



Australian Government

Department of Health and Ageing

SCHEDULE OF PHARMACEUTICAL BENEFITS

This Schedule is also available on the internet at

www.pbs.gov.au

EFFECTIVE 1 JUNE 2009 -

30 JUNE 2009

(ALL PREVIOUS EDITIONS CANCELLED)

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ISSN 1037-3667

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

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PHARMACEUTICAL BENEFITS

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

Fees, Patient Contributions and Safety Net Thresholds

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

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

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

SUMMARY OF CHANGES

ADDITIONS

Additions — Items

9425C	Adalimumab , Injection 40 mg in 0.8 mL pre-filled syringe (<i>Humira</i>)
9426D	Adalimumab , Injection 40 mg in 0.8 mL pre-filled pen (<i>Humira</i>)
9427E	Adalimumab , Injection 40 mg in 0.8 mL pre-filled syringe (<i>Humira</i>) (Diff. Max. Rpts)
9428F	Adalimumab , Injection 40 mg in 0.8 mL pre-filled pen (<i>Humira</i>) (Diff. Max. Rpts)
9429G	Etanercept , Injection set containing 4 vials powder for injection 25 mg and 4 pre-filled syringes solvent 1 mL (<i>Enbrel</i>)
9430H	Etanercept , Injection set containing 4 vials powder for injection 50 mg and 4 pre-filled syringes solvent 1 mL (<i>Enbrel</i>)
9431J	Etanercept , Injections 50 mg in 1 mL single use pre-filled syringes, 4 (<i>Enbrel</i>)
9424B	Pantoprazole sodium sesquihydrate , Sachet containing granules 40 mg (<i>Somac</i>)
9423Y	Pantoprazole sodium sesquihydrate , Sachet containing granules 40 mg (<i>Somac</i>) (Diff. Max. Rpts)

Additions — Brands

1884E	<i>Amoxycillin Sandoz, SZ</i> — Amoxycillin , Capsule 250 mg
3301R	<i>Amoxycillin Sandoz, SZ</i> — Amoxycillin , Capsule 250 mg (Dental)
8700X	<i>Esitalo, SZ</i> — Escitalopram oxalate , Tablet 10 mg (base)
8701Y	<i>Esitalo, SZ</i> — Escitalopram oxalate , Tablet 20 mg (base)
8414W	<i>Omegapharm Irinotecan, OE</i> — Irinotecan hydrochloride trihydrate , I.V. injection 40 mg in 2 mL
8415X	<i>Omegapharm Irinotecan, OE</i> — Irinotecan hydrochloride trihydrate , I.V. injection 100 mg in 5 mL
2456G	<i>Lisinopril Ranbaxy, RA</i> — Lisinopril , Tablet 5 mg
2457H	<i>Lisinopril Ranbaxy, RA</i> — Lisinopril , Tablet 10 mg
2458J	<i>Lisinopril Ranbaxy, RA</i> — Lisinopril , Tablet 20 mg
2834E	<i>APO-Pravastatin, TX</i> — Pravastatin sodium , Tablet 20 mg
9238F	<i>APO-Pravastatin, TX</i> — Pravastatin sodium , Tablet 20 mg (Diff. Max. Rpts)
8197K	<i>APO-Pravastatin, TX</i> — Pravastatin sodium , Tablet 40 mg

9239G	<i>APO-Pravastatin, TX</i> — Pravastatin sodium , Tablet 40 mg (Diff. Max. Rpts)
1760P	<i>APO-Roxithromycin, TX; Chem mart Roxithromycin, CH; Terry White Chemists Roxithromycin, TW</i> — Roxithromycin , Tablet 150 mg
8016X	<i>APO-Roxithromycin, TX; Chem mart Roxithromycin, CH; Terry White Chemists Roxithromycin, TW</i> — Roxithromycin , Tablet 300 mg
2285G	<i>Sebifin 250, RA</i> — Terbinafine hydrochloride , Tablet 250 mg (base)
2804N	<i>Sebifin 250, RA</i> — Terbinafine hydrochloride , Tablet 250 mg (base) (Diff. Max. Rpts)

DELETIONS

Deletions — Items

9000Q	Efalizumab , Injection set containing 4 vials powder for injection 125 mg and 4 pre-filled syringes diluent 1.3 mL (<i>Raptiva</i>)
9001R	Efalizumab , Injection set containing 4 vials powder for injection 125 mg and 4 pre-filled syringes diluent 1.3 mL (<i>Raptiva</i>) (Diff. Max. Rpts)
8766J	Glucose indicator—blood , Electrode strips, 50 (<i>GlucoCare Super Sensor</i>)
9262L	Glucose indicator—blood , Electrode strips, 50 (<i>GlucoCare Super Sensor</i>) (Diff. Max. Rpts)
8818D	Metoprolol succinate , Pack containing 15 tablets 23.75 mg (controlled release), 15 tablets 47.5 mg (controlled release) and 15 tablets 95 mg (controlled release) (<i>Toprol-XL Titration Pack</i>)
1733F	Oestrogens—conjugated , Tablet 300 micrograms (<i>Premarin</i>)
1734G	Oestrogens—conjugated , Tablet 625 micrograms (<i>Premarin</i>)
8168X	Oestrogens—conjugated with medroxyprogesterone acetate , Tablets 625 micrograms-2.5 mg, 28 (<i>Premia 2.5 Continuous</i>)
8169Y	Oestrogens—conjugated with medroxyprogesterone acetate , Tablets 625 micrograms-5 mg, 28 (<i>Premia 5 Continuous</i>)

Deletions — Brands

8220P	<i>Citalopram Winthrop, WA</i> — Citalopram hydrobromide , Tablet 20 mg (base)
1369C	<i>Enalapril Winthrop, WA</i> — Enalapril maleate , Tablet 20 mg
1182F	<i>Fosinopril Winthrop, WA</i> — Fosinopril sodium , Tablet 10 mg
1183G	<i>Fosinopril Winthrop, WA</i> — Fosinopril sodium , Tablet 20 mg
8400D	<i>Fosinopril/HCT Winthrop 10mg/12.5mg, WA</i> — Fosinopril sodium with hydrochlorothiazide , Tablet 10 mg-12.5 mg
8401E	<i>Fosinopril/HCT Winthrop 20mg/12.5mg, WA</i> — Fosinopril sodium with hydrochlorothiazide , Tablet 20 mg-12.5 mg
2592K	<i>Chem mart Isotretinoin, CH; Terry White Chemists Isotretinoin, TW</i> — Isotretinoin , Capsule 20 mg
1789E	<i>Penhexal VK, HX</i> — Phenoxymethylpenicillin , Capsule 250 mg
1705R	<i>Penhexal VK, HX</i> — Phenoxymethylpenicillin , Capsule 250 mg (Diff. Max. Rpts)
3363B	<i>Penhexal VK, HX</i> — Phenoxymethylpenicillin , Capsule 250 mg (Dental)
2965C	<i>Penhexal VK, HX</i> — Phenoxymethylpenicillin , Capsule 500 mg
3364C	<i>Penhexal VK, HX</i> — Phenoxymethylpenicillin , Capsule 500 mg (Dental)

ALTERATIONS

Alterations — Restrictions and Notes

9037P	Etanercept , Injection set containing 4 vials powder for injection 25 mg and 4 pre-filled syringes solvent 1 mL (<i>Enbrel</i>) [for the treatment of chronic plaque psoriasis]
9038Q	Etanercept , Injection set containing 4 vials powder for injection 50 mg and 4 pre-filled syringes solvent 1 mL (<i>Enbrel</i>) [for the treatment of chronic plaque psoriasis]
9091L	Etanercept , Injections 50 mg in 1 mL single use pre-filled syringes, 4 (<i>Enbrel</i>) [for the treatment of chronic plaque psoriasis]

Alterations — Number of Repeats

		<i>From</i>	<i>To</i>
9037P	Etanercept , Injection set containing 4 vials powder for injection 25 mg and 4 pre-filled syringes solvent 1 mL (<i>Enbrel</i>)	2	3
9038Q	Etanercept , Injection set containing 4 vials powder for injection 50 mg and 4 pre-filled syringes solvent 1 mL (<i>Enbrel</i>)	2	3
9091L	Etanercept , Injections 50 mg in 1 mL single use pre-filled syringes, 4 (<i>Enbrel</i>)	2	3

Alterations — Brands

<i>From:</i>	
1955X	Propylthiouracil , Tablet 50 mg (<i>PL</i>)
<i>To:</i>	
1955X	Propylthiouracil , Tablet 50 mg (<i>PTU</i>)
<i>From:</i>	
8280T	Vinorelbine tartrate , Solution for I.V. infusion 10 mg (base) in 1 mL (<i>Vinorelbine 10 Link</i>)
<i>To:</i>	
8280T	Vinorelbine tartrate , Solution for I.V. infusion 10 mg (base) in 1 mL (<i>Vinorelbine Link</i>)
<i>From:</i>	
8281W	Vinorelbine tartrate , Solution for I.V. infusion 50 mg (base) in 5 mL (<i>Vinorelbine 50 Link</i>)
<i>To:</i>	
8281W	Vinorelbine tartrate , Solution for I.V. infusion 50 mg (base) in 5 mL (<i>Vinorelbine Link</i>)

Alterations — Manufacturer's Code

		<i>From</i>	<i>To</i>
2688L	Azathioprine , Tablet 25 mg (<i>Imuran</i>)	GK	AS
2687K	Azathioprine , Tablet 50 mg (<i>Imuran</i>)	GK	AS
8350L	Tirofiban hydrochloride , Solution concentrate for I.V. infusion 12.5 mg (base) in 50 mL (<i>Aggrastat</i>)	MK	AS

SECTION 100

HIGHLY SPECIALISED DRUGS PROGRAM

ADDITIONS

Additions — Item

9638G	Deferiprone , Oral solution 100 mg per mL, 250 mL (<i>Ferriprox</i>)

Alterations — Restriction and Note

9617E	Infliximab , Powder for I.V. infusion 100 mg (<i>Remicade</i>)

Alterations — Manufacturer's Code

		<i>From</i>	<i>To</i>
6247T	Cidofovir , Solution for I.V. infusion 375 mg (anhydrous) in 5 mL single use vial (<i>Vistide</i>)	PU	GI

ADVANCE NOTICES

Advance Notice — Deletion of Items

The following items will be deleted from the Schedule of Pharmaceutical Benefits on 1 August 2009:

Deletions requested by the manufacturer —

- 1579D **Human chorionic gonadotrophin**, Injection set containing 3 ampoules powder for injection 500 units and 3 ampoules solvent 1 mL (*Pregnyl*)
- 1583H **Human chorionic gonadotrophin**, Injection set containing 3 ampoules powder for injection 500 units and 3 ampoules solvent 1 mL (*Pregnyl*) (**Diff. Max. Qty and Rpts**)
- 6176C **Human chorionic gonadotrophin**, Injection set containing 3 ampoules powder for injection 500 units and 3 ampoules solvent 1 mL (*Pregnyl*) (**Diff. Max. Qty and Rpts**)

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

Brands discontinued by the manufacturer —

- 1746X *Dymadon P, PC* — **Paracetamol**, Tablet 500 mg
- 5196L *Dymadon P, PC* — **Paracetamol**, Tablet 500 mg (**Dental**)
- 8784H *Dymadon P, PC* — **Paracetamol**, Tablet 500 mg (**Diff. Max. Qty**)
- 5224Y *Dymadon P, PC* — **Paracetamol**, Tablet 500 mg (**Dental**) (**Diff. Max. Qty**)

Addresses — Medicare Australia

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

NEW SOUTH WALES and AUSTRALIAN CAPITAL TERRITORY

Pharmaceutical Benefits Branch
130 George Street
Parramatta NSW 2150

General and IME **Tel: 132 290**
enquiries—

Orange Service Centre
189 Anson Street
Orange NSW 2800

General and IME **Tel: 132 290**
enquiries—

VICTORIA

Pharmaceutical Branch
Level 10
595 Collins Street
Melbourne VIC 3000

General and IME **Tel: 132 290**
enquiries—

QUEENSLAND

Pharmaceutical Services Branch
143 Turbot Street
Brisbane QLD 4000

General and IME **Tel: 132 290**
enquiries—

SOUTH AUSTRALIA and NORTHERN TERRITORY

Pharmaceutical Services Branch
209 Greenhill Road
Eastwood SA 5063

General and IME **Tel: 132 290**
enquiries—

WESTERN AUSTRALIA

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

General and IME **Tel: 132 290**
enquiries—

TASMANIA

Pharmaceutical Branch
242 Liverpool Street
Hobart TAS 7000

General and IME **Tel: 132 290**
enquiries—

NATIONAL PROGRAM MANAGEMENT

Pharmaceutical Benefits Branch
Medicare Australia
134 Reed Street
Tuggeranong ACT 2900
Telephone— (02) 6124 6333

Website— www.medicareaustralia.gov.au

Email— pbs@medicareaustralia.gov.au

Authority Prescription Applications

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

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

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

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

Mail Applications:

REPLY PAID No. 9857
PBS Authorities Section
Medicare Australia
GPO Box 9857
In your capital city

Telephone Applications:

Free call 1800 888 333
Australia-wide—24 hour service

For telephone applications please have the following information available:

Patient:

Medicare number
Surname
First name
Full residential address (including postcode)

PBS Authority Prescription Number:

Top right hand side of the handwritten PBS Authority Form

Your Prescriber Number:

Located below your address block on the personalised forms

Drug Information:

PBS item
Quantity required and number of repeats
Daily dose
Disease or purpose information

Requests for Drugs via the Special Access Scheme (SAS)

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

Department of Veterans' Affairs

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

Telephone Interpreter Service

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

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

Poisons Information Centres

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

NSW

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

VIC

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

QLD

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

WA

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

TAS

Tel: 131 126

NT

Tel: 131 126

ACT

Tel: 131 126

Drug Information Centres

NSW

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

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

QLD

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

WA

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

TAS

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

NT

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

ACT

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

VIC

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

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

SA

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

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

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

**National
Prescribing Service
(NPS)**

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

List of Contact Officers for Recalls of Therapeutic Goods

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

These officers may be contacted—

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

Australian Recall Coordinator

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

Australian Capital Territory

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

New South Wales

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

Victoria

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

Queensland

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

South Australia

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

Western Australia

Health Department of WA
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Department of Health and Community
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Index of Manufacturers' Codes

<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
AC	Alberto Culver Company 14 Loyalty Road North Rocks NSW 2151 Tel: (02) 9630 5099 Fax: (02) 9683 5026
AE	AFT Pharmaceuticals Pty Limited Unit 2, Level 5 255 George Street NSW 2000 Tel: 1800 097 639 Fax: 1800 097 810
AF	Alphapharm Pty Limited Chase Building 2 Wentworth Park Road Glebe NSW 2037 Tel: (02) 9298 3999 Fax: (02) 9566 4686
AG	Allergan Australia Pty Ltd 77 Ridge Street Gordon NSW 2072 Tel: 1800 252 224 Fax: (02) 9498 0290
AL	Alphapharm Medical A Division of Alphapharm Pty Limited Chase Building 2 Wentworth Park Road Glebe NSW 2037 Tel: (02) 9298 3999 Fax: (02) 9566 4686
AN	Amgen Australia Pty Ltd Level 7, 123 Epping Road North Ryde NSW 2113 Tel: (02) 9870 1333 Fax: (02) 9870 1344
AP	AstraZeneca Pty Ltd Alma Road North Ryde NSW 2113 Tel: (02) 9978 3500 Fax: (02) 9978 3700

<i>Code</i>	<i>Manufacturer</i>
AQ	Alcon Laboratories (Australia) Pty Ltd Allambie Grove Park 25 Frenchs Forest Road East Frenchs Forest NSW 2086 Tel: 1800 025 004 Fax: (02) 9452 5209
AS	Aspen Pharmacare Australia Pty Ltd First Floor 34-36 Chandos Street St Leonards NSW 2065 Tel: (02) 8436 8300 Fax: (02) 9901 3540
AT	Actelion Pharmaceuticals Australia Pty Ltd Level 2 West, Suites 48-50 7 Narabang Way Belrose NSW 2085 Tel: (02) 9486 4600 Fax: (02) 9986 1344
AV	Aventis Pharma Division of Sanofi-Aventis Australia Pty Limited Building D, Talavera Corporate Centre 12-24 Talavera Road Macquarie Park NSW 2113 Tel: (02) 8666 2000 Fax: (02) 8666 3000
AW	Arrow Pharmaceuticals Pty Ltd A member of Sigma Group of Companies 96 Merrindale Drive Croydon Vic 3136 Tel: (03) 9839 2800 Fax: (03) 9839 2753
AX	Sanofi Pasteur Pty Limited Building D, Talavera Corporate Centre 12-24 Talavera Road Macquarie Park NSW 2113 Tel: 1800 829 468 Fax: 1800 829 329
BB	Blackmores Ltd 23 Roseberry Street Balgowlah NSW 2093 Tel: (02) 9951 0111 Fax: (02) 9949 1954

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

BC	Bristol Laboratories A Division of Bristol-Myers Squibb Australia Pty Ltd 556 Princes Highway Noble Park Vic 3174 Tel: (03) 9213 4000 Fax: (03) 9701 1518
BD	Biogen Idec Australia Pty Ltd Suite 2, Level 4 123 Epping Road North Ryde NSW 2113 Tel: (02) 8875 3900 Fax: (02) 9889 1162
BE	BDF Australia Ltd 112-118 Talavera Road North Ryde NSW 2113 Tel: 1800 269 933 Fax: (02) 9887 3487
BF	Bellwether Pharma Limited Suite 2, Level 2 71 Epping Road North Ryde NSW 2113 Tel: (02) 8875 5700 Fax: (02) 9889 2250
BG	Biochemie Australia A Division of Sandoz Pty Ltd Level 4, Suite 7-19 100 Harris Street Pyrmont NSW 2009 Tel: (02) 9566 1500 Fax: (02) 9566 1458
BI	Biotech Pharmaceuticals Pty Ltd 83 Cherry Lane Laverton North Vic 3026 Tel: (03) 9278 7555 Fax: (03) 9369 6730
BK	Becton Dickinson Pty Ltd 80 Rushdale Street Knoxfield Vic 3180 Tel: (03) 9764 2444 Fax: (03) 9764 2550
BN	Bayer Australia Limited 875 Pacific Highway Pymble NSW 2073 Tel: (02) 9391 6000 Fax: (02) 9988 3311

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

BQ	Bristol-Myers Squibb Pharmaceuticals A Division of Bristol-Myers Squibb Australia Pty Ltd 556 Princes Highway Noble Park Vic 3174 Tel: (03) 9213 4000 Fax: (03) 9701 1518
BR	B. Braun Australia Pty Ltd Norwest Business Park 17 Lexington Drive Bella Vista NSW 2153 Tel: (02) 9629 0200 Fax: (02) 9629 0299
BU	Bausch & Lomb Surgical A Division of Bausch & Lomb (Australia) Pty Ltd Level 4, 113 Wicks Road North Ryde NSW 2113 Tel: (02) 9887 1444 Fax: (02) 9888 9642
BV	B.S.N. 315 Ferntree Gully Road Mount Waverley Vic 3149 Tel: (03) 8540 6777 Fax: 1800 671 000
BX	Baxter Healthcare Pty Limited 1 Baxter Drive Old Toongabbie NSW 2146 Tel: (02) 9848 1111 Fax: (02) 9848 1123
BY	Boehringer Ingelheim Pty Limited 78 Waterloo Road North Ryde NSW 2113 Tel: (02) 8875 8800 Fax: (02) 8875 8801
CC	ConvaTec A Division of Bristol-Myers Squibb Australia Pty Ltd 606 Hawthorn Road East Brighton Vic 3187 Tel: 1800 335 276 Fax: (03) 9525 0920
CF	CNS Pharma Pty Ltd Level 5, Deutsche Bank Place 126 Phillip Street Sydney NSW 2000 Tel: (02) 9629 0638 Fax: (02) 9629 0688

<i>Code</i>	<i>Manufacturer</i>
CH	Chem mart Pty Limited Level 7, 5 Queens Road Melbourne Vic 3004 Tel: (03) 9918 2500 Fax: (03) 9918 2006
CJ	Celgene Pty Ltd Level 7, 607 St Kilda Road Melbourne Vic 3004 Tel: (03) 9539 5500 Fax: (03) 9539 5566
CO	Chemists' Own Pty Ltd A member of Sigma Group of Companies 96 Merrindale Drive Croydon Vic 3136 Tel: (03) 9839 2800 Fax: (03) 9839 2753
CR	Pharmacor Limited 5/36 Campbell Avenue Cromer NSW 2099 Tel: (02) 9981 4470 Fax: (02) 9981 4475
CS	CSL Limited 45 Poplar Road Parkville Vic 3052 Tel: (03) 9389 1911 Fax: (03) 9388 2351
CT	Coloplast Pty Ltd 33 Gilby Road Mount Waverley Vic 3149 Tel: 1800 673 317 Fax: (03) 9541 1199
CX	Contact Lens Centre Australia Pty Ltd Unit D6, Hallmark Business Park Cnr Westall and Centre Roads Clayton Vic 3168 Tel: (03) 9543 1811 Fax: (03) 9543 8066
DB	Diabetes Association of Australia 26 Arundel Street Glebe NSW 2037 Tel: 1800 451 737 Fax: (02) 9566 4235

<i>Code</i>	<i>Manufacturer</i>
DT	DermaTech Laboratories Pty Ltd Unit 17, 167 Prospect Highway Seven Hills NSW 2147 Tel: (02) 9624 5874 Fax: (02) 9624 8822
EO	Ego Pharmaceuticals Pty Ltd 21-31 Malcolm Road Braeside Vic 3195 Tel: (03) 9587 1088 Fax: (03) 9580 7647
ES	EBOS Group Pty Ltd Unit 2, 109 Vanessa Street Kingsgrove NSW 2208 Tel: (02) 9502 8410 Fax: (02) 9502 8411
EX	Essex Laboratories Level 4, 66 Waterloo Road North Ryde NSW 2113 Tel: (02) 8988 8000 Fax: (02) 9852 7500
FA	F.H. Faulding & Co. Limited Level 6, 390 St Kilda Road Melbourne Vic 3004 Tel: (03) 9868 0700 Fax: (03) 9868 0111
FB	Pierre Fabre Medicament Australia Pty Limited Unit 26B, Parkview Business Centre 1 Maitland Place Baulkham Hills NSW 2153 Tel: (02) 8858 2800 Fax: (02) 8858 2888
FH	Faulding Healthcare Pty Ltd 87 Yarraman Place Virginia Qld 4014 Tel: (07) 3212 8777 Fax: (07) 3212 8790
FK	PharmaLink Pty Ltd Level 8, 67 Albert Avenue Chatswood NSW 2067 Tel: (02) 9080 7200 Fax: (02) 9080 7201

<i>Code</i>	<i>Manufacturer</i>
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 2753
FP	Ferring Pharmaceuticals Pty Ltd Suite 2B, Level 2 802 Pacific Highway Gordon NSW 2072 Tel: (02) 9497 2300 Fax: (02) 9497 2399
FR	Charles E. Frosst Division of Merck Sharp & Dohme (Australia) Pty Ltd 54-68 Ferndell Street South Granville NSW 2142 Tel: (02) 9795 9500 Fax: (02) 9795 9595
GA	Galderma Australia Pty Ltd Suite 4, 13B Narabang Way Belrose NSW 2085 Tel: (02) 9479 0600 Fax: (02) 9986 1699
GC	GlaxoSmithKline Consumer Healthcare 82 Hughes Avenue Ermington NSW 2115 Tel: (02) 9684 0888 Fax: (02) 9684 6958
GH	Goldshield Healthcare (Australia) Pty Ltd Suite 3, Level 1 118-124 Willoughby Road Crows Nest NSW 2059 Tel: (02) 9431 6333 Fax: (02) 9906 7147
GI	Gilead Sciences Pty Ltd Level 1, 128 Jolimont Road East Melbourne Vic 3002 Tel: (03) 9272 4400 Fax: (03) 9272 4435

<i>Code</i>	<i>Manufacturer</i>
GK	GlaxoSmithKline Australia Pty Ltd 1061 Mountain Highway Boronia Vic 3155 Tel: (03) 9721 6000 Fax: (03) 9729 5319
GM	Genepharm Pty Ltd 3/10 Inglewood Place Norwest Business Park Baulkham Hills NSW 2153 Tel: 1800 678 302 Fax: (02) 8818 2122
GN	Genepharm Australasia Limited Level 1, 263 City Road Southbank Vic 3006 Tel: 1800 508 168 Fax: (03) 9699 8333
GP	GP Laboratories A Division of Pfizer Pty Limited 38-42 Wharf Road West Ryde NSW 2114 Tel: (02) 9850 3333 Fax: (02) 9858 1347
GQ	Generic Health Pty Ltd Suite 1, Level 1 1175 Toorak Road Camberwell Vic 3124 Tel: (03) 9809 7900 Fax: (03) 9809 7999
GX	GenRx A Division of Apotex Pty Ltd 66 Waterloo Road North Ryde NSW 2113 Tel: (02) 8877 8333 Fax: (02) 8877 8377
GZ	Genzyme Australasia Pty Ltd Level 1, Building C 12-24 Talavera Road North Ryde NSW 2113 Tel: (02) 9978 3900 Fax: (02) 9889 3900
HA	Hamilton Laboratories Pty Ltd 217 Flinders Street Adelaide SA 5000 Tel: (08) 8223 2957 Fax: (08) 8232 1480

<i>Code</i>	<i>Manufacturer</i>
HC	Biotech Healthcare A division of Biotech Pharmaceuticals Pty Ltd 83 Cherry Lane Laverton North Vic 3026 Tel: (03) 9278 7555 Fax: (03) 9369 6730
HH	Hospira Pty Ltd (David Bull Laboratories, Faulding Pharmaceuticals) Level 6, 390 St Kilda Road Melbourne Vic 3004 Tel: (03) 9868 0700 Fax: (03) 9868 0111
HO	Hollister (Distributed in Australia by Liberty Medical Pty Ltd) Unit 6, 345 Ingles Street Port Melbourne Vic 3207 Tel: (03) 9673 4300 Fax: (03) 9646 4018
HR	Paul Hartmann Pty Ltd 27-28/11-21 Underwood Road Homebush NSW 2140 Tel: 1800 805 839 Fax: (02) 8762 7100
HS	healthsense 115 Sherriff Street Underdale SA 5032 Tel: (08) 8408 3200 Fax: (08) 8408 3383
HX	Hexal Australia Pty Ltd Level 4, Suite 7-19 100 Harris Street Pyrmont NSW 2009 Tel: (02) 9566 1500 Fax: (02) 9566 1458
IA	iNova Pharmaceuticals (Australia) Pty Limited 9-15 Chilvers Road Thornleigh NSW 2120 Tel: (02) 9875 6333 Fax: (02) 9875 6416

<i>Code</i>	<i>Manufacturer</i>
IQ	Ioquin A Division of Alcon Laboratories (Australia) Pty Ltd Allambie Grove Park 25 Frenchs Forest Road East Frenchs Forest NSW 2086 Tel: 1800 025 004 Fax: (02) 9452 5209
IS	Ipsen Pty Ltd Suite 6, 40 Montclair Avenue Glen Waverley Vic 3150 Tel: (03) 8544 8100 Fax: (03) 9562 5152
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

<i>Code</i>	<i>Manufacturer</i>
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
KY	Key Pharmaceuticals Pty Ltd 12 Lyonpark Road Macquarie Park NSW 2113 Tel: (02) 8113 6200 Fax: (02) 8113 6222
LB	Life Bioscience Pty Ltd 10 Atherton Road Oakleigh Vic 3166 Tel: 1800 114 610 Fax: (03) 8660 2785
LM	Link Medical Products Pty Ltd Level 1, Bridgepoint Centre 3 Brady Street Mosman NSW 2088 Tel: (02) 9960 0150 Fax: (02) 9960 0149
LN	Lennon Healthcare A Division of Aspen Pharmacare Australia Pty Ltd First Floor 34-36 Chandos Street St Leonards NSW 2065 Tel: (02) 8436 8300 Fax: (02) 9901 3540
LU	Lundbeck Australia Pty Ltd Unit 1, 10 Inglewood Place Norwest Business Park Baulkham Hills NSW 2153 Tel: (02) 9836 1655 Fax: (02) 9836 1755

<i>Code</i>	<i>Manufacturer</i>
LY	Eli Lilly Australia Pty Limited 112 Wharf Road West Ryde NSW 2114 Tel: (02) 9325 4444 Fax: (02) 9325 4410
MD	Macarthur Research Division of Roche Products Pty Ltd 4-10 Inman Road Dee Why NSW 2099 Tel: (02) 9454 9000 Fax: (02) 9981 3229
MF	Mundipharma Pty Ltd Level 33, 50 Bridge Street Sydney NSW 2000 Tel: (02) 9231 7200 Fax: (02) 9223 0011
MH	Molnlycke Health Care Pty Ltd Building 1, Ground Floor 14 Aquatic Drive Frenchs Forest NSW 2086 Tel: (02) 9453 1144 Fax: (02) 9453 1155
MI	Meditech Int. Pty Ltd Unit 5, 36 Campbell Avenue Cromer NSW 2099 Tel: (02) 9981 4470 Fax: (02) 9981 4475
MK	Merck Sharp & Dohme (Australia) Pty Ltd 54-68 Ferndell Street South Granville NSW 2142 Tel: (02) 9795 9500 Fax: (02) 9795 9595
MM	3M Pharmaceuticals Australia Pty Ltd 9-15 Chilvers Road Thornleigh NSW 2120 Tel: (02) 9875 6333 Fax: (02) 9875 6416
MQ	Alphapharm Pharmaceuticals Chase Building 2 Wentworth Park Road Glebe NSW 2037 Tel: (02) 9298 3999 Fax: (02) 9566 4686

<i>Code</i>	<i>Manufacturer</i>
MS	Abbott Diabetes Care (A Division of Abbott Australasia Pty Ltd) 666 Doncaster Road Doncaster Vic 3108 Tel: (03) 9843 7100 Fax: (03) 9855 8020
MT	Mentholatum Australasia Pty Ltd 12-16 Janine Street Scoresby Vic 3179 Tel: (03) 9763 0322 Fax: (03) 9763 2699
MW	McGaw Biomed Australia Pty Ltd c/- B. Braun Australia Pty Ltd Norwest Business Park 17 Lexington Drive Bella Vista NSW 2153 Tel: (02) 9629 0200 Fax: (02) 9629 0299
NA	National Diagnostic Products 22/39 Herbert Street St Leonards NSW 2065 Tel: (02) 9432 8100 Fax: (02) 9432 1151
NC	Novartis Consumer Health Australasia Pty Ltd 327-333 Police Road Mulgrave Vic 3170 Tel: (03) 9701 2711 Fax: (03) 9701 2911
NE	Norgine Pty Limited 3/14 Rodborough Road Frenchs Forest NSW 2086 Tel: (02) 9972 7500 Fax: (02) 9972 7522
NF	FlexPen Products of Novo Nordisk Pharmaceuticals Pty Ltd Level 3, 21 Solent Circuit Baulkham Hills NSW 2153 Tel: (02) 8858 3600 Fax: (02) 8858 3799
NI	InnoLet Products of Novo Nordisk Pharmaceuticals Pty Ltd Level 3, 21 Solent Circuit Baulkham Hills NSW 2153 Tel: (02) 8858 3600 Fax: (02) 8858 3799

<i>Code</i>	<i>Manufacturer</i>
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
NQ	Nycomed Pty Ltd 2 Lyonpark Road North Ryde NSW 2113 Tel: (02) 9859 6900 Fax: (02) 9859 6950
NT	Nestlé Australia Ltd 60 Bathurst Street Sydney NSW 2000 Tel: (02) 9931 2345 Fax: (02) 9931 2610
NU	Nutricia Australia Pty Limited Talavera Corporate Centre Level 4, Building D 12-24 Talavera Road North Ryde NSW 2113 Tel: (02) 8875 0300 Fax: (02) 8978 4841
NV	Novartis Pharmaceuticals Australia Pty Ltd 54 Waterloo Road North Ryde NSW 2113 Tel: (02) 9805 3555 Fax: (02) 9887 4551
OA	Orphan Australia Pty Ltd 48 Kangan Drive Berwick Vic 3806 Tel: (03) 9769 5744 Fax: (03) 9769 5944

<i>Code</i>	<i>Manufacturer</i>
OB	Oral B Laboratories Pty Ltd Level 3, 90 Mount Street North Sydney NSW 2060 Tel: (02) 9957 6499 Fax: (02) 9957 5383
OE	Omegapharm Pty Ltd 15a Leinster Street Ormond Vic 3204 Tel: (03) 9578 0806 Fax: (03) 9578 0806
OL	Owen Laboratories Division of Galderma Australia Pty Ltd 9 Rodborough Road Frenchs Forest NSW 2086 Tel: 1800 800 765 Fax: (02) 9975 5374
OM	Colgate Oral Care 345 George Street Sydney NSW 2000 Tel: (02) 9229 5600 Fax: (02) 9232 8448
ON	Orion Laboratories Pty Ltd 25-29 Delawney Street Balcatta WA 6021 Tel: (08) 9441 7800 Fax: (08) 9441 7888
OZ	Medical Specialties Australia Pty Ltd 54 Gibbes Street Chatswood NSW 2067 Tel: (02) 9417 7955 Fax: (02) 9417 5779
PC	Pfizer Consumer Healthcare Pty Ltd 32 Cawarra Road Caringbah NSW 2229 Tel: (02) 9710 6500 Fax: (02) 9710 6644
PD	Parke Davis Pty Ltd 32 Cawarra Road Caringbah NSW 2229 Tel: (02) 9710 6500 Fax: (02) 9710 6400

<i>Code</i>	<i>Manufacturer</i>
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
PK	Pharmatel Fresenius Kabi Pty Ltd Unit 6, 6-18 Bridge Road Hornsby NSW 2077 Tel: (02) 9472 2222 Fax: (02) 9472 2255
PL	Phebra 332 Burns Bay Road Lane Cove NSW 2066 Tel: (02) 9420 9199 Fax: (02) 9420 9177
PM	PMC Pharma A Division of AstraZeneca Pty Ltd Alma Road North Ryde NSW 2113 Tel: (02) 9978 3500 Fax: (02) 9978 3700
PP	Petrus Pharmaceuticals Pty Ltd Level 3, IBM Building 1060 Hay Street West Perth WA 6005 Tel: (08) 9368 5954 Fax: (08) 9368 6692
PU	Pharmacia & Upjohn Pty Limited 38-42 Wharf Road West Ryde NSW 2114 Tel: (02) 9850 3333 Fax: (02) 9858 1347

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

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

<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-Aventis Australia Pty Ltd Building D, Talavera Corporate Centre 12-24 Talavera Road Macquarie Park NSW 2113 Tel: (02) 8666 2000 Fax: (02) 8666 3000
SX	Stiefel Laboratories Pty Limited Unit 14, 5 Salisbury Road Castle Hill NSW 2154 Tel: (02) 9894 5088 Fax: (02) 9894 5016
SY	Schering AG 875 Pacific Highway Pymble NSW 2073 Tel: (02) 9391 6000 Fax: (02) 9988 3311
SZ	Sandoz Pty Ltd Level 4, Suite 7-19 100 Harris Street Pyrmont NSW 2009 Tel: (02) 9566 1500 Fax: (02) 9566 1458

<i>Code</i>	<i>Manufacturer</i>
TA	Actavis Australia Pty Ltd Deacons 225 George Street Sydney NSW 2000 Tel: (08) 8267 6121 Fax: (08) 8267 6121
TM	Technipro Marketing Pty Ltd Unit 10, 13 Berry Street Clyde NSW 2142 Tel: (02) 9897 5899 Fax: (02) 9897 5799
TS	Specialised Therapeutics Australia Pty Ltd Suite 3-4, 6 Westbrook Street East Kew Vic 3102 Tel: (03) 9859 1493 Fax: (03) 9859 6950
TW	Terry White Chemists Level 7, 5 Queens Road Melbourne Vic 3004 Tel: (03) 9918 2500 Fax: (03) 9918 2006
TX	Apotex Pty Ltd 66 Waterloo Road North Ryde NSW 2113 Tel: (02) 8877 8333 Fax: (02) 8877 8377
UC	UCB Pharma A Division of UCB Australia Pty Ltd Level 1, 1155 Malvern Road Malvern Vic 3144 Tel: (03) 9828 1800 Fax: (03) 9828 1860
UM	Unomedical Pty Ltd 11-17 Wilmette Place Mona Vale NSW 2103 Tel: (02) 9997 8033 Fax: (02) 9997 3760
VF	Vitaflo Australia Pty Ltd 110 Fyans Street South Geelong Vic 3220 Tel: (03) 5229 8222 Fax: (03) 5229 8225

<i>Code</i>	<i>Manufacturer</i>
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
WX	Wyeth Australia Pty Limited 17-19 Solent Circuit Norwest Business Park Baulkham Hills NSW 2153 Tel: (02) 9761 8200 Fax: (02) 9023 0000
WY	Wyeth Pharmaceuticals Division of Wyeth Australia Pty Limited 17-19 Solent Circuit Norwest Business Park Baulkham Hills NSW 2153 Tel: (02) 9761 8200 Fax: (02) 9023 0000
XF	Max Pharma Suite 2, 210 Whitehorse Road Balwyn Vic 3103 Tel: (03) 9888 5222 Fax: (03) 9888 5288

<i>Code</i>	<i>Manufacturer</i>
XP	Aaxis Pacific Pty Ltd 24-32 Forge Street Blacktown NSW 2148 Tel: (02) 9881 3333 Fax: (02) 9881 3322
YM	Symbion Pharmacy Services Pty Ltd Level 7, 5 Queens Road Melbourne Vic 3004 Tel: (03) 9918 2000 Fax: (03) 9918 2006
ZI	Shire Australia Pty Limited Level 9, Avaya House 123 Epping Road North Ryde NSW 2113 Tel: 1800 012 612 Fax: (02) 8875 7977
ZP	Spirit Pharmaceuticals Pty Ltd 117 Harrington Street The Rocks Sydney NSW 2000 Tel: (02) 9251 1088 Fax: (02) 9251 1099

Section 1 — Explanatory Notes

Introduction

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

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

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

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

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

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

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

1. The Schedule — Where to Find What

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

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

Section 1

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

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

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

Section 2

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

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

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

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

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

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

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

Section 3

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

Section 4

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

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

Repatriation Schedule of Pharmaceutical Benefits

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

2. Prescribing Medicines — Information for PBS Prescribers

PBS prescribers

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

PBS Prescription forms

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

For doctors:

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

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

For dentists:

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

For optometrists:

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

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

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

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

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

Ordering forms

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

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

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

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

Preparing general PBS prescriptions

Do's and Don't's

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

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

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

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

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

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

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

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

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

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

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

The following admixtures are not pharmaceutical benefits:

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

Writing the PBS prescription

The following rules apply for writing PBS prescriptions:

- they must be written in indelible form (i.e., ink or ball-point pen) in the prescriber's own handwriting (exceptions must be approved by Medicare Australia's Chief Executive Officer) either on the standard PBS prescription, or on paper approximately 18 cm x 12 cm, or they can be generated by computer on a form approved by Medicare Australia. For patient safety reasons, both the original and the duplicate must be legible;
- they must record the prescriber's name and address (and, in the case of dentists and optometrists, the prescriber number), the patient's name, address and entitlement status, and whether the prescription is under the PBS or RPBS;
- they should completely identify the pharmaceutical benefit by detailing the item, dose, form, strength, quantity and instructions for use;
- they should indicate where brand substitution is not permitted. PBS prescriptions must not be prepared using a computer prescribing program that contains a default which would result in all prescriptions being indicated as Brand Substitution Not Permitted;
- where 'solvent required' is included after the form, the volume and number of ampoules must be 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 providing medical services within a participating public hospital may prescribe the subsidised medication. The States of Victoria, Queensland and Western Australia and the Northern Territory have agreed to implement these arrangements.

Restrictions

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

Unrestricted benefits –have no restrictions on their therapeutic uses;

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

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

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

Authority PBS prescriptions

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

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

Authority PBS prescriptions cannot have retrospective approval.

Authority required PBS Prescriptions

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

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

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

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

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

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

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

Authority required (STREAMLINED) PBS Prescriptions

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

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

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

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

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

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

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

Writing authority PBS prescriptions

The following rules apply:

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

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

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

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

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

Maximum quantities and repeats

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

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

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

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

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

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

Regulation 24

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

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

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

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

Urgent cases

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

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

Drugs of addiction

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

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

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

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

Emergency drug (doctor's bag) supplies

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

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

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

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

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

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

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

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

How to prescribe these items?

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

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

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

Aboriginal and Torres Strait Islander identification

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

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

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

- Some people may give this information without being asked.

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

Asking about Aboriginal and/or Torres Strait Islander identification

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

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

Aboriginal and Torres Strait Islander health

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

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

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

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

Communication and cultural issues

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

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

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

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

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

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

You should:

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

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

3. Supplying Medicines — What Pharmacists Need to Know

Eligible suppliers

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

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

Unapproved pharmacists *cannot* supply pharmaceutical benefits.

Approval conditions for pharmacists

A pharmacist approved to supply medicines under the PBS:

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

Before supplying pharmaceutical benefits

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

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

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

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

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

Supplying pharmaceutical benefits

Do's and Don't's

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

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

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

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

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

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

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

Exceptions to this are:

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

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

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

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

What to do if the Schedule changes

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

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

Suspected forgery

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

Regulation 24

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

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

Repeat authorisations

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

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

Preparing Repeat Authorisation Forms

A Repeat Authorisation Form must show:

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

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

Repeat authorisations for injectables and solvents

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

Repeat authorisations for deferred supply

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

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

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

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

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

Authority PBS prescriptions

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

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

Urgent cases

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

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

Receipts

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

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

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

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

Emergency drug (doctor's bag) supplies

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

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

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

4. Patient Charges

Type of patient

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

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

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

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

Establishing entitlement

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

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

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

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

What to charge

Patient contribution

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

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

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

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

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

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

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

Patient contributions for early supply of some PBS medicines

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

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

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

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

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

Special patient contributions, brand premiums and therapeutic group premiums

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

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

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

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

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

Solvents

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

Increased quantities

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

Regulation 24

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

After hours

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

Delivery

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

5. The Safety Net Scheme

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

For the purposes of the scheme, the family includes:

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

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

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

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

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

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

Safety net thresholds

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

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

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

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

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

Safety net cross-over arrangements

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

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

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

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

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

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

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

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

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

Recording PBS prescriptions

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

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

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

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

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

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

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

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

Hospital PRF's

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

Multi-item forms

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

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

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

Qualifying PBS prescriptions

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

Lost PRF's

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

Retrospective entitlement and patient refunds

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

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

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

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

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

Applying for a Safety Net Entitlement/Concession Card

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

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

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

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

Issuing a Safety Net Entitlement/Concession Card

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

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

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

Issuing supplementary cards

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

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

Notification to Medicare Australia and claim for payment

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

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

Payment will not be made for void cards.

Lost Safety Net Entitlement/Concession Cards

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

Pharmacy record of issued cards

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

6. Medicare Australia Entitlement Checks

General Patients

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

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

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

Concessional Patients

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

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

Entitlement checking procedures

General Patients

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

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

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

Concessional Patients

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

Step by step

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

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

7. How Pharmacists Claim Reimbursement: Information Required

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

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

PBS Prescription identification

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

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

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

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

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

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

Serial numbers

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

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

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

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

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

Repeat authorisations for authority PBS prescriptions

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

Repeat authorisations for deferred supply

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

Injectable item ordered with a solvent

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

Dropper containers

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

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

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

PBS prescriptions paid on an average price basis

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

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

Pricing non-pre-priced extemporaneous preparations

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

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

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

Payment to Pharmacists for Dispensing Premium-free Substitutable Medicines

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

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

8. How Pharmacists Claim Reimbursement: Documents to be Submitted

A claim for pharmaceutical benefits consists of:

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

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

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

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

Completing the claim form

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

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

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

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

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

Lodging claims

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

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

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

Reconciliation statements

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

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

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

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

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

9. Pricing PBS Prescriptions

Pricing principles

The same pricing principles apply to all PBS prescriptions.

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

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

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

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

Pricing dates

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

Extemporaneously-prepared pharmaceutical benefits and containers are priced on the first day of May each year for items supplied as from the first day of August that year.

Pricing ready-prepared items

For maximum quantities

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

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

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

For lesser quantities

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

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

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

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

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

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

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

Wastage table percentage

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

Wastage Factor Table

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

The appropriate wastage table percentage is as follows:

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

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

Pricing extemporaneously-prepared items

General

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

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

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

The amount payable is the sum of:

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

Pricing of ingredients

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

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

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

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

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

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

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

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

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

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

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

Pricing PBS prescriptions where extra ingredients are added to a formula

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

Containers

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

A double size container is allowed for bulk powders.

Special provisions for extemporaneous PBS prescriptions outside the Standard Formulae List

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

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

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

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

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

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

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

10. Miscellaneous

References

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

Standards

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

Legislation

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

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SYMBOLS USED IN THE SCHEDULE

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

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

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

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

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

RESTRICTED BENEFITS

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

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

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

CODES FOR INJECTABLE ITEMS WITH ALLOWABLE SOLVENTS

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

BRAND EQUIVALENCE

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

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

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

BRAND PREMIUM POLICY

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

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

Basically the policy operates by:

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

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

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

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

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

THERAPEUTIC GROUP PREMIUM POLICY

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

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

Basically the policy operates by:

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

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

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

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

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

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

EMERGENCY DRUG (DOCTOR'S BAG) SUPPLIES

Code	Name, Manner of Administration and Form	Max. Qty	Dispensed	Proprietary Name and Manufacturer	
			Price for Max. Qty \$		
3451P	ADRENALINE Injection 1 mg in 1 mL (1 in 1,000)	5	19.91	AP	
3453R	ATROPINE SULFATE Injection 600 micrograms in 1 mL	10	20.11	AP	
3457Y	BENZTROPINE MESYLATE Injection 2 mg in 2 mL	5	22.41	Cogentin	FK
3487M	BENZYLPENICILLIN Powder for injection 3 g	1	12.32	BenPen	CS
3486L or	BENZYLPENICILLIN Powder for injection 600 mg or	10	* 42.49	BenPen	CS
3485K	PROCAINE PENICILLIN Injection 1.5 g	5	91.79	Cilicaine	SI
3455W or	CHLORPROMAZINE HYDROCHLORIDE Injection 50 mg in 2 mL or	10	16.39	Largactil	SW
3456X	HALOPERIDOL Injection 5 mg in 1 mL	10	21.85	Serenace	SI
3478C	CLONAZEPAM Oral liquid 2.5 mg per mL, 10 mL	‡ 1	10.30	Rivotril	RO
3472R or	DEXAMETHASONE SODIUM PHOSPHATE Injection equivalent to 4 mg dexamethasone phosphate in 1 mL or	5	17.65	HH	
3470P or	HYDROCORTISONE SODIUM SUCCINATE Injection equivalent to 100 mg hydrocortisone with 2 mL solvent or	2	* 16.71	Solu-Cortef	PH
3471Q	Injection equivalent to 250 mg hydrocortisone with 2 mL solvent	1	15.68	Solu-Cortef	PH
3458B	DIAZEPAM Injection 10 mg in 2 mL	5	11.86	HH	
3460D	DIHYDROERGOTAMINE MESYLATE Injection 1 mg in 1 mL	5	16.63	Dihydergot	NV
3463G	DIPHThERIA and TETANUS VACCINE, ADSORBED, DILUTED FOR ADULT USE Injection 0.5 mL in pre-filled syringe	20	* 274.59	ADT Booster	CS

EMERGENCY DRUG (DOCTOR'S BAG) SUPPLIES

			Dispensed Price for Max. Qty \$	Proprietary Name and Manufacturer	
Code	Name, Manner of Administration and Form	Max. Qty			
3466K	FRUSEMIDE Injection 20 mg in 2 mL	5	10.05	^a Frusehexal ^a Lasix	SZ SW
3467L	GLUCAGON HYDROCHLORIDE Injection set containing 1 mg (1 i.u.) and 1 mL solvent in disposable syringe	1	45.20	GlucaGen Hypokit	NO
3475X	GLYCERYL TRINITRATE Sublingual spray (pump pack) 400 micrograms per dose (200 doses)	‡ 1	19.70	Nitrolingual Pumpspray	SW
3473T	HYOSCINE BUTYLBROMIDE Injection 20 mg in 1 mL	5	22.31	Buscopan	BY
3474W	LIGNOCAINE HYDROCHLORIDE Injection 100 mg in 5 mL	5	36.90	PF	
3476Y or	METOCLOPRAMIDE HYDROCHLORIDE Injection 10 mg in 2 mL or	10	12.56	Maxolon	VT
3477B	PROCHLORPERAZINE Injection containing prochlorperazine mesylate 12.5 mg in 1 mL	10	16.39	Stemetil	SW
3479D or	MORPHINE SULFATE Injection 15 mg in 1 mL or	5	14.13	HH	
3480E	Injection 30 mg in 1 mL	5	15.61	HH	
3481F or	NALOXONE HYDROCHLORIDE Injection 800 micrograms in 2 mL or	5	* 118.09	Naloxone Min-I-Jet	CS
3482G	Injection 2 mg in 5 mL	2	* 77.65	Naloxone Min-I-Jet	CS

EMERGENCY DRUG (DOCTOR'S BAG) SUPPLIES

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

SPECIAL PHARMACEUTICAL BENEFITS

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

Code	Name, Restriction, Manner of Administration and form	Max. Qty	No. of Rpts	Premium	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									
AMOXYCILLIN									
1888J	Powder for paediatric oral drops 100 mg per mL, 20 mL	‡ 1	1	s0.61	# 12.78	# 13.39	14.17	Amoxil	GK
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	..	# 13.39	# 13.39	14.78	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	..	s437.01 s437.00 B75.30 s437.01	491.77 * 491.79 491.77	928.78 * 928.79 1004.08	32.90 32.90 32.90	^a Blenamax ^a HH ^a Blenoxane	SI BQ
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	s7.13	55.99	63.12	32.90	Keppra	UC
8655M	Tablet 500 mg	60	5	s11.91	89.37	101.28	32.90	Keppra	UC
8656N	Tablet 1 g	60	5	s19.84	144.90	164.74	32.90	Keppra	UC
Authority Required									
<i>Treatment of partial epileptic seizures which are not controlled satisfactorily by other anti-epileptic drugs, and where:</i>									
<i>(a) adverse events have occurred with other suitable PBS-listed drugs; or</i>									
<i>(b) drug interactions have occurred with other suitable PBS-listed drugs; or</i>									
<i>(c) drug interactions are expected to occur with other suitable PBS-listed drugs; or</i>									
<i>(d) transfer to another suitable PBS-listed drug would cause patient confusion resulting in problems with compliance; or</i>									
<i>(e) transfer to another suitable PBS-listed drug is likely to result in adverse clinical consequences.</i>									
9708Y	Tablet 250 mg	60	5	..	63.12	63.12	32.90	Keppra	UC

continued ➞

SPECIAL PHARMACEUTICAL BENEFITS

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

Code	Name, Restriction, Manner of Administration and form	Max. Qty	No. of Rpts	Premium	Reimburse- ment Price for Max. Qty \$	Total Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Proprietary Name and Manufacturer	
9709B	Tablet 500 mg	60	5	..	101.28	101.28	32.90	Keppra	UC
9710C	Tablet 1 g	60	5	..	164.74	164.74	32.90	Keppra	UC

NARATRIPTAN HYDROCHLORIDE

CAUTION:

Naratriptan is contraindicated in patients with known or suspected coronary artery disease. The drug should not be used within 24 hours of ergotamine or dihydroergotamine use.

Authority Required

Migraine attacks in patients receiving, or who have failed a reasonable trial of, prophylactic medication and where attacks in the past have usually failed to respond to oral therapy with ergotamine and other appropriate agents, or in whom these agents are contraindicated.

NOTE:

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

8298R	Tablet 2.5 mg (base)	4	5	s2.78	* 25.47	* 28.25	26.50	Naramig	GK

Authority Required

Migraine attacks in patients receiving, or who have failed a reasonable trial of, prophylactic medication and where attacks in the past have usually failed to respond to oral therapy with ergotamine and other appropriate agents, or in whom these agents are contraindicated, and where:

- (a) *adverse events have occurred with other suitable PBS-listed drugs; or*
- (b) *drug interactions have occurred with other suitable PBS-listed drugs; or*
- (c) *drug interactions are expected to occur with other suitable PBS-listed drugs; or*
- (d) *transfer to another suitable PBS-listed drug would cause patient confusion resulting in problems with compliance; or*
- (e) *transfer to another suitable PBS-listed drug is likely to result in adverse clinical consequences.*

NOTE:

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

9734H	Tablet 2.5 mg (base)	4	5	..	* 28.25	* 28.25	29.28	Naramig	GK

ZOLMITRIPTAN

CAUTION:

Zolmitriptan is contraindicated in patients with known or suspected coronary artery disease. The drug should not be used within 24 hours of ergotamine or dihydroergotamine use.

Authority Required

Migraine attacks in patients receiving, or who have failed a reasonable trial of, prophylactic medication and where attacks in the past have usually failed to respond to oral therapy with ergotamine and other appropriate agents, or in whom these agents are contraindicated.

NOTE:

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

8266C	Tablet 2.5 mg	4	5	s2.76	* 25.41	* 28.17	26.44	Zomig	AP

continued ➡

SPECIAL PHARMACEUTICAL BENEFITS

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

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

Authority Required

Migraine attacks in patients receiving, or who have failed a reasonable trial of, prophylactic medication and where attacks in the past have usually failed to respond to oral therapy with ergotamine and other appropriate agents, or in whom these agents are contraindicated, and where:

- (a) adverse events have occurred with other suitable PBS-listed drugs; or
- (b) drug interactions have occurred with other suitable PBS-listed drugs; or
- (c) drug interactions are expected to occur with other suitable PBS-listed drugs; or
- (d) transfer to another suitable PBS-listed drug would cause patient confusion resulting in problems with compliance; or
- (e) transfer to another suitable PBS-listed drug is likely to result in adverse clinical consequences.

NOTE:

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

9736K	Tablet 2.5 mg	4	5	..	* 28.17	* 28.17	29.20	Zomig	AP

PHARMACEUTICAL BENEFITS FOR DENTAL USE

AMOXYCILLIN

3310F	Powder for paediatric oral drops 100 mg per mL, 20 mL	‡ 1	..	s0.61	# 12.78	# 13.39	14.17	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								
• Antifungives and antiseptics for local oral treatment								
AMPHOTERICIN								
2931G	Lozenge 10 mg	20	1	..	10.91	11.94	Fungilin	BQ
NYSTATIN								
3033P	Oral suspension 100,000 units per mL, 24 mL	± 1	1	..	10.42	11.45	Mycostatin Nilstat	BQ SI
• Other agents for local oral treatment								
BENZYLAMINE HYDROCHLORIDE								
Restricted Benefit								
<i>Radiation induced mucositis.</i>								
1121B	Mouth and throat rinse 22.5 mg per 15 mL, 500 mL	± 1	1	..	21.83	22.86	Diffiam	IA
DRUGS FOR ACID RELATED DISORDERS								
Antacids								
• Combinations and complexes of aluminium, calcium and magnesium compounds								
ALUMINIUM HYDROXIDE with MAGNESIUM HYDROXIDE								
2157M	Oral suspension 200 mg-200 mg per 5 mL, 500 mL	2	5	..	* 15.65	16.68	Mylanta P	JT
ALUMINIUM HYDROXIDE with MAGNESIUM TRISILICATE and MAGNESIUM HYDROXIDE								
2159P	Oral suspension 250 mg-120 mg-120 mg per 5 mL, 500 mL	2	5	..	* 14.01	15.04	Gastrogel	FM
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	..	19.54	20.57 ^a	Magicul 200	AF
				b1.94	21.48	20.57 ^a	Tagamet	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	
1158Y	Tablet 400 mg	60	5	..	19.54	20.57	^a GenRx Cimetidine	GX
							^a Magicul 400	AF
				b1.94	21.48	20.57	^a Tagamet	GK
1159B	Tablet 800 mg	30	5	..	19.54	20.57	^a GenRx Cimetidine	GX
							^a Magicul 800	AF
FAMOTIDINE								
NOTE: <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	..	16.98	18.01	^a Ausfam 20	SI
							^a Chem mart	CH
							Famotidine	
							^a Famohexal	SZ
							^a GenRx Famotidine	GX
							^a Pamacid 20	AF
							^a Pepzan	GM
							^a Terry White	TW
							Chemists	
							Famotidine	
				b4.25	21.23	18.01	^a Pepcidine M	MK
2488Y	Tablet 40 mg	30	5	..	16.98	18.01	^a Ausfam 40	SI
							^a Chem mart	CH
							Famotidine	
							^a Famohexal	SZ
							^a GenRx Famotidine	GX
							^a Pamacid 40	AF
							^a Pepzan	GM
							^a Terry White	TW
							Chemists	
							Famotidine	
				b5.41	22.39	18.01	^a Pepcidine	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	..	18.63	19.66	^a Nizac	LN
							^a Tacidine	AF
				b5.60	24.23	19.66	^a Tazac	AS
1504E	Capsule 300 mg	30	5	..	18.63	19.66	^a Nizac	LN
							^a Tacidine	AF
				b5.60	24.23	19.66	^a Tazac	AS

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	..	17.44	18.47	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 SZ GM TW RA GK
1937Y	Effervescent tablet 150 mg (base)	60	5	τ3.26	* 20.73	18.50	Zantac	GK
1977C	Tablet 300 mg (base)	30	5	..	17.44	18.47	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 SZ GM TW RA GK
8162N	Syrup 150 mg (base) per 10 mL, 300 mL	2	5	τ2.20	* 23.49	22.32	Zantac Syrup	GK

RANITIDINE HYDROCHLORIDE

NOTE:

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

Authority Required

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

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

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

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

8903N	Effervescent tablet 150 mg (base)	60	5	..	* 20.73	21.76	Zantac	GK
8905Q	Syrup 150 mg (base) per 10 mL, 300 mL	2	5	..	* 23.49	24.52	Zantac Syrup	GK

ALIMENTARY TRACT AND METABOLISM—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 \$	

• Prostaglandins

MISOPROSTOL

CAUTION:

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

Authority Required (STREAMLINED)

2630

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

2631

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

2632

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

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

• Proton pump inhibitors

ESOMEPRAZOLE MAGNESIUM TRIHYDRATE

Restricted Benefit

Initial treatment of gastric ulcer.

NOTE:

Helicobacter pylori eradication therapy should be considered.

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

NOTE:

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

Restricted Benefit

Healing of gastro-oesophageal reflux disease.

NOTE:

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

8601Q	Tablet (enteric coated), equivalent to 40 mg esomeprazole	30	1	..	58.24	32.90	Nexium	AP

Restricted Benefit

Maintenance of healed gastro-oesophageal reflux disease.

NOTE:

No applications for increased maximum quantities will be authorised.

8600P	Tablet (enteric coated), equivalent to 20 mg esomeprazole	30	5	..	38.11	32.90	Nexium	AP

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	..	37.43	32.90	Zoton	WX
<u>NOTE:</u>								
<i>No applications for increased repeats will be authorised.</i>								
8528W	Sachet containing granules for oral suspension, 30 mg per sachet	28	1	r3.62	41.64	32.90	Zoton	WX
<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	..	23.57	24.60	Zoton	WX
2241Y	Capsule 30 mg	30	5	..	37.43	32.90	Zoton	WX
8529X	Sachet containing granules for oral suspension, 30 mg per sachet	28	5	r3.62	41.64	32.90	Zoton	WX
<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>								
8949B	Sachet containing granules for oral suspension, 30 mg per sachet	28	1	..	41.64	32.90	Zoton	WX
<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;</i>								
<i>Scleroderma oesophagus, in patients unable to take a solid dose form of a proton pump inhibitor.</i>								
8950C	Sachet containing granules for oral suspension, 30 mg per sachet	28	5	..	41.64	32.90	Zoton	WX

ALIMENTARY TRACT AND METABOLISM—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Proprietary Name and Manufacturer	
OMEPRAZOLE								
Restricted Benefit								
<i>Initial treatment of peptic ulcer.</i>								
NOTE:								
<i>Helicobacter pylori eradication therapy should be considered.</i>								
<i>No applications for increased repeats will be authorised.</i>								
9109K	Tablet 20 mg (as magnesium)	30	1	..	28.91	29.94	^a Acimax Tablets	AL
				B2.75	31.66	29.94	^a Omepral	PM
							^a Losec Tablets	AP
8331L	Tablet 20 mg	30	1	..	28.91	29.94	^a APO-Omeprazole	TX
							^a Chem mart	CH
							Omeprazole	
							^a GenRx Omeprazole	GX
							^a Meprazol	SZ
							^a Omeprazole-GA	GM
							^a Omeprazole	RA
							Ranbaxy	
							^a Omeprazole	WA
							Winthrop	
							^a Terry White	TW
							Chemists	
							Omeprazole	
NOTE:								
<i>Bioequivalence has been demonstrated between omeprazole tablet 20 mg and omeprazole tablet 20 mg (as magnesium).</i>								
1326T	Capsule 20 mg	30	1	..	28.91	29.94	Probitor	SZ
Restricted Benefit								
<i>Gastro-oesophageal reflux disease;</i>								
<i>Scleroderma oesophagus;</i>								
<i>Zollinger-Ellison syndrome.</i>								
8332M	Tablet 10 mg (as magnesium)	30	5	..	22.15	23.18	Losec Tablets	AP
9110L	Tablet 20 mg (as magnesium)	30	5	..	28.91	29.94	^a Acimax Tablets	AL
							^a Omepral	PM
				B2.75	31.66	29.94	^a Losec Tablets	AP

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	
8333N	Tablet 20 mg	30	5	..	28.91	29.94	^a APO-Omeprazole	TX
							^a Chem mart	CH
							Omeprazole	
							^a GenRx Omeprazole	GX
							^a Meprazol	SZ
							^a Omeprazole-GA	GM
							^a Omeprazole	RA
							Ranbaxy	
							^a Omeprazole	WA
							Winthrop	
							^a Terry White	TW
							Chemists	
							Omeprazole	

NOTE:

Bioequivalence has been demonstrated between omeprazole tablet 20 mg and omeprazole tablet 20 mg (as magnesium).

1327W	Capsule 20 mg	30	5	..	28.91	29.94	Probitor	SZ

PANTOPRAZOLE SODIUM SESQUIHYDRATE**Restricted Benefit**

Initial treatment of peptic ulcer.

NOTE:

Helicobacter pylori eradication therapy should be considered.

8007K	Tablet (enteric coated), equivalent to 40 mg pantoprazole	30	2	..	38.71	32.90	Somac	NQ

9423Y	Sachet containing granules 40 mg	30	2	..	38.71	32.90	Somac	NQ

NOTE:

No applications for increased repeats will be authorised.

Restricted Benefit

Gastro-oesophageal reflux disease.

8399C	Tablet (enteric coated), equivalent to 20 mg pantoprazole	30	5	..	21.94	22.97	Somac	NQ

Restricted Benefit

Gastro-oesophageal reflux disease.

Restricted Benefit

Scleroderma oesophagus;

Zollinger-Ellison syndrome.

8008L	Tablet (enteric coated), equivalent to 40 mg pantoprazole	30	5	..	38.71	32.90	Somac	NQ

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	
9424B	Sachet containing granules 40 mg	30	5	..	38.71	32.90	Somac	NQ
	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	..	37.35	32.90	Pariet	JC
	<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>							
8507R	Tablet 10 mg (enteric coated)	28	5	..	37.35	32.90	Pariet	JC
8508T	Tablet 20 mg (enteric coated)	30	5	..	37.35	32.90	Pariet	JC
	• Combinations for eradication of Helicobacter pylori							
	ESOMEPRAZOLE MAGNESIUM TRIHYDRATE and							
	CLARITHROMYCIN and AMOXYCILLIN							
	<u>Restricted Benefit</u>							
	<i>Eradication of Helicobacter pylori associated with peptic ulcer disease.</i>							
8738X	Pack containing 14 tablets (enteric coated) equivalent to 20 mg esomeprazole, 14 tablets clarithromycin 500 mg and 28 capsules amoxicillin 500 mg	± 1	..	..	80.93	32.90	Nexium Hp7	AP
	OMEPRAZOLE and CLARITHROMYCIN and							
	AMOXYCILLIN							
	<u>Restricted Benefit</u>							
	<i>Eradication of Helicobacter pylori associated with peptic ulcer disease.</i>							
8272J	Pack containing 14 capsules omeprazole 20 mg, 14 tablets clarithromycin 500 mg and 28 capsules amoxicillin 500 mg	± 1	..	..	73.75	32.90	Klacid Hp 7	AB

ALIMENTARY TRACT AND METABOLISM—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 \$		
• Other drugs for peptic ulcer and gastro-oesophageal reflux disease (GORD)								
SODIUM ALGINATE with CALCIUM CARBONATE and SODIUM BICARBONATE								
2014B	Oral liquid 1 g-320 mg-534 mg in 20 mL, 500 mL	2	5	..	* 14.25	15.28	Gaviscon P	RC
SUCRALFATE								
2055E	Tablet equivalent to 1 g anhydrous sucralfate	120	2	.. B2.18	23.98 26.16	25.01 ^a 25.01 ^a	Ulcyte Carafate	AF AS

DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS

Belladonna and derivatives, plain

• Belladonna alkaloids, tertiary amines

ATROPINE SULFATE

1089H	Injection 600 micrograms in 1 mL	10	1	..	20.11	21.14	AP	

Propulsives

• Propulsives

DOMPERIDONE

1347X	Tablet 10 mg	25	..	..	8.46	9.49	Motilium	JC

METOCLOPRAMIDE HYDROCHLORIDE

1207M	Tablet 10 mg	25	..	.. B3.02	7.77 10.79	8.80 8.80	Pramin Maxolon	AF VT

1206L	Injection 10 mg in 2 mL	10	..	..	12.56	13.59	Maxolon	VT

ANTIEMETICS AND ANTINAUSEANTS

Antiemetics and antinauseants

• Serotonin (5HT₃) antagonists

DOLASETRON MESYLATE

Restricted Benefit

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

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

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

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	
GRANISETRON HYDROCHLORIDE								
<u>Restricted Benefit</u>								
<i>Management of nausea and vomiting associated with cytotoxic chemotherapy being used to treat malignancy which occurs within 48 hours of chemotherapy administration.</i>								
<i>Increased maximum quantities will be limited to a maximum of 7 days per chemotherapy cycle.</i>								
8728J	Tablet 2 mg (base)	2	..	..	* 58.55	32.90	Kytril	HH
8729K	Concentrated injection 3 mg (base) in 3 mL	1	..	..	37.42	32.90	Kytril	HH
<u>Authority Required</u>								
<i>Management of nausea and vomiting associated with radiotherapy being used to treat malignancy.</i>								
8873B	Tablet 2 mg (base)	5	1	..	137.41	32.90	Kytril	HH
8730L	Concentrated injection 3 mg (base) in 3 mL	1	..	..	37.42	32.90	Kytril	HH
ONDANSETRON								
<u>Restricted Benefit</u>								
<i>Management of nausea and vomiting associated with cytotoxic chemotherapy being used to treat malignancy which occurs within 48 hours of chemotherapy administration.</i>								
<i>Increased maximum quantities will be limited to a maximum of 7 days per chemotherapy cycle.</i>								
8224W	Tablet 4 mg	4	..	..	40.38	32.90	^a APO-Ondansetron	TX
							^a Ondansetron-RL	RE
							^a Ondaz	HX
							^a Onsetron 4	SI
				b0.62	41.00	32.90	^a Zofran	GK
8225X	Tablet 8 mg	4	..	..	57.50	32.90	^a APO-Ondansetron	TX
							^a Ondansetron-RL	RE
							^a Ondaz	HX
							^a Onsetron 8	SI
				b0.69	58.19	32.90	^a Zofran	GK
8410P	Wafer 4 mg	4	..	..	40.38	32.90	^a Ondansetron-RL	RE
							Zydis	
							^a Ondaz Zydis	HX
				b0.62	41.00	32.90	^a Zofran Zydis	GK
8411Q	Wafer 8 mg	4	..	..	57.50	32.90	^a Ondansetron-RL	RE
							Zydis	
							^a Ondaz Zydis	HX
				b0.69	58.19	32.90	^a Zofran Zydis	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	
8226Y	I.V. injection 4 mg in 2 mL	1	..	..	25.38	26.41	^a Ondansetron-RL	RE
							^a Ondaz	HX
							^a Onsetron	SI
							^a PF	
				Ⓟ0.70	26.08	26.41	^a Zofran	GK
8227B	I.V. injection 8 mg in 4 mL	1	..	..	36.79	32.90	^a Ondansetron-RL	RE
							^a Ondaz	HX
							^a Onsetron	SI
							^a PF	
				Ⓟ0.69	37.48	32.90	^a Zofran	GK

Authority Required

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

1594X	Tablet 4 mg	10	1	..	88.19	32.90	^a APO-Ondansetron	TX
							^a Ondansetron-RL	RE
							^a Ondaz	HX
							^a Onsetron 4	SI
				Ⓟ0.69	88.88	32.90	^a Zofran	GK
1595Y	Tablet 8 mg	10	1	..	134.78	32.90	^a APO-Ondansetron	TX
							^a Ondansetron-RL	RE
							^a Ondaz	HX
							^a Onsetron 8	SI
				Ⓟ0.67	135.45	32.90	^a Zofran	GK
8412R	Wafer 4 mg	10	1	..	88.19	32.90	^a Ondansetron-RL	RE
							Zydis	
							^a Ondaz Zydis	HX
				Ⓟ0.69	88.88	32.90	^a Zofran Zydis	GK
8413T	Wafer 8 mg	10	1	..	134.78	32.90	^a Ondansetron-RL	RE
							Zydis	
							^a Ondaz Zydis	HX
				Ⓟ0.67	135.45	32.90	^a Zofran Zydis	GK
8233H	Syrup 4 mg per 5 mL, 50 mL	≠ 1	1	..	88.19	32.90	Zofran syrup	GK
							50 mL	
1596B	I.V. injection 4 mg in 2 mL	1	..	..	25.38	26.41	^a Ondansetron-RL	RE
							^a Ondaz	HX
							^a Onsetron	SI
							^a PF	
				Ⓟ0.70	26.08	26.41	^a Zofran	GK
1597C	I.V. injection 8 mg in 4 mL	1	..	..	36.79	32.90	^a Ondansetron-RL	RE
							^a Ondaz	HX
							^a Onsetron	SI
							^a PF	
				Ⓟ0.69	37.48	32.90	^a Zofran	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	
TROPISETRON HYDROCHLORIDE								
<u>Restricted Benefit</u>								
<i>Management of nausea and vomiting associated with cytotoxic chemotherapy being used to treat malignancy which occurs within 48 hours of chemotherapy administration.</i>								
<i>Increased maximum quantities will be limited to a maximum of 7 days per chemotherapy cycle.</i>								
2745L	Capsule 5 mg (base)	2	..	..	50.29	32.90	Navoban	NV
2746M	I.V. injection 5 mg (base) in 5 mL	1	..	..	28.86	29.89	Navoban	NV
• Other antiemetics								
APREPITANT								
<u>NOTE:</u>								
<i>Aprepitant is not PBS-subsidised for nausea and vomiting associated with radiotherapy being used to treat malignancy.</i>								
<u>Authority Required</u>								
<i>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:</i>								
<i>(a) altretamine;</i>								
<i>(b) carmustine;</i>								
<i>(c) cisplatin when a single dose constitutes a cycle of chemotherapy;</i>								
<i>(d) cyclophosphamide at a dose of 1500 mg per square metre per day or greater;</i>								
<i>(e) dacarbazine;</i>								
<i>(f) procarbazine when a single dose constitutes a cycle of chemotherapy;</i>								
<i>(g) streptozocin.</i>								
<i>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;</i>								
<i>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.</i>								
<i>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.</i>								
<u>NOTE:</u>								
<i>No applications for increased maximum quantities will be authorised. Prescribers should advise Medicare Australia of the number of cycles planned when requesting approval for repeats.</i>								
8808N	Pack containing 1 capsule 125 mg and 2 capsules 80 mg	± 1	..	..	147.91	32.90	Emend	MK
PROCHLORPERAZINE								
<u>CAUTION:</u>								
<i>Prochlorperazine may be associated with parkinsonism and tardive dyskinesia and should be used for short-term treatment only.</i>								
2893G	Tablet containing prochlorperazine maleate 5 mg	25	..	..	9.59	10.62	^a Stemizine	AV
				B2.50	12.09	10.62	^a Stemetil	SW

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	
2369Q	Injection containing prochlorperazine mesylate 12.5 mg in 1 mL	10	..	..	16.39	17.42	Stemetil	SW
2895J	Suppositories containing prochlorperazine equivalent to 25 mg prochlorperazine maleate, 5	‡ 1	2	..	19.50	20.53	Stemetil	SW

NOTE:

As prochlorperazine may be associated with parkinsonism and tardive dyskinesia it should be used for short-term treatment only. However, authorities for increased maximum quantities and/or repeats of prochlorperazine tablets will be granted for the treatment of emesis associated with malignant disease.

BILE AND LIVER THERAPY

Bile therapy

- **Bile acid preparations**

URSODEOXYCHOLIC ACID**Authority Required (STREAMLINED)**

1700

*Primary biliary cirrhosis.***NOTE:**

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

8448P	Capsule 250 mg	200	2	..	* 372.17	32.90	Ursofalk	OA

LAXATIVES

Laxatives

- **Contact laxatives**

BISACODYL**Restricted Benefit**

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

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

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

Patients receiving palliative care;

Terminal malignant neoplasia;

Anorectal congenital abnormalities;

Megacolon.

1259G	Tablet 5 mg	200	2	..	14.17	15.20	Bisalax Lax-Tab	AS AE
1260H	Suppositories 10 mg, 10	3	5	..	* 21.44	22.47	^a Petrus Bisacodyl Suppositories	PP
				B1.14	* 22.58	22.47	^a Dulcolax	BY

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	
1258F	Suppositories 10 mg, 12	3	4	..	* 18.62	19.65	Fleet Laxative Suppositories Petrus Bisacodyl Suppositories	FL PP

• Bulk producers

STERCULIA with FRANGULA BARK

Restricted Benefit

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

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

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

Patients receiving palliative care;

Terminal malignant neoplasia;

Anorectal congenital abnormalities;

Megacolon.

1104D	Granules 620 mg-80 mg per g (62%-8%), 500 g	± 1	1	..	24.52	25.55	Normacol Plus	NE

• Osmotically acting laxatives

LACTULOSE

Restricted Benefit

Hepatic coma or precoma (chronic porto-systemic encephalopathy);

Constipation in patients with malignant neoplasia.

3064G	Mixture 3.34 g per 5 mL, 500 mL	± 1	5	..	13.80	14.83	^a Actilax ^a Genlac ^a GenRx Lactulose ^a Lac-Dol ^a Lactocur ^a Duphalac	AF AW GX GM SZ SM
				B1.67	15.47	14.83		

MACROGOL 3350

Restricted Benefit

Constipation in patients with malignant neoplasia;

Chronic constipation or faecal impaction not adequately controlled with first line interventions such as bulk-forming agents;

Paraplegic and quadriplegic patients and others with severe neurogenic impairment of bowel function not responding to other oral therapies;

Patients receiving palliative care.

9146J	Sachets containing powder for solution 6.563 g with electrolytes, 30	± 1	5	..	18.10	19.13	Movicol-Half	NE

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	
8612G	<i>Sachets containing powder for solution 13.125 g with electrolytes, 30</i>	± 1	5	..	24.36	25.39	<i>Movicol</i>	<i>NE</i>

• **Enemas**
BISACODYL

Restricted Benefit

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

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

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

Patients receiving palliative care;

Terminal malignant neoplasia;

Anorectal congenital abnormalities;

Megacolon.

1263L	<i>Enemas 10 mg in 5 mL, 25</i>	± 1	2	..	39.48	32.90	<i>Bisalax</i>	<i>AS</i>

**SORBITOL with SODIUM CITRATE and SODIUM LAURYL
SULFOACETATE**

Restricted Benefit

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

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

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

Patients receiving palliative care;

Terminal malignant neoplasia;

Anorectal congenital abnormalities;

Megacolon.

2091C	<i>Enemas 3.125 g-450 mg-45 mg in 5 mL, 12</i>	2	2	..	* 36.15	32.90	<i>Microlax</i>	<i>JT</i>

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	

• Other laxatives

GLYCEROL

Restricted Benefit

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

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

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

Patients receiving palliative care;

Terminal malignant neoplasia;

Anorectal congenital abnormalities;

Megacolon.

2555L	Suppositories 700 mg (for infants), 12	3	5	..	* 17.93	18.96	PP	

2556M	Suppositories 1.4 g (for children), 12	3	5	..	* 18.35	19.38	PP	

2557N	Suppositories 2.8 g (for adults), 12	3	5	..	* 18.80	19.83	PP	

ANTIDIARRHEALS, INTESTINAL ANTIINFLAMMATORY/ ANTIINFECTIVE AGENTS

Intestinal antiinfectives

• Antibiotics

NEOMYCIN SULFATE

2325J	Tablet 500 mg	25	1	..	14.62	15.65	Neosulf	AF

NYSTATIN

1696G	Tablet 500,000 units	50	..	..	17.55	18.58	Nilstat	SI

1699K	Capsule 500,000 units	50	..	..	17.55	18.58	Nilstat	SI

VANCOMYCIN

Authority Required

Antibiotic associated pseudomembranous colitis due to Clostridium difficile which is unresponsive to metronidazole;

Antibiotic associated pseudomembranous colitis due to Clostridium difficile where there is intolerance to metronidazole.

NOTE:

Metronidazole has similar efficacy to vancomycin but may have less selective pressure to vancomycin resistant enterococci and is therefore the preferred treatment.

3113W	Capsule 125 mg (125,000 i.u.) vancomycin activity	40	..	..	* 244.81	32.90	Vancocin	AS

3114X	Capsule 250 mg (250,000 i.u.) vancomycin activity	40	..	..	* 465.61	32.90	Vancocin	AS

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	
Electrolytes with carbohydrates								
• Oral rehydration salt formulations								
ELECTROLYTE REPLACEMENT (ORAL)								
3196F	Sachets containing powder for oral solution 4.9 g, 10	‡ 1	..	..	12.90	13.93	^a O.R.S. ^a Repalyte New Formulation ^a restore O.R.S.	AS SW GM
NOTE:								
Each sachet contains sodium chloride 470 mg, potassium chloride 300 mg, sodium acid citrate 530 mg and glucose 3.56 g.								
Antipropulsives								
• Antipropulsives								
DIPHENOXYLATE HYDROCHLORIDE with ATROPINE SULFATE								
2501P	Tablet 2.5 mg-25 micrograms	20	..	.. B1.83	8.19 10.02	9.22 9.22	^a Lofenoxal ^a Lomotil	HC BI
LOPERAMIDE HYDROCHLORIDE								
1571Q	Capsule 2 mg	12	..	.. B0.94	8.16 9.10	9.19 9.19	^a Gastro-Stop Loperamide ^a Imodium	AS JT
Intestinal antiinflammatory agents								
• Corticosteroids acting locally								
HYDROCORTISONE ACETATE								
Restricted Benefit								
<i>Proctitis;</i>								
<i>Ulcerative colitis.</i>								
1502C	Rectal foam 90 mg per applicatorful, 14 applications, aerosol 21.1 g [For other listings for this drug see Generic/Proprietary Index]	2	3	..	* 38.55	32.90	Colifoam	AS
PREDNISOLONE SODIUM PHOSPHATE								
1920C	Retention enema equivalent to 20 mg prednisolone in 100 mL	28	3	..	* 220.75	32.90	Predsol	SI

continued ➞

ALIMENTARY TRACT AND METABOLISM—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Proprietary Name and Manufacturer	
PREDNISOLONE SODIUM PHOSPHATE								
<u>Restricted Benefit</u>								
<i>Proctitis;</i>								
<i>Ulcerative colitis.</i>								
2554K	Suppositories equivalent to 5 mg prednisolone, 10	3	3	..	* 38.39	32.90	Predsol	SI
• Aminosalicylic acid and similar agents								
BALSALAZIDE SODIUM								
<u>Authority Required (STREAMLINED)</u>								
1708								
<i>Ulcerative colitis where hypersensitivity to sulfonamides exists;</i>								
1709								
<i>Ulcerative colitis where intolerance to sulfasalazine exists.</i>								
<u>NOTE:</u>								
<i>Not for the treatment of Crohn's disease.</i>								
8845M	Capsule 750 mg	180	5	..	124.42	32.90	Colazide	PK
MESALAZINE								
<u>Restricted Benefit</u>								
<i>Acute episode of mild to moderate ulcerative proctitis.</i>								
<u>NOTE:</u>								
<i>Not for the treatment of Crohn's disease.</i>								
8752P	Suppositories 1 g, 28	± 1	..	..	127.29	32.90	Pentasa	FP
<u>NOTE:</u>								
<i>No applications for increased maximum quantities and/or repeats will be authorised.</i>								

<u>Authority Required (STREAMLINED)</u>								
1708								
<i>Ulcerative colitis where hypersensitivity to sulfonamides exists;</i>								
1709								
<i>Ulcerative colitis where intolerance to sulfasalazine exists;</i>								
2268								
<i>Crohn's disease where hypersensitivity to sulfonamides exists;</i>								
2269								
<i>Crohn's disease where intolerance to sulfasalazine exists.</i>								
1611T	Tablet 250 mg (enteric coated)	100	5	..	93.00	32.90	Mesasal	GK
8731M	Tablet 500 mg (enteric coated)	200	5	..	* 297.01	32.90	Salofalk	OA

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	
2214M	Tablet 500 mg (prolonged release)	200	5	..	* 297.01	32.90	Pentasa	FP
2234N	Sachet containing prolonged release granules, 1 g per sachet	100	5	..	279.20	32.90	Pentasa	FP
2287J	Sachet containing prolonged release granules, 2 g per sachet	60	5	..	311.87	32.90	Pentasa	FP

Authority Required (STREAMLINED)

1708

Ulcerative colitis where hypersensitivity to sulfonamides exists;

1709

Ulcerative colitis where intolerance to sulfasalazine exists.

NOTE:

Not for the treatment of Crohn's disease.

8598M	Sachet containing granules, 500 mg per sachet	200	5	..	* 297.01	32.90	Salofalk	OA
8599N	Sachet containing granules, 1 g per sachet	100	5	..	279.20	32.90	Salofalk	OA
9206M	Sachet containing granules, 1.5 g per sachet	60	5	..	244.49	32.90	Salofalk	OA

Authority Required (STREAMLINED)

1707

Acute episode of mild to moderate ulcerative colitis.

NOTE:

Not for the treatment of Crohn's disease.

8753Q	Enemas 1 g in 100 mL, 7	4	..	..	* 335.79	32.90	Pentasa	FP
8616L	Enemas 2 g in 60 mL, 7	4	..	..	* 335.79	32.90	Salofalk	OA
8617M	Enemas 4 g in 60 mL, 7	4	..	..	* 445.47	32.90	Salofalk	OA
8768L	Rectal foam 1 g per applicatorful, 14 applications, aerosol 80 g	4	..	..	* 335.79	32.90	Salofalk	OA

NOTE:

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

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	
OLSALAZINE SODIUM								
<u>Authority Required (STREAMLINED)</u>								
	1708	Ulcerative colitis where hypersensitivity to sulfonamides exists;						
	1709	Ulcerative colitis where intolerance to sulfasalazine exists.						
<u>NOTE:</u>								
Not for the treatment of Crohn's disease.								
1728Y	Capsule 250 mg	100	5	..	60.98	32.90	Dipentum	UC
8086N	Tablet 500 mg	100	5	..	102.86	32.90	Dipentum	UC
SULFASALAZINE								
2093E	Tablet 500 mg	200	5	..	* 52.31	32.90	Salazopyrin	PH
2096H	Tablet 500 mg (enteric coated)	200	5	..	* 56.61	32.90	^a Pyralin EN	KR
				B1.60	* 58.21	32.90	^a Salazopyrin-EN	PH

SULFASALAZINE

Restricted Benefit

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

NOTE:

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

9208P	Tablet 500 mg	200	11	..	* 52.31	32.90	Salazopyrin	PH
9209Q	Tablet 500 mg (enteric coated)	200	11	..	* 56.61	32.90	^a Pyralin EN	KR
				B1.60	* 58.21	32.90	^a Salazopyrin-EN	PH

DIGESTIVES, INCL. ENZYMES

Digestives, incl. enzymes

• **Enzyme preparations**

PANCREATIC EXTRACT

8556H	Capsule (containing enteric coated minimicrospheres) providing not less than 5,000 BP units of lipase activity	500	10	..	* 118.79	32.90	Creon 5000	SM
8020D	Capsule (containing enteric coated minimicrospheres) providing not less than 10,000 BP units of lipase activity	500	10	..	* 170.34	32.90	Creon 10,000	SM

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	
8021E	Capsule (containing enteric coated minimicrospheres) providing not less than 25,000 BP units of lipase activity	200	10	..	* 137.47	32.90	Creon 25,000	SM
9412J	Capsule (containing enteric coated minimicrospheres) providing not less than 40,000 BP units of lipase activity	200	10	..	* 215.19	32.90	Creon 40,000	SM

PANCREATIC EXTRACT

Restricted Benefit

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

NOTE:

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

9225M	Capsule (containing enteric coated minimicrospheres) providing not less than 5,000 BP units of lipase activity	500	21	..	* 118.79	32.90	Creon 5000	SM
9226N	Capsule (containing enteric coated minimicrospheres) providing not less than 10,000 BP units of lipase activity	500	21	..	* 170.34	32.90	Creon 10,000	SM
9227P	Capsule (containing enteric coated minimicrospheres) providing not less than 25,000 BP units of lipase activity	200	21	..	* 137.47	32.90	Creon 25,000	SM
9413K	Capsule (containing enteric coated minimicrospheres) providing not less than 40,000 BP units of lipase activity	200	21	..	* 215.19	32.90	Creon 40,000	SM

PANCRELIPASE

8366H	Capsule (containing enteric coated microtablets) providing not less than 25,000 BP units of lipase activity	200	10	..	* 137.47	32.90	Panzytrat 25000	TM

continued ➞

ALIMENTARY TRACT AND METABOLISM—CONT.

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

PANCRELIPASE

Restricted Benefit

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

NOTE:

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

9229R	Capsule (containing enteric coated microtablets) providing not less than 25,000 BP units of lipase activity	200	21	..	* 137.47	32.90	Panzytrat 25000	TM

DRUGS USED IN DIABETES

Insulins and analogues

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

INSULIN ASPART

8571D	Injection (human analogue) 100 units per mL, 10 mL	5	2	..	* 158.84	32.90	NovoRapid	NO
8435Y	Injections (human analogue) 100 units per mL, 3 mL, 5	5	1	..	* 263.79	32.90	NovoRapid FlexPen NovoRapid Penfill 3 mL	NF NO

INSULIN GLULISINE

9224L	Injection (human analogue) 100 units per mL, 10 mL	5	2	..	* 158.84	32.90	Apidra	SW
1921D	Injections (human analogue) 100 units per mL, 3 mL, 5	5	1	..	* 263.79	32.90	Apidra SoloStar	SW

INSULIN LISPRO

8084L	Injection (human analogue) 100 units per mL, 10 mL	5	2	..	* 158.84	32.90	Humalog	LY
8212F	Injections (human analogue) 100 units per mL, 3 mL, 5	5	1	..	* 263.79	32.90	Humalog	LY

INSULIN NEUTRAL

1713E	Injection (bovine) 100 units per mL, 10 mL	5	2	..	* 144.59	32.90	Hypurin Neutral	AS
1531N	Injection (human) 100 units per mL, 10 mL	5	2	..	* 133.39	32.90	Actrapid Humulin R	NO LY
1762R	Injections (human) 100 units per mL, 3 mL, 5	5	1	..	* 223.89	32.90	Actrapid Penfill 3 mL Humulin R	NO LY

ALIMENTARY TRACT AND METABOLISM—CONT.

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

ALIMENTARY TRACT AND METABOLISM—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed	Maximum	Proprietary Name and Manufacturer	
					Price for Max. Qty \$	Recordable Value for Safety Net \$		
• Insulins and analogues for injection, long-acting								
INSULIN DETEMIR								
<u>Restricted Benefit</u>								
Type 1 diabetes.								
9040T	Injections (human analogue) 100 units per mL, 3 mL, 5	5	1	..	* 432.29	32.90	Levemir FlexPen Levemir Penfill	NF NO
INSULIN GLARGINE								
9039R	Injections (human analogue) 100 units per mL, 3 mL, 5	5	1	..	* 432.29	32.90	Lantus Lantus SoloStar	SW AV
Blood glucose lowering drugs, excl. insulins								
• Biguanides								
METFORMIN HYDROCHLORIDE								
2430X	Tablet 500 mg	100	5	..	12.66	13.69	a Chem mart Metformin	CH
							a Diaformin	AF
							a Formet 500	SI
							a GenRx Metformin	GX
							a Glucohexal	SZ
							a Glucomet 500 mg	GM
							a Metforbell	BF
							a Metformin 500	CR
							a Metformin generichealth	GQ
							a Metformin Ranbaxy	RA
							a Terry White Chemists Metformin	TW
							a GN	
				B1.10	13.76	13.69	a Glucophage	MQ
				B1.79	14.45	13.69	a Diabex	AL
8884N	Tablet 500 mg (extended release)	90	5	..	13.99	15.02	a Diabex XR	AL
							a Diaformin XR	AF
							a Metex XR	SI

continued ➞

ALIMENTARY TRACT AND METABOLISM—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Proprietary Name and Manufacturer	
1801T	Tablet 850 mg	60	5	..	12.66	13.69	a Chem mart Metformin	CH
							a Diaformin 850	AF
							a Formet 850	SI
							a GenRx Metformin	GX
							a Glucohexal	SZ
							a Glucomet 850 mg	GM
							a Metforbell	BF
							a Metformin 850	CR
							a Metformin generichealth	GQ
							a Metformin Ranbaxy	RA
							a Terry White Chemists Metformin	TW
							a GN	
				B1.10	13.76	13.69	a Glucophage	MQ
				B1.79	14.45	13.69	a Diabex 850	AL
8607B	Tablet 1 g	90	5	..	17.61	18.64	a Diaformin 1000	AF
							a Formet 1000	SI
							a Glucohexal	SZ
							a Metformin-GA	GN
				B1.80	19.41	18.64	a Diabex 1000	AL
• Sulfonamides, urea derivatives GLIBENCLAMIDE CAUTION: Sulfonylureas may cause hypoglycaemia, particularly in the elderly.								
2939Q	Tablet 5 mg	100	5	..	11.27	12.30	a Glimel	AF
				B1.51	12.78	12.30	a Daonil	SW
GLICLAZIDE CAUTION: Sulfonylureas may cause hypoglycaemia, particularly in the elderly.								
8535F	Tablet 30 mg (modified release)	100	5	..	13.29	14.32	a Diamicron MR	SE
							a Glyade MR	AF
							a Oziclide MR	RA
2449X	Tablet 80 mg	100	5	..	13.09	14.12	a Chem mart Gliclazide	CH
							a GenRx Gliclazide	GX
							a Glyade	AF
							a Mellihexal	SZ
							a Nidem	SI
							a Terry White Chemists Gliclazide	TW
				B2.03	15.12	14.12	a Diamicron	SE

ALIMENTARY TRACT AND METABOLISM—CONT.

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

ALIMENTARY TRACT AND METABOLISM—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Proprietary Name and Manufacturer	
ROSIGLITAZONE MALEATE with METFORMIN HYDROCHLORIDE								
NOTE:								
<i>Rosiglitazone with metformin fixed dose combination tablet is not PBS-subsidised when used in combination with insulin.</i>								
Authority Required (STREAMLINED)								
2633								
<i>Type 2 diabetes in a patient whose HbA1c is greater than 7% prior to initiation of a thiazolidinedione (glitazone) despite treatment with metformin and where a sulfonylurea is contraindicated or not tolerated.</i>								
<i>The date and level of the HbA1c must be documented in the patient's medical records at the time glitazone treatment is initiated. The HbA1c must be no more than 4 months old at the time glitazone treatment is initiated.</i>								
NOTE:								
<i>Blood glucose monitoring may be used as an alternative assessment to HbA1c levels 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>A patient in these circumstances will be eligible for treatment where blood glucose monitoring over a 2 week period shows blood glucose levels greater than 10 mmol per L in more than 20% of tests. The results of this blood glucose monitoring, which must be no more than 4 months old at the time of initiation of glitazone therapy, must be documented in the patient's medical records.</i>								
9059T	Tablet 2 mg (base)-500 mg	56	5	..	64.66	32.90	Avandamet	GK
9060W	Tablet 2 mg (base)-1 g	56	5	..	68.00	32.90	Avandamet	GK
9061X	Tablet 4 mg (base)-500 mg	56	5	..	94.33	32.90	Avandamet	GK
9062Y	Tablet 4 mg (base)-1 g	56	5	..	97.66	32.90	Avandamet	GK

• Alpha glucosidase inhibitors

ACARBOSE

8188Y	Tablet 50 mg	90	5	..	30.47	31.50	Glucobay 50	BN
8189B	Tablet 100 mg	90	5	..	40.49	32.90	Glucobay 100	BN

• Thiazolidinediones

PIOGLITAZONE HYDROCHLORIDE

Authority Required (STREAMLINED)

2635

Dual oral combination therapy with metformin or a sulfonylurea

Type 2 diabetes, in combination with either metformin or a sulfonylurea, in a patient whose HbA1c is greater than 7% prior to initiation of a thiazolidinedione (glitazone) despite treatment with either metformin or a sulfonylurea and where a combination of metformin and a sulfonylurea is contraindicated or not tolerated. .

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

continued ➡

ALIMENTARY TRACT AND METABOLISM—CONT.

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

NOTE:

Pioglitazone hydrochloride is not PBS-subsidised as monotherapy.

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

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

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

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

Authority Required (STREAMLINED)

2638

Combination therapy with insulin

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

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

NOTE:

Pioglitazone hydrochloride is not PBS-subsidised as monotherapy.

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

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

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

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

Authority Required (STREAMLINED)

2648

Triple oral combination therapy with metformin and a sulfonylurea

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

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

continued ➡

ALIMENTARY TRACT AND METABOLISM—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 \$		
NOTE:								
<i>Pioglitazone hydrochloride is not PBS-subsidised as monotherapy.</i>								
<i>Blood glucose monitoring may be used as an alternative assessment to HbA1c levels 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>A patient in these circumstances will be eligible for treatment where blood glucose monitoring over a 2 week period shows blood glucose levels greater than 10 mmol per L in more than 20% of tests. The results of this blood glucose monitoring, which must be no more than 4 months old at the time of initiation of glitazone therapy, must be documented in the patient's medical records.</i>								
8694N	Tablet 15 mg (base)	28	5	..	61.09	32.90	Actos	LY
8695P	Tablet 30 mg (base)	28	5	..	90.76	32.90	Actos	LY
8696Q	Tablet 45 mg (base)	28	5	..	116.21	32.90	Actos	LY

ROSIGLITAZONE MALEATE

Authority Required (STREAMLINED)

2635

Dual oral combination therapy with metformin or a sulfonylurea

Type 2 diabetes, in combination with either metformin or a sulfonylurea, in a patient whose HbA1c is greater than 7% prior to initiation of a thiazolidinedione (glitazone) despite treatment with either metformin or a sulfonylurea and where a combination of metformin and a sulfonylurea is contraindicated or not tolerated. .

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

NOTE:

Rosiglitazone maleate is not PBS-subsidised as monotherapy.

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

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

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

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

8689H	Tablet 4 mg (base)	28	5	..	61.09	32.90	Avandia	GK
8690J	Tablet 8 mg (base)	28	5	..	90.76	32.90	Avandia	GK

ALIMENTARY TRACT AND METABOLISM—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 \$		
• Dipeptidyl peptidase 4 (DPP-4) inhibitors								
SITAGLIPTIN								
NOTE:								
Sitagliptin is not PBS-subsidised for use in combination with metformin and a sulfonylurea (triple oral therapy), as monotherapy or in combination with a thiazolidinedione (glitazone).								
Authority Required (STREAMLINED)								
3097								
Dual oral combination therapy with metformin or a sulfonylurea								
Type 2 diabetes, in combination with metformin or a sulfonylurea, in a patient whose HbA1c is greater than 7% prior to initiation of sitagliptin despite treatment with either metformin or a sulfonylurea and where a combination of metformin and a sulfonylurea is contraindicated or not tolerated.								
The date and level of the qualifying HbA1c must be documented in the patient's medical records at the time sitagliptin treatment is initiated. The HbA1c must be no more than 4 months old at the time sitagliptin treatment is initiated.								
Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:								
(a) clinical conditions with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or								
(b) red cell transfusion within the previous 3 months.								
A patient in these circumstances will be eligible for treatment where blood glucose monitoring over a 2 week period shows blood glucose levels greater than 10 mmol per L in more than 20% of tests. The results of this blood glucose monitoring, which must be no more than 4 months old at the time of initiation of sitagliptin therapy, must be documented in the patient's medical records.								
9180E	Tablet 25 mg (as phosphate monohydrate)	28	5	..	90.76	32.90	Januvia	MK
9181F	Tablet 50 mg (as phosphate monohydrate)	28	5	..	90.76	32.90	Januvia	MK
9182G	Tablet 100 mg (as phosphate monohydrate)	28	5	..	90.76	32.90	Januvia	MK

ALIMENTARY TRACT AND METABOLISM—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Proprietary Name and Manufacturer	
VITAMINS								
	Vitamin A and D, incl. combinations of the two							
	• Vitamin D and analogues							
	CALCITRIOL							
	<u>Authority Required (STREAMLINED)</u>							
	1165							
	<i>Hypocalcaemia due to renal disease;</i>							
	1166							
	<i>Hypoparathyroidism;</i>							
	1167							
	<i>Hypophosphataemic rickets;</i>							
	1467							
	<i>Vitamin D-resistant rickets;</i>							
	2636							
	<i>Treatment for established osteoporosis in patients with fracture due to minimal trauma. The fracture must have been demonstrated radiologically and the year of plain x-ray or CT-scan or MRI scan must be documented in the patient's medical records when treatment is initiated.</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>							
2502Q	Capsule 0.25 microgram	100	3	..	42.82	32.90	^a Calcitriol-DP	GM
							^a Citrihexal	SZ
							^a GenRx Calcitriol	GX
							^a Kosteo	SI
							^a Rocaltrol	RO
							^a Sical	AF
	Vitamin B₁, plain and in combination with vitamin B₆ and vitamin B₁₂							
	• Vitamin B₁, plain							
	THIAMINE HYDROCHLORIDE							
	<u>Authority Required (STREAMLINED)</u>							
	2384							
	<i>Prophylaxis of thiamine deficiency in an Aboriginal or a Torres Strait Islander person.</i>							
1070H	Tablet 100 mg	100	2	..	10.39	11.42	Betamin	SW

ALIMENTARY TRACT AND METABOLISM—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Proprietary Name and Manufacturer	
MINERAL SUPPLEMENTS								
Calcium								
• Calcium								
CALCIUM								
Authority Required (STREAMLINED)								
2212								
<i>Hyperphosphataemia associated with chronic renal failure.</i>								
8560M	Tablet 250 mg (as citrate)	240	1	..	* 21.77	22.80	Citracal	BN
3116B	Tablet (chewable) 500 mg (as carbonate)	240	1	..	* 26.59	27.62	Cal-Sup	IA
Potassium								
• Potassium								
POTASSIUM CHLORIDE								
2642C	Tablet 600 mg (sustained release)	200	1	..	* 12.87	13.90	^a Duro-K	NM
				..	12.87	13.90	Span-K	AS
				B2.80	* 15.67	13.90	^a Slow-K	NV
POTASSIUM CHLORIDE with POTASSIUM BICARBONATE								
3012M	Effervescent tablet 14 mmol potassium and 8 mmol chloride	60	1	..	12.64	13.67	^a K-Sol	LN
				B2.61	15.25	13.67	^a Chlorvescent	AS
ANABOLIC AGENTS FOR SYSTEMIC USE								
Anabolic steroids								
• Estren derivatives								
NANDROLONE DECANOATE								
Authority Required								
<i>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;</i>								
<i>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;</i>								
<i>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;</i>								
<i>Patients receiving PBS-subsidised therapy with this drug for osteoporosis prior to 1 February 2004;</i>								
<i>Patients on long-term treatment with corticosteroids.</i>								
NOTE:								
<i>Monotherapy for the treatment of osteoporosis does not exclude calcium supplementation.</i>								
1671Y	Injection 50 mg in 1 mL, disposable syringe	1	7	..	20.77	21.80	Deca-Durabolin	SH

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	..	11.99	13.02	Coumadin Marevan	SI FM
2209G	Tablet 2 mg	50	2	..	12.34	13.37	Coumadin	SI
2844Q	Tablet 3 mg	50	2	..	12.26	13.29	Marevan	FM
2211J	Tablet 5 mg	50	2	..	13.60	14.63	Coumadin Marevan	SI FM
• Heparin group								
DALTEPARIN SODIUM (Low Molecular Weight Heparin Sodium—porcine mucous)								
8603T	Injection 2,500 units (anti-Xa) in 0.2 mL single dose pre-filled syringe	10	1	..	55.18	32.90	Fragmin	PH
2816F	Injection 5,000 units (anti-Xa) in 0.2 mL single dose pre-filled syringe	10	1	..	57.22	32.90	Fragmin	PH
8271H	Injection 7,500 units (anti-Xa) in 0.75 mL single dose pre-filled syringe	10	1	..	83.22	32.90	Fragmin	PH
8269F	Injection 10,000 units (anti-Xa) in 1 mL single dose pre-filled syringe	10	1	..	108.95	32.90	Fragmin	PH
DALTEPARIN SODIUM (Low Molecular Weight Heparin Sodium—porcine mucous)								
Restricted Benefit Haemodialysis.								
8641T	Injection 2,500 units (anti-Xa) in 0.2 mL single dose pre-filled syringe	20	3	..	* 104.31	32.90	Fragmin	PH
8642W	Injection 5,000 units (anti-Xa) in 0.2 mL single dose pre-filled syringe	20	3	..	* 108.45	32.90	Fragmin	PH
8643X	Injection 7,500 units (anti-Xa) in 0.75 mL single dose pre-filled syringe	20	3	..	* 160.45	32.90	Fragmin	PH

BLOOD AND BLOOD FORMING ORGANS—CONT.

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

BLOOD AND BLOOD FORMING ORGANS—CONT.

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

BLOOD AND BLOOD FORMING ORGANS—CONT.

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

CLOPIDOGREL HYDROGEN SULFATE

Authority Required (STREAMLINED)

1719

Prevention of recurrence of ischaemic stroke or transient cerebral ischaemic events in patients with a history of symptomatic cerebrovascular ischaemic episodes while on therapy with low-dose aspirin;

1720

Prevention of recurrence of ischaemic stroke or transient cerebral ischaemic events in patients where low-dose aspirin poses an unacceptable risk of gastrointestinal bleeding;

1721

Prevention of recurrence of ischaemic stroke or transient cerebral ischaemic events in patients where there is a history of anaphylaxis, urticaria or asthma within 4 hours of ingestion of aspirin, other salicylates, or NSAIDs;

1722

Prevention of recurrence of myocardial infarction or unstable angina in patients with a history of symptomatic cardiac ischaemic events while on therapy with low-dose aspirin;

1723

Prevention of recurrence of myocardial infarction or unstable angina in patients where low-dose aspirin poses an unacceptable risk of gastrointestinal bleeding;

1724

Prevention of recurrence of myocardial infarction or unstable angina in patients where there is a history of anaphylaxis, urticaria or asthma within 4 hours of ingestion of aspirin, other salicylates, or NSAIDs;

3069

Treatment of acute coronary syndromes (myocardial infarction or unstable angina) in combination with aspirin to prevent early and long-term atherothrombotic events.

NOTE:

Not for prophylaxis of DVT or peripheral arterial disease.

8358X	Tablet 75 mg (base)	28	5	..	80.49	32.90	^a Iscover ^a Plavix	BQ SW

DIPYRIDAMOLE

Restricted Benefit

Prevention of recurrence of ischaemic stroke or transient cerebral ischaemic events:

- (a) *as adjunctive therapy with low-dose aspirin; or*
- (b) *where low-dose aspirin poses an unacceptable risk of gastrointestinal bleeding; or*
- (c) *where there is a history of anaphylaxis, urticaria or asthma within 4 hours of ingestion of aspirin, other salicylates, or NSAIDs.*

8335Q	Capsule 200 mg (sustained release)	60	5	..	36.53	32.90	Persantin SR	BY

DIPYRIDAMOLE with ASPIRIN

Restricted Benefit

Prevention of recurrence of ischaemic stroke or transient cerebral ischaemic events.

8382E	Capsule 200 mg (sustained release)-25 mg	60	5	..	36.76	32.90	Asasantin SR	BY

BLOOD AND BLOOD FORMING ORGANS—CONT.

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

BLOOD AND BLOOD FORMING ORGANS—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 \$	

• Enzymes

DROTRECOGIN ALFA (ACTIVATED)

Authority Required

Adult patients with severe sepsis who have a high risk of death as determined by acute dysfunction in at least 2 organs or modified Apache II score of at least 25.

Acute organ dysfunction is defined as follows:

- (a) (1) *For cardiovascular-system dysfunction, an arterial systolic blood pressure of less than or equal to 90 mmHg or mean arterial pressure of less than or equal to 70 mmHg for at least 1 hour despite adequate fluid resuscitation, adequate intravascular volume status or the use of vasopressors in an attempt to maintain a systolic blood pressure of greater than or equal to 90 mmHg or a mean arterial pressure of greater than or equal to 70 mmHg;*
- (2) *For kidney dysfunction, urine output of less than 0.5 mL per kg of body weight per hour for 1 hour despite adequate fluid resuscitation;*
- (3) *For respiratory-system dysfunction, a ratio of PaO₂ to FiO₂ of less than or equal to 250;*
- (4) *For haematologic dysfunction, a platelet count of less than 80,000 per cubic millimetre or which has decreased by 50 percent in the previous 3 days;*
- (5) *In the case of unexplained metabolic acidosis, a pH of less than or equal to 7.30 or a base deficit of greater than or equal to 5.0 mmol per L in association with a plasma lactate level of greater than 1.5 times the upper limit of the normal value for the reporting laboratory.*

NOTE:

Medical practitioners should request the appropriate quantity of vials at the time of the authority application, according to the weight of the patient, to achieve a dose of 24 micrograms per kg per hour over a maximum of 96 hours.

8614J	Powder for I.V. infusion 5 mg	1	..	..	466.71	32.90	Xigris	LY

RETEPLASE (Recombinant plasminogen activator)

Restricted Benefit

Treatment of acute myocardial infarction within 6 hours of onset of attack.

8253J	Pack containing 2 vials powder for injection 10 units, 2 single use pre-filled syringes with solvent, 2 reconstitution spikes and 2 needles	± 1	..	..	2066.53	32.90	Rapilysin 10 U	TA

TENECTEPLASE

Restricted Benefit

Treatment of acute myocardial infarction within 12 hours of onset of attack.

8526R	Powder for injection 40 mg with solvent	1	..	..	1960.33	32.90	Metalyse	BY
8527T	Powder for injection 50 mg with solvent	1	..	..	2056.63	32.90	Metalyse	BY

BLOOD AND BLOOD FORMING ORGANS—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Proprietary Name and Manufacturer	
• Direct thrombin inhibitors BIVALIRUDIN TRIFLUOROACETATE Authority Required (STREAMLINED) 3075 <i>A patient undergoing percutaneous coronary intervention.</i>								
8844L	Powder for I.V. injection 250 mg (base)	1	..	..	671.32	32.90	Angiomax	CS
• Other antithrombotic agents FONDAPARINUX SODIUM Authority Required (STREAMLINED) 2005 <i>Prevention of venous thromboembolic events in patients undergoing major hip surgery;</i> 2006 <i>Prevention of venous thromboembolic events in patients undergoing total knee replacement.</i>								
NOTE: <i>No applications for increased maximum quantities and/or repeats will be authorised.</i>								
8775W	Injection 2.5 mg in 0.5 mL single dose pre-filled syringe	7	..	..	140.11	32.90	Arixtra	GK

ANTHEMORRHAGICS

Antifibrinolytics

• Amino acids

TRANEXAMIC ACID

2180R	Tablet 500 mg	100	2	..	51.25	32.90	Cyklokapron	PH

ANTIANEMIC PREPARATIONS

Iron preparations

• Iron bivalent, oral preparations

FERROUS SULFATE

8815Y	Oral liquid 30 mg per mL, 250 mL	± 1	2	..	18.92	19.95	Ferro-Liquid	AE

• Iron trivalent, parenteral preparations

IRON POLYMALTOSE COMPLEX

2593L	Injection 100 mg (iron) in 2 mL	5	..	..	51.55	32.90	^a Ferrosig ^a Ferrum H	SI AS

BLOOD AND BLOOD FORMING ORGANS—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Proprietary Name and Manufacturer	
IRON SUCROSE								
Authority Required (STREAMLINED)								
2070								
<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	..	..	139.05	32.90	Venofer	AS
Iron in combination with folic acid FERROUS FUMARATE with FOLIC ACID								
9011G	Tablet 310 mg (equivalent to 100 mg iron)-350 micrograms	60	1	..	11.87	12.90	Ferro-f-tab	AE
Vitamin B₁₂ and folic acid								
Vitamin B₁₂ (cyanocobalamin and derivatives) HYDROXOCOBALAMIN								
Restricted Benefit								
<i>Pernicious anaemia;</i>								
<i>Other proven vitamin B₁₂ deficiencies;</i>								
<i>Prophylaxis after gastrectomy.</i>								
9048F	Injection 1 mg in 1 mL	3	..	..	16.79	17.82	Neo-B12	HH
NOTE:								
<i>One injection of hydroxocobalamin 1 mg every three months provides appropriate maintenance therapy in vitamin B₁₂ deficiencies.</i>								
Folic acid and derivatives FOLIC ACID								
2958Q	Tablet 500 micrograms	200	..	..	* 13.35	14.38	Megafol 0.5	AF
1437P	Tablet 5 mg	200	1	..	* 13.59	14.62	Megafol 5	AF
NOTE:								
The 5 mg strength tablet should be used in malabsorption states only.								

BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS

Blood and related products

- Blood substitutes and plasma protein fractions**

GELATIN - SUCCINYLATED

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

BLOOD AND BLOOD FORMING ORGANS—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Proprietary Name and Manufacturer	
	POLYGELINE							
2334W	I.V. infusion 17.5 g per 500 mL (3.5%) with electrolytes, 500 mL	3	..	..	* 45.32	32.90	Haemaccel	AE
	I.V. solutions							
	• Solutions for parenteral nutrition							
	GLUCOSE							
2245E	I.V. infusion 278 mmol (anhydrous) per L (5%), 1 L	5	1	..	* 25.49	26.52	BX	
	• Solutions affecting the electrolyte balance							
	ELECTROLYTE REPLACEMENT SOLUTION							
3199J	I.V. infusion 1 L	2	1	..	* 21.53	22.56	Plasma-Lyte 148	BX
	SODIUM CHLORIDE							
2264E	I.V. infusion 154 mmol per L (0.9%), 1 L	5	1	..	* 25.49	26.52	BX	
2260Y	I.V. infusion 513 mmol per L (3%), 1 L	2	1	..	* 17.79	18.82	BX	
	SODIUM CHLORIDE COMPOUND							
2266G	I.V. infusion 1 L	4	1	..	* 29.59	30.62	BX	
	SODIUM CHLORIDE with GLUCOSE							
2281C	I.V. infusion 31 mmol-222 mmol (anhydrous) per L (0.18%-4%), 1 L	5	1	..	* 25.49	26.52	BX	
2279Y	I.V. infusion 19 mmol-104 mmol (anhydrous) per 500 mL (0.225%-3.75%), 500 mL	5	1	..	* 31.59	32.62	BX	
2278X	I.V. infusion 39 mmol-69 mmol (anhydrous) per 500 mL (0.45%-2.5%), 500 mL	5	1	..	* 31.59	32.62	BX	
	SODIUM LACTATE COMPOUND							
9416N	I.V. infusion 500 mL	5	1	..	* 19.64	20.67	BR	
2286H	I.V. infusion 1 L	5	1	..	* 25.49	26.52	BX	

CARDIOVASCULAR SYSTEM

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

CARDIOVASCULAR SYSTEM—CONT.

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

CARDIOVASCULAR SYSTEM—CONT.

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

ADRENALINE

Authority Required

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

- (a) *has been assessed to be at significant risk of anaphylaxis by, or in consultation with, a clinical immunologist, allergist, paediatrician or respiratory physician. The name of the specialist consulted must be provided at the time of application for initial supply; or*
- (b) *has been discharged from hospital or an emergency department after treatment with adrenaline for acute allergic reaction with anaphylaxis;*

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

NOTE:

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

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

NOTE:

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

No repeats will be issued.

Vasodilators used in cardiac diseases

• Organic nitrates

GLYCERYL TRINITRATE

1459T	Tablets 600 micrograms, 100	± 1	5	..	11.96	12.99	^a Lycinate	FM
				B1.64	13.60	12.99	^a Anginine Stabilised	SI
8171C	Sublingual spray (pump pack) 400 micrograms per dose (200 doses)	± 1	5	..	19.70	20.73	Nitrolingual Pumpspray	SW

NOTE:

The spray should not be inhaled.

8027L	Transdermal patch releasing approximately 5 mg per 24 hours	30	5	..	28.20	29.23	Minitrans 5	IA
1515R	Transdermal patch releasing approximately 5 mg per 24 hours	30	5	..	28.20	29.23	Transiderm-Nitro 25	NV
8010N	Transdermal patch releasing approximately 5 mg per 24 hours	30	5	..	28.20	29.23	Nitro-Dur 5	SH

continued ➞

CARDIOVASCULAR SYSTEM—CONT.

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

CARDIOVASCULAR SYSTEM—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Proprietary Name and Manufacturer	
PERHEXILINE MALEATE								
CAUTION:								
<i>Regular monitoring of drug serum levels is recommended.</i>								
Authority Required (STREAMLINED)								
1023								
<i>Angina not responding to other therapy.</i>								
1822X	Tablet 100 mg	100	5	..	53.07	32.90	Pexsig	SI
ANTIHYPERTENSIVES								
Antiadrenergic agents, centrally acting								
• Methyldopa								
METHYLDOPA								
1629R	Tablet 250 mg	100	5	..	12.19	13.22	^a Hydopa	AF
				B2.24	14.43	13.22	^a Aldomet	AS
• Imidazoline receptor agonists								
CLONIDINE								
3145M	Tablet 100 micrograms	100	5	..	28.45	29.48	Catapres 100	BY
3141H	Tablet 150 micrograms	100	5	..	37.01	32.90	Catapres	BY
MOXONIDINE								
Restricted Benefit								
<i>Hypertension in patients receiving concurrent antihypertensive therapy.</i>								
9019Q	Tablet 200 micrograms	30	5	..	19.10	20.13	Physiotens	SM
9020R	Tablet 400 micrograms	30	5	..	28.35	29.38	Physiotens	SM
Antiadrenergic agents, peripherally acting								
• Alpha-adrenoceptor antagonists								
PRAZOSIN HYDROCHLORIDE								
1479W	Tablet 1 mg (base)	100	5	..	12.19	13.22	^a Chem mart Prazosin	CH
							^a GenRx Prazosin	GX
							^a Pressin 1	AF
							^a Terry White Chemists	TW
				B2.95	15.14	13.22	^a Prazosin Minipress	PF

continued ➞

CARDIOVASCULAR SYSTEM—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Proprietary Name and Manufacturer	
1480X	Tablet 2 mg (base)	100	5	..	14.50	15.53	^a Chem mart Prazosin	CH
							^a GenRx Prazosin	GX
							^a Pressin 2	AF
							^a Terry White Chemists Prazosin	TW
				B3.04	17.54	15.53	^a Minipress	PF
1478T	Tablet 5 mg (base)	100	5	..	20.42	21.45	^a Chem mart Prazosin	CH
							^a GenRx Prazosin	GX
							^a Pressin 5	AF
							^a Terry White Chemists Prazosin	TW
				B3.29	23.71	21.45	^a Minipress	PF

Arteriolar smooth muscle, agents acting on

• Hydrazinophthalazine derivatives

HYDRALAZINE HYDROCHLORIDE

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

• Pyrimidine derivatives

MINOXIDIL

Authority Required (STREAMLINED)

2759

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

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

DIURETICS

Low-ceiling diuretics, thiazides

• Thiazides, plain

HYDROCHLOROTHIAZIDE

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

Low-ceiling diuretics, excl. thiazides

• Sulfonamides, plain

CHLORTHALIDONE

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

CARDIOVASCULAR SYSTEM—CONT.

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

CARDIOVASCULAR SYSTEM—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Proprietary Name and Manufacturer	
• Aryloxyacetic acid derivatives ETHACRYNIC ACID <u>Restricted Benefit</u> <i>Patients hypersensitive to other oral diuretics.</i>								
8748K	Tablet 25 mg	200	1	..	* 196.87	32.90	Edecrin	FK
Potassium-sparing agents • Aldosterone antagonists EPLERENONE <u>CAUTION:</u> <i>Serum electrolytes should be checked regularly.</i> <u>Authority Required (STREAMLINED)</u> 2637 <i>Heart failure with a left ventricular ejection fraction of 40% or less occurring within 3 to 14 days following an acute myocardial infarction. Treatment with eplerenone must be commenced within 14 days of an acute myocardial infarction.</i> <i>The date of the acute myocardial infarction and the date of initiation of eplerenone treatment must be documented in the patient's medical records when PBS-subsidised treatment is initiated.</i>								
8879H	Tablet 25 mg	30	5	..	112.34	32.90	Inspra	PF
8880J	Tablet 50 mg	30	5	..	112.34	32.90	Inspra	PF
SPIRONOLACTONE <u>CAUTION:</u> <i>Serum electrolytes should be checked regularly.</i> <u>CAUTION:</u> <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	.. B1.84	12.06 13.90	13.09 13.09	^a Spiractin 25 ^a Aldactone	AF PH
2340E	Tablet 100 mg	100	5	.. B2.53	29.89 32.42	30.92 30.92	^a Spiractin 100 ^a Aldactone	AF PH
• Other potassium-sparing agents AMILORIDE HYDROCHLORIDE <u>CAUTION:</u> <i>Serum electrolytes should be checked regularly.</i>								
3109P	Tablet 5 mg	100	1	..	* 10.55	11.58	Kaluril	AF

CARDIOVASCULAR SYSTEM—CONT.

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

PERIPHERAL VASODILATORS

Peripheral vasodilators

• Other peripheral vasodilators

PHENOXYBENZAMINE HYDROCHLORIDE

Restricted Benefit

Phaeochromocytoma;

Neurogenic urinary retention.

1862B	Capsule 10 mg	100	5	..	66.93	32.90	Dibenyline	GH
1166J	Capsules 10 mg, 30	3	5	..	* 204.47	32.90	Dibenyline	GH
9286R	Capsules 10 mg, 100	‡ 1	5	..	1411.57	32.90	Dibenzyliline	GH

BETA BLOCKING AGENTS

Beta blocking agents

• Beta blocking agents, non-selective

OXPRENOLOL HYDROCHLORIDE

2942W	Tablet 20 mg	100	5	..	9.57	10.60	Corbeton 20	AF
2961W	Tablet 40 mg	100	5	..	11.35	12.38	Corbeton 40	AF
PINDOLOL								
3062E	Tablet 5 mg	100	5	..	11.05	12.08	^a Barbloc 5	AF
				b2.71	13.76	12.08	^a Visken 5	NV
3065H	Tablet 15 mg	50	5	..	13.28	14.31	^a Barbloc 15	AF
				b2.69	15.97	14.31	^a Visken 15	NV

CARDIOVASCULAR SYSTEM—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Proprietary Name and Manufacturer	
PROPRANOLOL HYDROCHLORIDE								
2565B	Tablet 10 mg	100	5	..	9.76	10.79	Deralin 10	AF
				B3.14	12.90	10.79	Inderal	AP
2566C	Tablet 40 mg	100	5	..	10.13	11.16	Deralin 40	AF
				B3.14	13.27	11.16	Inderal	AP
2899N	Tablet 160 mg	50	5	..	10.58	11.61	Deralin 160	AF

SOTALOL HYDROCHLORIDE

For listings see Generic/Proprietary Index

• **Beta blocking agents, selective**

ATENOLOL

1081X	Tablet 50 mg	30	5	..	9.84	10.87	a Atehexal	SZ
							a Atenolol-GA	GN
							a Chem mart	CH
							Atenolol	
							a GenRx Atenolol	GX
							a Noten	AF
							a Tensig	SI
							a Terry White	TW
							Chemists	
							Atenolol	
				B3.54	13.38	10.87	a Tenormin	AP

BISOPROLOL FUMARATE

Authority Required (STREAMLINED)

1734

Moderate to severe heart failure in patients stabilised on conventional therapy which must include an ACE-inhibitor if tolerated.

8604W	Tablet 2.5 mg	28	5	..	55.08	32.90	Bicor	AL
8605X	Tablet 5 mg	28	5	..	67.32	32.90	Bicor	AL
8606Y	Tablet 10 mg	28	5	..	82.63	32.90	Bicor	AL

METOPROLOL SUCCINATE

Authority Required (STREAMLINED)

1734

Moderate to severe heart failure in patients stabilised on conventional therapy which must include an ACE-inhibitor if tolerated.

