡1	2	..	20.46	4.90	Betnovate	SI
MOMETASONE FUROATE								
4342M	Cream 1 mg per g (0.1%), 45 g	‡1	..	..	24.65	4.90	Elocon	SH
4343N	Ointment 1 mg per g (0.1%), 45 g	‡1	..	..	24.65	4.90	Elocon	SH
NOTE:								
Application to large areas of skin for longer than four weeks is not recommended.								

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	
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	..	..	15.11	4.90	Kenacomb	BQ
CAUTION: For the short-term treatment of localised infective eczema only.								
ANTISEPTICS AND DISINFECTANTS								
Antiseptics and disinfectants								
Iodine products								
POVIDONE-IODINE								
4411E	Solution 100 mg per mL (10%), 100 mL	‡1	..	..	18.92	4.90	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	..	15.41	4.90	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	..	19.12	4.90	Polytar	SX
SALICYLIC ACID with BENZALKONIUM CHLORIDE, ALCOHOL and POLYOXYETHYLENE ETHERS								
4445Y	Scalp cleanser 20 mg-2 mg- 130 mg-216 mg per mL (2%- 0.2%-13%-21.6%), 250 mL	‡1	2	..	16.83	4.90	Ionil	GA

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	
4560B	SALICYLIC ACID with BENZALKONIUM CHLORIDE, ALCOHOL, COAL TAR and POLYOXYETHYLENE ETHERS Scalp cleanser 20 mg-2 mg- 130 mg-50 mg-216 mg per mL (2%-0.2%-13%-5%-21.6%), 250 mL	₹1	2	..	17.13	4.90	Ionil-T	GA
4447C	SALICYLIC ACID with COAL TAR SOLUTION, PINE TAR and UNDECYLENAMIDE Scalp cleanser 20 mg-10 mg- 10 mg-10 mg per mL (2%- 1%- 1%-1%), 250 mL	₹1	2	..	15.95	4.90	Sebitar	EO
4452H	SELENIUM SULFIDE Shampoo 25 mg per mL (2.5%), 125 mL	₹1	..	..	12.53	4.90	Selsun	AB
• Wart and anti-corn preparations								
4450F	SALICYLIC ACID with PODOPHYLLIN RESIN Paint 100 mg-200 mg per mL (10%-20%), 6 mL	₹1	1	..	13.65	4.90	Posalfilin	NE
• 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	..	14.37	4.90	Egoder Cream	EO
4280G	Ointment 5 mg-10 mg-10 mg per g (0.5%-1%-1%), 50 g	₹1	2	..	14.37	4.90	Egoder Ointment	EO
CATIONIC CONDITIONER with PANTHENOL								
NOTE: To be used in conjunction with the scalp cleanser salicylic acid with coal tar solution, pine tar and undecylenamide (code 4447C).								
4519W	Solution 250 mL	₹1	2	..	11.96	4.90	SebiRinse Conditioner	EO
HYDROLYZED COLLAGEN PROTEINS								
NOTE: To be used in conjunction with the two scalp cleansers: salicylic acid, benzalkonium chloride, alcohol and polyoxyethylene ethers (code 4445Y); and salicylic acid, benzalkonium chloride, alcohol, coal tar and polyoxyethylene ethers (code 4560B).								
4271T	Hair conditioner 250 mL	₹1	2	..	11.67	4.90	Ionil Rinse	GA

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	
CLOTRIMAZOLE—cont.								
4017K	Vaginal cream 100 mg per 5 g (2%), 20 g	‡1	..	..	13.43	4.90	Chem mart Clotrimazole 3 Day Cream GenRx Clotrimazole 3 Day Cream healthsense Clotrimazole 3 Day Cream Terry White Chemists Clotrimazole 3 Day Cream	CH GX HS TW
				..	13.54	4.90	Hexal Clofeme 3 Day Cream	HX
				..	15.71	4.90	Canesten 3	BN
MICONAZOLE NITRATE								
4020N	Pessaries 100 mg, 7	‡1	..	..	13.21	4.90	Monistat 7	JC
4021P	Vaginal cream 100 mg per 5 g (2%), 40 g	‡1	..	..	13.21	4.90	Monistat 7	JC
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	..	..	30.48	4.90	Aci-Jel	JC
SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM								
Estrogens								
• Natural and semisynthetic estrogens, plain								
OESTRADIOL								
<u>Restricted benefit</u>								
<i>Post-menopausal symptoms in women who have failed to respond using oral or topical oestrogens.</i>								
4365R	Implant 50 mg	1	..	..	71.76	4.90	OR	
4366T	Implant 100 mg	1	..	..	109.60	4.90	OR	

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	
UROLOGICALS								
Other urologicals, incl. antispasmodics								
• Drugs used in erectile dysfunction								
ALPROSTADIL								
Authority required								
<i>Specific accepted war-caused or service-related disabilities for males with vasculogenic, psychogenic or neurogenic erectile dysfunction.</i>								
<i>Authorisation will not be given for any additional prescriptions within 6 months or for any increased quantities or repeats.</i>								
4579B	Intracavernosal injection 10 micrograms with diluent in single use syringe	6	3	..	*81.35	4.90	Caverject Impulse	PH
4580C	Intracavernosal injection 20 micrograms with diluent in single use syringe	6	3	..	*102.35	4.90	Caverject Impulse	PH
SILDENAFIL CITRATE								
Authority required								
<i>Specific accepted war-caused or service-related disabilities for males with vasculogenic, psychogenic or neurogenic erectile dysfunction.</i>								
<i>Authorisation will not be given for any additional prescriptions within 6 months or for any increased quantities or repeats.</i>								
4584G	Tablet 25 mg (base)	4	5	..	56.83	4.90	Viagra	PF
4585H	Tablet 50 mg (base)	4	5	..	70.93	4.90	Viagra	PF
4586J	Tablet 100 mg (base)	4	5	..	76.30	4.90	Viagra	PF
TADALAFIL								
Authority required								
<i>Specific accepted war-caused or service-related disabilities for males with vasculogenic, psychogenic or neurogenic erectile dysfunction.</i>								
<i>Authorisation will not be given for any additional prescriptions within 6 months or for any increased quantities or repeats.</i>								
4596X	Tablet 10 mg	4	5	..	70.20	4.90	Cialis	LY
4597Y	Tablet 20 mg	4	5	..	75.51	4.90	Cialis	LY
• Other urologicals								
SODIUM BICARBONATE								
4458P	Capsule 840 mg	100	2	..	12.40	4.90	Sodibic	AS
CAUTION:								
For use in the treatment of renal disease.								
SODIUM CITRO-TARTRATE								
Restricted benefit								
<i>For relief of urinary symptoms when antibiotic or other therapy alone is inappropriate.</i>								
4049D	Sachets containing oral effervescent powder 4 g, 28	1	4	..	11.97	4.90	Ural Sachets	SI

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	
Drugs used in benign prostatic hypertrophy								
• Alpha-adrenoreceptor antagonists								
TERAZOSIN HYDROCHLORIDE								
<u>Authority required</u>								
<i>Treatment of benign prostatic hyperplasia where surgery is inappropriate, or where other drug treatment has failed or is contraindicated.</i>								
4396J	Starter pack containing 7 tablets 1 mg and 7 tablets 2 mg	1	..	..	18.19	4.90	Hytrin	AB
4397K	Tablet 2 mg	28	5	..	39.00	4.90	Hytrin	AB
4398L	Tablet 5 mg	28	5	..	56.92	4.90	Hytrin	AB
4399M	Tablet 10 mg	28	5	..	84.79	4.90	Hytrin	AB
• Testosterone-5-alpha reductase inhibitors								
FINASTERIDE								
<u>Authority required</u>								
<i>Treatment of benign prostatic hyperplasia where surgery is inappropriate, or where other drug treatment has failed or is contraindicated.</i>								
4233T	Tablet 5 mg	30	5	..	103.96	4.90	Proscar	MK
ANTIINFECTIVES FOR SYSTEMIC USE								
ANTIBACTERIALS FOR SYSTEMIC USE								
Macrolides, lincosamides and streptogramins								
• Macrolides								
AZITHROMYCIN								
<u>Restricted benefit</u>								
<i>Upper and lower respiratory tract infections.</i>								
4115N	Tablet 500 mg	3	..	..	32.58	4.90	Zithromax	PF
Quinolone antibacterials								
• Fluoroquinolones								
MOXIFLOXACIN								
HYDROCHLORIDE								
<u>Authority required</u>								
<i>For treatment, where other therapies have failed or are inappropriate, of:</i>								
<i>Community-acquired pneumonia;</i>								
<i>Acute bacterial exacerbations of chronic bronchitis;</i>								
<i>Acute bacterial sinusitis.</i>								
4329W	Tablet 400 mg (base)	5	1	..	45.66	4.90	Avelox	BN
4330X	Solution for I.V. infusion 400 mg (base) in 250 mL	3	..	..	*193.28	4.90	Avelox	BN

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
ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS							
ANTINEOPLASTIC AGENTS							
Antimetabolites							
• Pyrimidine analogues							
FLUOROURACIL							
4222F	Cream 50 mg per g (5%), 20 g	‡1	..	..	45.27	4.90	Efudix VT

IMMUNOSUPPRESSIVE AGENTS

Immunosuppressive agents

- **Selective immunosuppressive agents**

ALEFACEPT**NOTE:**

Any queries concerning the arrangements to prescribe alefacept may be directed to the Veterans' Affairs Pharmaceutical Approvals Centre (VAPAC) on 1800 552 580.

Written applications for authority to prescribe alefacept should be forwarded to:

Reply Paid 372

Veterans' Affairs Pharmaceutical Approvals Centre (VAPAC)

GPO Box 9998

BRISBANE QLD 4001

No telephone approvals will be granted for initial or continuing authority applications.

No application for increased maximum quantities and/or repeats will be authorised. A maximum of 2 courses of either intravenous or intramuscular alefacept (Amevive) treatment will be authorised in a 12-month period.

The assessment of the patient's response to the initial course of treatment should be made up to 24 weeks following commencement of the treatment course so that there is adequate time for a response to be demonstrated. Measurement of response should be made prior to the completion of the 24-week follow up to ensure continuity for those patients who meet the criteria. Use of alefacept in combination with other systemic therapies must be in line with the Therapeutic Goods Administration (TGA)-approved Product Information.

Authority required

Initial treatment by a dermatologist for patients who have severe chronic plaque psoriasis, in whom other systemic therapies are ineffective or inappropriate, with the following criteria:

(1) CD4+ lymphocyte counts above the lower limit of normal within 2 weeks prior to dosing;

AND

(2) Baseline Psoriasis Area and Severity Index (PASI) score of 15 or more (the date of PASI assessment must be provided); AND

(3) who have signed a patient agreement form indicating that they understand and acknowledge that RPBS-subsidised treatment will cease if the predetermined response criteria do not support continuation of RPBS-subsidised treatment.

REPATRIATION

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

ALEFACEPT—cont.

If the above requirements cannot be met, the application must state the reasons why these criteria cannot be met.

Applications for authorisation must be in writing and must include:

- (1) a completed authority prescription form;*
- (2) a completed Alefacept (Amevive) RPBS Authority Application - Supporting Information Form (contact the VAPAC on 1800 552 580 for a copy of this form); and*
- (3) a signed patient agreement form.*

Authority required

Initial RPBS-subsidised supply for continuing treatment by a dermatologist for patients who have severe chronic plaque psoriasis and were receiving treatment with alefacept prior to July 2004, who:

- (1) have demonstrated a response as specified in the criteria for continuing RPBS-subsidised treatment with alefacept (the date of assessment of the patient must be provided); and*
- (2) have signed a patient agreement form indicating that they understand and acknowledge that RPBS-subsidised treatment will cease if the predetermined response criteria do not support continuation of RPBS-subsidised treatment.*

Applications for authorisation must be in writing and must include:

- (1) a completed authority prescription form;*
- (2) a completed Alefacept (Amevive) RPBS Authority Application - Supporting Information Form (contact the VAPAC on 1800 552 580 for a copy of this form); and*
- (3) a signed patient agreement form.*

Authority required

Continuing RPBS-subsidised treatment by a dermatologist for patients who have severe chronic plaque psoriasis and who:

- (1) at the time of application, have demonstrated a reduction in PASI score of 75% or more from baseline at any time up to 24 weeks following commencement of initial treatment. Re-treatment may be initiated as needed, provided that CD4+ T-cell count is above 250 cells per microlitre and a minimum of 12 weeks has passed between courses of treatment; OR*
- (2) at the time of application, have demonstrated a reduction in PASI score of from at least 50% to up to 75% from baseline at any time up to 24 weeks following initiation of treatment. These patients may receive a second course of alefacept, provided that their CD4+ T-cell count is within the normal range and a minimum of 12 weeks has passed between courses of treatment. Patients must demonstrate a reduction of 75% or more from baseline PASI score at any time up to 24 weeks following the second course of treatment to be eligible to continue RPBS-subsidised treatment.*

Patients who fail to demonstrate an adequate response, as specified in the criteria for continuing treatment with alefacept, will not be eligible to recommence treatment. Patients unable to complete the course of treatment for reasons other than safety will be eligible to recommence treatment with alefacept within 12 months of the date on which treatment was ceased. Where re-treatment with alefacept after a break in RPBS-subsidised treatment with the drug is sought, the reason for and date of cessation of the previous treatment course with alefacept must be included in the application.

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	
ALEFACEPT—cont.								
<i>Applications for authorisation must be in writing and must include:</i>								
<i>(1) a completed authority prescription form; and</i>								
<i>(2) a completed Alefacept (Amevive) RPBS Authority Application - Supporting Information Form (contact the VAPAC on 1800 552 580 for a copy of this form).</i>								
4534P	Pack containing 4 vials powder for I.V. injection 7.5 mg with 4 vials solvent	1	2	..	5808.04	4.90	Amevive	BD
4535Q	Pack containing 4 vials powder for I.M. injection 15 mg with 4 vials solvent	1	2	..	5808.04	4.90	Amevive	BD

INFLIXIMAB**NOTE:**

Any queries concerning the arrangements to prescribe infliximab may be directed to the Veterans' Affairs Pharmaceutical Approvals Centre (VAPAC) on 1800 552 580.

Written applications for authority to prescribe infliximab should be forwarded to:

Reply Paid 372

Veterans' Affairs Pharmaceutical Approvals Centre (VAPAC)

GPO Box 9998

BRISBANE QLD 4001

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).

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	
<i>INFLIXIMAB—cont.</i>								
<u>Authority required</u>								
<i>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:</i>								
<i>(1) There is improvement in ESR and/or CRP; and</i>								
<i>(2) An ACR20 (American College of Rheumatology) response is achieved by 14 weeks after the commencement of therapy.</i>								
<i>Applications for authorisation must be in writing and must include:</i>								
<i>(1) a completed authority prescription form; and</i>								
<i>(2) a completed Infliximab (Remicade) RPBS Authority Application - Supporting Information form (contact the VAPAC on 1800 552 580 for a copy of the form).</i>								
4284L	Powder for I.V. infusion 100 mg	1	2	..	1016.26	4.90	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	..	35.15	4.90	Arthrotec 50	PH

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	..	12.33	4.90	Gold Cross	BI
4023R	Ointment BP, 100 g	‡1	1	..	10.58	4.90	Gold Cross	BI
4025W	Compound ointment APF 1934, 100 g	‡1	1	..	9.35	4.90	Gold Cross	BI
4026X	Liniment APF, 100 mL	‡1	1	..	8.32	4.90	Gold Cross	BI
4027Y	Compound liniment APF, 100 mL	‡1	1	..	10.02	4.90	Gold Cross	BI

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	
DRUGS FOR TREATMENT OF BONE DISEASES								
Drugs affecting bone structure and mineralization								
• Bisphosphonates								
RISEDRONATE SODIUM								
Authority required								
<i>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).</i>								
4443W	Tablet 5 mg	28	5	..	52.29	4.90	Actonel	AV
4444X	Tablet 35 mg	4	5	..	52.29	4.90	Actonel Once-a-Week	AV
NERVOUS SYSTEM								
ANALGESICS								
Opioids								
• Natural opium alkaloids								
MORPHINE SULFATE								
CAUTION:								
<i>The risk of drug dependence is high.</i>								
Restricted benefit								
<i>Chronic severe disabling pain not responding to non-narcotic analgesics.</i>								
NOTE:								
<i>Authorities for increased maximum quantities and/or repeats will be granted only for</i>								
<i>(i) chronic severe disabling pain associated with proven malignant neoplasia; or</i>								
<i>(ii) chronic severe disabling pain where treatment has been initiated by a specialist with appropriate expertise in pain management.</i>								
4349X	Tablet 200 mg (controlled release)	20	..	..	103.66	4.90	MS Contin	MF
• Diphenylpropylamine derivatives								
DEXTROPROPOXYPHENE								
NAPSYLATE								
CAUTION:								
<i>Chronic use of this preparation is likely to cause drug dependence.</i>								
4081T	Capsule 100 mg	50	..	..	*16.80	4.90	Doloxene	AS
Other analgesics and antipyretics								
• Salicylic acid and derivatives								
CODEINE PHOSPHATE with								
ASPIRIN								
4061R	Tablet soluble 8 mg-300 mg	50	2	..	11.99	4.90	Aspalgin	FM

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	
• Anilides CODEINE PHOSPHATE with PARACETAMOL								
4171M	Tablet 8 mg-500 mg	50	2	..	10.24	4.90	Panamax Co.	SW
				..	11.31	4.90	Codalgin	FM
4170L	Tablet 15 mg-500 mg	20	2	..	7.83	4.90	Prodeine 15	SW
• Other analgesics and antipyretics GABAPENTIN Authority required <i>To be approved for the treatment of refractory neuropathic pain not controlled by other drugs.</i>								
4591P	Capsule 100 mg	100	5	..	27.33	4.90	^a Gantin	AW
							^a Neurontin	PF
							^a Nupentin 100	AF
4592Q	Capsule 300 mg	100	5	..	79.27	4.90	^a DBL	MX
							^a Gabapentin	
							^a Douglas	GM
							^a Gabapentin	
							^a Gabahexal	HX
							^a 300mg	
							^a Gantin	AW
							^a GenRx	GX
							^a Gabapentin	
							^a Neurontin	PF
							^a Nupentin 300	AF
4593R	Capsule 400 mg	100	5	..	106.24	4.90	^a DBL	MX
							^a Gabapentin	
							^a Douglas	GM
							^a Gabapentin	
							^a Gabahexal	HX
							^a 400mg	
							^a Gantin	AW
							^a GenRx	GX
							^a Gabapentin	
							^a Neurontin	PF
							^a Nupentin 400	AF
4594T	Tablet 600 mg	100	5	..	165.62	4.90	Neurontin	PF
4595W	Tablet 800 mg	100	5	..	217.61	4.90	^a Gantin	AW
							^a Neurontin	PF

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	
PSYCHOLEPTICS								
Anxiolytics								
• Benzodiazepine derivatives								
BROMAZEPAM								
<u>Authority required</u>								
<i>Patients with terminal disease;</i>								
<i>Patients with refractory phobic or anxiety states.</i>								
<u>NOTE:</u>								
<i>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.</i>								
4150K	Tablet 3 mg	60	..	..	*25.19	4.90	Lexotan	RO
4151L	Tablet 6 mg	60	..	..	*30.95	4.90	Lexotan	RO
• Azapirodecanedione derivatives								
BUSPIRONE HYDROCHLORIDE								
<u>Authority required</u>								
<i>For the short-term treatment of anxiety.</i>								
4144D	Tablet 5 mg	50	..	..	29.96	4.90	Buspar	BQ
4145E	Tablet 10 mg	50	..	..	44.84	4.90	Buspar	BQ
Hypnotics and sedatives								
• Benzodiazepine derivatives								
FLUNITRAZEPAM								
<u>Authority required</u>								
<i>Patients with terminal disease;</i>								
<i>Patients with refractory phobic or anxiety states.</i>								
<u>NOTE:</u>								
<i>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.</i>								
4216X	Tablet 1 mg	30	..	..	12.05	4.90	Hypnodorm	AF
• Benzodiazepine related drugs								
ZOPICLONE								
<u>Restricted benefit</u>								
<i>For the short-term treatment of insomnia.</i>								
4522B	Tablet 7.5 mg	30	..	..	19.82	4.90 ^a	Imrest	AF
					21.33	4.90 ^a	Imovane	AV

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	
OTHER NERVOUS SYSTEM DRUGS								
Drugs used in addictive disorders								
• Drugs used in nicotine dependence								
NICOTINE								
Authority required								
<i>Patients who have indicated that they are ready to cease smoking and who have entered a support and counselling program.</i>								
NOTE:								
<i>Studies have shown that successful therapy with this drug is enhanced by patient participation in a support and counselling program.</i>								
4576W	Transdermal patches releasing approximately 5 mg per 16 hours, 7	2	..	..	*49.05	4.90	Nicorette Patch	PC
4571N	Transdermal patches releasing approximately 7 mg per 24 hours, 7	2	..	..	*43.95 *73.05	4.90 4.90	QuitX Nicabate CQ 7	AF GK
4577X	Transdermal patches releasing approximately 10 mg per 16 hours, 7	2	..	..	*53.39	4.90	Nicorette Patch	PC
4572P	Transdermal patches releasing approximately 14 mg per 24 hours, 7	2	..	..	*47.61 *73.05	4.90 4.90	QuitX Nicabate CQ 14	AF GK
4578Y	Transdermal patches releasing approximately 15 mg per 16 hours, 7	2	2	..	*58.69	4.90	Nicorette Patch	PC
4573Q	Transdermal patches releasing approximately 21 mg per 24 hours, 7	2	2	..	*52.01 *73.05	4.90 4.90	QuitX Nicabate CQ 21	AF GK
ANTIPARASITIC PRODUCTS, INSECTICIDES AND REPELLENTS								
ANTHELMINTICS								
Antinematodal agents								
• Benzimidazole derivatives								
4325P	MEBENDAZOLE Tablet 100 mg	6	..	..	18.19	4.90	Vermox	JC
RESPIRATORY SYSTEM								
NASAL PREPARATIONS								
Decongestants and other nasal preparations for topical use								
• Sympathomimetics, plain								
4377J	OXYMETAZOLINE HYDROCHLORIDE Nasal drops 500 micrograms per mL (0.05%), 15 mL	‡1	..	..	14.92	4.90	Drixine	SH
4378K	Nasal spray 500 micrograms per mL (0.05%), 15 mL	‡1	..	..	14.92	4.90	Drixine	SH
4379L	Nasal spray 500 micrograms per mL (0.05%), 18 mL	‡1	..	..	15.04	4.90	Logicin Rapid Relief	SI

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	
• Antiallergic agents, excl. corticosteroids								
LEVOCABASTINE HYDROCHLORIDE								
4311X	Nasal spray 500 micrograms per mL (0.05%), 10 mL (100 doses)	‡1	2	..	16.46	4.90	Livostin	JC
SODIUM CROMOGLYCATE								
4468E	Nasal spray metered dose pump 20 mg per mL (2%), 26 mL	‡1	5	..	18.48	4.90	Rynacrom	AV
• Corticosteroids								
BUDESONIDE								
Restricted benefit								
<i>Severe intractable rhinitis.</i>								
4092J	Aqueous nasal spray (pump pack) 64 micrograms per dose (120 doses)	‡1	..	..	26.03	4.90	Budamax Aqueous	PM
• Other nasal preparations								
IPRATROPIUM BROMIDE								
Restricted benefit								
<i>Severe intractable rhinorrhoea, associated with perennial rhinitis, unresponsive to insufflated nasal steroids.</i>								
4089F	Aqueous nasal spray (pump pack) 21 micrograms (anhydrous) per dose (180 doses)	‡1	5	..	20.50	4.90	Atrovent Nasal Aqueous	BY
4090G	Aqueous nasal spray (pump pack) 42 micrograms (anhydrous) per dose (180 doses)	‡1	5	..	26.64	4.90	Atrovent Nasal Forte	BY
Nasal decongestants for systemic use								
• Sympathomimetics								
PSEUDOEPHEDRINE HYDROCHLORIDE								
4420P	Tablet 60 mg	30	..	..	14.41	4.90	Logicin Sinus Sudafed Sinus & Nasal Decongestant	SI PC

DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES

Adrenergics, inhalants• **Adrenergics and other drugs for obstructive airway diseases****IPRATROPIUM BROMIDE with SALBUTAMOL SULFATE****Restricted benefit***Chronic obstructive pulmonary disease where treatment with a beta-agonist and ipratropium is indicated.*

4283K	Oral pressurised inhalation 20 micrograms (anhydrous)- 100 micrograms (base) per dose (200 doses)	2	5	..	*47.55	4.90	Combivent	BY

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	
COUGH AND COLD PREPARATIONS								
Expectorants, excl. combinations with cough suppressants								
• Expectorants								
	SENEGA and AMMONIA							
4074K	Mixture 200 mL	‡1	4	..	7.71	4.90	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	..	7.56	4.90	Gold Cross	BI
				..	12.30	4.90	Duro-Tuss	MM
ANTIHISTAMINES FOR SYSTEMIC USE								
Antihistamines for systemic use								
• Phenothiazine derivatives								
	PROMETHAZINE HYDROCHLORIDE							
4072H	Tablet 10 mg	50	2	..	13.04	4.90	Phenergan	AV
4073J	Tablet 25 mg	50	2	..	15.04	4.90	Phenergan	AV
CAUTION: Significant side effects may occur.								
• Piperazine derivatives								
	CETIRIZINE HYDROCHLORIDE							
4175R	Tablet 10 mg	30	..	..	36.74	4.90	Zyrtec	PC
• Other antihistamines for systemic use								
	FEXOFENADINE HYDROCHLORIDE							
4237B	Tablet 60 mg	60	..	..	*46.13	4.90	Telfast	AV
4238C	Tablet 120 mg	30	..	..	32.21	4.90	^a Xergic	AF
				..	38.81	4.90	^a Telfast 120	AV
	LORATADINE							
4313B	Tablet 10 mg	30	..	..	42.35	4.90	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	..	12.27	4.90	Antistine-Privine	NV
4032F	Eye drops 5 mg (phosphate)- 500 micrograms (hydrochloride) per mL (0.5%-0.05%), 15 mL	‡1	1	..	12.22	4.90	Albalon-A	AG

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	
NAPHAZOLINE HYDROCHLORIDE								
4035J	Eye drops 1 mg per mL (0.1%), 15 mL	‡1	1	..	11.46	4.90	Naphcon Forte	AQ
				..	12.28	4.90	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	..	12.53	4.90	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	..	11.46	4.90	Zincfrin	AQ
• Other antiallergics								
LEVOCABASTINE HYDROCHLORIDE								
4310W	Eye drops 500 micrograms per mL (0.05%), 4 mL (120 doses)	‡1	1	..	16.46	4.90	Livostin	JC

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	..	27.51	4.90	Ciproxin HC	AQ

Other otologicals

• Indifferent preparations

CARBAMIDE PEROXIDE								
4176T	Ear drops 65 mg per mL (6.5%), 12 mL	‡1	..	..	12.78	4.90	Ear Clear for Ear Wax Removal	KY
DICHLOOROBENZENE with CHLORIBUTOL and TURPENTINE OIL								
4180B	Ear drops 20 mg-50 mg-0.1 mL per mL (2%-5%-10%), 11 mL	‡1	..	..	12.48	4.90	Cerumol	AC
DOCUSATE SODIUM								
4199B	Ear drops 5 mg per mL (0.5%), 10 mL	‡1	..	..	12.85	4.90	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	..	64.29	4.90	Resonium-A	SW

REPATRIATION

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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)

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	

REPATRIATION

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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	

BLACK NECROTIC WOUND

Aims: 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.

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; (4) to absorb excess exudate.

Products: Activated Charcoal; Alginate with Charcoal; Foam with Charcoal.

MINOR SKIN TRAUMA

Aims: (1) to stop bleeding; (2) to prevent infection; (3) to minimise the surface defect; (4) to promote epithelialisation.

REPATRIATION

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ORDERING HARTMANN PRODUCTS

Hartmann wound dressings are available through the Hartmann Alliance only. To order please telephone the Hartmann Alliance distributor in your State/Territory as below.