8732N	Tablet 23.75 mg (controlled release)	15	..	..	20.61	21.64	Toprol-XL 23.75	AP
8733P	Tablet 47.5 mg (controlled release)	30	5	..	72.03	32.90	Toprol-XL 47.5	AP
8734Q	Tablet 95 mg (controlled release)	30	5	..	88.53	32.90	Toprol-XL 95	AP

continued ☞

CARDIOVASCULAR SYSTEM—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 \$			
8735R	Tablet 190 mg (controlled release)	30	5	..	109.17	32.90		Toprol-XL 190	AP
	METOPROLOL TARTRATE								
1324Q	Tablet 50 mg	100	5	..	10.41	11.44	a	Chem mart	CH
								Metoprolol	
							a	GenRx Metoprolol	GX
							a	Metohexal	SZ
							a	Metolol	GM
							a	Metrol 50	SI
							a	Minax 50	AF
							a	Terry White	TW
								Chemists	
								Metoprolol	
				B2.35	12.76	11.44		Lopresor 50	NV
				B3.25	13.66	11.44	a	Betaloc	AP
1325R	Tablet 100 mg	60	5	..	11.60	12.63	a	Chem mart	CH
								Metoprolol	
							a	GenRx Metoprolol	GX
							a	Metohexal	SZ
							a	Metolol	GM
							a	Metrol 100	SI
							a	Minax 100	AF
							a	Terry White	TW
								Chemists	
								Metoprolol	
				B2.35	13.95	12.63		Lopresor 100	NV
				B3.25	14.85	12.63	a	Betaloc	AP

CARDIOVASCULAR SYSTEM—CONT.

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

continued ➞

CARDIOVASCULAR SYSTEM—CONT.

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

Code	Name, Restriction, Manner of 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								
<u>NOTE:</u>								
The base-priced drugs in this therapeutic group are amlodipine, felodipine and nifedipine (except nifedipine controlled release tablet 20 mg).								
AMLODIPINE								
2751T	Tablet 5 mg (as besylate)	30	5	..	16.46	17.49	a Amlodipine-GA a Amlodipine generichealth a Amlodipine Sandoz a APO-Amlodipine a Chem mart Amlodipine a Ozlodip a Perivasc a Pharmacor Amlodipine 5 a Terry White Chemists Amlodipine	GM GQ SZ TX CH RA AF CR TW
					B3.91	20.37	a Norvasc	PF
1343Q	Tablet 5 mg (as maleate)	30	5	..	16.46	17.49	a Amlo 5	ZP
<u>NOTE:</u>								
Bioequivalence has been demonstrated between the tablet containing 5 mg amlodipine (as besylate) and the tablet containing 5 mg amlodipine (as maleate).								
2752W	Tablet 10 mg (as besylate)	30	5	..	24.40	25.43	a Amlodipine-GA a Amlodipine generichealth a Amlodipine Sandoz a APO-Amlodipine a Chem mart Amlodipine a Ozlodip a Perivasc a Pharmacor Amlodipine 10 a Terry White Chemists Amlodipine	GM GQ SZ TX CH RA AF CR TW
					B5.68	30.08	a Norvasc	PF
1345T	Tablet 10 mg (as maleate)	30	5	..	24.40	25.43	a Amlo 10	ZP
<u>NOTE:</u>								
Bioequivalence has been demonstrated between the tablet containing 10 mg amlodipine (as besylate) and the tablet containing 10 mg amlodipine (as maleate).								

CARDIOVASCULAR SYSTEM—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Proprietary Name and Manufacturer	
FELODIPINE								
2361G	Tablet 2.5 mg (extended release)	30	5	.. B5.00	13.05 18.05	14.08 14.08	^a Felodur ER 2.5 mg ^a Plendil ER	AL AP
2366M	Tablet 5 mg (extended release)	30	5	.. B5.00	15.71 20.71	16.74 16.74	^a Felodil XR 5 ^a Felodur ER 5 mg ^a Plendil ER	SI AL AP
2367N	Tablet 10 mg (extended release)	30	5	.. B5.00	23.38 28.38	24.41 24.41	^a Felodil XR 10 ^a Felodur ER 10 mg ^a Plendil ER	SI AL AP
LERCANIDIPINE HYDROCHLORIDE								
8534E	Tablet 10 mg	30	5	T2.01	22.04	21.06	Zanidip	SM
8679T	Tablet 20 mg	30	5	T4.02	33.04	30.05	Zanidip	SM
LERCANIDIPINE HYDROCHLORIDE								
Authority Required								
<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>								
8939L	Tablet 10 mg	30	5	..	22.04	23.07	Zanidip	SM
8940M	Tablet 20 mg	30	5	..	33.04	32.90	Zanidip	SM
NIFEDIPINE								
1694E	Tablet 10 mg	60	5	.. B1.17	15.43 16.60	16.46 16.46	^a Adefin 10 ^a Nypine 10 ^a Adalat 10	AF AW BN
1695F	Tablet 20 mg	60	5	.. B2.21	17.74 19.95	18.77 18.77	^a Adefin 20 ^a GenRx Nifedipine ^a Nifehexal ^a Nyefax 20 mg ^a Nypine 20 ^a Adalat 20	AF GX SZ GM AW BN
8610E	Tablet 20 mg (controlled release)	30	5	T2.26	19.97	18.74	Adalat Oros 20mg	BN
1906H	Tablet 30 mg (controlled release)	30	5	.. B2.54	18.64 21.18	19.67 19.67	^a Addos XR 30 ^a Adefin XL 30 ^a Adalat Oros 30	SI AF BN

continued ➡

CARDIOVASCULAR SYSTEM—CONT.

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

NIFEDIPINE

Authority Required

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

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

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

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

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

Selective calcium channel blockers with direct cardiac effects

• Phenylalkylamine derivatives

VERAPAMIL HYDROCHLORIDE

CAUTION:

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

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

CARDIOVASCULAR SYSTEM—CONT.

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

CARDIOVASCULAR SYSTEM—CONT.

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

AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM

ACE inhibitors, plain

• **ACE inhibitors, plain**

CAUTION:

Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

CAPTOPRIL

1147J	Tablet 12.5 mg	90	5	..	16.25	17.28	^a Acenorm 12.5 mg	AF
							^a Captohexal	SZ
							^a GenRx Captopril	GX
							^a GM	
1148K	Tablet 25 mg	90	5	..	20.84	21.87	^a Acenorm 25 mg	AF
							^a Captohexal	SZ
							^a GenRx Captopril	GX
							^a GM	
1149L	Tablet 50 mg	90	5	B3.67	24.51	21.87	^a Capoten	BQ
				..	35.27	32.90	^a Acenorm 50 mg	AF
							^a Captohexal	SZ
							^a GenRx Captopril	GX
				B3.66	38.93	32.90	^a GM	
							^a Capoten	BQ

CAPTOPRIL

Restricted Benefit

For patients unable to take a solid dose form of an ACE inhibitor.

8760C	Oral solution 5 mg per mL, 95 mL	± 1	5	..	111.39	32.90	Capoten	BQ

CARDIOVASCULAR SYSTEM—CONT.

					Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$		
Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium			Proprietary Name and Manufacturer	
ENALAPRIL MALEATE								
1370D	Tablet 5 mg	30	5	..	12.71	13.74	a Alphapril	AF
							a Auspril	SI
							a Chem mart	CH
							Enalapril	
							a Enahexal	SZ
							a Enalabell	BF
							a Enalapril-DP 5mg	GM
							a Enalapril	GQ
							generichealth	
							a Enalapril Winthrop	WA
							a GenRx Enalapril	GX
							a Terry White	TW
							Chemists	
Enalapril								
1368B	Tablet 10 mg	30	5	..	17.02	18.05	a Renitec M	MK
1369C	Tablet 20 mg	30	5	..	20.03	21.06	a Alphapril	AF
							a Auspril	SI
							a Chem mart	CH
							Enalapril	
							a Enahexal	SZ
							a Enalabell	BF
							a Enalapril-DP 20mg	GM
							a Enalapril	GQ
							generichealth	
							a GenRx Enalapril	GX
							a Terry White	TW
							Chemists	
							Enalapril	

CARDIOVASCULAR SYSTEM—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 \$		
FOSINOPRIL SODIUM								
1182F	Tablet 10 mg	30	5	..	15.22	16.25	a Fosinopril Sandoz	SZ
							a Fosipril 10	SI
							a GenRx Fosinopril	GX
							a Monace 10	AF
							a Monopril	BQ
1183G	Tablet 20 mg	30	5	..	19.82	20.85	a Fosinopril Sandoz	SZ
							a Fosipril 20	SI
							a GenRx Fosinopril	GX
							a Monace 20	AF
							a Monopril	BQ
LISINOPRIL								
2456G	Tablet 5 mg	30	5	..	13.70	14.73	a APO-Lisinopril	TX
							a Chem mart	CH
							Lisinopril	
							a Fibsol 5	SI
							a GenRx Lisinopril	GX
							a Liprace	GM
							a Lisinobell	BF
							a Lisinopril 5	CR
							a Lisinopril	GQ
							generichealth	
							a Lisinopril Hexal	HX
							a Lisinopril Ranbaxy	RA
							a Lisinopril Winthrop	WA
							a Lisodur	AF
							a Terry White Chemists Lisinopril	TW
				b2.08	15.78	14.73	a Zestril	AP
				b3.35	17.05	14.73	a Prinivil 5	MK

continued ➞

CARDIOVASCULAR SYSTEM—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 \$		
2457H	Tablet 10 mg	30	5	..	17.56	18.59	a APO-Lisinopril	TX
							a Chem mart	CH
							Lisinopril	
							a Fibsol 10	SI
							a GenRx Lisinopril	GX
							a Liprace	GM
							a Lisinobell	BF
							a Lisinopril 10	CR
							a Lisinopril	GQ
							generichealth	
							a Lisinopril Hexal	HX
							a Lisinopril Ranbaxy	RA
							a Lisinopril Winthrop	WA
							a Lisodur	AF
							a Terry White Chemists	TW
							Lisinopril	
2458J	Tablet 20 mg	30	5	..	20.56	21.59	a Zestril	AP
							a Prinivil 10	MK
							Lisinopril	
							a Fibsol 20	SI
							a GenRx Lisinopril	GX
							a Liprace	GM
							a Lisinobell	BF
							a Lisinopril 20	CR
							a Lisinopril	GQ
							generichealth	
							a Lisinopril Hexal	HX
							a Lisinopril Ranbaxy	RA
							a Lisinopril Winthrop	WA
							a Lisodur	AF
							a Terry White Chemists	TW
							Lisinopril	
					B2.08	22.64	a Zestril	AP
					B3.35	23.91	a Prinivil 20	MK

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Proprietary Name and Manufacturer	
PERINDOPRIL								
3050M	Tablet containing 2 mg perindopril erbumine	30	5	..	12.96	13.99	a Chem mart Perindopril a GenRx Perindopril a Indopril 2 a Perindo a Perindopril 2 a Perindopril-DP a Terry White Chemists Perindopril	CH GX SI AF CR GM TW
9006B	Tablet containing 2.5 mg perindopril arginine	30	5	..	12.96	13.99	a Coversyl 2.5mg	SE
<u>NOTE:</u> Bioequivalence has been demonstrated between perindopril erbumine 2 mg and perindopril arginine 2.5 mg.								
3051N	Tablet containing 4 mg perindopril erbumine	30	5	..	18.64	19.67	a Chem mart Perindopril a GenRx Perindopril a Indopril 4 a Perindo a Perindopril 4 a Perindopril-DP a Terry White Chemists Perindopril	CH GX SI AF CR GM TW
9007C	Tablet containing 5 mg perindopril arginine	30	5	..	18.64	19.67	a Coversyl 5mg	SE
<u>NOTE:</u> Bioequivalence has been demonstrated between perindopril erbumine 4 mg and perindopril arginine 5 mg.								
8704D	Tablet containing 8 mg perindopril erbumine	30	5	..	25.16	26.19	a Chem mart Perindopril a GenRx Perindopril a Indopril 8 a Perindo a Perindopril 8 a Perindopril-DP a Terry White Chemists Perindopril	CH GX SI AF CR GM TW
9008D	Tablet containing 10 mg perindopril arginine	30	5	..	25.16	26.19	a Coversyl 10mg	SE
<u>NOTE:</u> Bioequivalence has been demonstrated between perindopril erbumine 8 mg and perindopril arginine 10 mg.								

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
QUINAPRIL HYDROCHLORIDE							
1968N	Tablet 5 mg (base)	30	5	..	13.75	14.78	a Acquin 5 SI a APO-Quinapril TX a Filpril AF a Pharmacor CR Quinapril 5 a Quinapril-DP GM a Quinapril GQ generichealth a Quinapril Sandoz SZ a Accupril PF
				B0.49	14.24	14.78	
1969P	Tablet 10 mg (base)	30	5	..	17.00	18.03	a Acquin 10 SI a APO-Quinapril TX a Filpril AF a Pharmacor CR Quinapril 10 a Quinapril-DP GM a Quinapril GQ generichealth a Accupril PF
				B0.66	17.66	18.03	
1970Q	Tablet 20 mg (base)	30	5	..	19.61	20.64	a Acquin 20 SI a APO-Quinapril TX a Filpril AF a Pharmacor CR Quinapril 20 a Quinapril-DP GM a Quinapril GQ generichealth a Quinapril Sandoz SZ a Accupril PF
				B0.99	20.60	20.64	
RAMIPRIL							
1944H	Tablet 1.25 mg	30	5	..	11.17	12.20	a Prilace 1.25 SI a Ramace 1.25 mg AV a Ramipril Sandoz SZ a Ramipril Winthrop WA a Tritace 1.25 mg SW a Tryzan Tabs 1.25 AF
9120B	Capsule 1.25 mg	30	5	..	11.17	12.20	a Pharmacor CR Ramipril 1.25 a Ramipril-DP GM a Ramipril GQ generichealth a Tryzan Caps 1.25 AF

NOTE:

Ramipril 1.25 mg tablets and capsules are bioequivalent.

continued 

CARDIOVASCULAR SYSTEM—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Proprietary Name and Manufacturer	
1945J	Tablet 2.5 mg	30	5	..	13.57	14.60	a Prilace 2.5	SI
							a Ramace 2.5 mg	AV
							a Ramipril Sandoz	SZ
							a Ramipril Winthrop	WA
							a Tritace 2.5 mg	SW
							a Tryzan Tabs 2.5	AF
9121C	Capsule 2.5 mg	30	5	..	13.57	14.60	a Pharmacor Ramipril 2.5	CR
							a Ramipril-DP	GM
							a Ramipril generichealth	GQ
							a Tryzan Caps 2.5	AF
NOTE: Ramipril 2.5 mg tablets and capsules are bioequivalent.								
1946K	Tablet 5 mg	30	5	..	15.50	16.53	a Prilace 5	SI
							a Ramace 5 mg	AV
							a Ramipril Sandoz	SZ
							a Ramipril Winthrop	WA
							a Tritace 5 mg	SW
							a Tryzan Tabs 5	AF
9122D	Capsule 5 mg	30	5	..	15.50	16.53	a Pharmacor Ramipril 5	CR
							a Ramipril-DP	GM
							a Ramipril generichealth	GQ
							a Tryzan Caps 5	AF
NOTE: Ramipril 5 mg tablets and capsules are bioequivalent.								
1316G	Tablet 10 mg	30	5	..	22.80	23.83	a Ramipril Sandoz	SZ
							a Tritace	SW
							a Tryzan Tabs 10	AF
8470T	Capsule 10 mg	30	5	..	22.80	23.83	a GenRx Ramipril	GX
							a Pharmacor Ramipril 10	CR
							a Prilace 10	SI
							a Ramace 10 mg	AV
							a Ramipril-DP	GM
							a Ramipril generichealth	GQ
							a Ramipril Sandoz	SZ
							a Ramipril Winthrop	WA
							a Tritace 10 mg	SW
							a Tryzan Caps 10	AF

NOTE:
Ramipril 10 mg tablets and capsules are bioequivalent.

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	
8668F	Pack containing 7 tablets 2.5 mg, 21 tablets 5 mg and 10 capsules 10 mg	‡ 1	..	..	21.60	22.63	Tritace Titration Pack	SW
	TRANDOLAPRIL							
2791X	Capsule 500 micrograms	28	5	..	9.87	10.90	^a APO-Trandolapril ^a Dolapril 0.5 ^a Tranalpha ^a Trandolapril-DP	TX SI AF GM
				B1.57	11.44	10.90	^a Gopten	AB
2792Y	Capsule 1 mg	28	5	..	14.64	15.67	^a APO-Trandolapril ^a Dolapril 1 ^a Tranalpha ^a Trandolapril-DP	TX SI AF GM
				B1.57	16.21	15.67	^a Gopten	AB
2793B	Capsule 2 mg	28	5	..	15.80	16.83	^a APO-Trandolapril ^a Dolapril 2 ^a Tranalpha ^a Trandolapril-DP	TX SI AF GM
				B1.58	17.38	16.83	^a Gopten	AB
8758Y	Capsule 4 mg	28	5	..	24.23	25.26	^a APO-Trandolapril ^a Dolapril 4 ^a Tranalpha ^a Trandolapril-DP	TX SI AF GM
				B1.57	25.80	25.26	^a Gopten	AB

ACE inhibitors, combinations

CAUTION:

Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

• **ACE inhibitors and diuretics**

ENALAPRIL MALEATE with HYDROCHLOROTHIAZIDE

Restricted Benefit

Hypertension in patients who are not adequately controlled with 20 mg enalapril maleate.

8477E	Tablet 20 mg-6 mg	30	5	..	28.50	29.53	^a Enalapril/HCT Sandoz ^a Renitec Plus 20/6	SZ 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	
FOSINOPRIL SODIUM with HYDROCHLOROTHIAZIDE								
<u>Restricted Benefit</u> <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	..	21.83	22.86	^a APO-Fosinopril HCTZ 10/12.5	TX
							^a Fosinopril/HCT Sandoz 10mg/ 12.5mg	SZ
							^a Hyforil	RA
							^a Monoplus 10/12.5	BQ
8401E	Tablet 20 mg-12.5 mg	30	5	..	29.24	30.27	^a APO-Fosinopril HCTZ 20/12.5	TX
							^a Fosetic 20/12.5	ZP
							^a Fosinopril/HCT Sandoz 20mg/ 12.5mg	SZ
							^a Hyforil	RA
							^a Monoplus 20/12.5	BQ
PERINDOPRIL with INDAPAMIDE HEMIHYDRATE								
2190G	Tablet containing 2.5 mg perindopril arginine-0.625 mg indapamide hemihydrate	30	5	..	16.31	17.34	Coversyl Plus LD 2.5mg/0.625mg	SE
<u>PERINDOPRIL with INDAPAMIDE HEMIHYDRATE</u>								
<u>Restricted Benefit</u> <i>Hypertension in patients who are not adequately controlled with indapamide and/or perindopril.</i>								
8449Q	Tablet containing 4 mg perindopril erbumine-1.25 mg indapamide hemihydrate	30	5	..	29.15	30.18	^a Chem mart Perindopril/ Indapamide 4/ 1.25	CH
							^a GenRx Perindopril/ Indapamide 4/ 1.25	GX
							^a Perindo Combi 4/ 1.25	AF
							^a Terry White Chemists Perindopril/ Indapamide 4/ 1.25	TW

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	
2845R	Tablet containing 5 mg perindopril arginine-1.25 mg indapamide hemihydrate	30	5	..	29.15	30.18	^a Coversyl Plus 5mg/ 1.25mg	SE
NOTE: Bioequivalence has been demonstrated between perindopril erbumine/indapamide hemihydrate tablet 4 mg-1.25 mg and perindopril arginine/indapamide hemihydrate tablet 5 mg-1.25 mg.								
QUINAPRIL HYDROCHLORIDE with HYDROCHLOROTHIAZIDE								
Restricted Benefit Hypertension in patients who are not adequately controlled with either hydrochlorothiazide or quinapril hydrochloride monotherapy.								
8589C	Tablet 10 mg (base)-12.5 mg	30	5	..	19.22	20.25	Accuretic 10/ 12.5mg	PF
8590D	Tablet 20 mg (base)-12.5 mg	30	5	..	21.83	22.86	Accuretic 20/ 12.5mg	PF
• ACE inhibitors and calcium channel blockers								
LERCANIDIPINE HYDROCHLORIDE with ENALAPRIL MALEATE								
Restricted Benefit Hypertension in a patient who is not adequately controlled with either lercanidipine hydrochloride or enalapril maleate monotherapy.								
9144G	Tablet 10 mg-10 mg	30	5	..	31.06	32.09	Zan-Extra 10/10	SM
9145H	Tablet 10 mg-20 mg	30	5	..	34.07	32.90	Zan-Extra 10/20	SM
RAMIPRIL with FELODIPINE								
Restricted Benefit Hypertension in a patient not adequately controlled with either ramipril or felodipine monotherapy.								
2626F	Tablet 2.5 mg-2.5 mg (modified release)	30	5	..	20.63	21.66	Triasyn 2.5/2.5	SW
2629J	Tablet 5 mg-5 mg (modified release)	30	5	..	25.22	26.25	Triasyn 5.0/5.0	SW
TRANDOLAPRIL with VERAPAMIL HYDROCHLORIDE								
CAUTION: The myocardial depressant effects of verapamil hydrochloride and of beta-blocking drugs are additive.								
Restricted Benefit Hypertension in a patient who is not adequately controlled with either trandolapril or verapamil hydrochloride sustained release monotherapy.								
9387C	Tablet 2 mg-180 mg (sustained release)	28	5	..	22.95	23.98	Tarka 2/180	AB
2857J	Tablet 4 mg-240 mg (sustained release)	28	5	..	33.31	32.90	Tarka 4/240	AB

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	
Angiotensin II antagonists, plain								
• Angiotensin II antagonists, plain								
CANDESARTAN CILEXETIL								
8295N	Tablet 4 mg	30	5	..	20.49	21.52	Atacand	AP
8296P	Tablet 8 mg	30	5	..	24.30	25.33	Atacand	AP
8297Q	Tablet 16 mg	30	5	..	30.13	31.16	Atacand	AP
8889W	Tablet 32 mg	30	5	..	46.19	32.90	Atacand	AP
EPROSARTAN MESYLATE								
8397Y	Tablet 400 mg (base)	56	5	11.52	* 32.17	31.68	Teveten	SM
8447N	Tablet 600 mg (base)	28	5	..	30.60	31.63	Teveten	SM
EPROSARTAN MESYLATE								
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>								
8951D	Tablet 400 mg (base)	56	5	..	* 32.17	32.90	Teveten	SM
IRBESARTAN								
8246B	Tablet 75 mg	30	5	..	20.68	21.71	^a Avapro ^a Karvea	BQ SW
8247C	Tablet 150 mg	30	5	..	24.72	25.75	^a Avapro ^a Karvea	BQ SW
8248D	Tablet 300 mg	30	5	..	29.81	30.84	^a Avapro ^a Karvea	BQ SW
OLMESARTAN MEDOXOMIL								
2147B	Tablet 20 mg	30	5	..	24.72	25.75	Olmotec	SH
2148C	Tablet 40 mg	30	5	..	29.81	30.84	Olmotec	SH
TELMISARTAN								
8355R	Tablet 40 mg	28	5	..	21.23	22.26	Micardis	BY
8356T	Tablet 80 mg	28	5	..	28.48	29.51	Micardis	BY

CARDIOVASCULAR SYSTEM—CONT.

					Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$		
Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium			Proprietary Name and Manufacturer	
	VALSARTAN							
9368C	Tablet 40 mg	28	..	..	15.58	16.61	Diovan	NV
9369D	Tablet 80 mg	28	5	..	19.70	20.73	Diovan	NV
9370E	Tablet 160 mg	28	5	..	23.47	24.50	Diovan	NV
9371F	Tablet 320 mg	28	5	..	28.22	29.25	Diovan	NV

NOTE:

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

Angiotensin II antagonists, combinations

- **Angiotensin II antagonists and diuretics**

**CANDESARTAN CILEXETIL with
HYDROCHLOROTHIAZIDE**
Restricted Benefit

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

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

**EPROSARTAN MESYLATE with
HYDROCHLOROTHIAZIDE**
Restricted Benefit

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

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

IRBESARTAN with HYDROCHLOROTHIAZIDE
Restricted Benefit

Hypertension in patients who are not adequately controlled with either hydrochlorothiazide or irbesartan monotherapy.

8404H	Tablet 150 mg-12.5 mg	30	5	..	26.94	27.97	^a Avapro HCT 150/ 12.5 ^a Karvezide 150/12.5	BQ SW
8405J	Tablet 300 mg-12.5 mg	30	5	..	32.03	32.90	^a Avapro HCT 300/ 12.5 ^a Karvezide 300/12.5	BQ SW
2136K	Tablet 300 mg-25 mg	30	5	..	34.26	32.90	^a Avapro HCT 300/ 25 ^a Karvezide 300/25	BQ SW

CARDIOVASCULAR SYSTEM—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Proprietary Name and Manufacturer	
OLMESARTAN MEDOXOMIL with HYDROCHLOROTHIAZIDE								
<u>Restricted Benefit</u> <i>Hypertension in patients who are not adequately controlled with either hydrochlorothiazide or olmesartan medoxomil monotherapy.</i>								
2161R	Tablet 20 mg-12.5 mg	30	5	..	26.93	27.96	Olmotec Plus	SH
2166B	Tablet 40 mg-12.5 mg	30	5	..	32.01	32.90	Olmotec Plus	SH
2170F	Tablet 40 mg-25 mg	30	5	..	34.26	32.90	Olmotec Plus	SH
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	..	23.30	24.33	Micardis Plus 40/ 12.5 mg	BY
8623W	Tablet 80 mg-12.5 mg	28	5	..	30.55	31.58	Micardis Plus 80/ 12.5 mg	BY
9381R	Tablet 80 mg-25 mg	28	5	..	32.64	32.90	Micardis Plus 80/ 25 mg	BY
VALSARTAN with HYDROCHLOROTHIAZIDE								
<u>Restricted Benefit</u> <i>Hypertension in patients who are not adequately controlled with either hydrochlorothiazide or valsartan monotherapy.</i>								
9372G	Tablet 80 mg-12.5 mg	28	5	..	21.78	22.81	Co-Diovan 80/12.5	NV
9373H	Tablet 160 mg-12.5 mg	28	5	..	25.55	26.58	Co-Diovan 160/ 12.5	NV
9374J	Tablet 160 mg-25 mg	28	5	..	27.63	28.66	Co-Diovan 160/25	NV
• Angiotensin II antagonists and calcium channel blockers								
AMLODIPINE with VALSARTAN								
<u>Restricted Benefit</u> <i>Hypertension in patients who are not adequately controlled with either amlodipine or valsartan monotherapy.</i>								
9375K	Tablet 5 mg (as besylate)-80 mg	28	5	..	29.47	30.50	Exforge 5/80	NV
9376L	Tablet 5 mg (as besylate)-160 mg	28	5	..	33.25	32.90	Exforge 5/160	NV
9377M	Tablet 10 mg (as besylate)-160 mg	28	5	..	40.64	32.90	Exforge 10/160	NV

CARDIOVASCULAR SYSTEM—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 \$	

LIPID MODIFYING AGENTS

GENERAL STATEMENT FOR LIPID-LOWERING DRUGS PRESCRIBED AS PHARMACEUTICAL BENEFITS

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

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

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

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

continued ➞

CARDIOVASCULAR SYSTEM—CONT.

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

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

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

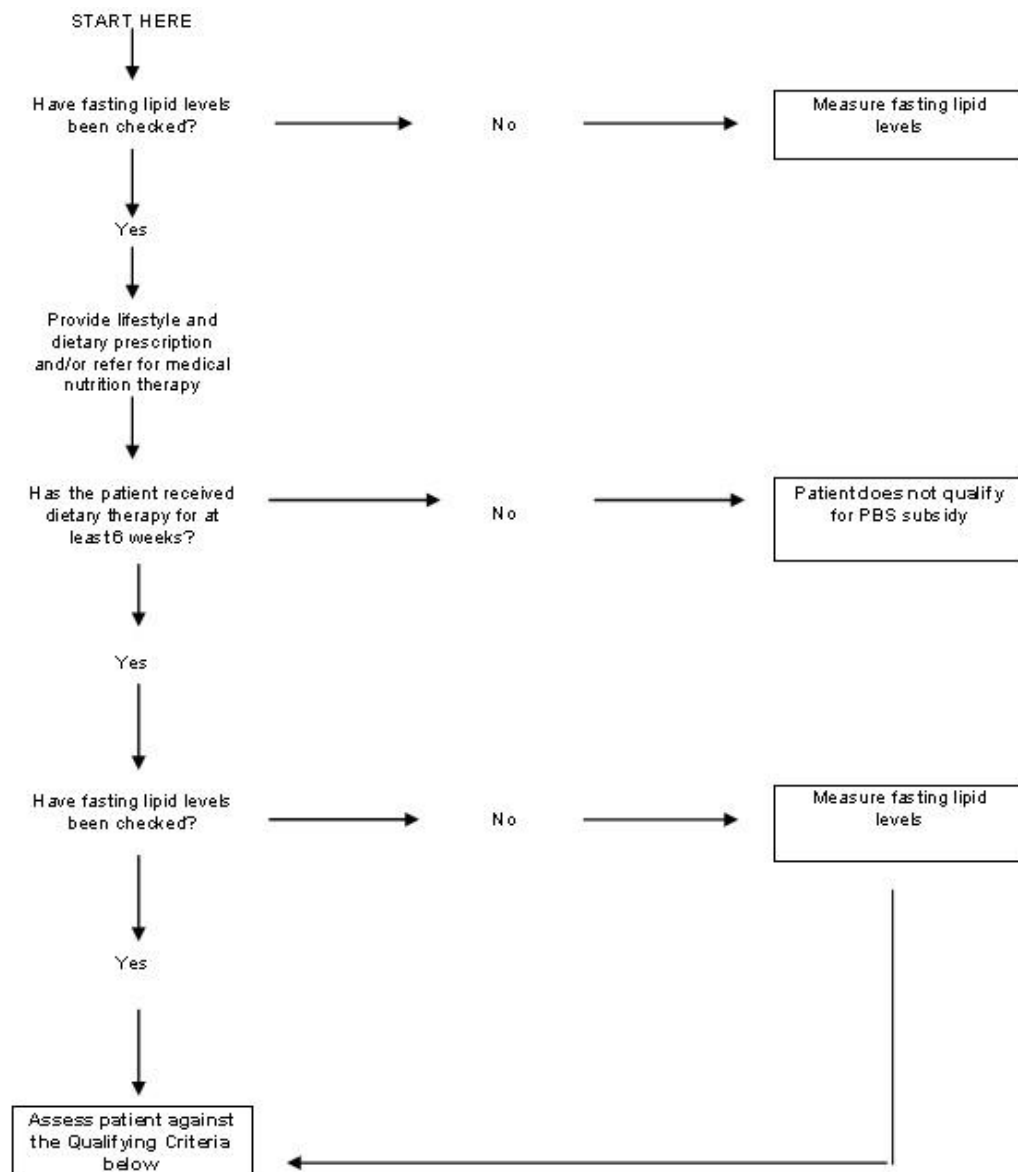
- coronary heart disease which has become symptomatic
- cerebrovascular disease which has become symptomatic
- peripheral vascular disease which has become symptomatic
- diabetes mellitus with microalbuminuria (defined as urinary albumin excretion rate of >20mcg/min or urinary albumin to creatinine ratio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

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

continued ➡

CARDIOVASCULAR SYSTEM—CONT.

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



continued ➞

CARDIOVASCULAR SYSTEM—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 \$	

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

Patients with diabetes mellitus not otherwise included

Aboriginal or Torres Strait Islander patients
Patients with hypertension

Patients with HDL cholesterol < 1 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

LIPID LEVELS FOR PBS SUBSIDY

total cholesterol > 5.5 mmol/L

total cholesterol > 6.5 mmol/L
or
total cholesterol > 5.5 mmol/L and
HDL cholesterol < 1 mmol/L

total cholesterol > 6.5 mmol/L

If aged 18 years or less at treatment initiation:
LDL cholesterol > 4 mmol/L

If aged more than 18 years at treatment initiation:
LDL cholesterol > 5 mmol/L
or
total cholesterol > 6.5 mmol/L
or
total cholesterol > 5.5 mmol/L and
HDL cholesterol < 1 mmol/L

continued 

CARDIOVASCULAR SYSTEM—CONT.

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

Patients not eligible under the above:

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

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

Patients not otherwise included

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

Lipid modifying agents, plain

- **HMG CoA reductase inhibitors**
ATORVASTATIN CALCIUM

Restricted Benefit

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

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

Restricted Benefit

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

NOTE:

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

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

CARDIOVASCULAR SYSTEM—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Proprietary Name and Manufacturer	
FLUVASTATIN SODIUM								
<u>Restricted Benefit</u>								
<i>For use in patients that meet the criteria set out in the General Statement for Lipid-Lowering Drugs.</i>								
8023G	Capsule 20 mg (fluvastatin)	28	5	..	26.22	27.25	^a Lescol	NV
				B3.28	29.50	27.25	^a Vastin	NM
8024H	Capsule 40 mg (fluvastatin)	28	5	..	30.78	31.81	^a Lescol	NV
				B3.58	34.36	31.81	^a Vastin	NM
2863Q	Tablet 80 mg (fluvastatin) (prolonged release)	28	5	..	47.14	32.90	Lescol XL	NV

Restricted Benefit

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

NOTE:

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

9234B	Capsule 20 mg (fluvastatin)	28	11	..	26.22	27.25	^a Lescol	NV
				B3.28	29.50	27.25	^a Vastin	NM
9235C	Capsule 40 mg (fluvastatin)	28	11	..	30.78	31.81	^a Lescol	NV
				B3.58	34.36	31.81	^a Vastin	NM
9236D	Tablet 80 mg (fluvastatin) (prolonged release)	28	11	..	47.14	32.90	Lescol XL	NV

CARDIOVASCULAR SYSTEM—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Proprietary Name and Manufacturer
PRAVASTATIN SODIUM							
<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	..	21.23	22.26	^a Chem mart CH Pravastatin ^a Cholstat 10 AF ^a GenRx Pravastatin GX ^a Lipostat 10 SI ^a Liprachol SZ ^a Pravastatin 10 CR ^a Pravastatin-DP GM ^a Pravastatin-GA 10 GN ^a Pravastatin GQ generichealth ^a Pravastatin WA Winthrop ^a Terry White TW Chemists Pravastatin ^a Pravachol BQ
				B3.52	24.75	22.26	
2834E	Tablet 20 mg	30	5	..	30.20	31.23	^a APO-Pravastatin TX Pravastatin CH ^a Cholstat 20 AF ^a GenRx Pravastatin GX ^a Lipostat 20 SI ^a Liprachol SZ ^a Pravastatin 20 CR ^a Pravastatin-DP GM ^a Pravastatin-GA 20 GN ^a Pravastatin GQ generichealth ^a Pravastatin WA Winthrop ^a Terry White TW Chemists Pravastatin ^a Vastoran RA ^a Pravachol BQ
				B3.52	33.72	31.23	

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CARDIOVASCULAR SYSTEM—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 \$	
Restricted Benefit							
<i>For use in patients who meet the criteria set out in the General Statement for Lipid-Lowering Drugs, and who are receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements.</i>							
NOTE:							
<i>No applications for increased maximum quantities and/or repeats will be authorised.</i>							
9237E	Tablet 10 mg	30	11	..	21.23	22.26	^a Chem mart CH
							Pravastatin
							^a Cholstat 10 AF
							^a GenRx Pravastatin GX
							^a Lipostat 10 SI
							^a Liprachol SZ
							^a Pravastatin 10 CR
							^a Pravastatin-DP GM
							^a Pravastatin-GA 10 GN
							^a Pravastatin GQ
							generichealth
							^a Pravastatin WA
							Winthrop
							^a Terry White TW
							Chemists
							Pravastatin
				B3.52	24.75	22.26	^a Pravachol BQ
9238F	Tablet 20 mg	30	11	..	30.20	31.23	^a APO-Pravastatin TX
							^a Chem mart CH
							Pravastatin
							^a Cholstat 20 AF
							^a GenRx Pravastatin GX
							^a Lipostat 20 SI
							^a Liprachol SZ
							^a Pravastatin 20 CR
							^a Pravastatin-DP GM
							^a Pravastatin-GA 20 GN
							^a Pravastatin GQ
							generichealth
							^a Pravastatin WA
							Winthrop
							^a Terry White TW
							Chemists
							Pravastatin
							^a Vastoran RA
				B3.52	33.72	31.23	^a Pravachol BQ

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CARDIOVASCULAR SYSTEM—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Proprietary Name and Manufacturer	
9239G	Tablet 40 mg	30	11	..	43.27	32.90	^a APO-Pravastatin	TX
							^a Chem mart	CH
							Pravastatin	
							^a Cholstat 40	AF
							^a GenRx Pravastatin	GX
							^a Lipostat 40	SI
							^a Liprachol	SZ
							^a Pravastatin 40	CR
							^a Pravastatin-DP	GM
							^a Pravastatin-GA 40	GN
							^a Pravastatin	GQ
							generichealth	
							^a Pravastatin	WA
							Winthrop	
							^a Terry White	TW
							Chemists	
							Pravastatin	
							^a Vastoran	RA
				B3.07	46.34	32.90	^a Pravachol	BQ
9240H	Tablet 80 mg	30	11	..	61.28	32.90	^a APO-Pravastatin	TX
							^a Chem mart	CH
							Pravastatin	
							^a Lipostat 80	SI
							^a Pravastatin-GA 80	GN
							^a Pravastatin	GQ
							generichealth	
							^a Terry White	TW
							Chemists	
							Pravastatin	
				B3.37	64.65	32.90	^a Pravachol	BQ

ROSUVASTATIN CALCIUM

Restricted Benefit

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

9042X	Tablet 5 mg (rosuvastatin)	30	5	..	50.75	32.90	Crestor	AP
9043Y	Tablet 10 mg (rosuvastatin)	30	5	..	69.48	32.90	Crestor	AP
9044B	Tablet 20 mg (rosuvastatin)	30	5	..	96.00	32.90	Crestor	AP
9045C	Tablet 40 mg (rosuvastatin)	30	5	..	134.01	32.90	Crestor	AP

CARDIOVASCULAR SYSTEM—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Proprietary Name and Manufacturer
SIMVASTATIN							
<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	..	19.46	20.49	^a Simvabell BF ^a Simvahexal SZ ^a Simvasyn CR ^a Zimstat AF ^a Zocor MK
				B2.95	22.41	20.49	
2011W	Tablet 10 mg	30	5	..	24.61	25.64	^a APO-Simvastatin TX ^a Chem mart CH ^a Simvastatin ^a GenRx Simvastatin GX ^a Ransim RA ^a Simvabell BF ^a Simvahexal SZ ^a Simvar 10 AW ^a Simvastatin-DP GM ^a Simvastatin GQ ^a generichealth ^a Simvastatin-Spirit ZP ^a 10 ^a Simvastatin WA ^a Winthrop ^a Simvasyn CR ^a Terry White TW ^a Chemists ^a Simvastatin ^a Zimstat AF ^a GN ^a Lipex 10 FR ^a Zocor MK
				B2.95	27.56	25.64	

continued ➞

CARDIOVASCULAR SYSTEM—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Proprietary Name and Manufacturer
2012X	Tablet 20 mg	30	5	..	32.77	32.90	^a APO-Simvastatin TX
							^a Chem mart CH
							Simvastatin
							^a GenRx Simvastatin GX
							^a Ransim RA
							^a Simvabell BF
							^a Simvahexal SZ
							^a Simvar 20 AW
							^a Simvastatin-DP GM
							^a Simvastatin GQ
							generichealth
							^a Simvastatin-Spirit ZP
							20
							^a Simvastatin WA
							Winthrop
							^a Simvasyn CR
8173E	Tablet 40 mg	30	5	..	44.02	32.90	^a Terry White TW
							Chemists
							Simvastatin
							^a Zimstat AF
							^a GN
							b2.95
							35.72
							32.90
							^a Lipex 20 FR
							^a Zocor MK
							^a APO-Simvastatin TX
							^a Chem mart CH
							Simvastatin
							^a GenRx Simvastatin GX
							^a Ransim RA
							^a Simvabell BF
							^a Simvahexal SZ
							^a Simvar 40 AW
							^a Simvastatin-DP GM
							^a Simvastatin GQ
							generichealth
							^a Simvastatin-Spirit ZP
							40
							^a Simvastatin WA
							Winthrop
							^a Simvasyn CR
							^a Terry White TW
							Chemists
							Simvastatin
							^a Zimstat AF
							^a GN
							b2.95
							46.97
							32.90
							^a Lipex 40 FR
							^a Zocor MK

continued ➡

CARDIOVASCULAR SYSTEM—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Proprietary Name and Manufacturer	
8313M	Tablet 80 mg	30	5	..	58.99	32.90	^a APO-Simvastatin	TX
							^a Chem mart	CH
							Simvastatin	
							^a GenRx Simvastatin	GX
							^a Ransim	RA
							^a Simvabell	BF
							^a Simvahexal	SZ
							^a Simvar 80	AW
							^a Simvastatin-DP	GM
							^a Simvastatin	GQ
							generichealth	
							^a Simvastatin-Spirit	ZP
							80	
							^a Simvastatin	WA
							Winthrop	
							^a Simvasyn	CR
							^a Terry White	TW
Chemists								
Simvastatin								
^a Zimstat	AF							
^a GN								
B2.95	61.94	32.90	^a Lipex 80	FR				
			^a Zocor	MK				

Restricted Benefit

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

NOTE:

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

9241J	Tablet 5 mg	30	11	..	19.46	20.49	^a Simvabell	BF
							^a Simvahexal	SZ
							^a Simvasyn	CR
							^a Zimstat	AF
							^a Zocor	MK

continued ➞

CARDIOVASCULAR SYSTEM—CONT.

					Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$			
Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium			Proprietary Name and Manufacturer		
9242K	Tablet 10 mg	30	11	..	24.61	25.64	^a APO-Simvastatin	TX	
							^a Chem mart	CH	
							Simvastatin		
							^a GenRx Simvastatin	GX	
							^a Ransim	RA	
							^a Simvabell	BF	
							^a Simvahexal	SZ	
							^a Simvar 10	AW	
							^a Simvastatin-DP	GM	
							^a Simvastatin	GQ	
							generichealth		
							^a Simvastatin-Spirit	ZP	
							10		
							^a Simvastatin	WA	
							Winthrop		
							^a Simvasyn	CR	
^a Terry White	TW								
	Chemists								
	Simvastatin								
	^a Zimstat	AF							
	^a GN								
	b2.95								
	27.56								
	25.64								
	^a Lipex 10	FR							
	^a Zocor	MK							
9243L	Tablet 20 mg	30	11	..	32.77	32.90	^a APO-Simvastatin	TX	
							^a Chem mart	CH	
							Simvastatin		
							^a GenRx Simvastatin	GX	
							^a Ransim	RA	
							^a Simvabell	BF	
							^a Simvahexal	SZ	
							^a Simvar 20	AW	
							^a Simvastatin-DP	GM	
							^a Simvastatin	GQ	
							generichealth		
							^a Simvastatin-Spirit	ZP	
							20		
							^a Simvastatin	WA	
							Winthrop		
							^a Simvasyn	CR	
^a Terry White	TW								
	Chemists								
	Simvastatin								
	^a Zimstat	AF							
	^a GN								
	b2.95								
	35.72								
	32.90								
	^a Lipex 20	FR							
	^a Zocor	MK							

continued ➡

CARDIOVASCULAR SYSTEM—CONT.

					Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$			
Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium			Proprietary Name and Manufacturer		
9244M	Tablet 40 mg	30	11	..	44.02	32.90	^a APO-Simvastatin	TX	
							^a Chem mart	CH	
							Simvastatin		
							^a GenRx Simvastatin	GX	
							^a Ransim	RA	
							^a Simvabell	BF	
							^a Simvahexal	SZ	
							^a Simvar 40	AW	
							^a Simvastatin-DP	GM	
							^a Simvastatin	GQ	
							generichealth		
							^a Simvastatin-Spirit	ZP	
							40		
							^a Simvastatin	WA	
							Winthrop		
							^a Simvasyn	CR	
							^a Terry White	TW	
9245N	Tablet 80 mg	30	11	..	58.99	32.90	Chemists		
							Simvastatin		
							^a Zimstat	AF	
							^a GN		
							^a Lipex 40	FR	
							^a Zocor	MK	
9245N	Tablet 80 mg	30	11	..	58.99	32.90	^a APO-Simvastatin	TX	
							^a Chem mart	CH	
							Simvastatin		
							^a GenRx Simvastatin	GX	
							^a Ransim	RA	
							^a Simvabell	BF	
							^a Simvahexal	SZ	
							^a Simvar 80	AW	
							^a Simvastatin-DP	GM	
							^a Simvastatin	GQ	
							generichealth		
							^a Simvastatin-Spirit	ZP	
							80		
							^a Simvastatin	WA	
							Winthrop		
							^a Simvasyn	CR	
							^a Terry White	TW	
9245N	Tablet 80 mg	30	11	..	61.94	32.90	Chemists		
							Simvastatin		
							^a Zimstat	AF	
							^a GN		
9245N	Tablet 80 mg	30	11	..	B2.95	61.94	32.90	^a Lipex 80	FR
								^a Zocor	MK

CARDIOVASCULAR SYSTEM—CONT.

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

• Fibrates

FENOFIBRATE

NOTE:

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

Restricted Benefit

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

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

Restricted Benefit

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

NOTE:

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

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

CARDIOVASCULAR SYSTEM—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Proprietary Name and Manufacturer	
GEMFIBROZIL								
NOTE:								
<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	..	29.27	30.30	^a Ausgem	SI
							^a Chem mart	CH
							Gemfibrozil	
							^a Gemhexal	SZ
							^a GenRx Gemfibrozil	GX
							^a Jezil	AF
							^a Lipazil 600 mg	GM
							^a Pharmacor	CR
							Gemfibrozil 600	
							^a Terry White	TW
							Chemists	
							Gemfibrozil	
				B2.95	32.22	30.30	^a Lopid	PF
Restricted Benefit								
<i>For use in patients who meet the criteria set out in the General Statement for Lipid-Lowering Drugs, and who are receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements.</i>								
NOTE:								
<i>No applications for increased maximum quantities and/or repeats will be authorised.</i>								
9248R	Tablet 600 mg	60	11	..	29.27	30.30	^a Ausgem	SI
							^a Chem mart	CH
							Gemfibrozil	
							^a Gemhexal	SZ
							^a GenRx Gemfibrozil	GX
							^a Jezil	AF
							^a Lipazil 600 mg	GM
							^a Pharmacor	CR
							Gemfibrozil 600	
							^a Terry White	TW
							Chemists	
							Gemfibrozil	
				B2.95	32.22	30.30	^a Lopid	PF
• Bile acid sequestrants								
CHOLESTYRAMINE								
2967E	Sachets 4.7 g (equivalent to 4 g cholestyramine), 50	2	5	..	* 57.03	32.90	Questran Lite	BQ

CARDIOVASCULAR SYSTEM—CONT.

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

CHOLESTYRAMINE

Restricted Benefit

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

NOTE:

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

9249T	Sachets 4.7 g (equivalent to 4 g cholestyramine), 50	2	11	..	* 57.03	32.90	Questran Lite	BQ

COLESTIPOL HYDROCHLORIDE

1224K	Sachets 5 g, 120	‡ 1	5	..	67.26	32.90	Colestid	PH

COLESTIPOL HYDROCHLORIDE

Restricted Benefit

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

NOTE:

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

9250W	Sachets 5 g, 120	‡ 1	11	..	67.26	32.90	Colestid	PH

• **Other lipid modifying agents**

EZETIMIBE

Authority Required (STREAMLINED)

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

2649

(a) coronary heart disease; or

2650

(b) diabetes mellitus; or

2651

(c) peripheral vascular disease; or

2652

(d) heterozygous familial hypercholesterolaemia; or

2653

(e) symptomatic cerebrovascular disease; or

2667

(f) family history of coronary heart disease; or

continued ➞

CARDIOVASCULAR SYSTEM—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Proprietary Name and Manufacturer
2668	<i>(g) hypertension.</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. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or</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. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.</i>						
	<u>Authority Required (STREAMLINED)</u>						
1989	<i>Patients eligible for PBS-subsidised lipid-lowering medication (according to the criteria set out in the General Statement for Lipid-Lowering Drugs) where treatment with an HMG CoA reductase inhibitor (statin) is contraindicated;</i>						
2669	<i>Patients eligible for PBS-subsidised lipid-lowering medication (according to the criteria set out in the General Statement for Lipid-Lowering Drugs) where treatment with an HMG CoA reductase inhibitor (statin) must be discontinued or reduced to a dose of 20 mg or less per day, because the patient developed a clinically important product-related adverse event during treatment with a statin.</i>						
	<i>A clinically important product-related adverse event is defined as follows:</i>						
	<i>(i) Severe myalgia (muscle symptoms without CK elevation) which is proven to be temporally associated with statin treatment; or</i>						
	<i>(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</i>						
	<i>(iii) Unexplained, persistent elevations of serum transaminases (greater than 3 times the upper limit of normal) during treatment with a statin.</i>						
	<u>Authority Required (STREAMLINED)</u>						
1991	<i>Homozygous sitosterolaemia;</i>						
2438	<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	..	70.54	32.90	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								
Authority Required (STREAMLINED)								
<i>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>								
2654								
<i>(a) coronary heart disease; or</i>								
2655								
<i>(b) diabetes mellitus; or</i>								
2656								
<i>(c) peripheral vascular disease; or</i>								
2657								
<i>(d) heterozygous familial hypercholesterolaemia; or</i>								
2658								
<i>(e) cerebrovascular disease which has become symptomatic; or</i>								
2678								
<i>(f) family history of coronary heart disease; or</i>								
2679								
<i>(g) hypertension;</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. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when the ezetimibe component is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when the ezetimibe component is initiated; or</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. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when the ezetimibe component is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when the ezetimibe component is initiated;</i>								
2431								
<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	..	107.42	32.90	Vytorin	MK
8882L	Tablet 10 mg-80 mg	30	5	..	123.54	32.90	Vytorin	MK

CARDIOVASCULAR SYSTEM—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed	Maximum	Proprietary Name and Manufacturer	
					Price for Max. Qty \$	Recordable Value for Safety Net \$		
• HMG CoA reductase inhibitors, other combinations								
AMLODIPINE BESYLATE with ATORVASTATIN CALCIUM								
<u>Restricted Benefit</u>								
<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; 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	..	51.37	32.90	Caduet 5/10	PF
9050H	Tablet 5 mg (base)-20 mg (base)	30	5	..	67.58	32.90	Caduet 5/20	PF
9051J	Tablet 5 mg (base)-40 mg (base)	30	5	..	88.63	32.90	Caduet 5/40	PF
9052K	Tablet 5 mg (base)-80 mg (base)	30	5	..	119.83	32.90	Caduet 5/80	PF
9053L	Tablet 10 mg (base)-10 mg (base)	30	5	..	58.56	32.90	Caduet 10/10	PF
9054M	Tablet 10 mg (base)-20 mg (base)	30	5	..	75.18	32.90	Caduet 10/20	PF
9055N	Tablet 10 mg (base)-40 mg (base)	30	5	..	96.23	32.90	Caduet 10/40	PF
9056P	Tablet 10 mg (base)-80 mg (base)	30	5	..	127.43	32.90	Caduet 10/80	PF

DERMATOLOGICALS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Proprietary Name and Manufacturer	
ANTIFUNGALS FOR DERMATOLOGICAL USE								
Antifungals for topical use								
• Antibiotics								
NYSTATIN								
<u>Authority Required (STREAMLINED)</u>								
2354								
<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	..	* 18.13	19.16	Mycostatin	BQ
• Imidazole and triazole derivatives								
BIFONAZOLE								
<u>Authority Required (STREAMLINED)</u>								
2354								
<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	..	* 30.69	31.72	Mycospor	BN
CLOTRIMAZOLE								
<u>Authority Required (STREAMLINED)</u>								
2354								
<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	..	* 19.27	20.30	Canesten	BN
KETOCONAZOLE								
<u>Authority Required (STREAMLINED)</u>								
2354								
<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	..	22.69	23.72	Nizoral 2% Cream	JT
9025B	Shampoo 10 mg per g (1%), 100 mL	± 1	1	..	17.17	18.20	Nizoral 1%	JT
1574W	Shampoo 20 mg per g (2%), 60 mL	± 1	1	..	17.88	18.91	Nizoral 2%	JT
MICONAZOLE								
<u>Authority Required (STREAMLINED)</u>								
2354								
<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	..	19.04	20.07	Daktarin	JT

DERMATOLOGICALS—CONT.

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

continued ➡

DERMATOLOGICALS—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed	Maximum	Proprietary Name and Manufacturer
					Price for Max. Qty \$	Recordable Value for Safety Net \$	
<u>Authority Required</u>							
<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>							
<u>NOTE:</u>							
<i>No applications for increased maximum quantities and/or repeats will be authorised.</i>							
2804N	Tablet 250 mg (base)	42	1	..	102.39	32.90	<i>a GenRx Terbinafine GX</i>
							<i>a Sebifin 250 RA</i>
							<i>a Tamsil SI</i>
							<i>a Terbihexal SZ</i>
							<i>a Terbinafine 250 CR</i>
							<i>a Terbinafine-DP GM</i>
							<i>a Zabel AF</i>
				B1.46	103.85	32.90	<i>a Lamisil NV</i>

ANTIPSORIATICS

Antipsoriatics for topical use

• Tars

COAL TAR - PREPARED

8864M	Gel 10 mg per g (1%), 100 mL	‡ 1	2	..	32.65	32.90	Exorex	GM

• Other antipsoriatics for topical use

CALCIPOTRIOL

Restricted Benefit*Chronic stable plaque type psoriasis vulgaris.*

8291J	Ointment 50 micrograms per g (0.005%), 30 g	‡ 1	1	..	27.63	28.66	Daivonex	CS
2080L	Cream 50 micrograms per g (0.005%), 30 g	‡ 1	1	..	27.63	28.66	Daivonex	CS

Restricted Benefit*Chronic stable plaque type psoriasis vulgaris of the scalp.*

9163G	Scalp solution 50 micrograms per mL (0.005%), 30 mL	‡ 1	1	..	27.63	28.66	Daivonex	CS

DERMATOLOGICALS—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Proprietary Name and Manufacturer	
Antipsoriatics for systemic use								
• Retinoids for treatment of psoriasis								
ACITRETIN								
CAUTION:								
<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 (STREAMLINED)								
1366								
<i>Severe intractable psoriasis;</i>								
1363								
<i>Severe forms of disorders of keratinisation.</i>								
2019G	Capsule 10 mg	100	2	..	205.34	32.90	Neotigason	TA
2020H	Capsule 25 mg	100	2	..	392.78	32.90	Neotigason	TA

ANTIBIOTICS AND CHEMOTHERAPEUTICS FOR DERMATOLOGICAL USE

Chemotherapeutics for topical use• **Sulfonamides**

**SILVER SULFADIAZINE with CHLORHEXIDINE
GLUCONATE**

Restricted Benefit

Prevention and treatment of infection in partial or full skin thickness loss due to burns;

Prevention and treatment of infection in partial or full skin thickness loss due to epidermolysis bullosa;

Stasis ulcers.

1996C	Cream 10 mg-2 mg per g (1%-0.2%), 50 g	± 1	..	..	18.38	19.41	Silvazine	SN
1997D	Cream 10 mg-2 mg per g (1%-0.2%), 100 g	± 1	..	..	21.17	22.20	Silvazine	SN

CORTICOSTEROIDS, DERMATOLOGICAL PREPARATIONS

Corticosteroids, plain• **Corticosteroids, weak (group I)**

HYDROCORTISONE

Restricted Benefit

Treatment of corticosteroid-responsive dermatoses.

1495Q	Cream 10 mg per g (1%), 50 g	± 1	1	..	8.27	9.30	Egocort Cream 1%	EO

DERMATOLOGICALS—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Proprietary Name and Manufacturer	
HYDROCORTISONE ACETATE								
<u>Restricted Benefit</u>								
<i>Treatment of corticosteroid-responsive dermatoses.</i>								
2887Y	Cream 10 mg per g (1%), 30 g	‡ 1	1	.. B1.90	8.61 10.51	9.64 9.64	^a Cortic-DS 1% ^a Sigmacort	FM SI
2881P	Cream 10 mg per g (1%), 50 g	‡ 1	1	.. B0.08 B1.91	8.27 8.35 10.18	9.30 9.30 9.30	^a Cortic-DS 1% ^a Cortef ^a Sigmacort	FM DT SI
2888B	Topical ointment 10 mg per g (1%), 30 g	‡ 1	1	.. B1.90	8.61 10.51	9.64 9.64	^a Cortic-DS 1% ^a Sigmacort	FM SI
2882Q	Topical ointment 10 mg per g (1%), 50 g	‡ 1	1	.. B1.91	8.27 10.18	9.30 9.30	^a Cortic-DS 1% ^a Sigmacort	FM 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	..	.. B3.30	* 14.45 * 17.75	15.48 15.48	^a Tricortone ^a Aristocort 0.02%	FM SI
2118L	Ointment 200 micrograms per g (0.02%), 100 g	2	..	.. B3.30	* 14.45 * 17.75	15.48 15.48	^a Tricortone ^a Aristocort 0.02%	FM 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	..	13.12	14.15	^a Diprosone ^a Eleuphrat	SH EX
1119X	Ointment 500 micrograms (base) per g (0.05%), 15 g	‡ 1	1	..	13.12	14.15	^a Diprosone ^a Eleuphrat	SH 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	..	.. B6.18	* 24.89 * 31.07	25.92 25.92	^a Antroquoril ^a Celestone-M ^b Cortival 1/5 ^b Betnovate 1/5	EX SH FM SI

continued ➡

DERMATOLOGICALS—CONT.

					Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$			
Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium			Proprietary Name and Manufacturer		
2813C	Cream 500 micrograms (base) per g (0.05%), 15 g	± 1	1	.. B1.91	8.12 10.03	9.15 9.15	^b Cortival 1/2 ^b Betnovate 1/2	FM SI	
2820K	Ointment 200 micrograms (base) per g (0.02%), 100 g	2	..	..	* 24.89	25.92	^a Antroquoril ^a Celestone-M	EX SH	
2815E	Ointment 500 micrograms (base) per g (0.05%), 15 g	± 1	1	.. B1.91	8.12 10.03	9.15 9.15	^b Cortival 1/2 ^b Betnovate 1/2	FM SI	

METHYLPREDNISOLONE ACEPONATE

Restricted Benefit

Treatment of corticosteroid-responsive dermatoses.

8054X	Cream 1 mg per g (0.1%), 15 g	‡ 1	..	..	14.02	15.05	Advantan	CS
8055Y	Ointment 1 mg per g (0.1%), 15 g	‡ 1	..	..	14.02	15.05	Advantan	CS
8128T	Fatty ointment 1 mg per g (0.1%), 15 g	‡ 1	..	..	14.02	15.05	Advantan	CS

Restricted Benefit

Eczema.

8618N	Lotion 1 mg per g (0.1%), 20 g	‡ 1	..	..	14.74	15.77	Advantan	CS

MOMETASONE FUROATE

Restricted Benefit

Treatment of corticosteroid-responsive dermatoses.

1913Q	Cream 1 mg per g (0.1%), 15 g	‡ 1	..	..	13.96	14.99	^a Elocon ^a Novasone	SH EX
1915T	Ointment 1 mg per g (0.1%), 15 g	‡ 1	..	..	13.96	14.99	^a Elocon ^a Novasone	SH EX
8043H	Lotion 1 mg per g (0.1% w/w), 30 mL	‡ 1	..	..	18.54	19.57	^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 (STREAMLINED)								
1354								
<i>Severe cystic acne not responsive to other therapy.</i>								
2591J	Capsule 10 mg	60	3	..	94.12	32.90	^a Oratane ^a Roaccutane	GM RO
2592K	Capsule 20 mg	60	3	..	143.36	32.90	^a GenRx Isotretinoin ^a Oratane	GX GM
				B2.37	145.73	32.90	^a Roaccutane	RO
2549E	Capsule 40 mg	30	3	..	129.96	32.90	Oratane	GM
OTHER DERMATOLOGICAL PREPARATIONS								
Other dermatological preparations								
• Other dermatologicals								
DAPSONE								
8801F	Tablet 25 mg	100	1	..	100.15	32.90	LM	
1272Y	Tablet 100 mg	100	1	..	113.41	32.90	LM	
IMIQUIMOD								
Authority Required								
<i>Treatment of biopsy confirmed primary (previously untreated) superficial basal cell carcinoma (sBCC) in patients with normal immune function for whom surgical excision, cryotherapy, or curettage with diathermy are inappropriate and topical drug therapy is required.</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	..	159.52	32.90	Aldara	IA

DERMATOLOGICALS—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 \$	

PIMECROLIMUS

Authority Required

Treatment of facial or eyelid atopic dermatitis in patients aged at least 3 months with 1 or more of the following contraindications to topical corticosteroids:

- (i) perioral dermatitis;*
- (ii) periorbital dermatitis;*
- (iii) rosacea;*
- (iv) epidermal atrophy;*
- (v) dermal atrophy;*
- (vi) allergy to topical corticosteroids;*
- (vii) cataracts;*
- (viii) glaucoma;*
- (ix) raised intraocular pressure.*

Authority Required

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

Failure to achieve satisfactory disease control with intermittent topical corticosteroid therapy is manifest by:

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

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

NOTE:

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

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								
<i>Contraception;</i>								
<i>Idiopathic menorrhagia where oral treatments are ineffective;</i>								
<i>Idiopathic menorrhagia where oral treatments are contraindicated.</i>								
8633J	Intrauterine drug delivery system 52 mg (releasing approximately 20 micrograms per 24 hours)	1	..	..	245.98	32.90	Mirena	SC
Other gynecologicals								
• Prolactine inhibitors								
BROMOCRIPTINE MESYLATE								
Restricted Benefit								
<i>Prevention of the onset of lactation in the puerperium for medical reasons.</i>								
1444B	Tablet 2.5 mg (base)	30	..	.. B2.84	19.15 21.99	20.18 ^a 20.18 ^a	Kripton 2.5 Parlodel	AF NV
Restricted Benefit								
<i>Acromegaly;</i>								
<i>Parkinson's disease;</i>								
<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>								
1443Y	Tablet 2.5 mg (base)	60	5	.. B2.92	32.30 35.22	32.90 ^a 32.90 ^a	Kripton 2.5 Parlodel	AF NV
1446D	Capsule 5 mg (base)	60	5	.. B2.91	49.82 52.73	32.90 ^a 32.90 ^a	Kripton 5 Parlodel	AF NV
1445C	Capsule 10 mg (base)	100	5	.. B3.08	155.51 158.59	32.90 ^a 32.90 ^a	Kripton 10 Parlodel	AF NV
CABERGOLINE								
Restricted Benefit								
<i>Prevention of the onset of lactation in the puerperium for medical reasons.</i>								
8115D	Tablet 500 micrograms	2	..	..	26.58	27.61	Dostinex	PH

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	
Authority Required (STREAMLINED)								
	2659							
	<i>Pathological hyperprolactinaemia where surgery is not indicated;</i>							
	2660							
	<i>Pathological hyperprolactinaemia where surgery has already been used with incomplete resolution;</i>							
	2661							
	<i>Pathological hyperprolactinaemia where radiotherapy is not indicated;</i>							
	2662							
	<i>Pathological hyperprolactinaemia where radiotherapy has already been used with incomplete resolution.</i>							
8114C	Tablet 500 micrograms	8	5	..	75.79	32.90	Dostinex	PH
QUINAGOLIDE HYDROCHLORIDE								
Authority Required (STREAMLINED)								
	2659							
	<i>Pathological hyperprolactinaemia where surgery is not indicated;</i>							
	2660							
	<i>Pathological hyperprolactinaemia where surgery has already been used with incomplete resolution;</i>							
	2661							
	<i>Pathological hyperprolactinaemia where radiotherapy is not indicated;</i>							
	2662							
	<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	..	..	11.04	12.07	Norprolac	FP
8822H	Tablet 75 micrograms (base)	30	5	..	54.36	32.90	Norprolac	FP

SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM

Hormonal contraceptives for systemic use

• Progestogens and estrogens, fixed combinations

LEVONORGESTREL with ETHINYLOESTRADIOL

1456P	Pack containing 21 tablets 125 micrograms-50 micrograms and 7 inert tablets	4	2	..	17.23	18.26	Microgynon 50 ED	SC
1393H	Tablets 150 micrograms-30 micrograms, 21	4	2	B12.69	29.92	18.26 ^a	Microgynon 30	SC

NOTE:

This product may be interchanged with products with "a" flagging in item 1394J.

continued ➞

GENITO URINARY SYSTEM AND SEX HORMONES—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Proprietary Name and Manufacturer	
1394J	Pack containing 21 tablets 150 micrograms-30 micrograms and 7 inert tablets	4	2	..	17.23	18.26	^a Levlen ED	SY
				B12.25	29.48	18.26	^b Monofeme 28	WX
				B12.69	29.92	18.26	^b Nordette 28	WY
							^a Microgynon 30 ED	SC

NOTE:

The products with "a" flagging may also be interchanged with item 1393H.

NORETHISTERONE with ETHINYLOESTRADIOL

2772X	Tablets 500 micrograms-35 micrograms, 21	4	2	B7.92	* 24.59	17.70	^a Brevinor	PH

NOTE:

This product may be interchanged with the products in item 2774B.

2774B	Pack containing 21 tablets 500 micrograms-35 micrograms and 7 inert tablets	4	2	..	* 16.67	17.70	^a Norimin 28 Day	KR
				B7.92	* 24.59	17.70	^a Brevinor	PH

NOTE:

These products may also be interchanged with item 2772X.

2773Y	Tablets 1 mg-35 micrograms, 21	4	2	B7.92	* 24.59	17.70	^a Brevinor-1	PH

NOTE:

This product may be interchanged with the products in item 2775C.

2775C	Pack containing 21 tablets 1 mg-35 micrograms and 7 inert tablets	4	2	..	* 16.67	17.70	^a Norimin-1 28 Day	KR
				B7.92	* 24.59	17.70	^a Brevinor-1	PH

NOTE:

These products may also be interchanged with item 2773Y.

NORETHISTERONE with MESTRANOL

3176E	Tablets 1 mg-50 micrograms, 21	4	2	..	* 16.67	17.70	Norinyl-1	PH
3179H	Pack containing 21 tablets 1 mg-50 micrograms and 7 inert tablets	4	2	..	* 16.67	17.70	Norinyl-1/28	PH

• Progestogens and estrogens, sequential preparations

LEVONORGESTREL with ETHINYLOESTRADIOL

1392G	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	2	..	17.23	18.26	^a Logynon ED	SY
				B12.25	29.48	18.26	^b Trifeme 28	WX
				B12.69	29.92	18.26	^b Triphasil 28	WY
							^a Triquilar ED	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	
NORETHISTERONE with ETHINYLOESTRADIOL								
2776D	Pack containing 12 tablets	4	2	..	* 16.67	17.70	^a Improvil 28 Day	KR
	500 micrograms-35 micrograms, 9 tablets 1 mg-35 micrograms and 7 inert tablets			B7.92	* 24.59	17.70	^a Synphasic	PH
• Progestogens								
ETONOGESTREL								
8487Q	Subcutaneous implant 68 mg	1	..	..	215.49	32.90	Implanon	SH
LEVONORGESTREL								
2913H	Tablets 30 micrograms, 28	4	2	..	16.89	17.92	Microlut 28	SC
MEDROXYPROGESTERONE ACETATE								
3118D	Injection 150 mg in 1 mL	1	1	..	14.21	15.24	^a Depo-Ralovera	KR
				B3.34	17.55	15.24	^a Depo-Provera	PH
[For other listings for this drug see Generic/Proprietary Index]								
NORETHISTERONE								
1967M	Tablets 350 micrograms, 28	4	2	..	* 16.67	17.70	Micronor	JC
				..	* 16.67	17.70	^a Locilan 28 Day	KR
				B4.00	* 20.67	17.70	^a Noriday 28 Day	PH
Androgens								
• 3-oxoandrogen (4) derivatives								
TESTOSTERONE								
Authority Required								
<i>Androgen deficiency in males with established pituitary or testicular disorders;</i>								
<i>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);</i>								
<i>Micropenis, pubertal induction, or constitutional delay of growth or puberty, in males under 18 years of age.</i>								
8098F	Subcutaneous implant 100 mg	6	..	..	* 209.15	32.90	SH	
8099G	Subcutaneous implant 200 mg	3	..	..	* 209.12	32.90	SH	
8830R	Transdermal gel 50 mg in 5 g sachet, 30	± 1	5	..	94.69	32.90	Testogel	SC
8460G	Transdermal patches 12.2 mg (releasing approximately 2.5 mg per 24 hours), 60	± 1	5	..	95.41	32.90	Androderm	HH
8619P	Transdermal patches 24.3 mg (releasing approximately 5 mg per 24 hours), 30	± 1	5	..	95.41	32.90	Androderm	HH

GENITO URINARY SYSTEM AND SEX HORMONES—CONT.

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

TESTOSTERONE ENANTHATE

Authority Required

Androgen deficiency in males with established pituitary or testicular disorders;

Androgen deficiency in males 40 years and older who do not have established pituitary or testicular disorders other than aging, confirmed by at least 2 morning blood samples taken on different mornings. Androgen deficiency is confirmed by testosterone less than 8 nmol per L, or 8-15 nmol per L with high LH (greater than 1.5 times the upper limit of the eugonadal reference range for young men);

Micropenis, pubertal induction, or constitutional delay of growth or puberty, in males under 18 years of age.

2114G	Injection 250 mg in 1 mL	3	3	..	33.05	32.90	Primoteston Depot	SC

TESTOSTERONE ESTERS

Authority Required

Androgen deficiency in males with established pituitary or testicular disorders;

Androgen deficiency in males 40 years and older who do not have established pituitary or testicular disorders other than aging, confirmed by at least 2 morning blood samples taken on different mornings. Androgen deficiency is confirmed by testosterone less than 8 nmol per L, or 8-15 nmol per L with high LH (greater than 1.5 times the upper limit of the eugonadal reference range for young men);

Micropenis, pubertal induction, or constitutional delay of growth or puberty, in males under 18 years of age.

2670M	Injection 100 mg	3	3	..	* 20.24	21.27	Sustanon 100	SH
2101N	Injection 250 mg	3	3	..	* 33.05	32.90	Sustanon 250	SH

TESTOSTERONE UNDECANOATE

Authority Required

Androgen deficiency in males with established pituitary or testicular disorders;

Androgen deficiency in males 40 years and older who do not have established pituitary or testicular disorders other than aging, confirmed by at least 2 morning blood samples taken on different mornings. Androgen deficiency is confirmed by testosterone less than 8 nmol per L, or 8-15 nmol per L with high LH (greater than 1.5 times the upper limit of the eugonadal reference range for young men);

Micropenis, pubertal induction, or constitutional delay of growth or puberty, in males under 18 years of age.

2115H	Capsule 40 mg	60	5	..	37.10	32.90	Andriol Testocaps	SH
9004X	I.M. injection 1,000 mg in 4 mL	1	1	..	146.98	32.90	Reandron 1000	SC

Estrogens

• *Natural and semisynthetic estrogens, plain*

OESTRADIOL

8274L	Tablet 2 mg	56	2	..	13.57	14.60	Zumenon	SM
1742Q	Vaginal tablets 25 micrograms, 15	‡ 1	2	..	22.81	23.84	Vagifem	NO

continued ➞

GENITO URINARY SYSTEM AND SEX HORMONES—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Proprietary Name and Manufacturer	
OESTRADIOL								
<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>								
<u>NOTE:</u>								
<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	..	17.33	18.36	Sandrena	SH
8761D	Transdermal patches 390 micrograms (releasing approximately 25 micrograms per 24 hours), 8	‡ 1	5	..	17.33	18.36	Estradot 25	NV
8311K	Transdermal patches 750 micrograms (releasing approximately 25 micrograms per 24 hours), 8	‡ 1	5	..	17.33	18.36	Estraderm MX 25	NV
8485N	Transdermal patches 2 mg (releasing approximately 25 micrograms per 24 hours), 4	‡ 1	5	..	17.33	18.36	Climara 25	SC
1743R	Transdermal patches 2 mg (releasing approximately 25 micrograms per 24 hours), 8	‡ 1	5	..	17.33	18.36	Estraderm 25	NV
8762E	Transdermal patches 585 micrograms (releasing approximately 37.5 micrograms per 24 hours), 8	‡ 1	5	..	17.33	18.36	Estradot 37.5	NV
8140K	Transdermal patches 1.5 mg (releasing approximately 50 micrograms per 24 hours), 8	‡ 1	5	..	17.33	18.36	Estraderm MX 50	NV
8125P	Transdermal patches 3.8 mg (releasing approximately 50 micrograms per 24 hours), 4	‡ 1	5	..	17.33	18.36	Climara 50	SC
1744T	Transdermal patches 4 mg (releasing approximately 50 micrograms per 24 hours), 8	‡ 1	5	..	17.33	18.36	Estraderm 50	NV
8763F	Transdermal patches 780 micrograms (releasing approximately 50 micrograms per 24 hours), 8	‡ 1	5	..	17.33	18.36	Estradot 50	NV
8486P	Transdermal patches 5.7 mg (releasing approximately 75 micrograms per 24 hours), 4	‡ 1	5	..	19.49	20.52	Climara 75	SC
8764G	Transdermal patches 1.17 mg (releasing approximately 75 micrograms per 24 hours), 8	‡ 1	5	..	19.49	20.52	Estradot 75	NV

continued ➡

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Proprietary Name and Manufacturer
8312L	Transdermal patches 3 mg (releasing approximately 100 micrograms per 24 hours), 8	\$ 1	5	..	19.49	20.52	Estraderm MX 100 NV
8126Q	Transdermal patches 7.6 mg (releasing approximately 100 micrograms per 24 hours), 4	\$ 1	5	..	19.49	20.52	Climara 100 SC
1745W	Transdermal patches 8 mg (releasing approximately 100 micrograms per 24 hours), 8	\$ 1	5	..	19.49	20.52	Estraderm 100 NV
8765H	Transdermal patches 1.56 mg (releasing approximately 100 micrograms per 24 hours), 8	\$ 1	5	..	19.49	20.52	Estradot 100 NV
OESTRADIOL VALERATE							
1663M	Tablet 1 mg	56	2	..	11.57	12.60	Progynova SC
1664N	Tablet 2 mg	56	2	..	13.94	14.97	Progynova SC
OESTRIOL							
1771F	Pessaries 500 micrograms, 15	\$ 1	2	..	20.83	21.86	Ovestin Ovula SH
1781R	Vaginal cream 1 mg per g (0.1%), 15 g	\$ 1	1	..	18.66	19.69	Ovestin SH
Progestogens							
• Pregnen (4) derivatives							
MEDROXYPROGESTERONE ACETATE							
2323G	Tablet 5 mg	56	2	.. B1.74	14.78 16.52	15.81 ^a 15.81 ^a	Ralovera Provera KR PH
2321E	Tablet 10 mg	30	2	.. B1.75	15.42 17.17	16.45 ^a 16.45 ^a	Medroxyhexal Ralovera SZ KR PH
2319C	Injection 50 mg in 1 mL	1	1	..	11.48	12.51	Depo-Provera PH
MEDROXYPROGESTERONE ACETATE							
<u>Restricted Benefit</u>							
<u>Endometriosis.</u>							
2722G	Tablet 10 mg	100	2	.. B1.64	31.78 33.42	32.81 ^a 32.81 ^a	Ralovera Provera KR PH
[For other listings for this drug see Generic/Proprietary Index]							

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	
• Pregnadien derivatives								
DYDROGESTERONE								
1350C	Tablet 10 mg	28	2	..	14.96	15.99	Duphaston	SM
• Estren derivatives								
NORETHISTERONE								
2993M	Tablet 5 mg	30	2	..	33.12	32.90	Primolut N	SC
Progestogens and estrogens in combination								
• Progestogens and estrogens, combinations								
OESTRADIOL with NORETHISTERONE ACETATE								
8353P	Tablets 1 mg-500 micrograms, 28	± 1	5	..	17.26	18.29	Kliovance	NO
8081H	Tablets 2 mg-1 mg, 28	± 1	5	..	17.26	18.29	Kliogest	NO
OESTRADIOL with NORETHISTERONE ACETATE								
<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	..	19.49	20.52	Estalis continuous 50/140	NV
8428N	Transdermal patches 510 micrograms-4.8 mg (releasing approximately 50 micrograms- 250 micrograms per 24 hours), 8	± 1	5	..	19.49	20.52	Estalis continuous 50/250	NV
• Progestogens and estrogens, sequential preparations								
OESTRADIOL and OESTRADIOL with DYDROGESTERONE								
8244X	Pack containing 14 tablets oestradiol 2 mg and 14 tablets oestradiol 2 mg with dydrogesterone 10 mg	± 1	5	..	17.34	18.37	Femoston 2/10	SM
OESTRADIOL and OESTRADIOL with NORETHISTERONE ACETATE								
1764W	Pack containing 12 tablets oestradiol 2 mg, 10 tablets oestradiol 2 mg with norethisterone acetate 1 mg and 6 tablets oestradiol 1 mg	± 1	5	..	17.26	18.29	Trisequens	NO

GENITO URINARY SYSTEM AND SEX HORMONES—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 \$		
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 780 micrograms (releasing approximately 50 micrograms per 24 hours) and 4 transdermal patches oestradiol with norethisterone acetate 620 micrograms-2.7 mg (releasing approximately 50 micrograms-140 micrograms per 24 hours)	± 1	5	..	19.49	20.52	Estalis sequi 50/ 140	NV
8426L	Pack containing 4 transdermal patches oestradiol 780 micrograms (releasing approximately 50 micrograms per 24 hours) and 4 transdermal patches oestradiol with norethisterone acetate 510 micrograms-4.8 mg (releasing approximately 50 micrograms-250 micrograms per 24 hours)	± 1	5	..	19.49	20.52	Estalis sequi 50/ 250	NV
8029N	Pack containing 4 transdermal patches oestradiol 4 mg (releasing approximately 50 micrograms per 24 hours) and 4 transdermal patches oestradiol with norethisterone acetate 10 mg-30 mg (releasing approximately 50 micrograms- 250 micrograms per 24 hours)	± 1	5	..	19.49	20.52	Estracombi	NV

Gonadotropins and other ovulation stimulants

• Gonadotropins

FOLLITROPIN ALFA

Restricted Benefit

Anovulatory infertility.

NOTE:

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

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

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

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	
<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	..	* 247.14	32.90	Gonal-f 75	SG
8674M	Injection set containing 1 vial powder for injection 1,050 i.u. and 1 pre-filled syringe solvent 2 mL	1	5	..	655.76	32.90	Gonal-f	SG

Restricted Benefit

Anovulatory infertility.

NOTE:

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

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

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

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

Restricted Benefit

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

8673L	Injection set containing 10 vials powder for injection 75 i.u. and 10 pre-filled syringes solvent 1 mL	1	5	..	470.25	32.90	Gonal-f 75	SG
8713N	Injection 300 i.u. in 0.5 mL multi-dose cartridge	3	5	..	* 563.00	32.90	Gonal-f Pen	SG
8675N	Injection set containing 1 vial powder for injection 450 i.u. and 1 pre-filled syringe solvent 1 mL	3	5	..	* 841.46	32.90	Gonal-f	SG
8714P	Injection 450 i.u. in 0.75 mL multi-dose cartridge	3	5	..	* 841.49	32.90	Gonal-f Pen	SG
8715Q	Injection 900 i.u. in 1.5 mL multi-dose cartridge	2	5	..	* 1114.81	32.90	Gonal-f Pen	SG

FOLLITROPIN BETA

Restricted Benefit

Anovulatory infertility.

continued ➞

GENITO URINARY SYSTEM AND SEX HORMONES—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 \$		
<u>NOTE:</u> <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>								
<u>Restricted Benefit</u> <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	..	* 563.00	32.90	Puregon 300 IU/ 0.36 mL	SH
8566W	Solution for injection 600 i.u. in 0.72 mL multi-dose cartridge	2	5	..	* 748.65	32.90	Puregon 600 IU/ 0.72 mL	SH
8871X	Solution for injection 900 i.u. in 1.08 mL multi-dose cartridge	2	5	..	* 1114.79	32.90	Puregon 900 IU/ 1.08 mL	SH

HUMAN CHORIONIC GONADOTROPHIN

Restricted Benefit

Anovulatory infertility.

NOTE:

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

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

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

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

Restricted Benefit

For the treatment of infertility in males due to hypogonadotrophic hypogonadism;

For the treatment of infertility in males associated with isolated luteinising hormone deficiency;

For the treatment of males who have combined deficiency of human growth hormone and gonadotrophins and in whom the absence of secondary sexual characteristics indicates a lag in maturation.

Restricted Benefit

For the treatment of boys over the age of 16 years who show clinical evidence of hypogonadism or delayed puberty. Treatment must not extend beyond 6 months.

1579D	Injection set containing 3 ampoules powder for injection 500 units and 3 ampoules solvent 1 mL	1	5	..	30.44	31.47	Pregnyl	SH

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	
1581F	Injection set containing 3 ampoules powder for injection 1,500 units and 3 ampoules solvent 1 mL	1	5	..	40.66	32.90	Pregnyl	SH
Restricted Benefit								
Cryptorchism not due to organic obstruction in boys over 12 months of age.								
1583H	Injection set containing 3 ampoules powder for injection 500 units and 3 ampoules solvent 1 mL	2	1	..	* 53.01	32.90	Pregnyl	SH
 • Ovulation stimulants, synthetic								
CLOMIPHENE CITRATE								
NOTE:								
Care must be taken to comply with the provisions of State/Territory law when prescribing clomiphene citrate.								
Restricted Benefit								
Anovulatory infertility;								
Patients undergoing in-vitro fertilisation.								
1211R	Tablet 50 mg	10	5	..	* 32.67	32.90	^a Clomhexal	HX
							^a Fermil	SI
							^a GenRx	GX
							Clomiphene	
				B0.14	32.81	32.90	^a Serophene	SG
				B3.90	36.57	32.90	^a Clomid	SW
 Antiandrogens								
• Antiandrogens, plain preparations								
CYPROTERONE ACETATE								
Authority Required (STREAMLINED)								
1230								
Moderate to severe androgenisation in non-pregnant women (acne alone is not a sufficient indication of androgenisation).								
CAUTION:								
This drug should not be used during pregnancy as it may result in feminisation of the male foetus.								
1269T	Tablet 50 mg	20	5	..	52.31	32.90	^a Cyprohexal	SZ
							^a Cyprone	AF
							^a Cyprostat	SY
							^a GenRx	GX
							Cyproterone Acetate	
							^a Procur	GM
				B3.13	55.44	32.90	^a Androcur	SC

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	
<u>Authority Required (STREAMLINED)</u>								
1014								
<i>Advanced carcinoma of the prostate;</i>								
1404								
<i>To reduce drive in sexual deviations in males.</i>								
1270W	Tablet 50 mg	100	5	..	* 207.29	32.90	^a Cyprohexal	SZ
							^a Cyprone	AF
							^a Cyprostat	SY
							^a GenRx	GX
							Cyproterone Acetate	
							^a Procur	GM
				B3.00	* 210.29	32.90	^a Androcur	SC
8019C	Tablet 100 mg	50	5	..	169.33	32.90	^a Cyprohexal	SZ
							^a Cyprostat-100	SY
							^a GenRx	GX
							Cyproterone Acetate	
							^a Procur 100	GM
				B1.65	170.98	32.90	^a Androcur-100	SC

Other sex hormones and modulators of the genital system

• Antigonadotropins and similar agents

DANAZOL

CAUTION:

Pregnancy must be excluded prior to administration of this drug.

Authority Required (STREAMLINED)

1090

Endometriosis, visually proven;

1151

Hereditary angio-oedema;

2639

Short-term treatment (up to 6 months) of intractable primary menorrhagia (Treatment of this indication is limited to 6 months. See Australian Product Information);

2640

Short-term treatment (up to 6 months) of severe benign (fibrocystic) breast disease or mastalgia associated with severe symptomatic benign breast disease in patients refractory to other treatments (Treatment of this indication is limited to 6 months. See Australian Product Information).

1285P	Capsule 100 mg	100	5	..	58.15	32.90	Azol 100	AF
1287R	Capsule 200 mg	100	5	..	86.54	32.90	Azol 200	AF

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	

GESTRINONE

Authority Required

Short-term treatment (up to 6 months) of visually proven endometriosis (only 1 course of not more than 6 months' therapy will be authorised).

8015W	Capsule 2.5 mg	8	5	..	81.38	32.90	Dimetrioese	SW

• **Selective estrogen receptor modulators**

RALOXIFENE HYDROCHLORIDE

For listings see Generic/Proprietary Index

UROLOGICALS

Other urologicals, incl. antispasmodics

• **Urinary antispasmodics**

OXYBUTYNIN HYDROCHLORIDE

Restricted Benefit

Detrusor overactivity.

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

PROPANTHELINE BROMIDE

Restricted Benefit

Detrusor overactivity.

1953T	Tablet 15 mg	200	5	..	* 26.03	27.06	Pro-Banthine	SI

• **Other urologicals**

PHENOXYBENZAMINE HYDROCHLORIDE

Restricted Benefit

Phaeochromocytoma;

Neurogenic urinary retention.

1862B	Capsule 10 mg	100	5	..	66.93	32.90	Dibenylene	GH
1166J	Capsules 10 mg, 30	3	5	..	* 204.47	32.90	Dibenylene	GH
9286R	Capsules 10 mg, 100	‡ 1	5	..	1411.57	32.90	Dibenzyline	GH

SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS

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 \$		

PITUITARY AND HYPOTHALAMIC HORMONES AND ANALOGUES

Anterior pituitary lobe hormones and analogues

• **ACTH**

TETRACOSACTRIN

2832C	Injection 1 mg in 1 mL	5	5	..	* 70.84	32.90	Synacthen Depot 1 mg/1 mL	NV

• **Thyrotropin**

THYROTROPIN ALFA

Authority Required

Ablation of thyroid remnant tissue, in combination with radioactive iodine, in a post thyroidectomy patient without known metastatic disease.

2700D	Powder for injection 0.9 mg, 2	1	..	..	1900.99	32.90	Thyrogen	GZ

Posterior pituitary lobe hormones

• **Vasopressin and analogues**

DESMOPRESSIN ACETATE

Authority Required (STREAMLINED)

1678

Cranial diabetes insipidus.

8662X	Tablet 200 micrograms	90	5	..	* 179.48	32.90	Minirin	FP
2129C	Intranasal solution 100 micrograms per mL, 2.5 mL	5	5	..	* 160.74	32.90	Minirin	FP
8711L	Nasal spray (pump pack) 10 micrograms per actuation, 60 actuations, 6 mL	2	5	..	* 160.61	32.90	Minirin Nasal Spray	FP

Authority Required (STREAMLINED)

2641

Primary nocturnal enuresis in patients aged 6 years or older who are refractory to an enuresis alarm;

2642

Primary nocturnal enuresis in patients aged 6 years or older for whom an enuresis alarm is contraindicated. The reason that an alarm is contraindicated must be documented in the patient's medical records when treatment is initiated.

NOTE:

Not to be used in preference to enuresis alarms.

Desmopressin nasal spray may be associated with an increased risk of hyponatraemia compared to the oral formulations.

8663Y	Tablet 200 micrograms	30	5	..	63.82	32.90	Minirin	FP

continued ➞

SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Proprietary Name and Manufacturer	
NOTE: <i>Only one application per six months with no more than twice the maximum quantity will be authorised for the tablets.</i>								
9398P	Wafer 120 micrograms (base)	30	5	..	70.42	32.90	Minirin Melt	FP
NOTE: <i>Only one application per 6 months with no more than twice the maximum quantity will be authorised for the wafers.</i>								
8712M	Nasal spray (pump pack) 10 micrograms per actuation, 60 actuations, 6 mL	± 1	5	..	83.30	32.90	Minirin Nasal Spray	FP

Hypothalamic hormones

• Gonadotropin-releasing hormones

NAFARELIN ACETATE

Authority Required

Initial treatment (up to 6 months) of visually proven endometriosis;

Subsequent treatment (up to 6 months) of visually proven endometriosis, where 2 years or more have elapsed since the end of the previous course and where a recent bone density assessment has been made. The date of the assessment must be provided.

2962X	Nasal spray (pump pack) 200 micrograms (base) per dose (60 doses)	± 1	5	..	95.08	32.90	Synarel	PH

CORTICOSTEROIDS FOR SYSTEMIC USE

Corticosteroids for systemic use, plain

• Mineralocorticoids

FLUDROCORTISONE ACETATE

1433K	Tablet 100 micrograms	200	1	..	* 23.87	24.90	Florinef	BQ

• Glucocorticoids

BETAMETHASONE ACETATE with BETAMETHASONE SODIUM PHOSPHATE

Restricted Benefit

Alopecia areata;

For local intra-articular or peri-articular infiltration;

Granulomata, dermal;

Keloid;

Lichen planus hypertrophic;

Lichen simplex chronicus;

Lupus erythematosus, chronic discoid;

Necrobiosis lipidica;

Uveitis.

2694T	Injection 3 mg-3.9 mg (equivalent to 5.7 mg betamethasone) in 1 mL	5	..	..	25.74	26.77	Celestone Chronodose	SH

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	
CORTISONE ACETATE								
1246N	Tablet 5 mg	50	4	..	14.87	15.90	Cortate	AS
1247P	Tablet 25 mg	60	4	..	17.31	18.34	Cortate	AS
DEXAMETHASONE								
1292B	Tablet 500 micrograms	30	4	..	8.41	9.44	Dexmethsone	AS
2507Y	Tablet 4 mg	30	4	..	11.97	13.00	Dexmethsone	AS
DEXAMETHASONE SODIUM PHOSPHATE								
2509C	Injection equivalent to 4 mg dexamethasone phosphate in 1 mL	5	..	..	17.65	18.68	HH	
1291Y	Injection equivalent to 8 mg dexamethasone phosphate in 2 mL	5	1	..	27.15	28.18	HH	
HYDROCORTISONE								
1499X	Tablet 4 mg	50	4	..	10.76	11.79	Hysone 4	AF
1500Y	Tablet 20 mg	60	4	..	14.40	15.43	Hysone 20	AF
HYDROCORTISONE SODIUM SUCCINATE								
1501B	Injection equivalent to 100 mg hydrocortisone with 2 mL solvent	2	..	..	* 16.71	17.74	Solu-Cortef	PH
3096Y	Injection equivalent to 250 mg hydrocortisone with 2 mL solvent	1	..	..	15.68	16.71	Solu-Cortef	PH
HYDROCORTISONE SODIUM SUCCINATE								
<u>Restricted Benefit</u>								
<i>For use in a hospital.</i>								
1510L	Injection equivalent to 100 mg hydrocortisone with 2 mL solvent	6	..	..	* 38.15	32.90	Solu-Cortef	PH
1511M	Injection equivalent to 250 mg hydrocortisone with 2 mL solvent	6	..	..	* 61.61	32.90	Solu-Cortef	PH
METHYLPREDNISOLONE ACETATE								
<u>Restricted Benefit</u>								
<i>For local intra-articular or peri-articular infiltration.</i>								
1928L	Injection 40 mg in 1 mL	5	..	..	24.92	25.95	^a Depo-Nisolone	KR
				b0.76	25.68	25.95	^a Depo-Medrol	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	
METHYLPREDNISOLONE SODIUM SUCCINATE								
2981X	Powder for injection equivalent to 40 mg methylprednisolone with diluent	5	..	..	36.41	32.90	Solu-Medrol	PF
8834Y	Powder for injection equivalent to 1 g methylprednisolone with diluent	1	..	..	98.67	32.90	Solu-Medrol	PF
PREDNISOLONE								
3152X	Tablet 1 mg	100	4	.. B0.46	8.00 8.46	9.03 ^a 9.03 ^a	Predsolone Panafcortelone	LN AS
1917X	Tablet 5 mg	60	4	..	8.15	9.18	Panafcortelone Solone	AS FM
1916W	Tablet 25 mg	30	4	..	9.90	10.93	Panafcortelone Solone	AS FM
PREDNISOLONE SODIUM PHOSPHATE								
8285C	Oral solution equivalent to 5 mg prednisolone per mL, 30 mL	‡ 1	5	.. B1.86	14.71 16.57	15.74 ^a 15.74 ^a	PredMix Redipred	LN AS
PREDNISONE								
1934T	Tablet 1 mg	100	4	.. B0.65	8.57 9.22	9.60 ^a 9.60 ^a	Predsone Panafcort	LN AS
1935W	Tablet 5 mg	60	4	..	8.92	9.95	Panafcort Sone	AS FM
1936X	Tablet 25 mg	30	4	..	11.29	12.32	Panafcort Sone	AS FM
TRIAMCINOLONE ACETONIDE								
<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>Psoriasis.</i>								
2990J	Injection 10 mg in 1 mL	5	..	..	25.74	26.77	<i>Kenacort-A10</i>	<i>BQ</i>

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	
THYROID THERAPY								
Thyroid preparations								
• Thyroid hormones								
LIOTHYRONINE SODIUM								
Authority Required (STREAMLINED)								
1219								
<i>Management of patients with thyroid cancer;</i>								
1858								
<i>Replacement therapy for hypothyroid patients who have documented intolerance to thyroxine sodium;</i>								
1859								
<i>Replacement therapy for hypothyroid patients who have documented resistance to thyroxine sodium;</i>								
1182								
<i>Initiation of thyroid therapy in severely hypothyroid patients.</i>								
2318B	Tablet 20 micrograms	100	2	..	83.10	32.90	Tertroxin	SI
THYROXINE SODIUM								
2174K	Tablet equivalent to 50 micrograms anhydrous thyroxine sodium	200	1	.. b1.30	24.00 25.30	25.03 ^a 25.03 ^a	Eutroxsig Oroxine	FM SI
9287T	Tablet equivalent to 75 micrograms anhydrous thyroxine sodium	200	1	.. b1.46	24.69 26.15	25.72 ^a 25.72 ^a	Eutroxsig Oroxine	FM SI
2175L	Tablet equivalent to 100 micrograms anhydrous thyroxine sodium	200	1	.. b1.31	24.64 25.95	25.67 ^a 25.67 ^a	Eutroxsig Oroxine	FM SI
2173J	Tablet equivalent to 200 micrograms anhydrous thyroxine sodium	200	1	.. b1.29	27.86 29.15	28.89 ^a 28.89 ^a	Eutroxsig Oroxine	FM SI
Antithyroid preparations								
• Thiouracils								
PROPYLTHIOURACIL								
1955X	Tablet 50 mg	200	2	..	* 49.21	32.90	PTU	PL
• Sulfur-containing imidazole derivatives								
CARBIMAZOLE								
1153Q	Tablet 5 mg	200	2	..	* 30.61	31.64	Neo-Mercazole	LM

PANCREATIC HORMONES

Glycogenolytic hormones

• Glycogenolytic hormones

GLUCAGON HYDROCHLORIDE

1449G	Injection set containing 1 mg (1 i.u.) and 1 mL solvent in disposable syringe	1	1	..	45.20	32.90	GlucaGen Hypokit	NO

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

CALCIUM HOMEOSTASIS

Parathyroid hormones and analogues

• Parathyroid hormones and analogues

TERIPARATIDE

NOTE:

Any queries concerning the arrangements to prescribe teriparatide 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 teriparatide 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.

Authority Required

Initial treatment, as the sole PBS-subsidised agent, by a specialist or consultant physician, for severe, established osteoporosis in a patient with a very high risk of fracture who:

(a) has a bone mineral density (BMD) T-score of -3.0 or less; and

(b) has had 2 or more fractures due to minimal trauma; and

(c) has experienced at least 1 symptomatic new fracture after at least 12 months continuous therapy with an anti-resorptive agent at adequate doses.

A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

If treatment with anti-resorptive therapy is contraindicated according to the relevant TGA-approved Product Information, details of the contraindication must be provided at the time of application.

If an intolerance of a severity necessitating permanent treatment withdrawal develops during the relevant period of use of one anti-resorptive agent, alternate anti-resorptive agents must be trialled so that the patient achieves the minimum requirement of 12 months continuous therapy. Details of accepted toxicities including severity can be found on the Medicare Australia website at www.medicareaustralia.gov.au and must be provided at the time of application.

Anti-resorptive therapies for osteoporosis and their adequate doses which will be accepted for the purposes of administering this restriction are alendronate sodium 10 mg per day or 70 mg once weekly, risedronate sodium 5 mg per day or 35 mg once weekly, raloxifene hydrochloride 60 mg per day (women only), etidronate 200 mg with calcium carbonate 1.25 g per day, strontium ranelate 2 g per day and zoledronic acid 5 mg per annum.

Authority applications must be made in writing and must include:

Details of prior anti-resorptive therapy, fracture history including the date(s), site(s), the symptoms associated with the fracture(s) which developed during the course of anti-resorptive therapy and the score of the qualifying BMD measurement.

NOTE:

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

SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS—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 \$	

Authority Required

Initial treatment, as the sole PBS-subsidised agent, by a specialist or consultant physician, for severe, established osteoporosis in a patient with a very high risk of fracture who was receiving treatment with teriparatide prior to 1 May 2009.

The authority application must be made in writing and the commencement date of treatment and the number of doses the patient has received of teriparatide must be provided with the application. The patient is eligible to receive a maximum of 18 months therapy of combined PBS-subsidised and non-PBS-subsidised therapy.

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

NOTE:

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

Authority Required

Continuing treatment for severe established osteoporosis where the patient has previously been issued with an authority prescription for this drug.

Teriparatide must only be used for a lifetime maximum of 18 months therapy (18 pens). Up to a maximum of 18 pens will be reimbursed through the PBS.

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

NOTE:

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

9411H	Injection 250 micrograms per mL, 3 mL in multi-dose pre-filled pen	1	5	..	437.94	32.90	Forteo	LY

NOTE:

Special Pricing Arrangements apply.

Anti-parathyroid agents**• Calcitonin preparations****SALCATONIN****NOTE:**

The maximum quantities for salcatonin shown represent the number of individual ampoules and NOT multiples of the manufacturer's packs. The pack size for both strengths is five ampoules.

Authority Required (STREAMLINED)

1392

Symptomatic Paget's disease of bone;

1412

Treatment initiated in a hospital (in-patient or out-patient) of hypercalcaemia.

2995P	Injection 50 i.u. in 1 mL	30	5	..	* 207.23	32.90	Miacalcic 50	NV
2997R	Injection 100 i.u. in 1 mL	15	5	..	* 160.70	32.90	Miacalcic 100	NV

SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS—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 \$	

• Other anti-parathyroid agents

CINACALCET HYDROCHLORIDE

Authority Required

Maintenance therapy, following initiation and stabilisation of treatment with cinacalcet, of a patient with chronic kidney disease on dialysis who has after 6 months treatment:

(a) a decrease of at least 30% in iPTH concentrations; or

(b) iPTH greater than 15 pmol per L and an (adjusted) serum calcium concentration of less than 2.6 mmol per L.

NOTE:

During the titration phase, intact PTH should be monitored 4 weekly (measured at least 12 hours post dose) and dose titrated until an appropriate iPTH concentration is achieved. During the titration phase, approval will be limited to sufficient supply for 4 weeks treatment at a time, with doses between 30 and 180 mg per day according to the patient's response and tolerability.

During the maintenance phase, approval will be limited to provide sufficient quantity for 4 weeks treatment up to a maximum of 6 months supply for doses between 30 and 180 mg per day according to the patient's response and tolerability. Intact PTH should be monitored quarterly (measured at least 12 hours post dose) and dose adjusted as necessary to maintain an appropriate iPTH concentration.

9157Y	Tablet 30 mg (base)	28	5	..	343.17	32.90	Sensipar	AN
9158B	Tablet 60 mg (base)	28	5	..	669.89	32.90	Sensipar	AN
9159C	Tablet 90 mg (base)	28	5	..	1001.84	32.90	Sensipar	AN

ANTIINFECTIVES FOR SYSTEMIC USE

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Proprietary Name and Manufacturer	
ANTIBACTERIALS FOR SYSTEMIC USE								
	Tetracyclines							
	• Tetracyclines							
	DOXYCYCLINE							
9105F	Tablet 100 mg (as monohydrate)	7	1	..	8.04	9.07	^a Chem mart Doxycycline ^a Doxyhexal ^a GenRx Doxycycline ^a Terry White Chemists Doxycycline	CH SZ GX TW
2709N	Tablet 100 mg (as hydrochloride)	7	1	..	8.04	9.07	^a Doxsig ^a Doxy-100 ^a Doxylin 100 b1.19 9.23 9.07 ^a Vibramycin	SI GM AF PF
NOTE: Bioequivalence has been demonstrated between doxycycline tablet 100 mg (as hydrochloride) and doxycycline tablet 100 mg (as monohydrate).								
2708M	Capsule 100 mg (as hydrochloride)	7	1	.. b1.15	8.04 9.19	9.07 9.07	^a DBL Doxycycline ^a Doryx	FA HH

DOXYCYCLINE

Restricted Benefit

Bronchiectasis in patients aged 8 years or older;

Chronic bronchitis in patients aged 8 years or older;

Severe acne.

9106G	Tablet 50 mg (as monohydrate)	25	5	..	9.64	10.67	^a Chem mart Doxycycline ^a Doxyhexal ^a Frakas ^a GenRx Doxycycline ^a Terry White Chemists Doxycycline	CH SZ SI GX TW
2711Q	Tablet 50 mg (as hydrochloride)	25	5	.. b1.25	9.64 10.89	10.67 10.67	^a Doxy-50 ^a Doxylin 50 ^a Vibra-Tabs	GM AF PF

NOTE:

Bioequivalence has been demonstrated between doxycycline tablet 50 mg (as hydrochloride) and doxycycline tablet 50 mg (as monohydrate).

continued ➞

ANTIINFECTIVES FOR SYSTEMIC USE—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Proprietary Name and Manufacturer	
2707L	Capsule 50 mg (as hydrochloride)	25	5	.. B1.31	9.64 10.95	10.67 10.67	^a DBL Doxycycline ^a Doryx	FA HH
Restricted Benefit Pelvic inflammatory disease.								
9107H	Tablet 100 mg (as monohydrate)	28	..	..	* 14.19	15.22	^a Chem mart Doxycycline ^a Doxyhexal ^a GenRx Doxycycline ^a Terry White Chemists Doxycycline	CH SZ GX TW
2702F	Tablet 100 mg (as hydrochloride)	28	..	..	* 14.19	15.22	^a Doxsig ^a Doxy-100 ^a Doxylin 100	SI GM AF
				B4.76	* 18.95	15.22	^a Vibramycin	PF
NOTE: Bioequivalence has been demonstrated between doxycycline tablet 100 mg (as hydrochloride) and doxycycline tablet 100 mg (as monohydrate).								
2703G	Capsule 100 mg (as hydrochloride)	28	..	.. B4.60	* 14.19 * 18.79	15.22 15.22	^a DBL Doxycycline ^a Doryx	FA HH
Restricted Benefit Urethritis.								
9108J	Tablet 100 mg (as monohydrate)	21	..	..	12.13	13.16	^a GenRx Doxycycline	GX
				..	* 12.14	13.17	^a Chem mart Doxycycline ^a Doxyhexal ^a Terry White Chemists Doxycycline	CH SZ TW
2714W	Tablet 100 mg (as hydrochloride)	21	..	..	* 12.14	13.17	^a Doxsig ^a Doxy-100 ^a Doxylin 100	SI GM AF
				B3.57	* 15.71	13.17	^a Vibramycin	PF
NOTE: Bioequivalence has been demonstrated between doxycycline tablet 100 mg (as hydrochloride) and doxycycline tablet 100 mg (as monohydrate).								
2715X	Capsule 100 mg (as hydrochloride)	21	..	.. B2.09	12.09 14.18	13.12 13.12	^a DBL Doxycycline ^a Doryx	FA HH

ANTIINFECTIVES FOR SYSTEMIC USE—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Proprietary Name and Manufacturer	
MINOCYCLINE								
CAUTION:								
There are concerns about the incidence of benign intracranial hypertension associated with this drug.								
3037W	Capsule 100 mg	11	..	..	9.22	10.25	Akamin 100	AF
NOTE:								
No applications for increased maximum quantities and/or repeats will be authorised.								
MINOCYCLINE								
CAUTION:								
<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	..	15.06	16.09	^a Akamin 50	AF
				B0.85	15.91	16.09	^a Minomycin-50	SI
Beta-lactam antibacterials, penicillins								
• Penicillins with extended spectrum								
AMOXYCILLIN								
1884E	Capsule 250 mg	20	1	..	8.12	9.15	^a Alphamox 250	AF
							^a Amohexal	HX
							^a Amoxycillin-DP	GM
							^a Amoxycillin	RA
							Ranbaxy	
							^a Amoxycillin	SZ
							Sandoz	
							^a APO-Amoxycillin	TX
							^a Chem mart	CH
							Amoxycillin	
							^a Cilamox	SI
							^a GenRx	GX
							Amoxycillin	
							^a Terry White	TW
							Chemists	
							Amoxycillin	
				B0.79	8.91	9.15	^a Amoxil	GK

continued ➡

ANTIINFECTIVES FOR SYSTEMIC USE—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Proprietary Name and Manufacturer	
1889K	Capsule 500 mg	20	1	..	10.22	11.25	a Alphamox 500	AF
							a Amohexal	HX
							a Amoxycillin-DP	GM
							a Amoxycillin	RA
							Ranbaxy	
							a Amoxycillin	SZ
							Sandoz	
							a APO-Amoxycillin	TX
							a Chem mart	CH
							Amoxycillin	
							a Cilamox	SI
							a GenRx	GX
							Amoxycillin	
							a Moxacin	AS
							a Terry White	TW
							Chemists	
							Amoxycillin	
				B0.80	11.02	11.25	a Amoxil	GK
1878W	Sachet containing oral powder 3 g	1	..	..	8.68	9.71	Amoxil	GK
1886G	Powder for syrup 125 mg per 5 mL, 100 mL	‡ 1	1	..	# 10.45	11.84	a Alphamox 125	AF
							a Amoxycillin	SZ
							Sandoz	
							a Bgramin	GM
							a Chem mart	CH
							Amoxycillin	
							a GenRx	GX
							Amoxycillin	
							a Ranmoxy	RA
							a Terry White	TW
							Chemists	
							Amoxycillin	
				B0.95	# 11.40	11.84	a Amoxil	GK
1887H	Powder for syrup 250 mg per 5 mL, 100 mL	‡ 1	1	..	# 11.29	12.68	a Alphamox 250	AF
							a Amohexal	HX
							a Amoxycillin	SZ
							Sandoz	
							a Bgramin	GM
							a Chem mart	CH
							Amoxycillin	
							a Cilamox	SI
							a GenRx	GX
							Amoxycillin	
							a Ranmoxy	RA
							a Terry White	TW
							Chemists	
							Amoxycillin	
				B0.79	# 12.08	12.68	a Amoxil Forte	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	
8705E	Powder for oral suspension 500 mg per 5 mL, 100 mL	‡ 1	1	..	# 14.30	15.69	Maxamox	SZ
AMOXYCILLIN								
<u>Restricted Benefit</u>								
<i>Acute exacerbations of chronic bronchitis.</i>								
8581P	Tablet 1 g	14	1	..	10.36	11.39	^a Amoxycillin	BG
				B1.17	11.53	11.39	^a Sandoz	SZ
							^a Maxamox	
AMPICILLIN								
2390T	Powder for injection 500 mg	5	1	..	10.65	11.68	^a Austrapen ^a Ibimicyn	LN GM
2977Q	Powder for injection 1 g	5	1	..	13.64	14.67	^a Aspen Ampicyn ^a Austrapen ^a Ibimicyn	AS LN GM
• Beta-lactamase sensitive penicillins								
BENZATHINE BENZYL PENICILLIN								
2267H	Injection 900 mg in 2.3 mL single use pre-filled syringe	10	..	..	292.68	32.90	Bicillin L-A	AS
BENZYL PENICILLIN								
1775K	Powder for injection 600 mg	10	1	..	* 42.49	32.90	BenPen	CS
2647H	Powder for injection 3 g	10	..	..	* 66.49	32.90	BenPen	CS
PHENOXYMETHYL PENICILLIN								
1787C	Tablet 250 mg	50	..	..	* 11.15	12.18	Abbocillin-VK Filmtab	SI
3028J	Tablet 500 mg	50	..	..	* 13.63	14.66	Abbocillin-VK Filmtab	SI
1789E	Capsule 250 mg	50	..	..	10.98	12.01	LPV	AS
				..	10.98	12.01	^a Cilicaine VK ^a Cilopen VK	FM GM
2965C	Capsule 500 mg	50	..	..	13.41	14.44	LPV	AS
				..	13.41	14.44	^a Cilicaine VK ^a Cilopen VK	FM GM
9143F	Oral suspension 150 mg (as benzathine) per 5 mL, 100 mL	2	1	..	* 21.97	23.00	Abbocillin-V Cilicaine V	SI FM

ANTIINFECTIVES FOR SYSTEMIC USE—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Proprietary Name and Manufacturer	
PHENOXYMETHYLPENICILLIN								
<u>Restricted Benefit</u>								
<i>Prophylaxis of recurrent streptococcal infections (including rheumatic fever).</i>								
1703P	Tablet 250 mg	50	5	..	* 11.15	12.18	Abbotcillin-VK Filmstab	SI
1705R	Capsule 250 mg	50	5	..	10.98	12.01	LPV	AS
				..	10.98	12.01	^a Cilicaine VK	FM
							^a Cilopen VK	GM
PROCAINE PENICILLIN								
1794K	Injection 1.5 g	5	..	..	91.79	32.90	Cilicaine	SI
• Beta-lactamase resistant penicillins								
DICLOXACILLIN								
<u>Restricted Benefit</u>								
<i>Serious staphylococcal infections.</i>								
8121K	Capsule 250 mg	24	..	..	11.02	12.05	^a Diclocil ^a Dicloxsig ^a Distaph 250	BQ SI AF
8122L	Capsule 500 mg	24	..	..	16.51	17.54	^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	..	..	15.06	16.09	^a Flubiclox ^a Flucil	GM AS
1525G	Powder for injection 1 g	5	1	..	20.23	21.26	^a Flubiclox ^a Flucil ^a HH	GM 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	
FLUCLOXACILLIN								
CAUTION:								
<i>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.</i>								
Restricted Benefit								
<i>Serious staphylococcal infections.</i>								
1526H	Capsule 250 mg (as sodium)	24	..	..	11.02	12.05	^a Flopen ^a Staphylex 250	AS AF
1527J	Capsule 500 mg (as sodium)	24	..	..	16.51	17.54	^a Flopen ^a Staphylex 500	AS AF
9149M	Powder for oral liquid 125 mg (as sodium) per 5 mL, 100 mL	‡ 1	..	..	# 15.97	17.36	LN	
9150N	Powder for oral liquid 250 mg (as sodium) per 5 mL, 100 mL	‡ 1	..	..	# 19.68	21.07	LN	
• 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	..	11.73	12.76	^a Clamoxyl Duo ^a Curam 500/125 ^a GA-Amclav 500/125 ^a Moxiclav Duo 500/125	AL SZ GM AW
				B1.55	13.28	12.76	^a Augmentin Duo	GK

continued ➞

ANTIINFECTIVES FOR SYSTEMIC USE—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Proprietary Name and Manufacturer	
CEPHALEXIN								
3058Y	Capsule 250 mg	20	1	..	8.42	9.45	a Cefalexin Sandoz	SZ
							a Cephabell	BF
							a Cephalixin Max	XF
							a Cephatrust 250	MI
							a Chem mart	CH
							Cephalixin	
							a Cilex	GM
							a GenRx Cephalixin	GX
							a Ialex	LN
							a Ibilex 250	AF
							a Rancef	RA
							a Sporahehexal	HX
							a Terry White	TW
							Chemists	
							Cephalixin	
				B3.30	11.72	9.45	a Keflex	AS
3119E	Capsule 500 mg	20	1	..	10.34	11.37	a Cefalexin Sandoz	SZ
							a Cephabell	BF
							a Cephalixin Max	XF
							a Cephatrust 500	MI
							a Chem mart	CH
							Cephalixin	
							a Cilex	GM
							a GenRx Cephalixin	GX
							a Ialex	LN
							a Ibilex 500	AF
							a Rancef	RA
							a Sporahehexal	HX
							a Terry White	TW
							Chemists	
							Cephalixin	
				B4.41	14.75	11.37	a Keflex	AS
3094W	Granules for syrup 125 mg per 5 mL, 100 mL	‡ 1	1	..	# 11.44	12.83	a Cefalexin Sandoz	SZ
							a Chem mart	CH
							Cephalixin	
							a Cilex	GM
							a GenRx Cephalixin	GX
							a Ialex	LN
							a Ibilex 125	AF
							a Terry White	TW
							Chemists	
							Cephalixin	
				B3.55	# 14.99	12.83	a Keflex	AS

continued 

ANTIINFECTIVES FOR SYSTEMIC USE—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Proprietary Name and Manufacturer	
3095X	Granules for syrup 250 mg per 5 mL, 100 mL	‡ 1	1	..	# 12.84	14.23	a Cefalexin Sandoz	SZ
							a Chem mart	CH
							Cephalexin	
							a Cilex	GM
							a GenRx Cephalexin	GX
							a Ialex	LN
							a Ibilex 250	AF
							a Terry White	TW
							Chemists	
							Cephalexin	
				B4.38	# 17.22	14.23	a Keflex	AS

CEPHAZOLIN

Restricted Benefit

Infections where positive bacteriological evidence confirms that this antibiotic is an appropriate therapeutic agent;

Septicaemia, suspected;

Septicaemia, proven.

1256D	Powder for injection 500 mg	10	..	..	* 45.13	32.90	HH	
1257E	Powder for injection 1 g	10	..	..	66.09	32.90	a Cefazolin Sandoz	SZ
							a Kefzol	AS
				..	* 66.09	32.90	a HH	

• **Second-generation cephalosporins**

CEFACLOR

CAUTION:

Serum sickness-like reactions have been reported with this drug, especially in children.

1169M	Tablet 375 mg (sustained release)	10	1	..	12.46	13.49	a Cefaclor-GA	GN
							a Chem mart	CH
							Cefaclor CD	
							a Douglas Cefaclor-	GM
							CD	
							a GenRx Cefaclor	GX
							CD	
							a Karlor CD	LN
							a Keflor CD	AF
							a Ozcef	RA
							a Terry White	TW
							Chemists	
							Cefaclor CD	
				B5.20	17.66	13.49	a Ceclor CD	AS

continued ➡

ANTIINFECTIVES FOR SYSTEMIC USE—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Proprietary Name and Manufacturer	
2460L	Powder for oral suspension 125 mg per 5 mL, 100 mL	‡ 1	1	..	# 13.10	14.49	a Aclor 125 a Cefaclor Sandoz a Chem mart Cefaclor a GenRx Cefaclor a Keflor a Ozcef a Terry White Chemists Cefaclor	AW SZ CH GX AF RA TW AS
				B4.18	# 17.28	14.49	a Ceclor	AS
2461M	Powder for oral suspension 250 mg per 5 mL, 75 mL	‡ 1	1	..	# 13.43	14.82	a Aclor 250 a Cefaclor Sandoz a Chem mart Cefaclor a GenRx Cefaclor a Keflor a Ozcef a Terry White Chemists Cefaclor	AW SZ CH GX AF RA TW AS
				B4.37	# 17.80	14.82	a Ceclor	AS
	CEFUROXIME AXETIL							
8292K	Tablet 250 mg (base)	14	1	..	18.19	19.22	Zinnat	GK

• Third-generation cephalosporins

CEFOTAXIME

Restricted Benefit

Infections where positive bacteriological evidence confirms that this antibiotic is an appropriate therapeutic agent;

Septicaemia, suspected;

Septicaemia, proven.

1085D	Powder for injection 1 g	10	..	..	27.27	28.30	a HH	
				B25.10	* 52.39	28.32	a Cefotaxime Sandoz	SZ
1086E	Powder for injection 2 g	10	..	..	44.60	32.90	a HH	
				B46.50	* 91.09	32.90	a Cefotaxime Sandoz	SZ

CEFTRIAXONE

Restricted Benefit

Gonorrhoea.

9058R	Powder for injection 500 mg	1	..	..	10.06	11.09	Ceftriaxone ICP	IZ

continued ➡

ANTIINFECTIVES FOR SYSTEMIC USE—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Proprietary Name and Manufacturer	
Restricted Benefit								
<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	..	..	* 26.34	27.37	Ceftriaxone ICP	IZ
1784X	Powder for injection 1 g	5	..	..	* 37.79	32.90	^a Ceftriaxone ICP	IZ
							^a Ceftriaxone Sandoz	SZ
							^a DBL Ceftriaxone	HH
							^a Rocephin	RO
				..	37.79	32.90	^a XF	
1785Y	Powder for injection 2 g	5	..	..	* 62.39	32.90	^a Ceftriaxone ICP	IZ
							^a Ceftriaxone Sandoz	SZ
							^a DBL Ceftriaxone	HH
							^a Rocephin	RO

• **Fourth-generation cephalosporins**
CEFEPIME

Authority Required

Treatment of febrile neutropenia.

8315P	Powder for injection 1 g (solvent required) (code 7079N applies to above item with approved solvent)	10	..	..	* 183.39	32.90	Maxipime	BQ
8316Q	Powder for injection 2 g (solvent required) (code 7085X applies to above item with approved solvent)	10	..	..	* 331.19	32.90	Maxipime	BQ

Sulfonamides and trimethoprim

• **Trimethoprim and derivatives**
TRIMETHOPRIM

2922T	Tablet 300 mg	7	1	..	8.05	9.08	^a Alprim	AF
				B1.03	9.08	9.08	^a Triprim	SI

• **Combinations of sulfonamides and trimethoprim, incl. derivatives**

TRIMETHOPRIM with SULFAMETHOXAZOLE

CAUTION:

There is an increased risk of severe adverse reactions with this combination in the elderly.

2949F	Tablet 80 mg-400 mg	10	1	..	8.24	9.27	Resprim	AF

continued ➞

ANTIINFECTIVES FOR SYSTEMIC USE—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Proprietary Name and Manufacturer	
2951H	Tablet 160 mg-800 mg	10	1	..	8.96	9.99	^a Bactrim DS	RO
				B1.10	10.06	9.99	^a Resprim Forte	AF
							^a Septrin Forte	SI
3103H	Oral suspension 40 mg-200 mg per 5 mL, 100 mL	‡ 1	1	..	8.62	9.65	Bactrim	RO
				B1.46	10.08	9.65	Septrin	SI

Macrolides, lincosamides and streptogramins

• Macrolides

AZITHROMYCIN

Restricted Benefit

Uncomplicated urethritis due to Chlamydia trachomatis;

Uncomplicated cervicitis due to Chlamydia trachomatis.

NOTE:

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

8200N	Tablet 500 mg	2	..	..	23.46	24.49	Zithromax	PF

Restricted Benefit

Trachoma.

NOTE:

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

8336R	Tablet 500 mg	2	2	..	23.46	24.49	Zithromax	PF
8201P	Powder for oral suspension 200 mg per 5 mL, 15 mL	‡ 1	..	..	# 23.01	24.40	Zithromax	PF

CLARITHROMYCIN

8318T	Tablet 250 mg	14	1	..	12.25	13.28	^a Chem mart Clarithromycin	CH
							^a Clarac	GM
							^a Clarihexal	SZ
							^a Clarithro 250	SI
							^a GenRx	GX
							Clarithromycin	
							^a Kalixocin	AF
							^a Terry White Chemists	TW
				B1.96	14.21	13.28	^a Klacid	AB

continued ➞

ANTIINFECTIVES FOR SYSTEMIC USE—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Proprietary Name and Manufacturer	
CLARITHROMYCIN								
<u>Restricted Benefit</u>								
<i>Bordetella pertussis;</i>								
<i>Atypical mycobacterial infections.</i>								
9192T	<i>Powder for oral liquid 250 mg per 5 mL, 50 mL</i>	‡ 1	..	..	# 36.83	32.90	<i>Klacid</i>	AB
ERYTHROMYCIN								
1404X	Capsule 250 mg	25	1	.. B1.35	9.00 10.35	10.03 10.03	^a DBL Erythromycin ^a Eryc	FA HH
ERYTHROMYCIN ETHYL SUCCINATE								
2750R	Tablet 400 mg (base)	25	1	.. B2.80	10.49 13.29	11.52 11.52	^a E-Mycin ^a E.E.S. 400 Filmtab	AF LM
2424N	Powder for oral liquid 200 mg (base) per 5 mL, 100 mL	‡ 1	1	.. B2.86	# 11.92 # 14.78	13.31 13.31	^a E-Mycin 200 ^a E.E.S. 200	AF LM
2428T	Powder for oral liquid 400 mg (base) per 5 mL, 100 mL	‡ 1	1	.. B2.89	# 13.00 # 15.89	14.39 14.39	^a E-Mycin 400 ^a E.E.S. Granules	AF LM
ERYTHROMYCIN LACTOBIONATE								
1397M	Powder for I.V. infusion 1 g (base)	5	..	..	* 50.94	32.90	Erythrocin-I.V.	LM
ROXITHROMYCIN								
8129W	Tablet for oral suspension 50 mg	10	1	..	12.46	13.49	Rulide D	SW
1760P	Tablet 150 mg	10	1	..	11.33	12.36	^a APO- Roxithromycin ^a Biaxsig ^a Chem mart Roxithromycin ^a Roxar 150 ^a Roxide ^a Roximycin ^a Terry White Chemists Roxithromycin	TX AV CH SI SZ AF TW SW
				B2.60	13.93	12.36	^a Rulide	SW

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	
8016X	Tablet 300 mg	5	1	..	11.33	12.36	a APO- Roxithromycin	TX
							a Biaxig	AV
							a Chem mart	CH
							Roxithromycin	
							a Roxar 300	SI
							a Roxide	SZ
							a Roximycin	AF
							a Terry White Chemists	TW
							Roxithromycin	
				B2.60	13.93	12.36	a Rulide	SW

• Lincosamides

CLINDAMYCIN

Restricted Benefit

Gram-positive coccal infections where these cannot be safely and effectively treated with a penicillin.

3138E	Capsule 150 mg	24	..	..	20.16	21.19	a Cleocin	KR
				B1.45	21.61	21.19	a Dalacin C	PH

LINCOMYCIN

2530E	Injection 600 mg in 2 mL	5	..	..	33.31	32.90	Lincocin	PH

Aminoglycoside antibacterials

• Other aminoglycosides

GENTAMICIN SULFATE

2824P	Injection 80 mg (base) in 2 mL	10	1	..	* 20.07	21.10	a HH	
				..	20.07	21.10	a PU	

TOBRAMYCIN SULFATE

Restricted Benefit

Infections where positive bacteriological evidence confirms that this antibiotic is an appropriate therapeutic agent;

Septicaemia, suspected;

Septicaemia, proven.