NSW & ACT	Paul Hartmann Pty Ltd	1800 805 839
VIC & TAS	Sutherland Medical	1300 664 027
QLD	Medical and Surgical Requisites Pty Ltd	1800 801 226
WA	Perth Surgical Supply Co	(08) 9344 3111
SA	McNeil's Surgical	(08) 8363 0888
NT	McNeil's Surgical	(08) 8948 4047

BANDAGE—ABSORBENT WOOL									
4651T	Bandage (natural, non-sterile) 10 cm x 2.7 m	6	..	..	*31.97	4.90	Soffban 7224	BV	
4653X	Bandage 10 cm x 3 m	6	..	..	18.45	4.90	Surepress 650948	CC	
BANDAGE—CALICO									
4717G	Bandage, triangular, large	‡1	..	..	11.92	4.90	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	..	..	*69.45	4.90	Comprilan 1027	BV	
4736G	Bandage, high stretch, 7.5 cm x 3 m	5	..	..	*82.85	4.90	Tensopress 66004347	BV	
4656C	Bandage, high stretch, 7.5 cm x 3.5 m	5	..	..	*67.10	4.90	Setopress 3504	SS	
4748X	Bandage, high stretch, 10 cm x 3 m	5	..	..	*71.65	4.90	Surepress 650947	CC	
				..	*108.00	4.90	Tensopress 66004348	BV	
4657D	Bandage, high stretch, 10 cm x 3.5 m	5	..	..	*54.40	4.90	Eloflex 2480	BV	
				..	*77.30	4.90	Setopress 3505	SS	
4658E	Bandage, four layer	5	..	..	*196.70	4.90	Profore 66050016	SN	
4598B	Bandage, four layer	5	..	..	*132.50	4.90	Profore Lite 66050415	SN	

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	
BANDAGE—COMPRESSION—cont.								
NOTE: <i>Treatment of varices and oedema associated with venous disease and lymphoedema; contraindicated in arterial disease.</i>								
Restricted benefit <i>Initial treatment of venous ulcers.</i>								
4938X	Bandage, two layer, 18 cm- 22 cm (red)	1	..	..	42.37	4.90	ProGuide 66000780	SN
4939Y	Bandage, two layer, 22 cm- 28 cm (yellow)	1	..	..	42.37	4.90	ProGuide 66000781	SN
4940B	Bandage, two layer, 28 cm- 32 cm (green)	1	..	..	42.37	4.90	ProGuide 66000782	SN
Restricted benefit <i>Continuation of treatment of venous ulcers where patient's ability to tolerate dressing has been demonstrated.</i>								
4941C	Bandage, two layer, 18 cm- 22 cm (red)	4	..	..	*154.03	4.90	ProGuide 66000780	SN
4942D	Bandage, two layer, 22 cm- 28 cm (yellow)	4	..	..	*154.03	4.90	ProGuide 66000781	SN
4943E	Bandage, two layer, 28 cm- 32 cm (green)	4	..	..	*154.03	4.90	ProGuide 66000782	SN
BANDAGE—RETENTION— COHESIVE—HEAVY								
4811F	Bandage 5 cm x 1.3 m	2	..	..	*12.41	4.90	Peg 7420	BK
4812G	Bandage 7.5 cm x 1.3 m	2	..	..	*15.55	4.90	Peg 7422	BK
4659F	Bandage 7.5 cm x 3 m	2	..	..	*18.19	4.90	Coplus 3629	BV
4813H	Bandage 10 cm x 1.3 m	2	..	..	*19.15	4.90	Peg 7423	BK
4660G	Bandage 10 cm x 2 m	2	..	..	*17.53	4.90	Coban 1584	MM
4814J	Bandage 15 cm x 1.3 m	2	..	..	*25.97	4.90	Peg 7425	BK
BANDAGE—RETENTION— COHESIVE—LIGHT								
4718H	Bandages 2.5 cm x 4 m, 2	‡1	..	..	10.98	4.90	Handygauze Cohesive 8631	BV
4719J	Bandage 6 cm x 4 m	2	..	..	*13.07	4.90	Handygauze Cohesive 8633	BV
4662J	Bandage 10 cm x 4 m	2	..	..	*15.41	4.90	Handygauze Cohesive 8635	BV

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	
BANDAGE—RETENTION— COTTON CREPE								
4727T	Bandage 5 cm x 2.3 m	2	..	..	*15.69 *16.51	4.90 4.90	Telfa 8252F Elastocrepe 36102520	KE BV
4728W	Bandage 7.5 cm x 2.3 m	2	..	..	*20.27 *20.45	4.90 4.90	Telfa 8253F Elastocrepe 36102420	KE BV
4729X	Bandage 10 cm x 2.3 m	2	..	..	*23.27 *25.61	4.90 4.90	Telfa 8254F Elastocrepe 36102320	KE BV
BANDAGE—TUBULAR								
4855M	Bandage 6.25 cm x 1 m	‡1	..	..	16.39	4.90	Tubigrip B 1520	SS
4856N	Bandage 6.75 cm x 1 m	‡1	..	..	16.39	4.90	Tubigrip C 1545	SS
4857P	Bandage 7.5 cm x 1 m	‡1	..	..	16.39	4.90	Tubigrip D 1546	SS
4858Q	Bandage 8.75 cm x 1 m	‡1	..	..	16.39	4.90	Tubigrip E 1547	SS
4859R	Bandage 10 cm x 1 m	‡1	..	..	16.39	4.90	Tubigrip F 1548	SS
4663K	Bandage, straight, size C	‡1	..	..	13.47	4.90	Elastoplast 2225	BE
4664L	Bandage, straight, size D	‡1	..	..	13.47	4.90	Elastoplast 2226	BE
4665M	Bandage, straight, size E	‡1	..	..	13.47	4.90	Elastoplast 2227	BE
4667P	Bandage, lightweight, 8.75 cm x 1 m	‡1	..	..	15.34	4.90	Tensogrip 36361259	BV
BANDAGE—TUBULAR (FINGER)								
4798M	Complete pack including applicator	‡1	..	..	16.01	4.90	Tubegauz 0501633	SS
4726R	Refill	‡1	..	..	12.15	4.90	Tubegauz 0501658	SS
BANDAGE—TUBULAR (LIGHTWEIGHT)								
4671W	Bandage, small limb size (red), 10 m	‡1	..	..	26.14	4.90	Tubifast 2434	SS
4672X	Bandage, medium limb size (green), 10 m	‡1	..	..	29.64	4.90	Tubifast 2436	SS
4673Y	Bandage, large limb size (blue), 10 m	‡1	..	..	33.05	4.90	Tubifast 2438	SS
BANDAGE—TUBULAR (LONG STOCKING)								
4674B	Bandage, small size	2	..	..	*37.45	4.90	Tubigrip 1482	SS
4797L	Bandage, medium size	2	..	..	*37.45	4.90	Tubigrip 1483	SS
4799N	Bandage, large size	2	..	..	*37.45	4.90	Tubigrip 1484	SS
4675C	Bandage, XX/large size	2	..	..	*37.45	4.90	Tubigrip 1486	SS

REPATRIATION

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BANDAGE—TUBULAR (SHORT STOCKING)								
4661H	Bandage, small B/C size	2	..	..	*28.11	4.90	Tubigrip 1479	SS
4815K	Bandage, medium C/D size	2	..	..	*28.11	4.90	Tubigrip 1480	SS
4816L	Bandage, large D/E size	2	..	..	*28.11	4.90	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	..	..	*26.93	4.90	Zincaband 3604	SS
4669R	Bandage 7.5 cm x 6 m	2	..	..	*27.37	4.90	Steripaste 3610	SS
4750B	Bandage 7.5 cm x 6 m	2	..	..	*59.63	4.90	Viscopaste 4948	SN
4749Y	Bandage 8 cm x 5 m (compression)	2	..	..	*35.89	4.90	Gelocast Elastic 1080	BV
4670T	Bandage 10 cm x 9.1 m	2	..	..	*26.53	4.90	Flexidress 650941	CC
4760M	Bandages 80 cm (stockings), 4	‡1	..	..	68.77	4.90	ZipZoc 66051550	SN
COTTON WOOL ROLL								
4701K	Roll 100 g	‡1	2	..	9.07	4.90	JJ 02013	JJ
DRESSING—ACTIVATED CHARCOAL (MALODOROUS WOUND)								
4742N	Dressings 10 cm x 10 cm, 10	‡1	..	..	77.71	4.90	CarboFLEX 403202	CC
4681J	Dressing 10.5 cm x 10.5 cm	10	..	..	*83.95	4.90	Actisorb Plus MAC031	JJ
4743P	Dressings 15 cm x 20 cm, 5	‡1	..	..	88.60	4.90	CarboFLEX 403204	CC
DRESSING—ALGINATE (CAVITY WOUND)								
NOTE: This dressing should be used only on moderately to heavily exuding wounds and should remain in place until saturated or for a maximum of 3 days.								
4832H	Rope 2 g	10	..	..	*113.99	4.90	Kaltostat 168117	CC
				..	*132.95	4.90	Sorbsan 1411	UM
4685N	Ropes 2 g (30 cm), 5	2	..	..	*80.85	4.90	Restore CalciCare 9940	HO
4682K	Ropes 2 g (40 cm), 6	2	..	..	*116.47	4.90	Comfeel SeaSorb Filler 3740	CT

REPATRIATION

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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	..	37.77	4.90	Restore CalciCare 9938	HO
				..	40.59	4.90	Algisite M 66000519	SN
				..	47.48	4.90	Kaltostat 168210	CC
4684M	Dressing 5 cm x 5 cm	10	1	..	*40.55	4.90	Comfeel SeaSorb Dressing 3705	CT
4683L	Dressings 7.5 cm x 12 cm, 10	‡1	1	..	89.81	4.90	Kaltostat 168212	CC
4831G	Dressing 10 cm x 10 cm	10	1	..	*79.95	4.90	Comfeel SeaSorb Dressing 3710	CT
				..	*82.25	4.90	Sorbsan 1410	UM
4700J	Dressings 10 cm x 10 cm, 10	‡1	1	..	70.37	4.90	Restore CalciCare 9937	HO
				..	78.61	4.90	Algisite M 66000520	SN
4691X	Dressings 15 cm x 20 cm, 10	‡1	1	..	191.05	4.90	Algisite M 66000521	SN
DRESSING with CADEXOMER IODINE								
NOTE: Suitable for yellow sloughy infected and malodorous wounds.								
4931M	Sachets 3 g, 7	‡1	..	..	53.45	4.90	Iodosorb Powder 66051070	SN
4932N	Tubes 10 g, 4	‡1	..	..	86.11	4.90	Iodosorb Ointment 66051240	SN
4933P	Tubes 20 g, 2	‡1	..	..	85.32	4.90	Iodosorb Ointment 66051230	SN
4935R	Sachets 5 g (6 cm x 4 cm), 5	‡1	..	..	76.91	4.90	Iodosorb 66051330	SN
4936T	Sachets 10 g (8 cm x 6 cm), 3	‡1	..	..	111.32	4.90	Iodosorb 66051340	SN
4937W	Sachets 17 g (10 cm x 8 cm), 2	‡1	..	..	117.25	4.90	Iodosorb 66051360	SN

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	
DRESSING—FILM								
4686P	Dressings 6 cm x 7 cm, 8	‡1	..	..	13.97	4.90	Nexcare Tegaderm Transparent H1624	MM
4687Q	Dressings 10 cm x 12 cm, 4	‡1	..	..	17.80	4.90	Nexcare Tegaderm Transparent H1626	MM
4893M	Dressings 10 cm x 12 cm, 10	‡1	..	..	24.96	4.90	Op-Site Flexigrid 4629	SN
4688R	Dressing 15 cm x 20 cm	6	..	..	*28.31	4.90	Tegaderm Transparent 1628	MM
DRESSING—FILM ISLAND								
4689T	Dressing 5 cm x 7 cm	10	..	..	*14.55	4.90	Tegaderm Transparent Island 3582	MM
4898T	Dressings 5 cm x 7.2 cm, 5	2	..	..	*21.73	4.90	Cutifilm Plus 76309	SN
4899W	Dressings 8 cm x 10 cm, 5	2	..	..	*34.47	4.90	Cutifilm Plus 76308	SN
4690W	Dressing 9 cm x 10 cm	10	..	..	*25.55	4.90	Tegaderm Transparent Island 3586	MM
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	..	..	*172.79	4.90	Lyof foam C 603025	SS
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.								
4692Y	Dressings (foam alternative) 10 cm x 10 cm, 10	‡1	..	..	53.53	4.90	CombiDERM 651031	CC
4693B	Dressings (foam alternative) 15 cm x 18 cm, 5	‡1	..	..	70.45	4.90	CombiDERM 651027	CC

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	
DRESSING—FOAM—LIGHT 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	..	40.26	4.90	Lyof foam Flat 603092	SS
4891K	Dressings 10 cm x 10 cm, 10	‡1	1	..	47.57	4.90	Lyof foam Flat 603093	SS
4878R	Dressings 20 cm x 15 cm, 10	‡1	..	..	100.59	4.90	Lyof foam Flat 603095	SS
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.								
4795J	Dressings 10 cm x 10 cm, 10	‡1	..	..	73.79	4.90	Lyof foam Extra 603088	SS
				..	107.62	4.90	Allevyn 66007637	SN
4590N	Dressings 12.5 cm x 12.5 cm, 10	‡1	..	..	101.39	4.90	Allevyn Adhesive 66000044	SN
NOTE: Care should be taken when changing <i>Allevyn Adhesive</i> dressings to avoid skin tears.								
4880W	Dressings 20 cm x 15 cm, 10	‡1	..	..	187.84	4.90	Lyof foam Extra 603090	SS
4694C	Dressing, cavity, conforming, 20 g	1	..	..	68.99	4.90	Cavicare 4563	SN
4927H	Non-adhesive waterproof semi-permeable absorbent foam pads 10 cm x 10 cm, 10	‡1	1	..	80.83	4.90	Biatain Non-adhesive 3410	CT
4928J	Non-adhesive waterproof semi-permeable absorbent foam pads 15 cm x 15 cm, 5	‡1	2	..	79.40	4.90	Biatain Non-adhesive 3413	CT
4929K	Adhesive waterproof semi-permeable absorbent foam pads 12 cm x 12 cm, 10	‡1	1	..	88.97	4.90	Biatain Adhesive 3420	CT
4930L	Adhesive waterproof semi-permeable absorbent foam pads 18 cm x 18 cm, 5	‡1	2	..	86.22	4.90	Biatain Adhesive 3423	CT
DRESSING—GAUZE (ABSORBENT PAD)								
4707R	Pads 5 cm x 5 cm, 100	‡1	..	..	12.29	4.90	Handy 5672	BV
4708T	Pads 10 cm x 10 cm, 100	‡1	..	..	25.21	4.90	Handy 5674	BV
DRESSING—GAUZE—EYE PAD								
4768Y	Pads, 12	‡1	..	..	11.28	4.90	Curity 4112	KE

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	
4759L	DRESSING—GAUZE—PARAFFIN Dressings 10 cm x 10 cm, 10	‡1	..	..	15.50	4.90	Jelonet 7404	SN
4845B	DRESSING—GAUZE—PARAFFIN with CHLORHEXIDINE ACETATE Dressings 10 cm x 10 cm, 10	‡1	2	..	20.32	4.90	Bactigras 7457	SN
4779M	DRESSING—GAUZE— POVIDONE-IODINE PAD Pads 22.5 cm x 7.5 cm, 12	‡1	2	..	31.09	4.90	Betadine	FH
4918W	DRESSING—HYDROACTIVE (CAVITY WOUND) Dressings 5 cm x 6 cm, 10	‡1	1	..	72.13	4.90	Allevyn Plus Cavity 66047571	SN
4919X	Dressings 10 cm x 10 cm, 5	2	1	..	*152.45	4.90	Allevyn Plus Cavity 66047573	SN
4949L	DRESSING—HYDROACTIVE (DEBRIDEMENT) Dressings 4 cm, 8	‡1	..	..	66.63	4.90	TenderWet 24 Active	HR
4948K	Dressings 5.5 cm, 8	‡1	..	..	67.39	4.90	TenderWet Active Cavity	HR
4950M	Dressings 7.5 cm x 7.5 cm, 8	‡1	..	..	90.92	4.90	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).								
4695D	DRESSING—HYDROACTIVE (SUPERFICIAL WOUND—HIGH EXUDATE) Dressings, island, 11 cm x 11 cm, 10	‡1	..	..	84.69	4.90	Tielle MT2440	JJ
4696E	Dressings, island, 18 cm x 18 cm, 5	‡1	..	..	100.66	4.90	Tielle MT2442	JJ
4905E	DRESSING—HYDROACTIVE (SUPERFICIAL WOUND—LIGHT EXUDATE) Dressings 5 cm x 6 cm, 10	‡1	1	..	49.80	4.90	Allevyn Thin 66047576	SN
4906F	Dressings 10 cm x 10 cm, 5	2	1	..	*90.85	4.90	Allevyn Thin 66047578	SN

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	
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	..	*57.55	4.90	Restore Plus 9956	HO
				..	*80.13	4.90	DuoDERM CGF H7660	CC
4921B	Dressings 10 cm x 10 cm, 10	‡1	1	..	67.25	4.90	Replicare Ultra 66000434	SN
				..	99.71	4.90	Aquacel 177902	CC
4945G	Dressings 10 cm x 10 cm, 10	‡1	1	..	46.10	4.90	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).								
4922C	Dressings 15 cm x 15 cm, 5	2	1	..	*129.35	4.90	Replicare Ultra 66000435	SN
				..	*207.43	4.90	Aquacel 177903	CC
4946H	Dressings 15 cm x 15 cm, 10	‡1	1	..	88.64	4.90	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	..	*131.99	4.90	Restore Plus 9957	HO
4854L	Dressings 20 cm x 20 cm, 3	3	1	..	*157.16	4.90	Restore Plus 9958	HO
4920Y	Dressings 20 cm x 20 cm, 5	2	1	..	*221.05	4.90	DuoDERM CGF H7662	CC
4923D	Dressings with alginate 10 cm x 10 cm, 10	‡1	1	..	72.38	4.90	Comfeel Plus Ulcer Dressing 3110	CT
4842W	Dressings, sacral, 5	2	1	..	*98.33	4.90	Restore Plus Sacral 9959	HO
				..	*154.01	4.90	Replicare Ultra 66000437	SN

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	
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	..	63.21	4.90	DuoDERM Gel H7990	CC
					63.80	4.90	Comfeel Purilon Gel 3900	CT
4894N	Tubes 25 g, 10	‡1	1	..	113.24	4.90	Intrasite Gel 7313	SN
4913N	Tubes 30 g, 3	3	1	..	*95.84	4.90	DuoDERM Gel H7987	CC
4914P	Tube 50 g	12	1	..	*92.27	4.90	Solugel 10336	JJ
4599C	Tube 50 g	6	1	..	*38.51	4.90	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	..	..	*81.93	4.90	Nu-Gel 2497	JJ
4806Y	Dressings 11 cm x 10 cm, 5	2	..	..	*51.75	4.90	Aquaclear	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	..	..	*12.59	4.90	Melolin 36101720	SN
4819P	Dressings 5 cm x 5 cm, 5	2	..	..	*12.09	4.90	Cutilin Non-Stick Wound Pad 76301	SN
4755G	Dressings 5 cm x 7.5 cm, 10	‡1	..	..	9.55	4.90	Telfa 1970C	KE
4909J	Dressing 7.6 cm x 7.6 cm	10	1	..	*14.05	4.90	Adaptic 2012	JJ
4758K	Dressings 7.5 cm x 10 cm, 6	‡1	..	..	9.75	4.90	Telfa 2140C	KE
4944F	Dressings 7.5 cm x 10 cm, 10	‡1	..	..	13.59	4.90	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	
DRESSING—NON-ADHERENT—cont.								
4862X	Dressings 10 cm x 10 cm, 5	2	..	..	*19.15	4.90	Cutilin Non-Stick Wound Pad 76300	SN
4861W	Dressings 10 cm x 10 cm, 10	‡1	..	..	26.23	4.90	Melolin 66974933	SN
4843X	Dressings, self-adhesive, 5 cm x 7.5 cm, 10	‡1	2	..	11.12	4.90	Telfa 6020C	KE
4844Y	Dressings, self-adhesive, 7.5 cm x 10 cm, 6	‡1	2	..	10.51	4.90	Telfa 7650C	KE
GAUZE and COTTON TISSUE (COMBINE ROLL)								
4767X	Wrapped pack 9 cm x 10 m	‡1	..	..	13.73	4.90	BSN 2902165	BV
4761N	Wrapped pack 10 cm x 10 m	‡1	..	..	13.46	4.90	JJ 12010	JJ
GLOVES PLASTIC (DISPOSABLE)								
4772E	Gloves, small, 100	‡1	..	..	10.68	4.90	Handy 4207	BV
4773F	Gloves, medium, 100	‡1	..	..	10.68	4.90	Handy 4208	BV
4774G	Gloves, large, 100	‡1	..	..	10.68	4.90	Handy 4209	BV
LUBRICATING AGENT								
4318G	Jelly 60 g	‡1	..	..	9.44	4.90	Surgical Lubricating Gel	BI
PRESSURE REDUCING PRODUCTS								
4676D	Sheet 10 cm x 10 cm x 3 mm	2	..	..	*26.27	4.90	Spenco Dermal Pad 10-553	KC
4677E	Sheet 10 cm x 10 cm x 12 mm	2	..	..	*47.39	4.90	Spenco Dermal Pad 10-561	KC
4678F	Butterfly shape 7 cm	5	..	..	*48.55	4.90	Comfeel Plus Pressure Relieving 3350	CT
4679G	Round 10 cm	5	..	..	*52.65	4.90	Comfeel Plus Pressure Relieving 3353	CT
TAPES—NON-WOVEN RETENTION (POLYACRYLATE)								
4915Q	Roll 2.5 cm x 9.1 m	‡1	..	..	11.32	4.90	Medipore 2961	MM
4863Y	Roll 2.5 cm x 10 m	‡1	..	..	14.65	4.90	Hypafix 71443-0	BV
4917T	Roll 2.5 cm x 10 m	‡1	..	..	9.57	4.90	Mefix 310250	MH
4916R	Roll 5 cm x 10 m	‡1	..	..	21.61	4.90	Hypafix 71443-1	BV
TAPES—PLASTER ADHESIVE ELASTIC								
4780N	Roll 2.5 cm x 2.5 m	‡1	..	..	11.21	4.90	Leukoplast 1071	BV
4781P	Roll 5 cm x 2.5 m	‡1	..	..	16.77	4.90	Leukoplast 1072	BV
4782Q	Roll 7.5 cm x 2.5 m	‡1	..	..	20.18	4.90	Leukoplast 1073	BV
4735F	Roll 10 cm x 2.5 m	‡1	..	..	20.39	4.90	Elastoplast 1004	BV

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	
TAPES—PLASTER ADHESIVE HYPOALLERGENIC								
4783R	Roll 1.25 cm x 5 m	‡1	..	..	8.90	4.90	Leukopor 2471	BV
4785W	Roll 1.25 cm x 5 m	‡1	..	..	9.17	4.90	Leukosilk 1021	BV
4794H	Roll 2.5 cm x 5 m	‡1	..	..	11.19	4.90	Leukopor 2472	BV
4787Y	Roll 2.5 cm x 5 m	‡1	..	..	11.67	4.90	Leukosilk 1022	BV
4788B	Stretch roll 5 cm x 5 m	‡1	..	..	15.47	4.90	Leukoflex 1124	BV
4790D	Roll 5 cm x 5 m	‡1	..	..	14.51	4.90	Leukopor 2474	BV
4789C	Roll 5 cm x 5 m	‡1	..	..	15.31	4.90	Leukosilk 1024	BV
4848E	Roll (dispenser) 1.9 cm x 5.4 m	‡1	..	..	9.58	4.90	Nexcare Durable Cloth First Aid Tape 799	MM
4849F	Roll (dispenser) 1.9 cm x 7.3 m	‡1	..	..	9.58	4.90	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 @ 19.36	PC
4118R		400 mg-400 mg-30 mg per 5 mL, 500 mL	1 @ 7.76	PC
4651T	Bandage—Absorbent Wool	10 cm x 2.7 m	1 @ 4.47	BV
4654Y	Bandage—Compression	8 cm x 5 m	1 @ 12.86	BV
4736G		7.5 cm x 3 m	1 @ 15.54	BV
4656C		7.5 cm x 3.5 m	1 @ 12.39	SS
4748X		10 cm x 3 m	1 @ 13.30	CC
			1 @ 20.57	BV
4657D		10 cm x 3.5 m	1 @ 9.85	BV
			1 @ 14.43	SS
4658E		Four layer	1 @ 38.31	SN
4598B		Four layer	1 @ 25.47	SN
4941C		Two layer, 18 cm-22 cm	1 @ 37.22	SN
4942D		Two layer, 22 cm-28 cm	1 @ 37.22	SN
4943E		Two layer, 28 cm-32 cm	1 @ 37.22	SN
4811F	Bandage—Retention—Cohesive— Heavy	5 cm x 1.3 m	1 @ 3.63	BK
4812G		7.5 cm x 1.3 m	1 @ 5.20	BK
4659F		7.5 cm x 3 m	1 @ 6.52	BV
4813H		10 cm x 1.3 m	1 @ 7.00	BK
4660G		10 cm x 2 m	1 @ 6.19	MM
4814J		15 cm x 1.3 m	1 @ 10.41	BK
4719J	Bandage—Retention—Cohesive— Light	6 cm x 4 m	1 @ 3.96	BV
4662J		10 cm x 4 m	1 @ 5.13	BV
4727T	Bandage—Retention—Cotton Crepe	5 cm x 2.3 m	1 @ 5.27	KE
			1 @ 5.68	BV
4728W		7.5 cm x 2.3 m	1 @ 7.56	KE
			1 @ 7.65	BV
4729X		10 cm x 2.3 m	1 @ 9.06	KE
			1 @ 10.23	BV
4674B	Bandage—Tubular (Long Stocking)	Small	1 @ 16.15	SS
4797L		Medium	1 @ 16.15	SS
4799N		Large	1 @ 16.15	SS
4675C		XX/large	1 @ 16.15	SS
4661H	Bandage—Tubular (Short Stocking)	Small B/C	1 @ 11.48	SS
4815K		Medium C/D	1 @ 11.48	SS
4816L		Large D/E	1 @ 11.48	SS
4668Q	Bandage—Zinc Paste	7.5 cm x 6 m	1 @ 10.89	SS
4669R		7.5 cm x 6 m	1 @ 11.11	SS
4750B		7.5 cm x 6 m	1 @ 27.24	SN
4749Y		8 cm x 5 m	1 @ 15.37	BV
4670T		10 cm x 9.1 m	1 @ 10.69	CC
4150K	Bromazepam	3 mg	30 @ 10.02	RO
4151L		6 mg	30 @ 12.90	RO
4333C	Calcium	500 mg	60 @ 4.22	MM
4055K	Calcium Carbonate with Glycine	420 mg-180 mg	100 @ 8.02	MM
4081T	Dextropropoxyphene Napsylate	100 mg	10 @ 2.33	AS
4681J	Dressing—Activated Charcoal (Malodorous Wound)	10.5 cm x 10.5 cm	1 @ 7.88	JJ

(APPLY WASTAGE FACTOR IN CALCULATING BROKEN QUANTITY PRICES)

Code	Approved Name	Form/Strength	Pack and Price \$	Manufacturer
4832H	Dressing—Alginate (Cavity Wound)	2 g	1 @ 12.78	UM
			5 @ 54.42	CC
4685N		2 g (30 cm), 5	1 @ 37.85	HO
4682K		2 g (40 cm), 6	1 @ 55.66	CT
4684M	Dressing—Alginate (Superficial Wound)	5 cm x 5 cm	1 @ 3.54	CT
4831G		10 cm x 10 cm	1 @ 7.48	CT
			1 @ 7.71	UM
4688R	Dressing—Film	15 cm x 20 cm	1 @ 3.86	MM
4689T	Dressing—Film Island	5 cm x 7 cm	1 @ 0.94	MM
4898T		5 cm x 7.2 cm, 5	1 @ 8.29	SN
4899W		8 cm x 10 cm, 5	1 @ 14.66	SN
4690W		9 cm x 10 cm	1 @ 2.04	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 @ 73.65	SN
4906F	Dressing—Hydroactive (Superficial Wound—Light Exudate)	10 cm x 10 cm, 5	1 @ 42.85	SN
4886E	Dressing—Hydroactive (Superficial Wound—Moderate Exudate)	10 cm x 10 cm, 5	1 @ 30.07	SN
4896Q	Dressing—Hydrocolloid (Cavity Wound)	30 g	1 @ 13.87	CC
4895P		50 g	1 @ 15.84	CT
4697F		6 g	1 @ 7.16	CT
4908H	Dressing—Hydrocolloid (Superficial Wound—Light Exudate)	10 cm x 10 cm, 5	1 @ 23.30	HO
4897R	Dressing—Hydrocolloid (Superficial Wound—Moderate Exudate)	10 cm x 10 cm, 5	1 @ 26.20	HO
			1 @ 37.49	CC
4922C		15 cm x 15 cm, 5	1 @ 62.10	SN
			1 @ 101.14	CC
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
			1 @ 74.43	SN
4913N	Dressing—Hydrogel—Amorphous	30 g, 3	1 @ 30.23	CC
4914P		50 g	1 @ 7.26	JJ
4599C		50 g	1 @ 5.56	SN
4911L	Dressing—Hydrogel—Sheet	9.5 cm x 10.2 cm, 5	1 @ 38.39	JJ
4806Y		11 cm x 10 cm, 5	1 @ 23.30	HR
4860T	Dressing—Non-Adherent	5 cm x 5 cm, 5	1 @ 3.72	SN
4819P		5 cm x 5 cm, 5	1 @ 3.47	SN
4909J		7.6 cm x 7.6 cm	1 @ 0.89	JJ
4862X		10 cm x 10 cm, 5	1 @ 7.00	SN
4237B	Fexofenadine Hydrochloride	60 mg	20 @ 13.66	AV
4246L	Glycerol	2.8 g, 12	1 @ 3.47	PP
4283K	Ipratropium Bromide with Salbutamol Sulfate	20 mcg (anhydrous)- 100 mcg (base) per dose (200 doses)	1 @ 21.20	BY
4330X	Moxifloxacin Hydrochloride	400 mg (base) in 250 mL	1 @ 62.71	BN

(APPLY WASTAGE FACTOR IN CALCULATING BROKEN QUANTITY PRICES)

Code	Name	Form/Strength	Pack and Price \$	Manufacturer	
4576W	Nicotine	Approx. 5 mg per 16 hours, 7	1 @	21.95	PC
4571N		Approx. 7 mg per 24 hours, 7	1 @	19.40	AF
4577X		Approx. 10 mg per 16 hours, 7	1 @	33.95	GK
4572P		Approx. 14 mg per 24 hours, 7	1 @	24.12	PC
4578Y		Approx. 15 mg per 16 hours, 7	1 @	21.23	AF
4573Q	Pressure Reducing Products	Approx. 21 mg per 24 hours, 7	1 @	33.95	GK
4676D		10 cm x 10 cm x 3 mm	1 @	10.56	KC
4677E		10 cm x 10 cm x 12 mm	1 @	21.12	KC
4678F		7 cm	1 @	8.68	CT
4679G		10 cm	1 @	9.50	CT

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for

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THERAPEUTIC GROUP PREMIUM POLICY

PHARMACEUTICAL BENEFIT ITEMS WHICH HAVE A THERAPEUTIC GROUP PREMIUM WITH EFFECT FROM 1 FEBRUARY 2007

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 \$

H₂-RECEPTOR ANTAGONISTS

<i>Zantac</i>	Effervescent tablet 150 mg (base)	60	4.18
<i>Zantac Syrup</i>	Syrup 150 mg (base) per 10 mL, 300 mL	2	2.10

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

<i>Adalat Oros 20mg</i>	Tablet 20 mg (controlled release)	30	3.30
<i>Norvasc</i>	Tablet 5 mg (base)	30	4.46
<i>Norvasc</i>	Tablet 10 mg (base)	30	6.48
<i>Zanidip</i>	Tablet 10 mg	30	1.07
<i>Zanidip</i>	Tablet 20 mg	30	3.70

The base-priced drugs in this therapeutic group are felodipine and nifedipine (except nifedipine controlled release tablet 20 mg).