1356J	Injection 80 mg (base) in 2 mL	10	1	..	* 64.59	32.90	HH	
8872Y	Injection 80 mg (base) in 2 mL (without preservative)	10	1	..	* 64.59	32.90	PU	

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	
Quinolone antibacterials								
• Fluoroquinolones								
CIPROFLOXACIN								
<u>Restricted Benefit</u>								
<i>Gonorrhoea.</i>								
<u>NOTE:</u>								
<i>No applications for increased maximum quantities and/or repeats will be authorised.</i>								
1311B	Tablet 250 mg	2	..	..	11.67	12.70	Ciproxin 250	BN
<u>Authority Required</u>								
<i>Respiratory tract infection proven or suspected to be caused by Pseudomonas aeruginosa in severely immunocompromised patients;</i>								
<i>Bacterial gastroenteritis in severely immunocompromised patients;</i>								
<i>Treatment of infections proven to be due to Pseudomonas aeruginosa or other gram-negative bacteria resistant to all other oral antimicrobials;</i>								
<i>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	..	..	25.90	26.93	^a C-Flox 250	AL
							^a Cifran	RA
							^a Ciprol 250	SI
							^a GenRx	GX
							Ciprofloxacin	
							^a Profloxin	SZ
				b1.45	27.35	26.93	^a Ciproxin 250	BN
1209P	Tablet 500 mg	14	..	..	44.32	32.90	^a C-Flox 500	AL
							^a Cifran	RA
							^a Ciprofloxacin 500	CR
							^a Ciprofloxacin-BW	BF
							^a Ciprol 500	SI
							^a GenRx	GX
							Ciprofloxacin	
							^a Profloxin	SZ
							^a Proquin	GM
							^a GN	
				b1.26	45.58	32.90	^a Ciproxin 500	BN

continued ➡

ANTIINFECTIVES FOR SYSTEMIC USE—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Proprietary Name and Manufacturer	
1210Q	Tablet 750 mg	14	..	..	62.07	32.90	^a C-Flox 750	AL
							^a Cifran	RA
							^a Ciprofloxacin 750	CR
							^a Ciprofloxacin-BW	BF
							^a Ciprol 750	SI
							^a GenRx	GX
							Ciprofloxacin	
							^a Profloxin	SZ
							^a Proquin	GM
							^a GN	
				B1.37	63.44	32.90	^a Ciproxin 750	BN
NORFLOXACIN								
Authority Required								
<i>Acute bacterial enterocolitis;</i>								
<i>Complicated urinary tract infection.</i>								
3010K	Tablet 400 mg	14	1	..	17.29	18.32	^a Chem mart	CH
							Norfloxacina	
							^a GenRx	GX
							Norfloxacina	
							^a Norfloxal	SZ
							^a Nufloxib	AF
							^a Roxin	SI
							^a Terry White	TW
							Chemists	
							Norfloxacina	
							^a GM	
				B3.62	20.91	18.32	^a Noroxin	MK
Other antibacterials								
• Glycopeptide antibacterials								
VANCOMYCIN								
Restricted Benefit								
<i>Prophylaxis of endocarditis in patients hypersensitive to penicillin.</i>								
3130R	Powder for injection 500 mg (500,000 i.u.) vancomycin activity	2	..	..	* 46.09	32.90	^a Vancocin CP	AS
							^a Vancomycin	SZ
							Sandoz	
							^a HH	
2269K	Powder for injection 1 g (1,000,000 i.u.) vancomycin activity	1	..	..	46.07	32.90	^a Vancomycin	SZ
							Sandoz	
							^a HH	

continued ➞

ANTIINFECTIVES FOR SYSTEMIC USE—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Proprietary Name and Manufacturer	
<u>Restricted Benefit</u>								
<i>Endophthalmitis;</i>								
<i>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	..	..	* 103.89	32.90	^a Vancocin CP ^a Vancomycin Sandoz ^a HH	AS SZ
2270L	Powder for injection 1 g (1,000,000 i.u.) vancomycin activity	3	..	..	* 123.41	32.90	^a Vancomycin Sandoz ^a HH	SZ
• Steroid antibacterials								
<i>FUSIDIC ACID</i>								
<u>Restricted Benefit</u>								
<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	..	90.46	32.90	Fucidin	CS
• Imidazole derivatives								
METRONIDAZOLE								
1636D	Tablet 200 mg	21	1	..	7.53	8.56	^a Metrogyl 200 ^a Metronide 200	AF AV
				B2.30	9.83	8.56	^a Flagyl	SW
1626N	Tablet 400 mg	5	2	..	7.45	8.48	Metrogyl 400	AF
1642K	Suppositories 500 mg, 10	‡ 1	..	..	22.73	23.76	Flagyl	SW
METRONIDAZOLE								
<u>Restricted Benefit</u>								
<i>Treatment of anaerobic infections.</i>								
1621H	Tablet 400 mg	21	1	..	9.60	10.63	^a Metrogyl 400 ^a Metronide 400	AF AV
				B2.30	11.90	10.63	^a Flagyl	SW

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	
<u>Restricted Benefit</u>								
<i>Prophylaxis in large bowel surgery;</i>								
<i>Treatment, in a hospital, of acute anaerobic sepsis.</i>								
1638F	I.V. infusion 500 mg in 100 mL	5	1	..	* 31.54	32.57	^a BX	
				..	* 31.54	32.57	^a DBL	HH
							<i>Metronidazole Intravenous Infusion</i>	
							^a Metronidazole Sandoz	SZ
METRONIDAZOLE BENZOATE								
1630T	Oral suspension 320 mg per 5 mL (equivalent to 200 mg metronidazole in 5 mL), 100 mL	‡ 1	..	..	16.74	17.77	Flagyl S	SW
TINIDAZOLE								
1465D	Tablet 500 mg	4	..	..	8.92	9.95	^a Simplotan	GP
				B2.51	11.43	9.95	^a Fasigyn	PF
• Nitrofurán derivatives								
NITROFURANTOIN								
<u>CAUTION:</u>								
Nitrofurantoin may cause peripheral neuritis and severe pulmonary reactions.								
1692C	Capsule 50 mg	30	1	..	19.95	20.98	Macrochantin	PU
1693D	Capsule 100 mg	30	1	..	25.83	26.86	Macrochantin	PU
• Other antibacterials								
HEXAMINE HIPPURATE								
3124K	Tablet 1 g	100	5	..	41.95	32.90	Hiprex	IA

ANTIMYCOTICS FOR SYSTEMIC USE

Antimycotics for systemic use

• **Antibiotics**

AMPHOTERICIN

1047D	Powder for injection 50 mg	1	..	..	34.22	32.90	Fungizone	BQ

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	
• Imidazole derivatives KETOCONAZOLE <u>Authority Required</u> <i>Symptomatic genital candidiasis recurring after treatment of at least 2 episodes with topical therapy.</i> CAUTION: <i>Hepatotoxicity has been reported with ketoconazole.</i>								
1573T	Tablet 200 mg	10	..	..	19.36	20.39	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> CAUTION: <i>Hepatotoxicity has been reported with ketoconazole.</i>								
1572R	Tablet 200 mg	30	5	..	41.74	32.90	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	..	149.34	32.90	^a DBL Fluconazole ^a Diflucan ^a Dizole 50 ^a Fluconazole Hexal ^a Fluzole 50 ^a Ozole	HH PF AF SZ SI RA
1472L	Capsule 100 mg	28	5	..	277.87	32.90	^a DBL Fluconazole ^a Diflucan ^a Dizole 100 ^a Fluconazole Hexal ^a Fluconazole Winthrop ^a Ozole	HH PF AF SZ WA 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	
1475P	Capsule 200 mg	28	5	..	520.33	32.90	^a APO-Fluconazole	TX
							^a DBL Fluconazole	HH
							^a Diflucan	PF
							^a Dizole 200	AF
							^a Fluconazole Hexal	SZ
							^a Fluconazole	WA
							Winthrop	
							^a Fluzole 200	SI
							^a Ozole	RA
1473M	Solution for I.V. infusion 100 mg in 50 mL	7	..	..	* 165.24	32.90	^a Diflucan	PF
							^a Fluconazole Hexal	SZ
1474N	Solution for I.V. infusion 200 mg in 100 mL	7	..	..	* 296.28	32.90	^a Diflucan	PF
							^a Fluconazole Hexal	SZ
							^a BX	
1757L	Solution for I.V. infusion 400 mg in 200 mL	1	..	..	73.32	32.90	BX	

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	..	246.36	32.90	Sporanox	JC

POSACONAZOLE

Authority Required

Treatment of invasive aspergillosis in patients intolerant to, or with disease refractory to, alternative therapy;

Treatment of fusariosis, zygomycosis, coccidioidomycosis, chromoblastomycosis and mycetoma in patients intolerant to, or with disease refractory to, alternative therapy.

Authority Required

Prophylaxis of invasive fungal infections, including both yeasts and moulds, in a patient who is at high risk of developing these infections, defined as follows:

(1) Neutropenia

Patients with anticipated neutropenia (an absolute neutrophil count of less than 500 cells per cubic millimetre) for at least 10 days, who are receiving chemotherapy for acute myelogenous leukaemia or myelodysplastic syndrome.

Treatment should continue until recovery of the neutrophil count to at least 500 cells per cubic millimetre.

Patients who have had a previous invasive fungal infection should have secondary prophylaxis during subsequent episodes of neutropenia.

continued ➞

ANTIINFECTIVES FOR SYSTEMIC USE—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 \$		
<i>(2) Graft versus host disease (GVHD)</i> <i>Patients with acute GVHD grades II to IV or extensive chronic GVHD, who are receiving intensive immunosuppressive therapy after allogeneic haematopoietic stem cell transplant.</i> <i>No more than 6 months therapy per episode will be PBS-subsidised.</i>								
9360P	Oral suspension 40 mg per mL, 105 mL	± 1	5	..	732.83	32.90	Noxafil	SH

VORICONAZOLE

Authority Required

For the treatment and maintenance therapy of definite or probable invasive aspergillosis in immunocompromised patients;

*For the treatment and maintenance therapy of serious fungal infections caused by *Scedosporium* species or *Fusarium* species;*

*For the treatment and maintenance therapy of serious *Candida* infections where:*

(a) treatment with amphotericin has failed; or

(b) treatment with amphotericin is not tolerated and the causative species is not susceptible to fluconazole; or

(c) treatment with fluconazole has failed; or

(d) treatment with fluconazole is not tolerated;

For the treatment and maintenance therapy of other serious invasive mycosis where:

(a) treatment with amphotericin has failed; or

(b) treatment with amphotericin is not tolerated.

9363T	Tablet 50 mg	56	..	..	700.44	32.90	Vfend	PF
9364W	Tablet 200 mg	56	..	..	2630.65	32.90	Vfend	PF

ANTIMYCOBACTERIALS

Drugs for treatment of tuberculosis

• **Hydrazides**

ISONIAZID

1554T	Tablet 100 mg	100	2	..	11.20	12.23	FM	

Drugs for treatment of lepra

• **Drugs for treatment of lepra**

DAPSONE

8801F	Tablet 25 mg	100	1	..	100.15	32.90	LM	
1272Y	Tablet 100 mg	100	1	..	113.41	32.90	LM	

RIFAMPICIN

Restricted Benefit

Prophylaxis of meningococcal disease in close contacts and carriers;

*Prophylactic treatment of contacts of patients with *Haemophilus influenzae* type B.*

1981G	Capsule 150 mg	10	..	..	10.07	11.10	Rimycin 150	AF
1984K	Capsule 300 mg	10	..	..	13.12	14.15	Rimycin 300	AF

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	
8025J	Syrup 100 mg per 5 mL, 60 mL	± 1	..	..	28.14	29.17	Rifadin	SW
<u>Authority Required</u>								
<i>Leprosy in adults.</i>								
1982H	Capsule 150 mg	100	..	..	36.58	32.90	Rimycin 150	AF
1983J	Capsule 300 mg	100	..	..	64.51	32.90	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	..	..	* 69.11	32.90	^a Acihexal	SZ
							^a Acyclo-V 200	AF
							^a Lovir	GM
				..	69.11	32.90	^a GenRx Aciclovir	GX
				B4.34	* 73.45	32.90	^a Zovirax 200 mg	GK

NOTE:

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

continued ➞

ANTIINFECTIVES FOR SYSTEMIC USE—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 \$		

Authority Required

Episodic treatment or suppressive therapy of moderate to severe recurrent genital herpes. Microbiological confirmation of diagnosis (viral culture, antigen detection or nucleic acid amplification by PCR) is required but need not delay treatment.

NOTE:

Aciclovir 200 mg is not PBS-subsidised for chickenpox, herpes zoster or herpes simplex infections other than genital herpes.

1007B	Tablet 200 mg	90	5	..	121.47	32.90	^a Aciclovir 200	CR
							^a Acihexal	SZ
							^a Acyclo-V 200	AF
							^a Chem mart	CH
							Aciclovir	
							^a GenRx Aciclovir	GX
							^a Lovir	GM
							^a Ozvir	RA
							^a Terry White Chemists	TW
							Aciclovir	
				B3.21	124.68	32.90	^a Zovirax 200 mg	GK

Authority Required

Treatment of patients with herpes zoster within 72 hours of the onset of the rash;

Herpes zoster ophthalmicus.

NOTE:

Aciclovir is effective only if commenced within 72 hours of onset of rash.

Aciclovir 800 mg is not PBS-subsidised for herpes simplex or chickenpox.

1052J	Tablet 800 mg	35	..	..	145.89	32.90	^a Aciclovir 800	CR
							^a Acihexal	SZ
							^a Acyclo-V 800	AF
							^a GenRx Aciclovir	GX
							^a Lovir	GM
				B1.56	147.45	32.90	^a Zovirax 800 mg	GK

NOTE:

No applications for repeats will be authorised.

Authority Required

Patients with advanced HIV disease (CD4 cell counts of less than 150 million per litre).

8234J	Tablet 800 mg	120	5	..	445.90	32.90	^a Acihexal	SZ
							^a Acyclo-V 800	AF
							^a Lovir	GM
							^a Zovirax 800 mg	GK
				B5.19	451.09	32.90		

ANTIINFECTIVES FOR SYSTEMIC USE—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 \$	

FAMCICLOVIR

Authority Required

Episodic treatment of moderate to severe recurrent genital herpes. Microbiological confirmation of diagnosis (viral culture, antigen detection or nucleic acid amplification by PCR) is required but need not delay treatment.

NOTE:

Famciclovir 125 mg is not PBS-subsidised for chickenpox, herpes zoster or herpes simplex infections other than genital herpes.

8092X	Tablet 125 mg	40	1	..	136.63	32.90	Famvir	NV

Authority Required

Episodic treatment of moderate to severe recurrent genital herpes. Microbiological confirmation of diagnosis (viral culture, antigen detection or nucleic acid amplification by PCR) is required but need not delay treatment.

NOTE:

Famciclovir 250 mg is not PBS-subsidised for chickenpox or herpes simplex infections other than genital herpes.

2274Q	Tablet 250 mg	20	1	..	136.63	32.90	Famvir	NV

Authority Required

Treatment of patients with herpes zoster within 72 hours of the onset of the rash.

NOTE:

Famciclovir is effective only if commenced within 72 hours of onset of rash.

Famciclovir 250 mg is not PBS-subsidised for chickenpox or herpes simplex infections other than genital herpes.

8002E	Tablet 250 mg	21	..	..	143.15	32.90	Famvir	NV

NOTE:

No applications for repeats will be authorised.

Authority Required

Suppressive therapy of moderate to severe recurrent genital herpes. Microbiological confirmation of diagnosis (viral culture, antigen detection or nucleic acid amplification by PCR) is required but need not delay treatment.

NOTE:

Famciclovir 250 mg is not PBS-subsidised for chickenpox or herpes simplex infections other than genital herpes.

8217L	Tablet 250 mg	56	5	..	356.50	32.90	Famvir	NV

Authority Required

Treatment of immunocompromised patients with herpes zoster within 72 hours of the onset of the rash.

continued ➞

ANTIINFECTIVES FOR SYSTEMIC USE—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 \$		

NOTE:

Famciclovir is effective only if commenced within 72 hours of onset of rash.

Famciclovir 500 mg is not PBS-subsidised for chickenpox.

Famciclovir 500 mg is not PBS-subsidised for herpes zoster, genital herpes or other herpes simplex infections in immunocompetent patients.

8897G	Tablet 500 mg	30	..	..	201.92	32.90	Famvir	NV

NOTE:

No applications for repeats will be authorised.

Authority Required

Episodic treatment or suppressive therapy of moderate to severe recurrent genital herpes in immunocompromised patients. Microbiological confirmation of diagnosis (viral culture, antigen detection or nucleic acid amplification by PCR) is required but need not delay treatment.

Authority Required

Episodic treatment of moderate to severe recurrent oral or labial herpes in a patient with HIV infection and a CD4 cell count of less than 500 million per litre. Microbiological confirmation of diagnosis (viral culture, antigen detection or nucleic acid amplification by PCR) is required but need not delay treatment.

Authority Required

Suppressive therapy of moderate to severe recurrent oral or labial herpes in a patient with HIV infection and:

(a) a CD4 cell count of less than 150 million per litre; or

(b) other opportunistic infections or AIDS defining tumours.

Microbiological confirmation of diagnosis (viral culture, antigen detection or nucleic acid amplification by PCR) is required but need not delay treatment.

8896F	Tablet 500 mg	56	5	..	356.50	32.90	Famvir	NV

NOTE:

Famciclovir 500 mg is not PBS-subsidised for chickenpox.

Famciclovir 500 mg is not PBS-subsidised for herpes zoster, genital herpes or other herpes simplex infections in immunocompetent patients.

VALACICLOVIR HYDROCHLORIDE**Authority Required**

Moderate to severe initial genital herpes. Microbiological confirmation of diagnosis (viral culture, antigen detection or nucleic acid amplification by PCR) is desirable but need not delay treatment.

NOTE:

Valaciclovir 500 mg is not PBS-subsidised for chickenpox or herpes simplex infections other than genital herpes.

8133C	Tablet 500 mg (base)	20	..	..	* 105.35	32.90	Valtrex	GK

NOTE:

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

ANTIINFECTIVES FOR SYSTEMIC USE—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 \$		

Authority Required

Episodic treatment or suppressive therapy of moderate to severe recurrent genital herpes. Microbiological confirmation of diagnosis (viral culture, antigen detection or nucleic acid amplification by PCR) is required but need not delay treatment.

NOTE:

Valaciclovir 500 mg is not PBS-subsidised for chickenpox or herpes simplex infections other than genital herpes.

8134D	Tablet 500 mg (base)	30	5	..	155.00	32.90	Valtrex	GK

Authority Required

*Treatment of patients with herpes zoster within 72 hours of the onset of the rash;
Herpes zoster ophthalmicus.*

NOTE:

Valaciclovir is effective only if commenced within 72 hours of onset of rash.

Valaciclovir 500 mg is not PBS-subsidised for chickenpox or herpes simplex infections other than genital herpes.

8064K	Tablet 500 mg (base)	42	..	..	213.63	32.90	Valtrex	GK

NOTE:

No applications for repeats will be authorised.

VACCINES

Bacterial vaccines

• ***Pneumococcal vaccines***

PNEUMOCOCCAL VACCINE, POLYVALENT

Restricted Benefit

*Splenectomised persons over 2 years of age;
Persons with Hodgkin's disease;
Persons at high risk of pneumococcal infections.*

1903E	Injection 0.5 mL (23 valent)	1	..	..	45.70	32.90	Pneumovax 23	CS

• ***Tetanus vaccines***

***DIPHTHERIA and TETANUS VACCINE, ADSORBED,
DILUTED FOR ADULT USE***

NOTE:

For immunisation of adults and children aged greater than or equal to 8 years.

8783G	Injection 0.5 mL in pre-filled syringe	5	..	..	74.91	32.90	ADT Booster	CS

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>Children up to 35 months of age at increased risk of adverse consequences from infections of the lower respiratory tract.</i>								
2265F	Injection (trivalent) 0.25 mL <i>(containing A/Brisbane/59/2007, A/Brisbane/10/2007 and B/Florida/4/2006 like strains)</i>	1	..	..	16.56	17.59	Fluvax Junior Vaxigrip Junior	CS AX
<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 <i>(containing A/Brisbane/59/2007, A/Brisbane/10/2007 and B/Florida/4/2006 like strains)</i>	1	..	..	19.20	20.23	Fluvax Influvac Vaxigrip	CS SM AX

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Proprietary Name and Manufacturer	
ANTINEOPLASTIC AGENTS								
Alkylating agents								
• Nitrogen mustard analogues								
CHLORAMBUCIL								
1163F	Tablet 2 mg	100	2	..	* 137.55	32.90	Leukeran	GK
CYCLOPHOSPHAMIDE								
1266P	Tablet 50 mg	50	2	..	30.86	31.89	Cycloblastin	PH
1079T	Powder for injection 500 mg (solvent required) (code 6704W applies to above item with approved solvent)	2	..	..	* 29.33	30.36	Endoxan	BX
1080W	Powder for injection 1 g (solvent required) (code 6710E applies to above item with approved solvent)	1	..	..	26.59	27.62	Endoxan	BX
1031G	Powder for injection 2 g (solvent required) (code 7055H applies to above item with approved solvent)	1	..	..	42.39	32.90	Endoxan	BX
IFOSFAMIDE								
Restricted Benefit								
<i>Relapsed or refractory germ cell tumours following first-line chemotherapy;</i>								
<i>Relapsed or refractory sarcomas following first-line chemotherapy.</i>								
8076C	Powder for I.V. injection 1 g	5	5	..	* 261.14	32.90	Holoxan	BX
8077D	Powder for I.V. injection 2 g	5	5	..	* 476.74	32.90	Holoxan	BX
MELPHALAN								
2547C	Tablet 2 mg	25	1	..	50.45	32.90	Alkeran	GK
• Alkyl sulphonates								
BUSULFAN								
1128J	Tablet 2 mg	100	..	..	85.83	32.90	Myleran	GK
• Ethylene imines								
THIOTEPA								
2345K	Powder for injection 15 mg	2	1	..	* 155.23	32.90	SI	

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Proprietary Name and Manufacturer	
• Nitrosoureas CARMUSTINE <u>Restricted Benefit</u> <i>Glioblastoma multiforme, suspected or confirmed, at the time of initial surgery.</i> <u>NOTE:</u> <i>Carmustine is not PBS-subsidised for use in conjunction with PBS-subsidised temozolomide.</i>								
8898H	Implants 7.7 mg, 8	± 1	..	..	16044.43	32.90	Gliadel	OA
FOTEMUSTINE <u>Authority Required</u> <i>Metastatic malignant melanoma.</i>								
8786K	Powder for injection 208 mg with solvent	1	4	..	1100.15	32.90	Muphoran	SE
• Other alkylating agents TEMOZOLOMIDE <u>Authority Required</u> <i>Glioblastoma multiforme concomitantly with radiotherapy.</i> <u>NOTE:</u> <i>Temozolomide is not PBS-subsidised for use in conjunction with PBS-subsidised carmustine.</i>								
8819E	Capsule 5 mg	15	2	..	* 207.62	32.90	Temodal	SH
8820F	Capsule 20 mg	15	2	..	* 567.50	32.90	Temodal	SH
8821G	Capsule 100 mg	15	2	..	* 2388.86	32.90	Temodal	SH
9361Q	Capsule 140 mg	15	2	..	* 3265.67	32.90	Temodal	SH
<u>NOTE:</u> <i>Applications for doses above 150 mg per day will not be authorised. No applications for increased repeats will be authorised.</i>								
<u>Authority Required</u> <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	..	73.32	32.90	Temodal	SH
8379B	Capsule 20 mg	5	5	..	203.96	32.90	Temodal	SH
8380C	Capsule 100 mg	5	5	..	807.79	32.90	Temodal	SH
9362R	Capsule 140 mg	5	5	..	1111.75	32.90	Temodal	SH
8381D	Capsule 250 mg	5	5	..	1862.88	32.90	Temodal	SH

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Proprietary Name and Manufacturer	
Antimetabolites								
• Folic acid analogues								
METHOTREXATE								
1622J	Tablet 2.5 mg	30	5	..	13.11	14.14	^a Methoblastin ^a HH	PH
2272N	Tablet 10 mg	15	1	..	22.37	23.40	Methoblastin	PH
2396D	Injection 5 mg in 2 mL	5	..	..	37.64	32.90	HH	
2395C	Injection 50 mg in 2 mL	5	..	..	36.93	32.90	HH PU	
8863L	Solution concentrate for I.V. infusion 500 mg in 20 mL	1	..	..	65.18	32.90	HH	
8851W	Solution concentrate for I.V. infusion 1000 mg in 10 mL	1	..	..	124.37	32.90	^a Methotrexate Ebewe ^a HH	IT
8852X	Solution concentrate for I.V. infusion 5000 mg in 50 mL	1	..	..	565.63	32.90	Methotrexate Ebewe	IT
METHOTREXATE								
<u>Restricted Benefit</u>								
<i>For patients requiring doses greater than 20 mg per week.</i>								
1623K	Tablet 10 mg	50	2	..	47.00	32.90	Methoblastin	PH
PEMETREXED DISODIUM								
<u>Authority Required</u>								
<i>Locally advanced or metastatic non-small cell lung cancer, after prior platinum-based chemotherapy.</i>								
<i>Doses greater than 500 mg per metre squared body surface area (BSA) will not be approved for PBS subsidy. The patient's BSA must be provided at the time of the authority approval.</i>								
<u>Authority Required</u>								
<i>Mesothelioma in combination with cisplatin.</i>								
<i>Doses greater than 500 mg per metre squared body surface area (BSA) will not be approved for PBS subsidy. The patient's BSA must be provided at the time of the authority approval.</i>								
<u>NOTE:</u>								
<i>No applications for increased maximum quantities for the 500 mg vial will be authorised.</i>								
9131N	Powder for I.V. infusion 100 mg (base)	1	3	..	359.42	32.90	Alimta	LY
9130M	Powder for I.V. infusion 500 mg (base)	1	3	..	1700.98	32.90	Alimta	LY

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Proprietary Name and Manufacturer	
RALTITREXED								
Authority Required								
<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	..	* 855.86	32.90	Tomudex	HH
• Purine analogues								
CLADRIBINE								
Authority Required								
<i>Hairy cell leukaemia.</i>								
8800E	Injection 10 mg in 5 mL	7	..	..	* 4629.14	32.90	Litak	OA
1811H	Solution for I.V. infusion 10 mg in 10 mL	7	..	..	4629.16	32.90	Leustatin	JC
FLUDARABINE PHOSPHATE								
Authority Required								
<i>B-cell chronic lymphocytic leukaemia in combination with cyclophosphamide where the patient has advanced disease (Binet Stage B or C) or evidence of progressive Stage A disease.</i>								
<i>Stage A progressive disease is defined by at least one of the following:</i>								
<i>persistent rise in lymphocyte count with doubling time less than 12 months;</i>								
<i>a downward trend in haemoglobin or platelets, or both;</i>								
<i>more than 50% increase in the size of liver, spleen, or lymph nodes, or appearance of these signs if not previously present;</i>								
<i>constitutional symptoms attributable to disease.</i>								
<i>The diagnosis of chronic lymphocytic leukaemia (CLL) must have been established based on:</i>								
<i>(a) a lymphocytosis, with more than 5,000 million lymphocytes per L in the peripheral blood; and</i>								
<i>(b) a clonal population of B-cells (CD5/CD19) documented by flow cytometry.</i>								
9184J	Tablet 10 mg	20	5	..	974.64	32.90	Fludara	BN
9185K	Powder for I.V. injection 50 mg	5	3	..	1598.44	32.90	^a Fludara	BN
9207N	Solution for I.V. injection 50 mg in 2 mL	5	3	..	1598.44	32.90	^a Fludarabine Ebewe	IT
NOTE:								
<i>The solution for I.V. injection and powder for I.V. injection (after reconstitution) are bioequivalent.</i>								
MERCAPTOPURINE								
1598D	Tablet 50 mg	100	2	..	* 251.51	32.90	Purinethol	GK
THIOGUANINE								
1233X	Tablet 40 mg	25	1	..	198.23	32.90	Lanvis	GK

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Proprietary Name and Manufacturer	
• Pyrimidine analogues								
CAPECITABINE								
<u>Authority Required</u>								
<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>								
<u>NOTE:</u>								
<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	..	123.50	32.90	Xeloda	RO
8362D	Tablet 500 mg	120	2	..	694.74	32.90	Xeloda	RO
CYTARABINE								
2884T	Injection 100 mg in 5 mL	10	1	..	* 95.09	32.90	PU	
FLUOROURACIL								
2528C	Injection 500 mg in 10 mL	10	..	..	* 57.29	32.90	^a HH	
				..	* 57.29	32.90	^a Fluorouracil Ebewe	IT
9005Y	Injection 1000 mg in 20 mL	5	..	..	* 50.14	32.90	Fluorouracil Ebewe	IT
GEMCITABINE HYDROCHLORIDE								
<u>Authority Required</u>								
<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	..	* 209.07	32.90	^a DBL Gemcitabine for Injection	HH
							^a Gemzar	LY
9401T	Solution concentrate for I.V. infusion 200 mg (base) in 20 mL	4	2	..	* 209.07	32.90	^a Gemcitabine Ebewe	IT
<u>NOTE:</u>								
<i>The powder for I.V. infusion 200 mg (base) (after reconstitution) and the solution concentrate for I.V. infusion 200 mg (base) are bioequivalent.</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	
8050Q	Powder for I.V. infusion 1 g (base)	2	2	..	* 481.23	32.90	^a DBL Gemcitabine for Injection	HH
							^a Gemzar	LY
9402W	Solution concentrate for I.V. infusion 1000 mg (base) in 100 mL	2	2	..	* 481.23	32.90	^a Gemcitabine Ebewe	IT
NOTE: The powder for I.V. infusion 1 g (base) (after reconstitution) and the solution concentrate for I.V. infusion 1000 mg (base) are bioequivalent.								
9414L	Powder for I.V. infusion 2 g (base)	1	2	..	482.31	32.90	DBL Gemcitabine for Injection	HH
Plant alkaloids and other natural products								
• Vinca alkaloids and analogues								
VINBLASTINE SULFATE								
2199R	Solution for I.V. injection 10 mg in 10 mL	5	..	..	105.41	32.90	HH	
VINCRISTINE SULFATE								
2374Y	I.V. injection 1 mg in 1 mL	10	..	..	* 160.91	32.90	^a HH ^a PU	
VINORELBINE TARTRATE								
Authority Required Locally advanced or metastatic non-small cell lung cancer.								
9009E	Capsule 20 mg (base)	20	2	..	* 2091.19	32.90	Navelbine	FB
9010F	Capsule 30 mg (base)	16	2	..	* 2481.19	32.90	Navelbine	FB
Authority Required Advanced breast cancer after failure of prior therapy which includes an anthracycline; Locally advanced or metastatic non-small cell lung cancer.								
8280T	Solution for I.V. infusion 10 mg (base) in 1 mL	16	2	..	* 1183.27	32.90	^a Navelbine ^a Vinorelbine Ebewe ^a Vinorelbine Link ^a HH	FB IT LM
8281W	Solution for I.V. infusion 50 mg (base) in 5 mL	4	2	..	* 1234.23	32.90	^a Navelbine ^a Vinorelbine Ebewe ^a Vinorelbine Link ^a HH	FB IT LM

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	
• Podophyllotoxin derivatives								
ETOPOSIDE								
1396L	Capsule 50 mg	20	..	..	470.79	32.90	Vepesid	BQ
1389D	Capsule 100 mg	10	..	..	413.19	32.90	Vepesid	BQ
1390E	Solution for I.V. infusion 100 mg in 5 mL	5	..	..	* 172.84	32.90	^a HH	IT
					172.86	32.90	^a Etoposide Ebewe	
8120J	Powder for I.V. infusion 100 mg (as phosphate)	5	..	..	* 172.84	32.90	Etopophos	BQ
8515E	Powder for I.V. infusion 1 g (as phosphate)	1	..	..	327.35	32.90	Etopophos	BQ
• Taxanes								
DOCETAXEL								
Authority Required								
<i>Neoadjuvant treatment of a patient with a WHO performance status of 1 or less, with inoperable Stage III, IVa or IVb squamous cell carcinoma of the oral cavity, larynx, oropharynx or hypopharynx, in combination with cisplatin and fluorouracil.</i>								
NOTE:								
<i>The carcinoma can be considered inoperable for technical or organ preservation reasons.</i>								
9291B	Injection set containing 1 single use vial concentrate for I.V. infusion 20 mg (anhydrous) in 0.5 mL and 1 single use vial solvent 1.5 mL	1	..	..	338.73	32.90	Taxotere	SW
Authority Required								
<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>								
Authority Required								
<i>Treatment of androgen independent (hormone refractory) metastatic carcinoma of the prostate in a patient with a Karnofsky performance-status score of at least 60%. Docetaxel must be used as first-line chemotherapy and administered in three weekly cycles.</i>								
NOTE:								
<i>A maximum of 10 cycles of treatment with docetaxel will be authorised under this restriction.</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	..	..	* 660.65	32.90	Taxotere	SW

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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 \$	

Authority Required

Neoadjuvant treatment of a patient with a WHO performance status of 1 or less, with inoperable Stage III, IVa or IVb squamous cell carcinoma of the oral cavity, larynx, oropharynx or hypopharynx, in combination with cisplatin and fluorouracil.

NOTE:

The carcinoma can be considered inoperable for technical or organ preservation reasons.

Authority Required

Adjuvant treatment of node-positive breast cancer in combination with an anthracycline and cyclophosphamide;

Advanced breast cancer after failure of prior therapy which includes an anthracycline;

Advanced metastatic ovarian cancer after failure of prior therapy which includes a platinum compound;

Locally advanced or metastatic non-small cell lung cancer;

Treatment of HER2 positive early breast cancer in combination with trastuzumab.

Authority Required

Treatment of androgen independent (hormone refractory) metastatic carcinoma of the prostate in a patient with a Karnofsky performance-status score of at least 60%. Docetaxel must be used as first-line chemotherapy and administered in three weekly cycles.

NOTE:

A maximum of 10 cycles of treatment with docetaxel will be authorised under this restriction.

8074Y	Injection set containing 1 single use vial concentrate for I.V. infusion 80 mg (anhydrous) in 2 mL and 1 single use vial solvent 6 mL	1	..	..	1299.91	32.90	Taxotere	SW

NAB PACLITAXEL

Authority Required

Metastatic breast cancer after failure of prior therapy which includes an anthracycline.

9415M	Powder for I.V. injection 100 mg (base)	1	..	..	455.66	32.90	Abraxane	TS

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	
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	..	..	* 969.64	32.90	^a Anzatax ^a Baxter Paclitaxel ^a Taxol ^a Paclitaxel Ebewe	HH BX BQ IT
8018B	Solution concentrate for I.V. infusion 100 mg in 16.7 mL	2	..	..	* 1284.57	32.90	^a Anzatax ^a Baxter Paclitaxel ^a Paclitaxel Ebewe ^a Taxol	HH BX IT BQ
3017T	Solution concentrate for I.V. infusion 150 mg in 25 mL	2	..	..	* 1868.01	32.90	^a Anzatax ^a Paclitaxel Ebewe ^a Taxol	HH IT BQ
8360B	Solution concentrate for I.V. infusion 300 mg in 50 mL	1	..	..	1885.41	32.90	^a Anzatax ^a Baxter Paclitaxel ^a Paclitaxel Ebewe ^a Taxol	HH BX IT BQ

Cytotoxic antibiotics and related substances

• Anthracyclines and related substances

DOXORUBICIN HYDROCHLORIDE

1336H	Solution for I.V. injection or intravesical administration 10 mg in 5 mL	4	..	..	* 142.43	32.90	^a Adriamycin Solution ^a Doxorubicin Ebewe ^a HH	PH IT
1340M	Solution for I.V. injection or intravesical administration 20 mg in 10 mL	4	..	..	* 245.83	32.90	Adriamycin Solution	PH
1342P	Solution for I.V. injection or intravesical administration 50 mg in 25 mL	3	..	..	* 417.32	32.90	^a Adriamycin Solution ^a Doxorubicin Ebewe ^a HH	PH IT
8827N	Solution for I.V. injection or intravesical administration 100 mg in 50 mL	1	..	..	286.20	32.90	Doxorubicin Ebewe	IT
8828P	Solution for I.V. injection or intravesical administration 200 mg in 100 mL	1	..	..	551.40	32.90	^a Adriamycin ^a Doxorubicin Ebewe	PF 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	
DOXORUBICIN HYDROCHLORIDE, PEGYLATED LIPOSOMAL								
<u>Authority Required</u>								
<i>Advanced epithelial ovarian cancer in women who have failed a first-line platinum-based chemotherapy regimen; Metastatic breast cancer, as monotherapy, after failure of prior therapy which includes capecitabine and a taxane; Metastatic breast cancer, as monotherapy, where therapy with capecitabine and/or a taxane is contraindicated.</i>								
8569B	Suspension for I.V. infusion 20 mg in 10 mL	1	..	..	702.62	32.90	Caelyx	SH
8570C	Suspension for I.V. infusion 50 mg in 25 mL	1	..	..	1621.36	32.90	Caelyx	SH
EPIRUBICIN HYDROCHLORIDE								
1375J	Solution for injection 10 mg in 5 mL	4	..	..	* 219.35	32.90	^a Epirubicin Ebewe ^a Pharmorubicin Solution	IT PH
1376K	Solution for injection 20 mg in 10 mL	4	..	..	* 401.07	32.90	Pharmorubicin Solution	PH
1377L	Solution for injection 50 mg in 25 mL	4	..	..	* 975.67	32.90	^a Epirubicin Ebewe ^a Pharmorubicin Solution ^a HH	IT PH
8817C	Solution for injection 100 mg in 50 mL	2	..	..	* 962.65	32.90	^a Epirubicin Ebewe ^a HH	IT
8858F	Solution for injection 200 mg in 100 mL	1	..	..	948.32	32.90	Epirubicin Ebewe	IT
IDARUBICIN HYDROCHLORIDE								
<u>Restricted Benefit</u>								
<i>Acute myelogenous leukaemia.</i>								
2446R	Capsule 5 mg	3	..	..	* 246.68	32.90	Zavedos	PH
2448W	Capsule 10 mg	3	..	..	* 451.19	32.90	Zavedos	PH
8530Y	Solution for I.V. injection 5 mg in 5 mL	3	..	..	568.45	32.90	Zavedos Solution	PH
8531B	Solution for I.V. injection 10 mg in 10 mL	6	..	..	2104.37	32.90	Zavedos Solution	PH
MITOZANTRONE HYDROCHLORIDE								
1932Q	Injection 10 mg (base) in 5 mL	1	..	..	157.90	32.90	^a Mitozantrone Ebewe ^a PU	IT

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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	
1929M	Injection 20 mg (base) in 10 mL	1	..	..	300.18	32.90	a Mitozantrone Ebewe	IT
							a Onkotrone	BX
							a HH	
							a PU	
1930N	Injection 25 mg (base) in 12.5 mL	1	..	..	369.02	32.90	a Onkotrone	BX
							a PU	
Other antineoplastic agents								
• Platinum compounds								
CARBOPLATIN								
1160C	Solution for I.V. injection 50 mg in 5 mL	2	..	..	* 67.87	32.90	a Carboplatin Ebewe	IT
							a HH	
							a PU	
1161D	Solution for I.V. injection 150 mg in 15 mL	6	..	..	* 431.51	32.90	a Carboplatin Ebewe	IT
							a HH	
							a PU	
1162E	Solution for I.V. injection 450 mg in 45 mL	2	..	..	* 279.95	32.90	a Baxter Carboplatin	BX
							a Carboplatin Ebewe	IT
							a HH	
							a PU	
CISPLATIN								
2578Q	I.V. injection 10 mg in 10 mL	1	..	..	14.42	15.45	PU	
2579R	I.V. injection 50 mg in 50 mL	1	..	..	28.60	29.63	a HH	
							a PU	
2580T	I.V. injection 100 mg in 100 mL	1	..	..	60.48	32.90	a Cisplatin Ebewe	IT
							a HH	
							a PU	
OXALIPLATIN								
Authority Required								
<i>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;</i>								
<i>Adjuvant treatment of stage III (Dukes C) colon cancer, in combination with 5-fluorouracil and folinic acid, following complete resection of the primary tumour.</i>								
NOTE:								
<i>Oxaliplatin is not PBS-subsidised for the treatment of patients with stage II (Dukes B) colon cancer.</i>								
<i>Oxaliplatin is not PBS-subsidised for the adjuvant treatment of patients with rectal cancer.</i>								
8847P	Solution concentrate for I.V. infusion 50 mg in 10 mL	1	2	..	370.25	32.90	a Eloxatin	SW

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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	
8539K	Powder for I.V. infusion 50 mg	1	2	..	370.25	32.90	^a Oxalatin ^a Oxaliplatin Ebewe ^a Winthrop Oxaliplatin ^a HH	ZP IT WA
NOTE: The solution concentrate for I.V. infusion 50 mg and powder for I.V. infusion 50 mg (after reconstitution) are bioequivalent.								
8848Q	Solution concentrate for I.V. infusion 100 mg in 20 mL	1	2	..	701.59	32.90	^a Eloxatin	SW
8540L	Powder for I.V. infusion 100 mg	1	2	..	701.59	32.90	^a Oxalatin ^a Oxaliplatin Ebewe ^a Winthrop Oxaliplatin ^a HH	ZP IT WA
NOTE: The solution concentrate for I.V. infusion 100 mg and powder for I.V. infusion 100 mg (after reconstitution) are bioequivalent.								
2310N	Solution concentrate for I.V. infusion 200 mg in 40 mL	1	2	..	1371.19	32.90	Eloxatin	SW

• Monoclonal antibodies CETUXIMAB

Authority Required

Initial treatment of stage III, IVa or IVb squamous cell cancer of the larynx, oropharynx or hypopharynx for the week prior to radiotherapy, where cisplatin is contraindicated according to the TGA-approved Product Information;

Initial treatment of stage III, IVa or IVb squamous cell cancer of the larynx, oropharynx or hypopharynx, in combination with radiotherapy, where cisplatin is not tolerated.

NOTE:

No applications for repeats will be authorised.

9136W	Solution for I.V. infusion 100 mg in 20 mL	1	..	..	390.63	32.90	Erbitux	SG
9097T	Solution for I.V. infusion 100 mg in 50 mL	1	..	..	390.63	32.90	Erbitux	SG
9137X	Solution for I.V. infusion 500 mg in 100 mL	1	..	..	1850.93	32.90	Erbitux	SG

continued ➞

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 \$		

Authority Required

Continuing treatment of stage III, IVa or IVb squamous cell cancer of the larynx, oropharynx or hypopharynx, in combination with radiotherapy, where cisplatin is either contraindicated or not tolerated.

NOTE:

A maximum lifetime supply for this indication is limited to a maximum of 8 treatments per site and to 10 treatments per site for patients in whom radiotherapy is interrupted.

9138Y	Solution for I.V. infusion 100 mg in 20 mL	1	6	..	390.63	32.90	Erbitux	SG
9098W	Solution for I.V. infusion 100 mg in 50 mL	1	6	..	390.63	32.90	Erbitux	SG
9139B	Solution for I.V. infusion 500 mg in 100 mL	1	6	..	1850.93	32.90	Erbitux	SG

RITUXIMAB

Authority Required

Relapsed or refractory low-grade B-cell non-Hodgkin's lymphoma;

Relapsed or refractory follicular B-cell non-Hodgkin's lymphoma.

8293L	Solution for I.V. infusion 100 mg in 10 mL	2	3	..	947.64	32.90	Mabthera	RO
8294M	Solution for I.V. infusion 500 mg in 50 mL	1	3	..	2339.56	32.90	Mabthera	RO

Authority Required

Treatment of previously untreated, CD20 positive, diffuse large B-cell non-Hodgkin's lymphoma, in combination with chemotherapy;

Treatment of symptomatic patients with previously untreated, CD20 positive, Stage III or IV, follicular, B-cell non-Hodgkin's lymphoma, in combination with chemotherapy.

8665C	Solution for I.V. infusion 100 mg in 10 mL	2	7	..	947.64	32.90	Mabthera	RO
8666D	Solution for I.V. infusion 500 mg in 50 mL	1	7	..	2339.56	32.90	Mabthera	RO

• Protein kinase inhibitors

DASATINIB

NOTE:

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

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

Any queries concerning patients who are enrolled on the Dasatinib Compassionate Program may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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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 \$	

Written applications for authority to prescribe dasatinib should be forwarded to:

Medicare Australia

Prior Written Approval of Specialised Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

Authority Required

Initial treatment, as the sole PBS-subsidised therapy, of a patient with chronic myeloid leukaemia in any disease phase bearing the Philadelphia chromosome or expressing the transcript, BCR-ABL, who has active leukaemia (as defined by presence on current pathology assessments of either the Philadelphia chromosome on cytogenetic or FISH analysis, or the presence of the transcript BCR-ABL greater than 1% on the international scale) and who has failed an adequate trial of imatinib.

Failure of an adequate trial of imatinib is defined as:

(i) Lack of response to initial imatinib therapy, defined as either:

— failure to achieve a haematological response after a minimum of 3 months therapy with imatinib for patients initially treated in chronic phase; or

— failure to achieve any cytogenetic response after a minimum of 6 months therapy with imatinib for patients initially treated in chronic phase as demonstrated on bone marrow biopsy by presence of greater than 95% Philadelphia chromosome positive cells; or

— failure to achieve a major cytogenetic response or a peripheral blood BCR-ABL level of less than 1% after a minimum of 12 months therapy with imatinib; OR

(ii) Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph positive cells on bone marrow biopsy), during ongoing imatinib therapy;

OR

(iii) Loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing in value by at least 5 fold to a level of greater than 1% confirmed on a subsequent test), during ongoing imatinib therapy;

OR

(iv) Development of accelerated phase or blast crisis in a patient previously prescribed imatinib for any phase of chronic myeloid leukaemia.

Accelerated phase is defined by the presence of 1 or more of the following:

(1) Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 15% but less than 30%; or

(2) Percentage of blasts plus promyelocytes in the peripheral blood or bone marrow greater than or equal to 30%; or

(3) Peripheral basophils greater than or equal to 20%; or

(4) Progressive splenomegaly to a size greater than or equal to 10 cm below the left costal margin to be confirmed on 2 occasions at least 4 weeks apart, or a greater than or equal to 50% increase in size below the left costal margin over 4 weeks; or

(5) Karyotypic evolution (chromosomal abnormalities in addition to a single Philadelphia chromosome).

Blast crisis is defined as either:

(1) Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 30%; or

(2) Extramedullary involvement other than spleen and liver; OR

(v) Disease progression (defined as a greater than or equal to 50% increase in peripheral white blood cell count, blast count, basophils or platelets) during first-line imatinib therapy in patients with accelerated phase or blast crisis chronic myeloid leukaemia;

OR

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	
<i>(vi) Grade 3 or 4 non-haematological toxicity that is imatinib related and necessitates permanent cessation of imatinib. For patients with imatinib related toxicities, leukaemia activity does not need to be demonstrated.</i> <i>Applications for authorisation must be in writing and must include:</i> <i>(a) a completed authority prescription form; and</i> <i>(b) a completed Chronic Myeloid Leukaemia Dasatinib/Nilotinib PBS Authority Application - Supporting Information Form; and</i> <i>(c) a signed patient acknowledgement; and</i> <i>(d) a bone marrow biopsy pathology report demonstrating the patient has active chronic myeloid leukaemia, either manifest as cytogenetic evidence of the Philadelphia chromosome, or RT-PCR level of BCR-ABL transcript greater than 1% on the international scale. (The date of the relevant pathology report needs to be provided); and</i> <i>(e) where there has been a loss of response to imatinib, a copy of the current confirming pathology report(s) from an Approved Pathology Authority or details of the dates of assessment in the case of progressive splenomegaly or extramedullary involvement; or</i> <i>(f) details of Grade 3 or 4 non-haematological toxicity.</i> NOTE: <i>Dasatinib will only be subsidised for patients with chronic myeloid leukaemia who are not receiving concomitant PBS-subsidised imatinib mesylate, nilotinib or interferon alfa therapy.</i> <i>Patients should be commenced on a dose of dasatinib of at least 100 mg (base) daily. Continuing therapy is dependent on patients demonstrating a major cytogenetic response to dasatinib therapy or a peripheral blood BCR-ABL level of less than 1% at 18 months and thereafter at 12 monthly intervals, irrespective of the daily dasatinib dose received.</i> <i>From 1 November 2008, under the PBS, a patient will be able to trial either dasatinib and/or nilotinib within the initial 18 month treatment period, providing the patient's CML is not resistant to the first second-line agent.</i> <i>Dasatinib is not PBS-subsidised for patients with CML that is resistant to nilotinib.</i>								
9282M	Tablet 20 mg	60	2	..	3245.93	32.90	Sprycel	BQ
9283N	Tablet 50 mg	60	2	..	5250.25	32.90	Sprycel	BQ
9284P	Tablet 70 mg	60	2	..	6464.58	32.90	Sprycel	BQ

Authority Required

Continuing treatment, as the sole PBS-subsidised therapy, of a patient who has received initial treatment with dasatinib as a pharmaceutical benefit for chronic myeloid leukaemia, and who has demonstrated either a major cytogenetic response, or less than 1% BCR-ABL level in the blood, to dasatinib in the preceding 18 months and thereafter at 12 monthly intervals.

Applications for authorisation must be in writing and must include:

- (1) *a completed authority prescription form; and*
- (2) *a completed Chronic Myeloid Leukaemia Dasatinib/Nilotinib Authority Application Form for continuing treatment; and*
- (3) *demonstration of continued response to treatment as evidenced by either:*
 - (a) *major cytogenetic response [see Note explaining definitions of response]. Where this has been supplied within the previous 12 months (or 18 months for the initial supply), only the date of the relevant pathology report needs to be provided; or*
 - (b) *a peripheral blood level of BCR-ABL of less than 1% on the international scale [see Note explaining definitions of response]. Where this has been supplied within the previous 12 months (or 18 months for the initial supply), only the date of the relevant pathology report needs to be provided.*

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 \$	

NOTE:

Definitions of response.

A major cytogenetic response is defined as less than 35% Philadelphia positive bone marrow cells.

A bone marrow or peripheral blood BCR-ABL level of less than 1% on the international scale (Blood 108: 28-37, 2006) also indicates a response, at least the biological equivalent of a major cytogenetic response.

Authority approval requirements.

For the purposes of assessing response to PBS-subsidised treatment with dasatinib, either cytogenetic analysis indicating the number of Philadelphia positive [t (9;22)] cells in the bone marrow measured by standard karyotyping, or quantitative PCR indicating the relative level of BCR-ABL transcript in the peripheral blood using the international scale, must be submitted. For bone marrow analyses, where the standard karyotyping is not informative for technical reasons, a cytogenetic analysis performed on the bone marrow by the use of fluorescence in situ hybridisation (FISH) with BCR-ABL specific probe must be submitted. The cytogenetic or peripheral blood quantitative PCR analyses must be submitted as follows:

(i) between 10 and 18 months of the commencement of treatment with dasatinib, at which time patients in whom a major cytogenetic response or peripheral blood BCR-ABL level of less than 1% has been demonstrated may receive authorisation for a further 12 months of treatment; and

(ii) at no greater than 12 month intervals thereafter, to demonstrate that the major cytogenetic response or peripheral blood BCR-ABL level of less than 1% has been sustained.

For each authority application where eligibility for continuing PBS-subsidised treatment is to be demonstrated, a copy of the cytogenetic analysis indicating the number of Philadelphia positive [t (9;22)] cells in the bone marrow measured by standard karyotyping, or a copy of the quantitative PCR indicating the relative level of BCR-ABL transcript in the peripheral blood using the international scale, must be submitted as described in (i) and (ii) above. For bone marrow analyses, where the standard karyotyping conducted at the time of application is not informative, a copy of a cytogenetic analysis conducted on the bone marrow using FISH with BCR-ABL specific probe must be submitted with the authority application. A copy of the non-informative standard karyotype analysis must be included with the authority application.

Where a patient has previously received PBS-subsidised treatment with dasatinib, no approval will be granted for PBS-subsidised re-treatment where that patient has at any time failed to meet the criteria for continuing treatment.

2478K	Tablet 20 mg	60	5	..	3245.93	32.90	Sprycel	BQ
2482P	Tablet 50 mg	60	5	..	5250.25	32.90	Sprycel	BQ
2485T	Tablet 70 mg	60	5	..	6464.58	32.90	Sprycel	BQ

Authority Required

Initial treatment, as monotherapy, of a patient with acute lymphoblastic leukaemia (ALL) bearing the Philadelphia chromosome or expressing the transcript, BCR-ABL, who has failed treatment with chemotherapy AND imatinib and where appropriate, allogeneic haemopoietic stem cell transplantation.

Failure of treatment is defined as either:

(i) Failure to achieve a complete morphological and cytogenetic remission after a minimum of 2 months treatment with intensive chemotherapy and imatinib;

(ii) Morphological or cytogenetic relapse of leukaemia after achieving a complete remission induced by chemotherapy and imatinib;

(iii) Morphological or cytogenetic relapse or persistence of leukaemia after allogeneic haemopoietic stem cell transplantation.

continued 

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 \$	

Patients must have active leukaemia, as defined by presence on current pathology assessments of either morphological infiltration of the bone marrow (greater than 5% lymphoblasts) or cerebrospinal fluid or other sites; OR

the presence of cells bearing the Philadelphia chromosome on cytogenetic or FISH analysis in the bone marrow of patients in morphological remission.

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

(a) a completed authority prescription form; and

(b) a completed Acute Lymphoblastic Leukaemia Dasatinib PBS Authority Application - Supporting Information Form; and

(c) a signed patient acknowledgement; and

(d) a pathology report demonstrating that the patient has active acute lymphoblastic leukaemia, either manifest as cytogenetic evidence of the Philadelphia chromosome, or morphological evidence of acute lymphoblastic leukaemia plus qualitative RT-PCR evidence of BCR-ABL transcript. The date of the relevant pathology report(s) need(s) to be provided.

Authority Required

Initial treatment, as monotherapy, of a patient with acute lymphoblastic leukaemia bearing the Philadelphia chromosome or expressing the transcript, BCR-ABL, who has been treated prior to 1 December 2007 and has failed treatment with chemotherapy and where appropriate, allogeneic haemopoietic stem cell transplantation.

Patients must have active leukaemia, as defined by presence on current pathology assessments of either morphological infiltration of the bone marrow (greater than 5% lymphoblasts) or cerebrospinal fluid or other sites; OR

the presence of cells bearing the Philadelphia chromosome on cytogenetic or FISH analysis in the bone marrow of patients in morphological remission.

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

(a) a completed authority prescription form; and

(b) a completed Acute Lymphoblastic Leukaemia Dasatinib PBS Authority Application - Supporting Information Form; and

(c) a signed patient acknowledgement; and

(d) a pathology report demonstrating that the patient has active acute lymphoblastic leukaemia, either manifest as cytogenetic evidence of the Philadelphia chromosome, or morphological evidence of acute lymphoblastic leukaemia plus qualitative RT-PCR evidence of BCR-ABL transcript. The date of the relevant pathology report(s) need(s) to be provided.

Authority Required

Continuing treatment, as monotherapy, of a patient with acute lymphoblastic leukaemia bearing the Philadelphia chromosome or expressing the transcript, BCR-ABL, where the patient has previously been issued with an authority prescription for dasatinib and does not have progressive disease.

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

NOTE:

Dasatinib will only be subsidised for patients with acute lymphoblastic leukaemia who are not receiving concomitant PBS-subsidised imatinib mesylate and who are not appropriate for an allogeneic haemopoietic stem cell transplant.

9125G	Tablet 20 mg	60	2	..	3245.93	32.90	Sprycel	BQ
9126H	Tablet 50 mg	60	2	..	5250.25	32.90	Sprycel	BQ
9127J	Tablet 70 mg	60	2	..	6464.58	32.90	Sprycel	BQ

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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 \$	

NOTE:

No applications for increased repeats will be authorised.

ERLOTINIB**Authority Required**

Initial PBS-subsidised treatment, as monotherapy, in a patient with locally advanced or metastatic (stage IIIB or IV) non-small cell lung cancer with a WHO performance status of 3 or less, after prior treatment with platinum-based chemotherapy, where:

- (1) (a) disease progression has occurred following treatment with docetaxel or pemetrexed; or*
- (b) treatment with docetaxel and pemetrexed is either contraindicated or cannot be tolerated; and*
- (2) further cytotoxic chemotherapy is not appropriate.*

Authority Required

Continuing PBS-subsidised treatment, as monotherapy, in a patient with locally advanced or metastatic (stage IIIB or IV) non-small cell lung cancer who has previously been issued with an authority prescription for this drug and who does not have progressive disease.

Authority Required

Initial PBS-subsidised treatment, as monotherapy, in a patient with locally advanced or metastatic (stage IIIB or IV) non-small cell lung cancer, after prior treatment with platinum-based chemotherapy:

- (1) where:*
 - (a) disease progression occurred following treatment with docetaxel or pemetrexed; or*
 - (b) treatment with docetaxel and pemetrexed was either contraindicated or could not be tolerated; and*
- (2) who has received treatment with erlotinib under the Erlotinib Access Programme prior to 1 August 2008; and*
- (3) who does not have progressive disease.*

9166K	Tablet 25 mg (as hydrochloride)	30	3	..	793.76	32.90	Tarceva	RO
9167L	Tablet 100 mg (as hydrochloride)	30	3	..	2702.91	32.90	Tarceva	RO
9168M	Tablet 150 mg (as hydrochloride)	30	3	..	3309.23	32.90	Tarceva	RO

GEFITINIB**NOTE:**

Any queries concerning the arrangements to prescribe gefitinib may be directed to Medicare Australia on 1800 700 270.

Written applications for authority to prescribe gefitinib should be forwarded to:

Medicare Australia

Prior Written Approval of Specialised Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

continued ➡

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 \$	

Authority Required

Initial PBS-subsidised treatment, as monotherapy, of locally advanced or metastatic non-small cell lung cancer in patients with a WHO performance status of 2 or less, where:

- (1) *disease progression has occurred following treatment with at least 1 chemotherapy agent; and*
- (2) *there is evidence that the patient has an activating mutation(s) of the epidermal growth factor receptor (EGFR) gene in tumour material. The mutation(s) must be demonstrated by analysis of the DNA sequence of the EGFR gene.*

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

- (1) *a completed authority prescription form; and*
- (2) *a completed Gefitinib (Iressa) PBS Authority Application for Use in the Treatment of Locally Advanced or Metastatic Non-Small Cell Lung Cancer - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and*
- (3) *details of the prior chemotherapy including the name(s) of drug(s) and date of the most recent treatment cycle; and*
- (4) *details of the patient's WHO performance status; and*
- (5) *a copy of the pathology report providing evidence of the presence of activating mutation(s) of the EGFR gene from an Approved Pathology Authority.*

Authority Required

Continuing PBS-subsidised treatment, as monotherapy, of locally advanced or metastatic non-small cell lung cancer in patients with a WHO performance status of 2 or less, where the patient has previously been issued with an authority prescription for gefitinib.

Applications for continuing treatment may be made in writing or on the telephone by contacting Medicare Australia on 1800 700 270.

8769M	Tablet 250 mg	30	1	..	3850.93	32.90	Iressa	AP

NOTE:

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

IMATINIB

NOTE:

Any queries concerning the arrangements to prescribe imatinib mesylate may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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

Written applications for authority to prescribe imatinib mesylate should be forwarded to:

Medicare Australia

Prior Written Approval of Specialised Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

For the following diseases, written authority is required at initiation and for continuation:

Chronic myeloid leukaemia (chronic phase);

Dermatofibrosarcoma protuberans;

Hypereosinophilic syndrome;

Chronic eosinophilic leukaemia;

Myelodysplastic or myeloproliferative disorder;

Aggressive systemic mastocytosis with eosinophilia.

continued 

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 \$	

NOTE:

Imatinib mesylate is not PBS-subsidised for the treatment of patients with resectable malignant gastrointestinal stromal tumours.

Authority Required

Initial PBS-subsidised treatment, for up to 3 months, of adult patients with a metastatic or unresectable malignant gastrointestinal stromal tumour which has been histologically confirmed by the detection of CD117 on immunohistochemical staining.

Patients who have not previously been treated with imatinib mesylate for a metastatic or unresectable malignant gastrointestinal stromal tumour must commence treatment at a dose not exceeding 400 mg per day for at least 3 months. Authority prescriptions for a higher dose will not be approved during this initial 3 month treatment period.

Patients who have previously been treated with non-PBS-subsidised imatinib mesylate for a metastatic or unresectable malignant gastrointestinal stromal tumour are eligible to receive up to 3 months treatment at a dose of up to 600 mg per day.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Imatinib Mesylate (Glivec) PBS Authority Application for Use in the Treatment of Gastrointestinal Stromal Tumour - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) a copy of a pathology report from an Approved Pathology Authority supporting the diagnosis of a gastrointestinal stromal tumour and confirming the presence of CD117 on immunohistochemical staining; and

(ii) a copy of the most recent (within 2 months of the application) computed tomography (CT) scan, magnetic resonance imaging (MRI) or ultrasound assessment of the tumour(s), including whether or not there is evidence of metastatic disease; and

(iii) where the application for authority to prescribe is being sought on the basis of an unresectable tumour, written evidence in support of that claim must be provided; and

(iv) for patients who commenced treatment with imatinib mesylate for a metastatic or unresectable malignant gastrointestinal stromal tumour prior to 1 December 2004, the date on which therapy with imatinib mesylate was commenced.

Authority Required

Continuing PBS-subsidised treatment, at a dose of up to 600 mg per day, of adult patients with a metastatic or unresectable malignant gastrointestinal stromal tumour who have previously been issued with an authority prescription for this drug.

Applications for continuing treatment may be made by telephone (1800 700 270, hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

NOTE:

Patients who achieve a response to treatment at an imatinib dose of 400 mg per day should be continued at this dose and assessed for response at regular intervals. Patients who fail to achieve a response to 400 mg per day may have their dose increased to 600 mg per day. Authority applications for doses higher than 600 mg per day will not be approved.

A response to treatment is defined as a decrease from baseline in the sum of the products of the perpendicular diameters of all measurable lesions of 50% or greater. (Response definition based on the Southwest Oncology Group standard criteria, see Demetri et al. N Engl J Med 2002; 347: 472-80.)

9111M	Tablet 100 mg (as mesylate)	60	2	..	2032.10	32.90	Glivec	NV
9112N	Tablet 400 mg (as mesylate)	30	2	..	3918.26	32.90	Glivec	NV

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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 \$	

NOTE:

No applications for increased repeats will be authorised.

Authority Required

Initial treatment of patients in the chronic phase of chronic myeloid leukaemia expressing the Philadelphia chromosome or the transcript, bcr-abl tyrosine kinase, and who have a primary diagnosis of chronic myeloid leukaemia.

Applications under this restriction will be limited to provide patients with a maximum of 18 months of therapy from the date the first application for initial treatment was approved.

Applications for authorisation must be in writing and must include:

- (1) a completed authority prescription form; and*
- (2) a completed Imatinib Mesylate (Glivec) PBS Authority Application for Use in the Treatment of Chronic Myeloid Leukaemia - Supporting Information form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and*
- (3) a pathology cytogenetic report conducted on peripheral blood or bone marrow supporting the diagnosis of chronic myeloid leukaemia to confirm eligibility for treatment, or a qualitative PCR report documenting the presence of the bcr-abl transcript in either peripheral blood or bone marrow; and*
- (4) a copy of a signed patient acknowledgement form indicating that the patient understands and acknowledges that PBS-subsidised treatment with imatinib mesylate for the chronic phase of chronic myeloid leukaemia will cease if subsequent testing demonstrates that:*
 - (i) the patient has failed to achieve a major cytogenetic response within the initial 18 months of treatment [see Note defining major cytogenetic response]; or*
 - (ii) the patient has failed to sustain a major cytogenetic response for 12 months from the date of the last pathology report that indicated that a major cytogenetic response had been achieved [see Note defining major cytogenetic response].*

NOTE:

Imatinib mesylate in the chronic phase of chronic myeloid leukaemia will only be subsidised for patients who are not receiving concomitant PBS-subsidised interferon alfa therapy.

Patients should be commenced on a dose of imatinib mesylate of 400 mg (base) daily and maintained on a minimum dose of imatinib mesylate of 400 mg (base) daily. Prescribing of lower doses should be carefully considered.

Continuing therapy is dependent on patients demonstrating a response to imatinib mesylate therapy following the initial 18 months of treatment and at 12 monthly intervals thereafter, irrespective of the daily imatinib mesylate dose received.

Authority Required

Continuing treatment of patients who have received initial treatment with imatinib mesylate as a pharmaceutical benefit for the chronic phase of chronic myeloid leukaemia and who have demonstrated either a major cytogenetic response or less than 1% bcr-abl level in the blood in the preceding 12 months.

Applications for authorisation must be in writing and must include:

- (1) a completed authority prescription form; and*
- (2) demonstration of continued response to treatment as evidenced by either:*
 - (a) major cytogenetic response [see Note explaining requirements]. Where this has been supplied within the previous 12 months, only the date of the relevant pathology report need be provided; or*
 - (b) a peripheral blood level of bcr-abl of less than 1% on the international scale [see Note explaining requirements]. Where this has been supplied within the previous 12 months, only the date of the relevant pathology report need be provided.*

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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 \$	

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.

Where a patient has previously received PBS-subsidised treatment with imatinib mesylate, no approval will be granted for PBS-subsidised re-treatment in the chronic phase of chronic myeloid leukaemia, where that patient has at any time failed to meet the criteria for continuing treatment.

9113P	Tablet 100 mg (as mesylate)	60	5	..	2032.10	32.90	Glivec	NV
9114Q	Tablet 400 mg (as mesylate)	30	5	..	3918.26	32.90	Glivec	NV

NOTE:

No applications for increased repeats will be authorised.

continued ➞

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 \$		

Authority Required

Treatment of patients in the accelerated phase of chronic myeloid leukaemia expressing the Philadelphia chromosome or the transcript, bcr-abl tyrosine kinase, and who have a primary diagnosis of chronic myeloid leukaemia. Progress to the accelerated phase is defined by the presence of 1 or more of the following:

- (1) *Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 15% but less than 30%; or*
- (2) *Percentage of blasts plus promyelocytes in the peripheral blood or bone marrow greater than or equal to 30%; or*

- (3) *Peripheral basophils greater than or equal to 20%; or*

- (4) *Progressive splenomegaly to a size greater than or equal to 10 cm below the left costal margin to be confirmed on 2 occasions at least 4 weeks apart, or a greater than or equal to 50% increase in size below the left costal margin over 4 weeks; or*

- (5) *Karyotypic evolution (chromosomal abnormalities in addition to a single Philadelphia chromosome).*

Applications for authorisation must be in writing and must include:

- (a) *a completed authority prescription form; and*
- (b) *a completed Imatinib Mesylate (Glivec) PBS Authority Application for Use in the Treatment of Chronic Myeloid Leukaemia - Supporting Information form, stating which of the above criteria are satisfied by the patient; and*
- (c) *a copy of the confirming pathology report from an Approved Pathology Authority in the case of criteria (1), (2), (3) and (5) above, or details of the dates of assessments in the case of progressive splenomegaly.*

Authority Required

Treatment of patients in the blast phase of chronic myeloid leukaemia expressing the Philadelphia chromosome or the transcript, bcr-abl tyrosine kinase, and who have a primary diagnosis of chronic myeloid leukaemia. Progress to myeloid blast crisis is defined as either:

- (1) *Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 30%; or*
- (2) *Extramedullary involvement other than spleen and liver.*

Applications for authorisation must be in writing and must include:

- (a) *a completed authority prescription form; and*
- (b) *a completed Imatinib Mesylate (Glivec) PBS Authority Application for Use in the Treatment of Chronic Myeloid Leukaemia - Supporting Information form, stating which of the above criteria are satisfied by the patient; and*
- (c) *a copy of the confirming pathology report from an Approved Pathology Authority in the case of criterion (1) above, or details of the date of assessment in the case of extramedullary involvement.*

Authority Required

Continuing treatment of patients with chronic myeloid leukaemia expressing the Philadelphia chromosome or the transcript, bcr-abl tyrosine kinase, where the patient has previously received PBS-subsidised treatment with imatinib mesylate of:

- (a) *the accelerated phase of chronic myeloid leukaemia; or*
- (b) *the blast phase of chronic myeloid leukaemia.*

9115R	Tablet 100 mg (as mesylate)	60	2	..	2032.10	32.90	Glivec	NV
9116T	Tablet 400 mg (as mesylate)	30	2	..	3918.26	32.90	Glivec	NV

NOTE:

No applications for increased repeats will be authorised.

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 \$	

Authority Required

Initial treatment in combination with chemotherapy as induction or consolidation of a newly diagnosed patient with acute lymphoblastic leukaemia (ALL) bearing the Philadelphia chromosome or expressing the transcript, BCR-ABL.

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

- (a) a completed authority prescription form; and*
- (b) a completed Acute Lymphoblastic Leukaemia Imatinib PBS Authority Application - Supporting Information Form; and*
- (c) a pathology cytogenetic report conducted on peripheral blood or bone marrow supporting the diagnosis of acute lymphoblastic leukaemia to confirm eligibility for treatment, with either cytogenetic evidence of the Philadelphia chromosome, or a qualitative PCR report documenting the presence of the BCR-ABL transcript in either peripheral blood or bone marrow. (The date of the relevant pathology report needs to be provided); and*
- (d) a signed patient acknowledgement.*

Authority Required

Initial treatment of a patient with acute lymphoblastic leukaemia bearing the Philadelphia chromosome or expressing the transcript BCR-ABL who was previously treated with imatinib mesylate under the Imatinib Compassionate Program and who meets all the PBS criteria.

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

- (a) a completed authority prescription form; and*
- (b) a completed Acute Lymphoblastic Leukaemia Imatinib PBS Authority Application - Supporting Information Form; and*
- (c) a pathology cytogenetic report conducted on peripheral blood or bone marrow supporting the diagnosis of acute lymphoblastic leukaemia to confirm eligibility for treatment, with either cytogenetic evidence of the Philadelphia chromosome, or a qualitative PCR report documenting the presence of the BCR-ABL transcript in either peripheral blood or bone marrow. (The date of the relevant pathology report needs to be provided); and*
- (d) a signed patient acknowledgement.*

Authority Required

Continuing treatment in combination with chemotherapy as maintenance of first complete remission of patients with acute lymphoblastic leukaemia bearing the Philadelphia chromosome or expressing the transcript, BCR-ABL.

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

Imatinib mesylate is available with a lifetime maximum of 24 months imatinib mesylate therapy for patients with acute lymphoblastic leukaemia reimbursed through the PBS.

Any queries concerning the arrangements to prescribe imatinib mesylate beyond 24 months may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

NOTE:

Allogeneic stem cell transplantation is the preferred therapy for eligible patients achieving a complete remission of Philadelphia positive acute lymphoblastic leukaemia.

9123E	Tablet 100 mg (as mesylate)	60	2	..	2032.10	32.90	Glivec	NV
9124F	Tablet 400 mg (as mesylate)	30	2	..	3918.26	32.90	Glivec	NV

NOTE:

No applications for increased repeats will be authorised.

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 \$	

Authority Required

Initial PBS-subsidised treatment of a patient with unresectable, locally recurrent or metastatic dermatofibrosarcoma protuberans.

Maximum dose: 800 mg per day.

- (1) *Where the application for authority to prescribe is being sought on the basis of unresectable tumour, written evidence in support of that claim must be provided; and*
- (2) *Where the application for authority to prescribe is being sought on the basis of locally recurrent disease, the site of the local recurrence must be specified; and*
- (3) *Where the application for authority to prescribe is being sought on the basis of metastatic disease, the site(s) of metastatic disease must be provided.*

Applications for authorisation for initial treatment must be made in writing and must include:

- (a) *a completed authority prescription form; and*
- (b) *a completed Rare Diseases Imatinib PBS Authority Application - Supporting Information Form; and*
- (c) *a signed patient acknowledgement.*

Authority Required

Continuing PBS-subsidised treatment of a patient with unresectable, locally recurrent or metastatic dermatofibrosarcoma protuberans who has previously been issued with an authority prescription for imatinib and who has demonstrated a response, but whose disease remains unresectable.

Maximum dose: 800 mg per day.

Applications for authorisation must be made in writing and must include:

- (a) *a completed authority prescription form; and*
- (b) *a completed Rare Diseases Imatinib PBS Authority Application - Supporting Information Form; and*
- (c) *a statement that the disease has not progressed on imatinib therapy.*

9172R	Tablet 100 mg (as mesylate)	60	2	..	2032.10	32.90	Glivec	NV
9173T	Tablet 400 mg (as mesylate)	30	2	..	3918.26	32.90	Glivec	NV

NOTE:

No applications for increased repeats will be authorised.

Authority Required

Initial PBS-subsidised treatment of a patient with hypereosinophilic syndrome or chronic eosinophilic leukaemia requiring treatment and confirmed to carry the FIP1L1-PDGfra fusion gene.

Maximum dose: 400 mg per day.

Applications for authorisation for initial treatment must be made in writing and must include:

- (a) *a completed authority prescription form; and*
- (b) *a completed Rare Diseases Imatinib PBS Authority Application - Supporting Information Form; and*
- (c) *a copy of the pathology report confirming the presence of the FIP1L1-PDGfra fusion gene; and*
- (d) *a copy of the full blood examination report confirming the presence of hypereosinophilic syndrome or chronic eosinophilic leukaemia; and*
- (e) *details of organ involvement requiring treatment, including a copy of the radiology, nuclear medicine, respiratory function or anatomical pathology reports as appropriate; and*
- (f) *a signed patient acknowledgement.*

continued ➞

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 \$		

Authority Required

Continuing PBS-subsidised treatment of a patient with hypereosinophilic syndrome or chronic eosinophilic leukaemia who has previously been issued with an authority prescription for imatinib and who has achieved and maintained a complete haematological response.

Maximum dose: 400 mg per day.

Applications for authorisation must be made in writing and must include:

- (a) a completed authority prescription form; and*
- (b) a completed Rare Diseases Imatinib PBS Authority Application - Supporting Information Form; and*
- (c) a copy of the full blood examination report which demonstrates a complete haematological response, with a normal eosinophil count; and*
- (d) a statement that the disease has not progressed on imatinib therapy.*

9174W	Tablet 100 mg (as mesylate)	60	2	..	2032.10	32.90	Glivec	NV
9175X	Tablet 400 mg (as mesylate)	30	2	..	3918.26	32.90	Glivec	NV

NOTE:

No applications for increased repeats will be authorised.

Authority Required

Initial PBS-subsidised treatment of a patient with a myelodysplastic or myeloproliferative disorder where:

- (1) there is confirmed evidence of a platelet-derived growth factor receptor (PDGFR) gene re-arrangement either by standard karyotyping, or FISH or PDGFRB fusion gene transcript; and*
- (2) the patient has previously failed an adequate trial of one or more of the following conventional therapies:*
 - cytarabine;
 - etoposide;
 - hydroxyurea.

Maximum dose: 400 mg per day.

Applications for authorisation for initial treatment must be made in writing and must include:

- (a) a completed authority prescription form; and*
- (b) a completed Rare Diseases Imatinib PBS Authority Application - Supporting Information Form; and*
- (c) a copy of the pathology report confirming the platelet-derived growth factor receptor (PDGFR) gene re-arrangement; and*
- (d) a copy of the bone marrow biopsy report which demonstrates the presence of a myelodysplastic or myeloproliferative disorder; and*
- (e) details of the prior therapy trialled and the response; and*
- (f) a signed patient acknowledgement.*

Authority Required

Continuing PBS-subsidised treatment of a patient with a PDGFRB fusion gene-positive myelodysplastic or myeloproliferative disorder who has previously been issued with an authority prescription for imatinib and who has demonstrated a complete haematological response.

Maximum dose: 400 mg per day.

Applications for authorisation must be made in writing and must include:

- (a) a completed authority prescription form; and*
- (b) a completed Rare Diseases Imatinib PBS Authority Application - Supporting Information Form; and*
- (c) a copy of the full blood examination report which demonstrates a complete haematological response; and*
- (d) a statement that the disease has not progressed on imatinib therapy.*

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	
9176Y	Tablet 100 mg (as mesylate)	60	2	..	2032.10	32.90	Glivec	NV
9177B	Tablet 400 mg (as mesylate)	30	2	..	3918.26	32.90	Glivec	NV

NOTE:

No applications for increased repeats will be authorised.

Authority Required

Initial PBS-subsidised treatment of a patient with aggressive systemic mastocytosis with eosinophilia where:

(1) there is confirmed evidence of the FIP1L1-PDGFRA fusion gene; and

(2) the patient has previously failed an adequate trial of one or more of the following conventional therapies:

— corticosteroids;

— hydroxyurea.

Maximum dose: 400 mg per day.

Applications for authorisation for initial treatment must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Rare Diseases Imatinib PBS Authority Application - Supporting Information Form; and

(c) a copy of the pathology report confirming the presence of the FIP1L1-PDGFRA fusion gene; and

(d) a copy of the bone marrow biopsy report and/or other tissue biopsy report confirming the diagnosis of aggressive systemic mastocytosis and a copy of the full blood examination report demonstrating eosinophilia; and

(e) details of symptomatic organ involvement requiring treatment, including a copy of the radiology, nuclear medicine, respiratory function or anatomical pathology reports as appropriate; and

(f) details of prior treatment trialled and the response; and

(g) a signed patient acknowledgement.

Authority Required

Continuing PBS-subsidised treatment of a patient with aggressive systemic mastocytosis confirmed to carry the FIP1L1-PDGFRA fusion gene, who has previously been issued with an authority prescription for imatinib and who has demonstrated a complete haematological response.

Maximum dose: 400 mg per day.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Rare Diseases Imatinib PBS Authority Application - Supporting Information Form; and

(c) a copy of the full blood examination report which demonstrates a complete haematological response; and

(d) a statement that the disease has not progressed on imatinib therapy.

9178C	Tablet 100 mg (as mesylate)	60	2	..	2032.10	32.90	Glivec	NV
9179D	Tablet 400 mg (as mesylate)	30	2	..	3918.26	32.90	Glivec	NV

NOTE:

No applications for increased repeats will be authorised.

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 \$	

LAPATINIB

NOTE:

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

Lapatinib should not be used in patients with a left ventricular ejection fraction (LVEF) of less than 45% or with symptomatic heart failure. Cardiac function must be tested by a suitable method including, for example, ECHO or MUGA, prior to seeking the initial authority approval and then at 3 monthly intervals during treatment.

Lapatinib is not PBS-subsidised when used in combination with Commonwealth-subsidised trastuzumab. Once PBS-subsidised lapatinib has been commenced, a patient cannot subsequently receive Commonwealth-subsidised trastuzumab.

If disease progression occurs, the prescribing doctor must contact Medicare Australia within one week on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) and lapatinib treatment must be ceased immediately.

Authority Required

Initial treatment, in combination with capecitabine, of a patient with HER2 positive metastatic breast cancer (equivalent to Stage IIIC or Stage IV) who has received prior therapy with an anthracycline and a taxane, each for at least 3 cycles, and whose disease has progressed despite treatment with trastuzumab for metastatic disease.

Authority applications for initial treatment must be made in writing and must include:

- (a) a completed authority prescription form;
- (b) a pathology report demonstrating HER2 positivity has been demonstrated by in situ hybridisation (ISH);
- (c) date of last treatment with a taxane and total number of cycles;
- (d) date of last treatment with an anthracycline and total number of cycles;
- (e) a signed patient acknowledgment;
- (f) dates of treatment with trastuzumab; and
- (g) date of demonstration of progression whilst on treatment with trastuzumab.

NOTE:

Treatment with trastuzumab for metastatic disease is defined as trastuzumab administered alone or in combination with chemotherapy for at least 6 weeks at standard doses.

Authority Required

Initial treatment, in combination with capecitabine, of a patient with HER2 positive metastatic breast cancer who was receiving treatment with lapatinib prior to 1 May 2008.

Authority applications for initial PBS-subsidised treatment must be made in writing and must include:

- (a) a completed authority prescription form;
- (b) a pathology report demonstrating that HER2 positivity has been demonstrated by in situ hybridisation (ISH);
- (c) a signed patient acknowledgment; and
- (d) the date the patient commenced non-PBS-subsidised treatment with lapatinib.

Authority Required

Continuing treatment, in combination with capecitabine, of a patient with HER2 positive metastatic breast cancer who has previously received treatment with PBS-subsidised lapatinib and who does not have progressive disease.

Authority applications must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a statement from the prescribing doctor that the disease has not progressed.

9148L	Tablet 250 mg (as ditosylate monohydrate)	140	2	..	* 3387.03	32.90	Tykerb	GK

NOTE:

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

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 \$	

NILOTINIB

NOTE:

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

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

Any queries concerning patients who are enrolled on the Nilotinib Compassionate Program may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Applications for authority to prescribe nilotinib should be forwarded to:

Medicare Australia

Prior Written Approval of Specialised Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

Authority Required

Initial treatment, as the sole PBS-subsidised therapy, of a patient with chronic myeloid leukaemia in chronic or accelerated phase bearing the Philadelphia chromosome or expressing the transcript, BCR-ABL, who has active leukaemia (as defined by presence on current pathology assessments of either the Philadelphia chromosome on cytogenetic or FISH analysis, or the presence of the transcript BCR-ABL greater than 1% on the international scale) and who has failed an adequate trial of imatinib.

Failure of an adequate trial of imatinib is defined as:

(i) Lack of response to initial imatinib therapy, defined as either:

— failure to achieve a haematological response after a minimum of 3 months therapy with imatinib for patients initially treated in chronic phase; or

— failure to achieve any cytogenetic response after a minimum of 6 months therapy with imatinib for patients initially treated in chronic phase as demonstrated on bone marrow biopsy by presence of greater than 95% Philadelphia chromosome positive cells; or

— failure to achieve a major cytogenetic response or a peripheral blood BCR-ABL level of less than 1% after a minimum of 12 months therapy with imatinib; OR

(ii) Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph positive cells on bone marrow biopsy), during ongoing imatinib therapy;

OR

(iii) Loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing in value by at least 5 fold to a level of greater than 1% confirmed on a subsequent test), during ongoing imatinib therapy;

OR

(iv) Development of accelerated phase in a patient previously prescribed imatinib for the chronic phase of chronic myeloid leukaemia.

continued ➡

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 \$		
<i>Accelerated phase is defined by the presence of 1 or more of the following:</i> (1) Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 15% but less than 30%; or (2) Percentage of blasts plus promyelocytes in the peripheral blood or bone marrow greater than or equal to 30%, provided that blast count is less than 30%; or (3) Peripheral basophils greater than or equal to 20%; or (4) Progressive splenomegaly to a size greater than or equal to 10 cm below the left costal margin to be confirmed on 2 occasions at least 4 weeks apart, or a greater than or equal to 50% increase in size below the left costal margin over 4 weeks; or (5) Karyotypic evolution (chromosomal abnormalities in addition to a single Philadelphia chromosome); OR (v) Disease progression (defined as a greater than or equal to 50% increase in peripheral white blood cell count, blast count, basophils or platelets) during first-line imatinib therapy in patients with accelerated phase chronic myeloid leukaemia, provided that blast crisis has been excluded on bone marrow biopsy; OR (vi) Grade 3 or 4 non-haematological toxicity that is imatinib related and necessitates permanent cessation of imatinib. For patients with imatinib related toxicities, leukaemia activity does not need to be demonstrated. <i>Applications for authorisation must be in writing and must include:</i> (a) a completed authority prescription form; and (b) a completed Chronic Myeloid Leukaemia Dasatinib/Nilotinib PBS Authority Application - Supporting Information Form; and (c) a signed patient acknowledgement; and (d) a bone marrow biopsy pathology report demonstrating the patient has active chronic myeloid leukaemia, either manifest as cytogenetic evidence of the Philadelphia chromosome, or RT-PCR level of BCR-ABL transcript greater than 1% on the international scale. (The date of the relevant pathology report needs to be provided); and (e) where there has been a loss of response to imatinib, a copy of the current confirming pathology report(s) from an Approved Pathology Authority; or (f) details of Grade 3 or 4 non-haematological imatinib related toxicity. NOTE: Nilotinib will only be subsidised for patients with chronic myeloid leukaemia who are not receiving concomitant PBS-subsidised imatinib mesylate, dasatinib or interferon alfa therapy. Patients should be commenced on a dose of nilotinib of 400 mg twice daily. Continuing therapy is dependent on patients demonstrating a major cytogenetic response to nilotinib therapy or a peripheral blood BCR-ABL level of less than 1% at 18 months and thereafter at 12 monthly intervals, irrespective of the daily nilotinib dose received. Nilotinib is not PBS-subsidised for patients with CML that is resistant to dasatinib. Nilotinib is not TGA-registered and not PBS-subsidised for patients with CML in blast crisis. Requests for doses of greater than nilotinib 400 mg twice daily will not be approved. From 1 November 2008, under the PBS, a patient will be able to trial either dasatinib and/or nilotinib within the initial 18 month treatment period, providing the patient's CML is not resistant to the first second-line agent.								
9285Q	Capsule 200 mg (as hydrochloride monohydrate)	112	2	..	* 5489.99	32.90	Tasigna	NV

continued ➡

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 \$	

Authority Required

Continuing treatment, as the sole PBS-subsidised therapy, of a patient who has received initial treatment with nilotinib as a pharmaceutical benefit for chronic myeloid leukaemia, and who has demonstrated either a major cytogenetic response, or less than 1% BCR-ABL level in the blood, to nilotinib in the preceding 18 months and thereafter at 12 monthly intervals.

Applications for authorisation must be in writing and must include:

- (1) a completed authority prescription form; and*
- (2) a completed Chronic Myeloid Leukaemia Dasatinib/Nilotinib Authority Application Form for continuing treatment; and*
- (3) demonstration of continued response to treatment as evidenced by either:*
 - (a) major cytogenetic response [see Note explaining definitions of response]. Where this has been supplied within the previous 12 months (or 18 months for the initial supply), only the date of the relevant pathology report needs to be provided; or*
 - (b) a peripheral blood level of BCR-ABL of less than 1% on the international scale [see Note explaining definitions of response]. Where this has been supplied within the previous 12 months (or 18 months for the initial supply), only the date of the relevant pathology report needs to be provided.*

NOTE:

Definitions of response.

A major cytogenetic response is defined as less than 35% Philadelphia positive bone marrow cells.

A bone marrow or peripheral blood BCR-ABL level of less than 1% on the international scale (Blood 108: 28-37, 2006) also indicates a response, at least the biological equivalent of a major cytogenetic response.

Authority approval requirements.

For the purposes of assessing response to PBS-subsidised treatment with nilotinib, either cytogenetic analysis indicating the number of Philadelphia positive [t (9;22)] cells in the bone marrow measured by standard karyotyping, or quantitative PCR indicating the relative level of BCR-ABL transcript in the peripheral blood using the international scale, must be submitted. For bone marrow analyses, where the standard karyotyping is not informative for technical reasons, a cytogenetic analysis performed on the bone marrow by the use of fluorescence in situ hybridisation (FISH) with BCR-ABL specific probe must be submitted. The cytogenetic or peripheral blood quantitative PCR analyses must be submitted as follows:

- (i) between 10 and 18 months of the commencement of treatment with nilotinib, at which time patients in whom a major cytogenetic response or peripheral blood BCR-ABL level of less than 1% has been demonstrated may receive authorisation for a further 12 months of treatment; and*
- (ii) at no greater than 12 month intervals thereafter, to demonstrate that the major cytogenetic response or peripheral blood BCR-ABL level of less than 1% has been sustained.*

For each authority application where eligibility for continuing PBS-subsidised treatment is to be demonstrated, a copy of the cytogenetic analysis indicating the number of Philadelphia positive [t (9;22)] cells in the bone marrow measured by standard karyotyping, or a copy of the quantitative PCR indicating the relative level of BCR-ABL transcript in the peripheral blood using the international scale, must be submitted as described in (i) and (ii) above. For bone marrow analyses, where the standard karyotyping conducted at the time of application is not informative, a copy of a cytogenetic analysis conducted on the bone marrow using FISH with BCR-ABL specific probe must be submitted with the authority application. A copy of the non-informative standard karyotype analysis must be included with the authority application.

Where a patient has previously received PBS-subsidised treatment with nilotinib, no approval will be granted for PBS-subsidised re-treatment where that patient has at any time failed to meet the criteria for continuing treatment.

9171Q	Capsule 200 mg (as hydrochloride monohydrate)	112	5	..	* 5489.99	32.90	Tasigna	NV

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 \$	

SORAFENIB

Authority Required

Initial treatment, as the sole PBS-subsidised agent, of advanced (BCLC Stage C) hepatocellular carcinoma in a patient with a WHO performance status of 2 or less and Child Pugh class A;

Continuing treatment, as the sole PBS-subsidised agent, of advanced hepatocellular carcinoma in a patient who has previously been treated with PBS-subsidised sorafenib and who does not have progressive disease.

NOTE:

Sorafenib is not PBS-subsidised for adjunctive treatment after resection, ablation or chemoembolization.

Sorafenib is not PBS-subsidised for maintenance therapy after disease progression.

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

9380Q	Tablet 200 mg (as tosylate)	120	2	..	* 6456.65	32.90	Nexavar	BN

NOTE:

Special Pricing Arrangements apply.

SUNITINIB

Authority Required

Initial treatment, as the sole PBS-subsidised therapy, of Stage IV clear cell variant renal cell carcinoma (RCC) in a patient who meets the Memorial Sloan Kettering Cancer Centre (MSKCC) low to intermediate risk group and has a WHO performance status of 2 or less.

NOTE:

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

9417P	Capsule 12.5 mg (as malate)	28	1	..	1833.77	32.90	Sutent	PF
9418Q	Capsule 25 mg (as malate)	28	1	..	3521.33	32.90	Sutent	PF
9419R	Capsule 50 mg (as malate)	28	1	..	6897.01	32.90	Sutent	PF

NOTE:

Special Pricing Arrangements apply.

Authority Required

Continuing treatment beyond 3 months, as the sole PBS-subsidised therapy, of Stage IV clear cell variant renal cell carcinoma (RCC) in a patient who has previously been issued with an authority prescription for sunitinib and who has stable or responding disease according to RECIST criteria.

NOTE:

RECIST Criteria is defined as follows:

Complete response (CR) is disappearance of all target lesions.

Partial response (PR) is a 30% decrease in the sum of the longest diameter of target lesions.

Progressive disease (PD) is a 20% increase in the sum of the longest diameter of target lesions.

Stable disease (SD) is small changes that do not meet above criteria.

Authority Required

Initial treatment, as the sole PBS-subsidised therapy, of Stage IV clear cell variant renal cell carcinoma (RCC) in a patient who was receiving treatment with sunitinib prior to 1 May 2009.

9420T	Capsule 12.5 mg (as malate)	28	3	..	1833.77	32.90	Sutent	PF

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	
9421W	Capsule 25 mg (as malate)	28	3	..	3521.33	32.90	Sutent	PF
9422X	Capsule 50 mg (as malate)	28	3	..	6897.01	32.90	Sutent	PF

NOTE:

Special Pricing Arrangements apply.

• **Other antineoplastic agents**

BORTEZOMIB

NOTE:

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

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

Applications for authority to prescribe bortezomib should be forwarded to:

Medicare Australia

Prior Written Approval of Specialised Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

Authority Required

Initial PBS-subsidised treatment, as monotherapy or in combination with a corticosteroid and/or cyclophosphamide, of multiple myeloma in a patient with a WHO performance status of 2 or less, who has progressive disease, who has received at least 1 prior therapy (other than thalidomide), who has undergone or is ineligible for a primary stem cell transplant and who has experienced treatment failure after a trial of at least four (4) weeks of thalidomide at a dose of at least 100 mg daily.

If the dosing requirement for thalidomide cannot be met, the application must state the reasons why this criterion cannot be satisfied.

Thalidomide treatment failure is defined as:

- (1) confirmed disease progression during or within 6 months of discontinuing thalidomide treatment; or
- (2) severe intolerance or toxicity unresponsive to clinically appropriate dose adjustment.

Progressive disease is defined as at least 1 of the following:

- (a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or
- (b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or
- (c) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or
- (d) an increase in the size or number of lytic bone lesions (not including compression fractures); or
- (e) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or
- (f) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Severe intolerance due to thalidomide is defined as unacceptable somnolence or sedation interfering with activities of daily living.

Toxicity from thalidomide is defined as peripheral neuropathy (Grade 2 or greater, interfering with function), drug-related seizures, serious Grade 3 or Grade 4 drug-related dermatological reactions, such as Stevens-Johnson Syndrome, or other Grade 3 or 4 toxicity.

continued ➡

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 \$	

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

- (1) a completed authority prescription form; and*
- (2) a completed Multiple Myeloma Authority Application - Supporting Information Form, which includes details of prior treatments including name(s) of drug(s) and date of most recent treatment cycle and record of prior stem cell transplant or ineligibility for prior stem cell transplant; the patient's WHO performance status; details of thalidomide treatment failure; details of the basis of the diagnosis of progressive disease; and nomination of which disease activity parameters will be used to assess response.*

To enable confirmation by Medicare Australia of response, current diagnostic reports of the following are required:

- (a) the level of serum monoclonal protein; and*
- (b) if Bence-Jones proteinuria is present, the results of 24-hour urinary light chain M protein excretion.*

If neither serum M protein or urine Bence-Jones protein are present in measurable quantities, additional diagnostic reports are required, including:

- (c) bone marrow aspirate and trephine; and*
- (d) if present, the size and location of lytic bone lesions (not including compression fractures); or*
- (e) if present, the size and location of all soft tissue plasmacytomas by clinical or radiographic examination i.e. MRI or CT-scan; or*
- (f) if present, the level of hypercalcaemia, corrected for albumin concentration; or*
- (g) if present, the serum free light chain levels.*

As these parameters will be used to determine response, results for (a) and (b) should be provided for all patients. Where the patient has oligo-secretory or non-secretory multiple myeloma, (c) must be provided and if relevant (d), (e) or (f). Where the prescriber plans to assess response in patients with oligo-secretory or non-secretory multiple myeloma with free light chain assays, (g) must be provided. Where 1 or more results cannot be provided, the application must state the reason(s) these cannot be provided; and

- (3) duration of thalidomide and daily dose prescribed; and*
- (4) a signed patient acknowledgment.*

Authority Required

Continuing PBS-subsidised treatment, as monotherapy or in combination with a corticosteroid and/or cyclophosphamide, of multiple myeloma in a patient who has previously received 4 treatment cycles of bortezomib and who, at the time of application, has demonstrated at least a partial response to bortezomib.

If serum M protein and urine Bence-Jones protein levels are measurable, partial response (PR) compared with baseline (prior to treatment with bortezomib) is defined as:

- (a) at least a 50% reduction in the level of serum M protein (monoclonal protein); or*
- (b) at least a 90% reduction in 24-hour urinary light chain M protein excretion or to less than 200 mg per 24 hours.*

If serum M protein and urine Bence-Jones protein levels are unmeasurable as in non-secretory/oligo-secretory multiple myeloma, partial response compared with baseline is defined as:

- (c) at least a 50% reduction in the difference between involved and uninvolved serum free light chain (FLC) levels.*

If serum M protein and urine Bence-Jones protein and serum FLC are unmeasurable/unavailable, partial response compared with baseline is defined as:

- (d) at least a 50% reduction in bone marrow plasma cells; or*
- (e) normalisation of corrected serum calcium to less than or equal to 2.65 mmol per L; or*
- (f) no increase in size or number of lytic bone lesions (development of compression fracture does not exclude response); or*
- (g) at least a 50% reduction in the size of soft tissue plasmacytoma (by clinical or applicable radiographic examination, i.e. MRI or CT-Scan).*

continued ➡

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 \$		
<i>For the purpose of assessing eligibility for continuing PBS-subsidised bortezomib treatment beyond 4 cycles, the patient must have achieved at least a partial response at the completion of cycle 4. The results of the response assessment must be included in a written application to Medicare Australia for further treatment. Where a response assessment is not submitted to Medicare Australia prior to cycle 5, patients will be deemed to have failed to respond to treatment with bortezomib. Continuing PBS-subsidised supply will not be approved if there is a gap of more than 6 months between the initial application and subsequent applications.</i> <i>The same parameters provided for the diagnosis of progressive disease are to be used to demonstrate at least a partial response to treatment.</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 Multiple Myeloma Authority Application - Supporting Information Form; and</i> <i>(3) diagnostic reports demonstrating the patient has achieved at least a partial response.</i> <i>Diagnostic reports must be no more than 1 month old at the time of application.</i> <i>Patients who fail to demonstrate at least a partial response after 8 cycles will not be eligible to receive further PBS-subsidised treatment with bortezomib.</i> <i>No more than 2 cycles of treatment beyond the cycle at which a confirmed complete response was first achieved will be authorised. Confirmation requires 2 determinations a minimum of 6 weeks apart.</i>								
9117W	Powder for injection 3.5 mg (solvent required) (code 7086Y applies to above item with approved solvent)	4	3	..	* 7001.95	32.90	Velcade	JC

Authority Required

Continuing PBS-subsidised treatment, as monotherapy or in combination with a corticosteroid and/or cyclophosphamide, of multiple myeloma in a patient who has previously received 8 treatment cycles with bortezomib and who, at the time of application, has demonstrated at least a partial response to bortezomib but who has not received 2 treatment cycles after first achieving a confirmed complete response.

If serum M protein and urine Bence-Jones protein levels are measurable, partial response (PR) compared with baseline (prior to treatment with bortezomib) is defined as:

- (a) at least a 50% reduction in the level of serum M protein (monoclonal protein); or*
- (b) at least a 90% reduction in 24-hour urinary light chain M protein excretion or to less than 200 mg per 24 hours.*

If serum M protein and urine Bence-Jones protein levels are unmeasurable as in non-secretory/oligo-secretory multiple myeloma, partial response compared with baseline is defined as:

- (c) the difference between involved and uninvolved serum free light chain (FLC) levels, with at least a 50% reduction in this value.*

If serum M protein and urine Bence-Jones protein levels and serum FLC are unmeasurable/unavailable, partial response compared with baseline is defined as:

- (d) at least a 50% reduction in bone marrow plasma cells; or*
- (e) normalisation of corrected serum calcium to less than or equal to 2.65 mmol per L; or*
- (f) no increase in size or number of lytic bone lesions (development of compression fracture does not exclude response); or*
- (g) at least a 50% reduction in the size of soft tissue plasmacytoma (by clinical or applicable radiographic examination, i.e. MRI or CT-Scan).*

The same parameters provided for the diagnosis of progressive disease are to be used to demonstrate at least a partial response to treatment.

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 \$	
<i>Diagnostic reports must be within 1 month of the date of application.</i> <i>For the purpose of assessing eligibility for continuing PBS-subsidised bortezomib treatment beyond 8 cycles, the patient must have achieved at least a partial response at the completion of cycle 8. The results of the response assessment must be included in a written application to Medicare Australia for further treatment. Where a response assessment is not submitted to Medicare Australia prior to cycle 9, patients will be deemed to have failed to respond to treatment with bortezomib. Continuing PBS-subsidised supply will not be approved if there is a gap of more than 10 months between the initial application and an application following completion of 8 treatment cycles.</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 Multiple Myeloma Authority Application - Supporting Information Form; and</i> <i>(3) diagnostic reports demonstrating the patient has achieved at least a partial response.</i> <i>No more than 2 cycles of treatment beyond the cycle at which the complete response was first achieved will be authorised. Confirmation requires 2 determinations a minimum of 6 weeks apart.</i> <i>Applications for PBS-subsidised treatment with bortezomib that extends beyond 11 cycles will not be approved.</i>							
<u>Authority Required</u>							
<i>Initial PBS-subsidised treatment of multiple myeloma in patients receiving treatment with bortezomib prior to 1 November 2007.</i>							
<i>Patients who fail to demonstrate at least a partial response after 4 cycles will not be eligible to receive further PBS-subsidised treatment with bortezomib.</i>							
<i>Diagnostic reports demonstrating at least a partial response must be within 1 month of the date of application.</i>							
<i>Patients may qualify for PBS-subsidised treatment under this restriction for a maximum of 3 cycles. To receive further treatment the patient must qualify under the continuing treatment criteria.</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 Multiple Myeloma Authority Application - Supporting Information Form; and</i>							
<i>(3) a signed patient acknowledgment; and</i>							
<i>(4) details including relevant reports of the basis of the diagnosis of progressive disease and nomination of which disease activity parameters will be used to assess response; and</i>							
<i>(5) if relevant, details including relevant reports for patients who have demonstrated a partial response and who have received 4 or more cycles.</i>							
9118X	Powder for injection 3.5 mg (solvent required) (code 7087B applies to above item with approved solvent)	4	2	..	* 7001.95	32.90	Velcade JC
HYDROXYUREA							
3093T	Capsule 500 mg	100	..	..	76.03	32.90	Hydrea BQ

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Proprietary Name and Manufacturer	
IRINOTECAN HYDROCHLORIDE TRIHYDRATE								
Authority Required								
<i>Metastatic colorectal cancer in patients with a WHO performance status of 2 or less.</i>								
NOTE:								
<i>In first-line usage, effectiveness and tolerance may be improved when irinotecan is combined with an infusional 5-fluorouracil regimen.</i>								
8414W	I.V. injection 40 mg in 2 mL	1	3	..	142.91	32.90	^a Camptosar ^a Irinotecan Sandoz ^a Omegapharm Irinotecan ^a HH	PU SZ OE
8415X	I.V. injection 100 mg in 5 mL	2	3	..	* 653.23	32.90	^a Camptosar ^a Irinotecan Sandoz ^a Omegapharm Irinotecan ^a HH	PU SZ OE
9410G	I.V. injection 300 mg in 15 mL	1	3	..	976.00	32.90	Camptosar	PF
9119Y	I.V. injection 500 mg in 25 mL	1	3	..	1623.97	32.90	HH	
TOPOTECAN HYDROCHLORIDE								
Authority Required								
<i>Advanced metastatic ovarian cancer after failure of prior therapy which includes a platinum compound.</i>								
8199M	Powder for I.V. infusion 4 mg (base)	5	1	..	2125.93	32.90	Hycamtin	GK
ENDOCRINE THERAPY								
Hormones and related agents								
• Progestogens								
MEDROXYPROGESTERONE ACETATE								
Restricted Benefit								
<i>Hormone-dependent advanced breast cancer.</i>								
2728N	Tablet 500 mg	30	2	..	132.91	32.90	Provera	PH
Restricted Benefit								
<i>Hormone-dependent breast cancer; Endometrial cancer.</i>								
2725K	Tablet 100 mg	100	2	..	95.20	32.90	Provera	PH
2316X	Tablet 200 mg	60	2	..	107.32	32.90	Provera	PH
2727M	Tablet 250 mg	60	2	..	132.67	32.90	Provera	PH
[For other listings for this drug see Generic/Proprietary Index]								

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	
MEGESTROL ACETATE								
<u>Restricted Benefit</u>								
<i>Hormone-dependent advanced breast cancer.</i>								
2734X	Tablet 160 mg	30	2	..	72.52	32.90	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	..	332.57	32.90	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	..	1108.33	32.90	Zoladex 10.8 Implant	AP
GOSERELIN ACETATE and BICALUTAMIDE								
<u>Authority Required</u>								
<i>Metastatic (equivalent to stage D) prostatic carcinoma in patients for whom a combination of an antiandrogen and a GnRH (LH-RH) agonist is required.</i>								
<u>NOTE:</u>								
<i>No applications for increased maximum quantities and/or repeats will be authorised.</i>								
9064C	Pack containing 1 subcutaneous implant goserelin 3.6 mg in pre-filled injection syringe and 28 tablets bicalutamide 50 mg	± 1	5	..	505.61	32.90	ZolaCos CP 3.6/50	AP
9065D	Pack containing 1 subcutaneous implant goserelin 10.8 mg in pre-filled injection syringe and 28 tablets bicalutamide 50 mg	± 1	..	..	1274.52	32.90	ZolaCos CP 10.8/50(28)	AP
9066E	Pack containing 1 subcutaneous implant goserelin 10.8 mg in pre-filled injection syringe and 84 tablets bicalutamide 50 mg	± 1	1	..	1606.90	32.90	ZolaCos CP 10.8/50(84)	AP

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	..	419.77	32.90	Lucrin Depot 7.5mg PDS	AB
8707G	Suspension for subcutaneous injection (modified release), 7.5 mg injection set	1	5	..	419.77	32.90	Eligard 1 month	HH
8876E	I.M. injection (modified release), powder for injection 22.5 mg with diluent in pre-filled dual-chamber syringe	1	1	..	1108.33	32.90	Lucrin Depot 3 Month PDS	AB
8708H	Suspension for subcutaneous injection (modified release), 22.5 mg injection set	1	1	..	1108.33	32.90	Eligard 3 month	HH
8877F	I.M. injection (modified release), powder for injection 30 mg with diluent in pre-filled dual-chamber syringe	1	1	..	1450.90	32.90	Lucrin Depot 4 Month PDS	AB
8709J	Suspension for subcutaneous injection (modified release), 30 mg injection set	1	1	..	1450.90	32.90	Eligard 4 month	HH
8859G	Suspension for subcutaneous injection (modified release), 45 mg injection set	1	..	..	2123.55	32.90	Eligard 6 month	HH
TRIPTORELIN EMBONATE								
Authority Required								
<i>Locally advanced (equivalent to stage C) or metastatic (equivalent to stage D) carcinoma of the prostate.</i>								
9378N	Powder for I.M. injection (prolonged release) 3.75 mg (base) with solvent, syringe and needles	1	5	..	419.77	32.90	Diphereline	IS
9379P	Powder for I.M. injection (prolonged release) 11.25 mg (base) with solvent, syringe and needles	1	1	..	1108.33	32.90	Diphereline	IS
Hormone antagonists and related agents								
• Anti-estrogens								
TAMOXIFEN CITRATE								
Restricted Benefit								
<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	..	38.45	32.90	^a Genox 10 ^a Tamoxen 10 mg	AF GM

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	
2110C	Tablet 20 mg (base)	60	5	..	59.81	32.90	^a Chem mart Tamoxifen	CH
							^a Genox 20	AF
							^a GenRx Tamoxifen	GX
							^a Tamosin	SI
							^a Tamoxen 20 mg	GM
							^a Tamoxifen Sandoz	SZ
							^a Terry White Chemists Tamoxifen	TW
				B3.82	* 63.65	32.90	^a Nolvadex-D	AP

TOREMIFENE CITRATE

Restricted Benefit

Treatment of hormone-dependent metastatic breast cancer in post-menopausal patients.

NOTE:

This drug is not PBS-subsidised for primary prevention of breast cancer.

8216K	Tablet 60 mg (base)	30	5	..	68.68	32.90	Fareston	SH

• Anti-androgens

BICALUTAMIDE

Authority Required

Metastatic (equivalent to stage D) prostatic carcinoma in combination with GnRH (LH-RH) agonist therapy.

NOTE:

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

8094B	Tablet 50 mg	28	5	..	194.99	32.90	^a APO-Bicalutamide	TX
							^a Bicalutamide-GA	GM
							^a Bicalutamide Ranbaxy	RA
							^a Calutex	SI
							^a Cosamide	AF
							^a Cosudex	AP

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	
CYPROTERONE ACETATE								
<u>Authority Required (STREAMLINED)</u>								
1014								
<i>Advanced carcinoma of the prostate;</i>								
1404								
<i>To reduce drive in sexual deviations in males.</i>								
1270W	Tablet 50 mg	100	5	..	* 207.29	32.90	^a Cyprohexal ^a Cyprone ^a Cyprostat ^a GenRx Cyproterone Acetate ^a Procur ^a Androcur	SZ AF SY GX GM SC
8019C	Tablet 100 mg	50	5	..	169.33	32.90	^a Cyprohexal ^a Cyprostat-100 ^a GenRx Cyproterone Acetate ^a Procur 100 ^a Androcur-100	SZ SY GX GM SC
				B1.65	170.98	32.90		
[For other listings for this drug see Generic/Proprietary Index]								

FLUTAMIDE

Authority Required

Metastatic (equivalent to stage D) prostatic carcinoma in combination with GnRH (LH-RH) agonist therapy.

NOTE:

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

1417N	Tablet 250 mg	100	5	..	212.60	32.90	^a Eulexin ^a Flutamin	SH AF

NILUTAMIDE

Authority Required

Locally advanced (equivalent to stage C) or metastatic (equivalent to stage D) prostatic carcinoma, in combination with GnRH (LH-RH) agonist therapy;

Locally advanced (equivalent to stage C) or metastatic (equivalent to stage D) prostatic carcinoma, in conjunction with surgical orchidectomy.

8131Y	Tablet 150 mg	30	5	..	236.13	32.90	Anandron	SW

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	
• Enzyme inhibitors ANASTROZOLE <u>Restricted Benefit</u> <i>Treatment of hormone-dependent breast cancer in post-menopausal women.</i> <u>NOTE:</u> <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	..	179.75	32.90	Arimidex	AP
EXEMESTANE <u>Restricted Benefit</u> <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> <u>NOTE:</u> <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	..	179.75	32.90	Aromasin	PH
LETROZOLE <u>Restricted Benefit</u> <i>Treatment of hormone-dependent advanced breast cancer in post-menopausal women;</i> <i>Treatment of hormone-dependent early breast cancer in post-menopausal women;</i> <i>Extended adjuvant treatment of hormone-dependent early breast cancer in post-menopausal women commencing within 6 months of ceasing treatment with tamoxifen citrate.</i> <u>NOTE:</u> <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> <i>This drug is not PBS-subsidised for extended adjuvant early breast cancer treatment where the total duration of letrozole (or any other aromatase inhibitor) treatment extends beyond 5 years.</i>								
8245Y	Tablet 2.5 mg	30	5	..	179.75	32.90	Femara 2.5 mg	NV

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Proprietary Name and Manufacturer	
IMMUNOSTIMULANTS								
Immunostimulants								
• Interferons								
INTERFERON ALFA-2a								
CAUTION:								
<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>								
<i>Myeloproliferative disease with excessive thrombocytosis.</i>								
8180M	Injection 3,000,000 i.u. in 0.5 mL single dose pre-filled syringe	15	4	..	* 505.79	32.90	Roferon-A	RO
Authority Required								
<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	..	* 264.29	32.90	Roferon-A	RO
8552D	Injection 6,000,000 i.u. in 0.5 mL single dose pre-filled syringe	5	4	..	* 344.29	32.90	Roferon-A	RO
8553E	Injection 9,000,000 i.u. in 0.5 mL single dose pre-filled syringe	5	4	..	* 505.69	32.90	Roferon-A	RO
Authority Required								
<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	..	* 505.79	32.90	Roferon-A	RO
8182P	Injection 4,500,000 i.u. in 0.5 mL single dose pre-filled syringe	5	5	..	* 264.29	32.90	Roferon-A	RO
8183Q	Injection 6,000,000 i.u. in 0.5 mL single dose pre-filled syringe	5	5	..	* 344.29	32.90	Roferon-A	RO
8184R	Injection 9,000,000 i.u. in 0.5 mL single dose pre-filled syringe	5	5	..	* 505.69	32.90	Roferon-A	RO

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Proprietary Name and Manufacturer	
INTERFERON ALFA-2b								
CAUTION:								
<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	..	* 605.60	32.90	Intron A Redipen	SH
Authority Required								
<i>Maintenance treatment of multiple myeloma once remission has been achieved with chemotherapy;</i>								
<i>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	..	* 605.60	32.90	Intron A Redipen	SH
8476D	Solution for injection 30,000,000 i.u. in 1.2 mL multi-dose injection pen	3	5	..	* 1005.32	32.90	Intron A Redipen	SH
INTERFERON BETA-1a								
Authority Required								
<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>								
8289G	Injection set comprising 1 vial powder for injection 30 micrograms (6,000,000 i.u.) with diluent	4	5	..	1056.34	32.90	Avonex	BD
8805K	Injection 30 micrograms (6,000,000 i.u.) in 0.5 mL single dose pre-filled syringe	4	5	..	1056.34	32.90	Avonex	BD
8403G	Injection 44 micrograms (12,000,000 i.u.) in 0.5 mL single dose pre-filled syringe	12	5	..	1056.34	32.90	Rebif 44	SG

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Proprietary Name and Manufacturer	
INTERFERON BETA-1b								
Authority Required								
<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 including 1 vial powder for injection 8,000,000 i.u. (250 micrograms) and solvent	15	5	..	1179.73	32.90	Betaferon	SC
• Other immunostimulants								
BCG IMMUNOTHERAPEUTIC (Bacillus Calmette-Guérin/Connaught strain)								
Restricted Benefit								
<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 × 10 ⁸ CFU and 1 vial diluent 3 mL	3	1	..	* 459.44	32.90	ImmuCyst	SW
BCG-TICE (Bacillus Calmette-Guérin/ Tice strain)								
Restricted Benefit								
<i>Primary and relapsing superficial urothelial carcinoma of the bladder.</i>								
1131M	Vial containing powder for intravesical administration approximately 5 × 10 ⁸ CFU	3	1	..	555.96	32.90	OncoTICE	SH

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS—CONT.

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

GLATIRAMER ACETATE

Authority Required

Initial treatment of clinically definite relapsing-remitting multiple sclerosis in ambulatory (without assistance or support) patients who have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to the multiple sclerosis, in the preceding 2 years. The diagnosis must be confirmed by magnetic resonance imaging of the brain and/or spinal cord and the date of the scan included in the authority application, unless the authority application is accompanied by written certification provided by a radiologist that an MRI scan is contraindicated because of the risk of physical (not psychological) injury to the patient. The authority will be limited to the maximum quantity and number of repeats indicated in the schedule;

Continuing treatment of clinically definite relapsing-remitting multiple sclerosis in patients previously issued with an authority prescription for this drug who do not show continuing progression of disability while on treatment with this drug and who have demonstrated compliance with, and an ability to tolerate, this therapy. Authorities will be limited to the maximum quantity and number of repeats indicated in the schedule.

8726G	Injection 20 mg in 1 mL single dose pre-filled syringe	28	5	..	1092.22	32.90	Copaxone	SW

IMMUNOSUPPRESSANTS

Immunosuppressants

• **Selective immunosuppressants**

EVEROLIMUS

CAUTION:

Careful monitoring of patients is mandatory.

Authority Required

Maintenance therapy, following initiation and stabilisation of treatment with everolimus and where therapy remains under the supervision and direction of the transplant unit reviewing that patient, of patients with:

- renal transplants. The name of the specialised transplant unit reviewing treatment and the date of the latest review at the specialised transplant unit must be included in the authority application; or*
- cardiac transplants. The name of the specialised transplant unit reviewing treatment and the date of the latest review at the specialised transplant unit must be included in the authority application.*

8840G	Tablet 0.25 mg	60	3	..	282.36	32.90	Certican	NV
8841H	Tablet 0.5 mg	60	3	..	543.40	32.90	Certican	NV
8842J	Tablet 0.75 mg	120	3	..	* 1578.19	32.90	Certican	NV

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	
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 (STREAMLINED)								
2643								
<i>Initial treatment of severe active rheumatoid arthritis where other disease modifying anti-rheumatic drugs (including methotrexate) are ineffective and/or inappropriate. Treatment must be initiated by a physician;</i>								
2681								
<i>Initial treatment of severe active psoriatic arthritis where other disease modifying anti-rheumatic drugs (including methotrexate) are ineffective and/or inappropriate. Treatment must be initiated by a physician.</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	..	..	218.58	32.90	Arava	SW

Authority Required (STREAMLINED)

2644

Treatment of severe active rheumatoid arthritis where other disease modifying anti-rheumatic drugs (including methotrexate) are ineffective and/or inappropriate. Treatment must be initiated by a physician;

2682

Treatment of severe active psoriatic arthritis where other disease modifying anti-rheumatic drugs (including methotrexate) are ineffective and/or inappropriate. Treatment must be initiated by a physician.

8374R	Tablet 10 mg	30	5	..	95.01	32.90	^a Arabloc ^a Arava	AV SW
8375T	Tablet 20 mg	30	5	..	141.53	32.90	^a Arabloc ^a Arava	AV SW

MYCOPHENOLATE MOFETIL

CAUTION:

Careful monitoring of patients is mandatory.

Authority Required

Maintenance therapy, following initiation and stabilisation of treatment with mycophenolate mofetil and where therapy remains under the supervision and direction of the transplant unit reviewing that patient, of patients with:

(a) *renal transplants. The name of the specialised transplant unit reviewing treatment and the date of the latest review at the specialised transplant unit must be included in the authority application; or*

(b) *cardiac transplants. The name of the specialised transplant unit reviewing treatment and the date of the latest review at the specialised transplant unit must be included in the authority application.*

8649F	Capsule 250 mg	300	3	..	627.38	32.90	CellCept	RO
8650G	Tablet 500 mg	150	3	..	627.38	32.90	CellCept	RO

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	
8651H	Powder for oral suspension 1 g per 5 mL, 165 mL	± 1	3	..	# 289.45	32.90	CellCept	RO
MYCOPHENOLATE SODIUM								
CAUTION:								
Careful monitoring of patients is mandatory.								
Authority Required								
Maintenance therapy, following initiation and stabilisation of treatment with mycophenolate sodium and where therapy remains under the supervision and direction of the transplant unit reviewing that patient, of patients with renal transplants. The name of the specialised transplant unit reviewing treatment and the date of the latest review at the specialised transplant unit must be included in the authority application.								
8652J	Tablet (enteric coated) 180 mg (mycophenolic acid)	120	3	..	262.99	32.90	Myfortic	NV
8653K	Tablet (enteric coated) 360 mg (mycophenolic acid)	120	3	..	503.10	32.90	Myfortic	NV
SIROLIMUS								
CAUTION:								
Careful monitoring of patients is mandatory.								
Authority Required								
Maintenance therapy, following initiation and stabilisation of treatment with sirolimus and where therapy remains under the supervision and direction of the transplant unit reviewing that patient, of patients with renal transplants. The name of the specialised transplant unit reviewing treatment and the date of the latest review at the specialised transplant unit must be included in the authority application.								
8724E	Tablet 1 mg	100	3	..	814.82	32.90	Rapamune	WX
8833X	Tablet 2 mg	100	3	..	1583.26	32.90	Rapamune	WX
8725F	Oral solution 1 mg per mL, 60 mL	± 1	3	..	529.31	32.90	Rapamune	WX

• Tumor necrosis factor alpha (TNF-alpha) inhibitors

ADALIMUMAB

NOTE:

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

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

Written applications for authority to prescribe adalimumab should be forwarded to:

Medicare Australia

Prior Written Approval of Specialised Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

continued ➡

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 \$	

NOTE:

TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying anti-rheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, etanercept, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-1 inhibitor (anakinra) and the T-cell co-stimulation modulator (abatacept).

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

PBS-subsidised infliximab, anakinra, rituximab and abatacept must be used in combination with methotrexate at a dose of at least 7.5 mg weekly. Where a patient cannot tolerate 7.5 mg of methotrexate weekly, they are only eligible to receive PBS-subsidised etanercept and adalimumab.

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

From 1 March 2008, under the PBS, all patients will be able to commence a Treatment Cycle where they may trial PBS-subsidised bDMARD agents without having to experience a disease flare when swapping to an alternate agent. Under these interchangeability arrangements, within a single Treatment Cycle, a patient may continue to receive long-term treatment with a bDMARD while they continue to show a response to therapy.

A patient who received PBS-subsidised bDMARD treatment prior to 1 March 2008 is considered to be in their first Cycle as of 1 March 2008.

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

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a Treatment Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised bDMARD therapy before they are eligible to commence the next Cycle.

For patients who have failed PBS-subsidised treatment with 3 bDMARDs prior to 1 March 2008 please contact Medicare Australia on 1800 700 270.

The 5-year break is measured from the date of the last approval for PBS-subsidised bDMARD treatment in the most recent Cycle to the date of the first application for initial treatment with a bDMARD under the new Treatment Cycle.

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

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

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

If patients fail to respond to a particular bDMARD within a single Treatment Cycle, they are not eligible to receive further PBS-subsidised treatment with that drug until they commence the next Cycle.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 March 2008.

(a) Initial treatment.

Applications for initial treatment should be made where:

- (i) a patient has received no prior PBS-subsidised bDMARD treatment in this Treatment Cycle and wishes to commence such therapy, excluding rituximab (Initial 1); or
- (ii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
- (iii) a patient wishes to re-commence treatment with a specific bDMARD following a break in PBS-subsidised therapy with that agent (Initial 2).

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 \$	

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for etanercept, adalimumab, anakinra and abatacept, 22 weeks of therapy for infliximab and 2 infusions of rituximab.

From 1 March 2008, a patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to Medicare Australia within 4 weeks.

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

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

Rituximab patients:

A further application may be submitted to Medicare Australia 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.

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

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

Assessments of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Rituximab patients:

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.

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

(2) Swapping therapy.

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

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

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

In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

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 \$	

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

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

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

NOTE:

(3) Baseline measurements to determine response.

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

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

The baseline joint and blood counts should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment.

(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent Treatment Cycle following a break in PBS-subsidised bDMARD therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have received treatment with at least 1 non-biological DMARD, at an adequate dose, for a minimum of 3 months at the time the ESR and/or CRP levels and the active joint count are measured.

(5) Patients 'grandfathered' onto PBS-subsidised treatment with rituximab or abatacept.

From 1 March 2008, a patient who commenced treatment with rituximab for severe rheumatoid arthritis prior to 7 March 2007 or abatacept for severe rheumatoid arthritis prior to 1 November 2007 and who was 'grandfathered' on to PBS-subsidised therapy, and who continues to receive treatment in the same Treatment Cycle, will have further applications for treatment with rituximab or abatacept assessed under the continuing treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment with abatacept will be authorised under this criterion.

'Grandfather' arrangements will only apply for the first Treatment Cycle. For the second and subsequent Cycles, a 'grandfather' patient must requalify for initial treatment under the criteria that applies to a new patient. See 'Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' above for further details.