ACE INHIBITORS, PLAIN

<i>Tritace Titration Pack</i>	Pack containing 7 tablets 2.5 mg, 21 tablets 5 mg and 10 capsules 10 mg	1	2.84

The base-priced drugs in this therapeutic group are captopril, enalapril maleate, fosinopril sodium, lisinopril, perindopril, quinapril hydrochloride, ramipril (except ramipril pack containing 7 tablets 2.5 mg, 21 tablets 5 mg and 10 capsules 10 mg) and trandolapril.

BRAND PREMIUM POLICY

BRANDS OF PHARMACEUTICAL BENEFIT ITEMS WHICH HAVE A BRAND PREMIUM AND THAT MAY BE SUBSTITUTED WITH EFFECT FROM 1 FEBRUARY 2007

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
<i>Abbecillin-V</i>	Paediatric oral suspension 125 mg per 5 mL, 100 mL	2	1.82	<i>Cilicaine V</i>
<i>Accupril</i>	Oral suspension 250 mg per 5 mL, 100 mL	2	1.80	<i>Cilicaine V</i>
	Tablet 5 mg (base)	30	0.49	<i>Acquin 5; Filpril</i>
	Tablet 10 mg (base)	30	0.66	<i>Acquin 10; Filpril</i>
	Tablet 20 mg (base)	30	0.98	<i>Acquin 20; Filpril</i>
<i>Adalat Oros 30</i>	Tablet 30 mg (controlled release)	30	3.70	<i>Addos XR 30; Adefin XL 30</i>
<i>Adalat Oros 60</i>	Tablet 60 mg (controlled release)	30	4.10	<i>Addos XR 60; Adefin XL 60</i>
<i>Adalat 10</i>	Tablet 10 mg	60	1.73	<i>Adefin 10; Nypine 10</i>
<i>Adalat 20</i>	Tablet 20 mg	60	3.20	<i>Adefin 20; Chem mart Nifedipine; GenRx Nifedipine; Nifehexal; Nyefax 20 mg; Nypine 20; Terry White Chemists Nifedipine</i>
<i>Airomir</i>	Oral pressurised inhalation 100 micrograms (base) per dose (200 doses), CFC-free formulation	2	0.60	<i>Asmol CFC-free; Epag</i>
<i>Aldactone</i>	Tablet 25 mg	100	1.84	<i>Spiractin 25</i>
	Tablet 100 mg	100	2.53	<i>Spiractin 100</i>
<i>Aldomet</i>	Tablet 250 mg	100	2.85	<i>Hydopa</i>
<i>Alphagan</i>	Eye drops 2 mg per mL (0.2%), 5 mL	1	1.70	<i>Enidin</i>
<i>Amaryl</i>	Tablet 1 mg	30	2.41	<i>Aylide 1; Diapride 1; Dimirel; Glimepiride Sandoz</i>
	Tablet 2 mg	30	2.41	<i>Aylide 2; Diapride 2; Dimirel; Glimepiride Sandoz</i>
	Tablet 3 mg	30	2.43	<i>Aylide 3; Diapride 3; Dimirel; Glimepiride Sandoz</i>
	Tablet 4 mg	30	2.42	<i>Aylide 4; Diapride 4; Dimirel; Glimepiride Sandoz</i>
<i>Amoxil</i>	Capsule 250 mg	20	1.00	<i>Alphamox 250; Amohexal; Amoxycillin-DP; Chem mart Amoxycillin; Cilamox; GenRx Amoxycillin; Moxacin; Terry White Chemists Amoxycillin</i>
	Capsule 500 mg	20	1.00	<i>Alphamox 500; Amohexal; Amoxycillin-DP; Chem mart Amoxycillin; Cilamox; GenRx Amoxycillin; Moxacin; Terry White Chemists Amoxycillin</i>
	Powder for syrup 125 mg per 5 mL, 100 mL	1	1.22	<i>Alphamox 125; Amohexal; Bgramin; Chem mart Amoxycillin; GenRx Amoxycillin; Moxacin; Terry White Chemists Amoxycillin</i>
<i>Amoxil Duo</i>	Tablet 1 g	14	1.49	<i>Amoxycillin Sandoz</i>
<i>Amoxil Forte</i>	Powder for syrup 250 mg per 5 mL, 100 mL	1	1.01	<i>Alphamox 250; Amohexal; Bgramin; Chem mart Amoxycillin; Cilamox; GenRx Amoxycillin; Terry White Chemists Amoxycillin</i>
<i>Amprace 10</i>	Tablet 10 mg	30	3.14	<i>Alphapril; Auspril; Chem mart Enalapril; Enahexal; Enalabell; Enalapril-DP 10mg; GenRx Enalapril; Terry White Chemists Enalapril</i>
<i>Amprace 20</i>	Tablet 20 mg	30	3.14	<i>Alphapril; Auspril; Chem mart Enalapril; Enahexal; Enalabell; Enalapril-DP 20mg; GenRx Enalapril; Terry White Chemists Enalapril</i>

Premium Priced Brand	Form and Strength	Max. Qty	Brand Premium \$	Benchmark Priced Brands
<i>Anafranil 25</i>	Tablet 25 mg	50	3.26	<i>Chem mart Clomipramine;</i> <i>GenRx Clomipramine; Placil;</i> <i>Terry White Chemists</i> <i>Clomipramine</i>
<i>Anaprox 550</i>	Tablet 550 mg	50	2.91	<i>Crysanal</i>
<i>Androcur</i>	Tablet 50 mg	20	4.58	<i>Cyprohexal; Cyprone; Cyprostat;</i> <i>GenRx Cyproterone Acetate;</i> <i>Procur</i>
	Tablet 50 mg	100	4.00	<i>Cyprohexal; Cyprone; Cyprostat;</i> <i>GenRx Cyproterone Acetate;</i> <i>Procur</i>
<i>Androcur-100</i>	Tablet 100 mg	50	2.01	<i>Cyprohexal; Cyprostat-100;</i> <i>GenRx Cyproterone Acetate;</i> <i>Procur 100</i>
<i>Anginine Stabilised</i>	Tablets 600 micrograms, 100	1	1.61	<i>Lycinat</i>
<i>Arava</i>	Tablet 10 mg	30	1.17	<i>Arabloc</i>
	Tablet 20 mg	30	1.17	<i>Arabloc</i>
<i>Aristocort 0.02%</i>	Cream 200 micrograms per g (0.02%), 100 g	2	3.18	<i>Tricortone</i>
	Ointment 200 micrograms per g (0.02%), 100 g	2	3.18	<i>Tricortone</i>
<i>Aropax</i>	Tablet 20 mg (base)	30	1.10	<i>Chem mart Paroxetine; Extine 20;</i> <i>GenRx Paroxetine; Oxetine;</i> <i>Paroxetine-DP; Paxtine;</i> <i>Terry White Chemists Paroxetine</i>
<i>Astrix</i>	Tablet 100 mg	112	1.32	<i>DBL Aspirin 100 mg</i>
<i>Atrovent</i>	Nebuliser solution single dose units 250 micrograms (anhydrous) in 1 mL, 30	2	0.92	<i>Aeron 250; Apoven 250;</i> <i>Chem mart Ipratropium;</i> <i>GenRx Ipratropium; Ipratrin;</i> <i>Ipravent;</i> <i>Terry White Chemists Ipratropium</i>
<i>Atrovent Adult</i>	Nebuliser solution single dose units 500 micrograms (anhydrous) in 1 mL, 30	2	0.90	<i>Aeron 500; Apoven 500;</i> <i>Chem mart Ipratropium;</i> <i>GenRx Ipratropium; Ipratrin Adult;</i> <i>Ipravent;</i> <i>Terry White Chemists Ipratropium</i>
<i>Augmentin</i>	Powder for syrup 125 mg-31.25 mg per 5 mL, 75 mL	1	0.96	<i>Clamohexal 125mg/31.25mg/5mL;</i> <i>Clamoxyl; Clavulin</i>
<i>Augmentin Duo</i>	Tablet 500 mg-125 mg	10	0.99	<i>Clamohexal Duo 500mg/125mg;</i> <i>Clamoxyl Duo; Clavulin Duo;</i> <i>Curam 500/125; Muric 500/125</i>
<i>Augmentin Duo forte</i>	Tablet 875 mg-125 mg	10	1.30	<i>Chem mart Amoxycillin and</i> <i>Clavulanic Acid;</i> <i>Clamohexal Duo Forte</i> <i>875mg/125mg; Clamoxyl Duo forte;</i> <i>Clavulin Duo Forte;</i> <i>Curam 875/125;</i> <i>GenRx Amoxycillin and Clavulanic</i> <i>Acid; Muric 875/125;</i> <i>Terry White Chemists Amoxycillin</i> <i>and Clavulanic Acid</i>
<i>Augmentin Duo 400</i>	Powder for syrup 400 mg-57 mg per 5 mL, 60 mL	1	0.98	<i>Clamohexal Duo 400mg/57mg/5mL;</i> <i>Clamoxyl Duo 400;</i> <i>Clavulin Duo 400</i>
<i>Aurorix</i>	Tablet 150 mg	60	0.93	<i>Amira 150; Arima;</i> <i>Chem mart Moclobemide;</i> <i>Clobemix; GenRx Moclobemide;</i> <i>Mohexal;</i> <i>Terry White Chemists Moclobemide</i>

Premium Priced Brand	Form and Strength	Max. Qty	Brand Premium \$	Benchmark Priced Brands
<i>Aurorix 300 mg</i>	Tablet 300 mg	60	1.86	<i>Amira 300; Arima 300; Chem mart Moclobemide; Clobemix; GenRx Moclobemide; Maosig; Mohexal; Terry White Chemists Moclobemide</i>
<i>Avanza</i>	Tablet 30 mg	30	2.17	<i>Axit 30; Mirtazapine-DP; Mirtazon</i>
	Tablet 45 mg	30	2.19	<i>Mirtazon</i>
<i>Azopt</i>	Eye drops 10 mg per mL (1%), 5 mL	1	0.98	<i>BrinzoQuin</i>
<i>Betaloc</i>	Tablet 50 mg	100	3.25	<i>Chem mart Metoprolol; GenRx Metoprolol; Metohexal; Metolol; Metrol 50; Minax 50; Terry White Chemists Metoprolol</i>
	Tablet 100 mg	60	3.25	<i>Chem mart Metoprolol; GenRx Metoprolol; Metohexal; Metolol; Metrol 100; Minax 100; Terry White Chemists Metoprolol</i>
<i>Betnovate 1/5</i>	Cream 200 micrograms (base) per g (0.02%), 100 g	2	6.00	<i>Cortival 1/5</i>
<i>Betnovate 1/2</i>	Cream 500 micrograms (base) per g (0.05%), 15 g	1	1.86	<i>Cortival 1/2</i>
	Ointment 500 micrograms (base) per g (0.05%), 15 g	1	1.86	<i>Cortival 1/2</i>
<i>Betoptic</i>	Eye drops, solution, 5 mg (base) per mL (0.5%), 5 mL	1	1.95	<i>BetoQuin</i>
<i>Blenoxane</i>	Powder for injection 15,000 i.u.	10	76.86	<i>Blenamax; MX brand</i>
<i>Brevinor</i>	Tablets 500 micrograms-35 micrograms, 21	4	7.68	<i>Norimin 28 Day</i>
	Pack containing 21 tablets 500 micrograms-35 micrograms and 7 inert tablets	4	7.68	<i>Norimin 28 Day</i>
<i>Brevinor-1</i>	Tablets 1 mg-35 micrograms, 21	4	7.68	<i>Norimin-1 28 Day</i>
	Pack containing 21 tablets 1 mg-35 micrograms and 7 inert tablets	4	7.68	<i>Norimin-1 28 Day</i>
<i>Capoten</i>	Tablet 12.5 mg	90	2.46	<i>Acenorm 12.5 mg; Captoprenal; Chem mart Captopril; GenRx Captopril; GM brand; Terry White Chemists Captopril; Topace</i>
	Tablet 25 mg	90	2.47	<i>Acenorm 25 mg; Captoprenal; Chem mart Captopril; GenRx Captopril; GM brand; Terry White Chemists Captopril; Topace</i>
	Tablet 50 mg	90	2.46	<i>Acenorm 50 mg; Captoprenal; Chem mart Captopril; GenRx Captopril; GM brand; Terry White Chemists Captopril; Topace</i>
<i>Carafate</i>	Tablet equivalent to 1 g anhydrous sucralfate	120	2.13	<i>Ulcyste</i>
<i>Cardizem</i>	Tablet 60 mg	90	2.55	<i>Chem mart Diltiazem; Coras; Diltahexal; Dilzem 60 mg; GenRx Diltiazem; Terry White Chemists Diltiazem; Vasocardol</i>
<i>Cardizem CD</i>	Capsule 180 mg (controlled delivery)	30	2.55	<i>Chem mart Diltiazem CD; Dilzem CD; GenRx Diltiazem CD; Terry White Chemists Diltiazem CD; Vasocardol CD</i>

Premium Priced Brand	Form and Strength	Max. Qty	Brand Premium \$	Benchmark Priced Brands
	Capsule 240 mg (controlled delivery)	30	2.56	Chem mart Diltiazem CD; Dilzem CD; GenRx Diltiazem CD; Terry White Chemists Diltiazem CD; Vasocardol CD
Ceclor	Capsule 360 mg (controlled delivery)	30	3.10	Vasocardol CD
	Powder for oral suspension 125 mg per 5 mL, 100 mL	1	2.54	Aclor 125; Chem mart Cefaclor; GenRx Cefaclor; Keflor; Terry White Chemists Cefaclor
	Powder for oral suspension 250 mg per 5 mL, 75 mL	1	2.62	Aclor 250; Chem mart Cefaclor; GenRx Cefaclor; Keflor; Terry White Chemists Cefaclor
Ceclor CD	Tablet 375 mg (sustained release)	10	2.91	Chem mart Cefaclor CD; Douglas Cefaclor-CD; GenRx Cefaclor CD; Karlor CD; Keflor CD; Ozcef; Terry White Chemists Cefaclor CD
Cefotaxime	Powder for injection 1 g	10	26.40	MX brand
Sandoz	Powder for injection 2 g	10	48.60	MX brand
Chlorvescent	Effervescent tablet 14 mmol K ⁺ and 8 mmol Cl ⁻	60	2.54	K-Sol
Ciloxan	Eye drops 3 mg per mL (0.3%), 5 mL	2	2.42	CiloQuin
Cipramil	Tablet 20 mg (base)	28	3.09	Celapram; Chem mart Citalopram; Ciazil; Citalopram-RL; GenRx Citalopram; Talam; Talohehexal; Terry White Chemists Citalopram
Ciproxin 250	Tablet 250 mg	14	1.85	C-Flox 250; Ciprofloxacin-BC; Ciprol 250; GenRx Ciprofloxacin; Profloxin
Ciproxin 500	Tablet 500 mg	14	1.85	C-Flox 500; Ciprofloxacin-BC; Ciprol 500; GenRx Ciprofloxacin; GN brand; Proflorin; Proquin
Ciproxin 750	Tablet 750 mg	14	1.83	C-Flox 750; Ciprol 750; GenRx Ciprofloxacin; GN brand; Proflorin; Proquin
Clomid	Tablet 50 mg	10	3.61	Clomhexal; Fermil; GenRx Clomiphene
Colgout	Tablet 500 micrograms	100	0.89	Lengout
Cordarone X 100	Tablet 100 mg	30	0.97	Aratac 100; Cardinorm; GenRx Amiodarone; Rithmik 100
Cordarone X 200	Tablet 200 mg	30	0.96	Aratac 200; Cardinorm; Chem mart Amiodarone; GenRx Amiodarone; Rithmik 200; Terry White Chemists Amiodarone
Dalacin C	Capsule 150 mg	25	1.41	Cleocin
Daonil	Tablet 5 mg	100	1.19	Glimel
Depo-Medrol	Injection 40 mg in 1 mL	5	0.74	Depo-Nisolone
Depo-Provera	Injection 150 mg in 1 mL	1	3.25	Depo-Ralovera
Diabex	Tablet 500 mg	100	1.80	Chem mart Metformin; Diaformin; Formet 500; GenRx Metformin; Glucohexal; Glucomet 500 mg; GN brand; Metforbell; Terry White Chemists Metformin
Diabex 850	Tablet 850 mg	60	2.09	Chem mart Metformin; Diaformin 850; Formet 850; GenRx Metformin; Glucohexal; Glucomet 850 mg; GN brand; Metforbell; Terry White Chemists Metformin
Diabex 1000	Tablet 1 g	90	1.80	Diaformin 1000; Formet 1000

Premium Priced Brand	Form and Strength	Max. Qty	Brand Premium \$	Benchmark Priced Brands
<i>Diamicron</i>	Tablet 80 mg	100	2.60	<i>Chem mart Gliclazide;</i> <i>GenRx Gliclazide; Glyade;</i> <i>Mellihexal; Nidem;</i> <i>Terry White Chemists Gliclazide</i>
<i>Doryx</i>	Capsule 100 mg	7	1.46	<i>DBL Doxycycline</i>
	Capsule 50 mg	25	1.66	<i>DBL Doxycycline</i>
	Capsule 100 mg	28	5.84	<i>DBL Doxycycline</i>
	Capsule 100 mg	21	2.66	<i>DBL Doxycycline</i>
<i>Duphalac</i>	Mixture 3.34 g per 5 mL, 500 mL	1	2.13	<i>Actilax; Genlac; GenRx Lactulose;</i> <i>Lac-Dol; Lactocur</i>
<i>Duratears</i>	Compound eye ointment 3.5 g	2	1.92	<i>Poly Visc</i>
<i>Durolax</i>	Suppositories 10 mg, 10	3	1.11	<i>Petrus Bisacodyl Suppositories</i>
<i>E.E.S. Granules</i>	Powder for oral liquid 400 mg (base) per 5 mL, 100 mL	1	1.71	<i>E-Mycin 400</i>
<i>E.E.S. 200</i>	Powder for oral liquid 200 mg (base) per 5 mL, 100 mL	1	2.12	<i>E-Mycin 200</i>
<i>E.E.S. 400 Filmtab</i>	Tablet 400 mg (base)	25	2.81	<i>E-Mycin</i>
<i>Epilim EC</i>	Tablet 200 mg (enteric coated)	200	1.28	<i>Valpro 200</i>
	Tablet 500 mg (enteric coated)	200	1.60	<i>Valpro 500</i>
<i>Eryc</i>	Capsule 250 mg	25	1.72	<i>DBL Erythromycin</i>
<i>Fasigyn</i>	Tablet 500 mg	4	2.44	<i>Simplotan</i>
<i>Feldene</i>	Capsule 10 mg	50	2.66	<i>Chem mart Piroxicam;</i> <i>GenRx Piroxicam; Mobilis 10;</i> <i>Terry White Chemists Piroxicam</i>
	Capsule 20 mg	25	2.64	<i>Chem mart Piroxicam;</i> <i>GenRx Piroxicam; Mobilis 20;</i> <i>Terry White Chemists Piroxicam</i>
<i>Feldene-D</i>	Dispersible tablet 10 mg	50	2.66	<i>GenRx Piroxicam Dispersible;</i> <i>Mobilis D-10; Pirohexal-D</i>
	Dispersible tablet 20 mg	25	2.64	<i>Chem mart Piroxicam Dispersible;</i> <i>GenRx Piroxicam Dispersible;</i> <i>Mobilis D-20; Pirohexal-D;</i> <i>Terry White Chemists Piroxicam Dispersible</i>
<i>Ferrum H</i>	Injection 100 mg (iron) in 2 mL	5	1.19	<i>Ferrosig</i>
<i>Flagyl</i>	Tablet 200 mg	21	1.92	<i>Metrogyl 200; Metronide 200</i>
	Tablet 400 mg	21	2.00	<i>Metrogyl 400; Metronide 400</i>
<i>Floxapen</i>	Capsule 250 mg	24	0.45	<i>Flopen; Floxsig; Staphylex 250</i>
	Capsule 500 mg	24	0.57	<i>Flopen; Floxsig; Staphylex 500</i>
	Powder for syrup 250 mg per 5 mL, 100 mL	1	0.09	<i>Flopen</i>
<i>Fosamax Once Weekly</i>	Tablet equivalent to 70 mg alendronic acid	4	0.82	<i>Alendro Once Weekly</i>
<i>Genteal</i>	Eye drops 3 mg per mL (0.3%), 15 mL (contains sodium perborate as preservative)	1	1.82	<i>In a Wink Moisturising</i>
<i>Genteal gel</i>	Ocular lubricating gel 3 mg-2 mg per g (0.3%-0.2%), 10 g	1	1.82	<i>HPMC PAA</i>
<i>Glucophage</i>	Tablet 500 mg	100	1.41	<i>Chem mart Metformin; Diaformin;</i> <i>Formet 500; GenRx Metformin;</i> <i>Glucohexal; Glucomet 500 mg;</i> <i>GN brand; Metforbell;</i> <i>Terry White Chemists Metformin</i>
	Tablet 850 mg	60	1.41	<i>Chem mart Metformin;</i> <i>Diaformin 850; Formet 850;</i> <i>GenRx Metformin; Glucohexal;</i> <i>Glucomet 850 mg; GN brand;</i> <i>Metforbell;</i> <i>Terry White Chemists Metformin</i>
<i>Gopten</i>	Capsule 500 micrograms	28	1.50	<i>Odrik</i>
	Capsule 1 mg	28	1.50	<i>Odrik</i>

Premium Priced Brand	Form and Strength	Max. Qty	Brand Premium \$	Benchmark Priced Brands
<i>Imdur Durule</i>	Capsule 2 mg	28	1.50	<i>Odrik</i>
	Tablet 60 mg (sustained release)	30	2.84	<i>Chem mart Isosorbide Mononitrate; Duride; GenRx Isosorbide Mononitrate; Imtrate 60 mg; Isomonit; Monodur 60 mg; Terry White Chemists Isosorbide Mononitrate</i>
<i>Imdur 120 mg</i>	Tablet 120 mg (sustained release)	30	3.00	<i>Monodur 120 mg</i>
<i>Imodium</i>	Capsule 2 mg	12	0.90	<i>Gastro-Stop Loperamide</i>
<i>Imuran</i>	Tablet 25 mg	100	1.51	<i>Azahexal</i>
	Tablet 50 mg	100	1.44	<i>Azahexal; Azamun; Azapin; GenRx Azathioprine; Thioprine</i>
<i>Indocid</i>	Capsule 25 mg	100	2.98	<i>Arthrexin</i>
<i>Isoptin</i>	Tablet 40 mg	100	0.97	<i>Anpec 40</i>
	Tablet 80 mg	100	0.97	<i>Anpec 80</i>
<i>Isoptin SR</i>	Tablet 240 mg (sustained release)	30	2.89	<i>Anpec SR; Cordilox SR</i>
<i>Isoptin 180 SR</i>	Tablet 180 mg (sustained release)	30	2.89	<i>Cordilox 180 SR</i>
<i>Isordil</i>	Tablet 10 mg	200	3.56	<i>Sorbidin</i>
<i>Keflex</i>	Capsule 250 mg	20	2.39	<i>Chem mart Cephalexin; Cilex; GenRx Cephalexin; Ialex; Ibilex 250; Rancef; Sporahehexal; Terry White Chemists Cephalexin</i>
	Capsule 500 mg	20	2.84	<i>Chem mart Cephalexin; Cilex; GenRx Cephalexin; Ialex; Ibilex 500; Rancef; Sporahehexal; Terry White Chemists Cephalexin</i>
	Granules for syrup 125 mg per 5 mL, 100 mL	1	2.47	<i>Chem mart Cephalexin; Cilex; GenRx Cephalexin; Ialex; Ibilex 125; Terry White Chemists Cephalexin</i>
	Granules for syrup 250 mg per 5 mL, 100 mL	1	2.82	<i>Chem mart Cephalexin; Cilex; GenRx Cephalexin; Ialex; Ibilex 250; Terry White Chemists Cephalexin</i>
<i>Keflin Neutral</i>	Powder for injection 1 g	10	0.28	<i>MX brand</i>
<i>Kefzol</i>	Powder for injection 1 g	10	2.42	<i>Cefazolin Sandoz; MX brand</i>
<i>Kenacomb Otic</i>	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	1.05	<i>Otocomb Otic</i>
	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	1.05	<i>Otocomb Otic</i>
<i>Klacid</i>	Tablet 250 mg	14	2.50	<i>Chem mart Clarithromycin; Clarac; Clarihexal; Clarithro 250; GenRx Clarithromycin; Kalixocin; Terry White Chemists Clarithromycin</i>
<i>Lacri-Lube</i>	Pack containing 2 tubes compound eye ointment 3.5 g	1	2.08	<i>Ircal</i>
<i>Lamictal</i>	Tablet 5 mg	56	0.97	<i>Elmendos; Lamitrin; Lamogine; Seaze 5</i>
	Tablet 25 mg	56	0.98	<i>Elmendos; GenRx Lamotrigine; Lamidus; Lamitrin; Lamogine; Lamotrigine-DP; Seaze 25</i>
	Tablet 50 mg	56	0.97	<i>Elmendos; GenRx Lamotrigine; Lamidus; Lamitrin; Lamogine; Lamotrigine-DP; Seaze 50</i>

Premium Priced Brand	Form and Strength	Max. Qty	Brand Premium \$	Benchmark Priced Brands
	Tablet 100 mg	56	0.97	Elmendos; GenRx Lamotrigine; Lamidus; Lamitrin; Lamogine; Lamotrigine-DP; Seaze 100
	Tablet 200 mg	56	0.96	Elmendos; GenRx Lamotrigine; Lamidus; Lamitrin; Lamogine; Lamotrigine-DP; Seaze 200
Lamisil	Tablet 250 mg (base)	42	1.93	GenRx Terbinafine; Tamsil; Terbihexal; Terbinafine-DP; Zabel
Lanoxin	Tablet 250 micrograms	100	1.75	Sigmaxin
Lanoxin-PG	Tablet 62.5 micrograms	200	1.74	Sigmaxin-PG
Lasix	Tablet 40 mg	100	1.08	Chem mart Frusemide; Frusehexal 40 mg; Frusid; GenRx Frusemide; Terry White Chemists Frusemide; Uremide
Lasix-M	Tablet 20 mg	100	1.08	Chem mart Frusemide; Frusid; GenRx Frusemide; Terry White Chemists Frusemide
Lexapro	Tablet 10 mg (base)	28	3.20	Esipram
	Tablet 20 mg (base)	28	5.34	Esipram
Lioresal 10	Tablet 10 mg	100	2.90	Baclo; Baclohexal; Chem mart Baclofen; Clofen 10; GenRx Baclofen; Stelax 10; Terry White Chemists Baclofen
Lioresal 25	Tablet 25 mg	100	2.90	Baclo; Baclohexal; Chem mart Baclofen; Clofen 25; GenRx Baclofen; Stelax 25; Terry White Chemists Baclofen
Lipex 5	Tablet 5 mg	30	0.68	Simvabell; Simvahexal; Simvastatin-RL; Zimstat
Lipex 10	Tablet 10 mg	30	0.68	Chem mart Simvastatin; GenRx Simvastatin; GN brand; Simvabell; Simvahexal; Simvar 10; Simvastatin-DP; Simvastatin-RL; Terry White Chemists Simvastatin; Zimstat
Lipex 20	Tablet 20 mg	30	0.68	Chem mart Simvastatin; GenRx Simvastatin; GN brand; Simvabell; Simvahexal; Simvar 20; Simvastatin-DP; Simvastatin-RL; Terry White Chemists Simvastatin; Zimstat
Lipex 40	Tablet 40 mg	30	0.70	Chem mart Simvastatin; GenRx Simvastatin; GN brand; Simvabell; Simvahexal; Simvar 40; Simvastatin-DP; Simvastatin-RL; Terry White Chemists Simvastatin; Zimstat
Lipex 80	Tablet 80 mg	30	0.67	Chem mart Simvastatin; GenRx Simvastatin; GN brand; Simvabell; Simvahexal; Simvar 80; Simvastatin-DP; Simvastatin-RL; Terry White Chemists Simvastatin; Zimstat
Liquifilm Forte	Eye drops 30 mg per mL (3%), 15 mL	1	5.80	PVA Forte
Liquifilm Tears	Eye drops 14 mg per mL (1.4%), 15 mL	1	1.66	PVA Tears
Lomotil	Tablet 2.5 mg-25 micrograms	20	1.78	Lofenoxal