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 \$	

Authority Required

Initial 1 (new patients)

Application for initial PBS-subsidised treatment with adalimumab, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of adults who:

- (a) have severe active rheumatoid arthritis; and*
- (b) have received no prior PBS-subsidised treatment with a bDMARD for this condition in this treatment cycle; and*
- (c) have failed to achieve an adequate response to the following treatments:*
 - (i) methotrexate at a dose of at least 20 mg weekly; and*
 - (ii) methotrexate (at a minimum dose of 7.5 mg weekly), in combination with 2 other non-biological disease modifying anti-rheumatic drugs (DMARDs), for a minimum of 3 months; and*
 - (iii) a minimum of 3 months' treatment with:*
 - leflunomide alone; or*
 - leflunomide in combination with methotrexate; or*
 - cyclosporin.*

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of the accepted toxicities, including severity, can be found on the Medicare Australia website [www.medicareaustralia.gov.au].

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

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L;

AND either

- (i) a total active joint count of at least 20 active (swollen and tender) joints; or*
- (ii) at least 4 active joints from the following list of major joints:*
 - elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or*
 - shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).*

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.

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

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

- (1) a completed authority prescription form; and*
- (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes details of the patient's ESR and CRP measurements and the patient's active joint count which must have been assessed no earlier than 1 month prior to the date of application; and*
- (3) a signed patient acknowledgement.*

A maximum of 16 weeks of treatment will be authorised under this restriction.

Where fewer than 3 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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 \$	

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

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

Authority Required

Initial 2 (change or re-commencement)

Application for an initial course of PBS-subsidised treatment with adalimumab, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of adults who:

(a) have a documented history of severe active rheumatoid arthritis; and

(b) have received prior PBS-subsidised bDMARD treatment for this condition in this treatment cycle and are eligible to receive further bDMARD therapy.

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

(1) a completed authority prescription form; and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].

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

A maximum of 16 weeks of treatment will be authorised under this restriction.

Where fewer than 3 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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

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

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

8737W	Injection 40 mg in 0.8 mL pre-filled syringe	2	3	..	1773.93	32.90	Humira	AB
9099X	Injection 40 mg in 0.8 mL pre-filled pen	2	3	..	1773.93	32.90	Humira	AB

continued ➞

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 \$		

NOTE:

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

Applications for treatment with adalimumab where the dosing frequency exceeds 40 mg per fortnight will not be approved.

Authority Required

Continuing treatment

Continuing PBS-subsidised treatment with adalimumab, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of adults:

- (a) who have a documented history of severe active rheumatoid arthritis; and
- (b) who have demonstrated an adequate response to treatment with adalimumab; and
- (c) whose most recent course of PBS-subsidised bDMARD treatment in this treatment cycle was with adalimumab.

An adequate response to treatment is defined as:

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

AND either of the following:

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

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

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

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

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

(1) a completed authority prescription form; and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].

A maximum of 24 weeks of treatment will be approved under this restriction.

Where fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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

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

8741C	Injection 40 mg in 0.8 mL pre-filled syringe	2	5	..	1773.93	32.90	Humira	AB
9100Y	Injection 40 mg in 0.8 mL pre-filled pen	2	5	..	1773.93	32.90	Humira	AB

continued 

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 \$	

NOTE:

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

Applications for treatment with adalimumab where the dosing frequency exceeds 40 mg per fortnight will not be approved.

NOTE:

TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS

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

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological agents at any 1 time. Where the term 'biological agents' appears in the following NOTES and restrictions, it only refers to adalimumab, etanercept and infliximab.

From 1 August 2006, all patients will be able to commence a 'Biological Treatment Cycle' (Cycle), where they may trial adalimumab, etanercept or infliximab without having to meet the initial treatment criteria, that is they will not need to experience a disease flare, when swapping to the alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

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

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

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

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

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

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).*

continued ➞

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 \$	

All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 16 weeks of therapy for all agents except for infliximab, for which a maximum of 22 weeks will be authorised. It is recommended that patients be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological agent supply.

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

Grandfather patients.

Applications for patients who commenced treatment with etanercept prior to 17 March 2005 or adalimumab and infliximab prior to 16 March 2006, may apply for initial PBS-subsidised treatment as continuing therapy under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with any biological agent prior to PBS listing of that agent.

Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment for all agents. Approval will be based on the criteria included in the relevant restriction.

(2) Continuing treatment.

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

Patients must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.

(3) Swapping therapy.

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

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

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

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

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

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.

continued 

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 \$	

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

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.

(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

Patients who wish to trial a second or subsequent treatment Cycle following a break in PBS-subsidised biological therapy of at least 5 years, must re-qualify for initial treatment with respect to both the indices of disease severity. Patients must have received treatment with methotrexate or sulfasalazine or leflunomide, at an adequate dose, for a minimum of 3 months at the time the ESR or CRP levels and the active joint counts are measured.

Authority Required

Initial 1

Initial PBS-subsidised treatment with adalimumab, by a rheumatologist or clinical immunologist with expertise in the management of psoriatic arthritis, of adults who:

- (1) have severe active psoriatic arthritis; and*
- (2) have received no prior PBS-subsidised biological treatment for this condition in this Treatment Cycle; and*
- (3) have failed to achieve an adequate response to:*
 - (a) methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months; and*
 - (b) sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months; or*
 - (c) leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months.*

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.

continued 

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 \$	

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

- (1) a completed authority prescription form; and*
 - (2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes details of the patient's ESR and CRP measurements and the patient's active joint count which must have been assessed no earlier than 1 month prior to the date of application; and*
 - (3) a copy of the signed patient acknowledgement form which is included in the Supporting Information Form.*
- Completion of this form declares that the patient understands and acknowledges that PBS-subsidised treatment will cease if they do not demonstrate the response to treatment required to support continuation of PBS-subsidised treatment at any assessment where a response must be demonstrated.*

Where fewer than 3 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Patients who fail to demonstrate a response to treatment with adalimumab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug, in this Treatment Cycle.

Authority Required

Initial 2

Initial PBS-subsidised treatment with adalimumab, by a rheumatologist or clinical immunologist with expertise in the management of psoriatic arthritis, of adults who:

- (1) have a documented history of severe active psoriatic arthritis; and*
- (2) have received prior PBS-subsidised biological treatment for this condition in this Treatment Cycle and are eligible to receive further biological therapy; and*
- (3) have not failed treatment with adalimumab during the current Treatment Cycle.*

Applications for patients who have demonstrated a response to PBS-subsidised adalimumab treatment within this Treatment Cycle and who wish to re-commence adalimumab treatment within the same Cycle following a break in therapy, will only be approved where evidence of a response to the patient's most recent course of PBS-subsidised adalimumab treatment has been submitted to Medicare Australia within 1 month of cessation of treatment.

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

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

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

- (1) a completed authority prescription form; and*
- (2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].*

Where fewer than 3 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Patients who fail to demonstrate a response to treatment with adalimumab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug, in this Treatment Cycle.

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 \$		
<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	..	1773.93	32.90	<i>Humira</i>	<i>AB</i>
9101B	<i>Injection 40 mq in 0.8 mL pre-filled pen</i>	2	3	..	1773.93	32.90	<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; and*
- (2) were receiving treatment with adalimumab prior to 16 March 2006; and*
- (3) have demonstrated a response as specified in the criteria for continuing PBS-subsidised treatment with adalimumab.*

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

- (1) a completed authority prescription form; and*
 - (2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and*
 - (3) a copy of the signed patient acknowledgement form which is included in the Supporting Information Form.*
- Completion of this form declares that the patient understands and acknowledges that PBS-subsidised treatment will cease if they do not demonstrate the response to treatment required to support continuation of PBS-subsidised treatment at any assessment where a response must be demonstrated.*

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

Where fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Patients who fail to demonstrate a response to treatment with adalimumab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug, in this Treatment Cycle.

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

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ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS—CONT.

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

Authority Required

Continuing treatment

Continuing PBS-subsidised treatment with adalimumab, by a rheumatologist or clinical immunologist with expertise in the management of psoriatic arthritis, of adults:

- (1) who have a documented history of severe active psoriatic arthritis; and
- (2) whose most recent course of PBS-subsidised biological agent for this condition in the current Treatment Cycle was with adalimumab; and
- (3) who, at the time of application, demonstrate an adequate response to treatment with adalimumab.

An adequate response to treatment with adalimumab is defined as:

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

- (i) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
- (ii) a reduction in the number of the following major active joints, from at least 4, by at least 50%:
 - elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
 - shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

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

- (1) a completed authority prescription form; and
- (2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].

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

Where fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Patients who fail to demonstrate a response to treatment with adalimumab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug, in this Treatment Cycle.

Once patients fail to respond to treatment with 3 biological agents, they are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may re-commence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

9034L	Injection 40 mg in 0.8 mL pre-filled syringe	2	5	..	1773.93	32.90	Humira	AB

9102C	Injection 40 mg in 0.8 mL pre-filled pen	2	5	..	1773.93	32.90	Humira	AB

continued ➞

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 \$	

NOTE:

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

Applications for treatment with adalimumab where the dosing frequency exceeds 40 mg per fortnight will not be approved.

NOTE:

TREATMENT OF ADULT PATIENTS WITH ACTIVE ANKYLOSING SPONDYLITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and infliximab for adult patients with active ankylosing spondylitis. Where the term 'tumour necrosis factor (TNF) alfa antagonist' appears in the following NOTES and restrictions, it refers to adalimumab, etanercept and infliximab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 TNF-alfa antagonists at any 1 time.

From 1 March 2007, under the PBS, all patients will be able to commence a treatment cycle where they may trial each PBS-subsidised TNF-alfa antagonist without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a TNF-alfa antagonist while they continue to show a response to therapy.

A patient who received PBS-subsidised TNF-alfa antagonist treatment prior to 1 March 2007 is considered to be in their first cycle as of 1 March 2007.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised TNF-alfa antagonist more than once. A patient who, prior to 1 March 2007, was authorised to receive PBS-subsidised initial treatment for ankylosing spondylitis with the same agent twice, is exempt from this condition in respect of applications approved prior to 1 March 2007.

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

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

A patient who has failed fewer than 3 TNF-alfa antagonists in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

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

(1) How to prescribe PBS-subsidised TNF-alfa antagonist therapy after 1 March 2007.

(a) Initial treatment.

Applications for initial treatment should be made where:

- (i) a patient has received no prior PBS-subsidised TNF-alfa antagonist treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or*
- (ii) a patient has received prior PBS-subsidised (initial or continuing) TNF-alfa antagonist therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or*
- (iii) a patient wishes to re-commence treatment with a specific TNF-alfa antagonist following a break in PBS-subsidised therapy with that agent (Initial 2).*

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for etanercept and adalimumab and 18 weeks of treatment for infliximab.

From 1 March 2007, a patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

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ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS—CONT.

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

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.

For second and subsequent courses of PBS-subsidised TNF-alfa antagonist treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

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

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

Assessments of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.

(2) Swapping therapy.

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

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

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

To avoid confusion, an application for a patient who wishes to swap to an alternate TNF-alfa antagonist should be accompanied by the approved authority prescription or remaining repeats for the TNF-alfa antagonist the patient is ceasing.

(3) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a TNF-alfa antagonist. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and Medicare Australia will assess response according to these revised baseline measurements.

For a new patient, the BASDAI used to determine the baseline must be measured while the patient is receiving NSAID therapy and completing their exercise program. However, this is not required for any subsequent BASDAI results for these patients, nor for patients who were 'grandfathered' on to TNF-alfa antagonist treatment.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response.

(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

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 \$	

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

(5) Patients 'grandfathered' onto PBS-subsidised treatment with adalimumab.

A patient who commenced treatment with adalimumab for active ankylosing spondylitis prior to 1 November 2006 and who continues to receive treatment at the time of application, may qualify for treatment under the initial 'grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment with adalimumab will be authorised under this criterion.

Following completion of the initial PBS-subsidised course, further applications for treatment with adalimumab will be assessed under the continuing treatment restriction.

Where pre-TNF-alfa antagonist treatment baselines cannot be provided, the following criteria must be met to demonstrate a response to treatment:

The BASDAI score must be either:

- (i) no more than 20% greater than the score included in the initial application for PBS-subsidised treatment; or*
- (ii) no greater than 2.*

AND

One of the following:

- (a) an ESR measurement no greater than 25 mm per hour; or*
- (b) a CRP measurement no greater than 10 mg per L.*

'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must requalify for initial treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' above for further details.

Authority Required

Initial 1 (new patients)

First course of PBS-subsidised treatment with adalimumab, by a rheumatologist, of an adult with active ankylosing spondylitis who has radiographically (plain X-ray) confirmed Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis and who has not received any PBS-subsidised treatment with either adalimumab, etanercept or infliximab in this treatment cycle; AND

(a) who has at least 2 of the following:

- (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; or*
- (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI) [for further information on the BASMI please refer to the Medicare Australia website at www.medicareaustralia.gov.au]; or*
- (iii) limitation of chest expansion relative to normal values for age and gender [for chest expansion normal values please refer to the Medicare Australia website at www.medicareaustralia.gov.au]; AND*

(b) who has failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months.

The application must include details of the NSAIDs trialled, their doses and duration of treatment. If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used.

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ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS—CONT.

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

If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication.

If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance. Details of the toxicities, including severity, which will be accepted for the purposes of administering this restriction can be found on the Medicare Australia website [www.medicareaustralia.gov.au].

For details on the appropriate minimum exercise program that will be accepted for the purposes of administering this restriction, please refer to the Medicare Australia website at www.medicareaustralia.gov.au.

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

- (a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale; AND*
- (b) an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 10 mg per L.*

The BASDAI must be determined at the completion of the 3 month NSAID and exercise trial, but prior to ceasing NSAID treatment. The BASDAI must be no more than 1 month old at the time of initial application.

Both ESR and CRP measures should be provided with the initial treatment application and both must be no more than 1 month old. If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reason this criterion cannot be satisfied.

Authority applications must be made in writing and must include:

- (a) a completed authority prescription form; and*
- (b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form [www.medicareaustralia.gov.au] which must include the following:*
 - (i) a copy of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and*
 - (ii) a completed BASDAI Assessment Form [www.medicareaustralia.gov.au]; and*
 - (iii) a completed Exercise Program Self Certification Form included in the supporting information form; and*
 - (iv) a signed patient acknowledgment form. Completion of this form declares that the patient understands and acknowledges that PBS-subsidised treatment with the TNF-alfa antagonists (adalimumab, etanercept or infliximab) for ankylosing spondylitis will cease if they do not demonstrate the response to treatment required to support continuation of PBS-subsidised treatment at any assessment where a response must be demonstrated.*

The assessment of the patient's response to the initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted to Medicare Australia no later than 4 weeks from the cessation of that treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

A maximum of 16 weeks of treatment with adalimumab will be approved under this criterion.

Where fewer than 3 repeats are initially requested with the authority prescription, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone.

Authority Required

Initial 2 (change or re-commencement for all patients)

Initial course of PBS-subsidised treatment with adalimumab, by a rheumatologist, of an adult with a documented history of active ankylosing spondylitis who, in this treatment cycle, has received prior PBS-subsidised treatment with either adalimumab, etanercept or infliximab for this condition and has not failed PBS-subsidised therapy with adalimumab.

To demonstrate a response to treatment the application must be accompanied by the results of the most recent course of TNF-alfa antagonist therapy within the timeframes specified in the relevant restriction.

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ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Proprietary Name and Manufacturer	
<i>Where the most recent course of PBS-subsidised TNF-α antagonist treatment was approved under an initial treatment restriction after 1 March 2007, the patient must have been assessed for response to that course following a minimum of 12 weeks of treatment. Where the most recent course of PBS-subsidised TNF-α antagonist treatment was approved under an initial treatment restriction prior to 1 March 2007, the patient must have been assessed for response to that course following at least 4 weeks of treatment. These assessments must be provided to Medicare Australia no later than 4 weeks from the date the course was ceased.</i> <i>If the response assessment to the previous course of TNF-α antagonist treatment is not submitted as detailed above, the patient will be deemed to have failed therapy with that particular course of TNF-α antagonist.</i> <i>Authority applications must be made in writing and must include:</i> <i>(a) a completed authority prescription form; and</i> <i>(b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form [www.medicareaustralia.gov.au] which includes a completed BASDAI Assessment Form with certification by the prescriber and the patient that the patient did not have access to their baseline BASDAI at the time of their assessment.</i> <i>A maximum of 16 weeks of treatment with adalimumab will be approved under this criterion.</i> <i>Where fewer than 3 repeats are initially requested with the authority prescription, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone.</i>								
9077R	Injection 40 mg in 0.8 mL pre-filled syringe	2	3	..	1773.93	32.90	Humira	AB
9103D	Injection 40 mg in 0.8 mL pre-filled pen	2	3	..	1773.93	32.90	Humira	AB

NOTE:

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

Applications for treatment with adalimumab where the dosing frequency exceeds 40 mg per fortnight will not be approved.

Authority Required

Initial ('grandfather' patients)

Initial PBS-subsidised course of adalimumab treatment, by a rheumatologist, of an adult with a documented history of active ankylosing spondylitis who has radiographically (plain X-ray) confirmed Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis and who was receiving treatment with adalimumab prior to 1 November 2006; AND

(a) is receiving treatment with adalimumab at the time of application; AND

(b) has not received prior PBS-subsidised treatment with infliximab or etanercept; AND

(c) whose current Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score is either:

(i) less than or equal to 5 on a 0-10 scale; OR

(ii) improved by at least 2 from baseline; AND

(d) who has:

(i) an ESR measurement no greater than 25 mm per hour; or

(ii) a CRP measurement no greater than 10 mg per L; or

(iii) an ESR or CRP measurement reduced by at least 20% from pre-treatment baseline.

The BASDAI assessment and ESR and/or CRP measurements provided must be no more than 1 month old at the time of application. Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and supplied in all subsequent continuing treatment applications.

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ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS—CONT.

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

Authority applications must be made in writing and must include:

- (a) a completed authority prescription form; and*
- (b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form [www.medicareaustralia.gov.au] which includes the following:*
 - (i) a copy of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and*
 - (ii) a completed BASDAI Assessment Form [www.medicareaustralia.gov.au]; and*
 - (iii) a signed patient acknowledgment form included in the supporting information form. Completion of this form declares that the patient understands and acknowledges that PBS-subsidised treatment with the TNF-alfa antagonists (adalimumab, etanercept or infliximab) for ankylosing spondylitis will cease if they do not demonstrate the response to treatment required to support continuation of PBS-subsidised treatment at any assessment where a response must be demonstrated.*

The assessment of the patient's response to this initial course of therapy must be made within the 4 weeks prior to completion of the course in order to ensure continuity of treatment.

A patient ceasing treatment or swapping to an alternate agent and wishing to demonstrate a response to treatment, must be assessed no earlier than 12 weeks from the commencement of PBS-subsidised treatment. This assessment must be provided to Medicare Australia no later than 4 weeks from the date that course was ceased.

If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

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

Where fewer than 5 repeats are initially requested with the authority prescription, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone.

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

Authority Required

Continuing treatment for all patients

Continuing PBS-subsidised treatment, by a rheumatologist, of an adult with a documented history of active ankylosing spondylitis who:

- (a) has demonstrated a response to treatment with adalimumab; and*
- (b) whose most recent course of PBS-subsidised therapy in this treatment cycle was with adalimumab.*

Response is defined as an improvement from baseline of at least 2 of the BASDAI and 1 of the following:

- (a) an ESR measurement no greater than 25 mm per hour; or*
- (b) a CRP measurement no greater than 10 mg per L; or*
- (c) an ESR or CRP measurement reduced by at least 20% from baseline.*

For a 'grandfather' patient who does not have baselines prior to commencing treatment with a TNF-alfa antagonist, see Note 5 for a definition of response to treatment.

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

The first application for continuing treatment following an initial treatment course must be made following a minimum of 12 weeks of treatment with adalimumab.

Applications for continuing treatment must be made in writing and should be posted to Medicare Australia no less than 2 weeks prior to the completion of the current treatment course.

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ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Proprietary Name and Manufacturer	
Written applications for authorisation must include: (a) a completed authority prescription form; and (b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form [www.medicareaustralia.gov.au] which includes a completed BASDAI Assessment Form with certification by the prescriber and the patient that the patient did not have access to their baseline BASDAI at the time of their continuing treatment assessment. All measurements provided must be no more than 1 month old at the time of application. A maximum of 24 weeks of treatment with adalimumab will be authorised under this criterion. Where fewer than 5 repeats are initially requested with the authority prescription, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone.								
9078T	Injection 40 mg in 0.8 mL pre-filled syringe	2	5	..	1773.93	32.90	Humira	AB
9104E	Injection 40 mg in 0.8 mL pre-filled pen	2	5	..	1773.93	32.90	Humira	AB

NOTE:

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

Applications for treatment with adalimumab where the dosing frequency exceeds 40 mg per fortnight will not be approved.

NOTE:

TREATMENT OF ADULT PATIENTS WITH SEVERE REFRACTORY CROHN DISEASE

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab and infliximab for adult patients with severe refractory Crohn disease. Where the term 'tumour necrosis factor (TNF) alpha antagonist' appears in the following NOTES and restrictions, it refers to adalimumab and infliximab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 2 TNF-alpha antagonists at any 1 time.

From 1 August 2008, under the PBS, all patients will be able to commence a treatment cycle where they may trial each PBS-subsidised TNF-alpha antagonist without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a TNF-alpha antagonist while they continue to show a response to therapy.

A patient who received PBS-subsidised TNF-alpha antagonist treatment prior to 1 August 2008 is considered to be in their first cycle as of 1 August 2008.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised TNF-alpha antagonist more than twice.

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

A patient who has failed fewer than 3 trials of TNF-alpha antagonists in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of TNF-alpha antagonists in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

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

(1) How to prescribe PBS-subsidised TNF-alpha antagonist therapy after 1 August 2008.

continued ➞

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 \$	

(a) Initial treatment.

Applications for initial treatment should be made where:

- (i) a patient has received no prior PBS-subsidised TNF-alfa antagonist treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
- (ii) a patient has received prior PBS-subsidised (initial or continuing) TNF-alfa antagonist therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
- (iii) a patient wishes to re-commence treatment with a specific TNF-alfa antagonist following a break in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and 14 weeks of therapy for infliximab.

From 1 August 2008, a patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.

For second and subsequent courses of PBS-subsidised TNF-alfa antagonist treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

Adalimumab only: Two completed authority prescriptions must be submitted with every initial application for adalimumab. One prescription must be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats. The second prescription must be written for 2 doses of 40 mg and 2 repeats.

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

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

Assessments of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised TNF-alfa antagonist is approved, a patient may swap if eligible to the alternate TNF-alfa antagonist within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Crohn Disease Activity Index (CDAI) Score, evidence of intestinal inflammation), or the prior corticosteroid therapy and immunosuppressive therapy.

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

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

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 \$	

To avoid confusion, an application for a patient who wishes to swap to the alternate TNF-alfa antagonist should be accompanied by the approved authority prescription or remaining repeats for the TNF-alfa antagonist the patient is ceasing.

(3) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements of the CDAI or evidence of intestinal inflammation submitted with the first authority application for a TNF-alfa antagonist. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and Medicare Australia will assess response according to these revised baseline measurements.

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

(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised TNF-alfa antagonist therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have received treatment with a corticosteroid and at least 1 immunosuppressive agent, at an adequate dose, for a minimum of 3 consecutive months immediately prior to the time the CDAI score or the indices of intestinal inflammation are measured.

(5) Patients 'grandfathered' onto PBS-subsidised treatment with adalimumab or infliximab.

A patient who commenced treatment with adalimumab for severe refractory Crohn disease prior to 9 November 2007 or infliximab prior to 7 March 2007 and who continues to receive treatment at the time of application, may qualify for treatment under the initial 'grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment with adalimumab or infliximab will be authorised under this criterion.

Following completion of the initial PBS-subsidised course, further applications for treatment with adalimumab or infliximab will be assessed under the continuing treatment restriction.

'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must requalify for initial treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' above for further details.

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 \$	

Authority Required

Initial 1 (new patients)

Initial treatment of Crohn disease in a patient assessed by CDAI.

Initial PBS-subsidised treatment with adalimumab by a gastroenterologist or a consultant physician as specified in the NOTE below, of a patient with severe refractory Crohn disease who satisfies the following criteria:

- (a) has confirmed Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician as specified in the NOTE below; and*
- (b) has signed a patient acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and*
- (c) has failed to achieve an adequate response to prior systemic therapy including:*
 - (i) a tapered course of steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period; and*
 - (ii) immunosuppressive therapy including:*
 - azathioprine at a dose of at least 2 mg per kg daily for 3 or more months; or*
 - 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months; or*
 - methotrexate at a dose of at least 15 mg weekly for 3 or more months.*

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application. .

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of the accepted toxicities including severity can be found on the Medicare Australia website (www.medicareaustralia.gov.au). .

The following initiation criterion indicates failure to achieve an adequate response and must be demonstrated in all patients at the time of the application:

- (a) have a severity of disease activity which results in a Crohn Disease Activity Index (CDAI) Score greater than or equal to 300 as assessed.*

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.

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

Applications for authorisation must be made in writing and must include:

- (a) two completed authority prescription forms; and*
- (b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:*
 - (i) the completed current Crohn Disease Activity Index (CDAI) calculation sheet including the date of assessment of the patient's condition; and*
 - (ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and*
 - (iii) the signed patient acknowledgement.*

A maximum of 16 weeks treatment will be authorised under this criterion.

continued ➡

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 \$	

Two completed authority prescriptions must be submitted with every initial application for adalimumab. One prescription must be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats. The second prescription must be written for 2 doses of 40 mg and 2 repeats. Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment with adalimumab may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

A CDAI assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks therapy so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with adalimumab.

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised adalimumab treatment.

Authority Required

Initial 2

Change or re-commencement of treatment of Crohn disease in a patient assessed by CDAI.

Initial PBS-subsidised treatment with adalimumab by a gastroenterologist or a consultant physician as specified in the NOTE below of a patient who:

- (a) has a documented history of severe refractory Crohn disease; and
- (b) in this treatment cycle, has received prior PBS-subsidised treatment with infliximab or adalimumab for this condition; and
- (c) has not failed PBS-subsidised therapy with adalimumab for this condition more than once in the current treatment cycle.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

To demonstrate a response to treatment the application must be accompanied by the results of the most recent course of TNF-alfa antagonist therapy within the timeframes specified in the relevant restriction.

Where the most recent course of PBS-subsidised TNF-alfa antagonist treatment was approved under an initial treatment restriction, the patient must have been assessed for response to that course following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

If the response assessment to the previous course of TNF-alfa antagonist treatment is not submitted as detailed above, the patient will be deemed to have failed therapy with that particular course of TNF-alfa antagonist.

Authority applications must be made in writing and must include:

- (a) two completed authority prescription forms; and
- (b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
 - (i) the completed current Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient's condition; and
 - (ii) details of prior TNF alfa antagonist treatment including details of date and duration of treatment.

continued ➡

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 \$	

Two completed authority prescriptions must be submitted with every initial application for adalimumab. One prescription must be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats. The second prescription must be written for 2 doses of 40 mg and 2 repeats. Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment with adalimumab may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

A CDAI assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks therapy so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with adalimumab.

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised adalimumab treatment.

Authority Required

Initial 1

Initial treatment of Crohn disease in a patient with short gut syndrome or an ostomy patient.

Initial PBS-subsidised treatment with adalimumab by a gastroenterologist, or consultant physician as specified in the NOTE below of a patient who satisfies the following criteria:

- (a) has confirmed Crohn disease defined by standard clinical, endoscopic and/or imaging features, including histological evidence with the diagnosis confirmed by a gastroenterologist or consultant physician as specified in the NOTE below; and
- (b) has diagnostic imaging or surgical evidence of short gut syndrome or has an ileostomy or colostomy; and
- (c) has evidence of intestinal inflammation; and
- (d) has signed a patient acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and
- (e) has failed to achieve an adequate response to prior systemic drug therapy including:
 - (i) a tapered course of steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period; and
 - (ii) immunosuppressive therapy including:
 - azathioprine at a dose of at least 2 mg per kg daily for 3 or more months; or
 - 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months; or
 - methotrexate at a dose of at least 15 mg weekly for 3 or more months.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of the accepted toxicities including severity can be found on the Medicare Australia website (www.medicareaustralia.gov.au).

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ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS—CONT.

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

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

(a) have evidence of intestinal inflammation, including:

(i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; AND/OR

(ii) faeces: higher than normal lactoferrin or calprotectin level; AND/OR

(iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery;

AND/OR

(b) be assessed clinically as being in a high faecal output state;

AND/OR

(c) be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of adalimumab.

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.

Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the continuing treatment restriction. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy.

Applications for authorisation must be made in writing and must include:

(a) two completed authority prescription forms; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and

(ii) reports and dates of the pathology or diagnostic imaging test(s) nominated as the response criterion, if relevant; and

(iii) date of the most recent clinical assessment; and

(iv) the signed patient acknowledgement.

All assessments, pathology tests and diagnostic imaging studies must be made within 1 month of the date of application.

A maximum of 16 weeks treatment will be authorised under this criterion.

Two completed authority prescriptions must be submitted with every initial application for adalimumab. One prescription must be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats. The second prescription must be written for 2 doses of 40 mg and 2 repeats. Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment with adalimumab may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

The assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks therapy so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with adalimumab.

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised adalimumab treatment.

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 \$	

Authority Required

Initial 2

Change or re-commencement of treatment of Crohn disease in a patient with short gut syndrome, an ostomy patient or a patient with extensive small intestine disease.

Initial PBS-subsidised treatment with adalimumab by a gastroenterologist or a consultant physician as specified in the NOTE below of a patient who:

- (a) has a documented history of severe refractory Crohn disease; and*
- (b) in this treatment cycle, has received prior PBS-subsidised treatment with infliximab or adalimumab for this condition; and*
- (c) has not failed PBS-subsidised therapy with adalimumab for this condition more than once in the current treatment cycle.*

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

To demonstrate a response to treatment the application must be accompanied by the results of the most recent course of TNF-alfa antagonist therapy within the timeframes specified in the relevant restriction.

Where the most recent course of PBS-subsidised TNF-alfa antagonist treatment was approved under an initial treatment restriction, the patient must have been assessed for response to that course following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

If the response assessment to the previous course of TNF-alfa antagonist treatment is not submitted as detailed above, the patient will be deemed to have failed therapy with that particular course of TNF-alfa antagonist.

Authority applications must be made in writing and must include:

- (a) two completed authority prescription forms; and*
- (b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:*
 - (i) reports and dates of the pathology or diagnostic imaging test(s) nominated as the response criteria, if relevant; and*
 - (ii) details of prior TNF alfa antagonist treatment including details of date and duration of treatment.*

A maximum of 16 weeks of treatment will be approved under this criterion.

Two completed authority prescriptions must be submitted with every initial application for adalimumab. One prescription must be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats. The second prescription must be written for 2 doses of 40 mg and 2 repeats. Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment with adalimumab may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

The assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of therapy so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with adalimumab.

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised adalimumab treatment.

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 \$	

Authority Required

Initial 1

Initial treatment of Crohn disease in a patient with extensive small intestine disease.

Initial PBS-subsidised treatment with adalimumab by a gastroenterologist or a consultant physician as specified in the NOTE below, of a patient with severe refractory Crohn disease who satisfies the following criteria:

(a) has confirmed Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or consultant physician as specified in the NOTE below; and

(b) has extensive small intestinal disease with radiological evidence of intestinal inflammation affecting more than 50 cm of the small intestine; and

(c) has signed a patient acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and

(d) has failed to achieve an adequate response to prior systemic therapy including:

(i) a tapered course of steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period; and

(ii) immunosuppressive therapy including:

— azathioprine at a dose of at least 2 mg per kg daily for 3 or more months; or

— 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months; or

— methotrexate at a dose of at least 15 mg weekly for 3 or more months.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application.

Details of the accepted toxicities including severity can be found on the Medicare Australia website (www.medicareaustralia.gov.au).

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

(a) have severity of disease activity which results in a Crohn Disease Activity Index (CDAI) Score greater than or equal to 220;

AND/OR

(b) have evidence of active intestinal inflammation, including:

(i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; AND/OR

(ii) faeces: higher than normal lactoferrin or calprotectin level; AND/OR

(iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery;

AND/OR

(c) be assessed clinically as being in a high faecal output state;

AND/OR

(d) be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of adalimumab.

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.

Code	Name, Restriction, Manner of 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>Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the continuing treatment restriction. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy.</i> <i>Applications for authorisation must be made in writing and must include:</i> <i>(a) two completed authority prescription forms; and</i> <i>(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:</i> <i>(i) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and</i> <i>(ii) (1) reports and dates of the pathology or diagnostic imaging test(s) nominated as the response criterion, if relevant; or</i> <i>(2) the completed current Crohn Disease Activity Index (CDAI) calculation sheet including the dates of assessment of the patient's condition, if relevant; and</i> <i>(iii) date of the most recent clinical assessment; and</i> <i>(iv) the signed patient acknowledgement.</i> <i>All assessments, pathology tests and diagnostic imaging studies must be made within 1 month of the date of application.</i> <i>A maximum of 16 weeks treatment of adalimumab will be authorised under his criterion.</i> <i>Two completed authority prescriptions must be submitted with every initial application for adalimumab. One prescription must be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats. The second prescription must be written for 2 doses of 40 mg and 2 repeats. Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment with adalimumab may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.</i> <i>The assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of therapy after the first dose so that there is adequate time for a response to be demonstrated.</i> <i>This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with adalimumab.</i> <i>It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised adalimumab treatment.</i>								
9186L	Injection 40 mg in 0.8 mL pre-filled syringe, 6	1	..	..	5035.93	32.90	Humira	AB
9187M	Injection 40 mg in 0.8 mL pre-filled pen, 6	1	..	..	5035.93	32.90	Humira	AB
NOTE: <i>No applications for increased maximum quantities and/or repeats will be authorised.</i>								
9188N	Injection 40 mg in 0.8 mL pre-filled syringe	2	2	..	1773.93	32.90	Humira	AB
9190Q	Injection 40 mg in 0.8 mL pre-filled pen	2	2	..	1773.93	32.90	Humira	AB

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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 \$	

NOTE:

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

Authority Required

Initial 3 (grandfather)

Initial PBS-subsidised treatment of Crohn disease in a patient assessed by CDAI who has previously received non-PBS-subsidised therapy with adalimumab.

Initial PBS-subsidised supply for continuing treatment with adalimumab by a gastroenterologist, a consultant physician as specified in the NOTE below, or other consultant physician in consultation with a gastroenterologist of a patient who:

- (a) has a documented history of severe refractory Crohn disease and was receiving treatment with adalimumab prior to 9 November 2007; and*
- (b) had a Crohn Disease Activity Index (CDAI) Score of greater than or equal to 300 prior to commencing treatment with adalimumab. Where a baseline CDAI assessment is not available, please call Medicare Australia on 1800 700 270 to discuss; and*
- (c) has signed a patient acknowledgement indicating that they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and*
- (d) has demonstrated or sustained an adequate response to treatment with adalimumab. For advice please contact Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).*

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

An adequate response to adalimumab treatment is defined as a reduction in Crohn Disease Activity Index (CDAI) Score to no greater than 150.

Applications for authorisation must be made in writing and must include:

- (a) a completed authority prescription form; and*
- (b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:*
 - (i) the completed current and baseline Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient's condition; and*
 - (ii) the signed patient acknowledgement.*

The current CDAI assessment must be no more than 1 month old at the time of application. The baseline CDAI assessment must be from immediately prior to commencing treatment with adalimumab.

The assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion.

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with adalimumab.

A maximum of 24 weeks treatment will be approved under this criterion.

Where fewer than 5 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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

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 \$	

Authority Required

Continuing treatment of Crohn disease in a patient assessed by CDAI.

Continuing PBS-subsidised treatment with adalimumab by a gastroenterologist, a consultant physician as specified in the NOTE below or other consultant physician in consultation with a gastroenterologist, of a patient who:

- (a) has a documented history of severe refractory Crohn disease; and*
- (b) has demonstrated or sustained an adequate response to treatment with adalimumab.*

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

An adequate response to adalimumab treatment is defined as a reduction in Crohn Disease Activity Index (CDAI) Score to a level no greater than 150.

Applications for authorisation must be made in writing and must include:

- (a) a completed authority prescription form; and*
- (b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:*
 - (i) the completed Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient's condition.*

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

If the application is the first application for continuing treatment with adalimumab, a CDAI assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of therapy so that there is adequate time for a response to be demonstrated.

The assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion.

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with adalimumab.

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

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

Where fewer than 5 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority Required

Continuing treatment of Crohn disease in a patient with short gut syndrome or an ostomy patient.

Continuing PBS-subsidised treatment with adalimumab by a gastroenterologist, a consultant physician as specified in the NOTE below or other consultant physician in consultation with a gastroenterologist, of a patient who:

- (a) has a documented history of severe refractory Crohn disease with intestinal inflammation and with short gut syndrome or with an ileostomy or colostomy; and*
- (b) has demonstrated or sustained an adequate response to treatment with adalimumab.*

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

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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 \$	

An adequate response to adalimumab treatment is defined as:

(a) improvement of intestinal inflammation as demonstrated by:

(i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; AND/OR

(ii) faeces: normalisation of lactoferrin or calprotectin level; AND/OR

(iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or

(b) reversal of high faecal output state; or

(c) avoidance of the need for surgery or total parenteral nutrition (TPN).

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) the reports and dates of the pathology or diagnostic imaging test(s) used to assess response to therapy or the date of clinical assessment.

The patient's assessment must be no more than 1 month old at the time of application.

If the application is the first application for continuing treatment with adalimumab, an assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of therapy after the first dose so that there is adequate time for a response to be demonstrated.

The assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion.

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with adalimumab.

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

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

Where fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority Required

Continuing treatment of Crohn disease in a patient with extensive small intestine disease.

Continuing PBS-subsidised treatment with adalimumab by a gastroenterologist, or consultant physician as specified in the NOTE below or other consultant physician in consultation with a gastroenterologist, of a patient who:

(a) has a documented history of severe refractory Crohn disease with extensive intestinal inflammation affecting more than 50 cm of the small intestine; and

(b) has demonstrated or sustained an adequate response to treatment with adalimumab.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

continued ➡

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 \$	

An adequate response to adalimumab treatment is defined as:

(a) a reduction in Crohn Disease Activity Index (CDAI) Score to no greater than 150; or

(b) improvement of intestinal inflammation as demonstrated by:

(i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; AND/OR

(ii) faeces: normalisation of lactoferrin or calprotectin level; AND/OR

(iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or

(c) reversal of high faecal output state; or

(d) avoidance of the need for surgery or total parenteral nutrition (TPN).

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) the completed Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient's condition; or

(ii) the reports and dates of the pathology test or diagnostic imaging test(s) used to assess response to therapy; or

(iii) the date of clinical assessment.

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

If the application is the first application for continuing treatment with adalimumab, an assessment of the patient's response must be made following a minimum of 12 weeks of therapy so that there is adequate time for a response to be demonstrated.

The assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion.

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with adalimumab.

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

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

Where fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS—CONT.

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

Authority Required

Initial 3

Initial PBS-subsidised treatment of Crohn disease in a patient with short gut syndrome, an ostomy patient, or a patient with extensive small intestine disease, who has previously received non-PBS-subsidised therapy with adalimumab.

Initial PBS-subsidised supply for continuing treatment with adalimumab by a gastroenterologist, a consultant physician as specified in the NOTE below, or other consultant physician in consultation with a gastroenterologist, of a patient who:

(a) has a documented history of severe refractory Crohn disease and was receiving treatment with adalimumab prior to 9 November 2007; and

(b) (1) has a history of extensive small intestinal disease with radiological evidence of intestinal inflammation affecting more than 50 cm of the small intestine; or

(2) has diagnostic imaging or surgical evidence of short gut syndrome or has an ileostomy or colostomy with a documented history of intestinal inflammation; and

(c) has signed a patient acknowledgement indicating that they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and

(d) has demonstrated or sustained an adequate response to treatment with adalimumab according to the criteria included in the relevant continuation restriction. For advice please contact Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

The same criteria used to determine an inadequate response to prior treatment at baseline must be used to determine response to treatment and eligibility for continuing therapy, according to the criteria included in the continuing treatment restriction.

An adequate response to adalimumab treatment is defined as:

(a) a reduction in Crohn Disease Activity Index (CDAI) Score to no greater than 150; or

(b) improvement of intestinal inflammation as demonstrated by:

(i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; AND/OR

(ii) faeces: normalisation of lactoferrin or calprotectin level; AND/OR

(iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or

(c) reversal of high faecal output state; or

(d) avoidance of the need for surgery or total parenteral nutrition (TPN).

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) (1) the completed current and baseline Crohn Disease Activity Index (CDAI) Score calculation sheet, where relevant, including the date of the assessment of the patient's condition; or

(2) the reports and dates of the current and baseline pathology or diagnostic imaging test(s) in order to assess response to therapy; or

(3) the date of clinical assessment(s); and

(ii) the signed patient acknowledgement.

The patient's assessment must be no more than 1 month old at the time of application. The baseline CDAI assessments must be from immediately prior to commencing treatment with adalimumab. Where a baseline assessment is not available, please call Medicare Australia on 1800 700 270 to discuss.

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 \$		
<i>The assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion.</i> <i>Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with adalimumab.</i> <i>Patients are eligible to receive continuing adalimumab treatment in courses of up to 24 weeks providing they continue to sustain the response.</i> <i>Patients who fail to demonstrate or sustain a response to treatment with adalimumab for Crohn disease as specified in the criteria for continuing treatment with adalimumab, will not be eligible to recommence PBS-subsidised treatment with this drug within 12 months of the date on which treatment was ceased.</i> <i>A maximum of 24 weeks treatment will be authorised under this criterion.</i> <i>Where fewer than 5 repeats are requested at the time of this application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).</i> <i>Patients may qualify for PBS-subsidised treatment under this restriction once only.</i>								
9189P	Injection 40 mg in 0.8 mL pre-filled syringe	2	5	..	1773.93	32.90	Humira	AB
9191R	Injection 40 mg in 0.8 mL pre-filled pen	2	5	..	1773.93	32.90	Humira	AB

NOTE:

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

NOTE:

TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, etanercept and infliximab, for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological agents' appears in the following NOTES and restrictions, it only refers to adalimumab, etanercept and infliximab.

From 1 June 2009, 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 an alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

A patient who received PBS-subsidised biological agent treatment for chronic plaque psoriasis prior to 1 June 2009 is considered to be in their first Cycle as of 1 June 2009.

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

Within the same Treatment Cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for a PBS-subsidised biological agent, they must change to an alternate agent if they wish to continue PBS-subsidised biological treatment. A patient who, prior to 1 June 2009, was authorised to receive PBS-subsidised initial treatment for chronic plaque psoriasis with the same agent twice, is exempt from this condition in respect of applications approved prior to 1 June 2009.

Patients must be assessed for response to each course of continuing treatment according to the criteria included in the relevant continuing treatment restriction.

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ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS—CONT.

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

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

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

Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle.

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

How to prescribe biological agents for the treatment of severe chronic plaque psoriasis after 1 June 2009.

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Application for approval for initial treatment.

Applications for a course of initial treatment should be made in the following situations:

- (i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); or*
- (ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under '(4) Swapping therapy' below]; or*
- (iii) patients who wish to re-commence treatment following a break in PBS-subsidised therapy with that agent (Initial 2).*

All applications for initial treatment will be limited to provide for a maximum of 16 weeks of treatment in the case of adalimumab and etanercept, and 22 weeks of treatment in the case of infliximab.

Grandfather patients (adalimumab only).

Applications for patients who commenced treatment with adalimumab prior to 1 March 2009, may be made for initial PBS-subsidised treatment as continuing therapy under the initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with a biological agent prior to PBS listing of that agent.

Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment. Approval will be based on the criteria included in the relevant restriction.

(2) Assessment of response to initial treatment.

When prescribing initial treatment with a biological agent, a PASI assessment must be conducted after at least 12 weeks of treatment. This assessment must be submitted to Medicare Australia within 1 month of the completion of this initial treatment course. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

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

(3) Application for continuing treatment.

Following the completion of an initial treatment course of a biological agent to which an adequate response has been demonstrated, patients may qualify to receive up to 24 weeks of continuing treatment with that biological agent. Patients are eligible to continue to receive continuous treatment with 24 week courses providing they continue to sustain a response.

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 \$	

For second and subsequent courses of PBS-subsidised treatment with adalimumab, etanercept or infliximab it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

Where a response assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to sustain a response to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

(4) Swapping therapy.

Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate agent within the same Treatment Cycle without having to requalify with respect to disease severity (i.e. a PASI score of greater than 15), or prior treatment requirements.

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

Patients may trial an alternate biological agent at any time, regardless of whether they are receiving therapy with a biological agent at the time of the application or not. However, they cannot swap to a particular agent if they have failed to respond to treatment with that particular agent within the same Cycle.

Patients who commenced treatment with adalimumab prior to 1 June 2009 access these interchangeability arrangements in the same way as patients who have not.

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

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

(5) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated, based on the baseline PASI assessment submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment authority is submitted within a Treatment Cycle and subsequent response will be assessed according to this revised PASI score.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatment applications.

(6) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

Patients who wish to trial a second or subsequent Biological Treatment Cycle, following a break in PBS-subsidised biological therapy of at least 5 years, must requalify for initial treatment according to the criteria of the relevant restriction and index of disease severity. Patients must have had at least 1 prior treatment, as listed in the criteria, for a minimum of 6 weeks, and must have a PASI assessment conducted preferably whilst still on treatment, but no later than 1 month following cessation of treatment. The PASI assessment must be no older than 1 month at the time of application.

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 \$	

Authority Required

Initial treatment [Initial 1, Whole body (New patients — No prior biological agent)]

Initial treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over who:

(a) have severe chronic plaque psoriasis where lesions have been present for at least 6 months from the time of initial diagnosis; and

(b) have not received any prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle; and

(c) have signed a patient and prescriber acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment (whole body); and

(d) have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 3 of the following 4 treatments:

(i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; and/or

(ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; and/or

(iii) cyclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; and/or

(iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks.

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity to necessitate permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of acceptable toxicities including severity, associated with phototherapy, methotrexate, cyclosporin and acitretin, can be found on the Medicare Australia website (www.medicareaustralia.gov.au).

The following initiation criterion indicates failure to achieve an adequate response and must be demonstrated in all patients at the time of the application:

(a) A current Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.

(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 1 month following cessation of each course of treatment.

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

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]]; and

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy]; and

(iii) the signed patient and prescriber acknowledgements.

A maximum of 16 weeks of treatment with adalimumab will be authorised under this restriction.

Where fewer than 4 repeats are requested at the time of the authority application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period beyond 16 weeks.

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 \$	

A PASI assessment of the patient's response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with adalimumab. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

It is recommended that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised adalimumab treatment.

Authority Required

Initial or re-Treatment [Initial 2, Whole body (Received prior biological agent under PBS)]

Treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over who:

- (a) have a documented history of severe chronic plaque psoriasis; and*
- (b) have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle; and*
- (c) have not failed PBS-subsidised therapy with adalimumab for the treatment of this condition in the current Treatment Cycle.*

Applications for authorisation must be made in writing and must include:

- (a) a completed authority prescription form; and*
- (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:*
 - (i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)];* and
 - (ii) details of prior biological treatment, including dosage, date and duration of treatment.*

Applications for patients who have demonstrated a response to PBS-subsidised adalimumab treatment within this Treatment Cycle and who wish to re-commence adalimumab treatment within the same Cycle following a break in therapy, will only be approved where evidence of the patient's response to their most recent course of PBS-subsidised adalimumab treatment has been submitted to Medicare Australia within 1 month of cessation of treatment.

A maximum of 16 weeks of treatment with adalimumab will be authorised under this restriction.

Where fewer than 4 repeats are requested at the time of the authority application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period beyond 16 weeks.

A PASI assessment of the patient's response to this course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with adalimumab. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

It is recommended that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised adalimumab treatment.

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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 \$	

Patients who fail to demonstrate a response to treatment with each of the biological agents, adalimumab, etanercept and infliximab, are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may re-commence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

Authority Required

Initial treatment [Initial 1, Face, hand, foot (New patients — No prior biological agent)]

Initial treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over who:

- (a) have severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis; and*
- (b) have not received any prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle; and*
- (c) have signed a patient and prescriber acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment (face, hand, foot); and*
- (d) have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 3 of the following 4 treatments:*
 - (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; and/or*
 - (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; and/or*
 - (iii) cyclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; and/or*
 - (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks.*

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity to necessitate permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of acceptable toxicities including severity, associated with phototherapy, methotrexate, cyclosporin and acitretin, can be found on the Medicare Australia website (www.medicareaustralia.gov.au).

The following initiation criterion indicates failure to achieve an adequate response and must be demonstrated in all patients at the time of the application:

- (a) Chronic plaque psoriasis classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where:*
 - (i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment; or*
 - (ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.*
- (b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 1 month following cessation of each course of treatment.*
- (c) The most recent PASI assessment must be no more than 1 month old at the time of application.*

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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 \$	

Applications for authorisation must be made in writing and must include:

- (a) a completed authority prescription form; and*
- (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:*
 - (i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)];* and
 - (ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy]; and*
 - (iii) the signed patient and prescriber acknowledgements.*

A maximum of 16 weeks of treatment with adalimumab will be authorised under this restriction.

Where fewer than 4 repeats are requested at the time of the authority application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period beyond 16 weeks.

A PASI assessment of the patient's response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with adalimumab. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

It is recommended that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised adalimumab treatment.

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

Authority Required

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

Treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over who:

- (a) have a documented history of severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot; and*
- (b) have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle; and*
- (c) have not failed PBS-subsidised therapy with adalimumab for the treatment of this condition in the current Treatment Cycle.*

Applications for authorisation must be made in writing and must include:

- (a) a completed authority prescription form; and*
- (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:*
 - (i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)];* and
 - (ii) details of prior biological treatment, including dosage, date and duration of treatment.*

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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 \$		

Applications for patients who have demonstrated a response to PBS-subsidised adalimumab treatment within this Treatment Cycle and who wish to re-commence adalimumab treatment within the same Cycle following a break in therapy, will only be approved where evidence of the patient's response to their most recent course of PBS-subsidised adalimumab treatment has been submitted to Medicare Australia within 1 month of cessation of treatment.

A maximum of 16 weeks of treatment with adalimumab will be authorised under this restriction.

Where fewer than 4 repeats are requested at the time of the authority application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period beyond 16 weeks.

A PASI assessment of the patient's response to this course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with adalimumab. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

It is recommended that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised adalimumab treatment.

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

Patients who fail to demonstrate a response to treatment with each of the biological agents, adalimumab, etanercept and infliximab, are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may re-commence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

NOTE:

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

9425C	Injection 40 mg in 0.8 mL pre-filled syringe	2	4	..	1773.93	32.90	Humira	AB
9426D	Injection 40 mg in 0.8 mL pre-filled pen	2	4	..	1773.93	32.90	Humira	AB

NOTE:

Special Pricing Arrangements apply.

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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 \$	

Authority Required

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

Initial PBS-subsidised supply for continuing treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over who:

(a) have a documented history of severe chronic plaque psoriasis and were receiving treatment with adalimumab prior to 1 March 2009; and

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

(c) have signed a patient and prescriber acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment (whole body); and

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

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) the completed Psoriasis Area and Severity Index (PASI) calculation sheet including the date of the assessment of the patient's condition at baseline (prior to initiation of adalimumab therapy) and the most recent PASI assessment [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy]; and

(iii) the signed patient and prescriber acknowledgements.

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 application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the treatment period beyond 24 weeks.

A PASI assessment of the patient's response to this initial PBS-subsidised course of therapy must be conducted within 4 weeks prior to completion of this course of treatment. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with adalimumab. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

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

It is recommended that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised adalimumab treatment.

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

continued ➞

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS—CONT.

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

Authority Required

Continuing treatment (Whole body)

Continuing PBS-subsidised treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over:

- (a) who have a documented history of severe chronic plaque psoriasis; and
- (b) whose most recent course of PBS-subsidised biological treatment for this condition in this Treatment Cycle was with adalimumab; and
- (c) who have demonstrated an adequate response to their most recent course of treatment with adalimumab.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the pre-biological treatment baseline value for this Treatment Cycle.

This assessment must be provided to Medicare Australia no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with adalimumab, the assessment of response must be after a minimum of 12 weeks of treatment with an initial course.

Applications for authorisation must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
 - (i) the completed Psoriasis Area and Severity Index (PASI) calculation sheet along with the date of the assessment of the patient's condition.

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

Approval will be based on the PASI assessment of response to the most recent course of treatment with adalimumab.

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

Where fewer than 5 repeats are requested at the time of the authority application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for continuing authority applications, or for treatment that would otherwise extend the treatment period beyond 24 weeks.

A PASI assessment of the patient's response must be conducted within 4 weeks prior to completion of this course of treatment. This assessment, which will be used to determine eligibility for further continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with adalimumab. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

It is recommended that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised adalimumab treatment.

Patients who fail to demonstrate a response to treatment with each of the biological agents, adalimumab, etanercept and infliximab, are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may re-commence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

continued ➞

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 \$	

Authority Required

Initial treatment [Initial 3, Face, hand, foot (Grandfather patients)]

Initial PBS-subsidised supply for continuing treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over:

- (a) who have a documented history of severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot and were receiving treatment with adalimumab prior to 1 March 2009; and*
- (b) whose disease, prior to treatment with adalimumab, 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 and prescriber acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment (face, hand, foot); and*
- (d) who have demonstrated a response as specified in the criterion included in the restriction for continuing PBS-subsidised treatment with adalimumab (face, hand, foot).*

Applications for authorisation must be made in writing and must include:

- (a) a completed authority prescription form; and*
- (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:*
 - (i) the completed Psoriasis Area and Severity Index (PASI) calculation sheet and face, hand, foot area diagrams along with the date of the assessment of the patient's condition at baseline (prior to initiation of adalimumab therapy) and the most recent PASI assessment [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) the signed patient and prescriber acknowledgements.*

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 application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period beyond 24 weeks.

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 adalimumab. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

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

It is recommended that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised adalimumab treatment.

The PASI assessment must be performed on the same affected area as assessed at baseline or prior to initiation of adalimumab treatment.

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

continued ➞

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS—CONT.

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

Authority Required

Continuing treatment (Face, hand, foot)

Continuing PBS-subsidised treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over:

(a) who have a documented history of severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot; and

(b) whose most recent course of PBS-subsidised biological treatment for this condition in this Treatment Cycle was with adalimumab; and

(c) who have demonstrated an adequate response to treatment with adalimumab.

An adequate response to adalimumab treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the pre-biological treatment baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the pre-biological treatment baseline value.

This assessment must be provided to Medicare Australia no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with adalimumab, the assessment of response must be after a minimum of 12 weeks of treatment with an initial course.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) the completed Psoriasis Area and Severity Index (PASI) calculation sheet and face, hand, foot area diagrams along with the date of the assessment of the patient's condition [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].

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

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

Where fewer than 5 repeats are requested at the time of the authority application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for continuing authority applications, or for treatment that would otherwise extend the treatment period beyond 24 weeks.

A PASI assessment of the patient's response must be conducted within 4 weeks prior to completion of this course of treatment. This assessment, which will be used to determine eligibility for further continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with adalimumab. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

It is recommended that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised adalimumab treatment.

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

continued ➡

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 \$		

Patients who fail to demonstrate a response to treatment with each of the biological agents, adalimumab, etanercept and infliximab, are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may re-commence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

NOTE:

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

9427E	Injection 40 mg in 0.8 mL pre-filled syringe	2	5	..	1773.93	32.90	Humira	AB
9428F	Injection 40 mg in 0.8 mL pre-filled pen	2	5	..	1773.93	32.90	Humira	AB

NOTE:

Special Pricing Arrangements apply.

ETANERCEPT

NOTE:

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

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

Written applications for authority to prescribe etanercept should be forwarded to:

Medicare Australia

Prior Written Approval of Specialised Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

NOTE:

TREATMENT OF ADULT PATIENTS WITH ACTIVE ANKYLOSING SPONDYLITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and infliximab for adult patients with active ankylosing spondylitis. Where the term 'tumour necrosis factor (TNF) alfa antagonist' appears in the following NOTES and restrictions, it refers to adalimumab, etanercept and infliximab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 TNF-alfa antagonists at any 1 time.

From 1 March 2007, under the PBS, all patients will be able to commence a treatment cycle where they may trial each PBS-subsidised TNF-alfa antagonist without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a TNF-alfa antagonist while they continue to show a response to therapy.

A patient who received PBS-subsidised TNF-alfa antagonist treatment prior to 1 March 2007 is considered to be in their first cycle as of 1 March 2007.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised TNF-alfa antagonist more than once. A patient who, prior to 1 March 2007, was authorised to receive PBS-subsidised initial treatment for ankylosing spondylitis with the same agent twice, is exempt from this condition in respect of applications approved prior to 1 March 2007.

continued ➞

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 \$	

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

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

A patient who has failed fewer than 3 TNF- α antagonists in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

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

(1) How to prescribe PBS-subsidised TNF- α antagonist therapy after 1 March 2007.

(a) Initial treatment.

Applications for initial treatment should be made where:

- (i) a patient has received no prior PBS-subsidised TNF- α antagonist treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
- (ii) a patient has received prior PBS-subsidised (initial or continuing) TNF- α antagonist therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
- (iii) a patient wishes to re-commence treatment with a specific TNF- α antagonist following a break in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for etanercept and adalimumab and 18 weeks of treatment for infliximab.

From 1 March 2007, a patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF- α antagonist.

For second and subsequent courses of PBS-subsidised TNF- α antagonist treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

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

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

Assessments of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF- α antagonist.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised TNF- α antagonist is approved, a patient may swap to an 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.

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 \$	

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

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

To avoid confusion, an application for a patient who wishes to swap to an alternate TNF-alfa antagonist should be accompanied by the approved authority prescription or remaining repeats for the TNF-alfa antagonist the patient is ceasing.

(3) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a TNF-alfa antagonist. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and Medicare Australia will assess response according to these revised baseline measurements.

For a new patient, the BASDAI used to determine the baseline must be measured while the patient is receiving NSAID therapy and completing their exercise program. However, this is not required for any subsequent BASDAI results for these patients, nor for patients who were 'grandfathered' on to TNF-alfa antagonist treatment.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response.

(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

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

(5) Patients 'grandfathered' onto PBS-subsidised treatment with etanercept.

From 1 March 2007, a patient who commenced treatment with etanercept for active ankylosing spondylitis prior to 1 July 2004 and who was 'grandfathered' onto PBS-subsidised therapy, and who continues to receive treatment in the same treatment cycle, will have further applications for treatment with etanercept assessed under the continuing treatment restriction.

Where pre-TNF-alfa antagonist treatment baselines were not provided, the following criteria must be met to demonstrate a response to treatment:

The BASDAI score must be either:

- (i) no more than 20% greater than the score included in the initial application for PBS-subsidised treatment; or*
- (ii) no greater than 2.*

AND

One of the following:

- (a) an ESR measurement no greater than 25 mm per hour; or*
- (b) a CRP measurement no greater than 10 mg per L.*

'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must requalify for initial treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' above for further details.

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 \$	

Authority Required

Initial 1 (new patients)

First course of PBS-subsidised treatment with etanercept, by a rheumatologist, of an adult with active ankylosing spondylitis who has radiographically (plain X-ray) confirmed Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis and who has not received any PBS-subsidised treatment with either adalimumab, etanercept or infliximab in this treatment cycle; AND

(a) who has at least 2 of the following:

(i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; or
(ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI) [for further information on the BASMI please refer to the Medicare Australia website at www.medicareaustralia.gov.au]; or

(iii) limitation of chest expansion relative to normal values for age and gender [for chest expansion normal values please refer to the Medicare Australia website at www.medicareaustralia.gov.au]; AND

(b) who has failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months.

The application must include details of the NSAIDs trialled, their doses and duration of treatment. If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used.

If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication.

If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance. Details of the toxicities, including severity, which will be accepted for the purposes of administering this restriction can be found on the Medicare Australia website [www.medicareaustralia.gov.au].

For details on the appropriate minimum exercise program that will be accepted for the purposes of administering this restriction, please refer to the Medicare Australia website at www.medicareaustralia.gov.au.

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

(a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale; AND

(b) an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 10 mg per L.

The BASDAI must be determined at the completion of the 3 month NSAID and exercise trial, but prior to ceasing NSAID treatment. The BASDAI must be no more than 1 month old at the time of initial application.

Both ESR and CRP measures should be provided with the initial treatment application and both must be no more than 1 month old. If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reason this criterion cannot be satisfied.

continued ➞

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 \$	

Authority applications must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form [www.medicareaustralia.gov.au] which must include the following:
 - (i) a copy of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and
 - (ii) a completed BASDAI Assessment Form [www.medicareaustralia.gov.au]; and
 - (iii) a completed Exercise Program Self Certification Form included in the supporting information form; and
 - (iv) a signed patient acknowledgment form. Completion of this form declares that the patient understands and acknowledges that PBS-subsidised treatment with the TNF-alfa antagonists (adalimumab, etanercept or infliximab) for ankylosing spondylitis will cease if they do not demonstrate the response to treatment required to support continuation of PBS-subsidised treatment at any assessment where a response must be demonstrated.

The assessment of the patient's response to the initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted to Medicare Australia no later than 4 weeks from the cessation of that treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

A maximum of 16 weeks of treatment with etanercept will be approved under this criterion.

Where fewer than 3 repeats are initially requested with the authority prescription, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone.

Authority Required

Initial 2 (change or re-commencement for all patients)

Initial course of PBS-subsidised treatment with etanercept, by a rheumatologist, of an adult with a documented history of active ankylosing spondylitis who, in this treatment cycle, has received prior PBS-subsidised treatment with either adalimumab, etanercept or infliximab for this condition and has not failed PBS-subsidised therapy with etanercept.

To demonstrate a response to treatment the application must be accompanied by the results of the most recent course of TNF-alfa antagonist therapy within the timeframes specified in the relevant restriction.

Where the most recent course of PBS-subsidised TNF-alfa antagonist treatment was approved under an initial treatment restriction after 1 March 2007, the patient must have been assessed for response to that course following a minimum of 12 weeks of treatment. Where the most recent course of PBS-subsidised TNF-alfa antagonist treatment was approved under an initial treatment restriction prior to 1 March 2007, the patient must have been assessed for response to that course following at least 4 weeks of treatment. These assessments must be provided to Medicare Australia no later than 4 weeks from the date the course was ceased.

If the response assessment to the previous course of TNF-alfa antagonist treatment is not submitted as detailed above, the patient will be deemed to have failed therapy with that particular course of TNF-alfa antagonist.

Authority applications must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form [www.medicareaustralia.gov.au] which includes a completed BASDAI Assessment Form with certification by the prescriber and the patient that the patient did not have access to their baseline BASDAI at the time of their assessment.

A maximum of 16 weeks of treatment with etanercept will be approved under this criterion.

Where fewer than 3 repeats are initially requested with the authority prescription, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone.

8778B	Injection set containing 4 vials powder for injection 25 mg and 4 pre-filled syringes solvent 1 mL	2	3	..	* 1828.57	32.90	Enbrel	WX

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	
9081Y	Injection set containing 4 vials powder for injection 50 mg and 4 pre-filled syringes solvent 1 mL	1	3	..	1773.94	32.90	Enbrel	WX
9085E	Injections 50 mg in 1 mL single use pre-filled syringes, 4	1	3	..	1773.94	32.90	Enbrel	WX

NOTE:

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

Authority Required

Continuing treatment for all patients

Continuing PBS-subsidised treatment, by a rheumatologist, of an adult with a documented history of active ankylosing spondylitis who:

(a) has demonstrated a response to treatment with etanercept; and

(b) whose most recent course of PBS-subsidised therapy in this treatment cycle was with etanercept.

Response is defined as an improvement from baseline of at least 2 of the BASDAI and 1 of the following:

(a) an ESR measurement no greater than 25 mm per hour; or

(b) a CRP measurement no greater than 10 mg per L; or

(c) an ESR or CRP measurement reduced by at least 20% from baseline.

For a 'grandfather' patient who does not have baselines prior to commencing treatment with a TNF-alfa antagonist, see Note 5 for a definition of response to treatment.

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

Where the most recent course of PBS-subsidised TNF-alfa antagonist treatment was approved under an initial treatment restriction after 1 March 2007, the patient must have been assessed for response to that course following a minimum of 12 weeks of treatment. Where the most recent course of PBS-subsidised TNF-alfa antagonist treatment was approved under an initial treatment restriction prior to 1 March 2007, the patient must have been assessed for response to that course following at least 4 weeks of treatment.

Applications for continuing treatment must be made in writing and should be posted to Medicare Australia no less than 2 weeks prior to the completion of the current treatment course.

Written applications for authorisation must include:

(a) a completed authority prescription form; and

(b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form [www.medicareaustralia.gov.au] which includes a completed BASDAI Assessment Form with certification by the prescriber and the patient that the patient did not have access to their baseline BASDAI at the time of their continuing treatment assessment.

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

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

Where fewer than 5 repeats are initially requested with the authority prescription, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone.

8779C	Injection set containing 4 vials powder for injection 25 mg and 4 pre-filled syringes solvent 1 mL	2	5	..	* 1828.57	32.90	Enbrel	WX

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	
9082B	Injection set containing 4 vials powder for injection 50 mg and 4 pre-filled syringes solvent 1 mL	1	5	..	1773.94	32.90	Enbrel	WX
9086F	Injections 50 mg in 1 mL single use pre-filled syringes, 4	1	5	..	1773.94	32.90	Enbrel	WX

NOTE:

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

NOTE:

TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS

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

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological agents at any 1 time. Where the term 'biological agents' appears in the following NOTES and restrictions, it only refers to adalimumab, etanercept and infliximab.

From 1 August 2006, all patients will be able to commence a 'Biological Treatment Cycle' (Cycle), where they may trial adalimumab, etanercept or infliximab without having to meet the initial treatment criteria, that is they will not need to experience a disease flare, when swapping to the alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

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

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

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

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

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

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

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

How to prescribe biological agents for the treatment of severe active psoriatic arthritis after 1 August 2006.

(1) Initial treatment.

continued 

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS—CONT.

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

Applications for initial treatment should be made where:

- (i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); and*
- (ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; and*
- (iii) patients wish to re-commence treatment with a specific biological agent following a break in PBS-subsidised therapy with that specific agent (Initial 2).*

All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 16 weeks of therapy for all agents except for infliximab, for which a maximum of 22 weeks will be authorised. It is recommended that patients be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological agent supply.

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

Grandfather patients.

Applications for patients who commenced treatment with etanercept prior to 17 March 2005 or adalimumab and infliximab prior to 16 March 2006, may apply for initial PBS-subsidised treatment as continuing therapy under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with any biological agent prior to PBS listing of that agent.

Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment for all agents. Approval will be based on the criteria included in the relevant restriction.

(2) Continuing treatment.

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

Patients must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.

(3) Swapping therapy.

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

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

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

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

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

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 \$	

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

(4) Baseline measurements to determine response.

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

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.

(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

Patients who wish to trial a second or subsequent treatment Cycle following a break in PBS-subsidised biological therapy of at least 5 years, must re-qualify for initial treatment with respect to both the indices of disease severity. Patients must have received treatment with methotrexate or sulfasalazine or leflunomide, at an adequate dose, for a minimum of 3 months at the time the ESR or CRP levels and the active joint counts are measured.

Authority Required

Initial 1

Initial PBS-subsidised treatment with etanercept, by a rheumatologist or clinical immunologist with expertise in the management of psoriatic arthritis, of adults who:

- (1) have severe active psoriatic arthritis; and*
- (2) have received no prior PBS-subsidised biological treatment for this condition in this Treatment Cycle; and*
- (3) have failed to achieve an adequate response to:*
 - (a) methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months; and*
 - (b) sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months; or*
 - (c) leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months.*

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).*

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 \$	

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

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

- (1) a completed authority prescription form; and*
 - (2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes details of the patient's ESR and CRP measurements and the patient's active joint count which must have been assessed no earlier than 1 month prior to the date of application; and*
 - (3) a copy of the signed patient acknowledgement form which is included in the Supporting Information Form.*
- Completion of this form declares that the patient understands and acknowledges that PBS-subsidised treatment will cease if they do not demonstrate the response to treatment required to support continuation of PBS-subsidised treatment at any assessment where a response must be demonstrated.*

Where fewer than 3 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Patients who fail to demonstrate a response to treatment with etanercept under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug, in this Treatment Cycle.

Authority Required

Initial 2

Initial PBS-subsidised treatment with etanercept, by a rheumatologist or clinical immunologist with expertise in the management of psoriatic arthritis, of adults who:

- (1) have a documented history of severe active psoriatic arthritis; and*
- (2) have received prior PBS-subsidised biological treatment for this condition in this Treatment Cycle and are eligible to receive further biological therapy; and*
- (3) have not failed treatment with etanercept during the current Treatment Cycle.*

Applications for patients who have demonstrated a response to PBS-subsidised etanercept treatment within this Treatment Cycle and who wish to re-commence etanercept treatment within the same Cycle following a break in therapy, will only be approved where evidence of a response to the patient's most recent course of PBS-subsidised etanercept treatment has been submitted to Medicare Australia within 1 month of cessation of treatment.

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

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

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

- (1) a completed authority prescription form; and*
- (2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].*

Where fewer than 3 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Patients who fail to demonstrate a response to treatment with etanercept under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug, in this Treatment Cycle.

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 \$		
<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	..	* 1828.57	32.90	Enbrel	WX
9083C	Injection set containing 4 vials powder for injection 50 mg and 4 pre-filled syringes solvent 1 mL	1	3	..	1773.94	32.90	Enbrel	WX
9087G	Injections 50 mg in 1 mL single use pre-filled syringes, 4	1	3	..	1773.94	32.90	Enbrel	WX

NOTE:

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

Authority Required

Initial 3

Initial PBS-subsidised supply for continuing treatment with etanercept, by a rheumatologist or clinical immunologist with expertise in the management of psoriatic arthritis, of adults who:

- (1) have a documented history of severe active psoriatic arthritis; and
- (2) were receiving treatment with etanercept prior to 17 March 2005; and
- (3) have demonstrated a response as specified in the criteria for continuing PBS-subsidised treatment with etanercept.

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

- (1) a completed authority prescription form; and
 - (2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and
 - (3) a copy of the signed patient acknowledgement form which is included in the Supporting Information Form.
- Completion of this form declares that the patient understands and acknowledges that PBS-subsidised treatment will cease if they do not demonstrate the response to treatment required to support continuation of PBS-subsidised treatment at any assessment where a response must be demonstrated.

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

Where fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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.

continued ➞

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 \$		
Authority Required								
<i>Continuing treatment</i>								
<i>Continuing PBS-subsidised treatment with etanercept, by a rheumatologist or clinical immunologist with expertise in the management of psoriatic arthritis, of adults:</i>								
<i>(1) who have a documented history of severe active psoriatic arthritis; and</i>								
<i>(2) whose most recent course of PBS-subsidised biological agent for this condition in the current Treatment Cycle was with etanercept; and</i>								
<i>(3) who, at the time of application, demonstrate an adequate response to treatment with etanercept.</i>								
<i>An adequate response to treatment with etanercept is defined as:</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; AND either of the following:</i>								
<i>(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</i>								
<i>(ii) a reduction in the number of the following major 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 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>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 Psoriatic Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].</i>								
<i>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.</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 700 270 (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>								
9036N	Injection set containing 4 vials powder for injection 25 mg and 4 pre-filled syringes solvent 1 mL	2	5	..	* 1828.57	32.90	Enbrel	WX
9084D	Injection set containing 4 vials powder for injection 50 mg and 4 pre-filled syringes solvent 1 mL	1	5	..	1773.94	32.90	Enbrel	WX
9088H	Injections 50 mg in 1 mL single use pre-filled syringes, 4	1	5	..	1773.94	32.90	Enbrel	WX

continued ➞

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 \$	

NOTE:

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

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

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying anti-rheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, etanercept, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-1 inhibitor (anakinra) and the T-cell co-stimulation modulator (abatacept).

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

PBS-subsidised infliximab, anakinra, rituximab and abatacept must be used in combination with methotrexate at a dose of at least 7.5 mg weekly. Where a patient cannot tolerate 7.5 mg of methotrexate weekly, they are only eligible to receive PBS-subsidised etanercept and adalimumab.

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

From 1 March 2008, under the PBS, all patients will be able to commence a Treatment Cycle where they may trial PBS-subsidised bDMARD agents without having to experience a disease flare when swapping to an alternate agent. Under these interchangeability arrangements, within a single Treatment Cycle, a patient may continue to receive long-term treatment with a bDMARD while they continue to show a response to therapy.

A patient who received PBS-subsidised bDMARD treatment prior to 1 March 2008 is considered to be in their first Cycle as of 1 March 2008.

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

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a Treatment Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised bDMARD therapy before they are eligible to commence the next Cycle.

For patients who have failed PBS-subsidised treatment with 3 bDMARDs prior to 1 March 2008 please contact Medicare Australia on 1800 700 270.

The 5-year break is measured from the date of the last approval for PBS-subsidised bDMARD treatment in the most recent Cycle to the date of the first application for initial treatment with a bDMARD under the new Treatment Cycle.

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

A patient who has failed fewer than 3 bDMARDs in a Treatment Cycle and who has a break in therapy of more than 5 years, may commence a new Treatment Cycle.

There is no limit to the number of Treatment Cycles a patient may undertake in their lifetime.

If patients fail to respond to a particular bDMARD within a single Treatment Cycle, they are not eligible to receive further PBS-subsidised treatment with that drug until they commence the next Cycle.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 March 2008.

continued ➡

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed	Maximum	Proprietary Name and Manufacturer
					Price for Max. Qty \$	Recordable Value for Safety Net \$	

(a) Initial treatment.

Applications for initial treatment should be made where:

- (i) a patient has received no prior PBS-subsidised bDMARD treatment in this Treatment Cycle and wishes to commence such therapy, excluding rituximab (Initial 1); or*
- (ii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or*
- (iii) a patient wishes to re-commence treatment with a specific bDMARD following a break in PBS-subsidised therapy with that agent (Initial 2).*

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for etanercept, adalimumab, anakinra and abatacept, 22 weeks of therapy for infliximab and 2 infusions of rituximab.

From 1 March 2008, a patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to Medicare Australia within 4 weeks.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

Rituximab patients:

A further application may be submitted to Medicare Australia 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Rituximab patients:

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD within the same Treatment Cycle without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.

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 \$	

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the same Treatment Cycle.

In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF- α antagonist treatment.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

NOTE:

(3) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a Treatment Cycle and Medicare Australia will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

The baseline joint and blood counts should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment.

(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent Treatment Cycle following a break in PBS-subsidised bDMARD therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have received treatment with at least 1 non-biological DMARD, at an adequate dose, for a minimum of 3 months at the time the ESR and/or CRP levels and the active joint count are measured.

(5) Patients 'grandfathered' onto PBS-subsidised treatment with rituximab or abatacept.

From 1 March 2008, a patient who commenced treatment with rituximab for severe rheumatoid arthritis prior to 7 March 2007 or abatacept for severe rheumatoid arthritis prior to 1 November 2007 and who was 'grandfathered' on to PBS-subsidised therapy, and who continues to receive treatment in the same Treatment Cycle, will have further applications for treatment with rituximab or abatacept assessed under the continuing treatment restriction.

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 \$	

A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment with abatacept will be authorised under this criterion.

'Grandfather' arrangements will only apply for the first Treatment Cycle. For the second and subsequent Cycles, a 'grandfather' patient must requalify for initial treatment under the criteria that applies to a new patient. See 'Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' above for further details.

Authority Required

Initial 1 (new patients)

Application for initial PBS-subsidised treatment with etanercept, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of adults who:

- (a) have severe active rheumatoid arthritis; and*
- (b) have received no prior PBS-subsidised treatment with a bDMARD for this condition in this treatment cycle; and*
- (c) have failed to achieve an adequate response to the following treatments:*
 - (i) methotrexate at a dose of at least 20 mg weekly; and*
 - (ii) methotrexate (at a minimum dose of 7.5 mg weekly), in combination with 2 other non-biological disease modifying anti-rheumatic drugs (DMARDs), for a minimum of 3 months; and*
 - (iii) a minimum of 3 months' treatment with:*
 - leflunomide alone; or*
 - leflunomide in combination with methotrexate; or*
 - cyclosporin.*

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application.

Details of the accepted toxicities, including severity, can be found on the Medicare Australia website [www.medicareaustralia.gov.au].

The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L;

AND either

- (i) a total active joint count of at least 20 active (swollen and tender) joints; or*
- (ii) at least 4 active joints from the following list of major joints:*
 - elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or*
 - shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).*

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

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ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed	Maximum	Proprietary Name and Manufacturer
					Price for Max. Qty \$	Recordable Value for Safety Net \$	

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and*
- (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes details of the patient's ESR and CRP measurements and the patient's active joint count which must have been assessed no earlier than 1 month prior to the date of application; and*
- (3) a signed patient acknowledgement.*

A maximum of 16 weeks of treatment will be authorised under this restriction.

Where fewer than 3 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Assessment of a patient's response to an initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with etanercept.

Patients who fail to demonstrate a response to treatment with etanercept under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug, in this treatment cycle. Patients may re-trial etanercept after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised bDMARD was approved in this cycle and the date of the first application under the new cycle.

Authority Required

Initial 2 (change or re-commencement)

Application for an initial course of PBS-subsidised treatment with etanercept, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of adults who:

- (a) have a documented history of severe active rheumatoid arthritis; and*
- (b) have received prior PBS-subsidised bDMARD treatment for this condition in this treatment cycle and are eligible to receive further bDMARD therapy.*

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and*
- (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].*

Applications for patients who have received PBS-subsidised treatment with etanercept within this treatment cycle and who wish to re-commence therapy with this drug within this same cycle, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised etanercept treatment, within the timeframes specified below.

A maximum of 16 weeks of treatment will be authorised under this restriction.

Where fewer than 3 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Where the most recent course of PBS-subsidised etanercept treatment was approved under either of the initial treatment restrictions (i.e. for patients with no prior PBS-subsidised bDMARD therapy or, under this restriction, for patients who have received previous PBS-subsidised bDMARD therapy), patients must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be provided to Medicare Australia no later than 4 weeks from the date that course was ceased.

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 \$	

Where the most recent course of PBS-subsidised etanercept treatment was approved under the continuing treatment criteria, patients must have been assessed for response, and the assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Patients who fail to demonstrate a response to treatment with etanercept under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug, in this treatment cycle. Patients may re-trial etanercept after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised bDMARD was approved in this cycle and the date of the first application under the new cycle.

Authority Required

Initial treatment, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of patients aged 18 years or older with a documented history of severe active polyarticular course juvenile chronic arthritis with onset prior to the age of 18 years; AND

(a) who have signed a patient agreement form indicating that they understand and acknowledge that PBS-subsidised treatment will cease if the predetermined response criteria do not support continuation of PBS-subsidised treatment; AND

(b) who have failed to achieve an adequate response to methotrexate at a dose of at least 20 mg weekly; AND

(c) who have failed to achieve an adequate response to methotrexate, in combination with 2 other disease modifying anti-rheumatic drugs (DMARDs), for a minimum of 3 months; AND

(d) who have subsequently failed to achieve an adequate response following a minimum of 3 months' treatment with:

(i) leflunomide alone; or

(ii) leflunomide in combination with methotrexate; or

(iii) cyclosporin.

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, or intolerance of a severity necessitating permanent treatment withdrawal develops during the relevant period of use, the patient is exempted from demonstrating an inadequate response to the above treatment regimens. Details of the contraindication or intolerance, including the degree of toxicity, must be provided at the time of application.

The following criteria must be met in order to demonstrate failure to achieve an adequate response:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either

(i) an active joint count of at least 20 active (swollen and tender) joints; or

(ii) at least 4 active joints from the following list:

— elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

— shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

The authority application must be in writing and must include sufficient information to determine the patient's eligibility according to the above criteria. The date of joint assessment must be provided.

Where fewer than 3 repeats are requested at the time of the initial authority application, authority approvals for sufficient repeats to complete a maximum of 4 months of treatment may be requested by telephone. Under no circumstances will telephone approvals be granted for initial or continuing authority applications, or for treatment that would otherwise extend the initial treatment period beyond 4 months.

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	
<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	..	* 1828.57	32.90	Enbrel	WX
8861J	Injection set containing 4 vials powder for injection 50 mg and 4 pre-filled syringes solvent 1 mL	1	3	..	1773.94	32.90	Enbrel	WX
9089J	Injections 50 mg in 1 mL single use pre-filled syringes, 4	1	3	..	1773.94	32.90	Enbrel	WX

NOTE:

No applications for increased maximum quantities and/or repeats will be authorised.

Authority Required

Continuing treatment

Continuing PBS-subsidised treatment with etanercept, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of adults:

- (a) who have a documented history of severe active rheumatoid arthritis; and
- (b) who have demonstrated an adequate response to treatment with etanercept; and
- (c) whose most recent course of PBS-subsidised bDMARD treatment in this treatment cycle was with etanercept.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

- (i) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
- (ii) a reduction in the number of the following major active joints, from at least 4, by at least 50%:
 - elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
 - shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].

A maximum of 24 weeks of treatment will be approved under this restriction.

Where fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

continued ➡

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 \$	

All applications for continuing treatment with etanercept must include a measurement of response to the prior course of therapy. This assessment must be provided to Medicare Australia no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with etanercept, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.

Patients who fail to demonstrate a response to treatment with etanercept under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug, in this treatment cycle. Patients may re-trial etanercept after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised bDMARD was approved in this cycle and the date of the first application under the new cycle.

Authority Required

Initial PBS-subsidised supply for continuing treatment, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of patients aged 18 years or older with a documented history of severe active polyarticular course juvenile chronic arthritis with onset prior to the age of 18 years, and who were receiving treatment with etanercept prior to 1 December 2002; AND

(a) who have signed a patient agreement form indicating that they understand and acknowledge that PBS-subsidised treatment will cease if the predetermined response criteria do not support continuation of PBS-subsidised treatment; AND

(b) who have demonstrated a response as specified in the criteria for continuing PBS-subsidised treatment with etanercept.

The authority application must be in writing and must include sufficient information to determine the patient's eligibility. The date of assessment of the patient must be provided.

Authority Required

Continuing PBS-subsidised treatment, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of patients aged 18 years or older with a documented history of severe active polyarticular course juvenile chronic arthritis with onset prior to the age of 18 years, who, at the time of application, demonstrate an adequate response to treatment with etanercept as manifested by:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND 1 or more of the following:

(i) an active joint count of fewer than 10 active (swollen and tender) joints; or

(ii) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or

(iii) a reduction in the number of the following active joints, from at least 4, by at least 50%:

— elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

— shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All authority applications for continuing treatment with etanercept must be in writing and must include sufficient information to determine the patient's response according to the above criteria. The date of assessment of the patient must be provided.

Patients who fail to demonstrate an adequate response, as specified in the criteria for continuing treatment with etanercept, will not be eligible to recommence treatment with etanercept within 12 months of the date on which treatment was ceased.

Where re-treatment with etanercept after a break in PBS-subsidised treatment with the drug is being sought, the reason for and date of cessation of the previous treatment course with etanercept must be included in the application.

8638P	Injection set containing 4 vials powder for injection 25 mg and 4 pre-filled syringes solvent 1 mL	2	5	..	* 1828.57	32.90	Enbrel	WX

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	
8862K	Injection set containing 4 vials powder for injection 50 mg and 4 pre-filled syringes solvent 1 mL	1	5	..	1773.94	32.90	Enbrel	WX
9090K	Injections 50 mg in 1 mL single use pre-filled syringes, 4	1	5	..	1773.94	32.90	Enbrel	WX

NOTE:

No applications for increased maximum quantities and/or repeats will be authorised.

NOTE:

TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, etanercept and infliximab, for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological agents' appears in the following NOTES and restrictions, it only refers to adalimumab, etanercept and infliximab.

From 1 June 2009, 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 an alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

A patient who received PBS-subsidised biological agent treatment for chronic plaque psoriasis prior to 1 June 2009 is considered to be in their first Cycle as of 1 June 2009.

Patients are eligible for PBS-subsidised treatment with only 1 biological agent at any 1 time.

Within the same Treatment Cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for a PBS-subsidised biological agent, they must change to an alternate agent if they wish to continue PBS-subsidised biological treatment. A patient who, prior to 1 June 2009, was authorised to receive PBS-subsidised initial treatment for chronic plaque psoriasis with the same agent twice, is exempt from this condition in respect of applications approved prior to 1 June 2009.

Patients must be assessed for response to each course of continuing treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a Treatment Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological agent therapy before they are eligible to commence the next Cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological agent treatment in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Treatment Cycle.

Patients for whom a break in PBS-subsidised therapy of less than 5 years duration has occurred, and, who have failed therapy fewer than 3 times within a particular Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.

Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle.

There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.

How to prescribe biological agents for the treatment of severe chronic plaque psoriasis after 1 June 2009.

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.

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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 \$	

Applications for a course of initial treatment should be made in the following situations:

- (i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); or*
- (ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under '(4) Swapping therapy' below]; or*
- (iii) patients who wish to re-commence treatment following a break in PBS-subsidised therapy with that agent (Initial 2).*

All applications for initial treatment will be limited to provide for a maximum of 16 weeks of treatment in the case of adalimumab and etanercept, and 22 weeks of treatment in the case of infliximab.

Grandfather patients (adalimumab only).

Applications for patients who commenced treatment with adalimumab prior to 1 March 2009, may be made for initial PBS-subsidised treatment as continuing therapy under the initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with a biological agent prior to PBS listing of that agent.

Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment. Approval will be based on the criteria included in the relevant restriction.

(2) Assessment of response to initial treatment.

When prescribing initial treatment with a biological agent, a PASI assessment must be conducted after at least 12 weeks of treatment. This assessment must be submitted to Medicare Australia within 1 month of the completion of this initial treatment course. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

(3) Application for continuing treatment.

Following the completion of an initial treatment course of a biological agent to which an adequate response has been demonstrated, patients may qualify to receive up to 24 weeks of continuing treatment with that biological agent. Patients are eligible to continue to receive continuous treatment with 24 week courses providing they continue to sustain a response.

For second and subsequent courses of PBS-subsidised treatment with adalimumab, etanercept or infliximab it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

Where a response assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to sustain a response to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

(4) Swapping therapy.

Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate agent within the same Treatment Cycle without having to requalify with respect to disease severity (i.e. a PASI score of greater than 15), or prior treatment requirements.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

Patients may trial an alternate biological agent at any time, regardless of whether they are receiving therapy with a biological agent at the time of the application or not. However, they cannot swap to a particular agent if they have failed to respond to treatment with that particular agent within the same Cycle.

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 \$	

Patients who commenced treatment with adalimumab prior to 1 June 2009 access these interchangeability arrangements in the same way as patients who have not.

To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the agent being ceased.

(5) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated, based on the baseline PASI assessment submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment authority is submitted within a Treatment Cycle and subsequent response will be assessed according to this revised PASI score.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatment applications.

(6) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

Patients who wish to trial a second or subsequent Biological Treatment Cycle, following a break in PBS-subsidised biological therapy of at least 5 years, must requalify for initial treatment according to the criteria of the relevant restriction and index of disease severity. Patients must have had at least 1 prior treatment, as listed in the criteria, for a minimum of 6 weeks, and must have a PASI assessment conducted preferably whilst still on treatment, but no later than 1 month following cessation of treatment. The PASI assessment must be no older than 1 month at the time of application.

Authority Required

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Initial treatment [Initial 1, Whole body (New patients — No prior biological agent)]

Initial treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over who:

(a) have severe chronic plaque psoriasis where lesions have been present for at least 6 months from the time of initial diagnosis; and

(b) have not received any prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle; and

(c) have signed a patient and prescriber acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment (whole body); and

(d) have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 3 of the following 4 treatments:

(i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; and/or

(ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; and/or

(iii) cyclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; and/or

(iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks.

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity to necessitate permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of acceptable toxicities including severity, associated with phototherapy, methotrexate, cyclosporin and acitretin, can be found on the Medicare Australia website (www.medicareaustralia.gov.au).

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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 \$	

The following initiation criterion indicates failure to achieve an adequate response and must be demonstrated in all patients at the time of the application:

- (a) A current Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.
- (b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 1 month following cessation of each course of treatment.
- (c) The most recent PASI assessment must be no more than 1 month old at the time of application.

Applications for authorisation must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
 - (i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and
 - (ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy]; and
 - (iii) the signed patient and prescriber acknowledgements.

A maximum of 16 weeks of treatment with etanercept will be authorised under this restriction.

Where fewer than 3 repeats are requested at the time of the authority application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period beyond 16 weeks.

A PASI assessment of the patient's response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with etanercept. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

It is recommended that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised etanercept treatment.

Authority Required

Initial or re-Treatment [Initial 2, Whole body (Received prior biological agent under PBS)]

Treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over who:

- (a) have a documented history of severe chronic plaque psoriasis; and
- (b) have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle; and
- (c) have not failed PBS-subsidised therapy with etanercept for the treatment of this condition in the current Treatment Cycle.

Applications for authorisation must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

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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 \$	

- (i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and
- (ii) details of prior biological treatment, including dosage, date and duration of treatment.

Applications for patients who have demonstrated a response to PBS-subsidised etanercept treatment within this Treatment Cycle and who wish to re-commence etanercept treatment within the same Cycle following a break in therapy, will only be approved where evidence of the patient's response to their most recent course of PBS-subsidised etanercept treatment has been submitted to Medicare Australia within 1 month of cessation of treatment.

A maximum of 16 weeks of treatment with etanercept will be authorised under this restriction.

Where fewer than 3 repeats are requested at the time of the authority application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period beyond 16 weeks.

A PASI assessment of the patient's response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with etanercept. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

It is recommended that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised etanercept treatment.

Patients who fail to demonstrate a response to treatment with each of the biological agents, adalimumab, etanercept and infliximab, are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may re-commence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

Authority Required

- Initial treatment [Initial 1, Face, hand, foot (New patients — No prior biological agent)]
- Initial treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over who:
- (a) have severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis; and
 - (b) have not received any prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle; and
 - (c) have signed a patient and prescriber acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment (face, hand, foot); and
 - (d) have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 3 of the following 4 treatments:
 - (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; and/or
 - (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; and/or
 - (iii) cyclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; and/or
 - (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks.

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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 \$	

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity to necessitate permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of acceptable toxicities including severity, associated with phototherapy, methotrexate, cyclosporin and acitretin, can be found on the Medicare Australia website (www.medicareaustralia.gov.au).

The following initiation criterion indicates failure to achieve an adequate response and must be demonstrated in all patients at the time of the application:

(a) Chronic plaque psoriasis classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where:

(i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment; or

(ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.

(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 1 month following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than 1 month old at the time of application.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy]; and

(iii) the signed patient and prescriber acknowledgements.

A maximum of 16 weeks of treatment with etanercept will be authorised under this restriction.

Where fewer than 3 repeats are requested at the time of the authority application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period beyond 16 weeks.

A PASI assessment of the patient's response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with etanercept. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

It is recommended that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised etanercept treatment.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

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 \$	

Authority Required

- **Initial or re-Treatment [Initial 2, Face, hand, foot (Received prior biological agent under PBS)]**
Treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over who:
(a) have a documented history of severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot; and
(b) have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle; and
(c) have not failed PBS-subsidised therapy with etanercept for the treatment of this condition in the current Treatment Cycle.

Applications for authorisation must be made in writing and must include:

- (a) a completed authority prescription form; and**
(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and
(ii) details of prior biological treatment, including dosage, date and duration of treatment.

Applications for patients who have demonstrated a response to PBS-subsidised etanercept treatment within this Treatment Cycle and who wish to re-commence etanercept treatment within the same Cycle following a break in therapy, will only be approved where evidence of the patient's response to their most recent course of PBS-subsidised etanercept treatment has been submitted to Medicare Australia within 1 month of cessation of treatment.

A maximum of 16 weeks of treatment with etanercept will be authorised under this restriction.

Where fewer than 3 repeats are requested at the time of the authority application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period beyond 16 weeks.

A PASI assessment of the patient's response to this course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with etanercept. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

It is recommended that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised etanercept treatment.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

Patients who fail to demonstrate a response to treatment with each of the biological agents, adalimumab, etanercept and infliximab, are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may re-commence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

NOTE:

No applications for increased maximum quantities and/or repeats will be authorised.

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ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Proprietary Name and Manufacturer	
9037P	Injection set containing 4 vials powder for injection 25 mg and 4 pre-filled syringes solvent 1 mL	2	3	..	* 1828.57	32.90	Enbrel	WX
9038Q	Injection set containing 4 vials powder for injection 50 mg and 4 pre-filled syringes solvent 1 mL	1	3	..	1773.94	32.90	Enbrel	WX
9091L	Injections 50 mg in 1 mL single use pre-filled syringes, 4	1	3	..	1773.94	32.90	Enbrel	WX

NOTE:

Special Pricing Arrangements apply.

Authority Required

Continuing treatment (Whole body)

Continuing PBS-subsidised treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over:

(a) who have a documented history of severe chronic plaque psoriasis; and

(b) whose most recent course of PBS-subsidised biological treatment for this condition in this Treatment Cycle was with etanercept; and

(c) who have demonstrated an adequate response to their most recent course of treatment with etanercept.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the pre-biological treatment baseline value for this Treatment Cycle.

This assessment must be provided to Medicare Australia no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with etanercept, the assessment of response must be after a minimum of 12 weeks of treatment with an initial course.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) the completed Psoriasis Area and Severity Index (PASI) calculation sheet along with the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 1 month old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with etanercept.

A maximum of 24 weeks of treatment with etanercept will be authorised under this restriction.

Where fewer than 5 repeats are requested at the time of the authority application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for continuing authority applications, or for treatment that would otherwise extend the treatment period beyond 24 weeks.

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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 \$	

A PASI assessment of the patient's response must be conducted within 4 weeks prior to completion of this course of treatment. This assessment must be submitted to Medicare Australia no later than 1 month from the date of completion of this course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with etanercept. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

It is recommended that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised etanercept treatment.

Patients who fail to demonstrate a response to treatment with each of the biological agents, adalimumab, etanercept and infliximab, are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may re-commence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

Authority Required

Continuing treatment (Face, hand, foot)

Continuing PBS-subsidised treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over:

- (a) who have a documented history of severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot; and*
- (b) whose most recent course of PBS-subsidised biological treatment for this condition in this Treatment Cycle was with etanercept; and*
- (c) who have demonstrated an adequate response to treatment with etanercept.*

An adequate response to etanercept treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

- (i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the pre-biological treatment baseline values; or*
- (ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the pre-biological treatment baseline value.*

This assessment must be provided to Medicare Australia no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with etanercept, the assessment of response must be after a minimum of 12 weeks of treatment with an initial course.

Applications for authorisation must be made in writing and must include:

- (a) a completed authority prescription form; and*
- (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:*
 - (i) the completed Psoriasis Area and Severity Index (PASI) calculation sheet and face, hand, foot area diagrams along with the date of the assessment of the patient's condition [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].*

The most recent PASI assessment must be no more than 1 month old at the time of application.

A maximum of 24 weeks of treatment with etanercept will be authorised under this restriction.

Where fewer than 5 repeats are requested at the time of the authority application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for continuing authority applications, or for treatment that would otherwise extend the treatment period beyond 24 weeks.

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	
<i>A PASI assessment of the patient's response must be conducted within 4 weeks prior to completion of this course of treatment. This assessment must be submitted to Medicare Australia no later than 1 month from the date of completion of this course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with etanercept. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.</i> <i>It is recommended that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised etanercept treatment.</i> <i>The PASI assessment for continuing treatment must be performed on the same affected area assessed at baseline. Patients who fail to demonstrate a response to treatment with each of the biological agents, adalimumab, etanercept and infliximab, are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may re-commence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.</i> <u>NOTE:</u> <i>No applications for increased maximum quantities and/or repeats will be authorised.</i>								
9429G	Injection set containing 4 vials powder for injection 25 mg and 4 pre-filled syringes solvent 1 mL	2	5	..	* 1828.57	32.90	Enbrel	WX
9430H	Injection set containing 4 vials powder for injection 50 mg and 4 pre-filled syringes solvent 1 mL	1	5	..	1773.94	32.90	Enbrel	WX
9431J	Injections 50 mg in 1 mL single use pre-filled syringes, 4	1	5	..	1773.94	32.90	Enbrel	WX

NOTE:

Special Pricing Arrangements apply.

• Interleukin inhibitors

ANAKINRA

NOTE:

Any queries concerning the arrangements to prescribe anakinra may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written applications for authority to prescribe anakinra should be forwarded to:

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.

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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
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NOTE:

TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying anti-rheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, etanercept, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-1 inhibitor (anakinra) and the T-cell co-stimulation modulator (abatacept).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

PBS-subsidised infliximab, anakinra, rituximab and abatacept must be used in combination with methotrexate at a dose of at least 7.5 mg weekly. Where a patient cannot tolerate 7.5 mg of methotrexate weekly, they are only eligible to receive PBS-subsidised etanercept and adalimumab.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.

From 1 March 2008, under the PBS, all patients will be able to commence a Treatment Cycle where they may trial PBS-subsidised bDMARD agents without having to experience a disease flare when swapping to an alternate agent. Under these interchangeability arrangements, within a single Treatment Cycle, a patient may continue to receive long-term treatment with a bDMARD while they continue to show a response to therapy.

A patient who received PBS-subsidised bDMARD treatment prior to 1 March 2008 is considered to be in their first Cycle as of 1 March 2008.

Within the same Treatment Cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a Treatment Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised bDMARD therapy before they are eligible to commence the next Cycle.

For patients who have failed PBS-subsidised treatment with 3 bDMARDs prior to 1 March 2008 please contact Medicare Australia on 1800 700 270.

The 5-year break is measured from the date of the last approval for PBS-subsidised bDMARD treatment in the most recent Cycle to the date of the first application for initial treatment with a bDMARD under the new Treatment Cycle.

A patient who has failed fewer than 3 bDMARDs in a Treatment Cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same Treatment Cycle.

A patient who has failed fewer than 3 bDMARDs in a Treatment Cycle and who has a break in therapy of more than 5 years, may commence a new Treatment Cycle.

There is no limit to the number of Treatment Cycles a patient may undertake in their lifetime.

If patients fail to respond to a particular bDMARD within a single Treatment Cycle, they are not eligible to receive further PBS-subsidised treatment with that drug until they commence the next Cycle.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 March 2008.

(a) Initial treatment.

Applications for initial treatment should be made where:

- (i) a patient has received no prior PBS-subsidised bDMARD treatment in this Treatment Cycle and wishes to commence such therapy, excluding rituximab (Initial 1); or
- (ii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
- (iii) a patient wishes to re-commence treatment with a specific bDMARD following a break in PBS-subsidised therapy with that agent (Initial 2).

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 \$	

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for etanercept, adalimumab, anakinra and abatacept, 22 weeks of therapy for infliximab and 2 infusions of rituximab.

From 1 March 2008, a patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to Medicare Australia within 4 weeks.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

Rituximab patients:

A further application may be submitted to Medicare Australia 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Rituximab patients:

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD within the same Treatment Cycle without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the same Treatment Cycle.

In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

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 \$	

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

NOTE:

(3) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a Treatment Cycle and Medicare Australia will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

The baseline joint and blood counts should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment.

(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent Treatment Cycle following a break in PBS-subsidised bDMARD therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have received treatment with at least 1 non-biological DMARD, at an adequate dose, for a minimum of 3 months at the time the ESR and/or CRP levels and the active joint count are measured.

(5) Patients 'grandfathered' onto PBS-subsidised treatment with rituximab or abatacept.

From 1 March 2008, a patient who commenced treatment with rituximab for severe rheumatoid arthritis prior to 7 March 2007 or abatacept for severe rheumatoid arthritis prior to 1 November 2007 and who was 'grandfathered' on to PBS-subsidised therapy, and who continues to receive treatment in the same Treatment Cycle, will have further applications for treatment with rituximab or abatacept assessed under the continuing treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment with abatacept will be authorised under this criterion.

'Grandfather' arrangements will only apply for the first Treatment Cycle. For the second and subsequent Cycles, a 'grandfather' patient must requalify for initial treatment under the criteria that applies to a new patient. See 'Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' above for further details.

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 \$	

Authority Required

Initial 1 (new patients)

Application for initial PBS-subsidised treatment with anakinra, in combination with methotrexate at a dose of at least 7.5 mg weekly, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of adults who:

- (a) have severe active rheumatoid arthritis; and*
- (b) have received no prior PBS-subsidised treatment with a bDMARD for this condition in this treatment cycle; and*
- (c) have failed to achieve an adequate response to the following treatments:*
 - (i) methotrexate at a dose of at least 20 mg weekly; and*
 - (ii) methotrexate (at a minimum dose of 7.5 mg weekly), in combination with 2 other non-biological disease modifying anti-rheumatic drugs (DMARDs), for a minimum of 3 months; and*
 - (iii) a minimum of 3 months' treatment with:*
 - leflunomide alone; or*
 - leflunomide in combination with methotrexate; or*
 - cyclosporin.*

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application.

Details of the accepted toxicities, including severity, can be found on the Medicare Australia website [www.medicareaustralia.gov.au].

The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L;

AND either

- (i) a total active joint count of at least 20 active (swollen and tender) joints; or*
- (ii) at least 4 active joints from the following list of major joints:*
 - elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or*
 - shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).*

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and*
- (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes details of the patient's ESR and CRP measurements and the patient's active joint count which must have been assessed no earlier than 1 month prior to the date of application; and*
- (3) a signed patient acknowledgement.*

A maximum of 16 weeks of treatment will be authorised under this restriction.

Where fewer than 3 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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 \$	

Assessment of a patient's response to an initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with anakinra.

Patients who fail to demonstrate a response to treatment with anakinra under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug, in this treatment cycle. Patients may re-trial anakinra after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised bDMARD was approved in this cycle and the date of the first application under the new cycle.

Authority Required

Initial 2 (change or re-commencement)

Application for an initial course of PBS-subsidised treatment with anakinra, in combination with methotrexate at a dose of at least 7.5 mg weekly, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of adults who:

- (a) have a documented history of severe active rheumatoid arthritis; and*
- (b) have received prior PBS-subsidised bDMARD treatment for this condition in this treatment cycle and are eligible to receive further bDMARD therapy.*

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and*
- (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].*

Applications for patients who have received PBS-subsidised treatment with anakinra within this treatment cycle and who wish to re-commence therapy with this drug within this same cycle, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised anakinra treatment, within the timeframes specified below.

A maximum of 16 weeks of treatment will be authorised under this restriction.

Where fewer than 3 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Where the most recent course of PBS-subsidised anakinra treatment was approved under either of the initial treatment restrictions (i.e. for patients with no prior PBS-subsidised bDMARD therapy or, under this restriction, for patients who have received previous PBS-subsidised bDMARD therapy), patients must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be provided to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised anakinra treatment was approved under the continuing treatment criteria, patients must have been assessed for response, and the assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Patients who fail to demonstrate a response to treatment with anakinra under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug, in this treatment cycle. Patients may re-trial anakinra after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised bDMARD was approved in this cycle and the date of the first application under the new cycle.

8773R	Injection 100 mg in 0.67 mL single use pre-filled syringe	28	3	..	1364.45	32.90	Kineret	AN

continued ➞

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 \$	

NOTE:

No applications for increased maximum quantities and/or repeats will be authorised.

Authority Required

Continuing treatment

Continuing PBS-subsidised treatment with anakinra, in combination with methotrexate at a dose of at least 7.5 mg weekly, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of adults:

- (a) who have a documented history of severe active rheumatoid arthritis; and
- (b) who have demonstrated an adequate response to treatment with anakinra; and
- (c) whose most recent course of PBS-subsidised bDMARD treatment in this treatment cycle was with anakinra.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

- (i) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
- (ii) a reduction in the number of the following major active joints, from at least 4, by at least 50%:
 - elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
 - shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].

A maximum of 24 weeks of treatment will be approved under this restriction.

Where fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

All applications for continuing treatment with anakinra must include a measurement of response to the prior course of therapy. This assessment must be provided to Medicare Australia no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with anakinra, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.

Patients who fail to demonstrate a response to treatment with anakinra under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug, in this treatment cycle. Patients may re-trial anakinra after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised bDMARD was approved in this cycle and the date of the first application under the new cycle.

8774T	Injection 100 mg in 0.67 mL single use pre-filled syringe	28	5	..	1364.45	32.90	Kineret	AN

NOTE:

No applications for increased maximum quantities and/or repeats will be authorised.

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 \$		
• Calcineurin inhibitors CYCLOSPORIN CAUTION: <i>Careful monitoring of patients is mandatory.</i> Authority Required <i>Maintenance therapy, following initiation and stabilisation of treatment with cyclosporin, of:</i> (a) <i>patients with organ or tissue transplants. Therapy must remain under the supervision and direction of the transplant unit reviewing the patient. The name of the specialised transplant unit reviewing treatment and the date of the latest review at the specialised transplant unit must be included in the authority application; or</i> (b) <i>patients with severe atopic dermatitis for whom other systemic therapies are ineffective or inappropriate. Therapy must remain under the supervision and direction of a dermatologist, clinical immunologist or specialised unit reviewing the patient. The name of the dermatologist, clinical immunologist or specialised unit reviewing treatment and the date of the latest review must be included in the authority application; or</i> (c) <i>patients with severe psoriasis for whom other systemic therapies are ineffective or inappropriate and in whom the disease has caused significant interference with quality of life. Therapy must remain under the supervision and direction of a dermatologist or specialised unit reviewing the patient. The name of the dermatologist or specialised unit reviewing treatment and the date of the latest review must be included in the authority application; or</i> (d) <i>patients with nephrotic syndrome in whom steroids and cytostatic drugs have failed or are not tolerated or are considered inappropriate and in whom renal function is unimpaired. Therapy must remain under the supervision and direction of a nephrologist or specialised unit reviewing the patient. The name of the nephrologist or specialised unit reviewing treatment and the date of the latest review must be included in the authority application; or</i> (e) <i>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> (a) <i>dermatologists or clinical immunologists of patients with severe atopic dermatitis for whom other systemic therapies are ineffective or inappropriate; or</i> (b) <i>dermatologists of patients with severe psoriasis for whom other systemic therapies are ineffective or inappropriate and in whom the disease has caused significant interference with quality of life; or</i> (c) <i>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	..	* 93.99	32.90	Neoral 10	NV
8658Q	Capsule 25 mg	60	3	..	* 102.49	32.90	^a Cicloral	SZ
				b2.28	* 104.77	32.90	^a Neoral 25	NV
8659R	Capsule 50 mg	60	3	..	* 206.51	32.90	^a Cicloral	SZ
				b2.24	* 208.75	32.90	^a Neoral 50	NV
8660T	Capsule 100 mg	60	3	..	* 395.87	32.90	^a Cicloral	SZ
				b2.26	* 398.13	32.90	^a Neoral 100	NV
8661W	Oral liquid 100 mg per mL, 50 mL	2	3	..	* 712.23	32.90	Neoral	NV

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, 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.</i>								
8646C	Capsule 500 micrograms	100	3	..	225.42	32.90	Prograf	JC
8647D	Capsule 1 mg	100	3	..	426.84	32.90	Prograf	JC
8648E	Capsule 5 mg	50	3	..	1052.87	32.90	Prograf	JC
• Other immunosuppressants								
AZATHIOPRINE								
2688L	Tablet 25 mg	100	2	..	36.75	32.90	a Azahexal a Imuran	SZ AS
2687K	Tablet 50 mg	100	2	..	56.07	32.90	a Azahexal a Azamun a Azapin a GenRx Azathioprine a Imuran a Thioprine	SZ GM SI GX AS AF
METHOTREXATE								
1622J	Tablet 2.5 mg	30	5	..	13.11	14.14	a Methoblastin a HH	PH
2272N	Tablet 10 mg	15	1	..	22.37	23.40	Methoblastin	PH

METHOTREXATE

Restricted Benefit

For patients requiring doses greater than 20 mg per week.

1623K	Tablet 10 mg	50	2	..	47.00	32.90	Methoblastin	PH

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								
• Acetic acid derivatives and related substances								
DICLOFENAC SODIUM								
1302M	Suppository 100 mg	40	3	..	* 24.49	25.52	Voltaren 100	NV
DICLOFENAC SODIUM								
<u>Restricted Benefit</u>								
<i>Chronic arthropathies (including osteoarthritis) with an inflammatory component;</i>								
<i>Bone pain due to malignant disease.</i>								
1299J	Tablet 25 mg (enteric coated)	100	3	..	* 12.63	13.66	^a Chem mart Diclofenac	CH
							^a Clonac 25	AW
							^a Diclofenac-GA	GN
							^a Diclohexal	SZ
							^a Dinac	GM
							^a GenRx Diclofenac	GX
							^a Terry White Chemists Diclofenac	TW
				..	12.64	13.67	^a Fenac 25	AF
				B1.96	* 14.59	13.66	^a Voltaren 25	NV
1300K	Tablet 50 mg (enteric coated)	50	3	..	10.62	11.65	^a Chem mart Diclofenac	CH
							^a Clonac 50	AW
							^a Diclohexal	SZ
							^a Dinac	GM
							^a Fenac	AF
							^a GenRx Diclofenac	GX
							^a Terry White Chemists Diclofenac	TW
				B1.96	12.58	11.65	^a Voltaren 50	NV
INDOMETHACIN								
2757D	Suppository 100 mg	40	3	..	* 22.07	23.10	Indocid	AS

continued ➞

MUSCULO-SKELETAL SYSTEM—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Proprietary Name and Manufacturer	
INDOMETHACIN								
<u>Restricted Benefit</u>								
<i>Chronic arthropathies (including osteoarthritis) with an inflammatory component;</i>								
<i>Bone pain due to malignant disease.</i>								
2454E	Capsule 25 mg	100	3	..	* 11.65	12.68	^a Arthrexin	AF
				B0.92	* 12.57	12.68	^a Indocid	AS
SULINDAC								
<u>Restricted Benefit</u>								
<i>Chronic arthropathies (including osteoarthritis) with an inflammatory component;</i>								
<i>Bone pain due to malignant disease.</i>								
2047R	Tablet 100 mg	100	3	..	* 15.91	16.94	Aclin	AF
2048T	Tablet 200 mg	50	3	..	14.85	15.88	Aclin 200	AF
• Oxicams								
MELOXICAM								
<u>NOTE:</u>								
<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>								
<u>Restricted Benefit</u>								
<i>Symptomatic treatment of osteoarthritis;</i>								
<i>Symptomatic treatment of rheumatoid arthritis.</i>								
8561N	Tablet 7.5 mg	30	3	..	21.68	22.71	^a Chem mart	CH
							Meloxicam	
							7.5 mg	
							^a GenRx Meloxicam	GX
							^a Meloxibell	BF
							^a Meloxicam-GA	GM
							^a Meloxicam	RA
							Ranbaxy	
							^a Meloxicam Sandoz	SZ
							^a Meloxicam	WA
							Winthrop	
							^a Movalis 7.5	SI
							^a Moxicam 7.5	AF
							^a Pharmacor	CR
							Meloxicam 7.5	
							^a Terry White	TW
							Chemists	
							Meloxicam	
							7.5 mg	
				B1.61	23.29	22.71	^a Mobic	BY

continued ➞

MUSCULO-SKELETAL SYSTEM—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Proprietary Name and Manufacturer	
8562P	Tablet 15 mg	30	3	..	28.86	29.89	^a Chem mart Meloxicam 15 mg	CH
							^a GenRx Meloxicam	GX
							^a Meloxicbell	BF
							^a Meloxicam-GA	GM
							^a Meloxicam Ranbaxy	RA
							^a Meloxicam Sandoz	SZ
							^a Meloxicam Winthrop	WA
							^a Movalis 15	SI
							^a Moxicam 15	AF
							^a Pharmacor Meloxicam 15	CR
							^a Terry White Chemists Meloxicam 15 mg	TW
				B1.63	30.49	29.89	^a Mobic	BY
8887R	Capsule 7.5 mg	30	3	..	21.68	22.71	^a Mobic	BY
							^a Movalis 7.5	SI
8888T	Capsule 15 mg	30	3	..	28.86	29.89	^a Mobic	BY
							^a Movalis 15	SI

PIROXICAM

Restricted Benefit

Chronic arthropathies (including osteoarthritis) with an inflammatory component.

1895R	Dispersible tablet 10 mg	50	3	..	12.07	13.10	Mobilis D-10	AF
1896T	Dispersible tablet 20 mg	25	3	..	11.77	12.80	^a Mobilis D-20	AF
				B2.64	14.41	12.80	^a Feldene-D	PF
1897W	Capsule 10 mg	50	3	..	12.07	13.10	^a Chem mart Piroxicam	CH
							^a GenRx Piroxicam	GX
							^a Mobilis 10	AF
							^a Terry White Chemists Piroxicam	TW
				B2.66	14.73	13.10	^a Feldene	PF

continued ➞

MUSCULO-SKELETAL SYSTEM—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Proprietary Name and Manufacturer	
1898X	Capsule 20 mg	25	3	..	11.77	12.80	^a Chem mart Piroxicam	CH
							^a GenRx Piroxicam	GX
							^a Mobilis 20	AF
							^a Terry White Chemists Piroxicam	TW
				B2.64	14.41	12.80	^a Feldene	PF
• Propionic acid derivatives								
IBUPROFEN								
3192B	Tablet 400 mg	30	..	..	8.76	9.79	Brufen	AB
IBUPROFEN								
<u>Restricted Benefit</u>								
<i>Chronic arthropathies (including osteoarthritis) with an inflammatory component; Bone pain due to malignant disease.</i>								
3198H	Tablet 200 mg	100	3	..	* 11.63	12.66	Rafen 200	AF
3190X	Tablet 400 mg	90	3	..	* 14.30	15.33	Brufen	AB
KETOPROFEN								
1588N	Suppository 100 mg	40	3	..	* 24.87	25.90	Orudis	SW
KETOPROFEN								
<u>Restricted Benefit</u>								
<i>Chronic arthropathies (including osteoarthritis) with an inflammatory component.</i>								
1590Q	Capsule 200 mg (sustained release)	28	3	..	19.47	20.50	^a Oruvail SR	AV
				B2.30	21.77	20.50	^a Orudis SR 200	SW
NAPROXEN								
<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	..	* 13.29	14.32	^a Inza 250	AF
				B2.34	* 15.63	14.32	^a Naprosyn	RO
1659H	Tablet 500 mg	50	3	..	12.48	13.51	^a Inza 500	AF
				B1.36	13.84	13.51	^a Naprosyn	RO

continued ➞

MUSCULO-SKELETAL SYSTEM—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Proprietary Name and Manufacturer	
1614Y	Tablet 750 mg (sustained release)	28	3	..	11.95	12.98	^a Proxen SR 750	MD
				B1.27	13.22	12.98	^a Naprosyn SR750	RO
1615B	Tablet 1 g (sustained release)	28	3	..	13.94	14.97	^a Proxen SR 1000	MD
				B1.34	15.28	14.97	^a Naprosyn SR1000	RO

Authority Required (STREAMLINED)

2270

Chronic arthropathies (including osteoarthritis) with an inflammatory component in patients unable to take a solid dose form of a non-steroidal anti-inflammatory agent;

2271

Bone pain due to malignant disease in patients unable to take a solid dose form of a non-steroidal anti-inflammatory agent.

1658G	Oral suspension 125 mg per 5 mL, 474 mL	± 1	3	..	77.74	32.90	Naprosyn	RO

NAPROXEN SODIUM

Restricted Benefit

Chronic arthropathies (including osteoarthritis) with an inflammatory component;

Bone pain due to malignant disease.

1795L	Tablet 550 mg	50	3	..	12.67	13.70	^a Crysanal	MD
				B2.29	14.96	13.70	^a Anaprox 550	RO

NOTE:

Naproxen sodium 550 mg is approximately equivalent to 500 mg of naproxen acid.

TIAPROFENIC ACID

CAUTION:

Cystitis and other urinary disorders have been reported with this drug.

NOTE:

The recommended maximum dose is 600 mg per day.

Restricted Benefit

Chronic arthropathies (including osteoarthritis) with an inflammatory component.

2103Q	Tablet 300 mg	60	3	..	17.15	18.18	Surgam	SW

• Fenamates

MEFENAMIC ACID

Restricted Benefit

Dysmenorrhoea;

Menorrhagia.

1824B	Capsule 250 mg	50	2	..	17.73	18.76	Ponstan	PD

Code	Name, Restriction, Manner of 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	..	31.88	32.90	Celebrex	PH
8440F	Capsule 200 mg	30	3	..	31.88	32.90	Celebrex	PH
Specific antirheumatic agents • Quinolines HYDROXYCHLOROQUINE SULFATE								
1512N	Tablet 200 mg	100	1	..	37.16	32.90	Plaquenil	SW
• Gold preparations AURANOFIN CAUTION: Regular blood and urine checks are essential.								
1095P	Tablet 3 mg	60	5	..	63.12	32.90	Ridaura	GH
SODIUM AUROTHIOMALATE CAUTION: Regular blood and urine checks are essential.								
2016D	Injection 10 mg	10	..	..	52.87	32.90	Myocrisin	SW
2017E	Injection 20 mg	10	1	..	80.03	32.90	Myocrisin	SW
2018F	Injection 50 mg	10	1	..	124.36	32.90	Myocrisin	SW
• Penicillamine and similar agents PENICILLAMINE CAUTION: Regular blood and urine checks are essential.								
2721F	Tablet 125 mg	100	1	..	31.20	32.23	D-Penamine	AL
2838J	Tablet 250 mg	100	1	..	43.08	32.90	D-Penamine	AL
• Other specific antirheumatic agents LEFLUNOMIDE <i>For listings see Generic/Proprietary Index</i>								

MUSCULO-SKELETAL SYSTEM—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Proprietary Name and Manufacturer	
MUSCLE RELAXANTS								
Muscle relaxants, centrally acting agents								
• Other centrally acting agents								
BACLOFEN								
2729P	Tablet 10 mg	100	5	..	31.65	32.68	a Baclo a Chem mart Baclofen a Clofen 10 a GenRx Baclofen a Stelax 10 a Terry White Chemists Baclofen	GM CH AF GX SI TW
				b2.26	33.91	32.68	a Lioresal 10	NV
2730Q	Tablet 25 mg	100	5	..	59.66	32.90	a Baclo a Chem mart Baclofen a Clofen 25 a GenRx Baclofen a Stelax 25 a Terry White Chemists Baclofen	GM CH AF GX SI TW
				b2.18	61.84	32.90	a Lioresal 25	NV
Muscle relaxants, directly acting agents								
• Dantrolene and derivatives								
DANTROLENE SODIUM								
<u>Restricted Benefit</u>								
<i>Treatment of chronic spasticity.</i>								
1779P	Capsule 25 mg	100	2	..	59.05	32.90	Dantrium	PU
1780Q	Capsule 50 mg	100	2	..	66.99	32.90	Dantrium	PU

MUSCULO-SKELETAL SYSTEM—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Proprietary Name and Manufacturer
ANTIGOUT PREPARATIONS							
Antigout preparations							
• Preparations inhibiting uric acid production							
ALLOPURINOL							
NOTE:							
The dose should be adjusted in accordance with renal function.							
2600W	Tablet 100 mg	200	2	..	12.76	13.79	a Allohexal SZ a Allosig FM a Chem mart CH Allopurinol a GenRx Allopurinol GX a Terry White TW Chemists Allopurinol .. * 12.77 13.80 a Progout 100 AF b1.91 14.67 13.79 a Zyloprim SI
2604C	Tablet 300 mg	60	2	..	9.99	11.02	a Allohexal SZ a Allosig FM a Chem mart CH Allopurinol a GenRx Allopurinol GX a Progout 300 AF a Terry White TW Chemists Allopurinol b1.80 11.79 11.02 a Zyloprim SI
• Preparations increasing uric acid excretion							
PROBENECID							
1940D	Tablet 500 mg	100	5	..	75.26	32.90	Pro-Cid PL
• Preparations with no effect on uric acid metabolism							
COLCHICINE							
1227N	Tablet 500 micrograms	100	2	..	10.91	11.94	a Lengout LN b0.91 11.82 11.94 a Colgout AS

MUSCULO-SKELETAL SYSTEM—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed	Maximum	Proprietary Name and Manufacturer
					Price for Max. Qty \$	Recordable Value for Safety Net \$	
DRUGS FOR TREATMENT OF BONE DISEASES							
Drugs affecting bone structure and mineralization							
• Bisphosphonates							
ALENDRONATE SODIUM							
Authority Required (STREAMLINED)							
2645							
Treatment as the sole PBS-subsidised anti-resorptive agent for osteoporosis in a patient aged 70 years of age or older with a Bone Mineral Density (BMD) T-score of -3.0 or less.							
The date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.							
Authority Required (STREAMLINED)							
2646							
Treatment as the sole PBS-subsidised anti-resorptive agent for established osteoporosis in patients with fracture due to minimal trauma. The fracture must have been demonstrated radiologically and the year of plain x-ray or CT-scan or MRI scan must be documented in the patient's medical records when treatment is initiated.							
A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.							
NOTE:							
Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, disodium etidronate, raloxifene hydrochloride, strontium ranelate and zoledronic acid.							
8511Y	Tablet equivalent to 70 mg alendronic acid	4	5	..	46.87	32.90	a Adronat AF a Alendrobell 70mg BF a Alendronate-GA GM a Alendronate SZ Sandoz a Alendro Once SI Weekly a APO-Alendronate TX a Chem mart CH Alendronate 70mg a Ossmax 70mg RA a Terry White TW Chemists Alendronate 70mg B1.42 48.29 32.90 a Fosamax Once MK Weekly

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	
<u>Authority Required (STREAMLINED)</u>								
1392 <i>Symptomatic Paget's disease of bone.</i>								
8090T	Tablet equivalent to 40 mg alendronic acid	30	5	..	138.14	32.90	Fosamax 40 mg	MK
DISODIUM ETIDRONATE								
<u>Authority Required (STREAMLINED)</u>								
1849 <i>Symptomatic Paget's disease of bone when calcitonin has been found to be unsatisfactory due to lack of efficacy;</i>								
1850 <i>Symptomatic Paget's disease of bone when calcitonin has been found to be unsatisfactory due to unacceptable side effects;</i>								
1153 <i>Heterotopic ossification.</i>								
2920Q	Tablet 200 mg	60	5	..	114.74	32.90	Didronel	PU
DISODIUM PAMIDRONATE								
<u>Authority Required (STREAMLINED)</u>								
1392 <i>Symptomatic Paget's disease of bone.</i>								
8461H	Concentrated injection 15 mg in 5 mL	4	..	..	* 263.79	32.90	^a Pamisol	HH
8208B	Injection set containing 4 vials powder for I.V. infusion 15 mg and 4 ampoules solvent 5 mL	1	..	..	263.78	32.90	^a Aredia 15 mg	NV
<u>NOTE:</u> <i>The concentrated injection 15 mg and powder for I.V. infusion 15 mg (after reconstitution) are bioequivalent.</i>								
8462J	Concentrated injection 30 mg in 10 mL	2	..	..	* 263.79	32.90	^a Pamisol	HH
8209C	Injection set containing 2 vials powder for I.V. infusion 30 mg and 2 ampoules solvent 10 mL	1	..	..	263.78	32.90	^a Aredia 30 mg	NV
<u>NOTE:</u> <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	..	..	263.78	32.90	Pamisol	HH
IBANDRONIC ACID								
<u>Restricted Benefit</u> <i>Bone metastases from breast cancer.</i>								
9357L	Tablet 50 mg (as ibandronate sodium monohydrate)	28	2	..	341.91	32.90	Bondronat	HH

MUSCULO-SKELETAL SYSTEM—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed	Maximum	Proprietary Name and Manufacturer
					Price for Max. Qty \$	Recordable Value for Safety Net \$	

RISEDRONATE SODIUM

Authority Required (STREAMLINED)

3070

Treatment as the sole PBS-subsidised anti-resorptive agent for corticosteroid-induced osteoporosis in a patient currently on long-term (at least 3 months), high-dose (at least 7.5 mg per day prednisolone or equivalent) corticosteroid therapy with a Bone Mineral Density (BMD) T-score of -1.5 or less.