Premium Priced Brand	Form and Strength	Max. Qty	Brand Premium \$	Benchmark Priced Brands
<i>Lopid</i>	Tablet 600 mg	60	3.38	<i>Ausgem</i> ; <i>Chem mart Gemfibrozil</i> ; <i>Gemhexal</i> ; <i>GenRx Gemfibrozil</i> ; <i>Jezil</i> ; <i>Lipazil 600 mg</i> ; <i>Terry White Chemists Gemfibrozil</i>
<i>LOSEC Tablets</i>	Tablet 20 mg	30	2.75	<i>Acimax Tablets</i> ; <i>Meprazol</i> ; <i>Omepral</i> ; <i>Omeprazole Winthrop</i>
<i>Luvox</i>	Tablet 50 mg	30	3.77	<i>Faverin 50</i> ; <i>Movox 50</i> ; <i>Voxam</i>
	Tablet 100 mg	30	3.77	<i>Faverin 100</i> ; <i>Movox 100</i> ; <i>Voxam</i>
<i>Maxamox</i>	Tablet 1 g	14	1.49	<i>Amoxycillin Sandoz</i>
<i>Menorest 37.5</i>	Transdermal patches 3.28 mg (releasing approximately 37.5 micrograms per 24 hours), 8	1	1.50	<i>Estradot 37.5</i>
<i>Menorest 50</i>	Transdermal patches 4.33 mg (releasing approximately 50 micrograms per 24 hours), 8	1	1.50	<i>Estradot 50</i>
<i>Menorest 75</i>	Transdermal patches 6.57 mg (releasing approximately 75 micrograms per 24 hours), 8	1	1.49	<i>Estradot 75</i>
<i>Menorest 100</i>	Transdermal patches 8.66 mg (releasing approximately 100 micrograms per 24 hours), 8	1	1.49	<i>Estradot 100</i>
<i>Microgynon 30</i>	Tablets 150 micrograms-30 micrograms, 21	4	11.16	<i>Levlen ED</i>
<i>Microgynon 30 ED</i>	Pack containing 21 tablets 150 micrograms-30 micrograms and 7 inert tablets	4	11.16	<i>Levlen ED</i>
<i>Minidiab</i>	Tablet 5 mg	100	3.97	<i>Melizide</i>
<i>Minipress</i>	Tablet 1 mg (base)	100	2.95	<i>Chem mart Prazosin</i> ; <i>GenRx Prazosin</i> ; <i>Pressin 1</i> ; <i>Terry White Chemists Prazosin</i>
	Tablet 2 mg (base)	100	3.04	<i>Chem mart Prazosin</i> ; <i>GenRx Prazosin</i> ; <i>Pressin 2</i> ; <i>Terry White Chemists Prazosin</i>
	Tablet 5 mg (base)	100	3.29	<i>Chem mart Prazosin</i> ; <i>GenRx Prazosin</i> ; <i>Pressin 5</i> ; <i>Terry White Chemists Prazosin</i>
<i>Minomycin-50</i>	Tablet 50 mg	60	1.08	<i>Akamin 50</i>
<i>Mobic</i>	Tablet 7.5 mg	30	1.79	<i>Movalis 7.5</i>
	Tablet 15 mg	30	1.79	<i>Movalis 15</i>
<i>Moduretic</i>	Tablet 50 mg-5 mg	100	3.30	<i>Amizide</i>
<i>Mogadon</i>	Tablet 5 mg	25	1.96	<i>Alodorm</i>
	Tablet 5 mg	50	3.92	<i>Alodorm</i>
<i>Mylanta P</i>	Tablet 200 mg-200 mg	200	0.40	<i>Gelusil</i>
	Oral suspension 200 mg-200 mg per 5 mL, 500 mL	2	0.30	<i>Gelusil</i>
<i>Naprosyn</i>	Tablet 250 mg	100	3.00	<i>Inza 250</i>
	Tablet 500 mg	50	1.75	<i>Inza 500</i>
<i>Naprosyn SR750</i>	Tablet 750 mg (sustained release)	28	1.62	<i>Proxen SR 750</i>
<i>Naprosyn SR1000</i>	Tablet 1 g (sustained release)	28	1.72	<i>Proxen SR 1000</i>
<i>Natrilix</i>	Tablet 2.5 mg	90	3.26	<i>Chem mart Indapamide</i> ; <i>Dapa-Tabs</i> ; <i>GenRx Indapamide</i> ; <i>Indahexal</i> ; <i>Insig</i> ; <i>Napamide 2.5 mg</i> ; <i>Terry White Chemists Indapamide</i>
<i>Neoral 25</i>	Capsule 25 mg	60	2.32	<i>Cicloral</i>
<i>Neoral 50</i>	Capsule 50 mg	60	2.30	<i>Cicloral</i>
<i>Neoral 100</i>	Capsule 100 mg	60	2.32	<i>Cicloral</i>
<i>Nolvadex</i>	Tablet 10 mg (base)	60	2.12	<i>Genox 10</i> ; <i>Tamoxen 10 mg</i>
<i>Nolvadex-D</i>	Tablet 20 mg (base)	60	3.82	<i>Chem mart Tamoxifen</i> ; <i>Genox 20</i> ; <i>GenRx Tamoxifen</i> ; <i>Tamosin</i> ; <i>Tamoxen 20 mg</i> ; <i>Tamoxifen Hexal</i> ; <i>Terry White Chemists Tamoxifen</i>

Premium Priced Brand	Form and Strength	Max. Qty	Brand Premium \$	Benchmark Priced Brands
<i>Nordette 28</i>	Pack containing 21 tablets 150 micrograms- 30 micrograms and 7 inert tablets	4	10.50	<i>Monofeme 28</i>
<i>Noriday 28 Day</i>	Tablets 350 micrograms, 28	4	3.88	<i>Locilan 28 Day</i>
<i>Normison</i>	Tablet 10 mg	25	1.77	<i>Temaze; Temtabs</i>
	Tablet 10 mg	50	3.54	<i>Temaze; Temtabs</i>
<i>Noroxin</i>	Tablet 400 mg	14	3.61	<i>Chem mart Norfloxacin;</i> <i>GenRx Norfloxacin; GM brand;</i> <i>Norflohexal; Nufloxib; Roxin;</i> <i>Terry White Chemists Norfloxacin</i>
<i>Ogen .625</i>	Tablet 730 micrograms (equivalent to 625 micrograms sodium oestrone sulfate)	56	1.43	<i>Genoral 0.625</i>
<i>Ogen 1.25</i>	Tablet 1.46 mg (equivalent to 1.25 mg sodium oestrone sulfate)	56	1.45	<i>Genoral 1.25</i>
<i>Oroxine</i>	Tablet equivalent to 50 micrograms anhydrous thyroxine sodium	200	1.27	<i>Eutroxsig</i>
	Tablet equivalent to 100 micrograms anhydrous thyroxine sodium	200	1.27	<i>Eutroxsig</i>
	Tablet equivalent to 200 micrograms anhydrous thyroxine sodium	200	1.26	<i>Eutroxsig</i>
<i>Orudis SR 200</i>	Capsule 200 mg (sustained release)	28	1.95	<i>Oruvail SR</i>
<i>Panadeine Forte</i>	Tablet 30 mg-500 mg	20	1.84	<i>Codalgin Forte; Codapane Forte;</i> <i>Dolaforte; Dymadon Forte;</i> <i>Prodeine Forte</i>
	Tablet 30 mg-500 mg	60	5.52	<i>Codalgin Forte; Codapane Forte;</i> <i>Dolaforte; Dymadon Forte;</i> <i>Prodeine Forte</i>
<i>Panadol Osteo</i>	Tablet 665 mg (modified release)	192	4.72	<i>Duatrol SR</i>
<i>Panafcort</i>	Tablet 1 mg	100	0.59	<i>Predsone</i>
<i>Panafcortelone</i>	Tablet 1 mg	100	0.59	<i>Predsolone</i>
<i>Parlodel</i>	Tablet 2.5 mg (base)	30	2.84	<i>Krypton 2.5</i>
	Tablet 2.5 mg (base)	60	2.92	<i>Krypton 2.5</i>
	Capsule 5 mg (base)	60	2.91	<i>Krypton 5</i>
	Capsule 10 mg (base)	100	3.08	<i>Krypton 10</i>
<i>Pepcidine</i>	Tablet 40 mg	30	5.41	<i>Ausfam 40; Chem mart Famotidine;</i> <i>Famohexal; GenRx Famotidine;</i> <i>Pamacid 40; Pepzan;</i> <i>Terry White Chemists Famotidine</i>
<i>Pepcidine M</i>	Tablet 20 mg	60	5.41	<i>Ausfam 20; Chem mart Famotidine;</i> <i>Famohexal; GenRx Famotidine;</i> <i>Pamacid 20; Pepzan;</i> <i>Terry White Chemists Famotidine</i>
<i>Plendil ER</i>	Tablet 2.5 mg (extended release)	30	3.01	<i>Felodur ER 2.5 mg</i>
	Tablet 5 mg (extended release)	30	3.35	<i>Felodur ER 5 mg</i>
	Tablet 10 mg (extended release)	30	4.67	<i>Felodur ER 10 mg</i>
<i>Pravachol</i>	Tablet 10 mg	30	0.47	<i>Chem mart Pravastatin; Cholstat 10;</i> <i>GenRx Pravastatin; Lipostat 10;</i> <i>Liprachol; Pravastatin-DP;</i> <i>Pravastatin-RL;</i> <i>Terry White Chemists Pravastatin</i>
	Tablet 20 mg	30	0.48	<i>Chem mart Pravastatin; Cholstat 20;</i> <i>GenRx Pravastatin; Lipostat 20;</i> <i>Liprachol; Pravastatin-DP;</i> <i>Pravastatin-RL;</i> <i>Terry White Chemists Pravastatin</i>
	Tablet 40 mg	30	0.50	<i>Chem mart Pravastatin; Cholstat 40;</i> <i>GenRx Pravastatin; Lipostat 40;</i> <i>Liprachol; Pravastatin-DP;</i> <i>Pravastatin-RL;</i> <i>Terry White Chemists Pravastatin</i>

Premium Priced Brand	Form and Strength	Max. Qty	Brand Premium \$	Benchmark Priced Brands
<i>Prinivil 5</i>	Tablet 80 mg	30	0.49	<i>Lipostat 80</i>
	Tablet 5 mg	30	1.95	<i>Chem mart Lisinopril; Fibsol 5; GenRx Lisinopril; Liprace; Lisinobell; Lisinopril Hexal; Lisodur; Terry White Chemists Lisinopril</i>
<i>Prinivil 10</i>	Tablet 10 mg	30	1.95	<i>Chem mart Lisinopril; Fibsol 10; GenRx Lisinopril; Liprace; Lisinobell; Lisinopril Hexal; Lisodur; Terry White Chemists Lisinopril</i>
<i>Prinivil 20</i>	Tablet 20 mg	30	1.95	<i>Chem mart Lisinopril; Fibsol 20; GenRx Lisinopril; Liprace; Lisinobell; Lisinopril Hexal; Lisodur; Terry White Chemists Lisinopril</i>
<i>Prothiaden</i>	Capsule 25 mg	50	2.00	<i>Dothep 25</i>
	Tablet 75 mg	30	1.03	<i>Dothep 75</i>
<i>Provera</i>	Tablet 5 mg	56	1.71	<i>Ralovera</i>
	Tablet 10 mg	30	1.70	<i>Medroxyhexal; Ralovera</i>
	Tablet 10 mg	100	1.59	<i>Ralovera</i>
<i>Prozac Tab</i>	Tablet 20 mg (base) (dispersible)	28	6.96	<i>Lovan 20 Tab</i>
<i>Prozac 20</i>	Capsule 20 mg (base)	28	6.96	<i>Auscap; Chem mart Fluoxetine; Fluohexal; Fluoxebell; Fluoxetine-DP; GenRx Fluoxetine; Lovan; Terry White Chemists Fluoxetine; Zactin</i>
<i>P.V. Carpine</i>	Eye drops 10 mg per mL (1%), 15 mL	1	2.53	<i>Pilopt</i>
	Eye drops 20 mg per mL (2%), 15 mL	1	2.51	<i>Pilopt</i>
	Eye drops 40 mg per mL (4%), 15 mL	1	2.49	<i>Pilopt</i>
	Eye drops 60 mg per mL (6%), 15 mL	1	2.43	<i>Pilopt</i>
<i>Quinate</i>	Tablet 300 mg	50	2.13	<i>Quinsul</i>
<i>Ramace 1.25 mg</i>	Tablet 1.25 mg	30	1.00	<i>Ramipril Sandoz; Ramipril Winthrop</i>
<i>Ramace 2.5 mg</i>	Tablet 2.5 mg	30	1.46	<i>Ramipril Sandoz; Ramipril Winthrop</i>
<i>Ramace 5 mg</i>	Tablet 5 mg	30	1.83	<i>Ramipril Sandoz; Ramipril Winthrop</i>
<i>Ramace 10 mg</i>	Capsule 10 mg	30	3.23	<i>Ramipril Sandoz; Ramipril Winthrop</i>
<i>Redipred</i>	Oral solution equivalent to 5 mg prednisolone per mL, 30 mL	1	1.78	<i>PredMix</i>
<i>Remeron</i>	Tablet 30 mg	30	25.83	<i>Axit 30; Mirtazapine-DP; Mirtazon</i>
<i>Renitec</i>	Tablet 10 mg	30	3.14	<i>Alphapril; Auspril; Chem mart Enalapril; Enahexal; Enalabell; Enalapril-DP 10mg; GenRx Enalapril; Terry White Chemists Enalapril</i>
	Tablet 5 mg	30	3.14	<i>Alphapril; Auspril; Chem mart Enalapril; Enahexal; Enalabell; Enalapril-DP 5mg; GenRx Enalapril; Terry White Chemists Enalapril</i>
<i>Renitec M</i>	Tablet 5 mg	30	3.14	<i>Alphapril; Auspril; Chem mart Enalapril; Enahexal; Enalabell; Enalapril-DP 5mg; GenRx Enalapril; Terry White Chemists Enalapril</i>
<i>Renitec 20</i>	Tablet 20 mg	30	3.14	<i>Alphapril; Auspril; Chem mart Enalapril; Enahexal; Enalabell; Enalapril-DP 20mg; GenRx Enalapril; Terry White Chemists Enalapril</i>
<i>Ritalin 10</i>	Tablet 10 mg	100	1.75	<i>Attenta</i>
<i>Rivotril</i>	Tablet 500 micrograms	200	4.58	<i>Paxam 0.5</i>
	Tablet 2 mg	200	5.20	<i>Paxam 2</i>
<i>Roaccutane</i>	Capsule 20 mg	60	2.42	<i>Chem mart Isotretinoin; GenRx Isotretinoin; Isohexal; Oratane; Terry White Chemists Isotretinoin</i>

Premium Priced Brand	Form and Strength	Max. Qty	Brand Premium \$	Benchmark Priced Brands
<i>Rulide</i>	Tablet 150 mg	10	2.42	<i>Biaxsig; Roxar 150; Roxide; Roximycin</i>
	Tablet 300 mg	5	2.42	<i>Biaxsig; Roxar 300; Roxide; Roximycin</i>
<i>Salazopyrin-EN</i>	Tablet 500 mg (enteric coated)	200	1.60	<i>Pyralin EN</i>
<i>Seprtin</i>	Oral suspension 40 mg-200 mg per 5 mL, 100 mL	1	1.85	<i>Resprim</i>
<i>Seprtin Forte</i>	Tablet 160 mg-800 mg	10	1.41	<i>Bactrim DS; Chem mart Trimethoprim with Sulfamethoxazole DS; GenRx Trimethoprim with Sulfamethoxazole DS; Resprim Forte; Terry White Chemists Trimethoprim with Sulfamethoxazole DS</i>
<i>Serepax</i>	Tablet 15 mg	25	1.74	<i>Alepam 15</i>
	Tablet 30 mg	25	1.85	<i>Alepam 30; Murelax</i>
	Tablet 15 mg	50	3.48	<i>Alepam 15</i>
	Tablet 30 mg	50	3.70	<i>Alepam 30; Murelax</i>
<i>Serophene</i>	Tablet 50 mg	10	0.18	<i>Clomhexal; Fermil; GenRx Clomiphene</i>
<i>Sigmacort</i>	Cream 10 mg per g (1%), 30 g	1	1.85	<i>Cortic-DS 1%</i>
	Cream 10 mg per g (1%), 50 g	1	1.86	<i>Cortic-DS 1%</i>
	Topical ointment 10 mg per g (1%), 30 g	1	1.85	<i>Cortic-DS 1%</i>
	Topical ointment 10 mg per g (1%), 50 g	1	1.86	<i>Cortic-DS 1%</i>
<i>Sinemet</i>	Tablet 250 mg-25 mg	100	3.10	<i>Levohexal</i>
<i>Sinemet 100/25</i>	Tablet 100 mg-25 mg	100	5.22	<i>Kinson</i>
<i>Slow-K</i>	Tablet 600 mg (sustained release)	200	2.78	<i>Duro-K</i>
<i>Sofradex</i>	Ear drops 500 micrograms-5 mg-50 micrograms per mL, 8 mL	1	1.71	<i>Otodex</i>
<i>Sotacor</i>	Tablet 80 mg	60	1.60	<i>GenRx Sotalol; Solavert; Sotahexal</i>
	Tablet 160 mg	60	1.74	<i>Cardol; Chem mart Sotalol; GenRx Sotalol; Solavert; Sotab; Sotahexal; Terry White Chemists Sotalol</i>
<i>Stemetil</i>	Tablet 5 mg	25	2.09	<i>Stemzine</i>
<i>Synphasic</i>	Pack containing 12 tablets 500 micrograms-35 micrograms, 9 tablets 1 mg-35 micrograms and 7 inert tablets	4	7.68	<i>Improvil 28 Day</i>
<i>Tagamet</i>	Tablet 200 mg	120	2.49	<i>Magicul 200</i>
	Tablet 400 mg	60	2.49	<i>GenRx Cimetidine; Magicul 400</i>
<i>Tambocor</i>	Tablet 100 mg	60	2.77	<i>Flecatab</i>
<i>Tazac</i>	Capsule 150 mg	60	5.28	<i>Nizac; Tacidine</i>
	Capsule 300 mg	30	5.28	<i>Nizac; Tacidine</i>
<i>Tears Naturale</i>	Eye drops 3 mg-1 mg per mL (0.3%-0.1%), 15 mL	1	1.63	<i>Poly-Tears</i>
<i>Tegretol 100</i>	Tablet 100 mg	200	3.00	<i>Carbamazepine Sandoz; Carbamazepine-BC</i>
<i>Tegretol 200</i>	Tablet 200 mg	200	3.30	<i>Carbamazepine Sandoz; Carbamazepine-BC; Teril</i>
<i>Tenormin</i>	Tablet 50 mg	30	3.55	<i>Anselol 50 mg; Atehexal; Chem mart Atenolol; GenRx Atenolol; Noten; Tensig; Terry White Chemists Atenolol</i>
<i>Ticlid</i>	Tablet 250 mg	60	2.20	<i>Ticlopidine Hexal; Tilodene</i>
<i>Timoptol</i>	Eye drops 2.5 mg (base) per mL (0.25%), 5 mL	1	1.05	<i>Tenopt</i>
	Eye drops 5 mg (base) per mL (0.5%), 5 mL	1	1.10	<i>Tenopt</i>
<i>Tofranil 10</i>	Tablet 10 mg	50	1.70	<i>Tolerade 10</i>
<i>Tofranil 25</i>	Tablet 25 mg	50	1.70	<i>Tolerade 25</i>

Premium Priced Brand	Form and Strength	Max. Qty	Brand Premium \$	Benchmark Priced Brands
<i>Tolvon</i>	Tablet 10 mg	50	1.93	<i>Lumin 10</i>
	Tablet 20 mg	50	2.90	<i>Lumin 20</i>
<i>Tramal</i>	Capsule 50 mg	20	1.45	<i>Chem mart Tramadol;</i> <i>GenRx Tramadol;</i> <i>Terry White Chemists Tramadol;</i> <i>Tramedo; Zydol</i>
<i>Tramal SR 100</i>	Tablet 100 mg (sustained release)	20	1.94	<i>Tramahexal SR; Zydol SR 100</i>
<i>Tramal SR 150</i>	Tablet 150 mg (sustained release)	20	1.94	<i>Tramahexal SR; Zydol SR 150</i>
<i>Tramal SR 200</i>	Tablet 200 mg (sustained release)	20	1.92	<i>Tramahexal SR; Zydol SR 200</i>
<i>Trandate</i>	Tablet 100 mg	100	2.73	<i>Presolol 100</i>
	Tablet 200 mg	100	2.89	<i>Presolol 200</i>
<i>Triphasil 28</i>	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	10.50	<i>Trifeme 28</i>
<i>Triprim</i>	Tablet 300 mg	7	1.32	<i>Alprim</i>
<i>Triquilar ED</i>	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	11.16	<i>Logynon ED</i>
<i>Tritace 1.25 mg</i>	Tablet 1.25 mg	30	3.00	<i>Ramipril Sandoz; Ramipril Winthrop</i>
<i>Tritace 2.5 mg</i>	Tablet 2.5 mg	30	3.00	<i>Ramipril Sandoz; Ramipril Winthrop</i>
<i>Tritace 5 mg</i>	Tablet 5 mg	30	3.00	<i>Ramipril Sandoz; Ramipril Winthrop</i>
<i>Tritace 10 mg</i>	Capsule 10 mg	30	3.23	<i>Ramipril Sandoz; Ramipril Winthrop</i>
<i>Valium</i>	Tablet 2 mg	50	1.27	<i>Antenex 2; Valpam 2</i>
	Tablet 5 mg	50	1.28	<i>Antenex 5; Diazepam-DP; Valpam 5</i>
<i>Vastin</i>	Capsule 20 mg (fluvastatin)	28	1.00	<i>Lescol</i>
	Capsule 40 mg (fluvastatin)	28	0.99	<i>Lescol</i>
<i>Ventolin CFC-free</i>	Oral pressurised inhalation 100 micrograms (base) per dose (200 doses), CFC-free formulation	2	1.00	<i>Asmol CFC-free; Epaq</i>
<i>Ventolin Nebules</i>	Nebuliser solution single dose units 2.5 mg (base) in 2.5 mL, 30	2	2.14	<i>Asmol 2.5 uni-dose; Butamol 2.5;</i> <i>Chem mart Salbutamol;</i> <i>GenRx Salbutamol; PU brand;</i> <i>Terry White Chemists Salbutamol</i>
	Nebuliser solution single dose units 5 mg (base) in 2.5 mL, 30	2	2.12	<i>Asmol 5 uni-dose; Butamol 5;</i> <i>Chem mart Salbutamol;</i> <i>GenRx Salbutamol;</i> <i>Terry White Chemists Salbutamol</i>
<i>Vibramycin</i>	Tablet 100 mg	7	1.53	<i>Chem mart Doxycycline; Doxsig;</i> <i>Doxy-100; Doxyhexal; Doxylin 100;</i> <i>GenRx Doxycycline;</i> <i>Terry White Chemists Doxycycline</i>
	Tablet 100 mg	28	6.12	<i>Chem mart Doxycycline; Doxsig;</i> <i>Doxy-100; Doxyhexal; Doxylin 100;</i> <i>GenRx Doxycycline;</i> <i>Terry White Chemists Doxycycline</i>
	Tablet 100 mg	21	4.59	<i>Chem mart Doxycycline; Doxsig;</i> <i>Doxy-100; Doxyhexal; Doxylin 100;</i> <i>GenRx Doxycycline;</i> <i>Terry White Chemists Doxycycline</i>
<i>Vibra-Tabs</i>	Tablet 50 mg	25	1.60	<i>Chem mart Doxycycline; Doxy-50;</i> <i>Doxyhexal; Doxylin 50; Frakas;</i> <i>GenRx Doxycycline;</i> <i>Terry White Chemists Doxycycline</i>
<i>Viscotears Liquid Gel</i>	Ocular lubricating gel 2 mg per g (0.2%), 10 g	1	0.98	<i>PAA</i>
<i>Visken 5</i>	Tablet 5 mg	100	2.71	<i>Barbloc 5</i>
<i>Visken 15</i>	Tablet 15 mg	50	2.69	<i>Barbloc 15</i>

Premium Priced Brand	Form and Strength	Max. Qty	Brand Premium \$	Benchmark Priced Brands
<i>Voltaren 25</i>	Tablet 25 mg (enteric coated)	100	3.18	<i>Chem mart Diclofenac; Clonac 25; Diclofenac-BC; Diclohexal; Dinac; Fenac 25; GenRx Diclofenac; Terry White Chemists Diclofenac</i>
<i>Voltaren 50</i>	Tablet 50 mg (enteric coated)	50	3.09	<i>Chem mart Diclofenac; Clonac 50; Diclohexal; Dinac; Fenac; GenRx Diclofenac; Terry White Chemists Diclofenac</i>
<i>Xanax</i>	Tablet 250 micrograms	50	1.05	<i>Alprax 0.25; Kalma 0.25; Zamhexal 0.25mg</i>
	Tablet 500 micrograms	50	1.12	<i>Alprax 0.5; Kalma 0.5; Zamhexal 0.5mg</i>
	Tablet 1 mg	50	1.32	<i>Alprax 1; Alprazolam-DP; Chem mart Alprazolam; GenRx Alprazolam; Kalma 1; Terry White Chemists Alprazolam; Zamhexal 1.0mg</i>
<i>Xanax Tri-Score</i>	Tablet 2 mg	50	1.60	<i>Alprax 2; Alprazolam-DP; Chem mart Alprazolam; GenRx Alprazolam; Kalma 2; Terry White Chemists Alprazolam; Zamhexal 2mg</i>
<i>Zantac</i>	Tablet 150 mg (base)	60	2.17	<i>Ausran; Chem mart Ranitidine; GenRx Ranitidine; Rani 2; Ranihexal; Ranoxyl; Terry White Chemists Ranitidine; Ulcaid</i>
	Tablet 300 mg (base)	30	2.17	<i>Ausran; Chem mart Ranitidine; GenRx Ranitidine; Rani 2; Ranihexal; Ranoxyl; Terry White Chemists Ranitidine; Ulcaid</i>
<i>Zestril</i>	Tablet 5 mg	30	2.65	<i>Chem mart Lisinopril; Fibsol 5; GenRx Lisinopril; Liprace; Lisinobell; Lisinopril Hexal; Lisodur; Terry White Chemists Lisinopril</i>
	Tablet 10 mg	30	2.65	<i>Chem mart Lisinopril; Fibsol 10; GenRx Lisinopril; Liprace; Lisinobell; Lisinopril Hexal; Lisodur; Terry White Chemists Lisinopril</i>
	Tablet 20 mg	30	2.65	<i>Chem mart Lisinopril; Fibsol 20; GenRx Lisinopril; Liprace; Lisinobell; Lisinopril Hexal; Lisodur; Terry White Chemists Lisinopril</i>
<i>Zocor</i>	Tablet 5 mg	30	0.68	<i>Simvabell; Simvahexal; Simvastatin-RL; Zimstat</i>
	Tablet 10 mg	30	0.68	<i>Chem mart Simvastatin; GenRx Simvastatin; GN brand; Simvabell; Simvahexal; Simvar 10; Simvastatin-DP; Simvastatin-RL; Terry White Chemists Simvastatin; Zimstat</i>
	Tablet 20 mg	30	0.68	<i>Chem mart Simvastatin; GenRx Simvastatin; GN brand; Simvabell; Simvahexal; Simvar 20; Simvastatin-DP; Simvastatin-RL; Terry White Chemists Simvastatin; Zimstat</i>

Premium Priced Brand	Form and Strength	Max. Qty	Brand Premium \$	Benchmark Priced Brands
	Tablet 40 mg	30	0.70	Chem mart Simvastatin; GenRx Simvastatin; GN brand; Simvabell; Simvahexal; Simvar 40; Simvastatin-DP; Simvastatin-RL; Terry White Chemists Simvastatin; Zimstat
	Tablet 80 mg	30	0.67	Chem mart Simvastatin; GenRx Simvastatin; GN brand; Simvabell; Simvahexal; Simvar 80; Simvastatin-DP; Simvastatin-RL; Terry White Chemists Simvastatin; Zimstat
Zofran	Tablet 4 mg	4	0.68	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	0.69	Ondansetron-RL; Ondaz
	I.V. injection 8 mg in 4 mL	1	0.67	Ondansetron-RL; Ondaz
	Tablet 4 mg	10	0.69	Ondansetron-RL; Ondaz; Onsetron 4
	Tablet 8 mg	10	0.68	Ondansetron-RL; Ondaz; Onsetron 8
Zofran Zydys	Wafer 4 mg	4	0.68	Ondansetron-RL Zydys; Ondaz Zydys
	Wafer 8 mg	4	0.69	Ondansetron-RL Zydys; Ondaz Zydys
	Wafer 4 mg	10	0.69	Ondansetron-RL Zydys; Ondaz Zydys
	Wafer 8 mg	10	0.68	Ondansetron-RL Zydys; Ondaz Zydys
Zoloft	Tablet 50 mg (base)	30	0.54	Chem mart Sertraline; Concorz; Eleva 50; GenRx Sertraline; Sertraline-DP; Setrona; Terry White Chemists Sertraline; Xydep 50
	Tablet 100 mg (base)	30	0.54	Chem mart Sertraline; Concorz; Eleva 100; GenRx Sertraline; Sertraline-DP; Setrona; Terry White Chemists Sertraline; Xydep 100
Zovirax 200 mg	Tablet 200 mg	50	5.78	Acihexal; Acyclo-V 200; GenRx Aciclovir; Lovir
	Tablet 200 mg	90	4.28	Acihexal; Acyclo-V 200; Chem mart Aciclovir; GenRx Aciclovir; Lovir; Ozvir; Terry White Chemists Aciclovir
Zovirax 800 mg	Tablet 800 mg	35	2.09	Acihexal; Acyclo-V 800; GenRx Aciclovir; Lovir
Zyban	Tablet 800 mg	120	7.19	Acihexal; Acyclo-V 800; Lovir
	Tablet 150 mg (sustained release)	30	0.87	Bupropion-RL; Clorprax
	Tablet 150 mg (sustained release)	90	0.87	Bupropion-RL; Clorprax
Zyloprim	Tablet 100 mg	200	2.43	Allohexal; Allosig; Chem mart Allopurinol; GenRx Allopurinol; Pro gout 100; Terry White Chemists Allopurinol
	Tablet 300 mg	60	2.29	Allohexal; Allosig; Chem mart Allopurinol; GenRx Allopurinol; Pro gout 300; Terry White Chemists Allopurinol