The duration and dose of corticosteroid therapy together with the date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

Authority Required (STREAMLINED)

2645

Treatment as the sole PBS-subsidised anti-resorptive agent for osteoporosis in a patient aged 70 years of age or older with a Bone Mineral Density (BMD) T-score of -3.0 or less.

The date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

Authority Required (STREAMLINED)

2646

Treatment as the sole PBS-subsidised anti-resorptive agent for established osteoporosis in patients with fracture due to minimal trauma. The fracture must have been demonstrated radiologically and the year of plain x-ray or CT-scan or MRI scan must be documented in the patient's medical records when treatment is initiated.

A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

NOTE:

Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, disodium etidronate, raloxifene hydrochloride, strontium ranelate and zoledronic acid.

8481J	Tablet 5 mg	28	5	..	52.91	32.90	Actonel	SW
8621R	Tablet 35 mg	4	5	..	52.91	32.90	Actonel Once-a-Week	SW

Authority Required (STREAMLINED)

1392

Symptomatic Paget's disease of bone.

8482K	Tablet 30 mg	28	1	..	304.19	32.90	Actonel	SW

SODIUM CLODRONATE TETRAHYDRATE

Restricted Benefit

Maintenance treatment of hypercalcaemia of malignancy refractory to anti-neoplastic therapy;

Multiple myeloma;

Bone metastases from breast cancer.

8132B	Capsule equivalent to 400 mg sodium clodronate	100	2	..	333.65	32.90	Bonefos	SC

continued ➡

MUSCULO-SKELETAL SYSTEM—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Proprietary Name and Manufacturer	
8265B	Tablet equivalent to 800 mg sodium clodronate	60	2	..	391.01	32.90	Bonefos 800 mg	SC
TILUDRONATE DISODIUM								
Authority Required (STREAMLINED)								
1392								
Symptomatic Paget's disease of bone.								
8267D	Tablet equivalent to 200 mg tiludronic acid	56	2	..	304.19	32.90	Skelid	HH
ZOLEDRONIC ACID								
Authority Required								
Treatment as the sole PBS-subsidised anti-resorptive agent for osteoporosis in women aged 70 years of age or older with a Bone Mineral Density (BMD) T-score of -3.0 or less.								
The date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.								
Only 1 treatment each year for 3 years per patient in a lifetime will be PBS-subsidised.								
Authority Required								
Treatment as the sole PBS-subsidised anti-resorptive agent for established osteoporosis in women with fracture due to minimal trauma.								
A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.								
In all cases, the fracture must have been demonstrated radiologically and the year of plain x-ray or CT-scan or MRI scan must be documented in the patient's medical records when treatment is initiated.								
Only 1 treatment each year for 3 years per patient in a lifetime will be PBS-subsidised;								
Treatment as the sole PBS-subsidised anti-resorptive agent for established osteoporosis in men with hip fracture due to minimal trauma.								
In all cases, the fracture must have been demonstrated radiologically and the year of plain x-ray or CT-scan or MRI scan must be documented in the patient's medical records when treatment is initiated.								
Only 1 treatment each year for 3 years per patient in a lifetime will be PBS-subsidised.								
NOTE:								
Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, disodium etidronate, raloxifene hydrochloride, strontium ranelate and zoledronic acid.								
9288W	Solution for I.V. infusion 5 mg (as monohydrate) in 100 mL	1	..	..	559.36	32.90	Aclasta	NV

MUSCULO-SKELETAL SYSTEM—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed	Maximum	Proprietary Name and Manufacturer
					Price for Max. Qty \$	Recordable Value for Safety Net \$	

• **Bisphosphonates, combinations**

ALENDRONATE SODIUM with COLECALCIFEROL

Authority Required (STREAMLINED)

2645

Treatment as the sole PBS-subsidised anti-resorptive agent for osteoporosis in a patient aged 70 years of age or older with a Bone Mineral Density (BMD) T-score of -3.0 or less.

The date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

Authority Required (STREAMLINED)

2646

Treatment as the sole PBS-subsidised anti-resorptive agent for established osteoporosis in patients with fracture due to minimal trauma. The fracture must have been demonstrated radiologically and the year of plain x-ray or CT-scan or MRI scan must be documented in the patient's medical records when treatment is initiated.

A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

NOTE:

Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, disodium etidronate, raloxifene hydrochloride, strontium ranelate and zoledronic acid.

9012H	Tablet equivalent to 70 mg alendronic acid with 70 micrograms colecalciferol	4	5	..	46.87	32.90	Fosamax Plus	MK

NOTE:

Fosamax Plus provides a supplemental intake of vitamin D. The amount of colecalciferol present in Fosamax Plus is not sufficient to use as the sole treatment for correction of vitamin D deficiency.

9183H	Tablet equivalent to 70 mg alendronic acid with 140 micrograms colecalciferol	4	5	..	46.87	32.90	Fosamax Plus 70 mg/140 mcg	MK

MUSCULO-SKELETAL SYSTEM—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed	Maximum	Proprietary Name and Manufacturer
					Price for Max. Qty \$	Recordable Value for Safety Net \$	

DISODIUM ETIDRONATE and CALCIUM CARBONATE

Authority Required (STREAMLINED)

2646

Treatment as the sole PBS-subsidised anti-resorptive agent for established osteoporosis in patients with fracture due to minimal trauma. The fracture must have been demonstrated radiologically and the year of plain x-ray or CT-scan or MRI scan must be documented in the patient's medical records when treatment is initiated. A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

NOTE:

Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, disodium etidronate, raloxifene hydrochloride, strontium ranelate and zoledronic acid.

8056B	Pack containing 28 tablets disodium etidronate 200 mg and 76 tablets calcium carbonate 1.25 g (equivalent to 500 mg calcium)	± 1	1	..	70.26	32.90	Didrocal	PU

NOTE:

No applications for increased maximum quantities and/or repeats will be authorised.

MUSCULO-SKELETAL SYSTEM—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed	Maximum	Proprietary Name and Manufacturer
					Price for Max. Qty \$	Recordable Value for Safety Net \$	
RISEDRONATE SODIUM and CALCIUM CARBONATE							
Authority Required (STREAMLINED)							
3070							
Treatment as the sole PBS-subsidised anti-resorptive agent for corticosteroid-induced osteoporosis in a patient currently on long-term (at least 3 months), high-dose (at least 7.5 mg per day prednisolone or equivalent) corticosteroid therapy with a Bone Mineral Density (BMD) T-score of -1.5 or less.							
The duration and dose of corticosteroid therapy together with the date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.							
Authority Required (STREAMLINED)							
2645							
Treatment as the sole PBS-subsidised anti-resorptive agent for osteoporosis in a patient aged 70 years of age or older with a Bone Mineral Density (BMD) T-score of -3.0 or less.							
The date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.							
Authority Required (STREAMLINED)							
2646							
Treatment as the sole PBS-subsidised anti-resorptive agent for established osteoporosis in patients with fracture due to minimal trauma. The fracture must have been demonstrated radiologically and the year of plain x-ray or CT-scan or MRI scan must be documented in the patient's medical records when treatment is initiated.							
A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.							
NOTE:							
Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, disodium etidronate, raloxifene hydrochloride, strontium ranelate and zoledronic acid.							
8899J	Pack containing 4 tablets risedronate sodium 35 mg and 24 tablets calcium carbonate 1.25 g (equivalent to 500 mg calcium)	± 1	5	..	52.91	32.90	Actonel Combi SW

MUSCULO-SKELETAL SYSTEM—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 \$	

RISEDRONATE SODIUM and CALCIUM CARBONATE with COLECALCIFEROL

Authority Required (STREAMLINED)

3070

Treatment as the sole PBS-subsidised anti-resorptive agent for corticosteroid-induced osteoporosis in a patient currently on long-term (at least 3 months), high-dose (at least 7.5 mg per day prednisolone or equivalent) corticosteroid therapy with a Bone Mineral Density (BMD) T-score of -1.5 or less.

The duration and dose of corticosteroid therapy together with the date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

Authority Required (STREAMLINED)

2645

Treatment as the sole PBS-subsidised anti-resorptive agent for osteoporosis in a patient aged 70 years of age or older with a Bone Mineral Density (BMD) T-score of -3.0 or less.

The date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

Authority Required (STREAMLINED)

2646

Treatment as the sole PBS-subsidised anti-resorptive agent for established osteoporosis in patients with fracture due to minimal trauma. The fracture must have been demonstrated radiologically and the year of plain x-ray or CT-scan or MRI scan must be documented in the patient's medical records when treatment is initiated.

A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

NOTE:

Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, disodium etidronate, raloxifene hydrochloride, strontium ranelate and zoledronic acid.

9147K	Pack containing 4 tablets risedronate sodium 35 mg and 24 sachets containing granules of calcium carbonate 2.5 g (equivalent to 1 g calcium) with colecalciferol 22 micrograms	£ 1	5	..	52.91	32.90	Actonel Combi D	SW

MUSCULO-SKELETAL SYSTEM—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed	Maximum	Proprietary Name and Manufacturer
					Price for Max. Qty \$	Recordable Value for Safety Net \$	
• Other drugs affecting bone structure and mineralization							
CALCITRIOL							
<u>Authority Required (STREAMLINED)</u>							
	1165						
	<i>Hypocalcaemia due to renal disease;</i>						
	1166						
	<i>Hypoparathyroidism;</i>						
	1167						
	<i>Hypophosphataemic rickets;</i>						
	1467						
	<i>Vitamin D-resistant rickets;</i>						
	2636						
	<i>Treatment for established osteoporosis in patients with fracture due to minimal trauma. The fracture must have been demonstrated radiologically and the year of plain x-ray or CT-scan or MRI scan must be documented in the patient's medical records when treatment is initiated.</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>						
2502Q	Capsule 0.25 microgram	100	3	..	42.82	32.90	^a Calcitriol-DP GM
							^a Citrihexal SZ
							^a GenRx Calcitriol GX
							^a Kosteo SI
							^a Rocaltrol RO
							^a Sical AF

RALOXIFENE HYDROCHLORIDE

Authority Required (STREAMLINED)

2647

Treatment as the sole PBS-subsidised anti-resorptive agent for established post-menopausal osteoporosis in patients with fracture due to minimal trauma. The fracture must have been demonstrated radiologically and the year of plain x-ray or CT-scan or MRI scan must be documented in the patient's medical records when treatment is initiated.

A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

NOTE:

Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, disodium etidronate, raloxifene hydrochloride, strontium ranelate and zoledronic acid.

8363E	Tablet 60 mg	28	5	..	57.44	32.90	Evista	LY

MUSCULO-SKELETAL SYSTEM—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed	Maximum	Proprietary Name and Manufacturer
					Price for Max. Qty \$	Recordable Value for Safety Net \$	

STRONTIUM RANELATE

Authority Required (STREAMLINED)

2758

Treatment as the sole PBS-subsidised anti-resorptive agent for osteoporosis in a woman aged 70 years or older with a bone mineral density (BMD) T-score of -3.0 or less.

The date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

Authority Required (STREAMLINED)

2647

Treatment as the sole PBS-subsidised anti-resorptive agent for established post-menopausal osteoporosis in patients with fracture due to minimal trauma. The fracture must have been demonstrated radiologically and the year of plain x-ray or CT-scan or MRI scan must be documented in the patient's medical records when treatment is initiated.

A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

NOTE:

Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, disodium etidronate, raloxifene hydrochloride, strontium ranelate and zoledronic acid.

3036T	Sachet containing granules for oral suspension 2 g	28	5	..	52.91	32.90	Protos 2 g	SE

TERIPARATIDE

NOTE:

Any queries concerning the arrangements to prescribe teriparatide 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 teriparatide 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.

Authority Required

Initial treatment, as the sole PBS-subsidised agent, by a specialist or consultant physician, for severe, established osteoporosis in a patient with a very high risk of fracture who:

(a) has a bone mineral density (BMD) T-score of -3.0 or less; and

(b) has had 2 or more fractures due to minimal trauma; and

(c) has experienced at least 1 symptomatic new fracture after at least 12 months continuous therapy with an anti-resorptive agent at adequate doses.

A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

If treatment with anti-resorptive therapy is contraindicated according to the relevant TGA-approved Product Information, details of the contraindication must be provided at the time of application.

continued ➞

MUSCULO-SKELETAL SYSTEM—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 \$	

If an intolerance of a severity necessitating permanent treatment withdrawal develops during the relevant period of use of one anti-resorptive agent, alternate anti-resorptive agents must be trialled so that the patient achieves the minimum requirement of 12 months continuous therapy. Details of accepted toxicities including severity can be found on the Medicare Australia website at www.medicareaustralia.gov.au and must be provided at the time of application.

Anti-resorptive therapies for osteoporosis and their adequate doses which will be accepted for the purposes of administering this restriction are alendronate sodium 10 mg per day or 70 mg once weekly, risedronate sodium 5 mg per day or 35 mg once weekly, raloxifene hydrochloride 60 mg per day (women only), etidronate 200 mg with calcium carbonate 1.25 g per day, strontium ranelate 2 g per day and zoledronic acid 5 mg per annum.

Authority applications must be made in writing and must include:

Details of prior anti-resorptive therapy, fracture history including the date(s), site(s), the symptoms associated with the fracture(s) which developed during the course of anti-resorptive therapy and the score of the qualifying BMD measurement.

NOTE:

No applications for increased maximum quantities and/or repeats will be authorised.

Authority Required

Initial treatment, as the sole PBS-subsidised agent, by a specialist or consultant physician, for severe, established osteoporosis in a patient with a very high risk of fracture who was receiving treatment with teriparatide prior to 1 May 2009.

The authority application must be made in writing and the commencement date of treatment and the number of doses the patient has received of teriparatide must be provided with the application. The patient is eligible to receive a maximum of 18 months therapy of combined PBS-subsidised and non-PBS-subsidised therapy.

Patients may qualify for PBS-subsidised treatment under this restriction once only.

NOTE:

No applications for increased maximum quantities and/or repeats will be authorised.

Authority Required

Continuing treatment for severe established osteoporosis where the patient has previously been issued with an authority prescription for this drug.

Teriparatide must only be used for a lifetime maximum of 18 months therapy (18 pens). Up to a maximum of 18 pens will be reimbursed through the PBS.

Authority applications for continuing treatment may be made by telephone to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

NOTE:

No applications for increased maximum quantities and/or repeats will be authorised.

9411H	Injection 250 micrograms per mL, 3 mL in multi-dose pre-filled pen	1	5	..	437.94	32.90	Forteo	LY

NOTE:

Special Pricing Arrangements apply.

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	..	..	16.44	17.47	FM

CODEINE PHOSPHATE with PARACETAMOL

1215Y	Tablet 30 mg-500 mg	20	..	..	7.65	8.68	a Codalgin Forte	FM
							a Codapane Forte	AL
							a Comfarol Forte	SZ
							a Dolaforte	CO
							a Prodeine Forte	AV
				B2.80	10.45	8.68	a Panadeine Forte	SW

NOTE:

Authorities for increased maximum quantities and/or repeats will not be granted except as detailed under the 'Authority required' listing of codeine phosphate with paracetamol below.

CODEINE PHOSPHATE with PARACETAMOL

Authority Required

Severe disabling pain not responding to non-narcotic analgesics.

NOTE:

Each authority approval will be limited to no more than 240 tablets per month for no more than 6 months.

8785J	Tablet 30 mg-500 mg	60	..	..	* 10.97	12.00	a Codalgin Forte	FM
							a Codapane Forte	AL
							a Comfarol Forte	SZ
							a Dolaforte	CO
							a Prodeine Forte	AV
				B8.40	* 19.37	12.00	a Panadeine Forte	SW

HYDROMORPHONE HYDROCHLORIDE

CAUTION:

The risk of drug dependence is high.

8420E	Injection 2 mg in 1 mL	5	..	..	13.51	14.54	Dilaudid	MF
8421F	Injection 10 mg in 1 mL	5	..	..	18.87	19.90	Dilaudid-HP	MF
8422G	Injection 50 mg in 5 mL	5	..	..	47.07	32.90	Dilaudid-HP	MF
8423H	Injection 500 mg in 50 mL	1	..	..	74.98	32.90	Dilaudid-HP	MF

continued ➡

NERVOUS SYSTEM—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 \$	
HYDROMORPHONE HYDROCHLORIDE							
CAUTION:							
<i>The risk of drug dependence is high.</i>							
<u>Restricted Benefit</u>							
<i>Chronic severe disabling pain not responding to non-narcotic analgesics.</i>							
<u>NOTE:</u>							
<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>							
9406C	Tablet 8 mg (modified release)	10	..	..	28.18	29.21	Jurnista JC
9407D	Tablet 16 mg (modified release)	10	..	..	40.89	32.90	Jurnista JC
9408E	Tablet 32 mg (modified release)	10	..	..	65.54	32.90	Jurnista JC
9409F	Tablet 64 mg (modified release)	10	..	..	108.88	32.90	Jurnista JC

Restricted Benefit*Severe disabling pain not responding to non-narcotic analgesics.***NOTE:***Authorities for increased maximum quantities and/or repeats will be granted only for:**(i) severe disabling pain associated with proven malignant neoplasia; or**(ii) chronic severe disabling pain not responding to non-narcotic analgesics where the total duration of narcotic analgesic treatment is less than 12 months; or**(iii) first application for treatment beyond 12 months of chronic severe disabling pain not responding to non-narcotic analgesics where the patient's pain management has been reviewed through consultation by the patient with another medical practitioner, and the clinical need for continuing narcotic analgesic treatment has been confirmed. The date of the consultation must be no more than 3 months prior to the application for a PBS authority. The full name of the medical practitioner consulted and the date of consultation are to be provided at the time of application; or**(iv) subsequent application for treatment of chronic severe disabling pain not responding to non-narcotic analgesics where a PBS authority prescription for treatment beyond 12 months has previously been issued for this patient.*

8541M	Tablet 2 mg	20	..	..	13.79	14.82	Dilaudid	MF
8542N	Tablet 4 mg	20	..	..	18.85	19.88	Dilaudid	MF

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	
8543P	Tablet 8 mg	20	..	..	28.61	29.64	Dilaudid	MF
8424J	Oral liquid 1 mg per mL, 473 mL	1	..	..	49.09	32.90	Dilaudid	MF

MORPHINE HYDROCHLORIDE

CAUTION:

The risk of drug dependence is high.

Restricted Benefit

Severe disabling pain not responding to non-narcotic analgesics.

NOTE:

Authorities for increased maximum quantities and/or repeats will be granted only for:

(i) severe disabling pain associated with proven malignant neoplasia; or

(ii) chronic severe disabling pain not responding to non-narcotic analgesics where the total duration of narcotic analgesic treatment is less than 12 months; or

(iii) first application for treatment beyond 12 months of chronic severe disabling pain not responding to non-narcotic analgesics where the patient's pain management has been reviewed through consultation by the patient with another medical practitioner, and the clinical need for continuing narcotic analgesic treatment has been confirmed. The date of the consultation must be no more than 3 months prior to the application for a PBS authority. The full name of the medical practitioner consulted and the date of consultation are to be provided at the time of application; or

(iv) subsequent application for treatment of chronic severe disabling pain not responding to non-narcotic analgesics where a PBS authority prescription for treatment beyond 12 months has previously been issued for this patient.

2122Q	Oral solution 2 mg per mL, 200 mL	1	..	..	18.73	19.76	Ordine 2	MF
2123R	Oral solution 5 mg per mL, 200 mL	1	..	..	21.64	22.67	Ordine 5	MF
2124T	Oral solution 10 mg per mL, 200 mL	1	..	..	26.24	27.27	Ordine 10	MF

MORPHINE SULFATE

CAUTION:

The risk of drug dependence is high.

1644M	Injection 10 mg in 1 mL	5	..	..	13.77	14.80	HH	
1645N	Injection 15 mg in 1 mL	5	..	..	14.13	15.16	HH	
1647Q	Injection 30 mg in 1 mL	5	..	..	15.61	16.64	HH	

MORPHINE SULFATE

CAUTION:

The risk of drug dependence is high.

Restricted Benefit

Severe disabling pain due to cancer not responding to non-narcotic analgesics.

8669G	Tablet 10 mg	20	..	..	14.85	15.88	Sevredol	MF

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	
8670H	Tablet 20 mg	20	..	..	15.99	17.02	Sevredol	MF

Restricted Benefit

Severe disabling pain not responding to non-narcotic analgesics.

NOTE:

Authorities for increased maximum quantities and/or repeats will be granted only for:

(i) severe disabling pain associated with proven malignant neoplasia; or

(ii) chronic severe disabling pain not responding to non-narcotic analgesics where the total duration of narcotic analgesic treatment is less than 12 months; or

(iii) first application for treatment beyond 12 months of chronic severe disabling pain not responding to non-narcotic analgesics where the patient's pain management has been reviewed through consultation by the patient with another medical practitioner, and the clinical need for continuing narcotic analgesic treatment has been confirmed. The date of the consultation must be no more than 3 months prior to the application for a PBS authority. The full name of the medical practitioner consulted and the date of consultation are to be provided at the time of application; or

(iv) subsequent application for treatment of chronic severe disabling pain not responding to non-narcotic analgesics where a PBS authority prescription for treatment beyond 12 months has previously been issued for this patient.

1646P	Tablet 30 mg	20	..	..	14.53	15.56	Anamorph	FM

Restricted Benefit

Chronic severe disabling pain not responding to non-narcotic analgesics.

NOTE:

Authorities for increased maximum quantities and/or repeats will be granted only for:

(i) chronic severe disabling pain associated with proven malignant neoplasia; or

(ii) chronic severe disabling pain not responding to non-narcotic analgesics where the total duration of narcotic analgesic treatment is less than 12 months; or

(iii) first application for treatment beyond 12 months of chronic severe disabling pain not responding to non-narcotic analgesics where the patient's pain management has been reviewed through consultation by the patient with another medical practitioner, and the clinical need for continuing narcotic analgesic treatment has been confirmed. The date of the consultation must be no more than 3 months prior to the application for a PBS authority. The full name of the medical practitioner consulted and the date of consultation are to be provided at the time of application; or

(iv) subsequent application for treatment of chronic severe disabling pain not responding to non-narcotic analgesics where a PBS authority prescription for treatment beyond 12 months has previously been issued for this patient.

8035X	Tablet 5 mg (controlled release)	20	..	..	15.89	16.92	MS Contin	MF
1653B	Tablet 10 mg (controlled release)	20	..	..	17.97	19.00	MS Contin	MF
8489T	Tablet 15 mg (controlled release)	20	..	..	21.52	22.55	MS Contin	MF
1654C	Tablet 30 mg (controlled release)	20	..	..	31.44	32.47	MS Contin	MF

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	
1655D	Tablet 60 mg (controlled release)	20	..	..	47.92	32.90	MS Contin	MF
1656E	Tablet 100 mg (controlled release)	20	..	..	62.58	32.90	MS Contin	MF
8349K	Capsule 10 mg (containing sustained release pellets)	20	..	..	17.97	19.00	Kapanol	GK
2839K	Capsule 20 mg (containing sustained release pellets)	20	..	..	22.20	23.23	Kapanol	GK
8491X	Capsule 30 mg (controlled release)	10	..	..	21.52	22.55	MS Mono	MF
2840L	Capsule 50 mg (containing sustained release pellets)	20	..	..	37.75	32.90	Kapanol	GK
8492Y	Capsule 60 mg (controlled release)	10	..	..	31.44	32.47	MS Mono	MF
8493B	Capsule 90 mg (controlled release)	10	..	..	36.15	32.90	MS Mono	MF
2841M	Capsule 100 mg (containing sustained release pellets)	20	..	..	60.83	32.90	Kapanol	GK
8494C	Capsule 120 mg (controlled release)	10	..	..	47.92	32.90	MS Mono	MF
8490W	Sachet containing controlled release granules for oral suspension, 20 mg per sachet	20	..	..	48.36	32.90	MS Contin Suspension 20 mg	MF
8146R	Sachet containing controlled release granules for oral suspension, 30 mg per sachet	20	..	..	49.60	32.90	MS Contin Suspension 30 mg	MF
8305D	Sachet containing controlled release granules for oral suspension, 60 mg per sachet	20	..	..	54.95	32.90	MS Contin Suspension 60 mg	MF
8306E	Sachet containing controlled release granules for oral suspension, 100 mg per sachet	20	..	..	67.09	32.90	MS Contin Suspension 100 mg	MF

Authority Required

Chronic severe disabling pain due to cancer.

8453X	Tablet 200 mg (controlled release)	20	..	..	104.50	32.90	MS Contin	MF
8454Y	Sachet containing controlled release granules for oral suspension, 200 mg per sachet	20	..	..	125.62	32.90	MS Contin Suspension 200 mg	MF

MORPHINE TARTRATE

CAUTION:

The risk of drug dependence is high.

1607N	Injection 120 mg in 1.5 mL	5	..	..	31.13	32.16	HH	

NERVOUS SYSTEM—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 \$	
OXYCODONE							
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>							
2481N	Suppository 30 mg	12	..	..	43.23	32.90	Proladone PL
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	..	..	11.87	12.90	Endone SI
8464L	Capsule 5 mg	20	..	..	11.87	12.90	OxyNorm MF
8501K	Capsule 10 mg	20	..	..	14.99	16.02	OxyNorm MF

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	
8502L	Capsule 20 mg	20	..	..	19.72	20.75	OxyNorm	MF
8644Y	Oral solution 5 mg per 5 mL, 250 mL	1	..	..	20.29	21.32	OxyNorm Liquid 5mg/5mL	MF

Restricted Benefit

Chronic severe disabling pain not responding to non-narcotic analgesics.

NOTE:

Authorities for increased maximum quantities and/or repeats will be granted only for:

(i) chronic severe disabling pain associated with proven malignant neoplasia; or

(ii) chronic severe disabling pain not responding to non-narcotic analgesics where the total duration of narcotic analgesic treatment is less than 12 months; or

(iii) first application for treatment beyond 12 months of chronic severe disabling pain not responding to non-narcotic analgesics where the patient's pain management has been reviewed through consultation by the patient with another medical practitioner, and the clinical need for continuing narcotic analgesic treatment has been confirmed. The date of the consultation must be no more than 3 months prior to the application for a PBS authority. The full name of the medical practitioner consulted and the date of consultation are to be provided at the time of application; or

(iv) subsequent application for treatment of chronic severe disabling pain not responding to non-narcotic analgesics where a PBS authority prescription for treatment beyond 12 months has previously been issued for this patient.

8681X	Tablet 5 mg (controlled release)	20	..	..	20.75	21.78	OxyContin	MF
8385H	Tablet 10 mg (controlled release)	20	..	..	21.52	22.55	OxyContin	MF
9399Q	Tablet 15 mg (controlled release)	20	..	..	27.50	28.53	OxyContin	MF
8386J	Tablet 20 mg (controlled release)	20	..	..	31.44	32.47	OxyContin	MF
9400R	Tablet 30 mg (controlled release)	20	..	..	40.79	32.90	OxyContin	MF
8387K	Tablet 40 mg (controlled release)	20	..	..	47.92	32.90	OxyContin	MF
8388L	Tablet 80 mg (controlled release)	20	..	..	71.27	32.90	OxyContin	MF

• **Phenylpiperidine derivatives**

FENTANYL

CAUTION:

The risk of drug dependence is high.

Restricted Benefit

Chronic severe disabling pain not responding to non-narcotic analgesics.

NOTE:

Authorities for increased maximum quantities and/or repeats will be granted only for:

(i) chronic severe disabling pain associated with proven malignant neoplasia; or

(ii) chronic severe disabling pain not responding to non-narcotic analgesics where the total duration of narcotic analgesic treatment is less than 12 months; or

continued ➞

NERVOUS SYSTEM—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 \$		
<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	..	..	46.73	32.90	Durogesic 12	JC
8891Y	Transdermal patch 4.2 mg (releasing approximately 25 micrograms per hour)	5	..	..	55.85	32.90	Durogesic 25	JC
8892B	Transdermal patch 8.4 mg (releasing approximately 50 micrograms per hour)	5	..	..	94.95	32.90	Durogesic 50	JC
8893C	Transdermal patch 12.6 mg (releasing approximately 75 micrograms per hour)	5	..	..	126.85	32.90	Durogesic 75	JC
8894D	Transdermal patch 16.8 mg (releasing approximately 100 micrograms per hour)	5	..	..	155.33	32.90	Durogesic 100	JC

NOTE:

Durogesic is not recommended in opioid naive patients with non-cancer pain, because of a high incidence of adverse events in these patients. Patients with cancer pain may be initiated on the lowest strength patch (12 micrograms per hour).

• **Diphenylpropylamine derivatives**

METHADONE HYDROCHLORIDE

CAUTION:

The risk of drug dependence is high.

Restricted Benefit

Severe disabling pain not responding to non-narcotic analgesics.

NOTE:

Authorities for increased maximum quantities and/or repeats will be granted only for:

(i) severe disabling pain associated with proven malignant neoplasia; or

(ii) chronic severe disabling pain not responding to non-narcotic analgesics where the total duration of narcotic analgesic treatment is less than 12 months; or

continued ➞

NERVOUS SYSTEM—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 \$		
<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	..	..	15.17	16.20	Physeptone	SI
1606M	Injection 10 mg in 1 mL	5	..	..	* 39.71	32.90	Physeptone	SI
• Oripavine derivatives								
BUPRENORPHINE								
<u>CAUTION:</u>								
<i>The risk of drug dependence is high.</i>								
<u>Restricted Benefit</u>								
<i>Chronic severe disabling pain not responding to non-narcotic analgesics.</i>								
<u>NOTE:</u>								
<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	..	..	26.27	27.30	Norspan	MF
8866P	Transdermal patch 10 mg (releasing approximately 10 micrograms per hour)	2	..	..	40.34	32.90	Norspan	MF
8867Q	Transdermal patch 20 mg (releasing approximately 20 micrograms per hour)	2	..	..	55.65	32.90	Norspan	MF

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 opioids TRAMADOL HYDROCHLORIDE <u>Restricted Benefit</u> <i>For acute 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>								
8455B	Capsule 50 mg	20	..	..	8.73	9.76	^a Chem mart Tramadol	CH
							^a GenRx Tramadol	GX
							^a Terry White Chemists Tramadol	TW
							^a Tramedo	AF
							^a Zydol	AW
				B2.42	11.15	9.76	^a Tramal	CS
<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	..	8.73	9.76	^a Chem mart Tramadol	CH
							^a GenRx Tramadol	GX
							^a Terry White Chemists Tramadol	TW
							^a Tramedo	AF
							^a Zydol	AW
				B2.42	11.15	9.76	^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 (twice daily sustained release)	20	..	..	11.20	12.23	Tramal SR 50	CS
8523N	Tablet 100 mg (twice daily sustained release)	20	..	..	13.43	14.46	^a Tramahexal SR	SZ
							^a Tramedo SR 100	AF
							^a Zydol SR 100	AW
				B4.51	17.94	14.46	^a Tramal SR 100	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	
9199E	Tablet 100 mg (once a day extended release)	10	..	..	12.94	13.97	Durotram XR	IA
8524P	Tablet 150 mg (twice daily sustained release)	20	..	..	16.02	17.05	^a Tramahexal SR	SZ
							^a Tramedo SR 150	AF
				B5.37	21.39	17.05	^a Zydol SR 150	AW
							^a Tramal SR 150	CS
8525Q	Tablet 200 mg (twice daily sustained release)	20	..	..	18.20	19.23	^a Tramahexal SR	SZ
							^a Tramedo SR 200	AF
				B6.09	24.29	19.23	^a Zydol SR 200	AW
							^a Tramal SR 200	CS
9200F	Tablet 200 mg (once a day extended release)	10	..	..	15.91	16.94	Durotram XR	IA
9201G	Tablet 300 mg (once a day extended release)	10	..	..	19.36	20.39	Durotram XR	IA
8843K	Oral drops 100 mg per mL, 10 mL	≠ 1	..	..	13.28	14.31	Tramal	CS

Restricted Benefit

Short-term treatment of acute pain.

NOTE:

No applications for increased maximum quantities and/or repeats will be authorised.

8582Q	Injection 100 mg in 2 mL	5	..	..	13.87	14.90	Tramal 100	CS

Other analgesics and antipyretics

• **Salicylic acid and derivatives**

ASPIRIN

1010E	Tablet 300 mg (dispersible)	96	1	..	8.21	9.24	Solprin	RC

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	..	7.99	9.02	a Chem mart Chemadol	CH
							a Dymadon P	PC
							a Febridol	GM
							a Panamax	SW
							a Paracetamol	SZ
							Sandoz	
							b Parahexal	HX
							a Paralgin	FM
							b Parmol	SI
							a Pharmacy Choice	YM
							Paracetamol	
							a Terry White	TW
							Chemists	
							Paracetamol	
1747Y	Oral liquid 120 mg per 5 mL, 100 mL	‡ 1	2	..	8.95	9.98	Panamax	SW
1770E	Oral liquid 240 mg per 5 mL, 200 mL	‡ 1	2	..	10.25	11.28	Panamax 240 Elixir	SW

PARACETAMOL

Restricted Benefit

Chronic arthropathies.

8784H	Tablet 500 mg	300	4	..	* 11.99	13.02	a Chem mart Chemadol	CH
							a Dymadon P	PC
							a Febridol	GM
							a Panamax	SW
							a Paracetamol	SZ
							Sandoz	
							b Parahexal	HX
							a Paralgin	FM
							b Parmol	SI
							a Pharmacy Choice	YM
							Paracetamol	
							a Terry White	TW
							Chemists	
							Paracetamol	

Restricted Benefit

Relief of persistent pain associated with osteoarthritis.

8814X	Tablet 665 mg (modified release)	192	5	..	* 16.21	17.24	Panadol Osteo	GC

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	
Antimigraine preparations								
• Ergot alkaloids								
DIHYDROERGOTAMINE MESYLATE								
1323P	Injection 1 mg in 1 mL	5	..	..	16.63	17.66	Dihydergot	NV
METHYSERGIDE								
2826R	Tablet 1 mg	100	2	..	* 44.53	32.90	Deseril	LM
• Selective 5HT₁-receptor agonists								
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 (STREAMLINED)								
2663								
<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	..	19.63	20.66	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 (STREAMLINED)								
2663								
<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	..	25.08	26.11	^a Sumagran 50	SI
				..	* 25.09	26.12	^a Imigran	GK
							^a Sumatab	AF
8885P	Tablet 50 mg (base) (fast disintegrating)	4	5	..	* 25.09	26.12	Imigran FDT	GK

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 antimigraine preparations CYPROHEPTADINE HYDROCHLORIDE <u>Restricted Benefit</u> <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	..	* 13.77	14.80	Periactin	AS
PIZOTIFEN MALATE								
3074T	Tablet 500 micrograms (base)	100	2	..	21.32	22.35	Sandomigran 0.5	NV
ANTIEPILEPTICS Antiepileptics • Barbiturates and derivatives PHENOBARBITONE <u>Restricted Benefit</u> <i>Epilepsy.</i>								
1850J	Tablet 30 mg	200	4	..	14.85	15.88	SI	
PHENOBARBITONE SODIUM								
<u>Restricted Benefit</u> <i>Epilepsy.</i>								
1853M	Injection 200 mg in 1 mL	5	..	..	32.82	32.90	FM	
PRIMIDONE								
1939C	Tablet 250 mg	200	2	..	52.12	32.90	Mysoline	LM
• Hydantoin derivatives PHENYTOIN								
1249R	Tablet 50 mg	200	2	..	29.69	30.72	Dilantin Infatabs	PF
2692Q	Paediatric oral suspension 30 mg per 5 mL, 500 mL	‡ 1	3	..	21.18	22.21	Dilantin	PF
PHENYTOIN SODIUM								
1873N	Capsule 30 mg	200	2	..	28.75	29.78	Dilantin Sodium	PF
1874P	Capsule 100 mg	200	2	..	29.69	30.72	Dilantin Sodium	PF

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	..	18.71	19.74	^a Carbamazepine Sandoz	SZ
				B2.55	21.26	19.74	^a Tegretol 100	NV
2419H	Tablet 200 mg	200	2	..	29.77	30.80	^a Carbamazepine Sandoz	SZ
				B2.74	32.51	30.80	^a Teril ^a Tegretol 200	AF NV
2426Q	Tablet 200 mg (controlled release)	200	2	..	30.26	31.29	Tegretol CR 200	NV
2431Y	Tablet 400 mg (controlled release)	200	2	..	50.59	32.90	Tegretol CR 400	NV
2427R	Oral suspension 100 mg per 5 mL, 300 mL	‡ 1	5	..	20.92	21.95	Tegretol Liquid	NV

OXCARBAZEPINE

Authority Required (STREAMLINED)

1587

Treatment of partial epileptic seizures and primary generalised tonic-clonic seizures, which are not controlled satisfactorily by other anti-epileptic drugs.

8584T	Tablet 150 mg	100	5	..	71.84	32.90	Trileptal	NV
8585W	Tablet 300 mg	100	5	..	114.65	32.90	Trileptal	NV
8586X	Tablet 600 mg	100	5	..	187.55	32.90	Trileptal	NV
8588B	Oral suspension 60 mg per mL, 250 mL	2	5	..	* 137.69	32.90	Trileptal	NV

• Fatty acid derivatives

SODIUM VALPROATE

CAUTION:

There are reports of fatal hepatotoxicity, particularly in children.

There is increasing evidence of dose-related teratogenesis from this drug.

2294R	Crushable tablet 100 mg	200	2	..	* 31.57	32.60	Epilim	SW
2289L	Tablet 200 mg (enteric coated)	200	2	..	* 33.43	32.90	^a Sodium Valproate Sandoz	SZ
							^a Valpro 200	AF
							^a Valproate Winthrop EC 200	WA
				B1.50	* 34.93	32.90	^a Epilim EC	SW

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	
2290M	Tablet 500 mg (enteric coated)	200	2	..	* 57.95	32.90	^a Sodium Valproate Sandoz	SZ
							^a Valpro 500	AF
							^a Valproate Winthrop EC 500	WA
				B1.50	* 59.45	32.90	^a Epilim EC	SW
2293Q	Oral liquid 200 mg per 5 mL, 300 mL	2	2	..	* 34.49	32.90	Epilim Liquid	SW
2295T	Syrup 200 mg per 5 mL, 300 mL	2	2	..	* 34.49	32.90	Epilim Syrup	SW

TIAGABINE HYDROCHLORIDE

Authority Required (STREAMLINED)

2664

Treatment of partial epileptic seizures which are not controlled satisfactorily by other anti-epileptic drugs.

8221Q	Tablet 5 mg (base)	100	5	..	* 72.21	32.90	Gabitril	OA
8222R	Tablet 10 mg (base)	100	5	..	* 138.41	32.90	Gabitril	OA
8223T	Tablet 15 mg (base)	100	5	..	* 196.45	32.90	Gabitril	OA

VIGABATRIN

CAUTION:

Visual field defects have been reported with this drug.

Authority Required (STREAMLINED)

1426

Treatment of epileptic seizures which are not controlled satisfactorily by other anti-epileptic drugs.

2667J	Tablet 500 mg	100	5	..	100.50	32.90	Sabril	SW
2668K	Oral powder, sachet 500 mg	60	5	..	67.27	32.90	Sabril	SW

• Other antiepileptics

GABAPENTIN

Authority Required (STREAMLINED)

2664

Treatment of partial epileptic seizures which are not controlled satisfactorily by other anti-epileptic drugs.

8505P	Capsule 100 mg	100	5	..	23.38	24.41	^a DBL Gabapentin	HH
							^a Gabatine 100	SI
							^a Gantin	AW
							^a Nupentin 100	AF
				B1.00	24.38	24.41	^a Neurontin	PF

continued ➞

NERVOUS SYSTEM—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Proprietary Name and Manufacturer	
1834M	Capsule 300 mg	100	5	..	61.58	32.90	^a DBL Gabapentin	HH
							^a Douglas	GM
							Gabapentin	
							300mg	
							^a Gabahexal 300mg	SZ
							^a Gabapentin 300	CR
							^a Gabatine 300	SI
							^a Gantin	AW
							^a GenRx Gabapentin	GX
							^a Nupentin 300	AF
							^a Pendine 300	AL
				B0.99	62.57	32.90	^a Neurontin	PF
1835N	Capsule 400 mg	100	5	..	81.81	32.90	^a DBL Gabapentin	HH
							^a Douglas	GM
							Gabapentin	
							400mg	
							^a Gabahexal 400mg	SZ
							^a Gabapentin 400	CR
							^a Gabatine 400	SI
							^a Gantin	AW
							^a GenRx Gabapentin	GX
							^a Nupentin 400	AF
							^a Pendine 400	AL
				B1.00	82.81	32.90	^a Neurontin	PF
8559L	Tablet 600 mg	100	5	..	126.34	32.90	^a Gabahexal 600mg	SZ
							^a Gabaran	RA
							^a GenRx Gabapentin	GX
				B1.00	127.34	32.90	^a Neurontin	PF
8389M	Tablet 800 mg	100	5	..	166.43	32.90	^a Gabaran	RA
							^a Gantin	AW
							^a GenRx Gabapentin	GX
							^a Pendine 800	AF
				B1.00	167.43	32.90	^a Neurontin	PF

LAMOTRIGINE

Authority Required (STREAMLINED)

1426

Treatment of epileptic seizures which are not controlled satisfactorily by other anti-epileptic drugs.

8063J	Tablet 5 mg	56	5	..	16.32	17.35	^a Lamogine	AF
							^a Seaze 5	SI
				B0.76	17.08	17.35	^a Lamictal	GK

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	
2848X	Tablet 25 mg	56	5	..	28.97	30.00	^a GenRx	GX
							Lamotrigine	
							^a Lamidus	RA
							^a Lamogine	AF
							^a Lamotrigine-DP	GM
							^a Lamotrigine-GA	GN
							^a Lamotrigine generichealth	GQ
							^a Lamotrigine Sandoz	SZ
							^a Lamotrust 25	MI
							^a Seaze 25	SI
				B0.77	29.74	30.00	^a Lamictal	GK
2849Y	Tablet 50 mg	56	5	..	43.81	32.90	^a GenRx	GX
							Lamotrigine	
							^a Lamidus	RA
							^a Lamogine	AF
							^a Lamotrigine-DP	GM
							^a Lamotrigine-GA	GN
							^a Lamotrigine generichealth	GQ
							^a Lamotrigine Sandoz	SZ
							^a Lamotrust 50	MI
							^a Seaze 50	SI
				B0.66	44.47	32.90	^a Lamictal	GK
2850B	Tablet 100 mg	56	5	..	67.06	32.90	^a GenRx	GX
							Lamotrigine	
							^a Lamidus	RA
							^a Lamogine	AF
							^a Lamotrigine-DP	GM
							^a Lamotrigine-GA	GN
							^a Lamotrigine generichealth	GQ
							^a Lamotrigine Sandoz	SZ
							^a Lamotrust 100	MI
							^a Seaze 100	SI
				B0.73	67.79	32.90	^a Lamictal	GK

continued ➞

NERVOUS SYSTEM—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Proprietary Name and Manufacturer	
2851C	Tablet 200 mg	56	5	..	108.58	32.90	^a GenRx	GX
							Lamotrigine	
							^a Lamidus	RA
							^a Lamogine	AF
							^a Lamotrigine-DP	GM
							^a Lamotrigine-GA	GN
							^a Lamotrigine generichealth	GQ
							^a Lamotrigine Sandoz	SZ
							^a Lamotrust 200	MI
							^a Seaze 200	SI
				80.72	109.30	32.90	^a Lamictal	GK

LEVETIRACETAM

Authority Required

Treatment of partial epileptic seizures, which are not controlled satisfactorily by other anti-epileptic drugs in a patient unable to take a solid dose form of levetiracetam.

9169N	Oral solution 100 mg per mL, 300 mL	± 1	5	..	110.99	32.90	Keppra	UC

SULTHIAME

2099L	Tablet 50 mg	200	2	..	45.69	32.90	Ospolot	PL
2100M	Tablet 200 mg	200	2	..	98.14	32.90	Ospolot	PL

TOPIRAMATE

Authority Required (STREAMLINED)

2797

Treatment of partial epileptic seizures, primary generalised tonic-clonic epileptic seizures and seizures of the Lennox-Gastaut syndrome, which are not controlled satisfactorily by other anti-epileptic drugs.

Authority Required (STREAMLINED)

2799

Prophylaxis of migraine in a patient who has experienced an average of 3 or more migraines per month over a period of at least 6 months, and who:

*(a) has a contraindication to beta-blockers, as described in the relevant TGA-approved Product Information; OR
(b) has experienced intolerance of a severity necessitating permanent withdrawal during treatment with a beta-blocker;*

AND

(c) has a contraindication to pizotifen because the weight gain associated with this drug poses an unacceptable risk; OR

(d) has experienced intolerance of a severity necessitating permanent withdrawal during treatment with pizotifen.

Details of the contraindication and/or intolerance(s) must be documented in the patient's medical records when treatment is initiated.

8163P	Tablet 25 mg	60	5	..	41.74	32.90	Topamax	JC
8164Q	Tablet 50 mg	60	5	..	62.42	32.90	Topamax	JC

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	
Authority Required (STREAMLINED)								
2797								
<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>								
8165R	Tablet 100 mg	60	5	..	96.75	32.90	Topamax	JC
8166T	Tablet 200 mg	60	5	..	158.45	32.90	Topamax	JC

Authority Required (STREAMLINED)

2798

Treatment of partial epileptic seizures, primary generalised tonic-clonic epileptic seizures and seizures of the Lennox-Gastaut syndrome, which are not controlled satisfactorily by other anti-epileptic drugs in patients unable to take a solid dose form of topiramate.

8371N	Capsule 15 mg	60	5	..	32.73	32.90	Topamax Sprinkle	JC
8372P	Capsule 25 mg	60	5	..	41.91	32.90	Topamax Sprinkle	JC
8520K	Capsule 50 mg	60	5	..	63.62	32.90	Topamax Sprinkle	JC

ANTI-PARKINSON DRUGS

Anticholinergic agents

• Tertiary amines

BENZHEXOL HYDROCHLORIDE

1109J	Tablet 2 mg	200	2	..	14.89	15.92	Artane	SI
1110K	Tablet 5 mg	200	1	..	21.58	22.61	Artane	SI

BIPERIDEN HYDROCHLORIDE

2544X	Tablet 2 mg	200	2	..	* 20.45	21.48	Akineton	LM

• Ethers of tropine or tropine derivatives

BENZTROPINE MESYLATE

2362H	Tablet 2 mg	60	2	..	12.33	13.36	Benztrop	PL
3038X	Injection 2 mg in 2 mL	5	..	..	22.41	23.44	Cogentin	FK

Dopaminergic agents

• Dopa and dopa derivatives

LEVODOPA with BENSERAZIDE

8218M	Dispersible tablet 50 mg-12.5 mg	100	5	..	22.57	23.60	Madopar Rapid 62.5	RO

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	
8219N	Dispersible tablet 100 mg-25 mg	100	5	..	38.49	32.90	Madopar Rapid 125	RO
2229H	Tablet 100 mg-25 mg	100	5	..	38.49	32.90	Madopar 125	RO
2228G	Tablet 200 mg-50 mg	100	5	..	49.58	32.90	Madopar	RO
2227F	Capsule 50 mg-12.5 mg	100	5	..	22.57	23.60	Madopar 62.5	RO
2225D	Capsule 100 mg-25 mg	100	5	..	38.49	32.90	Madopar 125	RO
2231K	Capsule 100 mg-25 mg (sustained release)	100	5	..	41.57	32.90	Madopar HBS	RO
2226E	Capsule 200 mg-50 mg	100	5	..	49.58	32.90	Madopar	RO
LEVODOPA with CARBIDOPA								
1242J	Tablet 100 mg-25 mg	100	5	.. B5.22	39.86 45.08	32.90 32.90	^a Kinson ^a Sinemet 100/25	AF MK
1245M	Tablet 250 mg-25 mg	100	5	.. B3.10	46.80 49.90	32.90 32.90	^a Levothal ^a Sinemet	SZ MK

LEVODOPA with CARBIDOPA

Authority Required (STREAMLINED)

1257

Parkinson's disease where fluctuations in motor function are not adequately controlled by frequent dosing with conventional formulations of levodopa with decarboxylase inhibitor.

1255C	Tablet 200 mg-50 mg (modified release)	100	5	..	67.44	32.90	Sinemet CR	MK

LEVODOPA with CARBIDOPA and ENTACAPONE

Authority Required (STREAMLINED)

2059

Parkinson's disease in patients being treated with levodopa—decarboxylase inhibitor combinations who are experiencing fluctuations in motor function due to end-of-dose effect;

2060

Parkinson's disease in patients stabilised on concomitant treatment with levodopa—decarboxylase inhibitor combinations and entacapone.

8797B	Tablet 50 mg-12.5 mg-200 mg	200	4	..	* 311.45	32.90	Stalevo 50/12.5/ 200mg	NV
8798C	Tablet 100 mg-25 mg-200 mg	200	4	..	* 341.49	32.90	Stalevo 100/25/ 200mg	NV
8799D	Tablet 150 mg-37.5 mg-200 mg	200	4	..	* 371.53	32.90	Stalevo 150/37.5/ 200mg	NV
9292C	Tablet 200 mg-50 mg-200 mg	200	4	..	* 399.19	32.90	Stalevo 200/50/ 200mg	NV

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	..	43.87	32.90	Symmetrel 100	NV
• Dopamine agonists BROMOCRIPTINE MESYLATE <u>Restricted Benefit</u> <i>Acromegaly;</i> <i>Parkinson's disease;</i> <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>								
1443Y	Tablet 2.5 mg (base)	60	5	..	32.30	32.90	^a Krypton 2.5	AF
				B2.92	35.22	32.90	^a Parlodel	NV
1446D	Capsule 5 mg (base)	60	5	..	49.82	32.90	^a Krypton 5	AF
				B2.91	52.73	32.90	^a Parlodel	NV
1445C	Capsule 10 mg (base)	100	5	..	155.51	32.90	^a Krypton 10	AF
				B3.08	158.59	32.90	^a Parlodel	NV
<i>[For other listings for this drug see Generic/Proprietary Index]</i>								
CABERGOLINE <u>Restricted Benefit</u> <i>Parkinson's disease.</i>								
8393R	Tablet 1 mg	30	5	..	69.49	32.90	Cabaser	PU
8394T	Tablet 2 mg	30	5	..	91.10	32.90	Cabaser	PU
PERGOLIDE MESYLATE <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	..	..	52.50	32.90	Permax	AS
2809W	Tablet 250 micrograms (base)	100	5	..	65.75	32.90	Permax	AS
2810X	Tablet 1 mg (base)	100	5	..	241.26	32.90	Permax	AS

NERVOUS SYSTEM—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 \$	
PRAMIPEXOLE HYDROCHLORIDE							
<u>CAUTION:</u>							
<i>Episodes of sudden onset of sleep without warning, during activity, have been reported with this drug.</i>							
<u>Restricted Benefit</u>							
<i>Parkinson's disease as adjunctive therapy in patients being treated with levodopa—decarboxylase inhibitor combinations.</i>							
9151P	Tablet 125 micrograms	30	..	..	11.31	12.34	Sifrol BY
9152Q	Tablet 250 micrograms	100	5	..	40.84	32.90	Sifrol BY
9153R	Tablet 1 mg	100	5	..	151.71	32.90	Sifrol BY

Restricted Benefit

Treatment of severe primary Restless Legs Syndrome in a patient who manifests all 4 diagnostic criteria below and whose baseline International Restless Legs Syndrome Rating Scale (IRLSRS) score is greater than or equal to 21 points prior to initiation of pramipexole.

The date and IRLSRS score must be documented in the patient's medical records at the time pramipexole treatment is initiated.

The diagnostic criteria for Restless Legs Syndrome are:

- (a) An urge to move the legs usually accompanied or caused by unpleasant sensations in the legs; and*
- (b) The urge to move or unpleasant sensations begin or worsen during periods of rest or inactivity such as lying or sitting; and*
- (c) The urge to move or unpleasant sensations are partially or totally relieved by movement, such as walking or stretching, at least as long as the activity continues; and*
- (d) The urge to move or unpleasant sensations are worse in the evening or night than during the day or only occur during the evening or night.*

Pramipexole is not PBS-subsidised for Restless Legs Syndrome secondary to other causes.

NOTE:

No applications for increased maximum quantities and/or repeats will be authorised.

9393J	Tablet 125 micrograms	30	2	..	11.31	12.34	Sifrol	BY
9394K	Tablet 250 micrograms	100	2	..	40.84	32.90	Sifrol	BY

• **Monoamine oxidase type B inhibitors**

SELEGILINE HYDROCHLORIDE

Restricted Benefit

Late stage Parkinson's disease as adjunctive therapy in patients being treated with levodopa—decarboxylase inhibitor combinations.

1973W	Tablet 5 mg	100	5	..	55.16	32.90	^a Eldepryl ^a Selgene	GM AF

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 (STREAMLINED) 2067 <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	..	* 281.39	32.90	Comtan	NV
PSYCHOLEPTICS Antipsychotics • Phenothiazine with aliphatic side-chain CHLORPROMAZINE HYDROCHLORIDE								
1196Y	Tablet 10 mg	100	5	..	10.06	11.09	Largactil	SW
1197B	Tablet 25 mg	100	5	..	10.66	11.69	Largactil	SW
1199D	Tablet 100 mg	100	5	..	17.01	18.04	Largactil	SW
1201F	Mixture 25 mg per 5 mL, 100 mL	‡ 1	5	..	11.27	12.30	Largactil	SW
1195X	Injection 50 mg in 2 mL	10	..	..	16.39	17.42	Largactil	SW
• Phenothiazine with piperazine structure FLUPHENAZINE DECANOATE								
1046C	Injection 12.5 mg in 0.5 mL	5	..	..	18.79	19.82	Modecate	BQ
3098C	Injection 25 mg in 1 mL	5	..	..	25.95	26.98	Modecate	BQ
1001Q	Injection 50 mg in 2 mL	5	..	..	37.22	32.90	Modecate	BQ
TRIFLUOPERAZINE HYDROCHLORIDE								
2185B	Tablet 1 mg (base)	100	5	..	12.88	13.91	Stelazine	GH
2386N	Tablet 2 mg (base)	100	5	..	13.05	14.08	Stelazine	GH
2186C	Tablet 5 mg (base)	100	5	..	13.43	14.46	Stelazine	GH
• Phenothiazines with piperidine structure PERICYAZINE								
3052P	Tablet 2.5 mg	100	5	..	9.98	11.01	Neulactil	SW
3053Q	Tablet 10 mg	100	5	..	14.03	15.06	Neulactil	SW
• Butyrophenone derivatives HALOPERIDOL								
2761H	Tablet 500 micrograms	100	5	..	9.62	10.65	Serenace	SI

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	
2767P	Tablet 1.5 mg	100	5	..	10.10	11.13	Serenace	SI
2770T	Tablet 5 mg	50	5	..	10.11	11.14	Serenace	SI
2763K	Oral liquid 2 mg per mL, 100 mL	‡ 1	5	..	17.04	18.07	Serenace	SI
2768Q	Injection 5 mg in 1 mL	10	..	..	21.85	22.88	Serenace	SI
HALOPERIDOL DECANOATE								
2765M	I.M. injection equivalent to 50 mg haloperidol in 1 mL	5	..	..	26.24	27.27	Haldol decanoate	JC
2766N	I.M. injection equivalent to 150 mg haloperidol in 3 mL	5	..	..	45.80	32.90	Haldol decanoate	JC
• Indole derivatives ZIPRASIDONE HYDROCHLORIDE <u>Authority Required (STREAMLINED)</u> 1589 <i>Schizophrenia.</i> <u>Authority Required (STREAMLINED)</u> 3084 <i>Monotherapy, for up to 6 months, of an episode of acute mania or mixed episodes associated with bipolar I disorder.</i>								
9070J	Capsule 20 mg (base)	60	5	..	90.18	32.90	Zeldox	PF
9071K	Capsule 40 mg (base)	60	5	..	174.68	32.90	Zeldox	PF
9072L	Capsule 60 mg (base)	60	5	..	253.20	32.90	Zeldox	PF
9073M	Capsule 80 mg (base)	60	5	..	330.00	32.90	Zeldox	PF
• Thioxanthene derivatives FLUPENTHIXOL DECANOATE								
2255Q	Oily I.M. injection 20 mg in 1 mL	5	..	..	18.79	19.82	Fluanxol Depot	LU
2256R	Oily I.M. injection 40 mg in 2 mL	5	..	..	25.95	26.98	Fluanxol Depot	LU
2257T	Oily I.M. injection 100 mg in 1 mL	5	..	..	44.44	32.90	Fluanxol Concentrated Depot	LU
ZUCLOPENTHIXOL DECANOATE								
8097E	Oily I.M. injection 200 mg in 1 mL	5	..	..	24.91	25.94	Clopixol Depot	LU

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	
• Diazepines, oxazepines and thiazepines OLANZAPINE <u>Authority Required (STREAMLINED)</u> 1589 Schizophrenia; 2044 Maintenance treatment of bipolar I disorder.								
8170B	Tablet 2.5 mg	28	5	..	53.12	32.90	Zyprexa	LY
8185T	Tablet 5 mg	28	5	..	98.84	32.90	Zyprexa	LY
8186W	Tablet 7.5 mg	28	5	..	146.68	32.90	Zyprexa	LY
8187X	Tablet 10 mg	28	5	..	193.57	32.90	Zyprexa	LY
8433W	Wafer 5 mg	28	5	..	98.84	32.90	Zyprexa Zydys	LY
8434X	Wafer 10 mg	28	5	..	193.57	32.90	Zyprexa Zydys	LY
QUETIAPINE FUMARATE <u>Authority Required (STREAMLINED)</u> 1589 Schizophrenia; 2765 Monotherapy, for up to 6 months, of an episode of acute mania associated with bipolar I disorder.								
8456C	Tablet 25 mg (base)	60	5	..	53.23	32.90	Seroquel	AP
8457D	Tablet 100 mg (base)	90	5	..	142.28	32.90	Seroquel	AP
8458E	Tablet 200 mg (base)	60	5	..	191.92	32.90	Seroquel	AP
8580N	Tablet 300 mg (base)	60	5	..	271.65	32.90	Seroquel	AP
 <u>Authority Required (STREAMLINED)</u> 1589 Schizophrenia.								
9202H	Tablet (modified release) equivalent to 50 mg quetiapine	60	5	..	100.68	32.90	Seroquel XR	AP
9203J	Tablet (modified release) equivalent to 200 mg quetiapine	60	5	..	196.14	32.90	Seroquel XR	AP
9204K	Tablet (modified release) equivalent to 300 mg quetiapine	60	5	..	276.55	32.90	Seroquel XR	AP
9205L	Tablet (modified release) equivalent to 400 mg quetiapine	60	5	..	369.71	32.90	Seroquel XR	AP

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	
• Benzamides AMISULPRIDE Authority Required (STREAMLINED) 1589 <i>Schizophrenia.</i>								
8594H	Tablet 100 mg	30	5	..	33.83	32.90	^a Amisulpride 100 Winthrop	WA
							^a Amisulpride Sandoz	SZ
							^a Solian 100	SW
8595J	Tablet 200 mg	60	5	..	120.75	32.90	^a Amisulpride 200 Winthrop	WA
							^a Amisulpride Sandoz	SZ
							^a Solian 200	SW
8596K	Tablet 400 mg	60	5	..	223.38	32.90	^a Amipride 400	SI
							^a Amisulpride 400 Winthrop	WA
							^a Amisulpride Sandoz	SZ
							^a Solian 400	SW
8736T	Oral solution 100 mg per mL, 60 mL	2	5	..	* 148.31	32.90	Solian Solution	SW
• Lithium LITHIUM CARBONATE <i>For listings see Generic/Proprietary Index</i>								
• Other antipsychotics ARIPIPRAZOLE Authority Required (STREAMLINED) 1589 <i>Schizophrenia.</i>								
8717T	Tablet 10 mg	30	5	..	151.82	32.90	Abilify	BQ
8718W	Tablet 15 mg	30	5	..	212.13	32.90	Abilify	BQ
8719X	Tablet 20 mg	30	5	..	253.00	32.90	Abilify	BQ
8720Y	Tablet 30 mg	30	5	..	303.06	32.90	Abilify	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	
PALIPERIDONE								
<u>Authority Required (STREAMLINED)</u>								
1589								
Schizophrenia.								
9140C	Tablet 3 mg (prolonged release)	28	5	..	248.48	32.90	Invega	JC
9141D	Tablet 6 mg (prolonged release)	28	5	..	248.48	32.90	Invega	JC
9142E	Tablet 9 mg (prolonged release)	28	5	..	248.48	32.90	Invega	JC
9194X	Tablet 12 mg (prolonged release)	28	5	..	248.48	32.90	Invega	JC
RISPERIDONE								
<u>Authority Required (STREAMLINED)</u>								
2061								
Behavioural disturbances characterised by psychotic symptoms and aggression in patients with dementia where non-pharmacological methods have been unsuccessful.								
CAUTION:								
In placebo controlled trials in elderly patients with dementia there was a significantly higher incidence of cerebrovascular adverse events, such as stroke (including fatalities) and transient ischaemic attacks, in patients treated with risperidone compared with patients treated with placebo.								
<u>Authority Required (STREAMLINED)</u>								
3083								
Treatment under the supervision of a paediatrician or psychiatrist, in combination with non-pharmacological measures, of severe behavioural disturbances in a patient aged less than 18 years with autism.								
Continuing PBS-subsidised treatment under the supervision of a paediatrician or psychiatrist, in combination with non-pharmacological measures, of severe behavioural disturbances in a patient 18 years of age or older with autism who was commenced on PBS-subsidised treatment with risperidone prior to turning 18 years of age.								
Behaviour disturbances are defined as severe aggression and injuries to self or others where non-pharmacological methods alone have been unsuccessful.								
The diagnosis of autism must be made based on the Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV) or ICD-10 international classification of mental and behavioural disorders.								
8787L	Tablet 0.5 mg	60	2	..	36.48	32.90	^a Risperidone-GA	GM
							^a Rixadone	AF
				..	* 36.50	32.90	^a APO-Risperidone	TX
							^a Rispa	SI
							^a Risperdal	JC
8788M	Tablet 0.5 mg (orally disintegrating)	56	2	..	* 34.45	32.90	Risperdal Quicklet	JC

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	
8789N	Tablet 1 mg	60	2	..	64.30	32.90	^a APO-Risperidone	TX
							^a Rispa	SI
							^a Risperdal	JC
							^a Risperidone-GA	GM
							^a Risperidone generichealth	GQ
							^a Rixadone	AF
8790P	Tablet 1 mg (orally disintegrating)	56	2	..	* 60.41	32.90	Risperdal Quicklet	JC
9293D	Oral solution 1 mg per mL, 100 mL	‡ 1	2	..	117.60	32.90	Risperdal	JC

Authority Required (STREAMLINED)

3083

Treatment under the supervision of a paediatrician or psychiatrist, in combination with non-pharmacological measures, of severe behavioural disturbances in a patient aged less than 18 years with autism.

Continuing PBS-subsidised treatment under the supervision of a paediatrician or psychiatrist, in combination with non-pharmacological measures, of severe behavioural disturbances in a patient 18 years of age or older with autism who was commenced on PBS-subsidised treatment with risperidone prior to turning 18 years of age.

Behaviour disturbances are defined as severe aggression and injuries to self or others where non-pharmacological methods alone have been unsuccessful.

The diagnosis of autism must be made based on the Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV) or ICD-10 international classification of mental and behavioural disorders.

9079W	Tablet 2 mg	60	2	..	123.15	32.90	^a APO-Risperidone	TX
							^a Rispa	SI
							^a Risperdal	JC
							^a Risperidone-GA	GM
							^a Risperidone generichealth	GQ
							^a Rixadone	AF
9080X	Tablet 2 mg (orally disintegrating)	56	2	..	* 115.35	32.90	Risperdal Quicklet	JC

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>Authority Required (STREAMLINED)</u>								
	1589							
	Schizophrenia.							
<u>Authority Required (STREAMLINED)</u>								
	2272							
	Adjunctive therapy to mood stabilisers for up to 6 months, of an episode of acute mania associated with bipolar I disorder.							
3169T	Tablet 1 mg	60	5	..	64.30	32.90	^a APO-Risperidone	TX
							^a Rispera	SI
							^a Risperdal	JC
							^a Risperidone-GA	GM
							^a Risperidone	GQ
							generichealth	
							^a Rixadone	AF
8792R	Tablet 1 mg (orally disintegrating)	56	5	..	* 60.41	32.90	Risperdal Quicklet	JC
3170W	Tablet 2 mg	60	5	..	123.15	32.90	^a APO-Risperidone	TX
							^a Rispera	SI
							^a Risperdal	JC
							^a Risperidone-GA	GM
							^a Risperidone	GQ
							generichealth	
							^a Rixadone	AF
8794W	Tablet 2 mg (orally disintegrating)	56	5	..	* 115.35	32.90	Risperdal Quicklet	JC
3171X	Tablet 3 mg	60	5	..	180.16	32.90	^a APO-Risperidone	TX
							^a Rispera	SI
							^a Risperdal	JC
							^a Risperidone-GA	GM
							^a Risperidone	GQ
							generichealth	
							^a Rixadone	AF
9075P	Tablet 3 mg (orally disintegrating)	56	5	..	* 168.55	32.90	Risperdal Quicklet	JC
3172Y	Tablet 4 mg	60	5	..	235.00	32.90	^a APO-Risperidone	TX
							^a Rispera	SI
							^a Risperdal	JC
							^a Risperidone-GA	GM
							^a Risperidone	GQ
							generichealth	
							^a Rixadone	AF
9076Q	Tablet 4 mg (orally disintegrating)	56	5	..	* 220.93	32.90	Risperdal Quicklet	JC
8100H	Oral solution 1 mg per mL, 100 mL	‡ 1	5	..	117.60	32.90	Risperdal	JC

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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>Authority Required (STREAMLINED)</u>								
1589								
Schizophrenia.								
8869T	Tablet 0.5 mg	60	5	..	36.48	32.90	^a Risperidone-GA	GM
							^a Rixadone	AF
				..	* 36.50	32.90	^a APO-Risperidone	TX
							^a Rispa	SI
							^a Risperdal	JC
8870W	Tablet 0.5 mg (orally disintegrating)	56	5	..	* 34.45	32.90	Risperdal Quicklet	JC
8780D	Powder for I.M. injection 25 mg (modified release) with 2 mL diluent in pre-filled syringe	2	5	..	* 320.71	32.90	Risperdal Consta	JC
8781E	Powder for I.M. injection 37.5 mg (modified release) with 2 mL diluent in pre-filled syringe	2	5	..	* 409.97	32.90	Risperdal Consta	JC
8782F	Powder for I.M. injection 50 mg (modified release) with 2 mL diluent in pre-filled syringe	2	5	..	* 499.33	32.90	Risperdal Consta	JC
Anxiolytics								
• Benzodiazepine derivatives								
ALPRAZOLAM								
<u>Authority Required</u>								
<i>Panic disorder where other treatments have failed or are inappropriate.</i>								
2130D	Tablet 250 micrograms	50	..	..	9.12	10.15	^a Alprax 0.25	SI
							^a Kalma 0.25	AF
							^a Zamhexal 0.25mg	SZ
				B1.04	10.16	10.15	^a Xanax	PH
2131E	Tablet 500 micrograms	50	..	..	11.05	12.08	^a Alprax 0.5	SI
							^a Kalma 0.5	AF
							^a Zamhexal 0.5mg	SZ
				B1.12	12.17	12.08	^a Xanax	PH
2132F	Tablet 1 mg	50	2	..	14.80	15.83	^a Alprax 1	SI
							^a Alprazolam-DP	GM
							^a Chem mart	CH
							Alprazolam	
							^a GenRx Alprazolam	GX
							^a Kalma 1	AF
							^a Terry White	TW
							Chemists	
							Alprazolam	
							^a Zamhexal 1.0mg	SZ
				B1.32	16.12	15.83	^a Xanax	PH

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	
8118G	Tablet 2 mg	50	2	..	19.63	20.66	^a Alprax 2	SI
							^a Alprazolam-DP	GM
							^a Chem mart	CH
							Alprazolam	
							^a GenRx Alprazolam	GX
							^a Kalma 2	AF
							^a Terry White	TW
							Chemists	
							Alprazolam	
				B1.60	21.23	20.66	^a Zamhexal 2mg	SZ
							^a Xanax Tri-Score	PH
DIAZEPAM								
3161J	Tablet 2 mg	50	..	..	7.36	8.39	^a Antenex 2	AF
				B0.59	7.95	8.39	^a Valpam 2	SI
				B0.86	8.22	8.39	Ducene	SU
							^a Valium	RO
3162K	Tablet 5 mg	50	..	..	7.50	8.53	^a Antenex 5	AF
							^a Diazepam-DP	GM
							^a Ranzepam	RA
							^a Valpam 5	SI
				B0.63	8.13	8.53	Ducene	SU
				B0.88	8.38	8.53	^a Valium	RO
2558P	Injection 10 mg in 2 mL	5	..	..	11.86	12.89	HH	
NOTE:								
Authorities for increased maximum quantities and/or repeats for the oral forms of diazepam will be granted only for								
(i) the treatment of disabling spasticity; or								
(ii) malignant neoplasia (late stage); or								
(iii) use by patients who are receiving long-term nursing care on account of age, infirmity or other condition in hospitals, nursing homes or residential facilities and who have been demonstrated, within the past six months, to be benzodiazepine dependent by an unsuccessful attempt at gradual withdrawal; or								
(iv) use by a patient who is receiving long-term nursing care and in respect of whom a Carer Allowance is payable as a disabled adult and who has been demonstrated, within the past six months, to be benzodiazepine dependent by an unsuccessful attempt at gradual withdrawal.								
Up to six months' treatment (i.e. one month's treatment with five repeats) may be requested.								
OXAZEPAM								
3132W	Tablet 15 mg	25	..	..	7.27	8.30	^a Alepam 15	AF
				B1.78	9.05	8.30	^a Serepax	SI
3133X	Tablet 30 mg	25	..	..	7.46	8.49	^a Alepam 30	AF
							^a Murelax	FM
				B1.90	9.36	8.49	^a Serepax	SI

continued ➡

NERVOUS SYSTEM—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 \$		

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	..	* 8.55	9.58	^a	Alepm 15	AF
					B3.56	* 12.11	^a	Serepax	SI
3135B	Tablet 30 mg	50	5	..	* 8.93	9.96	^a	Alepm 30	AF
							^a	Murelax	FM
							^a	Serepax	SI

- Other anxiolytics**

CLOMIPRAMINE HYDROCHLORIDE**Restricted Benefit**

Cataplexy associated with narcolepsy;

Obsessive-compulsive disorder;

Phobic disorders in adults.

1561E	Tablet 25 mg	50	2	..	16.40	17.43	^a	Chem mart	CH
								Clomipramine	
							^a	GenRx	GX
								Clomipramine	
							^a	Placil	AF
							^a	Terry White	TW
								Chemists	
							^a	Anafranil 25	NV
				B3.26	19.66	17.43			

Hypnotics and sedatives

- Benzodiazepine derivatives**

NITRAZEPAM

2723H	Tablet 5 mg	25	..	..	7.46	8.49	^a	Alodorm	AF
					B1.53	8.99	^a	Mogadon	VT

continued ➞

NERVOUS SYSTEM—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 \$		

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**

Myoclonic epilepsy;

Malignant neoplasia (late stage);

For use by patients who are receiving long-term nursing care on account of age, infirmity or other condition in hospitals, nursing homes or residential facilities and who have been demonstrated, within the past 6 months, to be benzodiazepine dependent by an unsuccessful attempt at gradual withdrawal;

For use by a patient who is receiving long-term nursing care and in respect of whom a Carer Allowance is payable as a disabled adult and who has been demonstrated, within the past 6 months, to be benzodiazepine dependent by an unsuccessful attempt at gradual withdrawal.

2732T	Tablet 5 mg	50	5	..	* 8.93	9.96	^a Alodorm	AF
					B3.06	9.96	^a Mogadon	VT

TEMAZEPAM

2089Y	Tablet 10 mg	25	..	..	7.46	8.49	^a Temaze	AF
					B1.38	8.49	^a Temtabs	FM
							^a Normison	SI

NOTE:

Authorities for increased maximum quantities and/or repeats will not be granted except as detailed under the 'Authority required' listing of temazepam below.

TEMAZEPAM**Authority Required**

Malignant neoplasia (late stage);

For use by patients who are receiving long-term nursing care on account of age, infirmity or other condition in hospitals, nursing homes or residential facilities and who have been demonstrated, within the past 6 months, to be benzodiazepine dependent by an unsuccessful attempt at gradual withdrawal;

For use by a patient who is receiving long-term nursing care and in respect of whom a Carer Allowance is payable as a disabled adult and who has been demonstrated, within the past 6 months, to be benzodiazepine dependent by an unsuccessful attempt at gradual withdrawal.

2088X	Tablet 10 mg	50	5	..	* 8.93	9.96	^a Temaze	AF
					B2.76	9.96	^a Temtabs	FM
							^a Normison	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	
PSYCHOANALEPTICS								
Antidepressants								
• Non-selective monoamine reuptake inhibitors								
AMITRIPTYLINE HYDROCHLORIDE								
2417F	Tablet 10 mg	50	2	..	8.01	9.04	Endep 10	AF
2418G	Tablet 25 mg	50	2	..	8.13	9.16	Endep 25	AF
2429W	Tablet 50 mg	50	2	..	8.46	9.49	Endep 50	AF
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	..	16.40	17.43	^a Chem mart Clomipramine	CH
							^a GenRx Clomipramine	GX
							^a Placil	AF
							^a Terry White Chemists Clomipramine	TW
				B3.26	19.66	17.43	^a Anafranil 25	NV
DOTHIEPIN HYDROCHLORIDE								
1357K	Capsule 25 mg	50	2	..	8.53	9.56	^a Dothep 25	AF
				B1.58	10.11	9.56	^a Prothiaden	AB
1358L	Tablet 75 mg	30	2	..	8.53	9.56	^a Dothep 75	AF
				B0.81	9.34	9.56	^a Prothiaden	AB
DOXEPIN HYDROCHLORIDE								
1012G	Tablet 50 mg (base)	50	2	..	9.28	10.31	Deptran 50	AF
1011F	Capsule 10 mg (base)	50	2	..	8.54	9.57	Deptran 10	AF
				B1.87	10.41	9.57	Sinequan	PF
1013H	Capsule 25 mg (base)	50	2	..	8.97	10.00	Deptran 25	AF
				B1.57	10.54	10.00	Sinequan	PF
IMIPRAMINE HYDROCHLORIDE								
2420J	Tablet 10 mg	50	2	..	8.24	9.27	^a Tolerade 10	LN
				B2.97	11.21	9.27	^a Tofranil 10	LM
2421K	Tablet 25 mg	50	2	..	8.24	9.27	^a Tolerade 25	LN
				B2.97	11.21	9.27	^a Tofranil 25	LM

[illegible]

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>							
<u>Restricted Benefit</u>							
<i>Moderate to severe generalised anxiety disorder (GAD), as defined by Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV) criteria, in a patient who has not responded to non-pharmacological therapy and:</i>							
<i>(a) for whom a GP Mental Health Care Plan, as described under item 2710 of the Medicare Benefits Schedule, has been prepared; or</i>							
<i>(b) who has been assessed by a psychiatrist;</i>							
<i>Continuing PBS-subsidised treatment, for moderate to severe generalised anxiety disorder (GAD), of a patient commenced on escitalopram prior to 1 March 2008.</i>							
<u>Restricted Benefit</u>							
<i>Moderate to severe social anxiety disorder (social phobia, SAD), as described by Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV) criteria, in a patient who has not responded to non-pharmacological therapy and:</i>							
<i>(a) for whom a GP Mental Health Care Plan, as described under item 2710 of the Medicare Benefits Schedule, has been prepared; or</i>							
<i>(b) who has been assessed by a psychiatrist;</i>							
<i>Continuing PBS-subsidised treatment, for moderate to severe social anxiety disorder (social phobia, SAD), of a patient commenced on escitalopram prior to 1 March 2008.</i>							
8700X	Tablet 10 mg (base)	28	5	..	28.98	30.01	^a Esipram CF
						^a Esitalo SZ	
				B4.89	33.87	30.01	^a Lexapro LU
8701Y	Tablet 20 mg (base)	28	5	..	29.12	30.15	^a Esipram CF
						^a Esitalo SZ	
				B7.16	36.28	30.15	^a Lexapro LU

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>Restricted Benefit</u>								
<i>Major depressive disorders.</i>								
<u>Restricted Benefit</u>								
<i>Moderate to severe generalised anxiety disorder (GAD), as defined by Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV) criteria, in a patient who has not responded to non-pharmacological therapy and:</i>								
<i>(a) for whom a GP Mental Health Care Plan, as described under item 2710 of the Medicare Benefits Schedule, has been prepared; or</i>								
<i>(b) who has been assessed by a psychiatrist;</i>								
<i>Continuing PBS-subsidised treatment, for moderate to severe generalised anxiety disorder (GAD), of a patient commenced on escitalopram prior to 1 November 2008.</i>								
<u>Restricted Benefit</u>								
<i>Moderate to severe social anxiety disorder (social phobia, SAD), as described by Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV) criteria, in a patient who has not responded to non-pharmacological therapy and:</i>								
<i>(a) for whom a GP Mental Health Care Plan, as described under item 2710 of the Medicare Benefits Schedule, has been prepared; or</i>								
<i>(b) who has been assessed by a psychiatrist;</i>								
<i>Continuing PBS-subsidised treatment, for moderate to severe social anxiety disorder (social phobia, SAD), of a patient commenced on escitalopram prior to 1 November 2008.</i>								
8849R	Oral solution 10 mg (base) per mL, 28 mL	± 1	5	..	28.98	30.01	Lexapro	LU
FLUOXETINE HYDROCHLORIDE								
<u>Restricted Benefit</u>								
<i>Major depressive disorders;</i>								
<i>Obsessive-compulsive disorder.</i>								
8270G	Tablet 20 mg (base) (dispersible)	28	5	..	20.38	21.41	^a Lovan 20 Tab	AL
				B4.13	24.51	21.41	^a Prozac Tab	LY
1434L	Capsule 20 mg (base)	28	5	..	20.38	21.41	^a Auscap	SI
							^a Chem mart	CH
							Fluoxetine	
							^a Fluohexal	SZ
							^a Fluoxebell	BF
							^a Fluoxetine 20	CR
							^a Fluoxetine-DP	GM
							^a GenRx Fluoxetine	GX
							^a Lovan	AL
							^a Terry White	TW
							Chemists	
							Fluoxetine	
							^a Zactin	AF
				B4.13	24.51	21.41	^a Prozac 20	LY

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
FLUVOXAMINE MALEATE							
<u>Restricted Benefit</u>							
<i>Major depressive disorders;</i>							
<i>Obsessive-compulsive disorder.</i>							
8512B	Tablet 50 mg	30	5	..	19.94	20.97	^a APO-Fluvoxamine TX ^a Faverin 50 SI ^a Movox 50 AL ^a Voxam SZ b2.96 22.90 20.97 ^a Luvox SM
8174F	Tablet 100 mg	30	5	..	27.12	28.15	^a APO-Fluvoxamine TX ^a Faverin 100 SI ^a Movox 100 AF ^a Voxam SZ b2.95 30.07 28.15 ^a Luvox SM
PAROXETINE							
<u>Restricted Benefit</u>							
<i>Major depressive disorders;</i>							
<i>Obsessive-compulsive disorder;</i>							
<i>Panic disorder.</i>							
2242B	Tablet 20 mg (as hydrochloride)	30	5	..	25.05	26.08	^a Chem mart CH Paroxetine ^a Extine 20 SI ^a GenRx Paroxetine GX ^a Paroxetine 20 CR ^a Paroxetine-DP GM ^a Paroxetine Sandoz SZ ^a Paroxetine WA Winthrop ^a Paxtine AF ^a Terry White TW Chemists Paroxetine b0.86 25.91 26.08 ^a Aropax GK
9197C	Tablet 20 mg (as mesilate)	30	5	..	25.05	26.08	^a Paroxetine GQ generichealth

NOTE:

Bioequivalence has been demonstrated between paroxetine tablet 20 mg (as hydrochloride) and paroxetine tablet 20 mg (as mesilate).

NERVOUS SYSTEM—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Proprietary Name and Manufacturer
SERTRALINE HYDROCHLORIDE							
<u>Restricted Benefit</u>							
<i>Major depressive disorders.</i>							
2236Q	Tablet 50 mg (base)	30	5	..	24.23	25.26	^a Chem mart CH Sertraline ^a Concorz SZ ^a Eleva 50 AF ^a GenRx Sertraline GX ^a Sertra 50 SI ^a Sertraline 50 CR ^a Sertraline-GA GM ^a Sertraline GQ generichealth ^a Sertraline WA Winthrop ^a Setrona RA ^a Terry White TW Chemists Sertraline ^a Xydep 50 AW ^a Zoloft PF
				B1.49	25.72	25.26	
2237R	Tablet 100 mg (base)	30	5	..	24.23	25.26	^a Chem mart CH Sertraline ^a Concorz SZ ^a Eleva 100 AF ^a GenRx Sertraline GX ^a Sertra 100 SI ^a Sertraline 100 CR ^a Sertraline-GA GM ^a Sertraline GQ generichealth ^a Sertraline WA Winthrop ^a Setrona RA ^a Terry White TW Chemists Sertraline ^a Xydep 100 AW ^a Zoloft PF
				B1.49	25.72	25.26	

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>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	..	24.23	25.26	^a Eleva 50	AF
							^a Xydep 50	AW
				B1.49	25.72	25.26	^a Zoloft	PF
8837D	Tablet 100 mg (base)	30	5	..	24.23	25.26	^a Eleva 100	AF
							^a Xydep 100	AW
				B1.49	25.72	25.26	^a Zoloft	PF
• Monoamine oxidase inhibitors, non-selective								
PHENELZINE SULFATE								
CAUTION:								
<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	..	99.67	32.90	Nardil	LM
TRANLYCYPROMINE SULFATE								
CAUTION:								
<i>This drug is an irreversible monoamine oxidase inhibitor.</i>								
2444P	Tablet 10 mg (base)	50	2	..	33.12	32.90	Parnate	GH
• Monoamine oxidase type A inhibitors								
MOCLOBEMIDE								
<u>Restricted Benefit</u>								
<i>Major depressive disorders.</i>								
1900B	Tablet 150 mg	60	5	..	18.33	19.36	^a Amira 150	AF
							^a Chem mart	CH
							Moclobemide	
							^a Clobemix	GM
							^a GenRx	GX
							Moclobemide	
							^a Mohexal	SZ
							^a Terry White	TW
							Chemists	
							Moclobemide	
				B0.72	19.05	19.36	^a Aurorix	RO

continued ➞

NERVOUS SYSTEM—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Proprietary Name and Manufacturer	
8003F	Tablet 300 mg	60	5	..	29.75	30.78	^a Amira 300	AF
							^a Chem mart	CH
							Moclobemide	
							^a Clobemix	GM
							^a GenRx	GX
							Moclobemide	
							^a Maosig	SI
							^a Mohexal	SZ
							^a Terry White	TW
							Chemists	
							Moclobemide	
				B1.45	31.20	30.78	^a Aurorix 300 mg	RO
• Other antidepressants								
DESVENLAFAXINE SUCCINATE								
<u>Restricted Benefit</u>								
Major depressive disorders.								
9366Y	Tablet 50 mg (base) (extended release)	28	5	..	42.88	32.90	Pristiq	WX
9367B	Tablet 100 mg (base) (extended release)	28	5	..	49.99	32.90	Pristiq	WX
DULOXETINE HYDROCHLORIDE								
<u>Restricted Benefit</u>								
Major depressive disorders.								
9155W	Capsule 30 mg (base)	28	..	..	37.79	32.90	Cymbalta	LY
9156X	Capsule 60 mg (base)	28	5	..	49.99	32.90	Cymbalta	LY
LITHIUM CARBONATE								
3059B	Tablet 250 mg	200	2	..	16.46	17.49	Lithicarb	AS
8290H	Tablet 450 mg (slow release)	200	2	..	* 33.87	32.90	Quilonum SR	GK
MIANSERIN HYDROCHLORIDE								
<u>CAUTION:</u>								
Neutropenia and agranulocytosis are more frequent in the elderly, especially in the early months of therapy.								
<u>Restricted Benefit</u>								
Severe depression.								
1627P	Tablet 10 mg	50	5	..	15.51	16.54	^a Lumin 10	AF
				B1.99	17.50	16.54	^a Tolvon	SH
1628Q	Tablet 20 mg	50	5	..	26.09	27.12	^a Lumin 20	AF
				B2.97	29.06	27.12	^a Tolvon	SH

NERVOUS SYSTEM—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Proprietary Name and Manufacturer	
MIRTAZAPINE								
<u>Restricted Benefit</u>								
<i>Major depressive disorders.</i>								
9365X	Tablet 15 mg	30	5	..	19.94	20.97	Axit 15	AF
8855C	Tablet 15 mg (orally disintegrating)	30	5	..	19.94	20.97	Avanza SolTab	SH
8513C	Tablet 30 mg	30	5	..	26.91	27.94	^a Axit 30	AF
							^a Chem mart	CH
							Mirtazapine	
							^a GenRx	GX
							Mirtazapine	
							^a Mirtazapine-DP	GM
							^a Mirtazapine	SZ
							Sandoz	
							^a Mirtazon	SI
							^a Terry White	TW
							Chemists	
							Mirtazapine	
				B1.70	28.61	27.94	^a Avanza	SH
8856D	Tablet 30 mg (orally disintegrating)	30	5	..	26.91	27.94	Avanza SolTab	SH
8883M	Tablet 45 mg	30	5	..	40.81	32.90	^a APO-Mirtazapine	TX
							^a Chem mart	CH
							Mirtazapine	
							^a Mirtazapine	SZ
							Sandoz	
							^a Mirtazon	SI
							^a Terry White	TW
							Chemists	
							Mirtazapine	
				B1.49	42.30	32.90	^a Avanza	SH
8857E	Tablet 45 mg (orally disintegrating)	30	5	..	40.81	32.90	Avanza SolTab	SH
REBOXETINE MESILATE								
<u>Restricted Benefit</u>								
<i>Major depressive disorders.</i>								
8583R	Tablet 4 mg (base)	60	5	..	38.33	32.90	Edronax	PH
VENLAFAXINE HYDROCHLORIDE								
<u>Restricted Benefit</u>								
<i>Major depressive disorders.</i>								
8868R	Capsule 37.5 mg (base) (modified release)	28	..	..	27.10	28.13	Efexor-XR	WX
8301X	Capsule 75 mg (base) (modified release)	28	5	..	42.88	32.90	Efexor-XR	WX

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	
8302Y	Capsule 150 mg (base) (modified release)	28	5	..	49.99	32.90	Efexor-XR	WX

Psychostimulants, agents used for ADHD and nootropics

• Centrally acting sympathomimetics

ATOMOXETINE HYDROCHLORIDE

Authority Required

Initial sole PBS-subsidised treatment of attention-deficit hyperactivity disorder (ADHD) diagnosed between the ages of 6 and 18 years inclusive, by a paediatrician or psychiatrist according to the DSM-IV criteria, where:

- (a) treatment with dexamphetamine sulfate or methylphenidate hydrochloride poses an unacceptable medical risk due to the following contraindications as specified in the TGA-approved product information:
- (1) The patient has a history of substance abuse or misuse (other than alcohol); and/or
 - (2) The patient has comorbid motor tics or Tourette's Syndrome; and/or
 - (3) The patient has comorbid severe anxiety diagnosed according to the DSM-IV; or
- (b) treatment with dexamphetamine sulfate or methylphenidate hydrochloride has resulted in the development or worsening of a comorbid mood disorder (diagnosed according to the DSM-IV criteria i.e. anxiety disorder, obsessive compulsive disorder, depressive disorder) of a severity necessitating permanent stimulant treatment withdrawal; or where the combination of stimulant treatment with another agent would pose an unacceptable medical risk of a severity necessitating permanent stimulant treatment withdrawal; or
- (c) treatment with dexamphetamine sulfate AND methylphenidate hydrochloride has resulted in the development of adverse reactions of a severity necessitating permanent treatment withdrawal:
- (1) Adverse effects on growth and weight; and/or
 - (2) Adverse effects on sleep including insomnia; and/or
 - (3) Adverse effects on appetite including anorexia.

NOTE:

No applications for increased maximum quantities and/or repeats will be authorised.

Authority Required

Continuing sole PBS-subsidised treatment where the patient has previously been issued with an authority prescription for this drug.

NOTE:

No applications for increased maximum quantities and/or repeats will be authorised.

9092M	Capsule 10 mg (base)	56	5	..	* 220.75	32.90	Strattera	LY
9093N	Capsule 18 mg (base)	56	5	..	* 220.75	32.90	Strattera	LY
9094P	Capsule 25 mg (base)	56	5	..	* 220.75	32.90	Strattera	LY
9095Q	Capsule 40 mg (base)	56	5	..	* 220.75	32.90	Strattera	LY
9096R	Capsule 60 mg (base)	56	5	..	* 220.75	32.90	Strattera	LY
9289X	Capsule 80 mg (base)	28	5	..	146.68	32.90	Strattera	LY
9290Y	Capsule 100 mg (base)	28	5	..	146.68	32.90	Strattera	LY

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	

DEXAMPHETAMINE SULFATE

NOTE:

Care must be taken to comply with the provisions of State/Territory law when prescribing dexamphetamine.

Authority Required

Use in attention deficit hyperactivity disorder, in accordance with State/Territory law;

Narcolepsy.

1165H	Tablet 5 mg	100	5	..	17.76	18.79	SI

METHYLPHENIDATE HYDROCHLORIDE

NOTE:

Care must be taken to comply with the provisions of State/Territory law when prescribing methylphenidate hydrochloride.

Authority Required

Use in attention deficit hyperactivity disorder, in accordance with State/Territory law.

8839F	Tablet 10 mg	100	5	..	16.87	17.90	Ritalin 10	NV

Authority Required

Treatment of attention deficit hyperactivity disorder (ADHD) in a patient aged 6 to 18 years inclusive, who has demonstrated a response to immediate release methylphenidate hydrochloride with no emergence of serious adverse events, and who requires continuous coverage over 12 hours.

2387P	Tablet 18 mg (extended release)	30	5	..	52.87	32.90	Concerta	JC
2172H	Tablet 27 mg (extended release)	30	5	..	57.23	32.90	Concerta	JC
2388Q	Tablet 36 mg (extended release)	30	5	..	61.93	32.90	Concerta	JC
2432B	Tablet 54 mg (extended release)	30	5	..	72.52	32.90	Concerta	JC

Authority Required

Treatment of attention deficit hyperactivity disorder in a patient aged 6 to 18 years inclusive, who has demonstrated a response to immediate release methylphenidate hydrochloride with no emergence of serious adverse events, and who requires continuous coverage over 8 hours.

2276T	Capsule 20 mg (modified release)	30	5	..	45.77	32.90	Ritalin LA	NV
2280B	Capsule 30 mg (modified release)	30	5	..	53.62	32.90	Ritalin LA	NV
2283E	Capsule 40 mg (modified release)	30	5	..	56.28	32.90	Ritalin LA	NV

MODAFINIL

NOTE:

Any queries concerning the arrangements to prescribe modafinil may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written applications for authority to prescribe modafinil should be forwarded to:

continued ➡

NERVOUS SYSTEM—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 \$	
Medicare Australia Prior Written Approval of Specialised Drugs Reply Paid 9826 GPO Box 9826 HOBART TAS 7001 <i>Further prescribing information is on the Medicare Australia website at www.medicareaustralia.gov.au.</i> NOTE: <i>Modafinil is not PBS-subsidised when used in combination with PBS-subsidised dexamphetamine sulfate.</i> Authority Required <i>Initial treatment, by a qualified sleep medicine practitioner or neurologist, of patients with narcolepsy where:</i> <i>(i) therapy with dexamphetamine sulfate poses an unacceptable medical risk; or</i> <i>(ii) intolerance to dexamphetamine sulfate of a severity necessitating permanent treatment withdrawal develops.</i> <i>The presence of any 1 of the following indicates treatment with dexamphetamine sulfate poses an unacceptable medical risk:</i> <i>(a) a psychiatric disorder;</i> <i>(b) a cardiac disorder;</i> <i>(c) a history of substance abuse;</i> <i>(d) glaucoma;</i> <i>(e) any other absolute contraindication to dexamphetamine sulfate as specified in the TGA-approved Product Information.</i> <i>Patients must meet the following definition of narcolepsy:</i> <i>Excessive daytime sleepiness, recurrent naps or lapses into sleep occurring almost daily for at least 3 months and:</i> <i>(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</i> <i>(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</i> <i>(iii) an electroencephalographic (EEG) recording showing the pathologically rapid development of REM sleep.</i> <i>The MSLT must be preceded by nocturnal polysomnography. Sleep prior to the MSLT must be at least 6 hours.</i> <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> Authority Required <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	..	* 346.55	32.90	Modavigil CS

NERVOUS SYSTEM—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 \$	

Anti-dementia drugs

• Anticholinesterases

DONEPEZIL HYDROCHLORIDE

Authority Required

INITIAL APPLICATION FOR THE TREATMENT OF MILD TO MODERATELY SEVERE ALZHEIMER'S DISEASE — Patients with an (S)MMSE of 10 or more.

Initial treatment, as the sole PBS-subsidised therapy, of mild to moderately severe Alzheimer's disease. Confirmation of this diagnosis must be made by a specialist/consultant physician (including a psychiatrist).

The authority application must include the result of the baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE). This baseline (S)MMSE must be a score of 10 or more. If this score is 25 - 30 points, the result of a baseline Alzheimer's Disease Assessment Scale, cognitive sub-scale (ADAS-Cog) may also be specified.

If an ADAS-Cog score is not supplied with the initial application, this scale cannot be used for the purpose of fulfilling the criteria for continued PBS supply.

This application must be made in writing, but initial supply may be sought by telephone.

For telephone applications, up to a maximum of 2 months' initial therapy will be authorised. This telephone application must be followed by a written authority application for no more than 1 month's therapy and sufficient repeats to complete a maximum of up to 6 months' initial treatment.

For written applications where no prior telephone approval has been issued, up to a maximum of 1 month's therapy plus 5 repeats will be authorised;

CONTINUING TREATMENT — (S)MMSE or ADAS-Cog improvement.

Continuing treatment, as the sole PBS-subsidised therapy, following initial PBS-subsidised therapy, of mild to moderately severe Alzheimer's disease in patients with demonstrated improvement in cognitive function as measured by:

(a) for patients with a baseline (S)MMSE score of 10 or more and less than 25, an increase of at least 2 points from baseline on the Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE);

(b) for patients with a baseline (S)MMSE score of at least 25 points, a decrease of at least 4 points from baseline on the Alzheimer's Disease Assessment Scale, cognitive sub-scale (ADAS-Cog) or an increase of at least 2 points from baseline on the Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE).

The initial authority application for continuing treatment must include the relevant result from the (S)MMSE or the ADAS-Cog and must be in writing.

Subsequent applications for continuing treatment can be made by telephone.

Authority Required

INITIAL APPLICATION FOR THE TREATMENT OF MILD TO MODERATELY SEVERE ALZHEIMER'S DISEASE — Patients with an (S)MMSE of 9 or less who require a clinician's assessment.

Initial treatment, as the sole PBS-subsidised therapy, of mild to moderately severe Alzheimer's disease of patients with a baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE) score of 9 or less, who are unable to register a score of 10 or more for reasons other than their Alzheimer's disease, as specified below. Confirmation of this diagnosis must be made by a specialist/consultant physician (including a psychiatrist).

Such patients will need to be assessed using the Clinicians Interview Based Impression of Severity (CIBIS) scale.

The authority application must include the result of the baseline (S)MMSE and specify to which group(s) (see below) the patient belongs.

NERVOUS SYSTEM—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 \$	

This application must be made in writing, but initial supply may be sought by telephone.

For telephone applications, up to a maximum of 2 months' initial therapy will be authorised. This telephone application must be followed by a written authority application for no more than 1 month's therapy and sufficient repeats to complete a maximum of up to 6 months' initial treatment.

For written applications where no prior telephone approval has been issued, up to a maximum of 1 month's therapy plus 5 repeats will be authorised.

Patients who qualify under this criterion are from 1 or more of the following groups:

- (1) Unable to communicate adequately because of lack of competence in English, in people of non-English speaking background;*
- (2) Limited education, as defined by less than 6 years of education, or who are illiterate or innumerate;*
- (3) Aboriginal or Torres Strait Islanders who, by virtue of cultural factors, are unable to complete an (S)MMSE test;*
- (4) Intellectual (developmental or acquired) disability, eg Down's syndrome;*
- (5) Significant sensory impairment despite best correction, which precludes completion of an (S)MMSE test;*
- (6) Prominent dysphasia, out of proportion to other cognitive and functional impairment;*

CONTINUING TREATMENT — Clinician assessed improvement.

Continuing treatment, as the sole PBS-subsidised therapy, following initial PBS-subsidised therapy, of mild to moderately severe Alzheimer's disease in patients with demonstrated improvement in function, based on a rating of "very much improved" or "much improved" on the Clinicians Interview Based Impression of Change (CIBIC) scale, which must be assessed by the same clinician who initiated treatment.

The initial authority application for continuing treatment must state the improvement achieved on the CIBIC scale and must be in writing.

Subsequent applications for continuing treatment can be made by telephone.

8495D	Tablet 5 mg	28	5	..	155.02	32.90	Aricept	PF
8496E	Tablet 10 mg	28	5	..	155.02	32.90	Aricept	PF

GALANTAMINE HYDROBROMIDE

Authority Required

INITIAL APPLICATION FOR THE TREATMENT OF MILD TO MODERATELY SEVERE ALZHEIMER'S DISEASE — Patients with an (S)MMSE of 10 or more.

Initial treatment, as the sole PBS-subsidised therapy, of mild to moderately severe Alzheimer's disease. Confirmation of this diagnosis must be made by a specialist/consultant physician (including a psychiatrist).

The authority application must include the result of the baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE). This baseline (S)MMSE must be a score of 10 or more. If this score is 25 - 30 points, the result of a baseline Alzheimer's Disease Assessment Scale, cognitive sub-scale (ADAS-Cog) may also be specified.

If an ADAS-Cog score is not supplied with the initial application, this scale cannot be used for the purpose of fulfilling the criteria for continued PBS supply.

This application must be made in writing, but initial supply may be sought by telephone.

For telephone applications, up to a maximum of 2 months' initial therapy will be authorised. This telephone application must be followed by a written authority application for no more than 1 month's therapy and sufficient repeats to complete a maximum of up to 6 months' initial treatment.

For written applications where no prior telephone approval has been issued, up to a maximum of 1 month's therapy plus 5 repeats will be authorised;

continued ➞

NERVOUS SYSTEM—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 \$	

CONTINUING TREATMENT — (S)MMSE or ADAS-Cog improvement.

Continuing treatment, as the sole PBS-subsidised therapy, following initial PBS-subsidised therapy, of mild to moderately severe Alzheimer's disease in patients with demonstrated improvement in cognitive function as measured by:

(a) for patients with a baseline (S)MMSE score of 10 or more and less than 25, an increase of at least 2 points from baseline on the Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE);

(b) for patients with a baseline (S)MMSE score of at least 25 points, a decrease of at least 4 points from baseline on the Alzheimer's Disease Assessment Scale, cognitive sub-scale (ADAS-Cog) or an increase of at least 2 points from baseline on the Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE).

The initial authority application for continuing treatment must include the relevant result from the (S)MMSE or the ADAS-Cog and must be in writing.

Subsequent applications for continuing treatment can be made by telephone.

Authority Required

INITIAL APPLICATION FOR THE TREATMENT OF MILD TO MODERATELY SEVERE ALZHEIMER'S DISEASE — Patients with an (S)MMSE of 9 or less who require a clinician's assessment.

Initial treatment, as the sole PBS-subsidised therapy, of mild to moderately severe Alzheimer's disease of patients with a baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE) score of 9 or less, who are unable to register a score of 10 or more for reasons other than their Alzheimer's disease, as specified below. Confirmation of this diagnosis must be made by a specialist/consultant physician (including a psychiatrist).

Such patients will need to be assessed using the Clinicians Interview Based Impression of Severity (CIBIS) scale. The authority application must include the result of the baseline (S)MMSE and specify to which group(s) (see below) the patient belongs.

This application must be made in writing, but initial supply may be sought by telephone.

For telephone applications, up to a maximum of 2 months' initial therapy will be authorised. This telephone application must be followed by a written authority application for no more than 1 month's therapy and sufficient repeats to complete a maximum of up to 6 months' initial treatment.

For written applications where no prior telephone approval has been issued, up to a maximum of 1 month's therapy plus 5 repeats will be authorised.

Patients who qualify under this criterion are from 1 or more of the following groups:

- (1) Unable to communicate adequately because of lack of competence in English, in people of non-English speaking background;*
- (2) Limited education, as defined by less than 6 years of education, or who are illiterate or innumerate;*
- (3) Aboriginal or Torres Strait Islanders who, by virtue of cultural factors, are unable to complete an (S)MMSE test;*
- (4) Intellectual (developmental or acquired) disability, eg Down's syndrome;*
- (5) Significant sensory impairment despite best correction, which precludes completion of an (S)MMSE test;*
- (6) Prominent dysphasia, out of proportion to other cognitive and functional impairment;*

CONTINUING TREATMENT — Clinician assessed improvement.

Continuing treatment, as the sole PBS-subsidised therapy, following initial PBS-subsidised therapy, of mild to moderately severe Alzheimer's disease in patients with demonstrated improvement in function, based on a rating of "very much improved" or "much improved" on the Clinicians Interview Based Impression of Change (CIBIC) scale, which must be assessed by the same clinician who initiated treatment.

The initial authority application for continuing treatment must state the improvement achieved on the CIBIC scale and must be in writing.

NERVOUS SYSTEM—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 \$		
Subsequent applications for continuing treatment can be made by telephone.								
8770N	Capsule 8 mg (base) (prolonged release)	28	5	..	130.39	32.90	Reminyl	JC
8771P	Capsule 16 mg (base) (prolonged release)	28	5	..	158.16	32.90	Reminyl	JC
8772Q	Capsule 24 mg (base) (prolonged release)	28	5	..	187.34	32.90	Reminyl	JC

RIVASTIGMINE

Authority Required

INITIAL APPLICATION FOR THE TREATMENT OF MILD TO MODERATELY SEVERE ALZHEIMER'S DISEASE — Patients with an (S)MMSE of 10 or more.

Initial treatment, as the sole PBS-subsidised therapy, of mild to moderately severe Alzheimer's disease. Confirmation of this diagnosis must be made by a specialist/consultant physician (including a psychiatrist).

The authority application must include the result of the baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE). This baseline (S)MMSE must be a score of 10 or more. If this score is 25 - 30 points, the result of a baseline Alzheimer's Disease Assessment Scale, cognitive sub-scale (ADAS-Cog) may also be specified.

If an ADAS-Cog score is not supplied with the initial application, this scale cannot be used for the purpose of fulfilling the criteria for continued PBS supply.

This application must be made in writing, but initial supply may be sought by telephone.

For telephone applications, up to a maximum of 2 months' initial therapy will be authorised. This telephone application must be followed by a written authority application for no more than 1 month's therapy and sufficient repeats to complete a maximum of up to 6 months' initial treatment.

For written applications where no prior telephone approval has been issued, up to a maximum of 1 month's therapy plus 5 repeats will be authorised;

CONTINUING TREATMENT — (S)MMSE or ADAS-Cog improvement.

Continuing treatment, as the sole PBS-subsidised therapy, following initial PBS-subsidised therapy, of mild to moderately severe Alzheimer's disease in patients with demonstrated improvement in cognitive function as measured by:

(a) for patients with a baseline (S)MMSE score of 10 or more and less than 25, an increase of at least 2 points from baseline on the Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE);

(b) for patients with a baseline (S)MMSE score of at least 25 points, a decrease of at least 4 points from baseline on the Alzheimer's Disease Assessment Scale, cognitive sub-scale (ADAS-Cog) or an increase of at least 2 points from baseline on the Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE).

The initial authority application for continuing treatment must include the relevant result from the (S)MMSE or the ADAS-Cog and must be in writing.

Subsequent applications for continuing treatment can be made by telephone.

continued ➞

NERVOUS SYSTEM—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 \$		

Authority Required

INITIAL APPLICATION FOR THE TREATMENT OF MILD TO MODERATELY SEVERE ALZHEIMER'S DISEASE — Patients with an (S)MMSE of 9 or less who require a clinician's assessment.

Initial treatment, as the sole PBS-subsidised therapy, of mild to moderately severe Alzheimer's disease of patients with a baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE) score of 9 or less, who are unable to register a score of 10 or more for reasons other than their Alzheimer's disease, as specified below. Confirmation of this diagnosis must be made by a specialist/consultant physician (including a psychiatrist).

Such patients will need to be assessed using the Clinicians Interview Based Impression of Severity (CIBIS) scale. The authority application must include the result of the baseline (S)MMSE and specify to which group(s) (see below) the patient belongs.

This application must be made in writing, but initial supply may be sought by telephone.

For telephone applications, up to a maximum of 2 months' initial therapy will be authorised. This telephone application must be followed by a written authority application for no more than 1 month's therapy and sufficient repeats to complete a maximum of up to 6 months' initial treatment.

For written applications where no prior telephone approval has been issued, up to a maximum of 1 month's therapy plus 5 repeats will be authorised.

Patients who qualify under this criterion are from 1 or more of the following groups:

- (1) Unable to communicate adequately because of lack of competence in English, in people of non-English speaking background;
- (2) Limited education, as defined by less than 6 years of education, or who are illiterate or innumerate;
- (3) Aboriginal or Torres Strait Islanders who, by virtue of cultural factors, are unable to complete an (S)MMSE test;
- (4) Intellectual (developmental or acquired) disability, eg Down's syndrome;
- (5) Significant sensory impairment despite best correction, which precludes completion of an (S)MMSE test;
- (6) Prominent dysphasia, out of proportion to other cognitive and functional impairment;

CONTINUING TREATMENT — Clinician assessed improvement.

Continuing treatment, as the sole PBS-subsidised therapy, following initial PBS-subsidised therapy, of mild to moderately severe Alzheimer's disease in patients with demonstrated improvement in function, based on a rating of "very much improved" or "much improved" on the Clinicians Interview Based Impression of Change (CIBIC) scale, which must be assessed by the same clinician who initiated treatment.

The initial authority application for continuing treatment must state the improvement achieved on the CIBIC scale and must be in writing.

Subsequent applications for continuing treatment can be made by telephone.

9161E	Transdermal patch 9 mg (releasing approximately 4.6 mg per 24 hours)	30	5	..	165.66	32.90	Exelon Patch 5	NV
9162F	Transdermal patch 18 mg (releasing approximately 9.5 mg per 24 hours)	30	5	..	165.66	32.90	Exelon Patch 10	NV

NERVOUS SYSTEM—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 \$	

RIVASTIGMINE HYDROGEN TARTRATE

Authority Required

INITIAL APPLICATION FOR THE TREATMENT OF MILD TO MODERATELY SEVERE ALZHEIMER'S DISEASE — Patients with an (S)MMSE of 10 or more.

Initial treatment, as the sole PBS-subsidised therapy, of mild to moderately severe Alzheimer's disease. Confirmation of this diagnosis must be made by a specialist/consultant physician (including a psychiatrist).

The authority application must include the result of the baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE). This baseline (S)MMSE must be a score of 10 or more. If this score is 25 - 30 points, the result of a baseline Alzheimer's Disease Assessment Scale, cognitive sub-scale (ADAS-Cog) may also be specified.

If an ADAS-Cog score is not supplied with the initial application, this scale cannot be used for the purpose of fulfilling the criteria for continued PBS supply.

This application must be made in writing, but initial supply may be sought by telephone.

For telephone applications, up to a maximum of 2 months' initial therapy will be authorised. This telephone application must be followed by a written authority application for no more than 1 month's therapy and sufficient repeats to complete a maximum of up to 6 months' initial treatment.

For written applications where no prior telephone approval has been issued, up to a maximum of 1 month's therapy plus 5 repeats will be authorised;

CONTINUING TREATMENT — (S)MMSE or ADAS-Cog improvement.

Continuing treatment, as the sole PBS-subsidised therapy, following initial PBS-subsidised therapy, of mild to moderately severe Alzheimer's disease in patients with demonstrated improvement in cognitive function as measured by:

(a) for patients with a baseline (S)MMSE score of 10 or more and less than 25, an increase of at least 2 points from baseline on the Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE);

(b) for patients with a baseline (S)MMSE score of at least 25 points, a decrease of at least 4 points from baseline on the Alzheimer's Disease Assessment Scale, cognitive sub-scale (ADAS-Cog) or an increase of at least 2 points from baseline on the Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE).

The initial authority application for continuing treatment must include the relevant result from the (S)MMSE or the ADAS-Cog and must be in writing.

Subsequent applications for continuing treatment can be made by telephone.

Authority Required

INITIAL APPLICATION FOR THE TREATMENT OF MILD TO MODERATELY SEVERE ALZHEIMER'S DISEASE — Patients with an (S)MMSE of 9 or less who require a clinician's assessment.

Initial treatment, as the sole PBS-subsidised therapy, of mild to moderately severe Alzheimer's disease of patients with a baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE) score of 9 or less, who are unable to register a score of 10 or more for reasons other than their Alzheimer's disease, as specified below. Confirmation of this diagnosis must be made by a specialist/consultant physician (including a psychiatrist).

Such patients will need to be assessed using the Clinicians Interview Based Impression of Severity (CIBIS) scale. The authority application must include the result of the baseline (S)MMSE and specify to which group(s) (see below) the patient belongs.

continued ➡

NERVOUS SYSTEM—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed		Maximum Recordable Value for Safety Net	Proprietary Name and Manufacturer
					Price for	Max. Qty		
					\$		\$	
<i>This application must be made in writing, but initial supply may be sought by telephone.</i> <i>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, as the sole PBS-subsidised therapy, following initial PBS-subsidised therapy, of mild to moderately severe Alzheimer's disease in patients with demonstrated improvement in function, based on a rating of "very much improved" or "much improved" on the Clinicians Interview Based Impression of Change (CIBIC) scale, which must be assessed by the same clinician who initiated treatment.</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	..	155.02	32.90	Exelon	NV
8498G	Capsule 3 mg (base)	56	5	..	155.02	32.90	Exelon	NV
8499H	Capsule 4.5 mg (base)	56	5	..	155.02	32.90	Exelon	NV
8500J	Capsule 6 mg (base)	56	5	..	155.02	32.90	Exelon	NV
8563Q	Oral solution 2 mg (base) per mL, 120 mL	± 1	5	..	155.02	32.90	Exelon	NV

• **Other anti-dementia drugs**
MEMANTINE HYDROCHLORIDE

Authority Required

INITIAL APPLICATION FOR THE TREATMENT OF MODERATELY SEVERE ALZHEIMER'S DISEASE —
Patients with an (S)MMSE of 10 to 14.

Initial treatment, as the sole PBS-subsidised therapy, of moderately severe Alzheimer's disease. Confirmation of this diagnosis must be made by a specialist/consultant physician (including a psychiatrist).

The authority application must include the result of the baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE). This baseline (S)MMSE must be a score of 10 to 14.

continued ➞

NERVOUS SYSTEM—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 \$	

This application must be made in writing, but initial supply may be sought by telephone.

For telephone applications, up to a maximum of 2 months' initial therapy will be authorised. This telephone application must be followed by a written authority application for no more than 1 month's therapy and sufficient repeats to complete a maximum of up to 6 months' initial treatment.

For written applications where no prior telephone approval has been issued, up to a maximum of 1 month's therapy plus 5 repeats will be authorised;

CONTINUING TREATMENT — (S)MMSE improvement.

Continuing treatment, as the sole PBS-subsidised therapy, following initial PBS-subsidised therapy, of moderately severe Alzheimer's disease in patients with demonstrated improvement in cognitive function as measured by an increase of at least 2 points from baseline on the Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE).

The initial authority application for continuing treatment must include the relevant result from the (S)MMSE and must be in writing.

Subsequent applications for continuing treatment can be made by telephone.

Authority Required

INITIAL APPLICATION FOR THE TREATMENT OF MODERATELY SEVERE ALZHEIMER'S DISEASE —

Patients with an (S)MMSE of 9 or less who require a clinician's assessment.

Initial treatment, as the sole PBS-subsidised therapy, of moderately severe Alzheimer's disease of patients with a baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE) score of 9 or less, who are unable to register a score of 10 to 14 for reasons other than their Alzheimer's disease, as specified below. Confirmation of this diagnosis must be made by a specialist/consultant physician (including a psychiatrist).

Such patients will need to be assessed using the Clinicians Interview Based Impression of Severity (CIBIS) scale.

The authority application must include the result of the baseline (S)MMSE and specify to which group(s) (see below) the patient belongs.

This application must be made in writing, but initial supply may be sought by telephone.

For telephone applications, up to a maximum of 2 months' initial therapy will be authorised. This telephone application must be followed by a written authority application for no more than 1 month's therapy and sufficient repeats to complete a maximum of up to 6 months' initial treatment.

For written applications where no prior telephone approval has been issued, up to a maximum of 1 month's therapy plus 5 repeats will be authorised.

Patients who qualify under this criterion are from 1 or more of the following groups:

- (1) Unable to communicate adequately because of lack of competence in English, in people of non-English speaking background;*
- (2) Limited education, as defined by less than 6 years of education, or who are illiterate or innumerate;*
- (3) Aboriginal or Torres Strait Islanders who, by virtue of cultural factors, are unable to complete an (S)MMSE test;*
- (4) Intellectual (developmental or acquired) disability, eg Down's syndrome;*
- (5) Significant sensory impairment despite best correction, which precludes completion of an (S)MMSE test;*
- (6) Prominent dysphasia, out of proportion to other cognitive and functional impairment;*

CONTINUING TREATMENT — Clinician assessed improvement.

Continuing treatment, as the sole PBS-subsidised therapy, following initial PBS-subsidised therapy, of moderately severe Alzheimer's disease in patients with demonstrated improvement in function, based on a rating of "very much improved" or "much improved" on the Clinicians Interview Based Impression of Change (CIBIC) scale, which must be assessed by the same clinician who initiated treatment.

The initial authority application for continuing treatment must state the improvement achieved on the CIBIC scale and must be in writing.

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	

Subsequent applications for continuing treatment can be made by telephone.

Authority Required

APPLICATION FOR THE TREATMENT OF MODERATELY SEVERE ALZHEIMER'S DISEASE — Patients who commenced treatment prior to 1 March 2008.

Continuing treatment, as the sole PBS-subsidised therapy, of a patient commenced on memantine prior to 1 March 2008.

Applications for continuing treatment can be made by telephone.

1956Y	Tablet 10 mg	56	5	..	123.22	32.90	Ebixa	LU
2059J	Oral drops 10 mg per g, 50 g	± 1	5	..	110.67	32.90	Ebixa	LU

OTHER NERVOUS SYSTEM DRUGS

Parasympathomimetics

• **Anticholinesterases**

PYRIDOSTIGMINE BROMIDE

2724J	Tablet 10 mg	100	5	..	19.24	20.27	Mestinon	VT
1959D	Tablet 60 mg	150	5	..	55.57	32.90	Mestinon	VT
2608G	Tablet 180 mg (modified release)	100	5	..	114.04	32.90	Mestinon Timespan	VT

• **Choline esters**

BETHANECHOL CHLORIDE

1062X	Tablet 10 mg	100	2	..	20.60	21.63	Uro-Carb	HA

Drugs used in addictive disorders

• **Drugs used in nicotine dependence**

BUPROPION HYDROCHLORIDE

NOTE:

Only one course of PBS-subsidised bupropion hydrochloride will be authorised per 12 months. The period between commencing a course of bupropion hydrochloride and varenicline tartrate must be at least 6 months. A course of treatment with bupropion hydrochloride is 9 weeks. No increased maximum quantities or repeats will be authorised. Clinical review is recommended within 2 to 3 weeks of the original prescription being requested.

Authority Required

Commencement of short-term, sole PBS-subsidised, therapy as an aid to achieving abstinence in a patient who has indicated they are ready to cease smoking and:

- (a) *who has entered a comprehensive support and counselling program; or*
- (b) *who is entering a comprehensive support and counselling program during the consultation at which this authority is requested.*

Details of the program must be specified in the authority application.

8465M	Tablet 150 mg (sustained release)	30	..	..	76.83	32.90	^a Clorprax	HX
							^a Prexaton	AF
				80.85	77.68	32.90	^a Zyban	GK

continued ➞

NERVOUS SYSTEM—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 \$		
<u>Authority Required</u>								
<i>Completion of short-term, sole PBS-subsidised, therapy as an aid to achieving abstinence in a patient who has previously been issued with an authority prescription for this drug and who is enrolled in a comprehensive support and counselling program.</i>								
8710K	Tablet 150 mg (sustained release)	90	..	..	168.10	32.90	^a Clorprax	HX
							^a Prexaton	AF
				B0.86	168.96	32.90	^a Zyban	GK

NICOTINE

Authority Required

Nicotine dependence in an Aboriginal or a Torres Strait Islander person as the sole PBS-subsidised therapy.

NOTE:

Only 2 courses of PBS-subsidised nicotine replacement therapy will be authorised per year.

No applications for increased maximum quantities and/or repeats will be authorised.

Benefit is improved if used in conjunction with a comprehensive support and counselling program.

9198D	Transdermal patch releasing approximately 15 mg per 16 hours	28	2	..	54.79	32.90	Nicorette Patch	JT

VARENICLINE

NOTE:

Only one course of PBS-subsidised varenicline tartrate will be authorised per year. The period between commencing a course of varenicline tartrate and bupropion hydrochloride must be at least 6 months. A course of treatment with varenicline tartrate is 12 weeks. No increased maximum quantities or repeats will be authorised. Clinical review is recommended within 2 to 3 weeks of the original prescription being requested.

Authority Required

Commencement of short-term, sole PBS-subsidised, therapy as an aid to achieving abstinence in a patient who has indicated they are ready to cease smoking and:

(a) who has entered a comprehensive support and counselling program; or

(b) who is entering a comprehensive support and counselling program during the consultation at which this authority is requested.

Details of the program must be specified in the authority application.

9128K	Box containing 11 tablets 0.5 mg (as tartrate) and 14 tablets 1 mg (as tartrate) in the first pack and 28 tablets 1 mg (as tartrate) in the second pack	± 1	..	..	103.33	32.90	Champix	PF

Authority Required

Completion of short-term, sole PBS-subsidised, therapy as an aid to achieving abstinence in a patient who has previously been issued with an authority prescription for this drug and who is enrolled in a comprehensive support and counselling program.

9129L	Tablet 1 mg (as tartrate)	112	..	..	* 232.63	32.90	Champix	PF

NERVOUS SYSTEM—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed	Maximum	Proprietary Name and Manufacturer	
					Price for Max. Qty \$	Recordable Value for Safety Net \$		

• **Drugs used in alcohol dependence**

ACAMPROSATE CALCIUM

Authority Required (STREAMLINED)

2665

For use within a comprehensive treatment program for alcohol dependence with the goal of maintaining abstinence.

NOTE:

No applications for increased maximum quantities and/or repeats will be authorised.

8357W	Tablet 333 mg (enteric coated)	180	1	..	166.15	32.90	Campral	AF

NALTREXONE HYDROCHLORIDE

CAUTION:

Naltrexone hydrochloride is contraindicated in patients receiving opioid drugs.

Authority Required

For use within a comprehensive treatment program for alcohol dependence with the goal of maintaining abstinence.

NOTE:

No applications for increased maximum quantities and/or repeats will be authorised.

8370M	Tablet 50 mg	30	1	..	143.33	32.90	^a Naltrexone QP ^a ReVia	XF BQ

Other nervous system drugs

• **Other nervous system drugs**

RILUZOLE

Authority Required

Initial treatment of amyotrophic lateral sclerosis, as diagnosed by a neurologist, in patients with disease duration of 5 years or less and who have at least 60 percent of predicted forced vital capacity within 2 months prior to commencing riluzole therapy and who:

(1) are ambulatory, and

(a) have not undergone tracheostomy, and

(b) have not experienced respiratory failure; OR

(2) are not ambulatory, and

(a) have not undergone tracheostomy, and

(b) have not experienced respiratory failure, and

(c) are either able to use upper limbs or able to swallow.

The date of diagnosis and the date and results of spirometry (in terms of percent of predicted forced vital capacity) must be supplied with the initial authority application.

Authority Required

Continuing treatment of amyotrophic lateral sclerosis in patients who have previously been issued with an authority prescription for this drug and who:

(1) are ambulatory, and

(a) have not undergone tracheostomy, and

(b) have not experienced respiratory failure; OR

(2) are not ambulatory, and

(a) have not undergone tracheostomy, and

(b) have not experienced respiratory failure, and

(c) are either able to use upper limbs or able to swallow.

continued ➡

NERVOUS SYSTEM—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed	Maximum	Proprietary Name and Manufacturer	
					Price for Max. Qty \$	Recordable Value for Safety Net \$		
8664B	Tablet 50 mg	56	5	..	661.57	32.90	Rilutek	SW
TETRABENAZINE								
<u>Authority Required (STREAMLINED)</u>								
1161								
Hyperkinetic extrapyramidal disorders.								
1330B	Tablet 25 mg	112	5	..	337.12	32.90	OA	

ANTIPARASITIC PRODUCTS, INSECTICIDES AND REPELLENTS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed	Maximum	Proprietary Name and Manufacturer	
					Price for Max. Qty \$	Recordable Value for Safety Net \$		

ANTIPROTOZOALS

Agents against amoebiasis and other protozoal diseases

• Nitroimidazole derivatives

METRONIDAZOLE

For listings see Generic/Proprietary Index

METRONIDAZOLE BENZOATE

For listings see Generic/Proprietary Index

TINIDAZOLE

For listings see Generic/Proprietary Index

• Other agents against amoebiasis and other protozoal diseases

ATOVAQUONE

Authority Required (STREAMLINED)

1433

Treatment of mild to moderate Pneumocystis carinii pneumonia in adult patients who are intolerant of trimethoprim/sulfamethoxazole therapy.

8300W	Oral suspension 750 mg per 5 mL, 210 mL	\$ 1	..	..	1034.14	32.90	Wellvone	GK

PYRIMETHAMINE

1966L	Tablet 25 mg	50	..	..	15.94	16.97	Daraprim	GK

Antimalarials

• Methanolquinolines

QUININE BISULFATE

CAUTION:

Severe thrombocytopenia has been reported with this drug.

Authority Required (STREAMLINED)

2142

Malaria.

1972T	Tablet 300 mg	50	2	..	12.02	13.05	Quinbisul	AS

QUININE SULFATE

CAUTION:

Severe thrombocytopenia has been reported with this drug.

Authority Required (STREAMLINED)

2142

Malaria.

1975Y	Tablet 300 mg	50	2	..	12.02	13.05	^a Quinsul	LN
				B2.17	14.19	13.05	^a Quinate	AS

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 (STREAMLINED)								
2446								
<i>Treatment of whipworm infestation in an Aboriginal or a Torres Strait Islander person.</i>								
9047E	Tablet 200 mg	6	..	..	32.67	32.90	Zentel	GK
Authority Required (STREAMLINED)								
1525								
<i>Treatment of tapeworm infestation.</i>								
8503M	Tablet 200 mg	6	1	..	32.67	32.90	Zentel	GK
Authority Required (STREAMLINED)								
1496								
<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	..	184.82	32.90	Eskazole	GK
• Tetrahydropyrimidine derivatives								
PYRANTEL EMBONATE								
3047J	Tablet 125 mg (base)	6	..	..	7.61	8.64	Anthel 125	AF
3048K	Tablet 250 mg (base)	6	..	..	9.05	10.08	Anthel 250	AF
• Avermectines								
IVERMECTIN								
Authority Required (STREAMLINED)								
1242								
<i>Onchocerciasis;</i>								
1388								
<i>Strongyloidiasis.</i>								
8359Y	Tablet 3 mg	4	..	..	30.88	31.91	Stromectol	MK

ANTIPARASITIC PRODUCTS, INSECTICIDES AND REPELLENTS—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 \$	

ECTOPARASITICIDES, INCL. SCABICIDES, INSECTICIDES AND REPELLENTS

Ectoparasiticides, incl. scabicides

• Pyrethrines, incl. synthetic compounds

PERMETHRIN

3054R	Cream 50 mg per g (5%), 30 g	± 1	1	..	16.34	17.37	Lyclear	JT

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

Patients with frequent episodes of asthma who are currently receiving treatment with oral corticosteroids;

Patients with frequent episodes of asthma who are currently receiving treatment with optimal doses of inhaled corticosteroids.

8136F	Capsule containing powder for oral inhalation 12 micrograms (for use in Foradile Aerolizer)	60	5	..	36.90	32.90	Foradile	NV
8239P	Powder for oral inhalation in breath actuated device 6 micrograms per dose (60 doses)	‡ 1	5	..	25.95	26.98	Oxis Turbuhaler	AP
8240Q	Powder for oral inhalation in breath actuated device 12 micrograms per dose (60 doses)	‡ 1	5	..	36.01	32.90	Oxis Turbuhaler	AP

SALBUTAMOL SULFATE

1099W	Capsule containing powder for oral inhalation 200 micrograms (base) (for use in Ventolin Rotahaler)	200	5	..	* 18.07	19.10	Ventolin Rotacaps	GK
8288F	Oral pressurised inhalation 100 micrograms (base) per dose (200 doses), CFC-free formulation	2	5	..	* 14.79	15.82	^a Airomir	IA
				B1.18	* 15.97	15.82	^a Asmol CFC-free	AL
							^a Ventolin CFC-free	GK

SALBUTAMOL SULFATE

Restricted Benefit

Patients unable to achieve co-ordinated use of other metered dose inhalers containing this drug.

8354Q	Oral pressurised inhalation in breath actuated device 100 micrograms (base) per dose (200 doses), CFC-free formulation	2	5	..	* 38.17	32.90	Airomir Autohaler	IA

continued ➞

RESPIRATORY SYSTEM—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Proprietary Name and Manufacturer	
<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>								
2000G	Nebuliser solution single dose units 2.5 mg (base) in 2.5 mL, 30	2	5	..	* 18.51	19.54	^a Asmol 2.5 uni-dose ^a Butamol 2.5 ^a GenRx Salbutamol ^a Pharmacor Salbutamol 2.5 ^a Salbutamol-GA ^a Salbutamol Sandoz ^a PU	AF SI GX CR GM SZ
				B1.46	* 19.97	19.54	^a Ventolin Nebules	GK
2001H	Nebuliser solution single dose units 5 mg (base) in 2.5 mL, 30	2	5	..	* 19.21	20.24	^a Asmol 5 uni-dose ^a Butamol 5 ^a GenRx Salbutamol ^a Pharmacor Salbutamol 5 ^a Salbutamol-GA ^a Salbutamol Sandoz ^a Ventolin Nebules	AF SI GX CR GM SZ GK
				B1.46	* 20.67	20.24		
2003K	Nebuliser solution 5 mg (base) per mL (0.5%), 30 mL	2	2	..	* 10.59	11.62	PU	
SALMETEROL XINAFOATE								
<u>Restricted Benefit</u>								
<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>								
8141L	Powder for oral inhalation in breath actuated device 50 micrograms (base) per dose (60 doses)	‡ 1	5	..	36.90	32.90	Serevent Accuhaler	GK
TERBUTALINE SULFATE								
1252X	Powder for oral inhalation in breath actuated device 500 micrograms per dose (200 doses)	‡ 1	5	..	17.40	18.43	Bricanyl Turbuhaler	AP

continued ➡

RESPIRATORY SYSTEM—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 \$	

TERBUTALINE SULFATE**Restricted Benefit**

Asthma in patients unable to use this drug delivered from a breath actuated device;

Chronic obstructive pulmonary disease in patients unable to use this drug delivered from a breath actuated device.

1251W	Nebuliser solution single dose units 5 mg in 2 mL, 30	2	5	..	* 40.37	32.90	Bricanyl Respules	AP

• **Adrenergics and other drugs for obstructive airway diseases**

BUDESONIDE with EFORMOTEROL FUMARATE**DIHYDRATE****Restricted Benefit**

Patients who previously had frequent episodes of asthma while receiving treatment with oral corticosteroids and who have been stabilised on concomitant inhaled eformoterol fumarate dihydrate and budesonide;

Patients who previously had frequent episodes of asthma while receiving treatment with optimal doses of inhaled corticosteroids and who have been stabilised on concomitant inhaled eformoterol fumarate dihydrate and budesonide;

For single maintenance and reliever therapy in a patient who experiences frequent asthma symptoms while receiving treatment with oral corticosteroids;

For single maintenance and reliever therapy in a patient who experiences frequent asthma symptoms while receiving treatment with inhaled corticosteroids;

For maintenance and reliever therapy in a patient who experiences frequent asthma symptoms while receiving treatment with a combination of an inhaled corticosteroid and a long-acting beta-2 agonist.

8796Y	Powder for oral inhalation in breath actuated device 100 micrograms-6 micrograms per dose (120 doses)	± 1	5	..	54.04	32.90	Symbicort Turbuhaler 100/ 6	AP
8625Y	Powder for oral inhalation in breath actuated device 200 micrograms-6 micrograms per dose (120 doses)	± 1	5	..	58.34	32.90	Symbicort Turbuhaler 200/ 6	AP

Restricted Benefit

Patients who previously had frequent episodes of asthma while receiving treatment with oral corticosteroids and who have been stabilised on concomitant inhaled eformoterol fumarate dihydrate and budesonide;

Patients who previously had frequent episodes of asthma while receiving treatment with optimal doses of inhaled corticosteroids and who have been stabilised on concomitant inhaled eformoterol fumarate dihydrate and budesonide.

NOTE:

Symbicort 400/12 is not recommended nor PBS-subsidised for use as 'maintenance and reliever' therapy.

8750M	Powder for oral inhalation in breath actuated devices 400 micrograms-12 micrograms per dose (60 doses), 2	1	5	..	86.46	32.90	Symbicort Turbuhaler 400/ 12	AP

RESPIRATORY SYSTEM—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 \$		
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;</i>								
<i>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	..	46.77	32.90	Seretide MDI 50/ 25	GK
8518H	Oral pressurised inhalation 125 micrograms-25 micrograms (base) per dose (120 doses), CFC-free formulation	± 1	5	..	58.88	32.90	Seretide MDI 125/ 25	GK
8430Q	Powder for oral inhalation in breath actuated device 100 micrograms-50 micrograms (base) per dose (60 doses)	± 1	5	..	46.77	32.90	Seretide Accuhaler 100/50	GK
8431R	Powder for oral inhalation in breath actuated device 250 micrograms-50 micrograms (base) per dose (60 doses)	± 1	5	..	58.88	32.90	Seretide Accuhaler 250/50	GK

Restricted Benefit

Patients who previously had frequent episodes of asthma while receiving treatment with oral corticosteroids and who have been stabilised on concomitant inhaled salmeterol xinafoate and fluticasone propionate;

Patients who previously had frequent episodes of asthma while receiving treatment with optimal doses of inhaled corticosteroids and who have been stabilised on concomitant inhaled salmeterol xinafoate and fluticasone propionate;

Symptomatic treatment of chronic obstructive pulmonary disease (COPD), where the FEV1 is less than 50% predicted normal and there is a history of repeated exacerbations with significant symptoms despite regular beta-2 agonist bronchodilator therapy.

NOTE:

Seretide is not indicated for the initiation of bronchodilator therapy in COPD.

8519J	Oral pressurised inhalation 250 micrograms-25 micrograms (base) per dose (120 doses), CFC-free formulation	± 1	5	..	78.24	32.90	Seretide MDI 250/ 25	GK

continued ➡

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	
8432T	Powder for oral inhalation in breath actuated device 500 micrograms-50 micrograms (base) per dose (60 doses)	‡ 1	5	..	78.24	32.90	Seretide Accuhaler 500/50	GK
Other drugs for obstructive airway diseases, inhalants								
• Glucocorticoids								
BECLOMETHASONE DIPROPIONATE								
8406K	Oral pressurised inhalation 50 micrograms per dose (200 doses), CFC-free formulation	‡ 1	5	..	18.86	19.89	Qvar 50	IA
8407L	Oral pressurised inhalation 100 micrograms per dose (200 doses), CFC-free formulation	‡ 1	5	..	33.03	32.90	Qvar 100	IA
BECLOMETHASONE DIPROPIONATE								
<u>Restricted Benefit</u>								
<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	..	27.44	28.47	Qvar 50 Autohaler	IA
8409N	Oral pressurised inhalation in breath actuated device 100 micrograms per dose (200 doses), CFC-free formulation	‡ 1	5	..	38.70	32.90	Qvar 100 Autohaler	IA
BUDESONIDE								
2070Y	Powder for oral inhalation in breath actuated device 100 micrograms per dose (200 doses)	‡ 1	5	..	22.91	23.94	Pulmicort Turbuhaler	AP
2071B	Powder for oral inhalation in breath actuated device 200 micrograms per dose (200 doses)	‡ 1	5	..	30.65	31.68	Pulmicort Turbuhaler	AP
2072C	Powder for oral inhalation in breath actuated device 400 micrograms per dose (200 doses)	‡ 1	5	..	45.41	32.90	Pulmicort Turbuhaler	AP

continued ➞

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								
<u>Authority Required (STREAMLINED)</u>								
1351								
<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	Nebuliser suspension single dose units 500 micrograms in 2 mL, 30	± 1	5	..	37.43	32.90	Pulmicort Respules	AP
2066R	Nebuliser suspension single dose units 1 mg in 2 mL, 30	± 1	5	..	48.57	32.90	Pulmicort Respules	AP
CICLESONIDE								
8853Y	Oral pressurised inhalation 80 micrograms per dose (120 doses), CFC-free formulation	± 1	5	..	25.72	26.75	Alvesco 80	NQ
8854B	Oral pressurised inhalation 160 micrograms per dose (120 doses), CFC-free formulation	± 1	5	..	41.82	32.90	Alvesco 160	NQ
FLUTICASONE PROPIONATE								
8516F	Oral pressurised inhalation 50 micrograms per dose (120 doses), CFC-free formulation	± 1	5	..	16.66	17.69	Flixotide Junior	GK
8345F	Oral pressurised inhalation 125 micrograms per dose (120 doses), CFC-free formulation	± 1	5	..	30.23	31.26	Flixotide	GK
8346G	Oral pressurised inhalation 250 micrograms per dose (120 doses), CFC-free formulation	± 1	1	..	49.29	32.90	Flixotide	GK
8147T	Powder for oral inhalation in breath actuated device 100 micrograms per dose (60 doses)	± 1	5	..	16.66	17.69	Flixotide Junior Accuhaler	GK
8148W	Powder for oral inhalation in breath actuated device 250 micrograms per dose (60 doses)	± 1	5	..	30.23	31.26	Flixotide Accuhaler	GK
8149X	Powder for oral inhalation in breath actuated device 500 micrograms per dose (60 doses)	± 1	1	..	49.29	32.90	Flixotide Accuhaler	GK
• Anticholinergics								
IPRATROPIUM BROMIDE								
8671J	Oral pressurised inhalation 21 micrograms per dose (200 doses), CFC-free formulation	2	5	..	* 34.85	32.90	Atrovent	BY

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	
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	..	* 36.85	32.90	^a Aeron 250 ^a APO-Ipratropium ^a Apoven 250 ^a Ipratrin ^a Ipravent ^a Atrovent	SI TX GM AF PU BY
				B0.72	* 37.57	32.90		
8238N	Nebuliser solution single dose units 500 micrograms (anhydrous) in 1 mL, 30	2	5	..	* 42.21	32.90	^a Aeron 500 ^a APO-Ipratropium ^a Apoven 500 ^a Ipratrin Adult ^a Ipravent ^a Atrovent Adult	SI TX GM AF PU BY
				B0.62	* 42.83	32.90		
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	Capsule containing powder for oral inhalation 18 micrograms (base) (for use in HandiHaler)	30	5	..	76.46	32.90	Spiriva	BY
• Antiallergic agents, excl. corticosteroids								
NEDOCROMIL SODIUM								
8365G	Oral pressurised inhalation 2 mg per dose (112 doses), CFC-free formulation	‡ 1	5	..	37.26	32.90	Tilade CFC-Free	SW
SODIUM CROMOGLYCATE								
2878L	Capsule containing powder for oral inhalation 20 mg (for use in Intal Spinhaler or Intal Halermatic)	100	5	..	32.53	32.90	Intal Spincaps	GM
2872E	Oral pressurised inhalation 1 mg per dose (200 doses)	‡ 1	5	..	31.35	32.38	Intal	SW
8767K	Oral pressurised inhalation 1 mg per dose (200 doses), CFC-free formulation	‡ 1	5	..	31.35	32.38	Intal CFC-Free	SW
8334P	Oral pressurised inhalation 5 mg per dose (112 doses), CFC-free formulation	‡ 1	5	..	37.24	32.90	Intal Forte CFC-Free	SW

RESPIRATORY SYSTEM—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 \$	

Adrenergics for systemic use

• Alpha- and beta-adrenoceptor agonists

ADRENALINE

1016L	Injection 1 mg in 1 mL (1 in 1,000)	5	1	..	19.91	20.94	AP

ADRENALINE

Authority Required

Initial supply for anticipated emergency treatment of acute allergic reactions with anaphylaxis in a patient who:

- (a) *has been assessed to be at significant risk of anaphylaxis by, or in consultation with, a clinical immunologist, allergist, paediatrician or respiratory physician. The name of the specialist consulted must be provided at the time of application for initial supply; or*
- (b) *has been discharged from hospital or an emergency department after treatment with adrenaline for acute allergic reaction with anaphylaxis;*

Continuing supply for anticipated emergency treatment of acute allergic reactions with anaphylaxis, where the patient has previously been issued with an authority prescription for this drug.

NOTE:

The auto-injector should be provided in the framework of a comprehensive anaphylaxis prevention program and an emergency action plan including training in recognition of the symptoms of anaphylaxis and the use of the auto-injector device. (For further information see the Australasian Society of Clinical Immunology and Allergy website at www.allergy.org.au.)

8697R	I.M. injection 150 micrograms in 0.3 mL single dose syringe auto-injector	1	..	..	105.57	32.90	EpiPen Jr.	AL
8698T	I.M. injection 300 micrograms in 0.3 mL single dose syringe auto-injector	1	..	..	105.57	32.90	EpiPen	AL

NOTE:

Authorities for increased maximum quantities, up to a maximum of 2, may be authorised for children aged less than 17 years where 2 auto-injectors are necessary to ensure 1 is on hand at all times. No increased maximum quantities will be authorised for patients aged 17 years or older.

No repeats will be issued.

• Selective beta-2-adrenoceptor agonists

SALBUTAMOL SULFATE

1103C	Syrup 2 mg (base) per 5 mL, 150 mL	2	5	..	* 21.77	22.80	Ventolin	GK

TERBUTALINE SULFATE

1034K	Injection 500 micrograms in 1 mL	5	..	..	30.16	31.19	Bricanyl	AP

RESPIRATORY SYSTEM—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 \$		
Other systemic drugs for obstructive airway diseases								
• Xanthines								
THEOPHYLLINE								
<u>CAUTION:</u>								
Because of variable effects of food on absorption of sustained release theophylline preparations, patients stabilised on one brand should not be changed to another without appropriate monitoring.								
8230E	Tablet 200 mg (sustained release)	100	5	..	11.73	12.76	Nuelin-SR 200	IA
2634P	Tablet 250 mg (sustained release)	100	5	..	12.89	13.92	Nuelin-SR 250	IA
8231F	Tablet 300 mg (sustained release)	100	5	..	14.27	15.30	Nuelin-SR 300	IA
2614N	Syrup 133.3 mg per 25 mL, 500 mL	± 1	5	..	10.39	11.42	Nuelin	IA

• **Leukotriene receptor antagonists**

MONTELUKAST SODIUM

NOTE:

Montelukast sodium is not PBS-subsidised for use in children with moderate or severe asthma. It is not intended as an alternative for children who require a corticosteroid as a preventer medication. Montelukast sodium is not PBS-subsidised for use in combination with other preventer medications. PBS subsidy for montelukast sodium will therefore cease for patients who require a preventer medication in addition to montelukast sodium.

NOTE:

No applications for increased maximum quantities and/or repeats will be authorised.

Authority Required (STREAMLINED)

2617

First-line preventer medication, as the single preventer agent for children aged 2 to 5 years with frequent intermittent or mild persistent asthma, as an alternative to sodium cromoglycate or nedocromil sodium.

8627C	Chewable tablet 4 mg (base)	28	5	..	47.50	32.90	Singulair	MK

Authority Required (STREAMLINED)

2618

First-line preventer medication, as the single preventer agent for children aged 6 to 14 years with frequent intermittent or mild persistent asthma, as an alternative to sodium cromoglycate or nedocromil sodium.

8628D	Chewable tablet 5 mg (base)	28	5	..	47.50	32.90	Singulair	MK

COUGH AND COLD PREPARATIONS

Expectorants, excl. combinations with cough suppressants

• **Mucolytics**

ACETYLCYSTEINE

Restricted Benefit

Bronchiectasis;

Cystic fibrosis.

8747J	Sterile inhalation solution 200 mg per mL (20%), 5 mL	30	3	..	* 146.54	32.90	Mucomyst	BQ

RESPIRATORY SYSTEM—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed	Maximum	Proprietary Name and Manufacturer
					Price for Max. Qty \$	Recordable Value for Safety Net \$	
Cough suppressants, excl. combinations with expectorants							
• <i>Opium alkaloids and derivatives</i>							
CODEINE PHOSPHATE							
1214X	Tablet 30 mg	20	..	..	16.44	17.47	FM

ANTI-HISTAMINES FOR SYSTEMIC USE

Antihistamines for systemic use							
• <i>Phenothiazine derivatives</i>							
PROMETHAZINE HYDROCHLORIDE							
1948M	Injection 50 mg in 2 mL	10	..	..	* 21.89	22.92	HH

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	..	23.46	24.49	Zithromax	PF
8201P	Powder for oral suspension 200 mg per 5 mL, 15 mL	‡ 1	..	..	# 23.01	24.40	Zithromax	PF
CHLORAMPHENICOL								
2360F	Eye drops 5 mg per mL (0.5%), 10 mL	‡ 1	2	..	10.57	11.60	Chloromycetin Chlorsig	PF SI
1171P	Eye ointment 10 mg per g (1%), 4 g	‡ 1	..	..	9.33	10.36	Chloromycetin Chlorsig	PF SI
GENTAMICIN SULFATE								
<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	..	18.59	19.62	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	..	18.85	19.88	Tobrex	AQ
2329N	Eye ointment 3 mg per g (0.3%), 3.5 g	‡ 1	..	..	21.95	22.98	Tobrex	AQ
• Sulfonamides								
SULFACETAMIDE SODIUM								
2063N	Eye drops 100 mg per mL (10%), 15 mL	‡ 1	2	..	13.35	14.38	Bleph 10	AG

SENSORY ORGANS—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Proprietary Name and Manufacturer	
• Antivirals ACICLOVIR <u>Restricted Benefit</u> <i>Herpes simplex keratitis.</i>								
1002R	Eye ointment 30 mg per g (3%), 4.5 g	‡ 1	..	..	34.63	32.90	Zovirax	GK
• Other antiinfectives CIPROFLOXACIN <u>Authority Required</u> <i>Bacterial keratitis.</i>								
1217C	Eye drops 3 mg per mL (0.3%), 5 mL	2	..	..	* 29.19	30.22	^a CiloQuin	IQ
				B2.06	* 31.25	30.22	^a Ciloxan	AQ
OFLOXACIN <u>Authority Required</u> <i>Bacterial keratitis.</i>								
8383F	Eye drops 3 mg per mL (0.3%), 5 mL	2	..	..	* 31.71	32.74	Ocuflox	AG
Antiinflammatory agents • Corticosteroids, plain DEXAMETHASONE								
1288T	Eye drops 1 mg per mL (0.1%), 5 mL	‡ 1	2	..	10.18	11.21	Maxidex	AQ
FLUOROMETHOLONE								
1204J	Eye drops 1 mg per mL (0.1%), 5 mL	‡ 1	5	..	10.18	11.21	Flucon FML Liquifilm	AQ AG
FLUOROMETHOLONE ACETATE								
1438Q	Eye drops 1 mg per mL (0.1%), 5 mL	‡ 1	2	..	10.18	11.21	Flarex	AQ
HYDROCORTISONE ACETATE								
1497T	Eye ointment 5 mg per g (0.5%), 5 g	‡ 1	..	..	11.35	12.38	Hycor	SI
2441L	Eye ointment 10 mg per g (1%), 5 g	‡ 1	..	..	12.65	13.68	Hycor	SI

SENSORY ORGANS—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Proprietary Name and Manufacturer	
• Corticosteroids and mydriatics in combination PREDNISOLONE ACETATE with PHENYLEPHRINE HYDROCHLORIDE								
<u>Restricted Benefit</u> Corneal grafts; Uveitis.								
3112T	Eye drops 10 mg-1.2 mg per mL (1%-0.12%), 10 mL	‡ 1	2	..	23.73	24.76	Prednefrin Forte	AG
• Antiinflammatory agents, non-steroids FLURBIPROFEN SODIUM								
8699W	Eye drops 300 micrograms per mL (0.03%), single dose units 0.4 mL, 5	1	..	..	14.94	15.97	Ocufen	AG
Antiglaucoma preparations and miotics • Sympathomimetics in glaucoma therapy APRACLOPIDINE HYDROCHLORIDE								
<u>Restricted Benefit</u> Short-term reduction of intra-ocular pressure in patients already on maximally tolerated anti-glaucoma therapy.								
8083K	Eye drops 5 mg (base) per mL (0.5%), 10 mL	‡ 1	2	..	41.34	32.90	Iopidine 0.5%	AQ
BRIMONIDINE TARTRATE								
8351M	Eye drops 2 mg per mL (0.2%), 5 mL	‡ 1	5	.. B1.74	20.56 22.30	21.59 21.59	^a Enidin ^a Alphagan	PE AG
BRIMONIDINE TARTRATE with TIMOLOL MALEATE								
<u>Restricted Benefit</u> Reduction of elevated intra-ocular pressure in patients with open-angle glaucoma who are not adequately controlled with timolol maleate 5 mg (base) per mL (0.5%) eye drops; Reduction of elevated intra-ocular pressure in patients with ocular hypertension who are not adequately controlled with timolol maleate 5 mg (base) per mL (0.5%) eye drops.								
8826M	Eye drops 2 mg-5 mg (base) per mL (0.2%-0.5%), 5 mL	‡ 1	5	..	26.76	27.79	Combigan	AG
• Parasympathomimetics PILOCARPINE HYDROCHLORIDE								
2595N	Eye drops 10 mg per mL (1%), 15 mL	‡ 1	5		12.48 12.48	13.51 13.51	Isopto Carpine ^a Pilopt ^a P.V. Carpine	AQ PE AG

continued ➞

SENSORY ORGANS—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Proprietary Name and Manufacturer	
2596P	Eye drops 20 mg per mL (2%), 15 mL	‡ 1	5	..	13.81	14.84	Isopto Carpine	AQ
				..	13.81	14.84	^a Pilopt	PE
							^a P.V. Carpine	AG
2598R	Eye drops 40 mg per mL (4%), 15 mL	‡ 1	5	..	16.83	17.86	Isopto Carpine	AQ
				..	16.83	17.86	^a Pilopt	PE
							^a P.V. Carpine	AG
2779G	Eye drops 60 mg per mL (6%), 15 mL	‡ 1	5	..	21.61	22.64	^a Pilopt	PE
							^a P.V. Carpine	AG
• Carbonic anhydrase inhibitors								
ACETAZOLAMIDE								
1004W	Tablet 250 mg	100	3	..	23.36	24.39	Diamox	SI
BRINZOLAMIDE								
8483L	Eye drops 10 mg per mL (1%), 5 mL	‡ 1	5	..	23.37	24.40	^a BrinzoQuin	IQ
				B1.23	24.60	24.40	^a Azopt	AQ
DORZOLAMIDE HYDROCHLORIDE								
8488R	Eye drops 20 mg (base) per mL (2%), 5 mL	‡ 1	5	..	20.86	21.89	Trusopt	MK
DORZOLAMIDE HYDROCHLORIDE with TIMOLOL MALEATE								
<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;</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.</i>								
8567X	Eye drops 20 mg (base)-5 mg (base) per mL (2%-0.5%), 5 mL	‡ 1	5	..	27.06	28.09	Cosopt	MK
• Beta blocking agents								
BETAXOLOL HYDROCHLORIDE								
2811Y	Eye drops, suspension, 2.5 mg (base) per mL (0.25%), 5 mL	‡ 1	5	..	14.86	15.89	Betoptic S	AQ
2825Q	Eye drops, solution, 5 mg (base) per mL (0.5%), 5 mL	‡ 1	5	..	14.86	15.89	^a BetoQuin	IQ
				B2.18	17.04	15.89	^a Betoptic	AQ
TIMOLOL MALEATE								
8803H	Eye gel 1 mg (base) per g (0.1%), 5 g	‡ 1	5	..	12.79	13.82	Nyogel	NV

continued 

SENSORY ORGANS—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Proprietary Name and Manufacturer	
1278G	Eye drops 2.5 mg (base) per mL (0.25%), 5 mL	‡ 1	5	.. B2.95	11.37 14.32	12.40 12.40	^a Tenopt ^a Timoptol	SI FR
1279H	Eye drops 5 mg (base) per mL (0.5%), 5 mL	‡ 1	5	.. B2.95	12.19 15.14	13.22 13.22	^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	..	11.37	12.40	Timoptol XE	MK
1926J	Eye drops (gellan gum solution) 5 mg (base) per mL (0.5%), 2.5 mL	‡ 1	5	..	12.19	13.22	Timoptol XE	MK
• Prostaglandin analogues								
BIMATOPROST								
8620Q	Eye drops 300 micrograms per mL (0.03%), 3 mL	‡ 1	5	..	41.71	32.90	Lumigan	AG
LATANOPROST								
8243W	Eye drops 50 micrograms per mL (0.005%), 2.5 mL	‡ 1	5	..	41.71	32.90	Xalatan	PU
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	..	46.39	32.90	Xalacom	PF
TRAVOPROST								
8597L	Eye drops 40 micrograms per mL (0.004%), 2.5 mL	‡ 1	5	..	41.71	32.90	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 latanoprost 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 latanoprost 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	..	46.39	32.90	Duotrav	AQ

SENSORY ORGANS—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Proprietary Name and Manufacturer	
Mydriatics and cycloplegics								
• Anticholinergics								
ATROPINE SULFATE								
1093M	Eye drops 10 mg per mL (1%), 15 mL	± 1	2	..	12.34	13.37	Atropt	SI
HOMATROPINE HYDROBROMIDE								
2541R	Eye drops 20 mg per mL (2%), 15 mL	± 1	2	..	17.54	18.57	Isopto Homatropine	AQ
Decongestants and antiallergics								
• Other antiallergics								
SODIUM CROMOGLYCAT								
<u>Restricted Benefit</u>								
Vernal kerato-conjunctivitis.								
1127H	Eye drops 20 mg per mL (2%), 10 mL	± 1	5	..	14.26	15.29	^a Cromolux ^a Opticrom	AE SW

Ocular vascular disorder agents

• Antineovascularisation agents

ANECORTAVE ACETATE

Authority Required

Initial treatment by an ophthalmologist, as the sole PBS-subsidised therapy, of predominantly (greater than or equal to 50%) classic, subfoveal choroidal neovascularisation (CNV) due to age-related macular degeneration (AMD), as diagnosed by fluorescein angiography, in a patient with a baseline visual acuity equal to or better than 6/60 (20/200).

No more than 10 treatments (1 initial and 9 continuing) per eye will be authorised.

Authority approvals will be administered by the PBS and Specialised Drugs Branch of Medicare Australia.

The first authority application for each eye must be made in writing, and must include:

(a) a completed authority prescription form; and

(b) a completed Subfoveal Choroidal Neovascularisation (CNV) - PBS Supporting Information Form [www.medicareaustralia.gov.au]; and

(c) a copy of the fluorescein angiogram demonstrating that the CNV is predominantly classic (greater than or equal to 50%).

Written applications for authority to prescribe anecortave acetate should be forwarded to:

Medicare Australia

Prior Written Approval of Specialised Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

Alternatively, the first authority application may be faxed to Medicare Australia on (03) 6215 5474 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Medicare Australia will then contact the prescriber by telephone. The original documentation must be posted to the above address after approval has been gained.

continued ➡

SENSORY ORGANS—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 \$	
<u>Authority Required</u> <i>Continuing treatment by an ophthalmologist, as the sole PBS-subsidised therapy, of predominantly (greater than or equal to 50%) classic, subfoveal choroidal neovascularisation (CNV) due to age-related macular degeneration (AMD) where the patient has previously been granted an authority prescription for the same eye.</i> <i>No more than 10 treatments (1 initial and 9 continuing) per eye will be authorised.</i> <i>Authority approvals will be administered by the PBS and Specialised Drugs Branch of Medicare Australia. Authority applications for continuing treatment in the same eye may be made by telephone on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).</i>							
2514H	Suspension for injection 15 mg in 0.5 mL	1	..	..	2015.93	32.90	Retaane AQ
RANIBIZUMAB							
<u>Authority Required</u> <i>Initial treatment by an ophthalmologist, as the sole PBS-subsidised therapy, of subfoveal choroidal neovascularisation (CNV) due to age-related macular degeneration (AMD), as diagnosed by fluorescein angiography.</i> <i>Where a fluorescein angiogram cannot be performed due to a contraindication as listed in the TGA-approved product information, details of the contraindication must be provided. A copy of the report of an alternative method of diagnosis must be included in the application, for example, optical coherence tomography (OCT) or red free photography.</i> <i>Authority approvals will be administered by the PBS and Specialised Drugs Branch of Medicare Australia.</i> <i>The first authority application for each eye must be made in writing, and must include:</i> <i>(a) a completed authority prescription form; and</i> <i>(b) a completed Subfoveal Choroidal Neovascularisation (CNV) - PBS Supporting Information Form [www.medicareaustralia.gov.au]; and</i> <i>(c) a copy of the fluorescein angiogram or alternative method of diagnosis where applicable.</i> <i>Written applications for authority to prescribe ranibizumab should be forwarded to:</i> <i>Medicare Australia</i> <i>Prior Written Approval of Specialised Drugs</i> <i>Reply Paid 9826</i> <i>GPO Box 9826</i> <i>HOBART TAS 7001</i> <i>Alternatively, the first authority application may be faxed to Medicare Australia on (03) 6215 5474 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Medicare Australia will then contact the prescriber by telephone. The original documentation must be posted to the above address after approval has been gained.</i>							
<u>Authority Required</u> <i>Continuing treatment by an ophthalmologist, as the sole PBS-subsidised therapy, of subfoveal choroidal neovascularisation (CNV) due to age-related macular degeneration (AMD) where the patient has previously been granted an authority prescription for the same eye.</i> <i>Authority approvals will be administered by the PBS and Specialised Drugs Branch of Medicare Australia. Authority applications for continuing treatment in the same eye may be made by telephone on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).</i>							
1382R	Solution for intravitreal injection 2.3 mg in 0.23 mL	1	2	..	1975.93	32.90	Lucentis NV

SENSORY ORGANS—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 \$	

VERTEPORFIN

Authority Required

Initial treatment by an ophthalmologist, as the sole PBS-subsidised therapy, of predominantly (greater than or equal to 50%) classic, subfoveal choroidal neovascularisation (CNV) due to age-related macular degeneration (AMD), as diagnosed by fluorescein angiography, in a patient with a baseline visual acuity equal to or better than 6/60 (20/200).

Authority approvals will be administered by the PBS and Specialised Drugs Branch of Medicare Australia.

The first authority application for each eye must be made in writing, and must include:

- (a) a completed authority prescription form; and*
- (b) a completed Subfoveal Choroidal Neovascularisation (CNV) - PBS Supporting Information Form [www.medicareaustralia.gov.au]; and*
- (c) a copy of the fluorescein angiogram demonstrating that the CNV is predominantly classic (greater than or equal to 50%).*

Written applications for authority to prescribe verteporfin should be forwarded to:

Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

Alternatively, the first authority application may be faxed to Medicare Australia on (03) 6215 5474 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Medicare Australia will then contact the prescriber by telephone. The original documentation must be posted to the above address after approval has been gained.

No more than 15 treatments (1 initial and 14 continuing) per eye will be authorised.

Medicare Australia should be notified if treatment is abandoned prior to completion of the laser activation step but after infusion of verteporfin. Telephone 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). The reason treatment is abandoned must be provided. Where such notification has been made, the treatment so affected will not count towards the maximum.

Authority Required

Initial PBS-subsidised treatment by an ophthalmologist, as the sole PBS-subsidised therapy, of predominantly (greater than or equal to 50%) classic, subfoveal choroidal neovascularisation (CNV) due to macular degeneration where the patient has been authorised by the Angiogram Review Panel to receive treatment with verteporfin in the same eye under the MBS Visudyne Therapy Program.

Authority approvals will be administered by the PBS and Specialised Drugs Branch of Medicare Australia.

The first authority application for each eye must be made in writing, and must include:

- (a) a completed authority prescription form; and*
- (b) a completed Subfoveal Choroidal Neovascularisation (CNV) - PBS Supporting Information Form [www.medicareaustralia.gov.au], which includes the date of review by the Angiogram Review Panel and the number of treatments administered in that eye under the MBS Visudyne Therapy Program; and*
- (c) a copy of the fluorescein angiogram demonstrating that the CNV is predominantly classic (greater than or equal to 50%).*

Written applications for authority to prescribe verteporfin should be forwarded to:

Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

continued ➞

SENSORY ORGANS—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 \$		
<i>Alternatively, the first authority application may be faxed to Medicare Australia on (03) 6215 5474 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Medicare Australia will then contact the prescriber by telephone. The original documentation must be posted to the above address after approval has been gained.</i> <i>A patient is eligible for a total of 15 subsidised treatments per eye. This maximum includes treatments administered under the MBS Visudyne Therapy Program and the PBS.</i> <i>Medicare Australia should be notified if treatment is abandoned prior to completion of the laser activation step but after infusion of verteporfin. Telephone 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). The reason treatment is abandoned must be provided. Where such notification has been made, the treatment so affected will not count towards the maximum.</i>								
Authority Required <i>Continuing treatment by an ophthalmologist, as the sole PBS-subsidised therapy, of predominantly (greater than or equal to 50%) classic, subfoveal choroidal neovascularisation (CNV) due to macular degeneration where the patient has previously been granted an authority prescription for the same eye.</i> <i>A patient is eligible for a total of 15 subsidised treatments per eye. This maximum includes treatments administered under the MBS Visudyne Therapy Program and the PBS.</i> <i>Medicare Australia should be notified if treatment is abandoned prior to completion of the laser activation step but after infusion of verteporfin. Telephone 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). The reason treatment is abandoned must be provided. Where such notification has been made, the treatment so affected will not count towards the maximum.</i> <i>Authority approvals will be administered by the PBS and Specialised Drugs Branch of Medicare Australia. Authority applications for continuing treatment in the same eye may be made by telephone on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).</i>								
1349B	Powder for I.V. infusion 15 mg	1	..	..	2245.93	32.90	Visudyne	NV
Other ophthalmologicals • Other ophthalmologicals CARBOMER								
Restricted Benefit <i>Severe dry eye syndrome, including Sjogren's syndrome.</i>								
8384G	Eye gel 2 mg per g (0.2%), 10 g	± 1	5	..	10.08	11.11	GelTears	BU
				..	10.08	11.11	^a PAA	NM
				B1.00	11.08	11.11	^a Viscotears	NV

continued ➞

SENSORY ORGANS—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 \$		
<u>Restricted Benefit</u>								
<i>For use in patients who have severe dry eye syndrome, including Sjogren's syndrome, and who are receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements.</i>								
<u>NOTE:</u>								
<i>No applications for increased maximum quantities and/or repeats will be authorised.</i>								
9210R	Eye gel 2 mg per g (0.2%), 10 g	± 1	11	..	10.08	11.11	GelTears	BU
				..	10.08	11.11	^a PAA	NM
				B1.00	11.08	11.11	^a Viscotears	NV

Authority Required (STREAMLINED)

1359

Severe dry eye syndrome in patients who are sensitive to preservatives in multi-dose eye drops.

8578L	Eye gel 2 mg per g (0.2%), single dose units 0.6 mL, 30	3	5	..	* 37.52	32.90	Viscotears	NV

CARBOMER 974

Authority Required (STREAMLINED)

1359

Severe dry eye syndrome in patients who are sensitive to preservatives in multi-dose eye drops.

8514D	Ocular lubricating gel 3 mg per g (0.3%), single dose units 0.5 g, 30	3	5	..	* 35.63	32.90	Poly Gel	AQ

CARMELLOSE SODIUM

Restricted Benefit

Severe dry eye syndrome, including Sjogren's syndrome.

8548X	Eye drops 5 mg per mL (0.5%), 15 mL	± 1	5	..	10.16	11.19	Refresh Tears Plus	AG
8593G	Eye drops 10 mg per mL (1%), 15 mL	± 1	5	..	10.16	11.19	Refresh Liquigel	AG

Restricted Benefit

For use in patients who have severe dry eye syndrome, including Sjogren's syndrome, and who are receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements.

NOTE:

No applications for increased maximum quantities and/or repeats will be authorised.

9211T	Eye drops 5 mg per mL (0.5%), 15 mL	± 1	11	..	10.16	11.19	Refresh Tears Plus	AG
9212W	Eye drops 10 mg per mL (1%), 15 mL	± 1	11	..	10.16	11.19	Refresh Liquigel	AG

continued ➡

SENSORY ORGANS—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Proprietary Name and Manufacturer	
<u>Authority Required (STREAMLINED)</u>								
1359								
<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	..	* 39.99	32.90	TheraTears	CX
2338C	Eye drops 5 mg per mL (0.5%), single dose units 0.4 mL, 30	3	5	..	* 35.63	32.90	Cellufresh	AG
2324H	Eye drops 10 mg per mL (1%), single dose units 0.4 mL, 30	3	5	..	* 35.63	32.90	Celluvisc	AG
8824K	Ocular lubricating gel 10 mg per mL (1%), single dose units 0.6 mL, 28	3	5	..	* 33.65	32.90	TheraTears	CX
CARMELLOSE SODIUM with GLYCERIN								
<u>Restricted Benefit</u>								
<i>Severe dry eye syndrome, including Sjogren's syndrome.</i>								
9355J	Eye drops 5 mg-9 mg per mL (0.5%-0.9%), 15 mL	± 1	3	..	10.16	11.19	Optive	AG
<u>NOTE:</u>								
<i>The shelf life of Optive is 6 months from the date of opening.</i>								
<u>Restricted Benefit</u>								
<i>For use in patients who have severe dry eye syndrome, including Sjogren's syndrome, and who are receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements.</i>								
<u>NOTE:</u>								
<i>No applications for increased maximum quantities and/or repeats will be authorised.</i>								
9356K	Eye drops 5 mg-9 mg per mL (0.5%-0.9%), 15 mL	± 1	7	..	10.16	11.19	Optive	AG
<u>NOTE:</u>								
<i>The shelf life of Optive is 6 months from the date of opening.</i>								
HYPROMELLOSE								
<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	..	10.08	11.11	^a In a Wink Moisturising	NM
				b1.86	11.94	11.11	^a Genteal	NV
2956N	Eye drops 5 mg per mL (0.5%), 15 mL	± 1	5	..	10.08	11.11	Methopt	SI

continued ➡

SENSORY ORGANS—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed	Maximum		Proprietary Name and Manufacturer	
					Price for Max. Qty \$	Recordable Value for Safety Net \$			
<u>Restricted Benefit</u>									
<i>For use in patients who have severe dry eye syndrome, including Sjogren's syndrome, and who are receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements.</i>									
<u>NOTE:</u>									
<i>No applications for increased maximum quantities and/or repeats will be authorised.</i>									
9213X	Eye drops 3 mg per mL (0.3%), 15 mL (contains sodium perborate as preservative)	± 1	11	..	10.08	11.11	^a	In a Wink Moisturising Genteal	NM NV
				B1.86	11.94	11.11	^a		
9214Y	Eye drops 5 mg per mL (0.5%), 15 mL	± 1	11	..	10.08	11.11		Methopt	SI
HYPROMELLOSE with CARBOMER 980									
<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	..	10.08	11.11	^a	HPMC PAA Genteal gel	NM NV
				B1.86	11.94	11.11	^a		
<u>Restricted Benefit</u>									
<i>For use in patients who have severe dry eye syndrome, including Sjogren's syndrome, and who are receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements.</i>									
<u>NOTE:</u>									
<i>No applications for increased maximum quantities and/or repeats will be authorised.</i>									
9215B	Ocular lubricating gel 3 mg-2 mg per g (0.3%-0.2%), 10 g	± 1	11	..	10.08	11.11	^a	HPMC PAA Genteal gel	NM NV
				B1.86	11.94	11.11	^a		
HYPROMELLOSE with DEXTRAN									
<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	..	10.30	11.33	^a	Poly-Tears Tears Naturale	IQ AQ
				B1.87	12.17	11.33	^a		

continued ➞

SENSORY ORGANS—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 \$		

Restricted Benefit

For use in patients who have severe dry eye syndrome, including Sjogren's syndrome, and who are receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements.

NOTE:

No applications for increased maximum quantities and/or repeats will be authorised.

9216C	Eye drops 3 mg-1 mg per mL (0.3%-0.1%), 15 mL	± 1	11	.. B1.87	10.30 12.17	11.33 11.33	^a Poly-Tears ^a Tears Naturale	IQ AQ

Authority Required (STREAMLINED)

1359

Severe dry eye syndrome in patients who are sensitive to preservatives in multi-dose eye drops.

8299T	Eye drops 3 mg-1 mg per mL (0.3%-0.1%), single dose units 0.4 mL, 28	3	5	..	* 36.41	32.90	Bion Tears	AQ

PARAFFIN

1754H	Compound eye ointment 3.5 g	2	5	.. B2.24	* 21.73 * 23.97	22.76 22.76	^a Poly Visc ^a Duratears	IQ AQ
1750D	Pack containing 2 tubes compound eye ointment 3.5 g	± 1	5	.. B2.24	21.06 21.06 23.30	22.09 22.09 22.09	^a Poly Visc ^a Ircal ^a Lacri-Lube	IQ PE AG

PARAFFIN

Restricted Benefit

For use in patients who are receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements.

NOTE:

No applications for increased maximum quantities and/or repeats will be authorised.

9217D	Compound eye ointment 3.5 g	2	11	.. B2.24	* 21.73 * 23.97	22.76 22.76	^a Poly Visc ^a Duratears	IQ AQ
9218E	Pack containing 2 tubes compound eye ointment 3.5 g	± 1	11	.. B2.24	21.06 21.06 23.30	22.09 22.09 22.09	^a Poly Visc ^a Ircal ^a Lacri-Lube	IQ PE 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	
POLYETHYLENE GLYCOL 400 with PROPYLENE GLYCOL								
<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	..	10.16	11.19	Systane	AQ
<u>Restricted Benefit</u>								
<i>For use in patients who have severe dry eye syndrome, including Sjogren's syndrome, and who are receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements.</i>								
NOTE:								
<i>No applications for increased maximum quantities and/or repeats will be authorised.</i>								
9219F	Eye drops 4 mg-3 mg per mL (0.4%-0.3%), 15 mL	‡ 1	11	..	10.16	11.19	Systane	AQ
<u>Authority Required (STREAMLINED)</u>								
1359								
<i>Severe dry eye syndrome in patients who are sensitive to preservatives in multi-dose eye drops.</i>								
9170P	Eye drops 4 mg-3 mg per mL (0.4%-0.3%), single dose units 0.8 mL, 28	2	5	..	* 33.65	32.90	Systane	AQ
POLYVINYL ALCOHOL								
<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	.. B1.71	10.08 11.79	11.11 11.11	^a PVA Tears ^a Liquifilm Tears	PE AG
8831T	Eye drops 14 mg per mL (1.4%), 15 mL (contains sodium chlorite/hydrogen peroxide as preservative)	‡ 1	5	..	10.08	11.11	Vistil	AE
2681D	Eye drops 30 mg per mL (3%), 15 mL	‡ 1	5	.. B5.94	10.08 16.02	11.11 11.11	^a PVA Forte ^a Liquifilm Forte	PE AG
8832W	Eye drops 30 mg per mL (3%), 15 mL (contains sodium chlorite/hydrogen peroxide as preservative)	‡ 1	5	..	10.08	11.11	Vistil Forte	AE

continued ➞

SENSORY ORGANS—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Proprietary Name and Manufacturer	
<u>Restricted Benefit</u>								
<i>For use in patients who have severe dry eye syndrome, including Sjogren's syndrome, and who are receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements.</i>								
<u>NOTE:</u>								
<i>No applications for increased maximum quantities and/or repeats will be authorised.</i>								
9220G	Eye drops 14 mg per mL (1.4%), 15 mL	± 1	11	.. B1.71	10.08 11.79	11.11 11.11	^a PVA Tears ^a Liquifilm Tears	PE AG
9221H	Eye drops 14 mg per mL (1.4%), 15 mL (contains sodium chlorite/hydrogen peroxide as preservative)	± 1	11	..	10.08	11.11	Vistil	AE
9222J	Eye drops 30 mg per mL (3%), 15 mL	± 1	11	.. B5.94	10.08 16.02	11.11 11.11	^a PVA Forte ^a Liquifilm Forte	PE AG
9223K	Eye drops 30 mg per mL (3%), 15 mL (contains sodium chlorite/hydrogen peroxide as preservative)	± 1	11	..	10.08	11.11	Vistil Forte	AE

TAMARINDUS INDICA SEED POLYSACCHARIDE

Authority Required (STREAMLINED)

1359

Severe dry eye syndrome in patients who are sensitive to preservatives in multi-dose eye drops.

2248H	Eye drops 10 mg per mL (1%), 0.5 mL, 20	3	5	..	* 35.63	32.90	Visine Professional	JT

OTOLOGICALS

Antiinfectives

• **Antiinfectives**

CHLORAMPHENICOL

1172Q	Ear drops (aqueous) 5 mg per mL (0.5%), 5 mL	± 1	2	..	10.62	11.65	Chloromycetin	PF

CIPROFLOXACIN

Authority Required

Treatment of chronic suppurative otitis media in an Aboriginal or a Torres Strait Islander person aged 1 month or older.

2480M	Ear drops 3 mg per mL (0.3%), 5 mL	± 1	1	..	18.85	19.88	Ciloxan	AQ

NEOMYCIN UNDECENOATE with BACITRACIN ZINC

2296W	Ear ointment 12 mg (3.5 mg base)-400 units per g, 10 g	± 1	..	..	8.23	9.26	Nemdyn	HA

SENSORY ORGANS—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 \$			
Corticosteroids and antiinfectives in combination									
• Corticosteroids and antiinfectives in combination									
DEXAMETHASONE with FRAMYCETIN SULFATE and GRAMICIDIN									
2781J	Ear drops	‡ 1	2	..	9.13	10.16	^a	Otodex	AV
	500 micrograms-5 mg-50 micrograms per mL, 8 mL			B2.00	11.13	10.16	^a	Sofradex	SW
TRIAMCINOLONE ACETONIDE with NEOMYCIN SULFATE, GRAMICIDIN and NYSTATIN									
2971J	Ear drops 1 mg-2.5 mg (base)- 250 micrograms-100,000 units per g (0.1%-0.25%-0.025%-100,000 units per g), 7.5 mL	‡ 1	2	..	10.95	11.98	^a	Otocomb Otic	BC
				B1.07	12.02	11.98	^a	Kenacomb Otic	BQ
2974M	Ear ointment 1 mg-2.5 mg (base)- 250 micrograms-100,000 units per g (0.1%-0.25%-0.025%-100,000 units per g), 5 g	‡ 1	2	..	7.85	8.88	^a	Otocomb Otic	BC
				B1.08	8.93	8.88	^a	Kenacomb Otic	BQ

OPHTHALMOLOGICAL AND OTOLOGICAL PREPARATIONS

Antiinfectives

• **Antiinfectives**

FRAMYCETIN SULFATE

1440T	Eye and ear drops 5 mg per mL (0.5%), 8 mL	‡ 1	2	..	9.68	10.71		Soframycin	SW

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	..	..	204.71	32.90	Albey Bee Venom	ES
INSECT ALLERGEN EXTRACT—PAPER WASP VENOM								
NOTE: Paper wasp venom is not European wasp venom.								
2918N	Injection set containing 550 micrograms	1	..	..	204.71	32.90	Albey Paper Wasp Venom	ES
INSECT ALLERGEN EXTRACT—YELLOW JACKET VENOM								
2883R	Injection set containing 550 micrograms	1	..	..	204.71	32.90	Albey Yellow Jacket Venom	ES
ALL OTHER THERAPEUTIC PRODUCTS								
All other therapeutic products								
• Antidotes								
NALOXONE HYDROCHLORIDE								
1752F	Injection 800 micrograms in 2 mL	1	..	..	29.43	30.46	Naloxone Min-I-Jet	CS
1753G	Injection 2 mg in 5 mL	1	..	..	43.06	32.90	Naloxone Min-I-Jet	CS
• Drugs for treatment of hyperkalemia and hyperphosphatemia								
LANTHANUM CARBONATE HYDRATE								
Authority Required								
<i>Maintenance therapy, following initiation and stabilisation of treatment with lanthanum carbonate, of hyperphosphataemia in a patient with chronic kidney disease on dialysis whose serum phosphate is not controlled on calcium and where:</i>								
<i>(a) serum phosphate is greater than 1.6 mmol per L; or</i>								
<i>(b) the serum calcium times phosphate product is greater than 4.0.</i>								
<i>at the commencement of therapy.</i>								
NOTE: <i>Not to be used in combination with sevelamer.</i>								
9403X	Chewable tablet 500 mg (base)	90	5	..	305.44	32.90	Fosrenol	ZI
9404Y	Chewable tablet 750 mg (base)	90	5	..	448.99	32.90	Fosrenol	ZI
9405B	Chewable tablet 1000 mg (base)	90	5	..	503.60	32.90	Fosrenol	ZI

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	
SEVELAMER HYDROCHLORIDE								
Authority Required								
<i>Maintenance therapy, following initiation and stabilisation of treatment with sevelamer hydrochloride, of hyperphosphataemia in a patient with chronic kidney disease on dialysis whose serum phosphate is not controlled on calcium and where:</i>								
<i>(a) serum phosphate is greater than 1.6 mmol per L; or</i>								
<i>(b) the serum calcium times phosphate product is greater than 4.0.</i>								
<i>at the commencement of therapy.</i>								
NOTE:								
<i>Not to be used in combination with lanthanum.</i>								
2142R	Tablet 800 mg	180	5	..	357.30	32.90	Renagel	GZ
• Detoxifying agents for antineoplastic treatment								
CALCIUM FOLINATE								
8740B	Injection equivalent to 50 mg folinic acid in 5 mL	5	5	..	* 154.39	32.90	^a Leucovorin Calcium	HH
				..	* 154.39	32.90	^a Leucovorin Calcium	PF
				..	154.39	32.90	^a Calcium Folate Ebewe	IT
8812T	Injection equivalent to 100 mg folinic acid in 10 mL	10	1	..	272.99	32.90	^a Leucovorin Calcium	PF
				..	* 272.99	32.90	^a Calcium Folate Ebewe	IT
9041W	Injection equivalent to 300 mg folinic acid in 30 mL	4	1	..	* 315.23	32.90	Leucovorin Calcium	HH
CALCIUM FOLINATE								
Restricted Benefit								
<i>Antidote to folic acid antagonists.</i>								
2308L	Tablet equivalent to 15 mg folinic acid	10	..	..	101.50	32.90	Leucovorin Calcium	HH
MESNA								
Restricted Benefit								
<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	..	72.38	32.90	Uromitexan	BX
8079F	Solution for I.V. injection 1 g in 10 mL	15	5	..	157.74	32.90	Uromitexan	BX

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	
• Drugs for treatment of hypercalcemia SODIUM ACID PHOSPHATE Authority Required (STREAMLINED) 1099 <i>Familial hypophosphataemia;</i> 1157 <i>Hypercalcaemia;</i> 1167 <i>Hypophosphataemic rickets;</i> 1467 <i>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	..	81.20	32.90	Phosphate Sandoz	NV

DIAGNOSTIC AGENTS

Urine tests**• Urine tests****COPPER SULFATE**

1228P	Diagnostic compound tablets, 36	2	3	..	* 71.05	32.90	Clinitest	BN

COPPER SULFATE**Restricted Benefit**

For use in patients who are receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements.

NOTE:

No applications for increased maximum quantities and/or repeats will be authorised.

9251X	Diagnostic compound tablets, 36	2	6	..	* 71.05	32.90	Clinitest	BN

GLUCOSE and KETONE INDICATOR—URINE

3106L	Reagent strips, 50	2	2	..	* 16.87	17.90	Keto-Diabur- Test 5000	RD
3107M	Reagent strips, 50	2	2	..	* 16.99	18.02	Keto-Diastix	BN

continued ➞

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 and KETONE INDICATOR—URINE**Restricted Benefit**

For use in patients who are receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements.

NOTE:

No applications for increased maximum quantities and/or repeats will be authorised.

9254C	Reagent strips, 50	2	4	..	* 16.87	17.90	Keto-Diabur- Test 5000	RD
9255D	Reagent strips, 50	2	4	..	* 16.99	18.02	Keto-Diastix	BN

GLUCOSE INDICATOR—URINE

2352T	Reagent strips, 50	2	2	..	* 19.39	20.42	Clinistix	BN
3104J	Reagent strips, 50	2	2	..	* 18.41	19.44	Diastix	BN

GLUCOSE INDICATOR—URINE**Restricted Benefit**

For use in patients who are receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements.

NOTE:

No applications for increased maximum quantities and/or repeats will be authorised.

9252Y	Reagent strips, 50	2	4	..	* 19.39	20.42	Clinistix	BN
9253B	Reagent strips, 50	2	4	..	* 18.41	19.44	Diastix	BN

Other diagnostic agents**• Tests for diabetes****GLUCOSE INDICATOR—BLOOD**

9193W	Electrode strips, 25	4	5	..	* 52.75	32.90	On-Call Plus	PZ
2979T	Electrode strips, 50	2	5	..	* 52.75	32.90	Accu-Chek Performa	RD
2891E	Electrode strips, 50	2	5	..	* 52.75	32.90	Advantage II	RD
9358M	Electrode strips, 50	2	5	..	* 52.75	32.90	FreeStyle	MS
8890X	Electrode strips, 50	2	5	..	* 52.75	32.90	Freestyle Papillon	MS
1820T	Electrode strips, 50	2	5	..	* 52.75	32.90	Glucoboy	DB
9013J	Electrode strips, 50	2	5	..	* 52.75	32.90	Glucocard 01 Sensor	OZ
8749L	Electrode strips, 50	2	5	..	* 52.75	32.90	GlucoOz	OZ

continued ➞

VARIOUS—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Proprietary Name and Manufacturer	
8682Y	Electrode strips, 50	2	5	..	* 52.75	32.90	MWD Pen Sensor Strips	WF
8723D	Electrode strips, 50	2	5	..	* 52.75	32.90	Omnitest EZ	BR
9063B	Electrode strips, 50	2	5	..	* 52.75	32.90	Omnitest Plus	BR
2263D	Electrode strips, 50	2	5	..	* 52.75	32.90	Optium Omega	MS
8825L	Electrode strips, 50	2	5	..	* 52.75	32.90	TrueTrack	DB
9154T	Electrode strips, 100	‡ 1	5	..	52.73	32.90	FreeStyle Lite	MS
8522M	Electrode strips, 100	‡ 1	5	..	52.73	32.90	Optium glucose	MS
8573F	Electrode strips, 100	‡ 1	5	..	52.73	32.90	SofTact	MS
8608C	Electrode strips, 100	‡ 1	5	..	52.73	32.90	TrueSense	MS
8190C	Reagent strips, 50	2	5	..	* 52.75	32.90	Accu-Chek Active	RD
8739Y	Reagent strips, 50	2	5	..	* 52.75	32.90	Accu-Chek Go	RD
8806L	Reagent strips, 51	2	5	..	* 52.75	32.90	Accu-Chek Integra	RD
2890D	Reagent strips, 50	2	5	..	* 52.75	32.90	Betachek	NA
2860M	Reagent strips, 50	2	5	..	* 52.75	32.90	Betachek G5	NA
8759B	Reagent strips, 50	2	5	..	* 52.75	32.90	CareSens	LB
2914J	Reagent strips, 50	2	5	..	* 45.47	32.90	Glucoflex-R	NA
2917M	Reagent strips, 50	2	5	..	* 45.47	32.90	Glucostix	BN
8795X	Reagent strips, 50	2	5	..	* 52.75	32.90	SensoCard	PX

GLUCOSE INDICATOR—BLOOD**Restricted Benefit**

For use in patients who are receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements.

NOTE:

No applications for increased maximum quantities and/or repeats will be authorised.

9256E	Electrode strips, 25	4	11	..	* 52.75	32.90	On-Call Plus	PZ
9257F	Electrode strips, 50	2	11	..	* 52.75	32.90	Accu-Chek Performa	RD
9258G	Electrode strips, 50	2	11	..	* 52.75	32.90	Advantage II	RD
9359N	Electrode strips, 50	2	11	..	* 52.75	32.90	FreeStyle	MS
9259H	Electrode strips, 50	2	11	..	* 52.75	32.90	Freestyle Papillon	MS
9260J	Electrode strips, 50	2	11	..	* 52.75	32.90	Glucoboy	DB

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	
9261K	Electrode strips, 50	2	11	..	* 52.75	32.90	Glucocard 01 Sensor	OZ
9263M	Electrode strips, 50	2	11	..	* 52.75	32.90	GlucoOz	OZ
9264N	Electrode strips, 50	2	11	..	* 52.75	32.90	MWD Pen Sensor Strips	WF
9265P	Electrode strips, 50	2	11	..	* 52.75	32.90	Omnitest EZ	BR
9266Q	Electrode strips, 50	2	11	..	* 52.75	32.90	Omnitest Plus	BR
9267R	Electrode strips, 50	2	11	..	* 52.75	32.90	Optium Omega	MS
9268T	Electrode strips, 50	2	11	..	* 52.75	32.90	TrueTrack	DB
9269W	Electrode strips, 100	‡ 1	11	..	52.73	32.90	FreeStyle Lite	MS
9270X	Electrode strips, 100	‡ 1	11	..	52.73	32.90	Optium glucose	MS
9271Y	Electrode strips, 100	‡ 1	11	..	52.73	32.90	SofTact	MS
9272B	Electrode strips, 100	‡ 1	11	..	52.73	32.90	TrueSense	MS
9273C	Reagent strips, 50	2	11	..	* 52.75	32.90	Accu-Chek Active	RD
9274D	Reagent strips, 50	2	11	..	* 52.75	32.90	Accu-Chek Go	RD
9275E	Reagent strips, 51	2	11	..	* 52.75	32.90	Accu-Chek Integra	RD
9276F	Reagent strips, 50	2	11	..	* 52.75	32.90	Betachek	NA
9277G	Reagent strips, 50	2	11	..	* 52.75	32.90	Betachek G5	NA
9278H	Reagent strips, 50	2	11	..	* 52.75	32.90	CareSens	LB
9279J	Reagent strips, 50	2	11	..	* 45.47	32.90	Glucoflex-R	NA
9280K	Reagent strips, 50	2	11	..	* 45.47	32.90	Glucostix	BN
9281L	Reagent strips, 50	2	11	..	* 52.75	32.90	SensoCard	PX

Authority Required (STREAMLINED)

1769

Patients who have previously received this product as a pharmaceutical benefit;

1770

Patients who have purchased a meter to be used with this product prior to 1 August 2003.

2926B	Electrode strips, 100	‡ 1	5	..	54.23	32.90	Precision Plus	MS

VARIOUS—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 \$	

GENERAL NUTRIENTS

Other nutrients• **Other nutrients****TRIGLYCERIDES, MEDIUM CHAIN****NOTE:**

No applications for increased maximum quantities and/or repeats will be authorised.

Authority Required

Chylous ascites;

Chylothorax;

Fat malabsorption due to liver disease, short gut syndrome, cystic fibrosis and gastrointestinal disorders;

Hyperlipoproteinaemia type 1;

Intractable childhood epilepsy or cerebrospinal fluid glucose transporter defect, requiring a ketogenic diet;

Long chain fatty acid oxidation disorders.

3128P	Oil 500 mL	2	5	..	* 51.95	32.90	MCT Oil	SB

• **Fat/carbohydrates/proteins/minerals/vitamins, combinations****AMINO ACIDS—SYNTHETIC, FORMULA****Authority Required**

Initial treatment for up to 3 months, by a clinical immunologist, suitably qualified allergist or gastroenterologist in a patient 18 years of age or less with eosinophilic oesophagitis who requires an amino acid based formula as a component of a dietary elimination programme. Treatment with oral steroids should not be commenced during the period of initial treatment.

Eosinophilic oesophagitis is demonstrated by the following criteria:

(i) Chronic symptoms of reflux that persisted despite a 2-month trial of a proton pump inhibitor or chronic dysphagia; and

(ii) A lack of demonstrable anatomic abnormality with the exception of stricture, which can be attributable to eosinophilic oesophagitis; and

(iii) Eosinophilic infiltration of the oesophagus, demonstrated by oesophageal biopsy specimens obtained by endoscopy and where the most densely involved oesophageal biopsy had 20 or more eosinophils in any single 400 x high powered field, along with normal antral and duodenal biopsies.

The date of birth of the patient must be included in the authority.

Authority Required

Continuing treatment by a clinical immunologist, suitably qualified allergist or gastroenterologist in a patient 18 years of age or less with eosinophilic oesophagitis who has responded to an initial course of PBS-subsidised treatment. Response to initial treatment is demonstrated by oesophageal biopsy specimens obtained by endoscopy, where the most densely involved oesophageal biopsy had 5 or less eosinophils in any single 400 x high powered field, along with normal antral and duodenal biopsies. The response criteria will not be deemed to have been met if oral steroids were commenced during initial treatment.

NOTE:

Authorities for increased maximum quantities, up to a maximum of 52, may be authorised.

2250K	Compound powder 400 g	12	5	..	* 531.23	32.90	EleCare	AB

VARIOUS—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 \$	
<u>Authority Required</u>							
<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 a child up to the age of 2 years. Combined intolerance is demonstrated when the child has failed to respond to a strict cows' milk protein free and strict soy protein free diet with a protein hydrolysate (with or without medium chain triglycerides) as the principal formula. The date of birth of the patient must be included in the authority application;</i>							
<i>Initial treatment, in consultation with a paediatric gastroenterologist or specialist allergist, for up to 3 months, of a child up to the age of 2 years with severe intolerance (not infant colic) to cows' milk protein. The date of birth of the patient must be included in the authority application.</i>							
<u>NOTE:</u>							
<i>No applications for increased maximum quantities and/or repeats will be authorised.</i>							
8574G	Compound powder 400 g	8	5	..	* 360.71	32.90	EleCare AB
8443J	Compound powder 400 g	8	5	..	* 360.71	32.90	Neocate SB
8754R	Compound powder 400 g	8	5	..	* 360.71	32.90	Neocate Advance SB
2244D	Compound powder 400 g	8	5	..	* 360.71	32.90	Neocate Advance Tropical Flavour SB

Authority Required

Continuing treatment for combined intolerance (not infant colic) to cows' milk protein, soy protein and protein hydrolysate formulae in a child up to the age of 2 years, where the child has been assessed by a suitably qualified allergist or paediatrician. The date of birth of the patient must be included in the authority application;

Treatment for combined intolerance (not infant colic) to cows' milk protein, soy protein and protein hydrolysate formulae in a child aged 2 years and over, where the child is assessed by a suitably qualified allergist or paediatrician at intervals not greater than 6 months. The date of birth of the patient must be included in the authority application;

Continuing treatment for severe intolerance (not infant colic) to cows' milk protein in a child up to the age of 2 years, where the child has been assessed by a paediatric gastroenterologist or specialist allergist and soy protein and protein hydrolysate formulae are not tolerated or not likely to be tolerated. The date of birth of the patient must be included in the authority application;

Treatment for severe intolerance (not infant colic) to cows' milk protein in a child aged 2 years and over, where the child is assessed by a paediatric gastroenterologist or specialist allergist at intervals not greater than 6 months. The date of birth of the patient must be included in the authority application;

Severe intestinal malabsorption including short bowel syndrome where protein hydrolysate formulae have failed;

Severe intestinal malabsorption including short bowel syndrome where the patient has been receiving parenteral nutrition.

NOTE:

Authorities for increased maximum quantities, up to a maximum of 20, may be authorised.

8575H	Compound powder 400 g	8	5	..	* 360.71	32.90	EleCare	AB
3066J	Compound powder 400 g	8	5	..	* 360.71	32.90	Neocate	SB
8755T	Compound powder 400 g	8	5	..	* 360.71	32.90	Neocate Advance	SB

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	
2553J	Compound powder 400 g	8	5	..	* 360.71	32.90	Neocate Advance Tropical Flavour	SB

AMINO ACID SYNTHETIC FORMULA supplemented with
LONG CHAIN POLYUNSATURATED FATTY ACIDS

Authority Required

Initial treatment, for up to 3 months, for combined intolerance (not infant colic) to cows' milk protein, soy protein and protein hydrolysate formulae in a child up to the age of 2 years. Combined intolerance is demonstrated when the child has failed to respond to a strict cows' milk protein free and strict soy protein free diet with a protein hydrolysate (with or without medium chain triglycerides) as the principal formula. The date of birth of the patient must be included in the authority application;

Initial treatment, in consultation with a paediatric gastroenterologist or specialist allergist, for up to 3 months, of a child up to the age of 2 years with severe intolerance (not infant colic) to cows' milk protein. The date of birth of the patient must be included in the authority application.

NOTE:

No applications for increased maximum quantities and/or repeats will be authorised.

2246F	Compound powder 400 g	8	5	..	* 367.43	32.90	Neocate LCP	SB

Authority Required

Continuing treatment for combined intolerance (not infant colic) to cows' milk protein, soy protein and protein hydrolysate formulae in a child up to the age of 2 years, where the child has been assessed by a suitably qualified allergist or paediatrician. The date of birth of the patient must be included in the authority application;

Treatment for combined intolerance (not infant colic) to cows' milk protein, soy protein and protein hydrolysate formulae in a child aged 2 years and over, where the child is assessed by a suitably qualified allergist or paediatrician at intervals not greater than 6 months. The date of birth of the patient must be included in the authority application;

Continuing treatment for severe intolerance (not infant colic) to cows' milk protein in a child up to the age of 2 years, where the child has been assessed by a paediatric gastroenterologist or specialist allergist and soy protein and protein hydrolysate formulae are not tolerated or not likely to be tolerated. The date of birth of the patient must be included in the authority application;

Treatment for severe intolerance (not infant colic) to cows' milk protein in a child aged 2 years and over, where the child is assessed by a paediatric gastroenterologist or specialist allergist at intervals not greater than 6 months. The date of birth of the patient must be included in the authority application;

Severe intestinal malabsorption including short bowel syndrome where protein hydrolysate formulae have failed;

Severe intestinal malabsorption including short bowel syndrome where the patient has been receiving parenteral nutrition.

NOTE:

Authorities for increased maximum quantities, up to a maximum of 20, may be authorised.

2560R	Compound powder 400 g	8	5	..	* 367.43	32.90	Neocate LCP	SB

VARIOUS—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 \$	
PROTEIN HYDROLYSATE FORMULA with MEDIUM CHAIN TRIGLYCERIDES							
NOTE:							
No applications for increased maximum quantities and/or repeats will be authorised.							
Authority Required							
Initial treatment, for up to 3 months, for intolerance (not infant colic) to both cows' milk protein and soy protein in a child up to the age of 2 years. Intolerance is demonstrated when the child has failed to respond to a strict cows' milk protein free diet with a soy protein as the principal formula. The date of birth of the patient must be included in the authority application;							
Continuing treatment for intolerance (not infant colic) to both cows' milk protein and soy protein in a child up to the age of 2 years, where clinical improvement has been demonstrated with the protein hydrolysate formula with medium chain triglycerides. The date of birth of the patient must be included in the authority application;							
Continuing treatment for intolerance (not infant colic) to both cows' milk protein and soy protein in a child aged 2 years and over, where the child has been assessed by a suitably qualified allergist or paediatrician. The date of birth of the patient must be included in the authority application.							
Authority Required							
Initial treatment, in consultation with a paediatric gastroenterologist or specialist allergist, for up to 3 months, of a child up to the age of 2 years with severe intolerance (not infant colic) to cows' milk protein. The date of birth of the patient must be included in the authority application;							
Continuing treatment for severe intolerance (not infant colic) to cows' milk protein in a child up to the age of 2 years, where clinical improvement has been demonstrated with the protein hydrolysate formula with medium chain triglycerides and soy protein is not tolerated or is likely not to be tolerated. The date of birth of the patient must be included in the authority application;							
Continuing treatment for severe intolerance (not infant colic) to cows' milk protein in a child aged 2 years and over, where the child has been assessed by a paediatric gastroenterologist or specialist allergist. The date of birth of the patient must be included in the authority application.							
Authority Required							
Biliary atresia;							
Chronic liver failure with fat malabsorption;							
Chylous ascites;							
Chylothorax;							
Cystic fibrosis;							
Enterokinase deficiency;							
Proven fat malabsorption;							
Severe diarrhoea of greater than 2 weeks' duration in an infant aged less than 4 months. The date of birth of the patient must be included in the authority application;							
Severe intestinal malabsorption including short bowel syndrome.							
2676W	Compound powder 400 g	8	5	..	* 171.51	32.90	Alfaré NT

continued ➞

VARIOUS—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed	Maximum	Proprietary Name and Manufacturer
					Price for Max. Qty \$	Recordable Value for Safety Net \$	

Authority Required

Initial treatment, for up to 3 months, for intolerance (not infant colic) to both cows' milk protein and soy protein in a child up to the age of 2 years. Intolerance is demonstrated when the child has failed to respond to a strict cows' milk protein free diet with a soy protein as the principal formula. The date of birth of the patient must be included in the authority application;

Continuing treatment for intolerance (not infant colic) to both cows' milk protein and soy protein in a child up to the age of 2 years, where clinical improvement has been demonstrated with the protein hydrolysate formula with medium chain triglycerides. The date of birth of the patient must be included in the authority application;

Continuing treatment for intolerance (not infant colic) to both cows' milk protein and soy protein in a child aged 2 years and over, where the child has been assessed by a suitably qualified allergist or paediatrician. The date of birth of the patient must be included in the authority application.

Authority Required

Initial treatment, in consultation with a paediatric gastroenterologist or specialist allergist, for up to 3 months, of a child up to the age of 2 years with severe intolerance (not infant colic) to cows' milk protein. The date of birth of the patient must be included in the authority application;

Continuing treatment for severe intolerance (not infant colic) to cows' milk protein in a child up to the age of 2 years, where clinical improvement has been demonstrated with the protein hydrolysate formula with medium chain triglycerides and soy protein is not tolerated or is likely not to be tolerated. The date of birth of the patient must be included in the authority application;

Continuing treatment for severe intolerance (not infant colic) to cows' milk protein in a child aged 2 years and over, where the child has been assessed by a paediatric gastroenterologist or specialist allergist. The date of birth of the patient must be included in the authority application.

Authority Required

Biliary atresia;

Chronic liver failure with fat malabsorption;

Chylous ascites;

Cystic fibrosis;

Enterokinase deficiency;

Proven fat malabsorption;

Severe diarrhoea of greater than 2 weeks' duration in an infant aged less than 4 months. The date of birth of the patient must be included in the authority application;

Severe intestinal malabsorption including short bowel syndrome.

8259Q	Compound powder 450 g	8	5	..	* 109.43	32.90	Pepti-Junior Gold	NU

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	
TRIGLYCERIDES—MEDIUM CHAIN, FORMULA								
NOTE:								
<i>No applications for increased maximum quantities and/or repeats will be authorised.</i>								
Restricted Benefit								
<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>								
NOTE:								
<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	..	* 420.87	32.90	Monogen	SB
Restricted Benefit								
<i>Chylous ascites;</i>								
<i>Chylothorax;</i>								
<i>Fat malabsorption due to liver disease, short gut syndrome, cystic fibrosis and gastrointestinal disorders.</i>								
NOTE:								
<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	..	* 467.03	32.90	Caprilon	SB
• Carbohydrates								
AMYLOPECTIN, MODIFIED LONG CHAIN								
Restricted Benefit								
<i>Glycogen storage disease.</i>								
9386B	Sachets 60 g, 30	4	5	..	* 751.87	32.90	Glycosade	VF
• 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	..	..	* 112.44	32.90	S-26 LF	WX
2350Q	Lactose-predigested powder infant formula 900 g	5	..	..	* 88.49	32.90	Karicare De-Lact	NU

continued ➡

VARIOUS—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 \$		

Authority Required

Proven chronic lactose intolerance in infants up to the age of 12 months. The date of birth of the patient must be included in the authority application. Lactose intolerance must have been proven by either:

(a) relief of symptoms on supervised withdrawal of lactose from the diet for 3 or 4 days and subsequent re-emergence of symptoms on rechallenge with lactose containing formulae or milk or food; or

(b) not less than 0.5% reducing substance in stool exudate tested with copper sulfate diagnostic compound tablet; or

(c) hydrogen breath test.

NOTE:

No applications for increased maximum quantities and/or repeats will be authorised.

8283Y	Infant formula powder 900 g	5	5	..	* 112.44	32.90	S-26 LF	WX
2349P	Lactose-predigested powder infant formula 900 g	5	5	..	* 88.49	32.90	Karicare De-Lact	NU

MILK POWDER—LACTOSE MODIFIED**Authority Required**

Acute lactose intolerance in children aged 1 year and over. The date of birth of the patient must be included in the authority application.

NOTE:

No applications for increased maximum quantities and/or repeats will be authorised. No more than 1 application per patient will be authorised.

2358D	Lactose-predigested powder 900 g	3	1	..	* 72.38	32.90	Digestelact	SJ

Authority Required

Proven chronic lactose intolerance in children aged 1 year and over who are significantly malnourished. The date of birth of the patient must be included in the authority application. Lactose intolerance must have been proven by either:

(a) relief of symptoms on supervised withdrawal of lactose from the diet for 3 or 4 days and subsequent re-emergence of symptoms on rechallenge with lactose containing formulae or milk or food; or

(b) not less than 0.5% reducing substance in stool exudate tested with copper sulfate diagnostic compound tablet; or

(c) hydrogen breath test.

NOTE:

No applications for increased maximum quantities and/or repeats will be authorised.

2357C	Lactose-predigested powder 900 g	3	10	..	* 72.38	32.90	Digestelact	SJ

MILK POWDER—SYNTHETIC**NOTE:**

No applications for increased maximum quantities and/or repeats will be authorised.

Authority Required

Hypercalcaemia in children under the age of 4 years.

3092R	Low calcium compound powder 400 g	8	5	..	* 380.95	32.90	Locasol	NU

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	
• Other combinations of nutrients								
AMINO ACID FORMULA without METHIONINE, THREONINE and VALINE and low in Isoleucine								
<u>Restricted Benefit</u>								
Methylmalonic acidemia;								
Propionic acidemia.								
3079C	Powder 200 g	5	5	..	* 1047.99	32.90	XMTVI Asadon	SB
AMINO ACID FORMULA without PHENYLALANINE								
<u>Restricted Benefit</u>								
Phenylketonuria.								
8554F	Capsules 500 mg, 200	16	5	..	* 1275.91	32.90	Phlexy-10	SB
8678R	Tablets 1 g, 75	24	5	..	* 1426.55	32.90	Phlexy-10	SB
8706F	Bars 42 g, 20	10	5	..	* 1570.89	32.90	Phlexy-10	SB
2347M	Sachets containing powder 20 g, 30	7	5	..	* 1462.48	32.90	Phlexy-10 Drink Mix	SB
3072Q	Powder 250 g	8	5	..	* 1209.43	32.90	PK AID II	SB
AMINO ACID FORMULA without PHENYLALANINE, TYROSINE and METHIONINE								
<u>Restricted Benefit</u>								
Tyrosinaemia.								
2379F	Powder 500 g	4	5	..	* 2671.55	32.90	XPTM Tyrosidon	SB
AMINO ACID FORMULA with VITAMINS, MINERALS and LONG CHAIN POLYUNSATURATED FATTY ACIDS without PHENYLALANINE								
<u>Restricted Benefit</u>								
Phenylketonuria.								
8479G	Infant formula, powder 400 g	8	5	..	* 703.19	32.90	XP Analog LCP	SB
AMINO ACID FORMULA with VITAMINS and MINERALS without LYSINE and low in TRYPTOPHAN								
<u>Restricted Benefit</u>								
An infant or young child with proven glutaric aciduria type 1.								
2650L	Infant formula, powder 400 g	8	5	..	* 673.27	32.90	XLYS, LOW TRY Analog	SB

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	
<u>Restricted Benefit</u>								
<i>A child aged less than 7 years with proven glutaric aciduria type 1.</i>								
2646G	Powder 500 g	8	5	..	* 1624.23	32.90	XYLYS, LOW TRY Maxamaid	SB
AMINO ACID FORMULA with VITAMINS and MINERALS without METHIONINE								
<u>Restricted Benefit</u>								
<i>For infants and very young children with pyridoxine non-responsive homocystinuria.</i>								
8417B	Infant formula, powder 400 g	8	5	..	* 768.87	32.90	XMET Analog	SB
<u>Restricted Benefit</u>								
<i>Pyridoxine non-responsive homocystinuria.</i>								
8677Q	Sachets 20 g, 30	4	5	..	* 1797.99	32.90	HCU gel	VF
8744F	Sachets 25 g, 30	4	5	..	* 3097.95	32.90	HCU express	VF
8328H	Powder 500 g	8	5	..	* 1784.31	32.90	XMET Maxamaid	SB
8416Y	Powder 500 g	8	5	..	* 2704.31	32.90	XMET Maxamum	SB
9133Q	Oral liquid 130 mL, 30	4	5	..	* 3097.95	32.90	HCU Cooler	VF
AMINO ACID FORMULA with VITAMINS and MINERALS without METHIONINE, THREONINE and VALINE and low in ISOLEUCINE								
<u>Restricted Benefit</u>								
<i>Methylmalonic acidaemia; Propionic acidaemia.</i>								
8058D	Infant formula, powder 400 g	8	5	..	* 629.03	32.90	XMTVI Analog	SB
8059E	Powder 500 g	8	5	..	* 1542.31	32.90	XMTVI Maxamaid	SB
8061G	Powder 500 g	8	5	..	* 1931.51	32.90	XMTVI Maxamum	SB
AMINO ACID FORMULA with VITAMINS and MINERALS without PHENYLALANINE								
<u>Restricted Benefit</u>								
<i>Phenylketonuria.</i>								
1411G	Sachets 18.2 g, 60	3	5	..	* 1639.64	32.90	add-ins	SB
8555G	Sachets 20 g, 30	4	5	..	* 890.59	32.90	PKU-gel	VF
8591E	Sachets 25 g, 30	4	5	..	* 1548.71	32.90	PKU-Express	VF
8804J	Sachets 27.8 g, 30	3	5	..	* 1549.01	32.90	Lophlex	SB

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	
8613H	Sachets 29 g, 30	4	5	..	* 891.67	32.90	Minaphlex	SB
8727H	Sachets 50 g, 30	3	5	..	* 1511.63	32.90	XP Maxamum	SB
2737C	Infant formula, powder 400 g	8	5	..	* 605.99	32.90	XP Analog	SB
8467P	Powder 325 g	10	5	..	* 861.39	32.90	Phenex-2	AB
8545R	Powder 400 g	8	5	..	* 848.15	32.90	Phenex-2	AB
2738D	Powder 500 g	8	5	..	* 883.59	32.90	XP Maxamaid	SB
2739E	Powder 500 g	8	5	..	* 1351.99	32.90	XP Maxamum	SB
8746H	Oral liquid 250 mL	90	5	..	* 1312.84	32.90	Easiphen	SB
9397N	Oral liquid 62.5 mL, 60	2	5	..	* 1058.93	32.90	Lophlex LQ 10	NU
2382J	Oral liquid 87 mL, 30	4	5	..	* 1034.35	32.90	PKU Cooler 10	VF
9021T	Oral liquid 125 mL, 30	3	5	..	* 1549.01	32.90	Lophlex LQ	SB
9396M	Oral liquid 125 mL, 36	4	5	..	* 1269.43	32.90	PKU Anamix Junior LQ	NU
8846N	Oral liquid 130 mL, 30	4	5	..	* 1547.91	32.90	PKU Cooler 15	VF
2474F	Oral liquid 174 mL, 30	4	5	..	* 2053.59	32.90	PKU Cooler 20	VF

**AMINO ACID FORMULA with VITAMINS and MINERALS
without PHENYLALANINE and TYROSINE**

**Restricted Benefit
Tyrosinaemia.**

8631G	Sachets 20 g, 30	4	5	..	* 1797.99	32.90	TYR gel	VF
8667E	Sachets 25 g, 30	4	5	..	* 3097.95	32.90	TYR Express	VF
9395L	Sachets 29 g, 30	4	5	..	* 1800.03	32.90	TYR Anamix Junior	NU
8445L	Infant formula, powder 400 g	8	5	..	* 768.87	32.90	XPhen, Tyr Analog	SB
8446M	Powder 500 g	8	5	..	* 1784.31	32.90	XPhen, Tyr Maxamaid	SB
3078B	Powder 500 g	8	5	..	* 2704.31	32.90	XPhen, Tyr Maxamum	SB
9132P	Oral liquid 130 mL, 30	4	5	..	* 3097.95	32.90	TYR Cooler	VF

VARIOUS—CONT.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Proprietary Name and Manufacturer	
AMINO ACID FORMULA with VITAMINS and MINERALS without VALINE, LEUCINE and ISOLEUCINE								
<u>Restricted Benefit</u> <i>Maple syrup urine disease.</i>								
8592F	Sachets 20 g, 30	4	5	..	* 1797.99	32.90	MSUD-gel	VF
8632H	Sachets 25 g, 30	4	5	..	* 3097.95	32.90	MSUD Express	VF
8745G	Sachets 29 g, 30	4	5	..	* 1800.03	32.90	Mapleflex	SB
2380G	Infant formula, powder 400 g	8	5	..	* 768.87	32.90	MSUD Analog	SB
8310J	Powder 500 g	4	5	..	* 2671.55	32.90	MSUD AID III	SB
8260R	Powder 500 g	8	5	..	* 1784.31	32.90	MSUD Maxamaid	SB
8057C	Powder 500 g	8	5	..	* 2704.31	32.90	MSUD Maxamum	SB
2375B	Oral liquid 130 mL, 30	4	5	..	* 3097.95	32.90	MSUD Express Cooler	VF
CARBOHYDRATE, FAT, VITAMINS, MINERALS and TRACE ELEMENTS								
<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	..	* 260.07	32.90	Pro-Phree	AB
8369L	Powder 400 g	8	5	..	* 291.03	32.90	Energivit	SB
CYSTINE with CARBOHYDRATE								
<u>Restricted Benefit</u> <i>Pyridoxine non-responsive homocystinuria.</i>								
9164H	Sachets 4 g containing 500 mg cystine, 30	4	5	..	* 515.59	32.90	Cystine Amino Acid Supplement	VF
ESSENTIAL AMINO ACIDS FORMULA with MINERALS and VITAMIN C								
<u>Restricted Benefit</u> <i>Gyrate atrophy of the choroid and retina; Urea cycle disorders.</i>								
8001D	Powder 200 g	10	5	..	* 633.69	32.90	Dialamine	SB
2027Q	Powder 400 g	5	5	..	* 633.74	32.90	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	
ESSENTIAL AMINO ACIDS FORMULA with VITAMINS and MINERALS								
<u>Restricted Benefit</u>								
<i>Gyrate atrophy of the choroid and retina;</i>								
<i>Urea cycle disorders.</i>								
9385Y	Sachets 12.5 g, 50	4	5	..	* 1516.07	32.90	EAA Supplement	VF
ISOLEUCINE with CARBOHYDRATE								
<u>Restricted Benefit</u>								
<i>Maple syrup urine disease.</i>								
9134R	Sachets 4 g containing 50 mg isoleucine, 30	4	5	..	* 515.59	32.90	Isoleucine Amino Acid Supplement	VF
MILK PROTEIN and FAT FORMULA with VITAMINS and MINERALS—CARBOHYDRATE FREE								
<u>Restricted Benefit</u>								
<i>Patients with intractable seizures requiring treatment with a ketogenic diet;</i>								
<i>Glucose transport protein defects;</i>								
<i>Pyruvate dehydrogenase deficiency;</i>								
<i>Infants and young children with glucose-galactose intolerance and multiple monosaccharide intolerance.</i>								
8630F	Powder 225 g	24	5	..	* 647.99	32.90	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	..	58.11	32.90	Metabolic Mineral Mixture	SB
PHENYLALANINE with CARBOHYDRATE								
<u>Restricted Benefit</u>								
<i>Tyrosinaemia.</i>								
9384X	Sachets 4 g containing 50 mg phenylalanine, 30	4	5	..	* 515.59	32.90	Phenylalanine Amino Acid Supplement	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	
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;</i>								
<i>Glucose transport protein defects;</i>								
<i>Pyruvate dehydrogenase deficiency;</i>								
<i>Infants and young children with glucose-galactose intolerance and multiple monosaccharide intolerance.</i>								
8577K	Liquid 384 mL	120	5	..	* 669.59	32.90	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	..	* 295.11	32.90	Duocal	SB
TRIGLYCERIDES—MEDIUM CHAIN, FORMULA NOTE:								
<i>No applications for increased maximum quantities and/or repeats will be authorised.</i>								
<u>Authority Required</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>								
NOTE:								
<i>MCT Pro-Cal is not indicated for the treatment of intractable childhood epilepsy or cerebrospinal fluid glucose transporter defect requiring a ketogenic diet.</i>								
9383W	Sachets 16 g, 25	4	5	..	* 215.19	32.90	MCT Pro-Cal	VF
TYROSINE with CARBOHYDRATE								
<u>Restricted Benefit</u>								
<i>Phenylketonuria.</i>								
9165J	Sachets 4 g containing 1 g tyrosine, 30	4	5	..	* 515.59	32.90	Tyrosine Amino Acid Supplement	VF
VALINE with CARBOHYDRATE								
<u>Restricted Benefit</u>								
<i>Maple syrup urine disease.</i>								
9135T	Sachets 4 g containing 50 mg valine, 30	4	5	..	* 515.59	32.90	Valine Amino Acid Supplement	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	
	WHEY PROTEIN FORMULA supplemented with AMINO ACIDS, LONG CHAIN POLYUNSATURATED FATTY 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>							
9382T	Sachets 100 g, 10	8	5	..	* 1328.87	32.90	RenaStart	VF
	WHEY PROTEIN FORMULA supplemented with AMINO ACIDS, VITAMINS and MINERALS, and low in PROTEIN, PHOSPHATE, POTASSIUM and LACTOSE							
	<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	..	* 1065.51	32.90	Kindergen	SB

ALL OTHER NON-THERAPEUTIC PRODUCTS

All other non-therapeutic products

• Solvents and diluting agents, incl. irrigating solutions

SODIUM CHLORIDE

2026P	Injection 9 mg per mL (0.9%), 10 mL	5	1	..	17.73	18.76	PF	

PREPARATIONS WHICH MAY BE PRESCRIBED FOR PATIENTS RECEIVING PALLIATIVE CARE

PREPARATIONS WHICH MAY BE PRESCRIBED FOR PATIENTS RECEIVING PALLIATIVE CARE

The prescribing of medications listed in this section is in accordance with the requirements for General Pharmaceutical Benefits in the Schedule unless otherwise detailed in the listing for the item.

In addition, certain additional principles have been applied by the Pharmaceutical Benefits Advisory Committee (PBAC) in recommending for whom these medications may be prescribed, and the number of repeats that may be approved by Medicare Australia. These principles have been encompassed in the listings for the items, and further details are provided below to help doctors prescribing under this section.

For the purposes of this section a patient receiving palliative care is defined as:

- *A patient with an active, progressive, far-advanced disease for whom the prognosis is limited and the focus of care is the quality of life.*

The provision for increased maximum quantities and up to 3 repeats on the *initial* authority prescription is intended to provide up to 4 months' therapy in total. Where *continuing* treatment is required the provision of repeats is subject to confirmation by the prescriber that a palliative care physician or palliative care service has been consulted regarding the care of the patient.

Prescribers must heed State/Territory laws when prescribing drugs listed as narcotic, specified or restricted and must notify, or receive approval from, the appropriate health authority.

When a Palliative Care authority application is for a drug of addiction, the following guidelines apply:

- the maximum quantity authorised is generally for 1 month's therapy;
- where supply for a longer period is warranted, quantities are for up to 3 months' therapy;
- telephone approvals are limited to 1 month's therapy.

Doctors should also state (on the prescription) the interval of repeat where repeats are called for, and ensure State/Territory health authorities are notified about ongoing treatment.

Prescribers should be aware that patients receiving palliative care may also access PBS items included in the general part of the Schedule of Pharmaceutical Benefits including narcotic preparations, according to the restrictions that apply to individual items and the requirements that apply to the general part of the Schedule.

**PREPARATIONS WHICH MAY BE PRESCRIBED FOR
PATIENTS RECEIVING PALLIATIVE CARE-cont.**

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed	Maximum	Proprietary Name and Manufacturer
					Price for Max. Qty \$	Recordable Value for Safety Net \$	

ALIMENTARY TRACT AND METABOLISM

STOMATOLOGICAL PREPARATIONS

Stomatological preparations

• **Other agents for local oral treatment**

BENZYDAMINE HYDROCHLORIDE

Authority Required

Initial supply (for up to 4 months) for palliative care patients where a painful mouth is a problem;

Continuing supply for palliative care patients where a painful mouth is a problem, and where consultation with a palliative care specialist or service has occurred.

NOTE:

No applications for increased repeats will be authorised.

5385K	Mouth and throat rinse 22.5 mg per 15 mL, 500 mL	± 1	3	..	21.83	22.86	Difflam	IA

Authority Required

Continuing supply for palliative care patients where a painful mouth is a problem.

NOTE:

No applications for repeats will be authorised.

5386L	Mouth and throat rinse 22.5 mg per 15 mL, 500 mL	± 1	..	..	21.83	22.86	Difflam	IA

CARMELLOSE SODIUM

Authority Required

Initial supply (for up to 4 months) for palliative care patients where dry mouth is a symptom;

Continuing supply for palliative care patients where dry mouth is a symptom, and where consultation with a palliative care specialist or service has occurred.

NOTE:

No applications for increased repeats will be authorised.

5333Q	Mouth spray 10 mg per mL, 25 mL	± 1	3	..	10.36	11.39	Aquae	HA
5334R	Mouth spray 10 mg per mL, 100 mL	± 1	3	..	12.03	13.06	Aquae	HA

Authority Required

Continuing supply for palliative care patients where dry mouth is a symptom.

NOTE:

No applications for repeats will be authorised.

5335T	Mouth spray 10 mg per mL, 25 mL	± 1	..	..	10.36	11.39	Aquae	HA
5336W	Mouth spray 10 mg per mL, 100 mL	± 1	..	..	12.03	13.06	Aquae	HA

PREPARATIONS WHICH MAY BE PRESCRIBED FOR PATIENTS RECEIVING PALLIATIVE CARE-cont.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Proprietary Name and Manufacturer	

DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS

Belladonna and derivatives, plain

- ***Belladonna alkaloids semisynthetic, quaternary ammonium compounds***

HYOSCINE BUTYLBROMIDE

Authority Required

Initial supply (for up to 4 months) for palliative care patients where colicky pain is a symptom;

Continuing supply for palliative care patients where colicky pain is a symptom, and where consultation with a palliative care specialist or service has occurred.

NOTE:

No applications for increased repeats will be authorised.

5317W	Injection 20 mg in 1 mL	5	3	..	22.31	23.34	Buscopan	BY

Authority Required

Continuing supply for palliative care patients where colicky pain is a symptom.

NOTE:

No applications for repeats will be authorised.

5318X	Injection 20 mg in 1 mL	5	..	..	22.31	23.34	Buscopan	BY

ANTIEMETICS AND ANTINAUSEANTS

Antiemetics and antinauseants

- ***Other antiemetics***

PROMETHAZINE HYDROCHLORIDE

Authority Required

Initial supply (for up to 4 months) for palliative care patients where nausea and/or vomiting is a problem;

Continuing supply for palliative care patients where nausea and/or vomiting is a problem, and where consultation with a palliative care specialist or service has occurred.

NOTE:

No applications for increased repeats will be authorised.

5325G	Tablet 10 mg	50	3	..	14.24	15.27	Phenergan	SW
5326H	Tablet 25 mg	50	3	..	16.33	17.36	Phenergan	SW
5327J	Oral liquid 5 mg per 5 mL, 100 mL	± 1	3	..	14.24	15.27	Phenergan	SW

continued ➞

PREPARATIONS WHICH MAY BE PRESCRIBED FOR PATIENTS RECEIVING PALLIATIVE CARE-cont.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Proprietary Name and Manufacturer	

Authority Required

Continuing supply for palliative care patients where nausea and/or vomiting is a problem.

NOTE:

No applications for repeats will be authorised.

5328K	Tablet 10 mg	50	..	..	14.24	15.27	Phenergan	SW
5329L	Tablet 25 mg	50	..	..	16.33	17.36	Phenergan	SW
5330M	Oral liquid 5 mg per 5 mL, 100 mL	± 1	..	..	14.24	15.27	Phenergan	SW

LAXATIVES

Laxatives

• **Contact laxatives**

BISACODYL

Authority Required

Initial supply (for up to 4 months) for palliative care patients where constipation is a problem;

Continuing supply for palliative care patients where constipation is a problem, and where consultation with a palliative care specialist or service has occurred.

NOTE:

No applications for increased repeats will be authorised.

5301B	Tablet 5 mg	200	3	..	14.17	15.20	Bisalax Lax-Tab	AS AE
5303D	Suppositories 10 mg, 10	3	3	..	* 21.44	22.47	^a Petrus Bisacodyl Suppositories	PP
				B1.14	* 22.58	22.47	^a Dulcolax	BY
5304E	Suppositories 10 mg, 12	3	3	..	* 18.62	19.65	Fleet Laxative Suppositories Petrus Bisacodyl Suppositories	FL PP

Authority Required

Continuing supply for palliative care patients where constipation is a problem.

NOTE:

No applications for repeats will be authorised.

5305F	Tablet 5 mg	200	..	..	14.17	15.20	Bisalax Lax-Tab	AS AE
5307H	Suppositories 10 mg, 10	3	..	..	* 21.44	22.47	^a Petrus Bisacodyl Suppositories	PP
				B1.14	* 22.58	22.47	^a Dulcolax	BY

continued ➡

PREPARATIONS WHICH MAY BE PRESCRIBED FOR PATIENTS RECEIVING PALLIATIVE CARE-cont.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Proprietary Name and Manufacturer	
5308J	Suppositories 10 mg, 12	3	..	..	* 18.62	19.65	Fleet Laxative Suppositories Petrus Bisacodyl Suppositories	FL PP

- **Bulk producers**

STERCULIA with FRANGULA BARK

Authority Required

Initial supply (for up to 4 months) for palliative care patients where constipation is a problem;

Continuing supply for palliative care patients where constipation is a problem, and where consultation with a palliative care specialist or service has occurred.

NOTE:

No applications for increased repeats will be authorised.

5322D	Granules 620 mg-80 mg per g (62%-8%), 500 g	± 1	3	..	24.52	25.55	Normacol Plus	NE

Authority Required

Continuing supply for palliative care patients where constipation is a problem.

NOTE:

No applications for repeats will be authorised.

5324F	Granules 620 mg-80 mg per g (62%-8%), 500 g	± 1	..	..	24.52	25.55	Normacol Plus	NE

- **Osmotically acting laxatives**

LACTULOSE

Authority Required

Initial supply (for up to 4 months) for palliative care patients where constipation is a problem;

Continuing supply for palliative care patients where constipation is a problem, and where consultation with a palliative care specialist or service has occurred.

NOTE:

No applications for increased repeats will be authorised.

5387M	Mixture 3.34 g per 5 mL, 500 mL	± 1	3	..	13.80	14.83	^a Actilax ^a Genlac ^a GenRx Lactulose ^a Lac-Dol ^a Lactocur ^a Duphalac	AF AW GX GM SZ SM
				81.67	15.47	14.83		

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	Maximum	Proprietary Name and Manufacturer
					Price for Max. Qty \$	Recordable Value for Safety Net \$	

Authority Required

Continuing supply for palliative care patients where constipation is a problem.

NOTE:

No applications for repeats will be authorised.

5388N	Mixture 3.34 g per 5 mL, 500 mL	± 1	..	..	13.80	14.83	^a Actilax	AF
							^a Genlac	AW
							^a GenRx Lactulose	GX
							^a Lac-Dol	GM
							^a Lactocur	SZ
				B1.67	15.47	14.83	^a Duphalac	SM

MACROGOL 3350

Authority Required

Initial supply (for up to 4 months) for palliative care patients where constipation is a problem;

Continuing supply for palliative care patients where constipation is a problem, and where consultation with a palliative care specialist or service has occurred.

NOTE:

No applications for increased repeats will be authorised.

5419F	Sachets containing powder for solution 6.563 g with electrolytes, 30	± 1	3	..	18.10	19.13	Movicol-Half	NE
5389P	Sachets containing powder for solution 13.125 g with electrolytes, 30	± 1	3	..	24.36	25.39	Movicol	NE

Authority Required

Continuing supply for palliative care patients where constipation is a problem.

NOTE:

No applications for repeats will be authorised.

5420G	Sachets containing powder for solution 6.563 g with electrolytes, 30	± 1	..	..	18.10	19.13	Movicol-Half	NE
5390Q	Sachets containing powder for solution 13.125 g with electrolytes, 30	± 1	..	..	24.36	25.39	Movicol	NE

PREPARATIONS WHICH MAY BE PRESCRIBED FOR PATIENTS RECEIVING PALLIATIVE CARE-cont.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed	Maximum	Proprietary Name and Manufacturer	
					Price for Max. Qty \$	Recordable Value for Safety Net \$		

• Enemas

BISACODYL

Authority Required

Initial supply (for up to 4 months) for palliative care patients where constipation is a problem;

Continuing supply for palliative care patients where constipation is a problem, and where consultation with a palliative care specialist or service has occurred.

NOTE:

No applications for increased repeats will be authorised.

5302C	Enemas 10 mg in 5 mL, 25	± 1	3	..	39.48	32.90	Bisalax	AS

Authority Required

Continuing supply for palliative care patients where constipation is a problem.

NOTE:

No applications for repeats will be authorised.

5306G	Enemas 10 mg in 5 mL, 25	± 1	..	..	39.48	32.90	Bisalax	AS

SORBITOL with SODIUM CITRATE and SODIUM LAURYL SULFOACETATE

Authority Required

Initial supply (for up to 4 months) for palliative care patients where constipation is a problem;

Continuing supply for palliative care patients where constipation is a problem, and where consultation with a palliative care specialist or service has occurred.

NOTE:

No applications for increased repeats will be authorised.

5331N	Enemas 3.125 g-450 mg-45 mg in 5 mL, 12	2	3	..	* 36.15	32.90	Microlax	JT

Authority Required

Continuing supply for palliative care patients where constipation is a problem.

NOTE:

No applications for repeats will be authorised.

5332P	Enemas 3.125 g-450 mg-45 mg in 5 mL, 12	2	..	..	* 36.15	32.90	Microlax	JT

PREPARATIONS WHICH MAY BE PRESCRIBED FOR PATIENTS RECEIVING PALLIATIVE CARE-cont.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed	Maximum	Proprietary Name and Manufacturer
					Price for Max. Qty \$	Recordable Value for Safety Net \$	

• **Other laxatives**

GLYCEROL

Authority Required

Initial supply (for up to 4 months) for palliative care patients where constipation is a problem;

Continuing supply for palliative care patients where constipation is a problem, and where consultation with a palliative care specialist or service has occurred.

NOTE:

No applications for increased repeats will be authorised.

5311M	Suppositories 700 mg (for infants), 12	3	3	..	* 17.93	18.96	PP
5312N	Suppositories 1.4 g (for children), 12	3	3	..	* 18.35	19.38	PP
5313P	Suppositories 2.8 g (for adults), 12	3	3	..	* 18.80	19.83	PP

Authority Required

Continuing supply for palliative care patients where constipation is a problem.

NOTE:

No applications for repeats will be authorised.

5314Q	Suppositories 700 mg (for infants), 12	3	..	..	* 17.93	18.96	PP
5315R	Suppositories 1.4 g (for children), 12	3	..	..	* 18.35	19.38	PP
5316T	Suppositories 2.8 g (for adults), 12	3	..	..	* 18.80	19.83	PP

**PREPARATIONS WHICH MAY BE PRESCRIBED FOR
PATIENTS RECEIVING PALLIATIVE CARE-cont.**

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Proprietary Name and Manufacturer
MUSCULO-SKELETAL SYSTEM							
ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS							
Antiinflammatory and antirheumatic products, non-steroids							
• Acetic acid derivatives and related substances							
DICLOFENAC SODIUM							
Authority Required							
<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	..	* 12.63	13.66	^a Chem mart CH
							Diclofenac
							^a Clonac 25 AW
							^a Diclofenac-GA GN
							^a Diclohexal SZ
							^a Dinac GM
							^a GenRx Diclofenac GX
							^a Terry White TW
							Chemists
							Diclofenac
				..	12.64	13.67	^a Fenac 25 AF
				B1.96	* 14.59	13.66	^a Voltaren 25 NV
5362F	Tablet 50 mg (enteric coated)	50	3	..	10.62	11.65	^a Chem mart CH
							Diclofenac
							^a Clonac 50 AW
							^a Diclohexal SZ
							^a Dinac GM
							^a Fenac AF
							^a GenRx Diclofenac GX
							^a Terry White TW
							Chemists
							Diclofenac
				B1.96	12.58	11.65	^a Voltaren 50 NV
5363G	Suppository 100 mg	40	3	..	* 24.49	25.52	Voltaren 100 NV

continued ➡

**PREPARATIONS WHICH MAY BE PRESCRIBED FOR
PATIENTS RECEIVING PALLIATIVE CARE-cont.**

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Proprietary Name and Manufacturer	
5364H	Tablet 25 mg (enteric coated)	100	..	..	* 12.63	13.66	^a Chem mart Diclofenac	CH
							^a Clonac 25	AW
							^a Diclofenac-GA	GN
							^a Diclohexal	SZ
							^a Dinac	GM
							^a GenRx Diclofenac	GX
							^a Terry White Chemists Diclofenac	TW
				..	12.64	13.67	^a Fenac 25	AF
				B1.96	* 14.59	13.66	^a Voltaren 25	NV
5365J	Tablet 50 mg (enteric coated)	50	..	..	10.62	11.65	^a Chem mart Diclofenac	CH
							^a Clonac 50	AW
							^a Diclohexal	SZ
							^a Dinac	GM
							^a Fenac	AF
							^a GenRx Diclofenac	GX
							^a Terry White Chemists Diclofenac	TW
				B1.96	12.58	11.65	^a Voltaren 50	NV
5366K	Suppository 100 mg	40	..	..	* 24.49	25.52	Voltaren 100	NV

INDOMETHACIN

Authority Required

Initial supply (for up to 4 months) for palliative care patients where severe pain is a problem;

Continuing supply for palliative care patients where severe pain is a problem, and where consultation with a palliative care specialist or service has occurred.

NOTE:

No applications for increased repeats will be authorised.

5377B	Capsule 25 mg	100	3	..	* 11.65	12.68	^a Arthrexin	AF
				B0.92	* 12.57	12.68	^a Indocid	AS
5378C	Suppository 100 mg	40	3	..	* 22.07	23.10	Indocid	AS

continued ➡

PREPARATIONS WHICH MAY BE PRESCRIBED FOR PATIENTS RECEIVING PALLIATIVE CARE-cont.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Proprietary Name and Manufacturer	

Authority Required

Continuing supply for palliative care patients where severe pain is a problem.

NOTE:

No applications for repeats will be authorised.

5379D	Capsule 25 mg	100	..	..	* 11.65	12.68	^a Arthrexin	AF
				B0.92	* 12.57	12.68	^a Indocid	AS
5380E	Suppository 100 mg	40	..	..	* 22.07	23.10	Indocid	AS

SULINDAC**Authority Required**

Initial supply (for up to 4 months) for palliative care patients where severe pain is a problem;

Continuing supply for palliative care patients where severe pain is a problem, and where consultation with a palliative care specialist or service has occurred.

NOTE:

No applications for increased repeats will be authorised.

5381F	Tablet 100 mg	100	3	..	* 15.91	16.94	Aclin	AF
5382G	Tablet 200 mg	50	3	..	14.85	15.88	Aclin 200	AF

Authority Required

Continuing supply for palliative care patients where severe pain is a problem.

NOTE:

No applications for repeats will be authorised.

5383H	Tablet 100 mg	100	..	..	* 15.91	16.94	Aclin	AF
5384J	Tablet 200 mg	50	..	..	14.85	15.88	Aclin 200	AF

- **Propionic acid derivatives**

IBUPROFEN**Authority Required**

Initial supply (for up to 4 months) for palliative care patients where severe pain is a problem;

Continuing supply for palliative care patients where severe pain is a problem, and where consultation with a palliative care specialist or service has occurred.

NOTE:

No applications for increased repeats will be authorised.

5367L	Tablet 200 mg	100	3	..	* 11.63	12.66	Rafen 200	AF
5368M	Tablet 400 mg	90	3	..	* 14.30	15.33	Brufen	AB

continued ➡

PREPARATIONS WHICH MAY BE PRESCRIBED FOR PATIENTS RECEIVING PALLIATIVE CARE-cont.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Proprietary Name and Manufacturer	

Authority Required

Continuing supply for palliative care patients where severe pain is a problem.

NOTE:

No applications for repeats will be authorised.

5369N	Tablet 200 mg	100	..	..	* 11.63	12.66	Rafen 200	AF
5370P	Tablet 400 mg	90	..	..	* 14.30	15.33	Brufen	AB

NAPROXEN

Authority Required

Initial supply (for up to 4 months) for palliative care patients where severe pain is a problem;

Continuing supply for palliative care patients where severe pain is a problem, and where consultation with a palliative care specialist or service has occurred.

NOTE:

No applications for increased repeats will be authorised.

5345H	Tablet 250 mg	100	3	..	* 13.29	14.32	^a Inza 250	AF
				B2.34	* 15.63	14.32	^a Naprosyn	RO
5346J	Tablet 500 mg	50	3	..	12.48	13.51	^a Inza 500	AF
				B1.36	13.84	13.51	^a Naprosyn	RO
5347K	Tablet 750 mg (sustained release)	28	3	..	11.95	12.98	^a Proxen SR 750	MD
				B1.27	13.22	12.98	^a Naprosyn SR750	RO
5348L	Tablet 1 g (sustained release)	28	3	..	13.94	14.97	^a Proxen SR 1000	MD
				B1.34	15.28	14.97	^a Naprosyn SR1000	RO

Authority Required

Continuing supply for palliative care patients where severe pain is a problem.

NOTE:

No applications for repeats will be authorised.

5349M	Tablet 250 mg	100	..	..	* 13.29	14.32	^a Inza 250	AF
				B2.34	* 15.63	14.32	^a Naprosyn	RO
5350N	Tablet 500 mg	50	..	..	12.48	13.51	^a Inza 500	AF
				B1.36	13.84	13.51	^a Naprosyn	RO
5351P	Tablet 750 mg (sustained release)	28	..	..	11.95	12.98	^a Proxen SR 750	MD
				B1.27	13.22	12.98	^a Naprosyn SR750	RO
5352Q	Tablet 1 g (sustained release)	28	..	..	13.94	14.97	^a Proxen SR 1000	MD
				B1.34	15.28	14.97	^a Naprosyn SR1000	RO

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	Maximum	Proprietary Name and Manufacturer	
					Price for Max. Qty \$	Recordable Value for Safety Net \$		

Authority Required

Initial supply (for up to 4 months) for palliative care patients where severe pain is a problem in patients unable to take a solid dose form of a non-steroidal anti-inflammatory agent;

Continuing supply for palliative care patients where severe pain is a problem, and where consultation with a palliative care specialist or service has occurred, in patients unable to take a solid dose form of a non-steroidal anti-inflammatory agent.

NOTE:

No applications for increased repeats will be authorised.

5397C	Oral suspension 125 mg per 5 mL, 474 mL	± 1	3	..	77.74	32.90	Naprosyn	RO

Authority Required

Continuing supply for palliative care patients where severe pain is a problem in patients unable to take a solid dose form of a non-steroidal anti-inflammatory agent.

NOTE:

No applications for repeats will be authorised.

5398D	Oral suspension 125 mg per 5 mL, 474 mL	± 1	..	..	77.74	32.90	Naprosyn	RO

NAPROXEN SODIUM**Authority Required**

Initial supply (for up to 4 months) for palliative care patients where severe pain is a problem;

Continuing supply for palliative care patients where severe pain is a problem, and where consultation with a palliative care specialist or service has occurred.

NOTE:

No applications for increased repeats will be authorised.

5353R	Tablet 550 mg	50	3	..	12.67	13.70	^a Crysanal	MD
				B2.29	14.96	13.70	^a Anaprox 550	RO

NOTE:

Naproxen sodium 550 mg is approximately equivalent to 500 mg of naproxen acid.

Authority Required

Continuing supply for palliative care patients where severe pain is a problem.

NOTE:

No applications for repeats will be authorised.

5354T	Tablet 550 mg	50	..	..	12.67	13.70	^a Crysanal	MD
				B2.29	14.96	13.70	^a Anaprox 550	RO

NOTE:

Naproxen sodium 550 mg is approximately equivalent to 500 mg of naproxen acid.

PREPARATIONS WHICH MAY BE PRESCRIBED FOR PATIENTS RECEIVING PALLIATIVE CARE-cont.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Proprietary Name and Manufacturer	

NERVOUS SYSTEM

ANALGESICS

Opioids

• Natural opium alkaloids

MORPHINE SULFATE

CAUTION:

The risk of drug dependence is high.

Authority Required

Initial supply (for up to 3 months) for palliative care patients with severe disabling pain not responding to non-narcotic analgesics;

Continuing supply (for up to 3 months) for palliative care patients with severe disabling pain not responding to non-narcotic analgesics, and where consultation with a palliative care specialist or service has occurred.

NOTE:

Telephone approvals are limited to 1 month's therapy.

5393W	Tablet 10 mg	20	2	..	14.85	15.88	Sevredol	MF
5394X	Tablet 20 mg	20	2	..	15.99	17.02	Sevredol	MF

Authority Required

Continuing supply (for up to 1 month) for palliative care patients with severe disabling pain not responding to non-narcotic analgesics.

NOTE:

No applications for repeats will be authorised.

5395Y	Tablet 10 mg	20	..	..	14.85	15.88	Sevredol	MF
5396B	Tablet 20 mg	20	..	..	15.99	17.02	Sevredol	MF

Authority Required

Initial supply (for up to 3 months) for palliative care patients with chronic severe disabling pain not responding to non-narcotic analgesics;

Continuing supply (for up to 3 months) for palliative care patients with chronic severe disabling pain not responding to non-narcotic analgesics, and where consultation with a palliative care specialist or service has occurred.

NOTE:

Telephone approvals are limited to 1 month's therapy.

5391R	Tablet 200 mg (controlled release)	20	2	..	104.50	32.90	MS Contin	MF

continued ➞

PREPARATIONS WHICH MAY BE PRESCRIBED FOR PATIENTS RECEIVING PALLIATIVE CARE-cont.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed	Maximum	Proprietary Name and Manufacturer	
					Price for Max. Qty \$	Recordable Value for Safety Net \$		

Authority Required

Continuing supply (for up to 1 month) for palliative care patients with chronic severe disabling pain not responding to non-narcotic analgesics.

NOTE:

No applications for repeats will be authorised.

5392T	Tablet 200 mg (controlled release)	20	..	..	104.50	32.90	MS Contin	MF

• **Phenylpiperidine derivatives**

FENTANYL

CAUTION:

The risk of drug dependence is high.

Authority Required

Initial supply for dose titration for breakthrough pain in palliative care patients with cancer who are receiving opioids for their persistent pain and where further escalation in the dose of morphine for breakthrough pain results in intolerable adverse effects.

NOTE:

No applications for increased repeats will be authorised.

5401G	Lozenges 200 micrograms (as citrate), 3	3	..	..	* 115.17	32.90	Actiq	OA
5402H	Lozenges 400 micrograms (as citrate), 3	3	..	..	* 115.17	32.90	Actiq	OA
5403J	Lozenges 600 micrograms (as citrate), 3	3	..	..	* 115.17	32.90	Actiq	OA
5404K	Lozenges 800 micrograms (as citrate), 3	3	..	..	* 115.17	32.90	Actiq	OA
5405L	Lozenges 1200 micrograms (as citrate), 3	3	..	..	* 115.17	32.90	Actiq	OA
5406M	Lozenges 1600 micrograms (as citrate), 3	3	..	..	* 115.17	32.90	Actiq	OA

Authority Required

First continuing supply (for up to 3 months) for breakthrough pain in palliative care patients with cancer who are receiving opioids for their persistent pain and where further escalation in the dose of morphine for breakthrough pain results in intolerable adverse effects;

Second and subsequent continuing supply (for up to 3 months) for breakthrough pain in palliative care patients with cancer who are receiving opioids for their persistent pain and where further escalation in the dose of morphine for breakthrough pain results in intolerable adverse effects, where consultation with a palliative care specialist or service has occurred.

NOTE:

No applications for increased repeats will be authorised.

Telephone approvals are limited to 1 month's therapy.

5407N	Lozenges 200 micrograms (as citrate), 3	20	2	..	* 679.70	32.90	Actiq	OA
5408P	Lozenges 400 micrograms (as citrate), 3	20	2	..	* 679.70	32.90	Actiq	OA

continued ➞

**PREPARATIONS WHICH MAY BE PRESCRIBED FOR
PATIENTS RECEIVING PALLIATIVE CARE-cont.**

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Proprietary Name and Manufacturer	
5409Q	Lozenges 600 micrograms (as citrate), 3	20	2	..	* 679.70	32.90	Actiq	OA
5410R	Lozenges 800 micrograms (as citrate), 3	20	2	..	* 679.70	32.90	Actiq	OA
5411T	Lozenges 1200 micrograms (as citrate), 3	20	2	..	* 679.70	32.90	Actiq	OA
5412W	Lozenges 1600 micrograms (as citrate), 3	20	2	..	* 679.70	32.90	Actiq	OA

Authority Required

Second and subsequent continuing supply (for up to 1 month) for breakthrough pain in palliative care patients with cancer who are receiving opioids for their persistent pain and where further escalation in the dose of morphine for breakthrough pain results in intolerable adverse effects.

NOTE:

No applications for increased repeats will be authorised.

5413X	Lozenges 200 micrograms (as citrate), 3	20	..	..	* 679.70	32.90	Actiq	OA
5414Y	Lozenges 400 micrograms (as citrate), 3	20	..	..	* 679.70	32.90	Actiq	OA
5415B	Lozenges 600 micrograms (as citrate), 3	20	..	..	* 679.70	32.90	Actiq	OA
5416C	Lozenges 800 micrograms (as citrate), 3	20	..	..	* 679.70	32.90	Actiq	OA
5417D	Lozenges 1200 micrograms (as citrate), 3	20	..	..	* 679.70	32.90	Actiq	OA
5418E	Lozenges 1600 micrograms (as citrate), 3	20	..	..	* 679.70	32.90	Actiq	OA

• **Diphenylpropylamine derivatives**

METHADONE HYDROCHLORIDE

CAUTION:

The risk of drug dependence is high.

Authority Required

Initial supply (for up to 3 months) for palliative care patients with chronic severe disabling pain not responding to non-narcotic analgesics;

Continuing supply (for up to 3 months) for palliative care patients with chronic severe disabling pain not responding to non-narcotic analgesics, and where consultation with a palliative care specialist or service has occurred.

NOTE:

Telephone approvals are limited to 1 month's therapy.

5399E	Oral liquid 25 mg per 5 mL, 200 mL	1	2	..	17.85	18.88	SI	

continued ➞

**PREPARATIONS WHICH MAY BE PRESCRIBED FOR
PATIENTS RECEIVING PALLIATIVE CARE-cont.**

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed	Maximum	Proprietary Name and Manufacturer
					Price for Max. Qty \$	Recordable Value for Safety Net \$	

Authority Required

Continuing supply (for up to 1 month) for palliative care patients with chronic severe disabling pain not responding to non-narcotic analgesics.

NOTE:

No applications for repeats will be authorised.

5400F	Oral liquid 25 mg per 5 mL, 200 mL	1	..	..	17.85	18.88	SI

Other analgesics and antipyretics

• **Anilides**

PARACETAMOL

Authority Required

Initial supply (for up to 4 months) for palliative care patients for analgesia or fever where alternative therapy cannot be tolerated;

Continuing supply for palliative care patients for analgesia or fever where alternative therapy cannot be tolerated, and where consultation with a palliative care specialist or service has occurred.

NOTE:

No applications for increased repeats will be authorised.

5343F	Tablet 665 mg (modified release)	192	3	..	* 16.21	17.24	Panadol Osteo	GC
5319Y	Suppositories 500 mg, 24	± 1	3	..	26.39	27.42	Panadol	GC

Authority Required

Continuing supply for palliative care patients for analgesia or fever where alternative therapy cannot be tolerated.

NOTE:

No applications for repeats will be authorised.

5344G	Tablet 665 mg (modified release)	192	..	..	* 16.21	17.24	Panadol Osteo	GC
5320B	Suppositories 500 mg, 24	± 1	..	..	26.39	27.42	Panadol	GC

PREPARATIONS WHICH MAY BE PRESCRIBED FOR PATIENTS RECEIVING PALLIATIVE CARE-cont.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed	Maximum		Proprietary Name and Manufacturer
					Price for Max. Qty \$	Recordable Value for Safety Net \$		

ANTIEPILEPTICS

Antiepileptics

• Benzodiazepine derivatives

CLONAZEPAM

Authority Required

Initial supply (for up to 4 months) for palliative care patients for the prevention of epilepsy;

Continuing supply for palliative care patients for the prevention of epilepsy, where consultation with a palliative care specialist or service has occurred.

NOTE:

No applications for increased repeats will be authorised.

5337X	Tablet 500 micrograms	100	3	..	12.88	13.91	^a	Paxam 0.5	AF
				B1.79	14.67	13.91	^a	Rivotril	RO
5338Y	Tablet 2 mg	100	3	..	18.95	19.98	^a	Paxam 2	AF
				B2.04	20.99	19.98	^a	Rivotril	RO
5339B	Oral liquid 2.5 mg per mL, 10 mL	2	3	..	* 14.61	15.64		Rivotril	RO

Authority Required

Continuing supply for palliative care patients for the prevention of epilepsy.

NOTE:

No applications for repeats will be authorised.

5340C	Tablet 500 micrograms	100	..	..	12.88	13.91	^a	Paxam 0.5	AF
				B1.79	14.67	13.91	^a	Rivotril	RO
5341D	Tablet 2 mg	100	..	..	18.95	19.98	^a	Paxam 2	AF
				B2.04	20.99	19.98	^a	Rivotril	RO
5342E	Oral liquid 2.5 mg per mL, 10 mL	2	..	..	* 14.61	15.64		Rivotril	RO

**PREPARATIONS WHICH MAY BE PRESCRIBED FOR
PATIENTS RECEIVING PALLIATIVE CARE-cont.**

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed	Maximum	Proprietary Name and Manufacturer
					Price for Max. Qty \$	Recordable Value for Safety Net \$	

PSYCHOLEPTICS

Anxiolytics

• **Benzodiazepine derivatives**

DIAZEPAM

Authority Required

Initial supply (for up to 4 months) for palliative care patients where anxiety is a problem;

Continuing supply for palliative care patients where anxiety is a problem, and where consultation with a palliative care specialist or service has occurred.

NOTE:

No applications for increased repeats will be authorised.

5355W	Tablet 2 mg	50	3	..	7.36	8.39	^a Antenex 2	AF
							^a Valpam 2	SI
					B0.59	7.95	8.39	Ducene
				B0.86	8.22	8.39	^a Valium	RO
5356X	Tablet 5 mg	50	3	..	7.50	8.53	^a Antenex 5	AF
							^a Diazepam-DP	GM
							^a Ranzepam	RA
							^a Valpam 5	SI
							B0.63	8.13
				B0.88	8.38	8.53	^a Valium	RO

Authority Required

Continuing supply for palliative care patients where anxiety is a problem.

NOTE:

No applications for repeats will be authorised.

5357Y	Tablet 2 mg	50	..	..	7.36	8.39	^a Antenex 2	AF			
							^a Valpam 2	SI			
							B0.59	7.95	8.39	Ducene	SU
							B0.86	8.22	8.39	^a Valium	RO
5358B	Tablet 5 mg	50	..	..	7.50	8.53	^a Antenex 5	AF			
							^a Diazepam-DP	GM			
							^a Ranzepam	RA			
							^a Valpam 5	SI			
							B0.63	8.13	8.53	Ducene	SU
	B0.88	8.38	8.53	^a Valium	RO						

PREPARATIONS WHICH MAY BE PRESCRIBED FOR PATIENTS RECEIVING PALLIATIVE CARE-cont.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed	Maximum		Proprietary Name and Manufacturer
					Price for Max. Qty \$	Recordable Value for Safety Net \$		
OXAZEPAM								
Authority Required								
Initial supply (for up to 4 months) for palliative care patients where anxiety is a problem;								
Continuing supply for palliative care patients where anxiety is a problem, and where consultation with a palliative care specialist or service has occurred.								
NOTE:								
No applications for increased repeats will be authorised.								
5371Q	Tablet 15 mg	50	3	..	* 8.55	9.58	^a	Alepam 15 AF
				B3.56	* 12.11	9.58	^a	Serepax SI
5372R	Tablet 30 mg	50	3	..	* 8.93	9.96	^a	Alepam 30 AF
							^a	Murelax FM
				B3.80	* 12.73	9.96	^a	Serepax SI

Authority Required*Continuing supply for palliative care patients where anxiety is a problem.***NOTE:***No applications for repeats will be authorised.*

5373T	Tablet 15 mg	50	..	..	* 8.55	9.58	^a	Alepam 15 AF
				B3.56	* 12.11	9.58	^a	Serepax SI
5374W	Tablet 30 mg	50	..	..	* 8.93	9.96	^a	Alepam 30 AF
							^a	Murelax FM
				B3.80	* 12.73	9.96	^a	Serepax SI

Hypnotics and sedatives**• Benzodiazepine derivatives****NITRAZEPAM****Authority Required***Initial supply (for up to 4 months) for palliative care patients where insomnia is a problem;**Continuing supply for palliative care patients where insomnia is a problem, and where consultation with a palliative care specialist or service has occurred.***NOTE:***No applications for increased repeats will be authorised.*

5359C	Tablet 5 mg	50	3	..	* 8.93	9.96	^a	Alodorm AF
				B3.06	* 11.99	9.96	^a	Mogadon VT

continued ➡

PREPARATIONS WHICH MAY BE PRESCRIBED FOR PATIENTS RECEIVING PALLIATIVE CARE-cont.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed	Maximum	Proprietary Name and Manufacturer	
					Price for Max. Qty \$	Recordable Value for Safety Net \$		

Authority Required

Continuing supply for palliative care patients where insomnia is a problem.

NOTE:

No applications for repeats will be authorised.

5360D	Tablet 5 mg	50	..	..	* 8.93	9.96	^a Alodorm	AF
					B3.06	* 11.99	^a Mogadon	VT

TEMAZEPAM

Authority Required

Initial supply (for up to 4 months) for palliative care patients where insomnia is a problem;

Continuing supply for palliative care patients where insomnia is a problem, and where consultation with a palliative care specialist or service has occurred.

NOTE:

No applications for increased repeats will be authorised.

5375X	Tablet 10 mg	50	3	..	* 8.93	9.96	^a Temaze	AF
							^a Temtabs	FM
					B2.76	* 11.69	^a Normison	SI

Authority Required

Continuing supply for palliative care patients where insomnia is a problem.

NOTE:

No applications for repeats will be authorised.

5376Y	Tablet 10 mg	50	..	..	* 8.93	9.96	^a Temaze	AF
							^a Temtabs	FM
					B2.76	* 11.69	^a Normison	SI

**PREPARATIONS WHICH MAY BE PRESCRIBED BY PARTICIPATING
DENTAL PRACTITIONERS FOR DENTAL TREATMENT ONLY**

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Proprietary Name and Manufacturer	
ALIMENTARY TRACT AND METABOLISM								
STOMATOLOGICAL PREPARATIONS								
Stomatological preparations								
• Antiinfectives and antiseptics for local oral treatment								
AMPHOTERICIN								
3306B	Lozenge 10 mg	20	..	..	10.91	11.94	Fungilin	BQ
NYSTATIN								
3343Y	Oral suspension 100,000 units per mL, 24 mL	‡ 1	..	..	10.42	11.45	Mycostatin Nilstat	BQ SI
• Other agents for local oral treatment								
BENZYDAMINE HYDROCHLORIDE								
Restricted Benefit								
<i>Radiation induced mucositis.</i>								
5032W	Mouth and throat rinse 22.5 mg per 15 mL, 500 mL	‡ 1	..	..	21.83	22.86	Difflam	IA
DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS								
Belladonna and derivatives, plain								
• Belladonna alkaloids, tertiary amines								
ATROPINE SULFATE								
5022H	Injection 600 micrograms in 1 mL	10	..	..	20.11	21.14	AP	
Propulsives								
• Propulsives								
METOCLOPRAMIDE HYDROCHLORIDE								
5151D	Tablet 10 mg	25	..	.. B3.02	7.77 10.79	8.80 8.80	Pramin Maxolon	AF VT
5153F	Injection 10 mg in 2 mL	10	..	..	12.56	13.59	Maxolon	VT

PREPARATIONS WHICH MAY BE PRESCRIBED BY PARTICIPATING DENTAL PRACTITIONERS FOR DENTAL TREATMENT ONLY—cont.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Proprietary Name and Manufacturer	
ANTIEMETICS AND ANTINAUSEANTS								
Antiemetics and antinauseants								
• Other antiemetics								
PROCHLORPERAZINE								
CAUTION:								
Prochlorperazine may be associated with parkinsonism and tardive dyskinesia and should be used for short-term treatment only.								
5205Y	Tablet containing prochlorperazine maleate 5 mg	25	..	.. B2.50	9.59 12.09	10.62 ^a 10.62 ^a	Stemzine Stemetil	AV SW
5206B	Injection containing prochlorperazine mesylate 12.5 mg in 1 mL	10	..	..	16.39	17.42	Stemetil	SW
5208D	Suppositories containing prochlorperazine equivalent to 25 mg prochlorperazine maleate, 5	‡ 1	..	..	19.50	20.53	Stemetil	SW
PROMETHAZINE HYDROCHLORIDE								
3374N	Injection 50 mg in 2 mL	10	..	..	* 21.89	22.92	HH	
ANTIDIARRHEALS, INTESTINAL ANTIINFLAMMATORY/ ANTIINFECTIVE AGENTS								
Intestinal antiinfectives								
• Antibiotics								
NYSTATIN								
3342X	Tablet 500,000 units	50	..	..	17.55	18.58	Nilstat	SI
3345C	Capsule 500,000 units	50	..	..	17.55	18.58	Nilstat	SI
BLOOD AND BLOOD FORMING ORGANS								
BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS								
I.V. solutions								
• Solutions for parenteral nutrition								
GLUCOSE								
5106R	I.V. infusion 278 mmol (anhydrous) per L (5%), 1 L	5	..	..	* 25.49	26.52	BX	
• Solutions affecting the electrolyte balance								
SODIUM CHLORIDE								
5212H	I.V. infusion 154 mmol per L (0.9%), 1 L	5	..	..	* 25.49	26.52	BX	
5213J	I.V. infusion 513 mmol per L (3%), 1 L	2	..	..	* 17.79	18.82	BX	

**PREPARATIONS WHICH MAY BE PRESCRIBED BY PARTICIPATING
DENTAL PRACTITIONERS FOR DENTAL TREATMENT ONLY—cont.**

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Proprietary Name and Manufacturer
SODIUM CHLORIDE with GLUCOSE							
5214K	I.V. infusion 31 mmol-222 mmol (anhydrous) per L (0.18%-4%), 1 L	5	..	..	* 25.49	26.52	BX
5215L	I.V. infusion 19 mmol-104 mmol (anhydrous) per 500 mL (0.225%-3.75%), 500 mL	5	..	..	* 31.59	32.62	BX
5216M	I.V. infusion 39 mmol-69 mmol (anhydrous) per 500 mL (0.45%-2.5%), 500 mL	5	..	..	* 31.59	32.62	BX

CARDIOVASCULAR SYSTEM

CARDIAC THERAPY

Antiarrhythmics, class I and III

• **Antiarrhythmics, class IB**

LIGNOCAINE HYDROCHLORIDE

5142P	Injection 100 mg in 5 mL	5	..	..	36.90	32.90	PF

Cardiac stimulants excl. cardiac glycosides

• **Adrenergic and dopaminergic agents**

ADRENALINE

5004J	Injection 1 mg in 1 mL (1 in 1,000)	5	..	..	19.91	20.94	AP

Vasodilators used in cardiac diseases

• **Organic nitrates**

GLYCERYL TRINITRATE

5108W	Tablets 600 micrograms, 100	‡ 1	..	..	11.96	12.99	^a Lycinat	FM
				B1.64	13.60	12.99	^a Anginine Stabilised	SI

DERMATOLOGICALS

CORTICOSTEROIDS, DERMATOLOGICAL PREPARATIONS

Corticosteroids, plain

• **Corticosteroids, weak (group I)**

HYDROCORTISONE ACETATE

Restricted Benefit

Treatment of corticosteroid-responsive dermatoses.

5111B	Cream 10 mg per g (1%), 30 g	‡ 1	..	..	8.61	9.64	^a Cortic-DS 1%	FM
				B1.90	10.51	9.64	^a Sigmacort	SI

continued ➡

**PREPARATIONS WHICH MAY BE PRESCRIBED BY PARTICIPATING
DENTAL PRACTITIONERS FOR DENTAL TREATMENT ONLY—cont.**

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Proprietary Name and Manufacturer	
5113D	Cream 10 mg per g (1%), 50 g	‡ 1	..	.. B0.08 B1.91	8.27 8.35 10.18	9.30 9.30 9.30	^a Cortic-DS 1% ^a Cortef ^a Sigmacort	FM DT SI
5112C	Topical ointment 10 mg per g (1%), 30 g	‡ 1	..	.. B1.90	8.61 10.51	9.64 9.64	^a Cortic-DS 1% ^a Sigmacort	FM SI
5114E	Topical ointment 10 mg per g (1%), 50 g	‡ 1	..	.. B1.91	8.27 10.18	9.30 9.30	^a Cortic-DS 1% ^a Sigmacort	FM SI

SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS

CORTICOSTEROIDS FOR SYSTEMIC USE

Corticosteroids for systemic use, plain

• **Glucocorticoids**

**BETAMETHASONE ACETATE with BETAMETHASONE
SODIUM PHOSPHATE**

Restricted Benefit

For local intra-articular or peri-articular infiltration;

Keloid;

Lichen planus hypertrophic.

5034Y	Injection 3 mg-3.9 mg (equivalent to 5.7 mg betamethasone) in 1 mL	5	..	..	25.74	26.77	Celestone Chronodose	SH

HYDROCORTISONE SODIUM SUCCINATE

Restricted Benefit

For use in a hospital.

5118J	Injection equivalent to 100 mg hydrocortisone with 2 mL solvent	6	..	..	* 38.15	32.90	Solu-Cortef	PH
5119K	Injection equivalent to 250 mg hydrocortisone with 2 mL solvent	6	..	..	* 61.61	32.90	Solu-Cortef	PH

METHYLPREDNISOLONE ACETATE

Restricted Benefit

For local intra-articular or peri-articular infiltration.

5148Y	Injection 40 mg in 1 mL	5	..	.. B0.76	24.92 25.68	25.95 25.95	^a Depo-Nisolone ^a Depo-Medrol	KR PH

**PREPARATIONS WHICH MAY BE PRESCRIBED BY PARTICIPATING
DENTAL PRACTITIONERS FOR DENTAL TREATMENT ONLY—cont.**

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Proprietary Name and Manufacturer	
TRIAMCINOLONE ACETONIDE								
<u>Restricted Benefit</u>								
<i>For local intra-articular or peri-articular infiltration;</i>								
<i>Keloid;</i>								
<i>Lichen planus hypertrophic.</i>								
5233K	Injection 10 mg in 1 mL	5	..	..	25.74	26.77	Kenacort-A10	BQ

PANCREATIC HORMONES

Glycogenolytic hormones

• **Glycogenolytic hormones**

GLUCAGON HYDROCHLORIDE

5105Q	Injection set containing 1 mg (1 i.u.) and 1 mL solvent in disposable syringe	1	..	..	45.20	32.90	GlucaGen Hypokit	NO

ANTIINFECTIVES FOR SYSTEMIC USE

ANTIBACTERIALS FOR SYSTEMIC USE

Tetracyclines

• **Tetracyclines**

DOXYCYCLINE

5082L	Tablet 100 mg (as monohydrate)	7	..	..	8.04	9.07	a Chem mart Doxycycline a Doxyhexal a GenRx Doxycycline a Terry White Chemists Doxycycline	CH SZ GX TW
3321T	Tablet 100 mg (as hydrochloride)	7	..	..	8.04	9.07	a Doxsig a Doxy-100 a Doxylin 100	SI GM AF
				B1.19	9.23	9.07	a Vibramycin	PF

NOTE:

Bioequivalence has been demonstrated between doxycycline tablet 100 mg (as hydrochloride) and doxycycline tablet 100 mg (as monohydrate).

3322W	Capsule 100 mg (as hydrochloride)	7	..	..	8.04	9.07	a DBL Doxycycline	FA
				B1.15	9.19	9.07	a Doryx	HH

**PREPARATIONS WHICH MAY BE PRESCRIBED BY PARTICIPATING
DENTAL PRACTITIONERS FOR DENTAL TREATMENT ONLY—cont.**

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Proprietary Name and Manufacturer
Beta-lactam antibacterials, penicillins							
• <i>Penicillins with extended spectrum</i>							
AMOXYCILLIN							
3301R	Capsule 250 mg	20	..	..	8.12	9.15	a Alphamox 250 AF a Amohexal HX a Amoxycillin-DP GM a Amoxycillin RA Ranbaxy a Amoxycillin SZ Sandoz a APO-Amoxycillin TX a Chem mart CH Amoxycillin a Cilamox SI a GenRx GX Amoxycillin a Terry White TW Chemists Amoxycillin
				b0.79	8.91	9.15	a Amoxil GK
3300Q	Capsule 500 mg	20	..	..	10.22	11.25	a Alphamox 500 AF a Amohexal HX a Amoxycillin-DP GM a Amoxycillin RA Ranbaxy a Amoxycillin SZ Sandoz a APO-Amoxycillin TX a Chem mart CH Amoxycillin a Cilamox SI a GenRx GX Amoxycillin a Moxacin AS a Terry White TW Chemists Amoxycillin
				b0.80	11.02	11.25	a Amoxil GK
3309E	Sachet containing oral powder 3 g	1	..	..	8.68	9.71	Amoxil GK

continued 

**PREPARATIONS WHICH MAY BE PRESCRIBED BY PARTICIPATING
DENTAL PRACTITIONERS FOR DENTAL TREATMENT ONLY—cont.**

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Proprietary Name and Manufacturer	
3302T	Powder for syrup 125 mg per 5 mL, 100 mL	‡ 1	..	..	# 10.45	11.84	a Alphamox 125 a Amoxycillin Sandoz a Bgramin a Chem mart Amoxycillin a GenRx Amoxycillin a Ranmoxy a Terry White Chemists Amoxycillin	AF SZ GM CH GX RA TW GK
				‡0.95	# 11.40	11.84	a Amoxil	GK
3393N	Powder for syrup 250 mg per 5 mL, 100 mL	‡ 1	..	..	# 11.29	12.68	a Alphamox 250 a Amohexal a Amoxycillin Sandoz a Bgramin a Chem mart Amoxycillin a Cilamox a GenRx Amoxycillin a Ranmoxy a Terry White Chemists Amoxycillin	AF HX SZ GM CH SI GX RA TW GK
				‡0.79	# 12.08	12.68	a Amoxil Forte	GK
5225B	Powder for oral suspension 500 mg per 5 mL, 100 mL	‡ 1	..	..	# 14.30	15.69	Maxamox	SZ
	AMPICILLIN							
3313J	Powder for injection 500 mg	5	..	..	10.65	11.68	a Austrapen a Ibimicyn	LN GM
3314K	Powder for injection 1 g	5	..	..	13.64	14.67	a Aspen Ampicyn a Austrapen a Ibimicyn	AS LN GM
• Beta-lactamase sensitive penicillins								
	BENZATHINE BENZYL PENICILLIN							
5027N	Injection 900 mg in 2.3 mL single use pre-filled syringe	10	..	..	292.68	32.90	Bicillin L-A	AS

**PREPARATIONS WHICH MAY BE PRESCRIBED BY PARTICIPATING
DENTAL PRACTITIONERS FOR DENTAL TREATMENT ONLY—cont.**

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Proprietary Name and Manufacturer	
BENZYL PENICILLIN								
3398W	Powder for injection 600 mg	10	..	..	* 42.49	32.90	BenPen	CS
3399X	Powder for injection 3 g	10	..	..	* 66.49	32.90	BenPen	CS
PHENOXYMETHYL PENICILLIN								
3360W	Tablet 250 mg	50	..	..	* 11.15	12.18	Abbocillin-VK Filmtab	SI
3361X	Tablet 500 mg	50	..	..	* 13.63	14.66	Abbocillin-VK Filmtab	SI
3363B	Capsule 250 mg	50	..	..	10.98	12.01	LPV	AS
					10.98	12.01	^a Cilicaine VK	FM
3364C	Capsule 500 mg	50	..	..	13.41	14.44	^a Cilopen VK	GM
					13.41	14.44	^a Cilopen VK	GM
5012T	Oral suspension 150 mg (as benzathine) per 5 mL, 100 mL	2	..	..	* 21.97	23.00	Abbocillin-V Cilicaine V	SI FM
PROCAINE PENICILLIN								
3371K	Injection 1.5 g	5	..	..	91.79	32.90	Cilicaine	SI
• <i>Beta-lactamase resistant penicillins</i>								
<i>DICLOXACILLIN</i>								
<u>Restricted Benefit</u>								
<i>Serious staphylococcal infections.</i>								
5096F	Capsule 250 mg	24	..	..	11.02	12.05	^a Diclocil ^a Dicloxsig ^a Distaph 250	BQ SI AF
5097G	Capsule 500 mg	24	..	..	16.51	17.54	^a Diclocil ^a Dicloxsig ^a Distaph 500	BQ SI AF
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	..	..	15.06	16.09	^a Flubiclox ^a Flucil	GM AS

continued ➡

**PREPARATIONS WHICH MAY BE PRESCRIBED BY PARTICIPATING
DENTAL PRACTITIONERS FOR DENTAL TREATMENT ONLY—cont.**

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Proprietary Name and Manufacturer	
5095E	Powder for injection 1 g	5	..	..	20.23	21.26	a Flubiclox a Flucil a HH	GM AS

FLUCLOXACILLIN

CAUTION:

Severe cholestatic hepatitis has been reported with this drug. Significant risk factors are age, particularly greater than 55 years, and duration of treatment longer than 14 days.

Restricted Benefit

Serious staphylococcal infections.

5090X	Capsule 250 mg (as sodium)	24	..	..	11.02	12.05	a Flopen a Staphylex 250	AS AF
5091Y	Capsule 500 mg (as sodium)	24	..	..	16.51	17.54	a Flopen a Staphylex 500	AS AF
5257Q	Powder for oral liquid 125 mg (as sodium) per 5 mL, 100 mL	‡ 1	..	..	# 15.97	17.36	LN	
5258R	Powder for oral liquid 250 mg (as sodium) per 5 mL, 100 mL	‡ 1	..	..	# 19.68	21.07	LN	

• **Combinations of penicillins, incl. beta-lactamase inhibitors**

AMOXYCILLIN with CLAVULANIC ACID

CAUTION:

Hepatotoxicity has been reported with this drug.

Restricted Benefit

Infections where resistance to amoxycillin is suspected;

Infections where resistance to amoxycillin is proven.

5008N	Tablet 500 mg-125 mg	10	..	..	11.73	12.76	a Clamoxyl Duo a Curam 500/125 a GA-Amclav 500/125 a Moxiclav Duo 500/125	AL SZ GM AW
				B1.55	13.28	12.76	a Augmentin Duo	GK

continued ➡

**PREPARATIONS WHICH MAY BE PRESCRIBED BY PARTICIPATING
DENTAL PRACTITIONERS FOR DENTAL TREATMENT ONLY—cont.**

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Proprietary Name and Manufacturer	
5006L	Tablet 875 mg-125 mg	10	..	..	14.17	15.20	^a Chem mart Amoxycillin and Clavulanic Acid	CH
							^a Clamoxyl Duo forte	AL
							^a Clavycillin 875/125	CR
							^a Curam 875/125	SZ
							^a GA-Amclav Forte 875/125	GM
							^a GenRx Amoxycillin and Clavulanic Acid	GX
							^a Moxiclav Duo Forte 875/125	AW
							^a Terry White Chemists Amoxycillin and Clavulanic Acid	TW
				B2.04	16.21	15.20	^a Augmentin Duo forte	GK
5009P	Powder for syrup 125 mg-31.25 mg per 5 mL, 75 mL	‡ 1	..	..	# 12.08	13.47	^a Clamoxyl	AL
				B1.51	# 13.59	13.47	^a Augmentin	GK
5011R	Powder for syrup 400 mg-57 mg per 5 mL, 60 mL	‡ 1	..	..	# 13.59	14.98	^a Clamoxyl Duo 400	AL
				B1.54	# 15.13	14.98	^a Augmentin Duo 400	GK

TICARCILLIN with CLAVULANIC ACID

Restricted Benefit

Infections where positive bacteriological evidence confirms that this antibiotic is an appropriate therapeutic agent.

5230G	Powder for injection 3 g-100 mg (solvent required) (code 7043Q applies to above item with approved solvent)	10	..	..	162.89	32.90	Timentin	GK

Other beta-lactam antibacterials

• ***First-generation cephalosporins***

CEFALOTIN

3376Q	Powder for injection 1 g	10	..	..	40.35	32.90	^a Cefalotin Sandoz ^a Keflin Neutral ^a HH	SZ 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	
CEPHALEXIN								
3317N	Capsule 250 mg	20	..	..	8.42	9.45	a Cefalexin Sandoz	SZ
							a Cephabell	BF
							a Cephalixin Max	XF
							a Cephatrust 250	MI
							a Chem mart	CH
							Cephalixin	
							a Cilex	GM
							a GenRx Cephalixin	GX
							a Ialex	LN
							a Ibilex 250	AF
							a Rancef	RA
							a Sporahexal	HX
							a Terry White	TW
							Chemists	
							Cephalixin	
				B3.30	11.72	9.45	a Keflex	AS
3318P	Capsule 500 mg	20	..	..	10.34	11.37	a Cefalexin Sandoz	SZ
							a Cephabell	BF
							a Cephalixin Max	XF
							a Cephatrust 500	MI
							a Chem mart	CH
							Cephalixin	
							a Cilex	GM
							a GenRx Cephalixin	GX
							a Ialex	LN
							a Ibilex 500	AF
							a Rancef	RA
							a Sporahexal	HX
							a Terry White	TW
							Chemists	
							Cephalixin	
				B4.41	14.75	11.37	a Keflex	AS
3319Q	Granules for syrup 125 mg per 5 mL, 100 mL	‡ 1	..	..	# 11.44	12.83	a Cefalexin Sandoz	SZ
							a Chem mart	CH
							Cephalixin	
							a Cilex	GM
							a GenRx Cephalixin	GX
							a Ialex	LN
							a Ibilex 125	AF
							a Terry White	TW
							Chemists	
							Cephalixin	
				B3.55	# 14.99	12.83	a Keflex	AS

continued ➡

**PREPARATIONS WHICH MAY BE PRESCRIBED BY PARTICIPATING
DENTAL PRACTITIONERS FOR DENTAL TREATMENT ONLY—cont.**

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Proprietary Name and Manufacturer	
3320R	Granules for syrup 250 mg per 5 mL, 100 mL	‡ 1	..	..	# 12.84	14.23	a Cefalexin Sandoz	SZ
							a Chem mart	CH
							Cephalexin	
							a Cilex	GM
							a GenRx Cephalexin	GX
							a Ialex	LN
							a Ibilex 250	AF
							a Terry White	TW
							Chemists	
							Cephalexin	
				B4.38	# 17.22	14.23	a Keflex	AS
• Second-generation cephalosporins								
CEFACLOR								
CAUTION:								
Serum sickness-like reactions have been reported with this drug, especially in children.								
5045M	Tablet 375 mg (sustained release)	10	..	..	12.46	13.49	a Cefaclor-GA	GN
							a Chem mart	CH
							Cefaclor CD	
							a Douglas Cefaclor-	GM
							CD	
							a GenRx Cefaclor	GX
							CD	
							a Karlor CD	LN
							a Keflor CD	AF
							a Ozcef	RA
							a Terry White	TW
							Chemists	
							Cefaclor CD	
				B5.20	17.66	13.49	a Ceclor CD	AS
5046N	Powder for oral suspension 125 mg per 5 mL, 100 mL	‡ 1	..	..	# 13.10	14.49	a Aclor 125	AW
							a Cefaclor Sandoz	SZ
							a Chem mart	CH
							Cefaclor	
							a GenRx Cefaclor	GX
							a Keflor	AF
							a Ozcef	RA
							a Terry White	TW
							Chemists	
							Cefaclor	
				B4.18	# 17.28	14.49	a Ceclor	AS

continued ➡

**PREPARATIONS WHICH MAY BE PRESCRIBED BY PARTICIPATING
DENTAL PRACTITIONERS FOR DENTAL TREATMENT ONLY—cont.**

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Proprietary Name and Manufacturer	
5047P	Powder for oral suspension 250 mg per 5 mL, 75 mL	‡ 1	..	..	# 13.43	14.82	^a Aclor 250 ^a Cefaclor Sandoz ^a Chem mart Cefaclor ^a GenRx Cefaclor ^a Keflor ^a Ozcef ^a Terry White Chemists Cefaclor	AW SZ CH GX AF RA TW AS
				B4.37	# 17.80	14.82	^a Ceclor	
	CEFUROXIME AXETIL							
5052X	Tablet 250 mg (base)	14	..	..	18.19	19.22	Zinnat	GK
• Third-generation cephalosporins								
CEFOTAXIME								
<u>Restricted Benefit</u>								
<i>Infections where positive bacteriological evidence confirms that this antibiotic is an appropriate therapeutic agent.</i>								
5048Q	Powder for injection 1 g	10	..	..	27.27	28.30	^a HH	
				B25.10	* 52.39	28.32	^a Cefotaxime Sandoz	SZ
5049R	Powder for injection 2 g	10	..	..	44.60	32.90	^a HH	
				B46.50	* 91.09	32.90	^a Cefotaxime Sandoz	SZ
Sulfonamides and trimethoprim								
• Combinations of sulfonamides and trimethoprim, incl. derivatives								
TRIMETHOPRIM with SULFAMETHOXAZOLE								
<u>CAUTION:</u>								
There is an increased risk of severe adverse reactions with this combination in the elderly.								
3389J	Tablet 80 mg-400 mg	10	..	..	8.24	9.27	Resprim	AF
3390K	Tablet 160 mg-800 mg	10	..	..	8.96	9.99	^a Bactrim DS ^a Resprim Forte	RO AF
				B1.10	10.06	9.99	^a Septrin Forte	SI
3391L	Oral suspension 40 mg-200 mg per 5 mL, 100 mL	‡ 1	..	..	8.62	9.65	Bactrim Septrin	RO SI
				B1.46	10.08	9.65		
Macrolides, lincosamides and streptogramins								
• Macrolides								
ERYTHROMYCIN								
3325B	Capsule 250 mg	25	..	..	9.00	10.03	^a DBL Erythromycin	FA
				B1.35	10.35	10.03	^a Eryc	HH

**PREPARATIONS WHICH MAY BE PRESCRIBED BY PARTICIPATING
DENTAL PRACTITIONERS FOR DENTAL TREATMENT ONLY—cont.**

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Proprietary Name and Manufacturer	
5157K	Suppositories 500 mg, 10	‡ 1	..	..	22.73	23.76	Flagyl	SW
METRONIDAZOLE								
<u>Restricted Benefit</u>								
<i>Treatment of anaerobic infections.</i>								
5155H	Tablet 400 mg	21	..	..	9.60	10.63	^a <i>Metrogyl 400</i>	AF
							^a <i>Metronide 400</i>	AV
				B2.30	11.90	10.63	^a <i>Flagyl</i>	SW
<u>Restricted Benefit</u>								
<i>Treatment, in a hospital, of acute anaerobic sepsis.</i>								
5154G	I.V. infusion 500 mg in 100 mL	5	..	..	* 31.54	32.57	^a <i>BX</i>	
				..	* 31.54	32.57	^a <i>DBL</i>	HH
							<i>Metronidazole</i>	
							<i>Intravenous</i>	
							<i>Infusion</i>	
							^a <i>Metronidazole</i>	SZ
							<i>Sandoz</i>	
 METRONIDAZOLE BENZOATE								
3341W	Oral suspension 320 mg per 5 mL (equivalent to 200 mg metronidazole in 5 mL), 100 mL	‡ 1	..	..	16.74	17.77	Flagyl S	SW

MUSCULO-SKELETAL SYSTEM

ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS

Antiinflammatory and antirheumatic products, non-steroids

• Acetic acid derivatives and related substances

DICLOFENAC SODIUM

5079H	Suppository 100 mg	40	..	..	* 24.49	25.52	Voltaren 100	NV

continued ➞

**PREPARATIONS WHICH MAY BE PRESCRIBED BY PARTICIPATING
DENTAL PRACTITIONERS FOR DENTAL TREATMENT ONLY—cont.**

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Proprietary Name and Manufacturer	
DICLOFENAC SODIUM								
<u>Restricted Benefit</u>								
<i>Chronic arthropathies (including osteoarthritis) with an inflammatory component;</i>								
<i>Bone pain due to malignant disease.</i>								
5076E	Tablet 25 mg (enteric coated)	100	..	..	* 12.63	13.66	^a Chem mart Diclofenac	CH
							^a Clonac 25	AW
							^a Diclofenac-GA	GN
							^a Diclohexal	SZ
							^a Dinac	GM
							^a GenRx Diclofenac	GX
							^a Terry White Chemists Diclofenac	TW
				..	12.64	13.67	^a Fenac 25	AF
				B1.96	* 14.59	13.66	^a Voltaren 25	NV
5077F	Tablet 50 mg (enteric coated)	50	..	..	10.62	11.65	^a Chem mart Diclofenac	CH
							^a Clonac 50	AW
							^a Diclohexal	SZ
							^a Dinac	GM
							^a Fenac	AF
							^a GenRx Diclofenac	GX
							^a Terry White Chemists Diclofenac	TW
				B1.96	12.58	11.65	^a Voltaren 50	NV
INDOMETHACIN								
5128X	Suppository 100 mg	40	..	..	* 22.07	23.10	Indocid	AS
INDOMETHACIN								
<u>Restricted Benefit</u>								
<i>Chronic arthropathies (including osteoarthritis) with an inflammatory component;</i>								
<i>Bone pain due to malignant disease.</i>								
5126T	Capsule 25 mg	100	..	..	* 11.65	12.68	^a Arthrexin	AF
				B0.92	* 12.57	12.68	^a Indocid	AS

**PREPARATIONS WHICH MAY BE PRESCRIBED BY PARTICIPATING
DENTAL PRACTITIONERS FOR DENTAL TREATMENT ONLY—cont.**

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Proprietary Name and Manufacturer	
SULINDAC								
<u>Restricted Benefit</u>								
<i>Chronic arthropathies (including osteoarthritis) with an inflammatory component;</i>								
<i>Bone pain due to malignant disease.</i>								
5217N	Tablet 100 mg	100	..	..	* 15.91	16.94	Aclin	AF
5218P	Tablet 200 mg	50	..	..	14.85	15.88	Aclin 200	AF
• Oxicams								
PIROXICAM								
<u>Restricted Benefit</u>								
<i>Chronic arthropathies (including osteoarthritis) with an inflammatory component.</i>								
5201R	Dispersible tablet 10 mg	50	..	..	12.07	13.10	Mobilis D-10	AF
5202T	Dispersible tablet 20 mg	25	..	..	11.77	12.80	^a Mobilis D-20	AF
				b2.64	14.41	12.80	^a Feldene-D	PF
5203W	Capsule 10 mg	50	..	..	12.07	13.10	^a Chem mart Piroxicam	CH
							^a GenRx Piroxicam	GX
							^a Mobilis 10	AF
							^a Terry White Chemists Piroxicam	TW
				b2.66	14.73	13.10	^a Feldene	PF
5204X	Capsule 20 mg	25	..	..	11.77	12.80	^a Chem mart Piroxicam	CH
							^a GenRx Piroxicam	GX
							^a Mobilis 20	AF
							^a Terry White Chemists Piroxicam	TW
				b2.64	14.41	12.80	^a Feldene	PF
• Propionic acid derivatives								
IBUPROFEN								
5124Q	Tablet 400 mg	30	..	..	8.76	9.79	Brufen	AB

continued ➞

**PREPARATIONS WHICH MAY BE PRESCRIBED BY PARTICIPATING
DENTAL PRACTITIONERS FOR DENTAL TREATMENT ONLY—cont.**

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Proprietary Name and Manufacturer	
IBUPROFEN								
<u>Restricted Benefit</u>								
<i>Chronic arthropathies (including osteoarthritis) with an inflammatory component;</i>								
<i>Bone pain due to malignant disease.</i>								
5121M	Tablet 200 mg	100	..	..	* 11.63	12.66	Rafen 200	AF
5123P	Tablet 400 mg	90	..	..	* 14.30	15.33	Brufen	AB
KETOPROFEN								
5139L	Suppository 100 mg	40	..	..	* 24.87	25.90	Orudis	SW
KETOPROFEN								
<u>Restricted Benefit</u>								
<i>Chronic arthropathies (including osteoarthritis) with an inflammatory component.</i>								
5136H	Capsule 200 mg (sustained release)	28	..	..	19.47	20.50	^a Oruvail SR	AV
				b2.30	21.77	20.50	^a Orudis SR 200	SW
NAPROXEN								
<u>Restricted Benefit</u>								
<i>Chronic arthropathies (including osteoarthritis) with an inflammatory component;</i>								
<i>Bone pain due to malignant disease.</i>								
5176K	Tablet 250 mg	100	..	..	* 13.29	14.32	^a Inza 250	AF
				b2.34	* 15.63	14.32	^a Naprosyn	RO
5177L	Tablet 500 mg	50	..	..	12.48	13.51	^a Inza 500	AF
				b1.36	13.84	13.51	^a Naprosyn	RO
5178M	Tablet 750 mg (sustained release)	28	..	..	11.95	12.98	^a Proxen SR 750	MD
				b1.27	13.22	12.98	^a Naprosyn SR750	RO
5179N	Tablet 1 g (sustained release)	28	..	..	13.94	14.97	^a Proxen SR 1000	MD
				b1.34	15.28	14.97	^a Naprosyn SR1000	RO
NAPROXEN SODIUM								
<u>Restricted Benefit</u>								
<i>Chronic arthropathies (including osteoarthritis) with an inflammatory component;</i>								
<i>Bone pain due to malignant disease.</i>								
5186Y	Tablet 550 mg	50	..	..	12.67	13.70	^a Crysanal	MD
				b2.29	14.96	13.70	^a Anaprox 550	RO

NOTE:

Naproxen sodium 550 mg is approximately equivalent to 500 mg of naproxen acid.

PREPARATIONS WHICH MAY BE PRESCRIBED BY PARTICIPATING DENTAL PRACTITIONERS FOR DENTAL TREATMENT ONLY—cont.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Proprietary Name and Manufacturer

NERVOUS SYSTEM

ANALGESICS

Opioids

• *Natural opium alkaloids*

CODEINE PHOSPHATE

5063L	Tablet 30 mg	20	..	..	16.44	17.47	FM

NOTE:

Prescribing of drugs of addiction by dentists is not permitted in some States/Territories.

CODEINE PHOSPHATE with PARACETAMOL

3316M	Tablet 30 mg-500 mg	20	..	..	7.65	8.68	a Codalgin Forte	FM
							a Codapane Forte	AL
							a Comfarol Forte	SZ
							a Dolaforte	CO
							a Prodeine Forte	AV
				82.80	10.45	8.68	a Panadeine Forte	SW

HYDROMORPHONE HYDROCHLORIDE

CAUTION:

The risk of drug dependence is high.

5129Y	Injection 2 mg in 1 mL	5	..	..	13.51	14.54	Dilaudid	MF
5130B	Injection 10 mg in 1 mL	5	..	..	18.87	19.90	Dilaudid-HP	MF
5131C	Injection 50 mg in 5 mL	5	..	..	47.07	32.90	Dilaudid-HP	MF

NOTE:

Prescribing of drugs of addiction by dentists is not permitted in some States/Territories.

HYDROMORPHONE HYDROCHLORIDE

CAUTION:

The risk of drug dependence is high.

Restricted Benefit

Severe disabling pain not responding to non-narcotic analgesics.

5115F	Tablet 2 mg	20	..	..	13.79	14.82	Dilaudid	MF
5116G	Tablet 4 mg	20	..	..	18.85	19.88	Dilaudid	MF
5117H	Tablet 8 mg	20	..	..	28.61	29.64	Dilaudid	MF
5132D	Oral liquid 1 mg per mL, 473 mL	1	..	..	49.09	32.90	Dilaudid	MF

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	

NOTE:

Prescribing of drugs of addiction by dentists is not permitted in some States/Territories.

Restricted Benefit

Chronic severe disabling pain not responding to non-narcotic analgesics.

3357Q	Tablet 8 mg (modified release)	10	..	..	28.18	29.21	Jurnista	JC
3358R	Tablet 16 mg (modified release)	10	..	..	40.89	32.90	Jurnista	JC
3367F	Tablet 32 mg (modified release)	10	..	..	65.54	32.90	Jurnista	JC
3368G	Tablet 64 mg (modified release)	10	..	..	108.88	32.90	Jurnista	JC

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	..	..	18.73	19.76	Ordine 2	MF
5238Q	Oral solution 5 mg per mL, 200 mL	1	..	..	21.64	22.67	Ordine 5	MF
5239R	Oral solution 10 mg per mL, 200 mL	1	..	..	26.24	27.27	Ordine 10	MF

NOTE:

Prescribing of drugs of addiction by dentists is not permitted in some States/Territories.

MORPHINE SULFATE**CAUTION:**

The risk of drug dependence is high.

5168B	Injection 10 mg in 1 mL	5	..	..	13.77	14.80	HH	
5169C	Injection 15 mg in 1 mL	5	..	..	14.13	15.16	HH	
5170D	Injection 30 mg in 1 mL	5	..	..	15.61	16.64	HH	

NOTE:

Prescribing of drugs of addiction by dentists is not permitted in some States/Territories.

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	
MORPHINE SULFATE								
CAUTION:								
<i>The risk of drug dependence is high.</i>								
Restricted Benefit								
<i>Severe disabling pain not responding to non-narcotic analgesics.</i>								
5163R	Tablet 30 mg	20	..	..	14.53	15.56	Anamorph	FM
NOTE:								
<i>Prescribing of drugs of addiction by dentists is not permitted in some States/Territories.</i>								
Restricted Benefit								
<i>Chronic severe disabling pain not responding to non-narcotic analgesics.</i>								
5162Q	Tablet 5 mg (controlled release)	20	..	..	15.89	16.92	MS Contin	MF
5164T	Tablet 10 mg (controlled release)	20	..	..	17.97	19.00	MS Contin	MF
5161P	Tablet 15 mg (controlled release)	20	..	..	21.52	22.55	MS Contin	MF
5165W	Tablet 30 mg (controlled release)	20	..	..	31.44	32.47	MS Contin	MF
5166X	Tablet 60 mg (controlled release)	20	..	..	47.92	32.90	MS Contin	MF
5167Y	Tablet 100 mg (controlled release)	20	..	..	62.58	32.90	MS Contin	MF
5246D	Capsule 10 mg (containing sustained release pellets)	20	..	..	17.97	19.00	Kapanol	GK
5240T	Capsule 20 mg (containing sustained release pellets)	20	..	..	22.20	23.23	Kapanol	GK
5064M	Capsule 30 mg (controlled release)	10	..	..	21.52	22.55	MS Mono	MF
5241W	Capsule 50 mg (containing sustained release pellets)	20	..	..	37.75	32.90	Kapanol	GK
5065N	Capsule 60 mg (controlled release)	10	..	..	31.44	32.47	MS Mono	MF
5066P	Capsule 90 mg (controlled release)	10	..	..	36.15	32.90	MS Mono	MF
5242X	Capsule 100 mg (containing sustained release pellets)	20	..	..	60.83	32.90	Kapanol	GK
5067Q	Capsule 120 mg (controlled release)	10	..	..	47.92	32.90	MS Mono	MF
5171E	Sachet containing controlled release granules for oral suspension, 20 mg per sachet	20	..	..	48.36	32.90	MS Contin Suspension 20 mg	MF
5243Y	Sachet containing controlled release granules for oral suspension, 30 mg per sachet	20	..	..	49.60	32.90	MS Contin Suspension 30 mg	MF

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	
5244B	Sachet containing controlled release granules for oral suspension, 60 mg per sachet	20	..	..	54.95	32.90	MS Contin Suspension 60 mg	MF
5245C	Sachet containing controlled release granules for oral suspension, 100 mg per sachet	20	..	..	67.09	32.90	MS Contin Suspension 100 mg	MF

NOTE:

Prescribing of drugs of addiction by dentists is not permitted in some States/Territories.

OXYCODONE**CAUTION:**

The risk of drug dependence is high.

Restricted Benefit

Severe disabling pain not responding to non-narcotic analgesics.

5194J	Suppository 30 mg	12	..	..	43.23	32.90	Proladone	PL

NOTE:

Prescribing of drugs of addiction by dentists is not permitted in some States/Territories.

OXYCODONE HYDROCHLORIDE**CAUTION:**

The risk of drug dependence is high.

Restricted Benefit

Severe disabling pain not responding to non-narcotic analgesics.

5195K	Tablet 5 mg	20	..	..	11.87	12.90	Endone	SI
5191F	Capsule 5 mg	20	..	..	11.87	12.90	OxyNorm	MF
5197M	Capsule 10 mg	20	..	..	14.99	16.02	OxyNorm	MF
5198N	Capsule 20 mg	20	..	..	19.72	20.75	OxyNorm	MF
5190E	Oral solution 5 mg per 5 mL, 250 mL	1	..	..	20.29	21.32	OxyNorm Liquid 5mg/5mL	MF

NOTE:

Prescribing of drugs of addiction by dentists is not permitted in some States/Territories.

Restricted Benefit

Chronic severe disabling pain not responding to non-narcotic analgesics.

5227D	Tablet 5 mg (controlled release)	20	..	..	20.75	21.78	OxyContin	MF
5247E	Tablet 10 mg (controlled release)	20	..	..	21.52	22.55	OxyContin	MF
5015Y	Tablet 15 mg (controlled release)	20	..	..	27.50	28.53	OxyContin	MF
5248F	Tablet 20 mg (controlled release)	20	..	..	31.44	32.47	OxyContin	MF

continued ➡

**PREPARATIONS WHICH MAY BE PRESCRIBED BY PARTICIPATING
DENTAL PRACTITIONERS FOR DENTAL TREATMENT ONLY—cont.**

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Proprietary Name and Manufacturer	
5016B	Tablet 30 mg (controlled release)	20	..	..	40.79	32.90	OxyContin	MF
5249G	Tablet 40 mg (controlled release)	20	..	..	47.92	32.90	OxyContin	MF
5250H	Tablet 80 mg (controlled release)	20	..	..	71.27	32.90	OxyContin	MF

NOTE:

Prescribing of drugs of addiction by dentists is not permitted in some States/Territories.

• **Other opioids**

TRAMADOL HYDROCHLORIDE

Restricted Benefit

For acute pain where aspirin and/or paracetamol alone are inappropriate or have failed;

For dosage titration in chronic pain where aspirin and/or paracetamol alone are inappropriate or have failed.

5232J	Capsule 50 mg	20	..	..	8.73	9.76	^a Chem mart Tramadol	CH
							^a GenRx Tramadol	GX
							^a Terry White Chemists Tramadol	TW
							^a Tramedo	AF
							^a Zydol	AW
				B2.42	11.15	9.76	^a Tramal	CS

Restricted Benefit

For pain where aspirin and/or paracetamol alone are inappropriate or have failed.

3338Q	Tablet 50 mg (twice daily sustained release)	20	..	..	11.20	12.23	Tramal SR 50	CS
5234L	Tablet 100 mg (twice daily sustained release)	20	..	..	13.43	14.46	^a Tramahexal SR	SZ
							^a Tramedo SR 100	AF
				B4.51	17.94	14.46	^a Zydol SR 100	AW
							^a Tramal SR 100	CS
5001F	Tablet 100 mg (once a day extended release)	10	..	..	12.94	13.97	Durotram XR	IA
5235M	Tablet 150 mg (twice daily sustained release)	20	..	..	16.02	17.05	^a Tramahexal SR	SZ
							^a Tramedo SR 150	AF
							^a Zydol SR 150	AW
				B5.37	21.39	17.05	^a Tramal SR 150	CS
5236N	Tablet 200 mg (twice daily sustained release)	20	..	..	18.20	19.23	^a Tramahexal SR	SZ
							^a Tramedo SR 200	AF
							^a Zydol SR 200	AW
				B6.09	24.29	19.23	^a Tramal SR 200	CS

continued ➡

**PREPARATIONS WHICH MAY BE PRESCRIBED BY PARTICIPATING
DENTAL PRACTITIONERS FOR DENTAL TREATMENT ONLY—cont.**

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Proprietary Name and Manufacturer	
5002G	Tablet 200 mg (once a day extended release)	10	..	..	15.91	16.94	Durotram XR	IA
5003H	Tablet 300 mg (once a day extended release)	10	..	..	19.36	20.39	Durotram XR	IA
5150C	Oral drops 100 mg per mL, 10 mL	‡ 1	..	..	13.28	14.31	Tramal	CS
<u>Restricted Benefit</u>								
<i>Short-term treatment of acute pain.</i>								
5231H	Injection 100 mg in 2 mL	5	..	..	13.87	14.90	Tramal 100	CS
Other analgesics and antipyretics								
• Salicylic acid and derivatives								
ASPIRIN								
5018D	Tablet 300 mg (dispersible)	96	..	..	8.21	9.24	Solprin	RC
• Anilides								
PARACETAMOL								
5196L	Tablet 500 mg	100	..	..	7.99	9.02	a Chem mart Chemadol	CH
							a Dymadon P	PC
							a Febridol	GM
							a Panamax	SW
							a Paracetamol	SZ
							Sandoz	
							b Parahexal	HX
							a Paralgin	FM
							b Parmol	SI
							a Pharmacy Choice Paracetamol	YM
							a Terry White Chemists Paracetamol	TW
3348F	Oral liquid 120 mg per 5 mL, 100 mL	‡ 1	..	..	8.95	9.98	Panamax	SW
3349G	Oral liquid 240 mg per 5 mL, 200 mL	‡ 1	..	..	10.25	11.28	Panamax 240 Elixir	SW

continued ➞

PREPARATIONS WHICH MAY BE PRESCRIBED BY PARTICIPATING DENTAL PRACTITIONERS FOR DENTAL TREATMENT ONLY—cont.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Proprietary Name and Manufacturer	
PARACETAMOL								
<u>Restricted Benefit</u>								
<i>Chronic arthropathies.</i>								
5224Y	Tablet 500 mg	300	..	..	* 11.99	13.02	^a Chem mart Chemadol	CH
							^a Dymadon P	PC
							^a Febridol	GM
							^a Panamax	SW
							^a Paracetamol Sandoz	SZ
							^b Parahexal	HX
							^a Paralgin	FM
							^b Parmol	SI
							^a Pharmacy Choice Paracetamol	YM
							^a Terry White Chemists Paracetamol	TW

ANTIEPILEPTICS

Antiepileptics

• Carboxamide derivatives

CARBAMAZEPINE

5039F	Tablet 100 mg	200	..	..	18.71	19.74	^a Carbamazepine Sandoz	SZ
				B2.55	21.26	19.74	^a Tegretol 100	NV
5040G	Tablet 200 mg	200	..	..	29.77	30.80	^a Carbamazepine Sandoz	SZ
				B2.74	32.51	30.80	^a Teril	AF
							^a Tegretol 200	NV
5038E	Tablet 200 mg (controlled release)	200	..	..	30.26	31.29	Tegretol CR 200	NV
5037D	Tablet 400 mg (controlled release)	200	..	..	50.59	32.90	Tegretol CR 400	NV
5041H	Oral suspension 100 mg per 5 mL, 300 mL	‡ 1	..	..	20.92	21.95	Tegretol Liquid	NV

ANTI-PARKINSON DRUGS

Anticholinergic agents

• Ethers of tropine or tropine derivatives

BENZTROPINE MESYLATE

5031T	Injection 2 mg in 2 mL	5	..	..	22.41	23.44	Cogentin	FK

**PREPARATIONS WHICH MAY BE PRESCRIBED BY PARTICIPATING
DENTAL PRACTITIONERS FOR DENTAL TREATMENT ONLY—cont.**

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Proprietary Name and Manufacturer	
PSYCHOLEPTICS								
Anxiolytics								
• Benzodiazepine derivatives								
DIAZEPAM								
5071X	Tablet 2 mg	50	..	..	7.36	8.39	^a Antenex 2	AF
							^a Valpam 2	SI
				b0.59	7.95	8.39	Ducene	SU
				b0.86	8.22	8.39	^a Valium	RO
5072Y	Tablet 5 mg	50	..	..	7.50	8.53	^a Antenex 5	AF
							^a Diazepam-DP	GM
							^a Ranzepam	RA
							^a Valpam 5	SI
				b0.63	8.13	8.53	Ducene	SU
				b0.88	8.38	8.53	^a Valium	RO
5073B	Injection 10 mg in 2 mL	5	..	..	11.86	12.89	HH	
OXAZEPAM								
5192G	Tablet 15 mg	25	..	..	7.27	8.30	^a Alepam 15	AF
				b1.78	9.05	8.30	^a Serepax	SI
5193H	Tablet 30 mg	25	..	..	7.46	8.49	^a Alepam 30	AF
							^a Murelax	FM
				b1.90	9.36	8.49	^a Serepax	SI
Hypnotics and sedatives								
• Benzodiazepine derivatives								
NITRAZEPAM								
5189D	Tablet 5 mg	25	..	..	7.46	8.49	^a Alodorm	AF
				b1.53	8.99	8.49	^a Mogadon	VT
TEMAZEPAM								
5221T	Tablet 10 mg	25	..	..	7.46	8.49	^a Temaze	AF
							^a Temtabs	FM
				b1.38	8.84	8.49	^a Normison	SI

RESPIRATORY SYSTEM

DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES

Adrenergics for systemic use

• **Alpha- and beta-adrenoceptor agonists**

ADRENALINE

5004J	Injection 1 mg in 1 mL (1 in 1,000)	5	..	..	19.91	20.94	AP	

**PREPARATIONS WHICH MAY BE PRESCRIBED BY PARTICIPATING
DENTAL PRACTITIONERS FOR DENTAL TREATMENT ONLY—cont.**

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Proprietary Name and Manufacturer	

SENSORY ORGANS

OPHTHALMOLOGICALS

Antiinfectives

• **Antibiotics**

CHLORAMPHENICOL

5055C	Eye drops 5 mg per mL (0.5%), 10 mL	‡ 1	..	..	10.57	11.60	Chloromycetin Chlorsig	PF SI

VARIOUS

ALL OTHER THERAPEUTIC PRODUCTS

All other therapeutic products

• **Antidotes**

NALOXONE HYDROCHLORIDE

5174H	Injection 800 micrograms in 2 mL	1	..	..	29.43	30.46	Naloxone Min-I-Jet	CS
5175J	Injection 2 mg in 5 mL	1	..	..	43.06	32.90	Naloxone Min-I-Jet	CS

ALL OTHER NON-THERAPEUTIC PRODUCTS

All other non-therapeutic products

• **Solvents and diluting agents, incl. irrigating solutions**

SODIUM CHLORIDE

5211G	Injection 9 mg per mL (0.9%), 10 mL	5	..	..	17.73	18.76	PF	

PREPARATIONS WHICH MAY BE PRESCRIBED BY AUTHORISED OPTOMETRISTS FOR OPTOMETRICAL TREATMENT ONLY

PREPARATIONS WHICH MAY BE PRESCRIBED BY AUTHORISED OPTOMETRISTS FOR OPTOMETRICAL TREATMENT ONLY

From 1 January 2008, optometrists accredited to prescribe under State or Territory legislation can apply for approval as PBS prescribers (*authorised optometrists*). Information for optometrists on becoming a PBS prescriber is available on the Medicare Australia website at: www.medicareaustralia.gov.au

The medications listed in this section are for prescribing by authorised optometrists only. Optometrists must not write PBS prescriptions for medicines listed elsewhere in the PBS Schedule.

The Pharmaceutical Benefits Advisory Committee (PBAC) is responsible for making recommendations regarding preparations for inclusion in the optometrist section.

Some products are included in more than one section of the Schedule. For a prescription to be eligible for subsidy, prescribers must ensure that they prescribe under the PBS only those medicines, and in accordance with the restrictions, listed for their practitioner type. Listing details for the same product may differ between sections and different PBS item codes apply for each prescriber type.

Optometrist PBS prescriptions are identifiable by colour, and include the words 'PBS/RPBS optometrist'. Prescriptions must include the optometrist's PBS prescriber number. The same optometrist prescription form is used to prescribe unrestricted, restricted or authority items. Only one item is allowed per form. Optometrist PBS prescriptions may include repeats.

Regulation 24 does not apply for optometrist prescribing. An optometrist cannot direct that original and repeat supplies of pharmaceutical benefits be supplied at the one time.

Authority prescriptions: Authority prescriptions for authority required items, or for increased quantities or repeats, require prior approval from Medicare Australia or the DVA for each prescription. (Refer to details in the Explanatory Notes section under Prescribing Medicines — Information for PBS prescribers and Supplying Medicines — What Pharmacists Need to Know, for more information on authority prescriptions.) DVA approval for non-Schedule items is not available for optometrist prescribing.

RPBS: Optometrists approved as PBS prescribers may write prescriptions for supply under the RPBS. The list of optometrist medicines under the RPBS is the same as the PBS. There are no optometrist listings in the Repatriation Schedule for prescribing for veterans only. There is no provision for optometrist prescribers to request approval to prescribe items that are not included in the PBS optometrist list (non-Schedule items).

State and Territory requirements: Optometrists may prescribe medications as private prescriptions according to their State/Territory prescribing accreditation. The medicines which can be prescribed differ between States and Territories. It is the optometrist's responsibility to ensure adherence to State/Territory law for all prescriptions (PBS and private) and additionally to all PBS requirements for PBS/RPBS prescriptions.

PREPARATIONS WHICH MAY BE PRESCRIBED BY AUTHORISED OPTOMETRISTS FOR OPTOMETRICAL TREATMENT ONLY

GENERAL STATEMENT FOR TOPICAL ANTI-GLAUCOMA DRUGS PRESCRIBED BY AUTHORISED OPTOMETRISTS AS PHARMACEUTICAL BENEFITS

Use the following guidelines to determine patient eligibility for subsidisation under the PBS for the following drugs prescribed by authorised optometrists:

- Betaxolol hydrochloride
- Bimatoprost
- Brimonidine tartrate
- Brimonidine tartrate with timolol maleate
- Brinzolamide
- Dorzolamide hydrochloride
- Dorzolamide hydrochloride with timolol maleate
- Latanoprost
- Latanoprost with timolol maleate
- Pilocarpine hydrochloride
- Timolol maleate
- Travoprost
- Travoprost with timolol maleate

By writing a PBS prescription, the prescriber is certifying the criteria set out in these guidelines are satisfied, and use is in accordance with the registered indications – refer to the current Product Information for details.

GUIDELINES FOR SHARED CARE OF GLAUCOMA PATIENTS

Under these guidelines, authorised optometrists who are approved to use therapeutic drugs in their practices and who have adequate professional indemnity cover, will be able to co-manage glaucoma patients in a shared care arrangement with an ophthalmologist.

Initial Referral to Ophthalmologist

An authorised optometrist who makes a provisional diagnosis of glaucoma is to refer the patient to an ophthalmologist for confirmation of the diagnosis and the development of a management plan.

Where clinically important delays are expected before the patient's first review by an ophthalmologist, the optometrist should seek interim advice on the patient's management from the ophthalmologist by telephone (or alternate means).

PREPARATIONS WHICH MAY BE PRESCRIBED BY AUTHORISED OPTOMETRISTS FOR OPTOMETRICAL TREATMENT ONLY

The patient's consent is to be obtained by the ophthalmologist and optometrist for all aspects of the management plan, including the sharing of care between the two practitioners, and the communication of clinical information to the patient's nominated general practitioner.

Patients being considered for anti-glaucoma therapy with a beta blocking agent should be assessed for any potential cardiovascular or respiratory risk by a medical practitioner (often the patient's general practitioner), prior to initiating therapy. This assessment should be repeated if a change in dose of the beta blocker is proposed.

Once the diagnosis of glaucoma is confirmed by the ophthalmologist and a treatment plan is in place for the patient, the optometrist can perform ongoing reviews to monitor the patient and prescribe topical drugs under the PBS providing that:

- Periodic review demonstrates the treatment to be effective, and
- Changes to management are only initiated following consultation between treating practitioners.

Patient Management Plan

The management plan must be in writing and specify the following:

1. All the agreed components of treatment including any drug therapy;
2. Target pressures and action to be taken if these are not achieved within a specified time frame;
3. An agreed approach to monitoring visual fields and optic disc imaging and action to be taken following changes in visual fields;
4. Triggers for referral for more immediate ophthalmological and general practitioner review;
5. Likely side effects from agreed treatment and the action to be taken to address these;
6. An agreed schedule for patient review by both practitioners;
7. Who is responsible for performing each of the required tests and the required frequency for performing them;
8. An agreed method for timely communication of clinical findings and patient management between the two practitioners and the patient's nominated general practitioner.

Ophthalmologists must be available for consultation by the treating optometrist and for consultation by the patient where that consultation has been recommended or requested by the optometrist.

The involvement of a pharmacist to provide medicines information, advice relating to administration and techniques to limit systemic absorption and side effects of ophthalmic medications is recommended.

**PREPARATIONS WHICH MAY BE PRESCRIBED BY AUTHORISED
OPTOMETRISTS FOR OPTOMETRICAL TREATMENT ONLY-cont.**

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Proprietary Name and Manufacturer	
• Antiinflammatory agents, non-steroids FLURBIPROFEN SODIUM								
5514F	Eye drops 300 micrograms per mL (0.03%), single dose units 0.4 mL, 5	1	..	..	14.94	15.97	Ocufen	AG
Antiglaucoma preparations and miotics • Sympathomimetics in glaucoma therapy BRIMONIDINE TARTRATE								
5534G	Eye drops 2 mg per mL (0.2%), 5 mL	± 1	5	..	20.56	21.59	^a Enidin	PE
				B1.74	22.30	21.59	^a Alphagan	AG
BRIMONIDINE TARTRATE with TIMOLOL MALEATE Restricted Benefit <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;</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.</i>								
5535H	Eye drops 2 mg-5 mg (base) per mL (0.2%-0.5%), 5 mL	± 1	5	..	26.76	27.79	Combigan	AG
• Parasympathomimetics PILOCARPINE HYDROCHLORIDE								
5536J	Eye drops 10 mg per mL (1%), 15 mL	± 1	5	..	12.48	13.51	Isopto Carpine	AQ
				..	12.48	13.51	^a Piloft	PE
							^a P.V. Carpine	AG
5537K	Eye drops 20 mg per mL (2%), 15 mL	± 1	5	..	13.81	14.84	Isopto Carpine	AQ
				..	13.81	14.84	^a Piloft	PE
							^a P.V. Carpine	AG
5538L	Eye drops 40 mg per mL (4%), 15 mL	± 1	5	..	16.83	17.86	Isopto Carpine	AQ
				..	16.83	17.86	^a Piloft	PE
							^a P.V. Carpine	AG
5539M	Eye drops 60 mg per mL (6%), 15 mL	± 1	5	..	21.61	22.64	^a Piloft	PE
							^a P.V. Carpine	AG
• Carbonic anhydrase inhibitors BRINZOLAMIDE								
5540N	Eye drops 10 mg per mL (1%), 5 mL	± 1	5	..	23.37	24.40	^a BrinzoQuin	IQ
				B1.23	24.60	24.40	^a Azopt	AQ

**PREPARATIONS WHICH MAY BE PRESCRIBED BY AUTHORISED
OPTOMETRISTS FOR OPTOMETRICAL TREATMENT ONLY-cont.**

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Proprietary Name and Manufacturer	
DORZOLAMIDE HYDROCHLORIDE								
5541P	Eye drops 20 mg (base) per mL (2%), 5 mL	± 1	5	..	20.86	21.89	Trusopt	MK
<i>DORZOLAMIDE HYDROCHLORIDE with TIMOLOL MALEATE</i>								
<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;</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.</i>								
5542Q	Eye drops 20 mg (base)-5 mg (base) per mL (2%-0.5%), 5 mL	± 1	5	..	27.06	28.09	Cosopt	MK
• Beta blocking agents								
BETAXOLOL HYDROCHLORIDE								
5543R	Eye drops, suspension, 2.5 mg (base) per mL (0.25%), 5 mL	± 1	5	..	14.86	15.89	Betoptic S	AQ
5544T	Eye drops, solution, 5 mg (base) per mL (0.5%), 5 mL	± 1	5	.. B2.18	14.86 17.04	15.89 ^a 15.89 ^a	BetoQuin Betoptic	IQ AQ
TIMOLOL MALEATE								
5546X	Eye gel 1 mg (base) per g (0.1%), 5 g	± 1	5	..	12.79	13.82	Nyogel	NV
5547Y	Eye drops 2.5 mg (base) per mL (0.25%), 5 mL	± 1	5	.. B2.95	11.37 14.32	12.40 ^a 12.40 ^a	Tenopt Timoptol	SI FR
5548B	Eye drops 5 mg (base) per mL (0.5%), 5 mL	± 1	5	.. B2.95	12.19 15.14	13.22 ^a 13.22 ^a	Tenopt Timoptol	SI FR
5549C	Eye drops (gellan gum solution) 2.5 mg (base) per mL (0.25%), 2.5 mL	± 1	5	..	11.37	12.40	Timoptol XE	MK
5550D	Eye drops (gellan gum solution) 5 mg (base) per mL (0.5%), 2.5 mL	± 1	5	..	12.19	13.22	Timoptol XE	MK
• Prostaglandin analogues								
BIMATOPROST								
5551E	Eye drops 300 micrograms per mL (0.03%), 3 mL	± 1	5	..	41.71	32.90	Lumigan	AG
LATANOPROST								
5552F	Eye drops 50 micrograms per mL (0.005%), 2.5 mL	± 1	5	..	41.71	32.90	Xalatan	PU

**PREPARATIONS WHICH MAY BE PRESCRIBED BY AUTHORISED
OPTOMETRISTS FOR OPTOMETRICAL TREATMENT ONLY-cont.**

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Proprietary Name and Manufacturer	
LATANOPROST with TIMOLOL MALEATE								
<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>								
5553G	Eye drops 50 micrograms-5 mg (base) per mL (0.005%-0.5%), 2.5 mL	± 1	5	..	46.39	32.90	Xalacom	PF
TRAVOPROST								
5554H	Eye drops 40 micrograms per mL (0.004%), 2.5 mL	± 1	5	..	41.71	32.90	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 latanoprost 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 latanoprost eye drops or travoprost eye drops.</i>								
5555J	Eye drops 40 micrograms-5 mg (base) per mL (0.004%-0.5%), 2.5 mL	± 1	5	..	46.39	32.90	Duotrav	AQ
Decongestants and antiallergics								
• Other antiallergics								
SODIUM CROMOGLYCATE								
<u>Restricted Benefit</u>								
<i>Vernal kerato-conjunctivitis.</i>								
5529B	Eye drops 20 mg per mL (2%), 10 mL	± 1	5	..	14.26	15.29	^a Cromolux ^a Opticrom	AE SW
Other ophthalmologicals								
• Other ophthalmologicals								
CARBOMER								
<u>Restricted Benefit</u>								
<i>Severe dry eye syndrome, including Sjogren's syndrome.</i>								
5503P	Eye gel 2 mg per g (0.2%), 10 g	± 1	5	..	10.08	11.11	GelTears	BU
				..	10.08	11.11	^a PAA	NM
				B1.00	11.08	11.11	^a Viscotears	NV

continued ➡

The shelf life of Optive is 6 months from the date of opening.

**PREPARATIONS WHICH MAY BE PRESCRIBED BY AUTHORISED
OPTOMETRISTS FOR OPTOMETRICAL TREATMENT ONLY-cont.**

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Proprietary Name and Manufacturer	
HYPROMELLOSE								
<u>Restricted Benefit</u>								
<i>Severe dry eye syndrome, including Sjogren's syndrome.</i>								
5518K	Eye drops 3 mg per mL (0.3%), 15 mL (contains sodium perborate as preservative)	± 1	5	.. B1.86	10.08 11.94	11.11 11.11	^a In a Wink Moisturising Gentleal	NM NV
5517J	Eye drops 5 mg per mL (0.5%), 15 mL	± 1	5	..	10.08	11.11	Methopt	SI
HYPROMELLOSE with CARBOMER 980								
<u>Restricted Benefit</u>								
<i>Severe dry eye syndrome, including Sjogren's syndrome.</i>								
5519L	Ocular lubricating gel 3 mg-2 mg per g (0.3%-0.2%), 10 g	± 1	5	.. B1.86	10.08 11.94	11.11 11.11	^a HPMC PAA Gentleal gel	NM NV
HYPROMELLOSE with DEXTRAN								
<u>Restricted Benefit</u>								
<i>Severe dry eye syndrome, including Sjogren's syndrome.</i>								
5520M	Eye drops 3 mg-1 mg per mL (0.3%-0.1%), 15 mL	± 1	5	.. B1.87	10.30 12.17	11.33 11.33	^a Poly-Tears Tears Naturale	IQ AQ
<u>Authority Required</u>								
<i>Severe dry eye syndrome in patients who are sensitive to preservatives in multi-dose eye drops.</i>								
5521N	Eye drops 3 mg-1 mg per mL (0.3%-0.1%), single dose units 0.4 mL, 28	3	5	..	* 36.41	32.90	Bion Tears	AQ
PARAFFIN								
5523Q	Compound eye ointment 3.5 g	2	5	.. B2.24	* 21.73 * 23.97	22.76 22.76	^a Poly Visc Duratears	IQ AQ
5522P	Pack containing 2 tubes compound eye ointment 3.5 g	± 1	5	.. B2.24	21.06 21.06 23.30	22.09 22.09 22.09	Poly Visc ^a Ircal ^a Lacri-Lube	IQ PE AG
POLYETHYLENE GLYCOL 400 with PROPYLENE GLYCOL								
<u>Restricted Benefit</u>								
<i>Severe dry eye syndrome, including Sjogren's syndrome.</i>								
5524R	Eye drops 4 mg-3 mg per mL (0.4%-0.3%), 15 mL	± 1	5	..	10.16	11.19	Systane	AQ

continued ➡

**PREPARATIONS WHICH MAY BE PRESCRIBED BY AUTHORISED
OPTOMETRISTS FOR OPTOMETRICAL TREATMENT ONLY-cont.**

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Proprietary Name and Manufacturer	

Authority Required

Severe dry eye syndrome in patients who are sensitive to preservatives in multi-dose eye drops.

5532E	Eye drops 4 mg-3 mg per mL (0.4%-0.3%), single dose units 0.8 mL, 28	2	5	..	* 33.65	32.90	Systane	AQ

POLYVINYL ALCOHOL

Restricted Benefit

Severe dry eye syndrome, including Sjogren's syndrome.

5526W	Eye drops 14 mg per mL (1.4%), 15 mL	± 1	5	.. B1.71	10.08 11.79	11.11 11.11	^a PVA Tears ^a Liquifilm Tears	PE AG
5527X	Eye drops 14 mg per mL (1.4%), 15 mL (contains sodium chlorite/hydrogen peroxide as preservative)	± 1	5	..	10.08	11.11	Vistil	AE
5525T	Eye drops 30 mg per mL (3%), 15 mL	± 1	5	.. B5.94	10.08 16.02	11.11 11.11	^a PVA Forte ^a Liquifilm Forte	PE AG
5528Y	Eye drops 30 mg per mL (3%), 15 mL (contains sodium chlorite/hydrogen peroxide as preservative)	± 1	5	..	10.08	11.11	Vistil Forte	AE

TAMARINDUS INDICA SEED POLYSACCHARIDE

Authority Required

Severe dry eye syndrome in patients who are sensitive to preservatives in multi-dose eye drops.

5531D	Eye drops 10 mg per mL (1%), 0.5 mL, 20	3	5	..	* 35.63	32.90	Visine Professional	JT

SECTION 100 ITEMS

In addition to the drugs and medicinal preparations available under normal PBS arrangements listed in this Schedule, a number of drugs are also available as pharmaceutical benefits but are distributed under alternative arrangements where these are considered more appropriate.

These alternative arrangements are provided for under section 100 of the *National Health Act 1953*. Several programs exist for the provision of drugs as pharmaceutical benefits in this way and this section lists those drugs which are available under the following programs:

HIGHLY SPECIALISED DRUGS PROGRAM

BOTULINUM TOXIN PROGRAM

HUMAN GROWTH HORMONE PROGRAM

IVF/GIFT PROGRAM

OPIATE DEPENDENCE TREATMENT PROGRAM

SPECIAL AUTHORITY PROGRAM

Complete details concerning the availability of drugs as benefits under these programs may be obtained by telephoning the relevant contact number(s) shown in each section, or in certain cases, by referring to the telephone number provided for individual drugs listings.

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer \$	Proprietary Name and Manufacturer

HIGHLY SPECIALISED DRUGS PROGRAM

The Australian Government provides funding for certain specialised medications under the Highly Specialised Drugs Program. Highly Specialised Drugs are medicines for the treatment of chronic conditions which, because of their clinical use or other special features, are restricted to supply through public and private hospitals having access to appropriate specialist facilities. To prescribe these drugs as pharmaceutical benefit items, medical practitioners are required to be affiliated with these specialist hospital units. A general practitioner or non-specialist hospital doctor may only prescribe Highly Specialised Drugs to provide maintenance therapy under the guidance of the treating specialist.

Benefits are available for the listed clinical indications only. There is no facility for individual patient approval for indications outside those listed.

To gain access to a Commonwealth funded drug under this program, a patient must attend a participating hospital and be a day admitted patient, a non-admitted patient or a patient on discharge, be under appropriate specialist medical care, meet the specific medical criteria and be an Australian resident in Australia (or other eligible person).

A patient will be required to pay a contribution for each supply of a highly specialised drug at a similar rate to the Pharmaceutical Benefits Scheme. Commonwealth subsidy is not available for hospital in-patients.

Reciprocal Health Care Agreement – Where a patient is entitled to be treated as an eligible person as a visitor from a country with which Australia has entered into a Reciprocal Health Care Agreement, the supply will be limited to the original prescription only. Repeat prescriptions for these patients are not permitted.

Private Hospitals – **In addition to the above requirements**, for Highly Specialised Drugs prescribed through private hospitals, claiming and approval of authority prescriptions is administered by Medicare Australia. Highly Specialised Drugs are authority required items. Medical practitioners must seek approval to prescribe these items as pharmaceutical benefits prior to their dispensing under the PBS. Approval of authority prescriptions by Medicare Australia may be obtained either by posting an Authority Prescription Form to Medicare Australia, or by using Medicare Australia's Authority Freecall service (1800 888 333). **Prescribers must quote the provider number of the hospital when applying.** Not more than two months' supply (one month's supply in the case of Clozapine), with provision for up to 5 repeats, will be authorised. Prescriptions for Highly Specialised Drugs can be dispensed by an approved private hospital's dispensary or by a community pharmacy.

The remuneration rates for Highly Specialised Drugs prescribed through private hospitals comprise the normal PBS ready- prepared dispensing fee plus a mark-up ascertained as follows:

- 10% for drugs with a price ex-manufacturer of less than \$40;
- \$4 for drugs with a price ex-manufacturer of between \$40 and \$100;
- 4% for drugs with a price ex-manufacturer of between \$100.01 and \$1000;
- \$40 for drugs with a price ex-manufacturer of greater than \$1000.

Public Hospitals – For Highly Specialised Drugs prescribed through public hospitals, claiming and access to the program is administered by the States/Territories Health Departments. Prescriptions for Highly Specialised Drugs can be dispensed by public hospital pharmacies.

If you would like further information about the Highly Specialised Drugs Program, please contact your pharmacy, Medicare Australia (Ph: 132 290) or the Australian Government adviser, the Highly Specialised Drugs Working Party Secretariat (Ph: (02) 6289 2331).

For information on Pharmaceutical Benefits Pricing Authority therapeutic relativity sheets please visit www.health.gov.au and search for 'relativity sheets'.

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer \$	Proprietary Name and Manufacturer	

HIGHLY SPECIALISED DRUGS PROGRAM

ABACAVIR SULFATE

Private hospital authority required

Treatment of HIV infection in patients with:

- (a) CD4 cell counts of less than 500 per cubic millimetre; or
- (b) viral load of greater than 10,000 copies per mL.

6264Q	Tablet 300 mg (base)	60	423.00	Ziagen	GK
6265R	Oral solution 20 mg (base) per mL, 240 mL	1	82.14	Ziagen	GK

NOTE:

Special Pricing Arrangements apply.

ABACAVIR SULFATE with LAMIVUDINE

Private hospital authority required

Treatment of HIV infection in patients over 12 years of age, weighing 40 kg or more, with:

- (a) CD4 cell counts of less than 500 per cubic millimetre; or
- (b) viral load of greater than 10,000 copies per mL.

6458X	Tablet 600 mg (base)-300 mg	30	564.00	Kivexa	GK

ABACAVIR SULFATE with LAMIVUDINE and ZIDOVUDINE

Private hospital authority required

Treatment of HIV infection in patients over 12 years of age, weighing 40 kg or more, with:

- (a) CD4 cell counts of less than 500 per cubic millimetre; or
- (b) viral load of greater than 10,000 copies per mL.

6327B	Tablet 300 mg (base)-150 mg-300 mg	60	852.00	Trizivir	GK

ABATACEPT

NOTE:

Any queries concerning the arrangements to prescribe abatacept may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written applications for authority to prescribe abatacept should be forwarded to:

Medicare Australia

Prior Written Approval of Specialised Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

Further prescribing information is on the Medicare Australia website at www.medicareaustralia.gov.au.

NOTE:

TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying anti-rheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, etanercept, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-1 inhibitor (anakinra) and the T-cell co-stimulation modulator (abatacept).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

continued ➞

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer \$	Proprietary Name and Manufacturer

PBS-subsidised infliximab, anakinra, rituximab and abatacept must be used in combination with methotrexate at a dose of at least 7.5 mg weekly. Where a patient cannot tolerate 7.5 mg of methotrexate weekly, they are only eligible to receive PBS-subsidised etanercept and adalimumab.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.

From 1 March 2008, under the PBS, all patients will be able to commence a Treatment Cycle where they may trial PBS-subsidised bDMARD agents without having to experience a disease flare when swapping to an alternate agent. Under these interchangeability arrangements, within a single Treatment Cycle, a patient may continue to receive long-term treatment with a bDMARD while they continue to show a response to therapy.

A patient who received PBS-subsidised bDMARD treatment prior to 1 March 2008 is considered to be in their first Cycle as of 1 March 2008.

Within the same Treatment Cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a Treatment Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised bDMARD therapy before they are eligible to commence the next Cycle.

For patients who have failed PBS-subsidised treatment with 3 bDMARDs prior to 1 March 2008 please contact Medicare Australia on 1800 700 270.

The 5-year break is measured from the date of the last approval for PBS-subsidised bDMARD treatment in the most recent Cycle to the date of the first application for initial treatment with a bDMARD under the new Treatment Cycle.

A patient who has failed fewer than 3 bDMARDs in a Treatment Cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same Treatment Cycle.

A patient who has failed fewer than 3 bDMARDs in a Treatment Cycle and who has a break in therapy of more than 5 years, may commence a new Treatment Cycle.

There is no limit to the number of Treatment Cycles a patient may undertake in their lifetime.

If patients fail to respond to a particular bDMARD within a single Treatment Cycle, they are not eligible to receive further PBS-subsidised treatment with that drug until they commence the next Cycle.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 March 2008.

(a) Initial treatment.

Applications for initial treatment should be made where:

- (i) a patient has received no prior PBS-subsidised bDMARD treatment in this Treatment Cycle and wishes to commence such therapy, excluding rituximab (Initial 1); or*
- (ii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or*
- (iii) a patient wishes to re-commence treatment with a specific bDMARD following a break in PBS-subsidised therapy with that agent (Initial 2).*

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for etanercept, adalimumab, anakinra and abatacept, 22 weeks of therapy for infliximab and 2 infusions of rituximab.

From 1 March 2008, a patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to Medicare Australia within 4 weeks.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer \$	Proprietary Name and Manufacturer

Rituximab patients:

A further application may be submitted to Medicare Australia 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Rituximab patients:

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD within the same Treatment Cycle without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the same Treatment Cycle.

In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF- α antagonist treatment.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

NOTE:

(3) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a Treatment Cycle and Medicare Australia will assess response according to these revised baseline measurements.

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer \$	Proprietary Name and Manufacturer

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

The baseline joint and blood counts should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment.

(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent Treatment Cycle following a break in PBS-subsidised bDMARD therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have received treatment with at least 1 non-biological DMARD, at an adequate dose, for a minimum of 3 months at the time the ESR and/or CRP levels and the active joint count are measured.

(5) Patients 'grandfathered' onto PBS-subsidised treatment with rituximab or abatacept.

From 1 March 2008, a patient who commenced treatment with rituximab for severe rheumatoid arthritis prior to 7 March 2007 or abatacept for severe rheumatoid arthritis prior to 1 November 2007 and who was 'grandfathered' on to PBS-subsidised therapy, and who continues to receive treatment in the same Treatment Cycle, will have further applications for treatment with rituximab or abatacept assessed under the continuing treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment with abatacept will be authorised under this criterion.

'Grandfather' arrangements will only apply for the first Treatment Cycle. For the second and subsequent Cycles, a 'grandfather' patient must requalify for initial treatment under the criteria that applies to a new patient. See 'Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' above for further details.

Public and private hospital authority required

Initial 1 (new patients)

Application for initial PBS-subsidised treatment with abatacept, in combination with methotrexate at a dose of at least 7.5 mg weekly, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of adults who:

- (a) have severe active rheumatoid arthritis; and
- (b) have received no prior PBS-subsidised treatment with a bDMARD for this condition in this treatment cycle; and
- (c) have failed to achieve an adequate response to the following treatments:
 - (i) methotrexate at a dose of at least 20 mg weekly; and
 - (ii) methotrexate (at a minimum dose of 7.5 mg weekly), in combination with 2 other non-biological disease modifying anti-rheumatic drugs (DMARDs), for a minimum of 3 months; and
 - (iii) a minimum of 3 months' treatment with:
 - leflunomide alone; or
 - leflunomide in combination with methotrexate; or
 - cyclosporin.

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of the accepted toxicities, including severity, can be found on the Medicare Australia website [www.medicareaustralia.gov.au].

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer \$	Proprietary Name and Manufacturer

The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:
an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L;

AND either

(i) a total active joint count of at least 20 active (swollen and tender) joints; or

(ii) at least 4 active joints from the following list of major joints:

— elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

— shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes details of the patient's ESR and CRP measurements and the patient's active joint count which must have been assessed no earlier than 1 month prior to the date of application; and

(3) a signed patient acknowledgement.

A maximum of 16 weeks of treatment will be authorised under this restriction.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion. Up to a maximum of 4 repeats may be authorised.

Where fewer than 4 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Assessment of a patient's response to an initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with abatacept.

Patients who fail to demonstrate a response to treatment with abatacept under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug, in this treatment cycle. Patients may re-trial abatacept after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised bDMARD was approved in this cycle and the date of the first application under the new cycle.

Public and private hospital authority required

Initial 2 (change or re-commencement)

Application for an initial course of PBS-subsidised treatment with abatacept, in combination with methotrexate at a dose of at least 7.5 mg weekly, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of adults who:

(a) have a documented history of severe active rheumatoid arthritis; and

(b) have received prior PBS-subsidised bDMARD treatment for this condition in this treatment cycle and are eligible to receive further bDMARD therapy.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer \$	Proprietary Name and Manufacturer

Applications for patients who have received PBS-subsidised treatment with abatacept within this treatment cycle and who wish to re-commence therapy with this drug within this same cycle, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised abatacept treatment, within the timeframes specified below.

A maximum of 16 weeks of treatment will be authorised under this restriction.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion. Up to a maximum of 4 repeats may be authorised.

Where fewer than 4 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Where the most recent course of PBS-subsidised abatacept treatment was approved under either of the initial treatment restrictions (i.e. for patients with no prior PBS-subsidised bDMARD therapy or, under this restriction, for patients who have received previous PBS-subsidised bDMARD therapy), patients must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be provided to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised abatacept treatment was approved under the continuing treatment criteria, patients must have been assessed for response, and the assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Patients who fail to demonstrate a response to treatment with abatacept under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug, in this treatment cycle. Patients may re-trial abatacept after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised bDMARD was approved in this cycle and the date of the first application under the new cycle.

Public and private hospital authority required

Initial 3 ('grandfather' patients)

Initial PBS-subsidised supply for continuing treatment with abatacept, in combination with methotrexate at a dose of at least 7.5 mg weekly, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of an adult who:

- (a) has a documented history of severe active rheumatoid arthritis; and*
- (b) was receiving treatment with abatacept prior to 1 November 2007; and*
- (c) has demonstrated a response as specified in the criteria for continuing PBS-subsidised treatment with abatacept.*

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and*
- (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form [www.medicareaustralia.gov.au] which includes the signed patient acknowledgement.*

The same indices of disease severity used to establish baseline at the commencement of treatment with a bDMARD must be used for assessment of all continuing applications.

The assessment of the patient's response to a continuing course of therapy must be made within 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled in order to ensure continuity of treatment for those patients who meet the continuation criterion.

A maximum of 24 weeks of treatment with abatacept will be approved under this criterion.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion. Up to a maximum of 5 repeats may be authorised.

Where fewer than 5 repeats are initially requested with the authority prescription, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Patients may qualify for PBS-subsidised treatment under this restriction once only.

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer \$	Proprietary Name and Manufacturer	
	<i>Patients who fail to demonstrate a response to treatment with 3 bDMARDs are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may re-commence a new bDMARD Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised bDMARD was approved in this Cycle and the date of the first application under the new Cycle.</i> Public and private hospital authority required <i>Continuing treatment</i> <i>Continuing PBS-subsidised treatment with abatacept, in combination with methotrexate at a dose of at least 7.5 mg weekly, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of adults:</i> <i>(a) who have a documented history of severe active rheumatoid arthritis; and</i> <i>(b) who have demonstrated an adequate response to treatment with abatacept; and</i> <i>(c) whose most recent course of PBS-subsidised bDMARD treatment in this treatment cycle was with abatacept.</i> <i>An adequate response to treatment is defined as:</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 either of the following:</i> <i>(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</i> <i>(ii) a reduction in the number of the following major 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 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>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 Rheumatoid Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].</i> <i>A maximum of 24 weeks of treatment will be approved under this restriction.</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. Up to a maximum of 5 repeats may be authorised.</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 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).</i> <i>All applications for continuing treatment with abatacept must include a measurement of response to the prior course of therapy. This assessment must be provided to Medicare Australia no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with abatacept, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.</i> <i>Patients who fail to demonstrate a response to treatment with abatacept under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug, in this treatment cycle. Patients may re-trial abatacept after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised bDMARD was approved in this cycle and the date of the first application under the new cycle.</i>				
9621J	Powder for I.V. infusion 250 mg	1	504.43	Orencia	BQ

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer \$	Proprietary Name and Manufacturer	
ADEFOVIR DIPIVOXIL					
<u>Private hospital authority required</u>					
<i>Chronic hepatitis B in a patient who has failed antihepadnaviral therapy and who satisfies all of the following criteria:</i>					
<i>(1)(a) Repeatedly elevated serum ALT levels while on concurrent antihepadnaviral therapy of greater than or equal to 6 months duration in conjunction with documented chronic hepatitis B infection; or</i>					
<i>(b) Repeatedly elevated HBV DNA levels one log greater than the nadir value or failure to achieve a 1 log reduction in HBV DNA within 3 months, whilst on previous antihepadnaviral therapy except in patients with evidence of poor compliance;</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>					
NOTE:					
<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 but not with other PBS-subsidised antihepadnaviral therapy.</i>					
6450L	Tablet 10 mg	30	625.00	Hepsera	GI
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>					
9607P	Injection 20 mg in 2 mL	5	77.86	Apomine	HH
ATAZANAVIR					
<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 (as sulfate)	60	521.91	Reyataz	BQ
6452N	Capsule 200 mg (as sulfate)	60	695.88	Reyataz	BQ
9614B	Capsule 300 mg (as sulfate)	30	521.91	Reyataz	BQ
AZITHROMYCIN					
<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>(a) of cerebral origin; or</i>					
<i>(b) due to multiple sclerosis; or</i>					

continued ➞

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer \$	Proprietary Name and Manufacturer	
	(c) due to spinal cord injury; or (d) due to spinal cord disease.				
6284R	Intrathecal injection 10 mg in 5 mL	1	148.37	Lioresal Intrathecal	NV

BOSENTAN MONOHYDRATE**CAUTION:**

Bosentan monohydrate is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 3 months following cessation of treatment with this drug.

NOTE:

Any queries concerning the arrangements to prescribe bosentan monohydrate may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written applications for authority to prescribe bosentan monohydrate should be forwarded to:

Medicare Australia

Prior Written Approval of Specialised Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

NOTE:

Bosentan monohydrate is not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with scleroderma, where the total lung capacity is less than 70% of that predicted.

Bosentan monohydrate is not PBS-subsidised when used in combination with PBS-subsidised iloprost trometamol, PBS-subsidised epoprostenol sodium, PBS-subsidised sildenafil citrate or PBS-subsidised sitaxentan sodium.

The following provides some explanatory notes regarding the availability of PBS-subsidised treatment with:

(a) bosentan monohydrate, of primary pulmonary hypertension, pulmonary arterial hypertension secondary to scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology), in patients with disease of WHO Functional Class III or IV severity; AND

(b) iloprost trometamol, of primary pulmonary hypertension, drug-induced pulmonary arterial hypertension or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class III or IV severity; AND

(c) epoprostenol sodium, of primary pulmonary hypertension, in patients with disease of WHO Functional Class III or IV severity; AND

(d) sildenafil citrate, of primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class III severity; AND

(e) sitaxentan sodium, of primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class III severity.

Adult patients:

From 1 April 2008, adult patients with primary pulmonary hypertension will be able to access, through the PBS, bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate (WHO Class III only) or sitaxentan sodium (WHO Class III only). Once these patients are approved initial treatment with 1 of these 5 drugs, they may swap between bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate and sitaxentan sodium at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary. (New baselines may be submitted where the patient has failed to respond to their current treatment.)

Patients may only swap to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate or sitaxentan sodium if they have not failed prior PBS-subsidised treatment with that drug.

continued ➡

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer \$	Proprietary Name and Manufacturer

Adult patients with pulmonary arterial hypertension secondary to scleroderma will be able to access, through the PBS, bosentan monohydrate, iloprost trometamol, sildenafil citrate (WHO Class III only) or sitaxentan sodium (WHO Class III only). Once these patients are approved initial treatment with 1 of these 4 drugs, they may swap between bosentan monohydrate, iloprost trometamol, sildenafil citrate and sitaxentan sodium at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary. (New baselines may be submitted where the patient has failed to respond to their current treatment.)

Patients may only swap to bosentan monohydrate, iloprost trometamol, sildenafil citrate or sitaxentan sodium if they have not failed prior PBS-subsidised treatment with that drug.

Adult patients with pulmonary arterial hypertension secondary to connective tissue disease other than scleroderma will be able to access, through the PBS, iloprost trometamol, sildenafil citrate (WHO Class III only) or sitaxentan sodium (WHO Class III only). Once these patients are approved initial treatment with 1 of these 3 drugs, they may swap between iloprost trometamol, sildenafil citrate and sitaxentan sodium at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary. (New baselines may be submitted where the patient has failed to respond to their current treatment.)

Patients may only swap to iloprost trometamol, sildenafil citrate or sitaxentan sodium if they have not failed prior PBS-subsidised treatment with that drug.

Patients with drug-induced pulmonary arterial hypertension are only eligible for treatment with iloprost trometamol. They may not swap to bosentan monohydrate, epoprostenol sodium, sildenafil citrate or sitaxentan sodium.

Patients with pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are only eligible for treatment with bosentan monohydrate. They may not swap to epoprostenol sodium, iloprost trometamol, sildenafil citrate or sitaxentan sodium.

Patients under 18 years of age:

From 1 April 2008, patients aged less than 18 years with primary pulmonary hypertension are eligible to receive PBS-subsidised treatment with bosentan monohydrate, epoprostenol sodium, iloprost trometamol, sildenafil citrate (WHO Class III only) or sitaxentan sodium (WHO Class III only). Once these patients are approved initial treatment with 1 of these 5 drugs, they may swap between bosentan monohydrate, epoprostenol sodium, iloprost trometamol, sildenafil citrate and sitaxentan sodium at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary. (New baselines may be submitted where the patient has failed to respond to their current treatment.)

Patients may only swap to bosentan monohydrate, epoprostenol sodium, iloprost trometamol, sildenafil citrate or sitaxentan sodium if they have not failed prior PBS-subsidised treatment with that drug.

1. Definition of primary pulmonary hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease, including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology).

Primary pulmonary hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease, including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows:

- (i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary capillary wedge pressure (PCWP) less than 18 mmHg; or*
- (ii) mPAP greater than 30 mmHg with exercise and PCWP less than 18 mmHg; or*
- (iii) where a right heart catheter cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.*

2. Definition of WHO Functional Class III or IV disease severity.

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer \$	Proprietary Name and Manufacturer

(a) WHO Functional Class III disease severity is defined as follows:

Patients with pulmonary hypertension resulting in marked limitation of physical activity who are comfortable at rest and on ordinary physical activity experience dyspnoea or fatigue, chest pain or near syncope.

(b) WHO Functional Class IV disease severity is defined as follows:

Patients with the inability to carry out any physical activity without symptoms. These patients manifest signs of right heart failure. Dyspnoea and/or fatigue may even be present at rest. Discomfort is increased by any physical activity.

3. Designated hospitals.

Refer to the Medicare Australia website at www.medicareaustralia.gov.au for a list of designated hospitals.

4. Test requirements to establish baseline for initiation of treatment and response to treatment for continuation of treatment.

(a) Initiation of treatment.

The first written application for PBS-subsidised treatment with the first of either bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate or sitaxentan sodium should be accompanied by the results of a right heart catheter (RHC) composite assessment, plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

- (1) RHC plus ECHO composite assessments;
- (2) RHC composite assessment plus 6MWT;
- (3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted to Medicare Australia for consideration based on the results of the following test combinations, which are listed in descending order of preference:

- (1) ECHO composite assessment plus 6MWT;
- (2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a reason outlining why the particular test/s could not be conducted must be provided with the authority application.

NOTE:

Where patients were initiated on PBS-subsidised treatment either with bosentan monohydrate on or after 1 March 2004, with iloprost trometamol on or after 1 April 2005, with epoprostenol sodium on or after 1 August 2006, with sildenafil citrate on or after 1 March 2007, with sitaxentan sodium on or after 1 April 2008, or with bosentan monohydrate (for PAH associated with congenital systemic-to-pulmonary shunt) on or after 1 August 2008, the test results provided with the initial application must be no more than 2 months old at the time of application. These results will form the baseline against which response assessments will be made.

Where patients received treatment with either bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate or sitaxentan sodium prior to being commenced on PBS-subsidised treatment with the first of either bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate or sitaxentan sodium, the test requirements above still apply. The results that will form the baseline against which response assessments will be made will be those measured at the time patients commenced non-PBS-subsidised treatment with either bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate or sitaxentan sodium, whichever of the 5 drugs the patient received first.

(b) Continuation of treatment.

The following list outlines the preferred test combination, in descending order, for the purposes of continuation of PBS-subsidised treatment:

- (1) RHC plus ECHO composite assessments plus 6MWT;
- (2) RHC plus ECHO composite assessments;
- (3) RHC composite assessment plus 6MWT;
- (4) ECHO composite assessment plus 6MWT;
- (5) RHC composite assessment only;
- (6) ECHO composite assessment only.

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer \$	Proprietary Name and Manufacturer

The results of the same tests as conducted at baseline should be provided with each written continuing treatment application (i.e. every 6 months), except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a reason why the test(s) could not be conducted must be provided with the application.

The test(s) results provided with the application for continuing treatment must be no more than 2 months old at the time of application.

5. Definition of response to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, sitaxentan sodium or prior vasodilator treatment.

For adult patients with 2 or more baseline tests, response to treatment is defined as 2 or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For adult patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For adult patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least 1 of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

6. Authority approval requirements. [The following 2 sections are only relevant to the PBS listing of bosentan monohydrate. The requirements specific to iloprost trometamol, epoprostenol sodium, sildenafil citrate or sitaxentan sodium are given in parts 6 and 7 of the NOTE included in the iloprost trometamol, epoprostenol sodium, sildenafil citrate or sitaxentan sodium Schedule entry respectively.]

(a) Initiation of PBS-subsidised treatment with bosentan monohydrate, where the patient has not received prior PBS-subsidised treatment with iloprost trometamol, epoprostenol sodium, sildenafil citrate or sitaxentan sodium.

All applications for initial treatment must be made in writing, must include 2 separate authority prescriptions and must be submitted to Medicare Australia for authorisation. The total duration of initial PBS-subsidised treatment that will be approved with this first written application is up to 6 months.

Approvals for the first authority prescription will be limited to 1 month of therapy with the 62.5 mg strength tablet, with the quantity approved based on the dosage recommendations in the Therapeutic Goods Administration (TGA)-approved Product Information. No repeats will be authorised for this prescription. The second authority prescription may be written for either the 62.5 mg tablet or the 125 mg tablet strengths. Where the 62.5 mg tablet strength is required, please contact Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) for further advice. Approvals for the second authority prescription will be limited to 1 month of treatment, with the quantity approved based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 4 repeats. The approved second authority prescription will be returned to the prescriber by Medicare Australia 2 weeks after the date of the approval of the first authority prescription, to allow for the uninterrupted completion of the 6 month initial treatment course. Medicare Australia will contact prescribers prior to dispatch of the second authority prescription to confirm the tablet strength required for the patient.

(b) Continuation of treatment.

Written applications for continuing treatment must be submitted to Medicare Australia for authorisation every 6 months. Approvals will be limited to provide sufficient supply for up to a maximum of 6 months of treatment, based on the dosage recommendations in the TGA-approved Product Information.

Applications for continuing treatment will only be approved for patients who have currently demonstrated a response to treatment with bosentan monohydrate.

The assessment of the patient's response to the first and subsequent 6 month courses of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated. Applications for continuing treatment with bosentan monohydrate should be made prior to the completion of the 6 month treatment course to ensure continuity for those patients who respond to treatment, as assessed by the treating physician.

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer \$	Proprietary Name and Manufacturer

(c) Swapping between bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate and sitaxentan sodium.

For eligible patients, applications to swap between these 5 drugs must be made under the relevant initial treatment restriction. Patients should be assessed for response to the treatment they are ceasing at the time the application to swap therapy is being made. Patients who fail to demonstrate a response or for whom no assessment results are submitted with the application to swap therapy may not re-commence PBS-subsidised treatment with the drug they are ceasing.

It is important that patients are assessed for response to every course of treatment approved within the timeframes specified in the relevant restriction, in order to maximise the choice of treatment.

To avoid confusion, applications for patients who wish to swap to an alternate treatment should be accompanied by the previously approved authority prescription, or remaining repeats, for the treatment the patient is ceasing.

(d) Cessation of treatment.

Patients who fail to demonstrate a response to PBS-subsidised bosentan monohydrate treatment at the times where an assessment is required must cease PBS-subsidised bosentan monohydrate therapy.

For patients ceasing treatment, approval will only be granted to provide sufficient supply of the 62.5 mg tablet strength to allow gradual dose reduction over a period of no more than 1 month duration. Prescribers should telephone Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) to receive authorisation for this final supply and to ensure no unintended break in treatment occurs.

7. Re-treatment with bosentan monohydrate.

Patients who do not respond to treatment are not eligible to receive further PBS-subsidised treatment with bosentan monohydrate under any circumstances.

8. Further information.

A tabulated representation of the above information and the restriction can be obtained from the Medicare Australia website at www.medicareaustralia.gov.au.

Public and private hospital authority required

Initial (new adult patients)

Application for initial PBS-subsidised treatment with bosentan monohydrate of adult patients who have not received prior PBS-subsidised treatment with iloprost trometamol, epoprostenol sodium, sildenafil citrate or sitaxentan sodium and who have been assessed by a physician from a designated hospital to have:

(a) WHO Functional Class III primary pulmonary hypertension and a mean right atrial pressure of 8 mmHg or less, as measured by RHC, unless a RHC is contraindicated on clinical grounds; OR

(b) WHO Functional Class III pulmonary arterial hypertension secondary to scleroderma and a mean right atrial pressure of 8 mmHg or less, as measured by RHC, unless a RHC is contraindicated on clinical grounds.

Patients must have failed to respond [see Note for definition of response] to 6 or more weeks of appropriate vasodilator treatment unless intolerance or a contraindication to such treatment exists.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted to Medicare Australia for consideration based on the test results of the ECHO composite assessment plus 6MWT or the ECHO composite assessment only.

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Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer \$	Proprietary Name and Manufacturer

Applications for authorisation must be in writing and must include:

- (1) two completed authority prescription forms [see Note for authority approval requirements]; and
 (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form [www.medicareaustralia.gov.au] which includes results from the 3 tests below, where available:

- (i) RHC composite assessment; and
 (ii) ECHO composite assessment; and
 (iii) 6MWT; and

(3) a signed patient acknowledgment indicating that the patient understands and acknowledges that PBS-subsidised treatment with bosentan monohydrate for primary pulmonary hypertension, pulmonary arterial hypertension secondary to scleroderma or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology), OR with iloprost trometamol for primary pulmonary hypertension, drug-induced pulmonary arterial hypertension or pulmonary arterial hypertension secondary to connective tissue disease, OR with epoprostenol sodium for primary pulmonary hypertension, OR with sildenafil citrate for primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, OR with sitaxentan sodium for primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, will cease if the treating physician determines that the patient has not achieved a response to treatment [see Note for definition of response].

Details of prior vasodilator treatment, including the dose and duration of treatment, must be provided at the time of application. Where the patient has an adverse event to a vasodilator or where vasodilator treatment is contraindicated, details on the nature of the adverse event or contraindication according to the TGA-approved Product Information must also be provided with the application.

Where fewer than 3 tests (see requirement 2 above) are able to be performed on clinical grounds, a reason outlining why the particular test/s could not be conducted must be provided with the authority application [see Note for test requirements].

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. No repeats will be authorised for the first authority prescription issued under this criterion [see Note for full details of authority approval requirements]. A maximum of 4 repeats will be authorised for the second authority prescription issued under this criterion. Where fewer than 4 repeats are initially requested with the second authority prescription, authority approvals for sufficient repeats to complete a maximum of 6 months of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Public and private hospital authority required

Initial (new adult patients)

Application for initial PBS-subsidised treatment with bosentan monohydrate of adult patients who have not received prior PBS-subsidised treatment with iloprost trometamol, epoprostenol sodium, sildenafil citrate or sitaxentan sodium and who have been assessed by a physician from a designated hospital to have:

- (a) WHO Functional Class III primary pulmonary hypertension and a mean right atrial pressure greater than 8 mmHg, as measured by RHC, unless a RHC is contraindicated on clinical grounds; OR
 (b) WHO Functional Class III pulmonary arterial hypertension secondary to scleroderma and a mean right atrial pressure greater than 8 mmHg, as measured by RHC, unless a RHC is contraindicated on clinical grounds; OR
 (c) WHO Functional Class IV primary pulmonary hypertension; OR
 (d) WHO Functional Class IV pulmonary arterial hypertension secondary to scleroderma.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted to Medicare Australia for consideration based on the test results of the ECHO composite assessment plus 6MWT or the ECHO composite assessment only.

continued ➞

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer \$	Proprietary Name and Manufacturer

Applications for authorisation must be in writing and must include:

- (1) two completed authority prescription forms [see Note for authority approval requirements]; and
- (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form [www.medicareaustralia.gov.au] which includes results from the 3 tests below, where available:

- (i) RHC composite assessment; and
- (ii) ECHO composite assessment; and
- (iii) 6MWT; and

(3) a signed patient acknowledgment indicating that the patient understands and acknowledges that PBS-subsidised treatment with bosentan monohydrate for primary pulmonary hypertension, pulmonary arterial hypertension secondary to scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology), OR with iloprost trometamol for primary pulmonary hypertension, drug-induced pulmonary arterial hypertension or pulmonary arterial hypertension secondary to connective tissue disease, OR with epoprostenol sodium for primary pulmonary hypertension, OR with sildenafil citrate for primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, OR with sitaxentan sodium for primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, will cease if the treating physician determines that the patient has not achieved a response to treatment [see Note for definition of response].

Where fewer than 3 tests (see requirement 2 above) are able to be performed on clinical grounds, a reason outlining why the particular test/s could not be conducted must be provided with the authority application [see Note for test requirements].

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. No repeats will be authorised for the first authority prescription issued under this criterion [see Note for full details of authority approval requirements]. A maximum of 4 repeats will be authorised for the second authority prescription issued under this criterion. Where fewer than 4 repeats are initially requested with the second authority prescription, authority approvals for sufficient repeats to complete a maximum of 6 months of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Public and private hospital authority required

Initial (new patients under 18 years of age)

Application for initial PBS-subsidised treatment of patients aged less than 18 years who have not received prior PBS-subsidised treatment with epoprostenol sodium or sildenafil citrate and who have been assessed by a physician from a designated hospital to have:

WHO Functional Class III primary pulmonary hypertension and either a mean right atrial pressure of 8 mmHg or less, as measured by RHC, or, where a RHC cannot be performed on clinical grounds, normal right ventricular function as assessed by ECHO.

Patients must have failed to respond [see Note for definition of response] to 6 or more weeks of appropriate prior vasodilator treatment unless intolerance or a contraindication to such treatment exists.

Applications for authorisation must be in writing and must include:

- (1) two completed authority prescription forms [see Note for authority approval requirements]; and
- (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form [www.medicareaustralia.gov.au] which includes results from the 3 tests below, where available:

- (i) RHC composite assessment; and
- (ii) ECHO composite assessment; and
- (iii) 6MWT; and

(3) a patient acknowledgment, signed by the parent or authorised guardian, indicating that they understand and acknowledge that PBS-subsidised treatment with bosentan monohydrate, epoprostenol sodium or sildenafil citrate for primary pulmonary hypertension will cease if the treating physician determines that the patient has not achieved a response to treatment [see Note for definition of response].

Details of prior vasodilator treatment, including the dose and duration of treatment, must be provided at the time of application. Where the patient has an adverse event to a vasodilator or where vasodilator treatment is contraindicated, details on the nature of the adverse event or contraindication according to the TGA-approved Product Information must also be provided with the application.

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer \$	Proprietary Name and Manufacturer

Where fewer than 3 tests (see requirement 2 above) are able to be performed on clinical grounds, a reason outlining why the particular test/s could not be conducted must be provided with the authority application [see Note for test requirements].

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. No repeats will be authorised for the first authority prescription issued under this criterion [see Note for full details of authority approval requirements]. A maximum of 4 repeats will be authorised for the second authority prescription issued under this criterion. Where fewer than 4 repeats are initially requested with the second authority prescription, authority approvals for sufficient repeats to complete a maximum of 6 months of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Public and private hospital authority required

Initial (new patients under 18 years of age)

Application for initial PBS-subsidised treatment of patients aged less than 18 years who have not received prior PBS-subsidised treatment with epoprostenol sodium or sildenafil citrate and who have been assessed by a physician from a designated hospital to have:

- (a) WHO Functional Class III primary pulmonary hypertension and either a mean right atrial pressure greater than 8 mmHg, as measured by RHC, or, where a RHC cannot be performed on clinical grounds, right ventricular dysfunction as assessed by ECHO; OR
- (b) WHO Functional Class IV primary pulmonary hypertension.

Applications for authorisation must be in writing and must include:

- (1) two completed authority prescription forms [see Note for authority approval requirements]; and
- (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form [www.medicareaustralia.gov.au] which includes results from the 3 tests below, where available:
 - (i) RHC composite assessment; and
 - (ii) ECHO composite assessment; and
 - (iii) 6MWT; and
- (3) a patient acknowledgment, signed by the parent or authorised guardian, indicating that they understand and acknowledge that PBS-subsidised treatment with bosentan monohydrate, epoprostenol sodium or sildenafil citrate for primary pulmonary hypertension will cease if the treating physician determines that the patient has not achieved a response to treatment [see Note for definition of response].

Where fewer than 3 tests (see requirement 2 above) are able to be performed on clinical grounds, a reason outlining why the particular test/s could not be conducted must be provided with the authority application [see Note for test requirements].

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. No repeats will be authorised for the first authority prescription issued under this criterion [see Note for full details of authority approval requirements]. A maximum of 4 repeats will be authorised for the second authority prescription issued under this criterion. Where fewer than 4 repeats are initially requested with the second authority prescription, authority approvals for sufficient repeats to complete a maximum of 6 months of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Public and private hospital authority required

Initial (new patients)

Application for initial PBS-subsidised treatment with bosentan monohydrate of a patient who has been assessed by a physician from a designated hospital to have WHO Functional Class III or IV pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology).

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer \$	Proprietary Name and Manufacturer

Applications for authorisation must be in writing and must include:

(1) two completed authority prescription forms [see Note for authority approval requirements]; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form [www.medicareaustralia.gov.au] which includes results from the 3 tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6MWT; and

(3) a signed patient acknowledgment indicating that the patient understands and acknowledges that PBS-subsidised treatment with bosentan monohydrate for primary pulmonary hypertension, pulmonary arterial hypertension secondary to scleroderma or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology), OR with iloprost trometamol for primary pulmonary hypertension, drug-induced pulmonary arterial hypertension or pulmonary arterial hypertension secondary to connective tissue disease, OR with epoprostenol sodium for primary pulmonary hypertension, OR with sildenafil citrate for primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, OR with sitaxentan sodium for primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, will cease if the treating physician determines that the patient has not achieved a response to treatment [see Note for definition of response].

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted to Medicare Australia for consideration based on the test results of the ECHO composite assessment plus 6MWT or the ECHO composite assessment only.

Where fewer than 3 tests (see requirement 2 above) are able to be performed on clinical grounds, a reason outlining why the particular test/s could not be conducted must be provided with the authority application [see Note for test requirements].

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. No repeats will be authorised for the first authority prescription issued under this criterion [see Note for full details of authority approval requirements]. A maximum of 4 repeats will be authorised for the second authority prescription issued under this criterion. Where fewer than 4 repeats are initially requested with the second authority prescription, authority approvals for sufficient repeats to complete a maximum of 6 months of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Public and private hospital authority required

Initial (grandfather patients)

Application for initial PBS-subsidised treatment with bosentan monohydrate of a patient who was receiving treatment with bosentan monohydrate prior to 1 August 2008 and who has been assessed by a physician from a designated hospital to have pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology).

continued ➞

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer \$	Proprietary Name and Manufacturer

Applications for authorisation must be in writing and must include:

- (1) a completed authority prescription form [see Note for authority approval requirements]; and
- (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form [www.medicareaustralia.gov.au] which includes results from the 3 tests below, where available:

- (i) RHC composite assessment; and
- (ii) ECHO composite assessment; and
- (iii) 6MWT; and

(3) a signed patient acknowledgment indicating that the patient understands and acknowledges that PBS-subsidised treatment with bosentan monohydrate for primary pulmonary hypertension, pulmonary arterial hypertension secondary to scleroderma or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology), OR with iloprost trometamol for primary pulmonary hypertension, drug-induced pulmonary arterial hypertension or pulmonary arterial hypertension secondary to connective tissue disease, OR with epoprostenol sodium for primary pulmonary hypertension, OR with sildenafil citrate for primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, OR with sitaxentan sodium for primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, will cease if the treating physician determines that the patient has not achieved a response to treatment [see Note for definition of response].

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted to Medicare Australia for consideration based on the test results of the ECHO composite assessment plus 6MWT or the ECHO composite assessment only.

Where fewer than 3 tests (see requirement 2 above) are able to be performed on clinical grounds, a reason outlining why the particular test/s could not be conducted must be provided with the authority application [see Note for test requirements].

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. The number of repeats authorised will be dependent on the duration of prior bosentan monohydrate therapy. Where patients have received less than 6 months of non-PBS-subsidised treatment with bosentan monohydrate, sufficient repeats to allow the patient to complete a total of 6 months of combined PBS-subsidised and non-PBS-subsidised therapy may be requested. Where patients have received 6 months or more of non-PBS-subsidised treatment with bosentan monohydrate, a maximum of 5 repeats may be requested. Where fewer than the maximum allowable number of repeats are requested at the time of application, authority approvals for the remainder of the allowable repeats may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Public and private hospital authority required

Initial (change or re-commencement for adult patients)

Application for initial treatment with bosentan monohydrate of adult patients with either of the following:

- (a) primary pulmonary hypertension or pulmonary arterial hypertension secondary to scleroderma who wish to re-commence PBS-subsidised bosentan monohydrate after a break in therapy and who have demonstrated a response to their most recent course of PBS-subsidised treatment with bosentan monohydrate; OR
- (b) primary pulmonary hypertension or pulmonary arterial hypertension secondary to scleroderma and whose most recent course of PBS-subsidised treatment was with iloprost trometamol, sildenafil citrate or sitaxentan sodium; OR
- (c) primary pulmonary hypertension and whose most recent course of PBS-subsidised treatment was with epoprostenol sodium.

Applications for authorisation must be in writing and must include:

- (1) two completed authority prescription forms [see Note for authority approval requirements]; and
- (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form [www.medicareaustralia.gov.au] which includes the results on which approval for the first application for PBS-subsidised bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate or sitaxentan sodium, whichever was initiated first, was granted; and
- (3) the date of the first application for PBS-subsidised treatment with bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate or sitaxentan sodium, whichever was initiated first; and
- (4) the results of the patient's response to treatment with their last course of PBS-subsidised bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate or sitaxentan sodium.

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer \$	Proprietary Name and Manufacturer

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. No repeats will be authorised for the first authority prescription issued under this criterion [see Note for full details of authority approval requirements]. A maximum of 4 repeats will be authorised for the second authority prescription issued under this criterion. Where fewer than 4 repeats are initially requested with the second authority prescription, authority approvals for sufficient repeats to complete a maximum of 6 months of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Public and private hospital authority required

Initial (change or re-commencement for patients under 18 years of age)

Application for initial treatment with bosentan monohydrate of patients aged less than 18 years with either of the following:

(a) primary pulmonary hypertension who wish to re-commence PBS-subsidised bosentan monohydrate after a break in therapy and who have demonstrated a response to their most recent course of PBS-subsidised treatment with bosentan monohydrate; OR

(b) primary pulmonary hypertension and whose most recent course of PBS-subsidised treatment was with epoprostenol sodium or sildenafil citrate.

Applications for authorisation must be in writing and must include:

(1) two completed authority prescription forms [see Note for authority approval requirements]; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form [www.medicareaustralia.gov.au] which includes the results on which approval for the first application for PBS-subsidised bosentan monohydrate, epoprostenol sodium or sildenafil citrate, whichever was initiated first, was granted; and

(3) the date of the first application for PBS-subsidised treatment with bosentan monohydrate, epoprostenol sodium or sildenafil citrate, whichever was initiated first; and

(4) the results of the patient's response to treatment with their last course of PBS-subsidised bosentan monohydrate, epoprostenol sodium or sildenafil citrate.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. No repeats will be authorised for the first authority prescription issued under this criterion [see Note for full details of authority approval requirements]. A maximum of 4 repeats will be authorised for the second authority prescription issued under this criterion. Where fewer than 4 repeats are initially requested with the second authority prescription, authority approvals for sufficient repeats to complete a maximum of 6 months of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Public and private hospital authority required

Continuing treatment (all patients)

Continuing PBS-subsidised treatment with bosentan monohydrate of patients who have received approval for initial PBS-subsidised treatment with bosentan monohydrate and who have been assessed by a physician from a designated hospital to have achieved a response to their most recent course of bosentan monohydrate treatment [see Note for definition of response].

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form [www.medicareaustralia.gov.au] which includes results from the 3 tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6MWT.

Where fewer than 3 tests (see requirement 2 above) are able to be performed on clinical grounds, a reason outlining why the particular test/s could not be conducted must be provided with the authority application [see Note for test requirements].

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. A maximum of 5 repeats will be authorised.

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer \$	Proprietary Name and Manufacturer	

Where fewer than 5 repeats are initially requested under this criterion, authority approvals for sufficient repeats to complete a maximum of 6 months of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Public and private hospital authority required

Cessation of treatment (all patients)

Final PBS-subsidised supply for patients with WHO Functional Class III or IV primary pulmonary hypertension or WHO Functional Class III or IV pulmonary arterial hypertension secondary to scleroderma or WHO Functional Class III or IV pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology), who have not responded to bosentan monohydrate therapy [see Note for definition of response], to allow for gradual cessation of treatment.

Applications for authorisation under this criterion should be made on the telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) [see Note on authority approval requirements].

Approval will only be granted for the 62.5 mg tablet strength. The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment.

Under no circumstances will telephone approvals be granted for treatment that would extend the final treatment period beyond 1 month.

6429J	Tablet 62.5 mg (base)	60	4035.00	Tracleer	AT
6430K	Tablet 125 mg (base)	60	4035.00	Tracleer	AT

NOTE:

Special Pricing Arrangements apply.

CIDOFOVIR

Private hospital authority required

Treatment of cytomegalovirus retinitis in patients with AIDS.

6247T	Solution for I.V. infusion 375 mg (anhydrous) in 5 mL single use vial	1	900.00	Vistide	GI

CINACALCET HYDROCHLORIDE

Private hospital authority required

Management, including initiation and stabilisation, by a nephrologist, of a patient with chronic kidney disease on dialysis who has sustained secondary hyperparathyroidism with iPTH of at least 50 pmol per L, not responding to conventional therapy.

NOTE:

During the titration phase, intact PTH should be monitored 4 weekly (measured at least 12 hours post dose) and dose titrated until an appropriate iPTH concentration is achieved. During the titration phase, approval will be limited to sufficient supply for 4 weeks treatment at a time, with doses between 30 and 180 mg per day according to the patient's response and tolerability.

During the maintenance phase, approval will be limited to provide sufficient quantity for 4 weeks treatment up to a maximum of 6 months supply for doses between 30 and 180 mg per day according to the patient's response and tolerability. Intact PTH should be monitored quarterly (measured at least 12 hours post dose) and dose adjusted as necessary to maintain an appropriate iPTH concentration.

"Sustained" means the abnormality was detected on at least 2 blood samples collected over a period of 2 to 4 months.

Private hospital authority required

Management, including initiation and stabilisation, by a nephrologist, of a patient with chronic kidney disease on dialysis who has sustained secondary hyperparathyroidism with iPTH of at least 15 pmol per L and less than 50 pmol per L AND an (adjusted) serum calcium concentration at least 2.6 mmol per L, not responding to conventional treatment.

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer \$	Proprietary Name and Manufacturer	

NOTE:

During the titration phase, intact PTH should be monitored 4 weekly (measured at least 12 hours post dose) and dose titrated until an appropriate iPTH concentration is achieved. During the titration phase, approval will be limited to sufficient supply for 4 weeks treatment at a time, with doses between 30 and 180 mg per day according to the patient's response and tolerability.

During the maintenance phase, approval will be limited to provide sufficient quantity for 4 weeks treatment up to a maximum of 6 months supply for doses between 30 and 180 mg per day according to the patient's response and tolerability. Intact PTH should be monitored quarterly (measured at least 12 hours post dose) and dose adjusted as necessary to maintain an appropriate iPTH concentration.

"Sustained" means the abnormality was detected on at least 2 blood samples collected over a period of 2 to 4 months.

9625N	Tablet 30 mg (base)	28	296.86	Sensipar	AN
9626P	Tablet 60 mg (base)	28	593.72	Sensipar	AN
9627Q	Tablet 90 mg (base)	28	890.58	Sensipar	AN

CLARITHROMYCIN**Private hospital authority required**

Treatment of Mycobacterium avium complex infections.

6151R	Tablet 250 mg	100	36.12	Klacid	AB
6152T	Tablet 500 mg	100	72.24	Klacid	AB

CLOZAPINE**Private hospital authority required**

Schizophrenia in patients who are:

- (a) non-responsive to other neuroleptic agents; or*
- (b) intolerant of other neuroleptic agents.*

6101D	Tablet 25 mg	100	70.56	^a Clopine 25	HH
				^a Clozaril 25	NV
6417R	Tablet 50 mg	100	141.12	Clopine 50	HH
6102E	Tablet 100 mg	100	264.60	^a Clopine 100	HH
				^a Clozaril 100	NV
6418T	Tablet 200 mg	100	529.20	Clopine 200	HH
9632Y	Oral liquid 50 mg per mL, 100 mL	1	135.00	Clopine Suspension	HH

CYCLOSPORIN**CAUTION:**

Careful monitoring of patients is mandatory.

Private hospital authority required

Management of rejection in patients following organ or tissue transplantation, under the supervision and direction of a transplant unit. Management includes initiation, stabilisation and review of therapy as required;

Management (which includes initiation, stabilisation and review of therapy) by:

- (a) dermatologists or clinical immunologists of patients with severe atopic dermatitis for whom other systemic therapies are ineffective or inappropriate; or*
- (b) dermatologists of patients with severe psoriasis for whom other systemic therapies are ineffective or inappropriate and in whom the disease has caused significant interference with quality of life; or*

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer \$	Proprietary Name and Manufacturer	
	(c) nephrologists of patients with nephrotic syndrome in patients in whom steroids and cytostatic drugs have failed or are not tolerated or are considered inappropriate and in whom renal function is unimpaired; or (d) rheumatologists or clinical immunologists of patients with severe active rheumatoid arthritis for whom classical slow-acting anti-rheumatic agents (including methotrexate) are ineffective or inappropriate.				
6232B	Capsule 10 mg	60	37.20	Neoral 10	NV
6352H	Capsule 25 mg	30	40.80	^a Cicloral ^a Neoral 25	SZ NV
	NOTE: A brand premium of \$0.97 applies to Neoral 25 brand. Both brands may not be available in all hospitals.				
6353J	Capsule 50 mg	30	84.87	^a Cicloral ^a Neoral 50	SZ NV
	NOTE: A brand premium of \$1.05 applies to Neoral 50 brand. Both brands may not be available in all hospitals.				
6354K	Capsule 100 mg	30	172.92	^a Cicloral ^a Neoral 100	SZ NV
	NOTE: A brand premium of \$1.06 applies to Neoral 100 brand. Both brands may not be available in all hospitals.				
6125J	Oral liquid 100 mg per mL, 50 mL	1	315.79	Neoral	NV
	Private hospital authority required For use by organ or tissue transplant recipients.				
6109M	Solution concentrate for I.V. infusion 50 mg in 1 mL	10	54.10	Sandimmun	NV
	DARBEPOETIN ALFA Private hospital authority required Treatment of anaemia requiring transfusion, defined as a haemoglobin level of less than 100 g per L, where intrinsic renal disease, as assessed by a nephrologist, is the primary cause of the anaemia.				
6320P	Injection 10 micrograms in 0.4 mL pre-filled syringe	4	187.41	Aranesp	AN
6321Q	Injection 20 micrograms in 0.5 mL pre-filled syringe	4	352.96	Aranesp	AN
6488L	Injection 20 micrograms in 0.5 mL pre-filled injection pen	1	88.24	Aranesp SureClick	AN
6322R	Injection 30 micrograms in 0.3 mL pre-filled syringe	4	482.87	Aranesp	AN
6323T	Injection 40 micrograms in 0.4 mL pre-filled syringe	4	586.10	Aranesp	AN
6489M	Injection 40 micrograms in 0.4 mL pre-filled injection pen	1	146.53	Aranesp SureClick	AN
6324W	Injection 50 micrograms in 0.5 mL pre-filled syringe	4	724.62	Aranesp	AN
6325X	Injection 60 micrograms in 0.3 mL pre-filled syringe	4	850.87	Aranesp	AN
6490N	Injection 60 micrograms in 0.3 mL pre-filled injection pen	1	212.72	Aranesp SureClick	AN
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

continued ↻

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer \$	Proprietary Name and Manufacturer	

6365B	Injection 150 micrograms in 0.3 mL pre-filled syringe	4	2055.00	Aranesp	AN
6493R	Injection 150 micrograms in 0.3 mL pre-filled injection pen	1	513.75	Aranesp SureClick	AN

DARUNAVIR**Private hospital authority required**

Treatment, in combination with other antiretroviral agents, and co-administered with 100 mg ritonavir twice daily, of HIV infection in an antiretroviral experienced patient with:

- (a) evidence of HIV replication (viral load greater than 10,000 copies per mL); and/or
(b) CD4 cell counts of less than 500 per cubic millimetre.

A patient must have failed previous treatment with, or have resistance to, 3 different antiretroviral regimens which have included:

- (i) at least 1 non-nucleoside reverse transcriptase inhibitor; and
(ii) at least 1 nucleoside reverse transcriptase inhibitor; and
(iii) at least 2 protease inhibitors.

9616D	Tablet 300 mg (as ethanolate)	120	1101.38	Prezista	JC

DEFERASIROX**Private hospital authority required**

Chronic iron overload in adults, adolescents and children 6 years and older associated with disorders of erythropoiesis;

Chronic iron overload in paediatric patients aged 2 to 5 years, associated with disorders of erythropoiesis, who are intolerant to desferrioxamine or in whom desferrioxamine has proven ineffective.

6499C	Tablet 125 mg (dispersible)	28	233.58	Exjade	NV
6500D	Tablet 250 mg (dispersible)	28	467.15	Exjade	NV
9600G	Tablet 500 mg (dispersible)	28	934.30	Exjade	NV

NOTE:

Special Pricing Arrangements apply.

DEFERIPRONE**Private hospital authority required**

Iron overload in patients with thalassaemia major who are unable to take desferrioxamine therapy;

Iron overload in patients with thalassaemia major in whom desferrioxamine therapy has proven ineffective.

6416Q	Tablet 500 mg	100	450.56	Ferriprox	OA
9638G	Oral solution 100 mg per mL, 250 mL	1	225.28	Ferriprox	OA

DELAVIRDINE MESYLATE**Private hospital authority required**

Treatment of HIV infection in patients with:

- (a) CD4 cell counts of less than 500 per cubic millimetre; or
(b) viral load of greater than 10,000 copies per mL.

6243N	Tablet 100 mg	360	271.58	Rescriptor	PF

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer \$	Proprietary Name and Manufacturer	
DEFERRIOXAMINE MESYLATE					
<u>Private hospital authority required</u>					
<i>Disorders of erythropoiesis associated with treatment-related chronic iron overload.</i>					
6113R	Powder for injection 500 mg	10	97.02	^a HH ^a Desferal 500 mg	NV
<u>NOTE:</u>					
<i>A brand premium of \$8.03 applies to Desferal 500 mg brand. Both brands may not be available in all hospitals.</i>					
6270B	Powder for injection 2 g	1	38.81	^a HH ^a Desferal 2 g	NV
<u>NOTE:</u>					
<i>A brand premium of \$0.39 applies to Desferal 2 g brand. Both brands may not be available in all hospitals.</i>					
DIDANOSINE					
<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>					
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					
<u>Private hospital authority required</u>					
<i>Treatment of hypercalcaemia of malignancy refractory to anti-neoplastic therapy.</i>					
6286W	Concentrated injection 15 mg in 5 mL	1	55.75	^a Pamisol	HH
6290C	Injection set containing 4 vials powder for I.V. infusion 15 mg and 4 ampoules solvent 5 mL	1	223.02	^a Aredia 15 mg	NV
<u>NOTE:</u>					
<i>The concentrated injection 15 mg and powder for I.V. infusion 15 mg (after reconstitution) are bioequivalent.</i>					
6287X	Concentrated injection 30 mg in 10 mL	1	111.51	^a Pamisol	HH
6279L	Injection set containing 2 vials powder for I.V. infusion 30 mg and 2 ampoules solvent 10 mL	1	223.02	^a Aredia 30 mg	NV
<u>NOTE:</u>					
<i>The concentrated injection 30 mg and powder for I.V. infusion 30 mg (after reconstitution) are bioequivalent.</i>					
6288Y	Concentrated injection 60 mg in 10 mL	1	223.02	Pamisol	HH

continued ➞

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer \$	Proprietary Name and Manufacturer	
<u>Private hospital authority required</u>					
<i>Treatment of hypercalcaemia of malignancy refractory to anti-neoplastic therapy.</i>					
<u>Private hospital authority required</u>					
<i>Multiple myeloma;</i>					
<i>Bone metastases from breast cancer.</i>					
6289B	Concentrated injection 90 mg in 10 mL	1	334.53	^a Pamisol	HH
6223M	Injection set containing 1 vial powder for I.V. infusion 90 mg and 1 ampoule solvent 10 mL	1	334.53	^a Aredia 90 mg	NV

NOTE:

The concentrated injection 90 mg and powder for I.V. infusion 90 mg (after reconstitution) are bioequivalent.

DORNASE ALFA**Private hospital authority required**

Use by cystic fibrosis patients who satisfy all of the following criteria:

- (1) are 5 years of age or older;*
- (2) have a FVC greater than 40% predicted for age, gender and height;*
- (3) have evidence of chronic suppurative lung disease (cough and sputum most days of the week, or greater than 3 respiratory tract infections of more than 2 weeks' duration in any 12 months, or objective evidence of obstructive airways disease);*
- (4) are participating in a 4 week trial as detailed below or have achieved a 10% or greater improvement in FEV1 (compared to baseline established prior to dornase alfa treatment) after a 4 week trial.*

In order for patients to be eligible for participation in the HSD program, the following conditions must be met:

- (1) Patients must be assessed at cystic fibrosis clinics/centres which are under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis and the prescribing of dornase alfa under the HSD program is limited to such physicians. If attendance at such units is not possible because of geographical isolation, management (including prescribing) may be by specialist physician or paediatrician in consultation with such a unit;*
- (2) The measurement of lung function is to be conducted by independent (other than the treating doctor) experienced personnel at established lung function testing laboratories, unless this is not possible because of geographical isolation;*
- (3) Prior to dornase alfa therapy, a baseline measurement of FEV1 must be undertaken during a stable period of the disease;*
- (4) Initial therapy is limited to 4 weeks' treatment with dornase alfa at a dose of 2.5 mg daily;*
- (5) At or towards the end of the initial 4 weeks' trial, patients must be reassessed and a further FEV1 measurement be undertaken (single test under conditions as above). Patients who achieve a 10% or greater improvement in FEV1 (compared to baseline established prior to dornase alfa treatment) are eligible for continued subsidy under the HSD program at a dose of 2.5 mg daily;*
- (6) Patients who fail to meet a 10% or greater improvement in FEV1 after the initial 4 weeks' treatment at a dose of 2.5 mg daily, may have 1 further trial in the next 12 months but not before 3 months after the initial trial;*
- (7) Following an initial 6 months' therapy, a global assessment must be undertaken involving the patient, the patient's family (in the case of paediatric patients) and the treating physician(s) to establish that all agree that dornase alfa treatment is continuing to produce worthwhile benefits. (Dornase alfa therapy should cease if there is not general agreement of benefit as there is always the possibility of harm from unnecessary use.) Further reassessments are to be undertaken at six-monthly intervals;*
- (8) Other aspects of treatment, such as physiotherapy, must be continued;*
- (9) Where there is documented evidence that a patient already receiving dornase alfa therapy would have met the criteria for subsidy (i.e. satisfied the criteria for the 4 week trial and achieved a 10% or greater improvement in FEV1) then the patient is eligible to continue treatment under the HSD program. Where such evidence is not available, patients will need to satisfy the initiation and continuation criteria as for new patients. (Four weeks is considered a suitable wash-out period).*

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer \$	Proprietary Name and Manufacturer	
NOTE: <i>It is highly desirable that all patients be included in the national cystic fibrosis patient data-base.</i>					
6120D	Solution for inhalation 2.5 mg (2,500 units) in 2.5 mL	30	1180.00	Pulmozyme	RO
DOXORUBICIN HYDROCHLORIDE, PEGYLATED LIPOSOMAL					
Private hospital authority required <i>Treatment of AIDS-related Kaposi's sarcoma in patients with CD4 cell counts of less than 200 per cubic millimetre and:</i> <i>(a) extensive mucocutaneous involvement; or</i> <i>(b) extensive visceral involvement.</i>					
6249X	Suspension for I.V. infusion 20 mg in 10 mL	1	622.99	Caelyx	SH
EFAVIRENZ					
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>					
9618F	Tablet 200 mg	90	452.64	Stocrin	MK
6356M	Tablet 600 mg	30	452.64	Stocrin	MK
6372J	Oral solution 30 mg per mL, 180 mL	1	135.79	Stocrin	MK
NOTE: <i>Special Pricing Arrangements apply.</i>					
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>					
6137B	Capsule 200 mg	30	282.00	Emtriva	GI
ENFUVIRTIDE					
Private hospital authority required <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

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer \$	Proprietary Name and Manufacturer	
ENTECAVIR MONOHYDRATE					
<u>Private hospital authority required</u>					
<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)(a) Abnormal serum ALT levels in conjunction with documented chronic hepatitis B infection; or</i>					
<i>(b) Elevated HBV DNA levels in conjunction with documented chronic hepatitis B infection;</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>					

NOTE:

PBS-subsidised entecavir monohydrate must be used as monotherapy.

9602J	Tablet 0.5 mg	30	384.30	Baraclude	BQ

Private hospital authority required

Patients with chronic hepatitis B who have failed lamivudine therapy and who satisfy all of the following criteria:

(1)(a) Repeatedly elevated serum ALT levels while on concurrent antihepadnaviral therapy of greater than or equal to 6 months duration in conjunction with documented chronic hepatitis B infection; or

(b) Repeatedly elevated HBV DNA levels one log greater than the nadir value or failure to achieve a 1 log reduction in HBV DNA within 3 months, whilst on previous antihepadnaviral therapy except in patients with evidence of poor compliance;

(2) Female patients of child-bearing age are not pregnant, not breast-feeding, and are using an effective form of contraception.

Persons with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy.

NOTE:

Patients should have undergone a liver biopsy at some point since initial diagnosis to obtain histological evidence of chronic hepatitis.

PBS-subsidised entecavir monohydrate must be used as monotherapy.

9603K	Tablet 1 mg	30	625.00	Baraclude	BQ

EPOETIN ALFA**Private hospital authority required**

Treatment of anaemia requiring transfusion, defined as a haemoglobin level of less than 100 g per L, where intrinsic renal disease, as assessed by a nephrologist, is the primary cause of the anaemia.

6251B	Injection 1,000 units in 0.5 mL pre-filled syringe	6	147.00	Eprex 1000	JC
6204M	Injection 2,000 units in 0.5 mL pre-filled syringe	6	272.00	Eprex 2000	JC
6205N	Injection 3,000 units in 0.3 mL pre-filled syringe	6	351.00	Eprex 3000	JC
6206P	Injection 4,000 units in 0.4 mL pre-filled syringe	6	447.00	Eprex 4000	JC
6302Q	Injection 5,000 units in 0.5 mL pre-filled syringe	6	556.50	Eprex 5000	JC
6303R	Injection 6,000 units in 0.6 mL pre-filled syringe	6	660.60	Eprex 6000	JC
6305W	Injection 8,000 units in 0.8 mL pre-filled syringe	6	856.80	Eprex 8000	JC

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Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer \$	Proprietary Name and Manufacturer	
6207Q	Injection 10,000 units in 1 mL pre-filled syringe	6	1037.00	Eprex 10000	JC
6434P	Injection 20,000 units in 0.5 mL pre-filled syringe	6	2040.00	Eprex 20,000	JC
9623L	Injection 30,000 units in 0.75 mL pre-filled syringe	6	3015.00	Eprex 30,000	JC
6339P	Injection 40,000 units in 1 mL pre-filled syringe	1	660.00	Eprex 40,000	JC

EPOETIN BETA**Private hospital authority required**

Treatment of anaemia requiring transfusion, defined as a haemoglobin level of less than 100 g per L, where intrinsic renal disease, as assessed by a nephrologist, is the primary cause of the anaemia.

6479B	Injection 1,000 units in 0.3 mL pre-filled syringe	6	147.00	NeoRecormon	RO
6480C	Injection 2,000 units in 0.3 mL pre-filled syringe	6	272.00	NeoRecormon	RO
6481D	Injection 3,000 units in 0.3 mL pre-filled syringe	6	351.00	NeoRecormon	RO
6482E	Injection 4,000 units in 0.3 mL pre-filled syringe	6	447.00	NeoRecormon	RO
6483F	Injection 5,000 units in 0.3 mL pre-filled syringe	6	556.50	NeoRecormon	RO
6484G	Injection 6,000 units in 0.3 mL pre-filled syringe	6	660.60	NeoRecormon	RO
6485H	Injection 10,000 units in 0.6 mL pre-filled syringe	6	1037.00	NeoRecormon	RO
6486J	Injection 20,000 units in 0.6 mL pre-filled syringe	6	2040.00	NeoRecormon	RO
6487K	Injection 30,000 units in 0.6 mL pre-filled syringe	1	502.50	NeoRecormon	RO

EPOPROSTENOL SODIUM**NOTE:**

Any queries concerning the arrangements to prescribe epoprostenol sodium may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written applications for authority to prescribe epoprostenol sodium should be forwarded to:

Medicare Australia

Prior Written Approval of Specialised Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

NOTE:

Epoprostenol sodium is not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with scleroderma, where the total lung capacity is less than 70% of that predicted.

Epoprostenol sodium is not PBS-subsidised when used in combination with PBS-subsidised bosentan monohydrate, PBS-subsidised iloprost trometamol, PBS-subsidised sildenafil citrate or PBS-subsidised sitaxentan sodium.

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Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer \$	Proprietary Name and Manufacturer

The following provides some explanatory notes regarding the availability of PBS-subsidised treatment with:

(a) bosentan monohydrate, of primary pulmonary hypertension or pulmonary arterial hypertension secondary to scleroderma, in patients with disease of WHO Functional Class III or IV severity; AND

(b) iloprost trometamol, of primary pulmonary hypertension, drug-induced pulmonary arterial hypertension or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class III or IV severity; AND

(c) epoprostenol sodium, of primary pulmonary hypertension, in patients with disease of WHO Functional Class III or IV severity; AND

(d) sildenafil citrate, of primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class III severity; AND

(e) sitaxentan sodium, of primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class III severity.

Adult patients:

From 1 April 2008, adult patients with primary pulmonary hypertension will be able to access, through the PBS, bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate (WHO Class III only) or sitaxentan sodium (WHO Class III only). Once these patients are approved initial treatment with 1 of these 5 drugs, they may swap between bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate and sitaxentan sodium at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary. (New baselines may be submitted where the patient has failed to respond to their current treatment.)

Patients may only swap to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate or sitaxentan sodium if they have not failed prior PBS-subsidised treatment with that drug.

Adult patients with pulmonary arterial hypertension secondary to scleroderma will be able to access, through the PBS, bosentan monohydrate, iloprost trometamol, sildenafil citrate (WHO Class III only) or sitaxentan sodium (WHO Class III only). Once these patients are approved initial treatment with 1 of these 4 drugs, they may swap between bosentan monohydrate, iloprost trometamol, sildenafil citrate and sitaxentan sodium at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary. (New baselines may be submitted where the patient has failed to respond to their current treatment.)

Patients may only swap to bosentan monohydrate, iloprost trometamol, sildenafil citrate or sitaxentan sodium if they have not failed prior PBS-subsidised treatment with that drug.

Adult patients with pulmonary arterial hypertension secondary to connective tissue disease other than scleroderma will be able to access, through the PBS, iloprost trometamol, sildenafil citrate (WHO Class III only) or sitaxentan sodium (WHO Class III only). Once these patients are approved initial treatment with 1 of these 3 drugs, they may swap between iloprost trometamol, sildenafil citrate and sitaxentan sodium at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary. (New baselines may be submitted where the patient has failed to respond to their current treatment.)

Patients may only swap to iloprost trometamol, sildenafil citrate or sitaxentan sodium if they have not failed prior PBS-subsidised treatment with that drug.

Patients with drug-induced pulmonary arterial hypertension are only eligible for treatment with iloprost trometamol. They may not swap to bosentan monohydrate, epoprostenol sodium, sildenafil citrate or sitaxentan sodium.

continued ➡

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer \$	Proprietary Name and Manufacturer

Patients under 18 years of age:

From 1 April 2008, patients aged less than 18 years with primary pulmonary hypertension are eligible to receive PBS-subsidised treatment with bosentan monohydrate, epoprostenol sodium, iloprost trometamol, sildenafil citrate (WHO Class III only) or sitaxentan sodium (WHO Class III only). Once these patients are approved initial treatment with 1 of these 5 drugs, they may swap between bosentan monohydrate, epoprostenol sodium, iloprost trometamol, sildenafil citrate and sitaxentan sodium at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary. (New baselines may be submitted where the patient has failed to respond to their current treatment.)

Patients may only swap to bosentan monohydrate, epoprostenol sodium, iloprost trometamol, sildenafil citrate or sitaxentan sodium if they have not failed prior PBS-subsidised treatment with that drug.

1. Definition of primary pulmonary hypertension, drug-induced pulmonary arterial hypertension or pulmonary arterial hypertension secondary to connective tissue disease, including scleroderma.

Primary pulmonary hypertension, drug-induced pulmonary arterial hypertension or pulmonary arterial hypertension secondary to connective tissue disease, including scleroderma, are defined as follows:

- (i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary capillary wedge pressure (PCWP) less than 18 mmHg; or
- (ii) mPAP greater than 30 mmHg with exercise and PCWP less than 18 mmHg; or
- (iii) where a right heart catheter cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

2. Definition of WHO Functional Class III or IV disease severity.

(a) WHO Functional Class III disease severity is defined as follows:

Patients with pulmonary hypertension resulting in marked limitation of physical activity who are comfortable at rest and on ordinary physical activity experience dyspnoea or fatigue, chest pain or near syncope.

(b) WHO Functional Class IV disease severity is defined as follows:

Patients with the inability to carry out any physical activity without symptoms. These patients manifest signs of right heart failure. Dyspnoea and/or fatigue may even be present at rest. Discomfort is increased by any physical activity.

3. Designated hospitals.

Refer to the Medicare Australia website at www.medicareaustralia.gov.au for a list of designated hospitals.

4. Test requirements to establish baseline for initiation of treatment and response to treatment for continuation of treatment.

(a) Initiation of treatment.

The first written application for PBS-subsidised treatment with the first of either bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate or sitaxentan sodium should be accompanied by the results of a right heart catheter (RHC) composite assessment, plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements.

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.

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NOTE:

Where patients were initiated on PBS-subsidised treatment either with bosentan monohydrate on or after 1 March 2004, with iloprost trometamol on or after 1 April 2005, with epoprostenol sodium on or after 1 August 2006, with sildenafil citrate on or after 1 March 2007, with sitaxentan sodium on or after 1 April 2008, or with bosentan monohydrate (for PAH associated with congenital systemic-to-pulmonary shunt) on or after 1 August 2008, the test results provided with the initial application must be no more than 2 months old at the time of application. These results will form the baseline against which response assessments will be made.

Where patients received treatment with either bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate or sitaxentan sodium prior to being commenced on PBS-subsidised treatment with the first of either bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate or sitaxentan sodium, the test requirements above still apply. The results that will form the baseline against which response assessments will be made will be those measured at the time patients commenced non-PBS-subsidised treatment with either bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate or sitaxentan sodium, whichever of the 5 drugs the patient received first.

(b) Continuation of treatment.

The following list outlines the preferred test combination, in descending order, for the purposes of continuation of PBS-subsidised treatment:

- (1) RHC plus ECHO composite assessments plus 6MWT;
- (2) RHC plus ECHO composite assessments;
- (3) RHC composite assessment plus 6MWT;
- (4) ECHO composite assessment plus 6MWT;
- (5) RHC composite assessment only;
- (6) ECHO composite assessment only.

The results of the same tests as conducted at baseline should be provided with each written continuing treatment application (i.e. every 6 months), except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a reason why the test(s) could not be conducted must be provided with the application.

The test(s) results provided with the application for continuing treatment must be no more than 2 months old at the time of application.

5. Definition of response to epoprostenol sodium, bosentan monohydrate, iloprost trometamol, sildenafil citrate, sitaxentan sodium or prior vasodilator treatment.

For adult patients with 2 or more baseline tests, response to treatment is defined as 2 or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For adult patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For adult patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least 1 of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

6. Authority approval requirements. [The following 2 sections are only relevant to the PBS listing of epoprostenol sodium. The requirements specific to bosentan monohydrate, iloprost trometamol, sildenafil citrate and sitaxentan sodium are given in parts 6 and 7 of the NOTE included in the bosentan monohydrate, iloprost trometamol, sildenafil citrate and sitaxentan sodium Schedule entry respectively.]

(a) Initiation of PBS-subsidised treatment with epoprostenol sodium, where the patient has not received prior PBS-subsidised treatment with bosentan monohydrate, iloprost trometamol, sildenafil citrate or sitaxentan sodium. All applications for initial treatment must be made in writing, must include an authority prescription and must be submitted to Medicare Australia for authorisation. The total duration of initial PBS-subsidised treatment that will be approved with this first written application is up to 6 months, based on the dosage recommendations in the TGA-approved Product Information.

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(b) Continuation of treatment.

Written applications for continuing treatment must be submitted to Medicare Australia for authorisation every 6 months. Approvals will be limited to provide sufficient supply for up to a maximum of 6 months of treatment, based on the dosage recommendations in the TGA-approved Product Information.

Applications for continuing treatment will only be approved for patients who have currently demonstrated a response to treatment with epoprostenol sodium.

The assessment of the patient's response to the first and subsequent 6 month courses of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated. Applications for continuing treatment with epoprostenol sodium should be made prior to the completion of the 6 month treatment course to ensure continuity for those patients who respond to treatment, as assessed by the treating physician.

(c) Swapping between bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate and sitaxentan sodium.

For eligible patients, applications to swap between these 5 drugs must be made under the relevant initial treatment restriction. Patients should be assessed for response to the treatment they are ceasing at the time the application to swap therapy is being made. Patients who fail to demonstrate a response or for whom no assessment results are submitted with the application to swap therapy may not re-commence PBS-subsidised treatment with the drug they are ceasing.

It is important that patients are assessed for response to every course of treatment approved within the timeframes specified in the relevant restriction, in order to maximise the choice of treatment.

To avoid confusion, applications for patients who wish to swap to an alternate treatment should be accompanied by the previously approved authority prescription, or remaining repeats, for the treatment the patient is ceasing.

(d) Cessation of treatment.

Patients who fail to demonstrate a response to PBS-subsidised epoprostenol sodium treatment at the times where an assessment is required must cease PBS-subsidised epoprostenol sodium therapy.

7. Re-treatment with epoprostenol sodium.

Patients who do not respond to treatment are not eligible to receive further PBS-subsidised treatment with epoprostenol sodium under any circumstances.

8. Further information.

A tabulated representation of the above information and the restriction can be obtained from the Medicare Australia website at www.medicareaustralia.gov.au.

Public and private hospital authority required

Initial (new adult patients)

Application for initial PBS-subsidised treatment with epoprostenol sodium of adult patients who have not received prior PBS-subsidised treatment with bosentan monohydrate, iloprost trometamol, sildenafil citrate or sitaxentan sodium and who have been assessed by a physician from a designated hospital to have:

WHO Functional Class III primary pulmonary hypertension and a mean right atrial pressure of 8 mmHg or less, as measured by RHC, unless a RHC is contraindicated on clinical grounds.

Patients must have failed to respond [see Note for definition of response] to 6 or more weeks of appropriate vasodilator treatment unless intolerance or a contraindication to such treatment exists.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted to Medicare Australia for consideration based on the test results of the ECHO composite assessment plus 6MWT or the ECHO composite assessment only.

continued ➞

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer \$	Proprietary Name and Manufacturer

Applications for authorisation must be in writing and must include:

- (1) a completed authority prescription form [see Note for authority approval requirements]; and
 (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form [www.medicareaustralia.gov.au] which includes results from the 3 tests below, where available:

- (i) RHC composite assessment; and
 (ii) ECHO composite assessment; and
 (iii) 6MWT; and

(3) a signed patient acknowledgment indicating that the patient understands and acknowledges that PBS-subsidised treatment with epoprostenol sodium for primary pulmonary hypertension, OR with iloprost trometamol for primary pulmonary hypertension, drug-induced pulmonary arterial hypertension or pulmonary arterial hypertension secondary to connective tissue disease, OR with bosentan monohydrate for primary pulmonary hypertension or pulmonary arterial hypertension secondary to scleroderma, OR with sildenafil citrate for primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, OR with sitaxentan sodium for primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, will cease if the treating physician determines that the patient has not achieved a response to treatment [see Note for definition of response].

Details of prior vasodilator treatment, including the dose and duration of treatment, must be provided at the time of application. Where the patient has an adverse event to a vasodilator or where vasodilator treatment is contraindicated, details on the nature of the adverse event or contraindication according to the TGA-approved Product Information must also be provided with the application.

Where fewer than 3 tests (see requirement 2 above) are able to be performed on clinical grounds, a reason outlining why the particular test/s could not be conducted must be provided with the authority application [see Note for test requirements].

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. A maximum of 5 repeats may be requested. Where fewer than 5 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 6 months of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Public and private hospital authority required

Initial (new adult patients)

Application for initial PBS-subsidised treatment with epoprostenol sodium of adult patients who have not received prior PBS-subsidised treatment with bosentan monohydrate, iloprost trometamol, sildenafil citrate or sitaxentan sodium and who have been assessed by a physician from a designated hospital to have:

- (a) WHO Functional Class III primary pulmonary hypertension and a mean right atrial pressure greater than 8 mmHg, as measured by RHC, unless a RHC is contraindicated on clinical grounds; OR
 (b) WHO Functional Class IV primary pulmonary hypertension.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted to Medicare Australia for consideration based on the test results of the ECHO composite assessment plus 6MWT or the ECHO composite assessment only.

continued ➞

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer \$	Proprietary Name and Manufacturer

Applications for authorisation must be in writing and must include:

- (1) a completed authority prescription form [see Note for authority approval requirements]; and
- (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form [www.medicareaustralia.gov.au] which includes results from the 3 tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6MWT; and

(3) a signed patient acknowledgment indicating that the patient understands and acknowledges that PBS-subsidised treatment with epoprostenol sodium for primary pulmonary hypertension, OR with iloprost trometamol for primary pulmonary hypertension, drug-induced pulmonary arterial hypertension or pulmonary arterial hypertension secondary to connective tissue disease, OR with bosentan monohydrate for primary pulmonary hypertension or pulmonary arterial hypertension secondary to scleroderma, OR with sildenafil citrate for primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, OR with sitaxentan sodium for primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, will cease if the treating physician determines that the patient has not achieved a response to treatment [see Note for definition of response].

Where fewer than 3 tests (see requirement 2 above) are able to be performed on clinical grounds, a reason outlining why the particular test/s could not be conducted must be provided with the authority application [see Note for test requirements].

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. A maximum of 5 repeats may be requested. Where fewer than 5 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 6 months of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Public and private hospital authority required

Initial (new patients under 18 years of age)

Application for initial PBS-subsidised treatment of patients aged less than 18 years who have not received prior PBS-subsidised treatment with bosentan monohydrate or sildenafil citrate and who have been assessed by a physician from a designated hospital to have WHO Functional Class III primary pulmonary hypertension with a mean right atrial pressure of 8 mmHg or less, as measured by RHC, or, where a RHC cannot be performed on clinical grounds, normal right ventricular function as assessed by ECHO.

Patients must have failed to respond [see Note for definition of response] to 6 or more weeks of appropriate prior vasodilator treatment unless intolerance or a contraindication to such treatment exists.

Applications for authorisation must be in writing and must include:

- (1) a completed authority prescription form [see Note for authority approval requirements]; and
- (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form [www.medicareaustralia.gov.au] which includes results from the 3 tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6MWT; and

(3) a patient acknowledgment, signed by the parent or authorised guardian, indicating that they understand and acknowledge that PBS-subsidised treatment with epoprostenol sodium, bosentan monohydrate or sildenafil citrate for primary pulmonary hypertension will cease if the treating physician determines that the patient has not achieved a response to treatment [see Note for definition of response].

Details of prior vasodilator treatment, including the dose and duration of treatment, must be provided at the time of application. Where the patient has an adverse event to a vasodilator or where vasodilator treatment is contraindicated, details on the nature of the adverse event or contraindication according to the TGA-approved Product Information must also be provided with the application.

Where fewer than 3 tests (see requirement 2 above) are able to be performed on clinical grounds, a reason outlining why the particular test/s could not be conducted must be provided with the authority application [see Note for test requirements].

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer \$	Proprietary Name and Manufacturer

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. A maximum of 5 repeats will be authorised under this criterion. Where fewer than 5 repeats are initially requested, authority approvals for sufficient repeats to complete a maximum of 6 months of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Public and private hospital authority required

Initial (new patients under 18 years of age)

Application for initial PBS-subsidised treatment of patients aged less than 18 years who have not received prior PBS-subsidised treatment with bosentan monohydrate or sildenafil citrate and who have been assessed by a physician from a designated hospital to have:

- (a) WHO Functional Class III primary pulmonary hypertension and either a mean right atrial pressure greater than 8 mmHg, as measured by RHC, or, where a RHC cannot be performed on clinical grounds, right ventricular dysfunction as assessed by ECHO; OR*
- (b) WHO Functional Class IV primary pulmonary hypertension.*

Applications for authorisation must be in writing and must include:

- (1) a completed authority prescription form [see Note for authority approval requirements]; and*
- (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form [www.medicareaustralia.gov.au] which includes results from the 3 tests below, where available:*
 - (i) RHC composite assessment; and*
 - (ii) ECHO composite assessment; and*
 - (iii) 6MWT; and*
- (3) a patient acknowledgment, signed by the parent or authorised guardian, indicating that they understand and acknowledge that PBS-subsidised treatment with epoprostenol sodium, bosentan monohydrate or sildenafil citrate for primary pulmonary hypertension will cease if the treating physician determines that the patient has not achieved a response to treatment [see Note for definition of response].*

Where fewer than 3 tests (see requirement 2 above) are able to be performed on clinical grounds, a reason outlining why the particular test/s could not be conducted must be provided with the authority application [see Note for test requirements].

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. A maximum of 5 repeats will be authorised under this criterion. Where fewer than 5 repeats are initially requested, authority approvals for sufficient repeats to complete a maximum of 6 months of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Public and private hospital authority required

Initial (change or re-commencement for all adult patients)

Application for initial PBS-subsidised treatment with epoprostenol sodium of adult patients with either of the following:

- (a) primary pulmonary hypertension who wish to re-commence PBS-subsidised epoprostenol sodium after a break in therapy and who have demonstrated a response to their most recent course of PBS-subsidised treatment with epoprostenol sodium; OR*
- (b) primary pulmonary hypertension and whose most recent course of PBS-subsidised treatment was with bosentan monohydrate, iloprost trometamol, sildenafil citrate or sitaxentan sodium.*

Applications for authorisation must be in writing and must include:

- (1) a completed authority prescription form [see Note for authority approval requirements]; and*
- (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form [www.medicareaustralia.gov.au] which includes the results on which approval for the first application for PBS-subsidised epoprostenol sodium, iloprost trometamol, bosentan monohydrate, sildenafil citrate or sitaxentan sodium, whichever was initiated first, was granted; and*
- (3) the date of the first application for PBS-subsidised treatment with epoprostenol sodium, iloprost trometamol, bosentan monohydrate, sildenafil citrate or sitaxentan sodium, whichever was initiated first; and*
- (4) the results of the patient's response to treatment with their last course of PBS-subsidised epoprostenol sodium, iloprost trometamol, bosentan monohydrate, sildenafil citrate or sitaxentan sodium.*

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer \$	Proprietary Name and Manufacturer	
	<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>Initial (change or re-commencement for all patients under 18 years of age)</i> <i>Application for initial PBS-subsidised treatment with epoprostenol sodium of patients aged less than 18 years with either of the following:</i> <i>(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</i> <i>(b) primary pulmonary hypertension and whose most recent course of PBS-subsidised treatment was with bosentan monohydrate or sildenafil citrate.</i> <i>Applications for authorisation must be in writing and must include:</i> <i>(1) a completed authority prescription form [see Note for authority approval requirements]; and</i> <i>(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form [www.medicareaustralia.gov.au] which includes the results on which approval for the first application for PBS-subsidised epoprostenol sodium, bosentan monohydrate or sildenafil citrate, whichever was initiated first, was granted; and</i> <i>(3) the date of the first application for PBS-subsidised treatment with epoprostenol sodium, bosentan monohydrate or sildenafil citrate, whichever was initiated first; and</i> <i>(4) the results of the patient's response to treatment with their last course of PBS-subsidised epoprostenol sodium, bosentan monohydrate or sildenafil citrate.</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> Public and private hospital authority required <i>Continuing treatment (all patients)</i> <i>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].</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 [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>				
6477X	Powder for I.V. infusion 500 micrograms (base) with diluent	1	41.69	Flolan	GK
continued ➞					

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer \$	Proprietary Name and Manufacturer	
6478Y	Powder for I.V. infusion 1.5 mg (base) with diluent	1	83.37	Flolan	GK

ETANERCEPT**NOTE:**

Any queries concerning the arrangements to prescribe etanercept may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe etanercept should be forwarded to:

Medicare Australia

Prior Written Approval of Specialised Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

Public and private hospital authority required

Initial treatment by a paediatric rheumatologist, or under the supervision of a paediatric rheumatology treatment centre, of patients under 18 years who have severe active polyarticular course juvenile chronic arthritis; AND
(a) whose parent or authorised guardian has signed a patient agreement form indicating that they understand and acknowledge that PBS-subsidised treatment will cease if the predetermined response criteria do not support continuation of PBS-subsidised treatment; AND

(b) who have demonstrated either:

(i) severe intolerance of, or toxicity due to, methotrexate (see below for definition of severe intolerance and toxicity); or

(ii) failure to achieve an adequate response to 1 or more of the following treatment regimens:

— oral or parenteral methotrexate at a dose of at least 20 mg per square metre weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; or

— oral methotrexate at a dose of at least 10 mg per square metre weekly together with at least 1 other DMARD, alone or in combination with corticosteroids, for a minimum of 3 months. (Note: use of alternative DMARDs in children is dependent on approval by the Therapeutic Goods Administration as age restrictions may apply.)

Severe intolerance is defined as intractable nausea and vomiting and general malaise unresponsive to manoeuvres, including reducing or omitting concomitant NSAIDs on the day of methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses over 24 hours.

Toxicity is defined as evidence of hepatotoxicity with repeated elevations of transaminases, bone marrow suppression temporally related to methotrexate use, pneumonitis, or serious sepsis.

The following criteria must be met in order to demonstrate failure to achieve an adequate response to either of the above treatment regimens:

(a) an active joint count of at least 20 active (swollen and tender) joints; OR

(b) at least 4 active joints from the following list:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

If treatment with methotrexate alone or in combination with another DMARD is contraindicated according to the relevant TGA-approved Product Information, or intolerance develops during the period of use such that permanent withdrawal is necessary and a suitably effective treatment regimen cannot be implemented, this exempts the requirement to demonstrate an inadequate response within the time period specified above for these agents.

The authority application must be in writing and must include the information used to determine the patient's eligibility under the criteria above. The date of the joint assessment must be provided.

Only 16 weeks of treatment will be approved. The assessment of the patient's response to initial treatment should be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated.

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer \$	Proprietary Name and Manufacturer	
	<u>Public and private hospital authority required</u> <i>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</i> <i>(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</i> <i>(b) who have demonstrated a response as specified in the criteria for continuing PBS-subsidised treatment with etanercept.</i> <i>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.</i> <i>Only 6 months of treatment will be approved.</i> <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; OR</i> <i>(b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; OR</i> <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	WX

continued ➞

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer \$	Proprietary Name and Manufacturer	

Public and private hospital authority required

Continuing PBS-subsidised treatment by a rheumatologist, or under the supervision of a paediatric rheumatology treatment centre, of severe active polyarticular course juvenile chronic arthritis in patients 18 years or older who have demonstrated an adequate response to treatment with etanercept as manifested by:

- (a) an active joint count of fewer than 10 active (swollen and tender) joints; OR*
- (b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; OR*
- (c) a reduction in the number of the following active joints, from at least 4, by at least 50%:*
 - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or*
 - (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).*

All authority applications for continuing treatment with etanercept must be in writing and must include sufficient information to determine the patient's response according to the above criteria. The date of the joint assessment must be provided.

Only 6 months of treatment per application will be approved. Applications for continuing treatment with etanercept should be made prior to the completion of 16 weeks of treatment to ensure continuity for those patients who meet the criteria.

Patients who fail to demonstrate an adequate response, as specified in the criteria for continuing treatment with etanercept, will not be eligible to recommence treatment with etanercept within 12 months of the date on which treatment was ceased.

Withdrawal of treatment with etanercept should be considered in patients who have achieved and sustained complete remission of disease for 12 months. Subsequent applications for PBS-subsidised re-treatment with etanercept will be subject to the authority conditions applying to initial treatment and will not be authorised within 12 months of the date on which treatment with etanercept was ceased.

Where re-treatment with etanercept after a break in PBS-subsidised treatment with the drug is being sought, the reason for and date of cessation of the previous treatment course with etanercept must be included in the application.

Where a patient with severe active polyarticular course juvenile chronic arthritis continues treatment with etanercept and is 18 years or older, etanercept 50 mg may be prescribed.

9615C	Injections 50 mg in 1 mL single use pre-filled syringes, 4	1	1630.01	Enbrel	WX

EVEROLIMUS

CAUTION:

Careful monitoring of patients is mandatory.

Private hospital authority required

Management of rejection, under the supervision and direction of a transplant unit, in patients receiving this drug for:

- (a) prophylaxis of renal allograft rejection. Management includes initiation, stabilisation and review of therapy as required; or*
- (b) prophylaxis of cardiac allograft rejection. Management includes initiation, stabilisation and review of therapy as required.*

6459Y	Tablet 0.25 mg	60	240.30	Certican	NV
6460B	Tablet 0.5 mg	60	480.60	Certican	NV
6461C	Tablet 0.75 mg	60	720.90	Certican	NV

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer \$	Proprietary Name and Manufacturer

FILGRASTIM

Private hospital authority required

For use in a patient undergoing induction and consolidation therapy for acute myeloid leukaemia;

Mobilisation of peripheral blood progenitor cells to facilitate harvest of such cells for autologous transplantation into a patient with a non-myeloid malignancy who has had myeloablative or myelosuppressive therapy;

Mobilisation of peripheral blood progenitor cells, in a normal volunteer, for use in allogeneic transplantation;

A patient receiving marrow-ablative chemotherapy and subsequent bone marrow transplantation;

A patient with a non-myeloid malignancy receiving marrow-ablative chemotherapy and subsequent autologous peripheral blood progenitor cell transplantation;

A patient with breast cancer receiving standard dose adjuvant chemotherapy who has had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned;

A patient receiving chemotherapy for B-cell chronic lymphocytic leukaemia with fludarabine and cyclophosphamide who has had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned;

A patient receiving first-line chemotherapy for Hodgkin disease who has had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned;

A patient receiving chemotherapy for myeloma who has had a prior episode of febrile neutropenia, and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned;

A patient with severe congenital neutropenia (absolute neutrophil count of less than 100 million cells per litre measured on 3 occasions, with readings at least 2 weeks apart, and in whom a bone marrow examination has shown evidence of maturational arrest of the neutrophil lineage);

A patient with severe chronic neutropenia (absolute neutrophil count of less than 1,000 million cells per litre measured on 3 occasions, with readings at least 2 weeks apart, or evidence of neutrophil dysfunction, and, either having experienced a life-threatening infectious episode requiring hospitalisation and treatment with intravenous antibiotics in the previous 12 months, or having recurrent clinically significant infections (a minimum of 3 in the previous 12 months));

A patient with chronic cyclic neutropenia (absolute neutrophil count of less than 500 million cells per litre lasting for 3 days per cycle, measured over 3 separate cycles, and, either having experienced a life-threatening infectious episode requiring hospitalisation and treatment with intravenous antibiotics, or having recurrent clinically significant infections (a minimum of 3 in the previous 12 months)).

Private hospital authority required

A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in:

- (a) acute lymphoblastic leukaemia; or*
- (b) breast cancer (adjuvant chemotherapy with docetaxel in combination with an anthracycline and cyclophosphamide); or*
- (c) germ cell tumours; or*
- (d) infants and children with CNS tumours; or*
- (e) neuroblastoma; or*
- (f) non-Hodgkin lymphoma (aggressive grades; or low grade receiving an anthracycline-containing regimen); or*

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer \$	Proprietary Name and Manufacturer	
	(g) relapsed Hodgkin disease; or (h) sarcoma.				
6126K	Injection 300 micrograms in 1 mL	10	1504.00	Neupogen	AN
6291D	Injection 300 micrograms in 0.5 mL single use pre-filled syringe	10	1504.00	Neupogen	AN
6127L	Injection 480 micrograms in 1.6 mL	10	2407.00	Neupogen	AN
6292E	Injection 480 micrograms in 0.5 mL single use pre-filled syringe	10	2407.00	Neupogen	AN
FOSAMPRENAVIR CALCIUM					
	<u>Private hospital authority required</u>				
	Treatment, in combination with 2 or more other antiretroviral drugs, of HIV infection in patients with:				
	(a) CD4 cell counts of less than 500 per cubic millimetre; or				
	(b) viral load of greater than 10,000 copies per mL.				
6453P	Tablet 700 mg (base)	60	568.74	Telzir	GK
	<u>NOTE:</u>				
	Special Pricing Arrangements apply.				
6454Q	Oral liquid 50 mg (base) per mL, 225 mL	1	101.56	Telzir	GK
FOSCARNET SODIUM					
	<u>Private hospital authority required</u>				
	Treatment of cytomegalovirus retinitis in patients with AIDS;				
	Treatment of aciclovir-resistant herpes simplex virus infection in immunocompromised patients with HIV infection.				
6134W	I.V. infusion 24 mg per mL, 250 mL	6	395.00	Foscavir	AP
GANCICLOVIR					
	<u>Private hospital authority required</u>				
	Cytomegalovirus retinitis in severely immunocompromised patients.				
6256G	Intravitreal implant 4.5 mg	1	6000.00	Vitraser	BU
GANCICLOVIR SODIUM					
	<u>Private hospital authority required</u>				
	Cytomegalovirus retinitis in severely immunocompromised patients;				
	Prophylaxis of cytomegalovirus disease in bone marrow transplant patients at risk of cytomegalovirus disease;				
	Prophylaxis of cytomegalovirus disease in solid organ transplant patients at risk of cytomegalovirus disease.				
6136Y	Powder for I.V. infusion equivalent to 500 mg ganciclovir	5	280.00	Cymevene	RO
IBANDRONIC ACID					
	<u>Private hospital authority required</u>				
	Bone metastases from breast cancer.				
9619G	Concentrated injection for I.V. infusion 6 mg (as ibandronate sodium monohydrate) in 6 mL	1	341.36	Bondronat	HH

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer \$	Proprietary Name and Manufacturer

ILOPROST TROMETAMOL**NOTE:**

Any queries concerning the arrangements to prescribe iloprost trometamol may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written applications for authority to prescribe iloprost trometamol should be forwarded to:

Medicare Australia

Prior Written Approval of Specialised Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

NOTE:

Iloprost trometamol is not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with scleroderma, where the total lung capacity is less than 70% of that predicted.

Iloprost trometamol is not PBS-subsidised when used in combination with PBS-subsidised bosentan monohydrate, PBS-subsidised epoprostenol sodium, PBS-subsidised sildenafil citrate or PBS-subsidised sitaxentan sodium.

The following provides some explanatory notes regarding the availability of PBS-subsidised treatment with:

- (a) bosentan monohydrate, of primary pulmonary hypertension or pulmonary arterial hypertension secondary to scleroderma, in patients with disease of WHO Functional Class III or IV severity; AND*
- (b) iloprost trometamol, of primary pulmonary hypertension, drug-induced pulmonary arterial hypertension or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class III or IV severity; AND*
- (c) epoprostenol sodium, of primary pulmonary hypertension, in patients with disease of WHO Functional Class III or IV severity; AND*
- (d) sildenafil citrate, of primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class III severity; AND*
- (e) sitaxentan sodium, of primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class III severity.*

Adult patients:

From 1 April 2008, adult patients with primary pulmonary hypertension will be able to access, through the PBS, bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate (WHO Class III only) or sitaxentan sodium (WHO Class III only). Once these patients are approved initial treatment with 1 of these 5 drugs, they may swap between bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate and sitaxentan sodium at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary. (New baselines may be submitted where the patient has failed to respond to their current treatment.)

Patients may only swap to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate or sitaxentan sodium if they have not failed prior PBS-subsidised treatment with that drug.

Adult patients with pulmonary arterial hypertension secondary to scleroderma will be able to access, through the PBS, bosentan monohydrate, iloprost trometamol, sildenafil citrate (WHO Class III only) or sitaxentan sodium (WHO Class III only). Once these patients are approved initial treatment with 1 of these 4 drugs, they may swap between bosentan monohydrate, iloprost trometamol, sildenafil citrate and sitaxentan sodium at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary. (New baselines may be submitted where the patient has failed to respond to their current treatment.)

Patients may only swap to bosentan monohydrate, iloprost trometamol, sildenafil citrate or sitaxentan sodium if they have not failed prior PBS-subsidised treatment with that drug.

continued ➞

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer \$	Proprietary Name and Manufacturer

Adult patients with pulmonary arterial hypertension secondary to connective tissue disease other than scleroderma will be able to access, through the PBS, iloprost trometamol, sildenafil citrate (WHO Class III only) or sitaxentan sodium (WHO Class III only). Once these patients are approved initial treatment with 1 of these 3 drugs, they may swap between iloprost trometamol, sildenafil citrate and sitaxentan sodium at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary. (New baselines may be submitted where the patient has failed to respond to their current treatment.)

Patients may only swap to iloprost trometamol, sildenafil citrate or sitaxentan sodium if they have not failed prior PBS-subsidised treatment with that drug.

Patients with drug-induced pulmonary arterial hypertension are only eligible for treatment with iloprost trometamol. They may not swap to bosentan monohydrate, epoprostenol sodium, sildenafil citrate or sitaxentan sodium.

Patients under 18 years of age:

From 1 April 2008, patients aged less than 18 years with primary pulmonary hypertension are eligible to receive PBS-subsidised treatment with bosentan monohydrate, epoprostenol sodium, iloprost trometamol, sildenafil citrate (WHO Class III only) or sitaxentan sodium (WHO Class III only). Once these patients are approved initial treatment with 1 of these 5 drugs, they may swap between bosentan monohydrate, epoprostenol sodium, iloprost trometamol, sildenafil citrate and sitaxentan sodium at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary. (New baselines may be submitted where the patient has failed to respond to their current treatment.)

Patients may only swap to bosentan monohydrate, epoprostenol sodium, iloprost trometamol, sildenafil citrate or sitaxentan sodium if they have not failed prior PBS-subsidised treatment with that drug.

1. Definition of primary pulmonary hypertension, drug-induced pulmonary arterial hypertension or pulmonary arterial hypertension secondary to connective tissue disease, including scleroderma.

Primary pulmonary hypertension, drug-induced pulmonary arterial hypertension or pulmonary arterial hypertension secondary to connective tissue disease, including scleroderma, are defined as follows:

- (i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary capillary wedge pressure (PCWP) less than 18 mmHg; or*
- (ii) mPAP greater than 30 mmHg with exercise and PCWP less than 18 mmHg; or*
- (iii) where a right heart catheter cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.*

2. Definition of WHO Functional Class III or IV disease severity.

(a) WHO Functional Class III disease severity is defined as follows:

Patients with pulmonary hypertension resulting in marked limitation of physical activity who are comfortable at rest and on ordinary physical activity experience dyspnoea or fatigue, chest pain or near syncope.

(b) WHO Functional Class IV disease severity is defined as follows:

Patients with the inability to carry out any physical activity without symptoms. These patients manifest signs of right heart failure. Dyspnoea and/or fatigue may even be present at rest. Discomfort is increased by any physical activity.

3. Designated hospitals.

Refer to the Medicare Australia website at www.medicareaustralia.gov.au for a list of designated hospitals.

4. Test requirements to establish baseline for initiation of treatment and response to treatment for continuation of treatment.

(a) Initiation of treatment.

The first written application for PBS-subsidised treatment with the first of either bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate or sitaxentan sodium should be accompanied by the results of a right heart catheter (RHC) composite assessment, plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements.

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Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

- (1) RHC plus ECHO composite assessments;*
- (2) RHC composite assessment plus 6MWT;*
- (3) RHC composite assessment only.*

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted to Medicare Australia for consideration based on the results of the following test combinations, which are listed in descending order of preference:

- (1) ECHO composite assessment plus 6MWT;*
- (2) ECHO composite assessment only.*

Where fewer than 3 tests are able to be performed on clinical grounds, a reason outlining why the particular test/s could not be conducted must be provided with the authority application.

NOTE:

Where patients were initiated on PBS-subsidised treatment either with bosentan monohydrate on or after 1 March 2004, with iloprost trometamol on or after 1 April 2005, with epoprostenol sodium on or after 1 August 2006, with sildenafil citrate on or after 1 March 2007, with sitaxentan sodium on or after 1 April 2008, or with bosentan monohydrate (for PAH associated with congenital systemic-to-pulmonary shunt) on or after 1 August 2008, the test results provided with the initial application must be no more than 2 months old at the time of application. These results will form the baseline against which response assessments will be made.

Where patients received treatment with either bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate or sitaxentan sodium prior to being commenced on PBS-subsidised treatment with the first of either bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate or sitaxentan sodium, the test requirements above still apply. The results that will form the baseline against which response assessments will be made will be those measured at the time patients commenced non-PBS-subsidised treatment with either bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate or sitaxentan sodium, whichever of the 5 drugs the patient received first.

(b) Continuation of treatment.

The following list outlines the preferred test combination, in descending order, for the purposes of continuation of PBS-subsidised treatment:

- (1) RHC plus ECHO composite assessments plus 6MWT;*
- (2) RHC plus ECHO composite assessments;*
- (3) RHC composite assessment plus 6MWT;*
- (4) ECHO composite assessment plus 6MWT;*
- (5) RHC composite assessment only;*
- (6) ECHO composite assessment only.*

The results of the same tests as conducted at baseline should be provided with each written continuing treatment application (i.e. every 6 months), except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a reason why the test(s) could not be conducted must be provided with the application.

The test(s) results provided with the application for continuing treatment must be no more than 2 months old at the time of application.

5. Definition of response to iloprost trometamol, bosentan monohydrate, epoprostenol sodium, sildenafil citrate, sitaxentan sodium or prior vasodilator treatment.

For adult patients with 2 or more baseline tests, response to treatment is defined as 2 or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For adult patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For adult patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

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6. Authority approval requirements. [The following 2 sections are only relevant to the PBS listing of iloprost trometamol. The requirements specific to bosentan monohydrate, epoprostenol sodium, sildenafil citrate and sitaxentan sodium are given in parts 6 and 7 of the NOTE included in the bosentan monohydrate, epoprostenol sodium, sildenafil citrate and sitaxentan sodium Schedule entry respectively.]

(a) Initiation of PBS-subsidised treatment with iloprost trometamol, where the patient has not received prior PBS-subsidised treatment with bosentan monohydrate, epoprostenol sodium, sildenafil citrate or sitaxentan sodium. All applications for initial treatment must be made in writing, must include an authority prescription and must be submitted to Medicare Australia for authorisation. The total duration of initial PBS-subsidised treatment that will be approved with this first written application is up to 6 months, based on the dosage recommendations in the TGA-approved Product Information.

(b) Continuation of treatment.

Written applications for continuing treatment must be submitted to Medicare Australia for authorisation every 6 months. Approvals will be limited to provide sufficient supply for up to a maximum of 6 months of treatment, based on the dosage recommendations in the TGA-approved Product Information.

Applications for continuing treatment will only be approved for patients who have currently demonstrated a response to treatment with iloprost trometamol.

The assessment of the patient's response to the first and subsequent 6 month courses of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated. Applications for continuing treatment with iloprost trometamol should be made prior to the completion of the 6 month treatment course to ensure continuity for those patients who respond to treatment, as assessed by the treating physician.

(c) Swapping between bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate and sitaxentan sodium.

For eligible patients, applications to swap between these 5 drugs must be made under the relevant initial treatment restriction. Patients should be assessed for response to the treatment they are ceasing at the time the application to swap therapy is being made. Patients who fail to demonstrate a response or for whom no assessment results are submitted with the application to swap therapy may not re-commence PBS-subsidised treatment with the drug they are ceasing.

It is important that patients are assessed for response to every course of treatment approved within the timeframes specified in the relevant restriction, in order to maximise the choice of treatment.

To avoid confusion, applications for patients who wish to swap to an alternate treatment should be accompanied by the previously approved authority prescription, or remaining repeats, for the treatment the patient is ceasing.

(d) Cessation of treatment.

Patients who fail to demonstrate a response to PBS-subsidised iloprost trometamol treatment at the times where an assessment is required must cease PBS-subsidised iloprost trometamol therapy.

7. Re-treatment with iloprost trometamol.

Patients who do not respond to treatment are not eligible to receive further PBS-subsidised treatment with iloprost trometamol under any circumstances.

8. Further information.

A tabulated representation of the above information and the restriction can be obtained from the Medicare Australia website at www.medicareaustralia.gov.au.

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Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer \$	Proprietary Name and Manufacturer

Public and private hospital authority required

Initial (new patients)

Application for initial PBS-subsidised treatment with iloprost trometamol of patients who have not received prior PBS-subsidised treatment with bosentan monohydrate, epoprostenol sodium, sildenafil citrate or sitaxentan sodium and who have been assessed by a physician from a designated hospital to have:

(a) WHO Functional Class III primary pulmonary hypertension and a mean right atrial pressure of 8 mmHg or less, as measured by RHC, unless a RHC is contraindicated on clinical grounds; OR

(b) WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease and a mean right atrial pressure of 8 mmHg or less, as measured by RHC, unless a RHC is contraindicated on clinical grounds; OR

(c) WHO Functional Class III drug-induced pulmonary arterial hypertension and a mean right atrial pressure of 8 mmHg or less, as measured by RHC, unless a RHC is contraindicated on clinical grounds.

Patients must have failed to respond [see Note for definition of response] to 6 or more weeks of appropriate vasodilator treatment unless intolerance or a contraindication to such treatment exists.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted to Medicare Australia for consideration based on the test results of the ECHO composite assessment plus 6MWT or the ECHO composite assessment only.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form [see Note for authority approval requirements]; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form [www.medicareaustralia.gov.au] which includes results from the 3 tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6MWT; and

(3) a signed patient acknowledgment indicating that the patient understands and acknowledges that PBS-subsidised treatment with iloprost trometamol for primary pulmonary hypertension, drug-induced pulmonary arterial hypertension or pulmonary arterial hypertension secondary to connective tissue disease, OR with bosentan monohydrate for primary pulmonary hypertension or pulmonary arterial hypertension secondary to scleroderma, OR with epoprostenol sodium for primary pulmonary hypertension, OR with sildenafil citrate for primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, OR with sitaxentan sodium for primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, will cease if the treating physician determines that the patient has not achieved a response to treatment [see Note for definition of response].

Details of prior vasodilator treatment, including the dose and duration of treatment, must be provided at the time of application. Where the patient has an adverse event to a vasodilator or where vasodilator treatment is contraindicated, details on the nature of the adverse event or contraindication according to the TGA-approved Product Information must also be provided with the application.

Where fewer than 3 tests (see requirement 2 above) are able to be performed on clinical grounds, a reason outlining why the particular test/s could not be conducted must be provided with the authority application [see Note for test requirements].

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. A maximum of 5 repeats may be requested. Where fewer than 5 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 6 months of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer \$	Proprietary Name and Manufacturer

Public and private hospital authority required

Initial (new patients)

Application for initial PBS-subsidised treatment with iloprost trometamol of patients who have not received prior PBS-subsidised treatment with bosentan monohydrate, epoprostenol sodium, sildenafil citrate or sitaxentan sodium and who have been assessed by a physician from a designated hospital to have:

- (a) WHO Functional Class III primary pulmonary hypertension and a mean right atrial pressure greater than 8 mmHg, as measured by RHC, unless a RHC is contraindicated on clinical grounds; OR*
- (b) WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease and a mean right atrial pressure greater than 8 mmHg, as measured by RHC, unless a RHC is contraindicated on clinical grounds; OR*
- (c) WHO Functional Class III drug-induced pulmonary arterial hypertension and a mean right atrial pressure greater than 8 mmHg, as measured by RHC, unless a RHC is contraindicated on clinical grounds; OR*
- (d) WHO Functional Class IV primary pulmonary hypertension; OR*
- (e) WHO Functional Class IV pulmonary arterial hypertension secondary to connective tissue disease; OR*
- (f) WHO Functional Class IV drug-induced pulmonary arterial hypertension.*

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted to Medicare Australia for consideration based on the test results of the ECHO composite assessment plus 6MWT or the ECHO composite assessment only.

Applications for authorisation must be in writing and must include:

- (1) a completed authority prescription form [see Note for authority approval requirements]; and*
- (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form [www.medicareaustralia.gov.au] which includes results from the 3 tests below, where available:*
 - (i) RHC composite assessment; and*
 - (ii) ECHO composite assessment; and*
 - (iii) 6MWT; and*
- (3) a signed patient acknowledgment indicating that the patient understands and acknowledges that PBS-subsidised treatment with iloprost trometamol for primary pulmonary hypertension, drug-induced pulmonary arterial hypertension or pulmonary arterial hypertension secondary to connective tissue disease, OR with bosentan monohydrate for primary pulmonary hypertension or pulmonary arterial hypertension secondary to scleroderma, OR with epoprostenol sodium for primary pulmonary hypertension, OR with sildenafil citrate for primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, OR with sitaxentan sodium for primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, will cease if the treating physician determines that the patient has not achieved a response to treatment [see Note for definition of response].*

Where fewer than 3 tests (see requirement 2 above) are able to be performed on clinical grounds, a reason outlining why the particular test/s could not be conducted must be provided with the authority application [see Note for test requirements].

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. A maximum of 5 repeats may be requested. Where fewer than 5 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 6 months of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer \$	Proprietary Name and Manufacturer

Public and private hospital authority required

Initial (change or re-commencement for all patients)

Application for initial PBS-subsidised treatment with iloprost trometamol of patients with either of the following:

- (a) primary pulmonary hypertension, drug-induced pulmonary arterial hypertension or pulmonary arterial hypertension secondary to connective tissue disease who wish to re-commence PBS-subsidised iloprost trometamol after a break in therapy and who have demonstrated a response to their most recent course of PBS-subsidised treatment with iloprost trometamol; OR*
- (b) primary pulmonary hypertension or pulmonary arterial hypertension secondary to scleroderma and whose most recent course of PBS-subsidised treatment was with bosentan monohydrate; OR*
- (c) primary pulmonary hypertension and whose most recent course of PBS-subsidised treatment was with epoprostenol sodium; OR*
- (d) primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease and whose most recent course of PBS-subsidised treatment was with sildenafil citrate; OR*
- (e) primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease and whose most recent course of PBS-subsidised treatment was with sitaxentan sodium.*

Applications for authorisation must be in writing and must include:

- (1) a completed authority prescription form [see Note for authority approval requirements]; and*
- (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form [www.medicareaustralia.gov.au] which includes the results on which approval for the first application for PBS-subsidised iloprost trometamol, bosentan monohydrate, epoprostenol sodium, sildenafil citrate or sitaxentan sodium, whichever was initiated first, was granted; and*
- (3) the date of the first application for PBS-subsidised treatment with iloprost trometamol, bosentan monohydrate, epoprostenol sodium, sildenafil citrate or sitaxentan sodium, whichever was initiated first; and*
- (4) the results of the patient's response to treatment with their last course of PBS-subsidised iloprost trometamol, bosentan monohydrate, epoprostenol sodium, sildenafil citrate or sitaxentan sodium.*

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. A maximum of 5 repeats may be requested.

Where fewer than 5 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 6 months of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Public and private hospital authority required

Continuing treatment (all patients)

Continuing PBS-subsidised treatment with iloprost trometamol of patients who have received approval for initial PBS-subsidised treatment with iloprost trometamol, and who have been assessed by a physician from a designated hospital to have achieved a response to their most recent course of iloprost trometamol treatment [see Note for definition of response].

Applications for authorisation must be in writing and must include:

- (1) a completed authority prescription form; and*
- (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form [www.medicareaustralia.gov.au] which includes results from the 3 tests below, where available:*
 - (i) RHC composite assessment; and*
 - (ii) ECHO composite assessment; and*
 - (iii) 6MWT.*

Where fewer than 3 tests (see requirement 2 above) are able to be performed on clinical grounds, a reason outlining why the particular test/s could not be conducted must be provided with the authority application [see Note for test requirements].

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. A maximum of 5 repeats may be requested.

Where fewer than 5 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 6 months of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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6456T	Solution for inhalation 20 micrograms (base) in 2 mL <u>NOTE:</u> <i>Special Pricing Arrangements apply.</i>	30	1076.00	Ventavis	SC
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

INFLIXIMABNOTE:

Any queries concerning the arrangements to prescribe infliximab may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe infliximab should be forwarded to:

Medicare Australia

Prior Written Approval of Specialised Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

NOTE:**TREATMENT OF ADULT PATIENTS WITH ACTIVE ANKYLOSING SPONDYLITIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and infliximab for adult patients with active ankylosing spondylitis. Where the term 'tumour necrosis factor (TNF) alfa antagonist' appears in the following NOTES and restrictions, it refers to adalimumab, etanercept and infliximab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 TNF-alfa antagonists at any 1 time.

From 1 March 2007, under the PBS, all patients will be able to commence a treatment cycle where they may trial each PBS-subsidised TNF-alfa antagonist without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a TNF-alfa antagonist while they continue to show a response to therapy.

A patient who received PBS-subsidised TNF-alfa antagonist treatment prior to 1 March 2007 is considered to be in their first cycle as of 1 March 2007.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised TNF-alfa antagonist more than once. A patient who, prior to 1 March 2007, was authorised to receive PBS-subsidised initial treatment for ankylosing spondylitis with the same agent twice, is exempt from this condition in respect of applications approved prior to 1 March 2007.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised TNF-alfa antagonist therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised TNF-alfa antagonist treatment in the most recent cycle to the date of the first application for initial treatment with a TNF-alfa antagonist under the new treatment cycle.

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Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer \$	Proprietary Name and Manufacturer

A patient who has failed fewer than 3 TNF-alfa antagonists in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 TNF-alfa antagonists in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised TNF-alfa antagonist therapy after 1 March 2007.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised TNF-alfa antagonist treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or

(ii) a patient has received prior PBS-subsidised (initial or continuing) TNF-alfa antagonist therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to re-commence treatment with a specific TNF-alfa antagonist following a break in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for etanercept and adalimumab and 18 weeks of treatment for infliximab.

From 1 March 2007, a patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.

For second and subsequent courses of PBS-subsidised TNF-alfa antagonist treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific TNF-alfa antagonist, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing TNF-alfa antagonist treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted TNF-alfa antagonist supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised TNF-alfa antagonist is approved, a patient may swap to an alternate TNF-alfa antagonist within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI), or the prior NSAID therapy and exercise program requirements.

A patient may trial an alternate TNF-alfa antagonist at any time, regardless of whether they are receiving therapy (initial or continuing) with a TNF-alfa antagonist at the time of the application. However, they cannot swap to a particular TNF-alfa antagonist if they have failed to respond to prior treatment with that drug within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

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To avoid confusion, an application for a patient who wishes to swap to an alternate TNF-alfa antagonist should be accompanied by the approved authority prescription or remaining repeats for the TNF-alfa antagonist the patient is ceasing.

(3) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a TNF-alfa antagonist. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and Medicare Australia will assess response according to these revised baseline measurements.

For a new patient, the BASDAI used to determine the baseline must be measured while the patient is receiving NSAID therapy and completing their exercise program. However, this is not required for any subsequent BASDAI results for these patients, nor for patients who were 'grandfathered' on to TNF-alfa antagonist treatment.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response.

(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised TNF-alfa antagonist therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have received treatment with at least 1 NSAID, at an adequate dose, for a minimum of 3 consecutive months immediately prior to the time the BASDAI, ESR and/or CRP levels are measured.

(5) Patients 'grandfathered' onto PBS-subsidised treatment with infliximab.

From 1 March 2007, a patient who commenced treatment with infliximab for active ankylosing spondylitis prior to 1 March 2004 and who was 'grandfathered' onto PBS-subsidised therapy, and who continues to receive treatment in the same treatment cycle, will have further applications for treatment with infliximab assessed under the continuing treatment restriction.

Where pre-TNF-alfa antagonist treatment baselines were not provided, the following criteria must be met to demonstrate a response to treatment:

The BASDAI score must be either:

- (i) no more than 20% greater than the score included in the initial application for PBS-subsidised treatment; or*
- (ii) no greater than 2.*

AND

One of the following:

- (a) an ESR measurement no greater than 25 mm per hour; or*
- (b) a CRP measurement no greater than 10 mg per L.*

'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must requalify for initial treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' above for further details.

continued ➡

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer \$	Proprietary Name and Manufacturer

Public and private hospital authority required

Initial 1 (new patients)

First course of PBS-subsidised treatment with infliximab, by a rheumatologist, of an adult with active ankylosing spondylitis who has radiographically (plain X-ray) confirmed Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis and who has not received any PBS-subsidised treatment with either adalimumab, etanercept or infliximab in this treatment cycle; AND

(a) who has at least 2 of the following:

(i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; or

(ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI) [for further information on the BASMI please refer to the Medicare Australia website at www.medicareaustralia.gov.au]; or

(iii) limitation of chest expansion relative to normal values for age and gender [for chest expansion normal values please refer to the Medicare Australia website at www.medicareaustralia.gov.au]; AND

(b) who has failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months.

The application must include details of the NSAIDs trialled, their doses and duration of treatment. If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used.

If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication.

If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance. Details of the toxicities, including severity, which will be accepted for the purposes of administering this restriction can be found on the Medicare Australia website [www.medicareaustralia.gov.au].

For details on the appropriate minimum exercise program that will be accepted for the purposes of administering this restriction, please refer to the Medicare Australia website at www.medicareaustralia.gov.au.

The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of the initial application:

(a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale; AND

(b) an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 10 mg per L.

The BASDAI must be determined at the completion of the 3 month NSAID and exercise trial, but prior to ceasing NSAID treatment. The BASDAI must be no more than 1 month old at the time of initial application.

Both ESR and CRP measures should be provided with the initial treatment application and both must be no more than 1 month old. If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reason this criterion cannot be satisfied.

Authority applications must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form [www.medicareaustralia.gov.au] which must include the following:

(i) a copy of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and

(ii) a completed BASDAI Assessment Form [www.medicareaustralia.gov.au]; and

(iii) a completed Exercise Program Self Certification Form included in the supporting information form; and

(iv) a signed patient acknowledgment form. Completion of this form declares that the patient understands and acknowledges that PBS-subsidised treatment with the TNF-alfa antagonists (adalimumab, etanercept or infliximab) for ankylosing spondylitis will cease if they do not demonstrate the response to treatment required to support continuation of PBS-subsidised treatment at any assessment where a response must be demonstrated.

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The assessment of the patient's response to the initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted to Medicare Australia no later than 4 weeks from the cessation of that treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

A maximum of 18 weeks of treatment with infliximab will be approved under this criterion.

At the time of the authority application, the doctor should request the appropriate number of vials, based on the weight of the patient, to provide for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised.

Where fewer than 3 repeats are initially requested with the authority prescription, authority approvals for sufficient repeats to complete a maximum of 18 weeks of treatment may be requested by telephone.

Public and private hospital authority required

Initial 2 (change or re-commencement for all patients)

Initial course of PBS-subsidised treatment with infliximab, by a rheumatologist, of an adult with a documented history of active ankylosing spondylitis who, in this treatment cycle, has received prior PBS-subsidised treatment with either adalimumab, etanercept or infliximab for this condition and has not failed PBS-subsidised therapy with infliximab.

To demonstrate a response to treatment the application must be accompanied by the results of the most recent course of TNF-alfa antagonist therapy within the timeframes specified in the relevant restriction.

Where the most recent course of PBS-subsidised TNF-alfa antagonist treatment was approved under an initial treatment restriction after 1 March 2007, the patient must have been assessed for response to that course following a minimum of 12 weeks of treatment. Where the most recent course of PBS-subsidised TNF-alfa antagonist treatment was approved under an initial treatment restriction prior to 1 March 2007, the patient must have been assessed for response to that course following at least 4 weeks of treatment. These assessments must be provided to Medicare Australia no later than 4 weeks from the date the course was ceased.

If the response assessment to the previous course of TNF-alfa antagonist treatment is not submitted as detailed above, the patient will be deemed to have failed therapy with that particular course of TNF-alfa antagonist.

Authority applications must be made in writing and must include:

- (a) a completed authority prescription form; and*
- (b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form [www.medicareaustralia.gov.au] which includes a completed BASDAI Assessment Form with certification by the prescriber and the patient that the patient did not have access to their baseline BASDAI at the time of their assessment.*

A maximum of 18 weeks of treatment with infliximab will be approved under this criterion.

At the time of the authority application, the doctor should request the appropriate number of vials, based on the weight of the patient, to provide for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised.

Where fewer than 3 repeats are initially requested with the authority prescription, authority approvals for sufficient repeats to complete a maximum of 18 weeks of treatment may be requested by telephone.

Public and private hospital authority required

Continuing treatment for all patients

Continuing PBS-subsidised treatment, by a rheumatologist, of an adult with a documented history of active ankylosing spondylitis who:

- (a) has demonstrated a response to treatment with infliximab; and*
- (b) whose most recent course of PBS-subsidised therapy in this treatment cycle was with infliximab.*

Response is defined as an improvement from baseline of at least 2 of the BASDAI and 1 of the following:

- (a) an ESR measurement no greater than 25 mm per hour; or*
- (b) a CRP measurement no greater than 10 mg per L; or*
- (c) an ESR or CRP measurement reduced by at least 20% from baseline.*

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For a 'grandfather' patient who does not have baselines prior to commencing treatment with a TNF-alfa antagonist, see Note 5 for a definition of response to treatment.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and supplied in all subsequent continuing treatment applications.

Where the most recent course of PBS-subsidised TNF-alfa antagonist treatment was approved under an initial treatment restriction after 1 March 2007, the patient must have been assessed for response to that course following a minimum of 12 weeks of treatment. Where the most recent course of PBS-subsidised TNF-alfa antagonist treatment was approved under an initial treatment restriction prior to 1 March 2007, the patient must have been assessed for response to that course following at least 4 weeks of treatment.

Applications for continuing treatment must be made in writing and should be posted to Medicare Australia no less than 2 weeks prior to the completion of the current treatment course.

Written applications for authorisation must include:

(a) a completed authority prescription form; and

(b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form [www.medicareaustralia.gov.au] which includes a completed BASDAI Assessment Form with certification by the prescriber and the patient that the patient did not have access to their baseline BASDAI at the time of their continuing treatment assessment.

All measurements provided must be no more than 1 month old at the time of application.

A maximum of 24 weeks of treatment with infliximab will be authorised under this criterion.

At the time of the authority application, the doctor should request the appropriate number of vials, based on the weight of the patient, to provide for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised.

Where fewer than 3 repeats are initially requested with the authority prescription, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone.

6448J	Powder for I.V. infusion 100 mg	1	751.70	Remicade	SH

NOTE:

TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying anti-rheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, etanercept, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-1 inhibitor (anakinra) and the T-cell co-stimulation modulator (abatacept).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

PBS-subsidised infliximab, anakinra, rituximab and abatacept must be used in combination with methotrexate at a dose of at least 7.5 mg weekly. Where a patient cannot tolerate 7.5 mg of methotrexate weekly, they are only eligible to receive PBS-subsidised etanercept and adalimumab.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.

From 1 March 2008, under the PBS, all patients will be able to commence a Treatment Cycle where they may trial PBS-subsidised bDMARD agents without having to experience a disease flare when swapping to an alternate agent. Under these interchangeability arrangements, within a single Treatment Cycle, a patient may continue to receive long-term treatment with a bDMARD while they continue to show a response to therapy.

A patient who received PBS-subsidised bDMARD treatment prior to 1 March 2008 is considered to be in their first Cycle as of 1 March 2008.

Within the same Treatment Cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once.

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Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a Treatment Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised bDMARD therapy before they are eligible to commence the next Cycle.

For patients who have failed PBS-subsidised treatment with 3 bDMARDs prior to 1 March 2008 please contact Medicare Australia on 1800 700 270.

The 5-year break is measured from the date of the last approval for PBS-subsidised bDMARD treatment in the most recent Cycle to the date of the first application for initial treatment with a bDMARD under the new Treatment Cycle.

A patient who has failed fewer than 3 bDMARDs in a Treatment Cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same Treatment Cycle.

A patient who has failed fewer than 3 bDMARDs in a Treatment Cycle and who has a break in therapy of more than 5 years, may commence a new Treatment Cycle.

There is no limit to the number of Treatment Cycles a patient may undertake in their lifetime.

If patients fail to respond to a particular bDMARD within a single Treatment Cycle, they are not eligible to receive further PBS-subsidised treatment with that drug until they commence the next Cycle.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 March 2008.

(a) Initial treatment.

Applications for initial treatment should be made where:

- (i) a patient has received no prior PBS-subsidised bDMARD treatment in this Treatment Cycle and wishes to commence such therapy, excluding rituximab (Initial 1); or*
- (ii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or*
- (iii) a patient wishes to re-commence treatment with a specific bDMARD following a break in PBS-subsidised therapy with that agent (Initial 2).*

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for etanercept, adalimumab, anakinra and abatacept, 22 weeks of therapy for infliximab and 2 infusions of rituximab.

From 1 March 2008, a patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to Medicare Australia within 4 weeks.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

Rituximab patients:

A further application may be submitted to Medicare Australia 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

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Rituximab patients:

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD within the same Treatment Cycle without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the same Treatment Cycle.

In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

NOTE:

(3) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a Treatment Cycle and Medicare Australia will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

The baseline joint and blood counts should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment.

(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

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A patient who wishes to trial a second or subsequent Treatment Cycle following a break in PBS-subsidised bDMARD therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have received treatment with at least 1 non-biological DMARD, at an adequate dose, for a minimum of 3 months at the time the ESR and/or CRP levels and the active joint count are measured.

(5) Patients 'grandfathered' onto PBS-subsidised treatment with rituximab or abatacept.

From 1 March 2008, a patient who commenced treatment with rituximab for severe rheumatoid arthritis prior to 7 March 2007 or abatacept for severe rheumatoid arthritis prior to 1 November 2007 and who was 'grandfathered' on to PBS-subsidised therapy, and who continues to receive treatment in the same Treatment Cycle, will have further applications for treatment with rituximab or abatacept assessed under the continuing treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment with abatacept will be authorised under this criterion.

'Grandfather' arrangements will only apply for the first Treatment Cycle. For the second and subsequent Cycles, a 'grandfather' patient must requalify for initial treatment under the criteria that applies to a new patient. See 'Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' above for further details.

Public and private hospital authority required

Initial 1 (new patients)

Application for initial PBS-subsidised treatment with infliximab, in combination with methotrexate at a dose of at least 7.5 mg weekly, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of adults who:

- (a) have severe active rheumatoid arthritis; and*
- (b) have received no prior PBS-subsidised treatment with a bDMARD for this condition in this treatment cycle; and*
- (c) have failed to achieve an adequate response to the following treatments:*
 - (i) methotrexate at a dose of at least 20 mg weekly; and*
 - (ii) methotrexate (at a minimum dose of 7.5 mg weekly), in combination with 2 other non-biological disease modifying anti-rheumatic drugs (DMARDs), for a minimum of 3 months; and*
 - (iii) a minimum of 3 months' treatment with:*
 - leflunomide alone; or*
 - leflunomide in combination with methotrexate; or*
 - cyclosporin.*

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application.

Details of the accepted toxicities, including severity, can be found on the Medicare Australia website [www.medicareaustralia.gov.au].

The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L;

AND either

- (i) a total active joint count of at least 20 active (swollen and tender) joints; or*
- (ii) at least 4 active joints from the following list of major joints:*
 - elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or*
 - shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).*

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.

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If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and*
- (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes details of the patient's ESR and CRP measurements and the patient's active joint count which must have been assessed no earlier than 1 month prior to the date of application; and*
- (3) a signed patient acknowledgement.*

A maximum of 22 weeks of treatment will be authorised under this restriction.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 3 mg per kg. Up to a maximum of 3 repeats may be authorised.

Where fewer than 3 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 22 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Assessment of a patient's response to an initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab.

Patients who fail to demonstrate a response to treatment with infliximab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug, in this treatment cycle. Patients may re-trial infliximab after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised bDMARD was approved in this cycle and the date of the first application under the new cycle.

Public and private hospital authority required

Initial 2 (change or re-commencement)

Application for an initial course of PBS-subsidised treatment with infliximab, in combination with methotrexate at a dose of at least 7.5 mg weekly, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of adults who:

- (a) have a documented history of severe active rheumatoid arthritis; and*
- (b) have received prior PBS-subsidised bDMARD treatment for this condition in this treatment cycle and are eligible to receive further bDMARD therapy.*

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and*
- (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].*

Applications for patients who have received PBS-subsidised treatment with infliximab within this treatment cycle and who wish to re-commence therapy with this drug within this same cycle, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised infliximab treatment, within the timeframes specified below.

A maximum of 22 weeks of treatment will be authorised under this restriction.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 3 mg per kg. Up to a maximum of 3 repeats may be authorised.

Where fewer than 3 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 22 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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Where the most recent course of PBS-subsidised infliximab treatment was approved under either of the initial treatment restrictions (i.e. for patients with no prior PBS-subsidised bDMARD therapy or, under this restriction, for patients who have received previous PBS-subsidised bDMARD therapy), patients must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be provided to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised infliximab treatment was approved under the continuing treatment criteria, patients must have been assessed for response, and the assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Patients who fail to demonstrate a response to treatment with infliximab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug, in this treatment cycle. Patients may re-trial infliximab after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised bDMARD was approved in this cycle and the date of the first application under the new cycle.

Public and private hospital authority required

Continuing treatment

Continuing PBS-subsidised treatment with infliximab, in combination with methotrexate at a dose of at least 7.5 mg weekly, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of adults:

- (a) who have a documented history of severe active rheumatoid arthritis; and*
- (b) who have demonstrated an adequate response to treatment with infliximab; and*
- (c) whose most recent course of PBS-subsidised bDMARD treatment in this treatment cycle was with infliximab.*

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

- (i) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or*
- (ii) a reduction in the number of the following major active joints, from at least 4, by at least 50%:*
 - elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or*
 - shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).*

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and*
- (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].*

A maximum of 24 weeks of treatment will be approved under this restriction.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 3 mg per kg. Up to a maximum of 2 repeats may be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

All applications for continuing treatment with infliximab must include a measurement of response to the prior course of therapy. This assessment must be provided to Medicare Australia no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with infliximab, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.

Patients who fail to demonstrate a response to treatment with infliximab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug, in this treatment cycle. Patients may re-trial infliximab after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised bDMARD was approved in this cycle and the date of the first application under the new cycle.

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer \$	Proprietary Name and Manufacturer	

6397Q	Powder for I.V. infusion 100 mg	1	751.70	Remicade	SH

NOTE:**TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents (adalimumab, etanercept and infliximab) for adult patients with severe active psoriatic arthritis.

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological agents at any 1 time. Where the term 'biological agents' appears in the following NOTES and restrictions, it only refers to adalimumab, etanercept and infliximab.

From 1 August 2006, all patients will be able to commence a 'Biological Treatment Cycle' (Cycle), where they may trial adalimumab, etanercept or infliximab without having to meet the initial treatment criteria, that is they will not need to experience a disease flare, when swapping to the alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

Following demonstration of response to initial treatment, these biological agents are available under the PBS for continuing treatment as set out in the continuing treatment restriction for each agent.

Once patients have either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological therapy before they are eligible to commence another Cycle [further details are under '(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' below].

The 5-year break in therapy will be measured from the date the last approval for PBS-subsidised treatment was granted in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Cycle.

Within the same Cycle, patients are not allowed to fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for any biological agent, they must change to an alternate agent which they have not previously failed, if they wish to continue PBS-subsidised biological treatment.

Patients for whom a break in PBS-subsidised therapy of less than 5 years has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.

Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle.

There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.

How to prescribe biological agents for the treatment of severe active psoriatic arthritis after 1 August 2006.

(1) Initial treatment.

Applications for initial treatment should be made where:

- (i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); and
- (ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; and
- (iii) patients wish to re-commence treatment with a specific biological agent following a break in PBS-subsidised therapy with that specific agent (Initial 2).

All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 16 weeks of therapy for all agents except for infliximab, for which a maximum of 22 weeks will be authorised. It is recommended that patients be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological agent supply.

continued 

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer \$	Proprietary Name and Manufacturer

Patients must be assessed for response to any course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.

Grandfather patients.

Applications for patients who commenced treatment with etanercept prior to 17 March 2005 or adalimumab and infliximab prior to 16 March 2006, may apply for initial PBS-subsidised treatment as continuing therapy under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with any biological agent prior to PBS listing of that agent.

Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment for all agents. Approval will be based on the criteria included in the relevant restriction.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological agent, patients may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. Patients are eligible to receive continuing biological treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

Patients must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.

(3) Swapping therapy.

Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate biological agent without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements.

Patients may swap to an alternate biological agent at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological agent at the time of the application or not.

Patients may alternate between therapy with any biological agent of their choice (1 at a time) providing:

- (i) they have not received PBS-subsidised treatment with that particular biological agent previously; or*
- (ii) they have demonstrated an adequate response to that particular biological agent if they have previously trialled it on the PBS.*

To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the biological agent the patient is ceasing.

(4) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements of the indices of disease severity submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment authority is submitted within a treatment Cycle and Medicare Australia will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.

(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer \$	Proprietary Name and Manufacturer

Patients who wish to trial a second or subsequent treatment Cycle following a break in PBS-subsidised biological therapy of at least 5 years, must re-qualify for initial treatment with respect to both the indices of disease severity. Patients must have received treatment with methotrexate or sulfasalazine or leflunomide, at an adequate dose, for a minimum of 3 months at the time the ESR or CRP levels and the active joint counts are measured.

Public and private hospital authority required

Initial 1

Initial PBS-subsidised treatment with infliximab, by a rheumatologist or clinical immunologist with expertise in the management of psoriatic arthritis, of adults who:

- (1) have severe active psoriatic arthritis; and*
- (2) have received no prior PBS-subsidised biological treatment for this condition in this Treatment Cycle; and*
- (3) have failed to achieve an adequate response to:*
 - (a) methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months; and*
 - (b) sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months; or*
 - (c) leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months.*

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity to necessitate permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of acceptable toxicities, including severity, can be found on the Medicare Australia website (www.medicareaustralia.gov.au).

The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either

- (i) an active joint count of at least 20 active (swollen and tender) joints; or*
- (ii) at least 4 active joints from the following list of major joints:*
 - elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or*
 - shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).*

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and*
 - (2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes details of the patient's ESR and CRP measurements and the patient's active joint count which must have been assessed no earlier than 1 month prior to the date of application; and*
 - (3) a copy of the signed patient acknowledgement form which is included in the Supporting Information Form.*
- Completion of this form declares that the patient understands and acknowledges that PBS-subsidised treatment will cease if they do not demonstrate the response to treatment required to support continuation of PBS-subsidised treatment at any assessment where a response must be demonstrated.*

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats may be authorised.

Where fewer than 3 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 22 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer \$	Proprietary Name and Manufacturer

Patients who fail to demonstrate a response to treatment with infliximab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug, in this Treatment Cycle.

Public and private hospital authority required

Initial 2

Initial PBS-subsidised treatment with infliximab, by a rheumatologist or clinical immunologist with expertise in the management of psoriatic arthritis, of adults who:

- (1) have a documented history of severe active psoriatic arthritis; and*
- (2) have received prior PBS-subsidised biological treatment for this condition in this Treatment Cycle and are eligible to receive further biological therapy; and*
- (3) have not failed treatment with infliximab during the current Treatment Cycle.*

Applications for patients who have demonstrated a response to PBS-subsidised infliximab treatment within this Treatment Cycle and who wish to re-commence infliximab treatment within the same Cycle following a break in therapy, will only be approved where evidence of a response to the patient's most recent course of PBS-subsidised infliximab treatment has been submitted to Medicare Australia within 1 month of cessation of treatment.

Where the most recent course of PBS-subsidised infliximab treatment was approved under either of the initial treatment restrictions (i.e. for patients with no prior PBS-subsidised biological therapy or, under this restriction, for patients who have received previous PBS-subsidised biological therapy), patients must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be provided to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised infliximab treatment was approved under the continuing treatment criteria, patients must have been assessed for response, and the assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and*
- (2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].*

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats may be authorised.

Where fewer than 3 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 22 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Patients who fail to demonstrate a response to treatment with infliximab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug, in this Treatment Cycle.

Once patients fail to respond to treatment with 3 biological agents, they are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may re-commence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

Public and private hospital authority required

Initial 3

Initial PBS-subsidised supply for continuing treatment with infliximab, by a rheumatologist or clinical immunologist with expertise in the management of psoriatic arthritis, of adults who:

- (1) have a documented history of severe active psoriatic arthritis; and*
- (2) were receiving treatment with infliximab prior to 16 March 2006; and*
- (3) have demonstrated a response as specified in the criteria for continuing PBS-subsidised treatment with infliximab.*

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer \$	Proprietary Name and Manufacturer

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and*
 - (2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and*
 - (3) a copy of the signed patient acknowledgement form which is included in the Supporting Information Form.*
- Completion of this form declares that the patient understands and acknowledges that PBS-subsidised treatment will cease if they do not demonstrate the response to treatment required to support continuation of PBS-subsidised treatment at any assessment where a response must be demonstrated.*

A maximum of 24 weeks of treatment with infliximab will be authorised under this restriction.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats may be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Patients who fail to demonstrate a response to treatment with infliximab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug, in this Treatment Cycle.

Patients may qualify for PBS-subsidised treatment under this restriction once only.

Public and private hospital authority required

Continuing treatment

Continuing PBS-subsidised treatment with infliximab, by a rheumatologist or clinical immunologist with expertise in the management of psoriatic arthritis, of adults:

- (1) who have a documented history of severe active psoriatic arthritis; and*
- (2) whose most recent course of PBS-subsidised biological agent for this condition in the current Treatment Cycle was with infliximab; and*
- (3) who, at the time of application, demonstrate an adequate response to treatment with infliximab.*

An adequate response to treatment with infliximab is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following:

- (i) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or*
- (ii) a reduction in the number of the following major active joints, from at least 4, by at least 50%:*
 - elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or*
 - shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).*

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and*
- (2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].*

All applications for continuing treatment with infliximab must include a measurement of response to the prior course of therapy. This assessment must be provided to Medicare Australia no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with infliximab, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with the initial treatment course.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats may be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer \$	Proprietary Name and Manufacturer	

Patients who fail to demonstrate a response to treatment with infliximab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug, in this Treatment Cycle.

Once patients fail to respond to treatment with 3 biological agents, they are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may re-commence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

6496X	Powder for I.V. infusion 100 mg	1	751.70	Remicade	SH

NOTE:

TREATMENT OF ADULT PATIENTS WITH SEVERE REFRACTORY CROHN DISEASE

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab and infliximab for adult patients with severe refractory Crohn disease. Where the term 'tumour necrosis factor (TNF) alfa antagonist' appears in the following NOTES and restrictions, it refers to adalimumab and infliximab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 2 TNF-alfa antagonists at any 1 time.

From 1 August 2008, under the PBS, all patients will be able to commence a treatment cycle where they may trial each PBS-subsidised TNF-alfa antagonist without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a TNF-alfa antagonist while they continue to show a response to therapy.

A patient who received PBS-subsidised TNF-alfa antagonist treatment prior to 1 August 2008 is considered to be in their first cycle as of 1 August 2008.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised TNF-alfa antagonist more than twice.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised TNF-alfa antagonist therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised TNF-alfa antagonist treatment in the most recent cycle to the date of the first application for initial treatment with a TNF-alfa antagonist under the new treatment cycle.

A patient who has failed fewer than 3 trials of TNF-alfa antagonists in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of TNF-alfa antagonists in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised TNF-alfa antagonist therapy after 1 August 2008.

(a) Initial treatment.

Applications for initial treatment should be made where:

- (i) a patient has received no prior PBS-subsidised TNF-alfa antagonist treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or*
- (ii) a patient has received prior PBS-subsidised (initial or continuing) TNF-alfa antagonist therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or*
- (iii) a patient wishes to re-commence treatment with a specific TNF-alfa antagonist following a break in PBS-subsidised therapy with that agent (Initial 2).*

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and 14 weeks of therapy for infliximab.

From 1 August 2008, a patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.

continued ➞

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer \$	Proprietary Name and Manufacturer

For second and subsequent courses of PBS-subsidised TNF-alfa antagonist treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

Adalimumab only: Two completed authority prescriptions must be submitted with every initial application for adalimumab. One prescription must be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats. The second prescription must be written for 2 doses of 40 mg and 2 repeats.

(b) Continuing treatment. Following the completion of an initial treatment course with a specific TNF-alfa antagonist, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing TNF-alfa antagonist treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted TNF-alfa antagonist supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised TNF-alfa antagonist is approved, a patient may swap if eligible to the alternate TNF-alfa antagonist within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Crohn Disease Activity Index (CDAI) Score, evidence of intestinal inflammation), or the prior corticosteroid therapy and immunosuppressive therapy.

A patient may trial the alternate TNF-alfa antagonist at any time, regardless of whether they are receiving therapy (initial or continuing) with a TNF-alfa antagonist at the time of the application. However, they cannot swap to a particular TNF-alfa antagonist if they have failed to respond to prior treatment with that drug two times within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to the alternate TNF-alfa antagonist should be accompanied by the approved authority prescription or remaining repeats for the TNF-alfa antagonist the patient is ceasing.

(3) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements of the CDAI or evidence of intestinal inflammation submitted with the first authority application for a TNF-alfa antagonist. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and Medicare Australia will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications.

(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised TNF-alfa antagonist therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have received treatment with a corticosteroid and at least 1 immunosuppressive agent, at an adequate dose, for a minimum of 3 consecutive months immediately prior to the time the CDAI score or the indices of intestinal inflammation are measured.

(5) Patients 'grandfathered' onto PBS-subsidised treatment with adalimumab or infliximab.

continued 

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer \$	Proprietary Name and Manufacturer

A patient who commenced treatment with adalimumab for severe refractory Crohn disease prior to 9 November 2007 or infliximab prior to 7 March 2007 and who continues to receive treatment at the time of application, may qualify for treatment under the initial 'grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment with adalimumab or infliximab will be authorised under this criterion.

Following completion of the initial PBS-subsidised course, further applications for treatment with adalimumab or infliximab will be assessed under the continuing treatment restriction.

'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must requalify for initial treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' above for further details.

Public and private hospital authority required

Initial 1 (new patients)

Initial treatment of Crohn disease in a patient assessed by CDAI.

Initial PBS-subsidised treatment with infliximab by a gastroenterologist or a consultant physician as specified in the NOTE below, of a patient with severe refractory Crohn disease who satisfies the following criteria:

- (a) has confirmed Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician as specified in the NOTE below; and*
- (b) has signed a patient acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and*
- (c) has failed to achieve an adequate response to prior systemic therapy including:*
 - (i) a tapered course of steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period; and*
 - (ii) immunosuppressive therapy including:*
 - azathioprine at a dose of at least 2 mg per kg daily for 3 or more months; or*
 - 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months; or*
 - methotrexate at a dose of at least 15 mg weekly for 3 or more months.*

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application. .

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of the accepted toxicities including severity can be found on the Medicare Australia website (www.medicareaustralia.gov.au). .

The following initiation criterion indicates failure to achieve an adequate response and must be demonstrated in all patients at the time of the application:

- (a) have a severity of disease activity which results in a Crohn Disease Activity Index (CDAI) Score greater than or equal to 300 as assessed.*

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.

The most recent CDAI assessment must be no more than 1 month old at the time of application.

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer \$	Proprietary Name and Manufacturer

Applications for authorisation must be made in writing and must include:

- (a) a completed authority prescription form; and*
- (b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:*
 - (i) the completed current Crohn Disease Activity Index (CDAI) calculation sheet including the date of assessment of the patient's condition; and*
 - (ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and*
 - (iii) the signed patient acknowledgement.*

A maximum quantity and number of repeats to provide for an initial course of infliximab consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete the 3 doses of infliximab may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

A CDAI assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab.

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment.

Public and private hospital authority required

Initial 2

Change or re-commencement of treatment of Crohn disease in a patient assessed by CDAI.

Initial PBS-subsidised treatment with infliximab by a gastroenterologist or a consultant physician as specified in the NOTE below of a patient who:

- (a) has a documented history of severe refractory Crohn disease; and*
- (b) in this treatment cycle, has received prior PBS-subsidised treatment with infliximab or adalimumab for this condition; and*
- (c) has not failed PBS-subsidised therapy with infliximab for this condition more than once in the current treatment cycle.*

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

To demonstrate a response to treatment the application must be accompanied by the results of the most recent course of TNF-alfa antagonist therapy within the timeframes specified in the relevant restriction.

Where the most recent course of PBS-subsidised TNF-alfa antagonist treatment was approved under an initial treatment restriction, the patient must have been assessed for response to that course following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

If the response assessment to the previous course of TNF-alfa antagonist treatment is not submitted as detailed above, the patient will be deemed to have failed therapy with that particular course of TNF-alfa antagonist.

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer \$	Proprietary Name and Manufacturer

Authority applications must be made in writing and must include:

- (a) a completed authority prescription form; and*
- (b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:*
 - (i) the completed current Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient's condition; and*
 - (ii) details of prior TNF alfa antagonist treatment including details of date and duration of treatment.*

A maximum quantity and number of repeats to provide for an initial course of infliximab consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete the 3 doses of infliximab may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

A CDAI assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab.

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment.

Public and private hospital authority required

Continuing treatment of Crohn disease in a patient assessed by CDAI.

Continuing PBS-subsidised treatment with infliximab by a gastroenterologist, a consultant physician as specified in the NOTE below or other consultant physician in consultation with a gastroenterologist, of a patient who:

- (a) has a documented history of severe refractory Crohn disease; and*
- (b) has demonstrated or sustained an adequate response to treatment with infliximab.*

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

An adequate response to infliximab treatment is defined as a reduction in Crohn Disease Activity Index (CDAI) Score to a level no greater than 150.

Applications for authorisation must be made in writing and must include:

- (a) a completed authority prescription form; and*
- (b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:*
 - (i) the completed Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient's condition.*

The CDAI assessment must be no more than 1 month old at the time of application.

If the application is the first application for continuing treatment with infliximab, a CDAI assessment of the patient's response must be made up to 12 weeks after the first dose so that there is adequate time for a response to be demonstrated.

The assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion.

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with infliximab.

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer \$	Proprietary Name and Manufacturer

Patients are eligible to receive continuing infliximab treatment in courses of up to 24 weeks providing they continue to sustain the response.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats will be authorised. No applications for increased repeats will be authorised.

Where fewer than 2 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Public and private hospital authority required

Initial 1

Initial treatment of Crohn disease in a patient with short gut syndrome or an ostomy patient.

Initial PBS-subsidised treatment with infliximab by a gastroenterologist, or consultant physician as specified in the NOTE below of a patient who satisfies the following criteria:

- (a) has confirmed Crohn disease defined by standard clinical, endoscopic and/or imaging features, including histological evidence with the diagnosis confirmed by a gastroenterologist or consultant physician as specified in the NOTE below; and*
- (b) has diagnostic imaging or surgical evidence of short gut syndrome or has an ileostomy or colostomy; and*
- (c) has evidence of intestinal inflammation; and*
- (d) has signed a patient acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and*
- (e) has failed to achieve an adequate response to prior systemic drug therapy including:*
 - (i) a tapered course of steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period; and*
 - (ii) immunosuppressive therapy including:*
 - azathioprine at a dose of at least 2 mg per kg daily for 3 or more months; or*
 - 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months; or*
 - methotrexate at a dose of at least 15 mg weekly for 3 or more months.*

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of the accepted toxicities including severity can be found on the Medicare Australia website (www.medicareaustralia.gov.au).

The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the application:

- (a) have evidence of intestinal inflammation, including:*
 - (i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; AND/OR*
 - (ii) faeces: higher than normal lactoferrin or calprotectin level; AND/OR*
 - (iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery;*
- AND/OR*
- (b) be assessed clinically as being in a high faecal output state;*
- AND/OR*
- (c) be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of infliximab.*

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer \$	Proprietary Name and Manufacturer

Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the continuing treatment restriction. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy.

Applications for authorisation must be made in writing and must include:

- (a) a completed authority prescription form; and*
- (b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:*
 - (i) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and*
 - (ii) reports and dates of the pathology or diagnostic imaging test(s) nominated as the response criterion, if relevant; and*
 - (iii) date of the most recent clinical assessment; and*
 - (iv) the signed patient acknowledgement.*

All assessments, pathology tests and diagnostic imaging studies must be made within 1 month of the date of application.

A maximum quantity and number of repeats to provide for an initial course of infliximab consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete the 3 doses of infliximab may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

The assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab.

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment.

Public and private hospital authority required

Initial 2

Change or re-commencement of treatment of Crohn disease in a patient with short gut syndrome, an ostomy patient or a patient with extensive small intestine disease.

Initial PBS-subsidised treatment with infliximab by a gastroenterologist or a consultant physician as specified in the NOTE below of a patient who:

- (a) has a documented history of severe refractory Crohn disease; and*
- (b) in this treatment cycle, has received prior PBS-subsidised treatment with infliximab or adalimumab for this condition; and*
- (c) has not failed PBS-subsidised therapy with infliximab for this condition more than once in the current treatment cycle.*

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

To demonstrate a response to treatment the application must be accompanied by the results of the most recent course of TNF- α antagonist therapy within the timeframes specified in the relevant restriction.

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer \$	Proprietary Name and Manufacturer

Where the most recent course of PBS-subsidised TNF-alfa antagonist treatment was approved under an initial treatment restriction, the patient must have been assessed for response to that course following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

If the response assessment to the previous course of TNF-alfa antagonist treatment is not submitted as detailed above, the patient will be deemed to have failed therapy with that particular course of TNF-alfa antagonist.

Authority applications must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) reports and dates of the pathology or diagnostic imaging test(s) nominated as the response criteria, if relevant; and

(ii). details of prior TNF alfa antagonist treatment including details of date and duration of treatment.

A maximum quantity and number of repeats to provide for an initial course of infliximab consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

The assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of therapy so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab.

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment.

Public and private hospital authority required

Continuing treatment of Crohn disease in a patient with short gut syndrome or an ostomy patient.

Continuing PBS-subsidised treatment with infliximab by a gastroenterologist, a consultant physician as specified in the NOTE below or other consultant physician in consultation with a gastroenterologist, of a patient who:

(a) has a documented history of severe refractory Crohn disease with intestinal inflammation and with short gut syndrome or with an ileostomy or colostomy; and

(b) has demonstrated or sustained an adequate response to treatment with infliximab.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

An adequate response to infliximab treatment is defined as:

(a) improvement of intestinal inflammation as demonstrated by:

(i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; AND/OR

(ii) faeces: normalisation of lactoferrin or calprotectin level; AND/OR

(iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or

(b) reversal of high faecal output state; or

(c) avoidance of the need for surgery or total parenteral nutrition (TPN).

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer \$	Proprietary Name and Manufacturer

Applications for authorisation must be made in writing and must include:

- (a) a completed authority prescription; and*
- (b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:*
- (i) the reports and dates of the pathology or diagnostic imaging test(s) used to assess response to therapy or the date of clinical assessment.*

The patient's assessment must be no more than 1 month old at the time of application.

If the application is the first application for continuing treatment with infliximab, an assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.

The assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion.

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with infliximab.

Patients are eligible to receive continuing infliximab treatment in courses of up to 24 weeks providing they continue to sustain the response.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats will be authorised. No applications for increased repeats will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Public and private hospital authority required

Initial 1

Initial treatment of Crohn disease in a patient with extensive small intestine disease.

Initial PBS-subsidised treatment with infliximab by a gastroenterologist or a consultant physician as specified in the NOTE below, of a patient with severe refractory Crohn disease who satisfies the following criteria:

- (a) has confirmed Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or consultant physician as specified in the NOTE below; and*
- (b) has extensive small intestinal disease with radiological evidence of intestinal inflammation affecting more than 50 cm of the small intestine; and*
- (c) has signed a patient acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and*
- (d) has failed to achieve an adequate response to prior systemic therapy including:*
 - (i) a tapered course of steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period; and*
 - (ii) immunosuppressive therapy including:*
 - azathioprine at a dose of at least 2 mg per kg daily for 3 or more months; or*
 - 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months; or*
 - methotrexate at a dose of at least 15 mg weekly for 3 or more months.*

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application.

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Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer \$	Proprietary Name and Manufacturer

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of the accepted toxicities including severity can be found on the Medicare Australia website (www.medicareaustralia.gov.au).

The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the application:

(a) have severity of disease activity which results in a Crohn Disease Activity Index (CDAI) Score greater than or equal to 220;

AND/OR

(b) have evidence of active intestinal inflammation, including:

(i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; AND/OR

(ii) faeces: higher than normal lactoferrin or calprotectin level; AND/OR

(iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery;

AND/OR

(c) be assessed clinically as being in a high faecal output state;

AND/OR

(d) be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of infliximab.

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.

Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the continuing treatment restriction. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and

(ii) (1) reports and dates of the pathology or diagnostic imaging test(s) nominated as the response criterion, if relevant; or

(2) the completed current Crohn Disease Activity Index (CDAI) calculation sheet including the dates of assessment of the patient's condition, if relevant; and

(iii) date of the most recent clinical assessment; and

(iv) the signed patient acknowledgement.

All assessments, pathology tests and diagnostic imaging studies must be made within 1 month of the date of application.

A maximum quantity and number of repeats to provide for an initial course of infliximab consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete the 3 doses of infliximab may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

The assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab.

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer \$	Proprietary Name and Manufacturer

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment.

Public and private hospital authority required

Continuing treatment of Crohn disease in a patient with extensive small intestine disease.

Continuing PBS-subsidised treatment with infliximab by a gastroenterologist, or consultant physician as specified in the NOTE below or other consultant physician in consultation with a gastroenterologist, of a patient who:

- (a) has a documented history of severe refractory Crohn disease with extensive intestinal inflammation affecting more than 50 cm of the small intestine; and*
- (b) has demonstrated or sustained an adequate response to treatment with infliximab.*

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

An adequate response to infliximab treatment is defined as:

- (a) a reduction in Crohn Disease Activity Index (CDAI) Score to no greater than 150; or*
- (b) improvement of intestinal inflammation as demonstrated by:*
 - (i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; AND/OR*
 - (ii) faeces: normalisation of lactoferrin or calprotectin level; AND/OR*
 - (iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or*
- (c) reversal of high faecal output state; or*
- (d) avoidance of the need for surgery or total parenteral nutrition (TPN).*

Applications for authorisation must be made in writing and must include:

- (a) a completed authority prescription form; and*
- (b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:*
 - (i) the completed Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient's condition; or*
 - (ii) the reports and dates of the pathology test or diagnostic imaging test(s) used to assess response to therapy; or*
 - (iii) the date of clinical assessment.*

All assessments must be no more than 1 month old at the time of application.

If the application is the first application for continuing treatment with infliximab, an assessment of the patient's response must be made up to 12 weeks after the first dose (6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.

The assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion.

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with infliximab.

Patients are eligible to receive continuing infliximab treatment in courses of up to 24 weeks providing they continue to sustain the response.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats will be authorised. No applications for increased repeats will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer \$	Proprietary Name and Manufacturer

Public and private hospital authority required

Initial 3 (grandfather)

Initial PBS-subsidised treatment of Crohn disease in a patient assessed by CDAI who has previously received non-PBS-subsidised therapy with infliximab.

Initial PBS-subsidised supply for continuing treatment with infliximab by a gastroenterologist, a consultant physician as specified in the NOTE below, or other consultant physician in consultation with a gastroenterologist of a patient who:

- (a) has a documented history of severe refractory Crohn disease and was receiving treatment with infliximab prior to 7 March 2007; and***
- (b) had a Crohn Disease Activity Index (CAI) Score of greater than or equal to 300 prior to commencing treatment with infliximab. Where a baseline CDAI assessment is not available, please call Medicare Australia on 1800 700 270 to discuss; and***
- (c) has signed a patient acknowledgement indicating that they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and***
- (d) has demonstrated or sustained an adequate response to treatment with infliximab. For advice please contact Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).***

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

An adequate response to infliximab treatment is defined as a reduction in Crohn Disease Activity Index (CAI) Score to no greater than 150.

Applications for authorisation must be made in writing and must include:

- (a) a completed authority prescription form; and***
- (b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:***
 - (i) the completed current and baseline Crohn Disease Activity Index (CAI) Score calculation sheet including the date of the assessment of the patient's condition; and***
 - (ii) the signed patient acknowledgement.***

The current CDAI assessment must be no more than 1 month old at the time of application. The baseline CDAI assessment must be from immediately prior to commencing treatment with infliximab.

The assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion.

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with infliximab.

Patients are eligible to receive continuing infliximab treatment in courses of up to 24 weeks providing they continue to sustain the response.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats will be authorised. No applications for increased repeats will be authorised.

Where fewer than 2 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Patients may qualify for PBS-subsidised treatment under this restriction once only.

Public and private hospital authority required

Initial 3

Initial PBS-subsidised treatment of Crohn disease in a patient with short gut syndrome, an ostomy patient, or a patient with extensive small intestine disease, who has previously received non-PBS-subsidised therapy with infliximab.

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer \$	Proprietary Name and Manufacturer

Initial PBS-subsidised supply for continuing treatment with infliximab by a gastroenterologist, a consultant physician as specified in the NOTE below, or other consultant physician in consultation with a gastroenterologist, of a patient who:

- (a) has a documented history of severe refractory Crohn disease and was receiving treatment with infliximab prior to 7 March 2007; and*
- (b) (1) has a history of extensive small intestinal disease with radiological evidence of intestinal inflammation affecting more than 50 cm of the small intestine; or*
- (2) has diagnostic imaging or surgical evidence of short gut syndrome or has an ileostomy or colostomy with a documented history of intestinal inflammation; and*
- (c) has signed a patient acknowledgement indicating that they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and*
- (d) has demonstrated or sustained an adequate response to treatment with infliximab according to the criteria included in the relevant continuation restriction. For advice please contact Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).*

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

The same criteria used to determine an inadequate response to prior treatment at baseline must be used to determine response to treatment and eligibility for continuing therapy, according to the criteria included in the continuing treatment restriction.

An adequate response to infliximab treatment is defined as:

- (a) a reduction in Crohn Disease Activity Index (CDAI) Score to no greater than 150; or*
- (b) improvement of intestinal inflammation as demonstrated by:*
 - (i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; AND/OR*
 - (ii) faeces: normalisation of lactoferrin or calprotectin level; AND/OR*
 - (iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or*
- (c) reversal of high faecal output state; or*
- (d) avoidance of the need for surgery or total parenteral nutrition (TPN).*

Applications for authorisation must be made in writing and must include:

- (a) a completed authority prescription form; and*
- (b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:*
 - (i) (1) the completed current and baseline Crohn Disease Activity Index (CDAI) Score calculation sheet, where relevant, including the date of the assessment of the patient's condition; or*
 - (2) the reports and dates of the current and baseline pathology or diagnostic imaging test(s) in order to assess response to therapy; or*
 - (3) the date of clinical assessment(s); and*
 - (ii) the signed patient acknowledgement.*

The patient's assessment must be no more than 1 month old at the time of application. The baseline CDAI assessments must be from immediately prior to commencing treatment with infliximab. Where a baseline assessment is not available, please call Medicare Australia on 1800 700 270 to discuss.

The assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion.

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with infliximab.

Patients are eligible to receive continuing infliximab treatment in courses of up to 24 weeks providing they continue to sustain the response.

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer \$	Proprietary Name and Manufacturer	
	<i>At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats will be authorised. No applications for increased repeats will be authorised.</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 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).</i> <i>Patients may qualify for PBS-subsidised treatment under this restriction once only.</i>				
9613Y	Powder for I.V. infusion 100 mg	1	751.70	Remicade	SH

Public and private hospital authority required

Initial treatment of Crohn disease in a paediatric patient.

Initial PBS-subsidised treatment by a gastroenterologist, paediatrician or consultant physician as specified in the NOTE below, of a patient aged 6 to 17 years inclusive with moderate to severe refractory Crohn disease who satisfies the following criteria:

(a) has confirmed Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or consultant physician as specified in the NOTE below; and

(b) whose parent or authorised guardian has signed a patient acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and

(c) has failed to achieve an adequate response to 2 of the following 3 conventional prior therapies including:

(i) a tapered course of steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period;

(ii) an 8 week course of enteral nutrition;

(iii) immunosuppressive therapy including:

— azathioprine at a dose of at least 2 mg per kg daily for 3 or more months; or

— 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months; or

— methotrexate at a dose of at least 10 mg per square metre weekly for 3 or more months.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application.

Details of the accepted toxicities including severity can be found on the Medicare Australia website (www.medicareaustralia.gov.au).

The following initiation criterion indicates failure to achieve an adequate response and must be demonstrated in all patients at the time of the application:

(a) severity of disease activity which results in a Paediatric Crohn Disease Activity Index (PCDAI) Score greater than or equal to 30 as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.

(b) The most recent PCDAI assessment must be no more than 1 month old at the time of application.

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.

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Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer \$	Proprietary Name and Manufacturer

Applications for authorisation must be made in writing and must include:

- (a) a completed authority prescription form; and*
- (b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:*
 - (i) the completed current Paediatric Crohn Disease Activity Index (PCDAI) calculation sheet including the date of assessment of the patient's condition; and*
 - (ii) details of previous systemic drug therapy [dosage, date of commencement and duration of therapy], or dates of enteral nutrition; and*
 - (iii) the signed patient acknowledgement.*

A maximum quantity and number of repeats to provide for an initial course of infliximab consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete the 3 doses of infliximab may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

A PCDAI assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab.

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment.

Public and private hospital authority required

Continuing treatment of Crohn disease in a patient initiated on PBS-subsidised treatment as a paediatric patient.

Continuing PBS-subsidised treatment with infliximab by a gastroenterologist, paediatrician, consultant physician as specified in the NOTE below or other consultant physician in consultation with a gastroenterologist, of a patient who:

- (a) has a documented history of moderate to severe refractory Crohn disease; and*
- (b) has demonstrated or sustained an adequate response to treatment with infliximab.*

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

An adequate response to infliximab treatment is defined as a reduction in Paediatric Crohn Disease Activity Index (PCDAI) Score by at least 15 points as compared to baseline AND a total PCDAI score of 30 points or less.

Applications for authorisation must be made in writing and must include:

- (a) a completed authority prescription form; and*
- (b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:*
 - (i) the completed Paediatric Crohn Disease Activity Index (PCDAI) calculation sheet along with the date of the assessment of the patient's condition.*

The PCDAI assessment must be no more than 1 month old at the time of application.

If the application is the first application for continuing treatment with infliximab, a PCDAI assessment of the patient's response must be made up to 12 weeks after the first dose so that there is adequate time for a response to be demonstrated.

The assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion.

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with infliximab.

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Patients are eligible to receive continuing infliximab treatment in courses of up to 24 weeks providing they continue to sustain the response.

Patients who fail to demonstrate or sustain a response to treatment with infliximab for Crohn disease as specified in the criteria for continuing treatment with infliximab, will not be eligible to receive PBS-subsidised treatment with this drug within 12 months of the date on which treatment was ceased.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats will be authorised. No applications for increased repeats will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Public and private hospital authority required

Initial PBS-subsidised treatment of Crohn disease in a paediatric patient who has previously received non-PBS-subsidised therapy with infliximab.

Initial PBS-subsidised supply for continuing treatment with infliximab by a gastroenterologist, paediatrician, consultant physician as specified in the NOTE below or other consultant physician in consultation with a gastroenterologist, of a patient aged 6 to 17 years inclusive who:

- (a) has a documented history of moderate to severe refractory Crohn disease and was receiving treatment with infliximab prior to 4 July 2007; and*
- (b) had a Paediatric Crohn Disease Activity Index (PCDAI) Score of greater than 30 prior to commencing treatment with infliximab. Where a baseline CDAI assessment is not available, please call Medicare Australia on 1800 700 270 to discuss; and*
- (c) whose parent or authorised guardian has signed a patient acknowledgement indicating that they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and*
- (d) has demonstrated or sustained an adequate response to treatment with infliximab. For advice please contact Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).*

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

An adequate response to infliximab treatment is defined as a reduction in Paediatric Crohn Disease Activity Index (PCDAI) Score by at least 15 points as compared to baseline AND a total PCDAI score of 30 points or less.

Applications for authorisation must be made in writing and must include:

- (a) a completed authority prescription form; and*
- (b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:*
 - (i) the completed current and baseline Paediatric Crohn Disease Activity Index (PCDAI) calculation sheet along with the date of the assessment of the patient's condition; and*
 - (ii) the signed patient acknowledgement.*

The current PCDAI assessment must be no more than 1 month old at the time of application. The baseline PCDAI assessment must be from immediately prior to commencing treatment with infliximab.

The assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion.

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with infliximab.

Patients are eligible to receive continuing infliximab treatment in courses of up to 24 weeks providing they continue to sustain the response.

Patients who fail to demonstrate or sustain a response to treatment with infliximab for Crohn disease as specified in the criteria for continuing treatment with infliximab, will not be eligible to recommence PBS-subsidised treatment with this drug within 12 months of the date on which treatment was ceased.

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer \$	Proprietary Name and Manufacturer	
	<i>At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats will be authorised. No applications for increased repeats will be authorised.</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 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).</i> <i>Patients may qualify for PBS-subsidised treatment under this restriction once only.</i>				
9612X	Powder for I.V. infusion 100 mg	1	751.70	Remicade	SH
	NOTE: TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS <i>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 chronic plaque psoriasis. Therefore, where the term 'biological agents' appears in the following NOTES and restrictions, it only refers to adalimumab, etanercept and infliximab.</i> <i>From 1 June 2009, 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 an alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.</i> <i>A patient who received PBS-subsidised biological agent treatment for chronic plaque psoriasis prior to 1 June 2009 is considered to be in their first Cycle as of 1 June 2009.</i> <i>Patients are eligible for PBS-subsidised treatment with only 1 biological agent at any 1 time.</i> <i>Within the same Treatment Cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for a PBS-subsidised biological agent, they must change to an alternate agent if they wish to continue PBS-subsidised biological treatment. A patient who, prior to 1 June 2009, was authorised to receive PBS-subsidised initial treatment for chronic plaque psoriasis with the same agent twice, is exempt from this condition in respect of applications approved prior to 1 June 2009.</i> <i>Patients must be assessed for response to each course of continuing treatment according to the criteria included in the relevant continuing treatment restriction.</i> <i>Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a Treatment Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological agent therapy before they are eligible to commence the next Cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological agent treatment in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Treatment Cycle.</i> <i>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.</i> <i>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.</i> <i>There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.</i> <i>How to prescribe biological agents for the treatment of severe chronic plaque psoriasis after 1 June 2009.</i> <i>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.</i> <i>(1) Application for approval for initial treatment.</i>				

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Applications for a course of initial treatment should be made in the following situations:

- (i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); or*
- (ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under '(4) Swapping therapy' below]; or*
- (iii) patients who wish to re-commence treatment following a break in PBS-subsidised therapy with that agent (Initial 2).*

All applications for initial treatment will be limited to provide for a maximum of 16 weeks of treatment in the case of adalimumab and etanercept, and 22 weeks of treatment in the case of infliximab.

Grandfather patients (adalimumab only).

Applications for patients who commenced treatment with adalimumab prior to 1 March 2009, may be made for initial PBS-subsidised treatment as continuing therapy under the initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with a biological agent prior to PBS listing of that agent.

Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment. Approval will be based on the criteria included in the relevant restriction.

(2) Assessment of response to initial treatment.

When prescribing initial treatment with a biological agent, a PASI assessment must be conducted after at least 12 weeks of treatment. This assessment must be submitted to Medicare Australia within 1 month of the completion of this initial treatment course. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

(3) Application for continuing treatment.

Following the completion of an initial treatment course of a biological agent to which an adequate response has been demonstrated, patients may qualify to receive up to 24 weeks of continuing treatment with that biological agent. Patients are eligible to continue to receive continuous treatment with 24 week courses providing they continue to sustain a response.

For second and subsequent courses of PBS-subsidised treatment with adalimumab, etanercept or infliximab it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

Where a response assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to sustain a response to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

(4) Swapping therapy.

Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate agent within the same Treatment Cycle without having to requalify with respect to disease severity (i.e. a PASI score of greater than 15), or prior treatment requirements.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

Patients may trial an alternate biological agent at any time, regardless of whether they are receiving therapy with a biological agent at the time of the application or not. However, they cannot swap to a particular agent if they have failed to respond to treatment with that particular agent within the same Cycle.

Patients who commenced treatment with adalimumab prior to 1 June 2009 access these interchangeability arrangements in the same way as patients who have not.

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To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the agent being ceased.

(5) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated, based on the baseline PASI assessment submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment authority is submitted within a Treatment Cycle and subsequent response will be assessed according to this revised PASI score.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatment applications.

(6) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

Patients who wish to trial a second or subsequent Biological Treatment Cycle, following a break in PBS-subsidised biological therapy of at least 5 years, must requalify for initial treatment according to the criteria of the relevant restriction and index of disease severity. Patients must have had at least 1 prior treatment, as listed in the criteria, for a minimum of 6 weeks, and must have a PASI assessment conducted preferably whilst still on treatment, but no later than 1 month following cessation of treatment. The PASI assessment must be no older than 1 month at the time of application.

Public and private hospital authority required

Initial treatment [Initial 1, Whole body (New patients — No prior biological agent)]

Initial treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over who:

(a) have severe chronic plaque psoriasis where lesions have been present for at least 6 months from the time of initial diagnosis; and

(b) have not received any prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle; and

(c) have signed a patient and prescriber acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment (whole body); and

(d) have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 3 of the following 4 treatments:

(i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; and/or

(ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; and/or

(iii) cyclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; and/or

(iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks.

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity to necessitate permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of acceptable toxicities including severity, associated with phototherapy, methotrexate, cyclosporin and acitretin, can be found on the Medicare Australia website (www.medicareaustralia.gov.au).

The following initiation criterion indicates failure to achieve an adequate response and must be demonstrated in all patients at the time of the application:

(a) A current Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.

(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 1 month following cessation of each course of treatment.

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(c) The most recent PASI assessment must be no more than 1 month old at the time of application.

Applications for authorisation must be made in writing and must include:

- (a) a completed authority prescription form; and*
- (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:*
 - (i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)];*
 - (ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy]; and*
 - (iii) the signed patient and prescriber acknowledgements.*

A maximum of 22 weeks of treatment with infliximab will be authorised under this restriction.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised.

Where fewer than 3 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 22 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period beyond 22 weeks.

A PASI assessment of the patient's response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

It is recommended that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment.

Public and private hospital authority required

- *Initial or re-Treatment [Initial 2, Whole body (Received prior biological agent under PBS)]*
Treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over who:
- (a) have a documented history of severe chronic plaque psoriasis; and*
 - (b) have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle; and*
 - (c) have not failed PBS-subsidised therapy with infliximab for the treatment of this condition in the current Treatment Cycle.*

Applications for authorisation must be made in writing and must include:

- (a) a completed authority prescription form; and*
- (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:*
 - (i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)];*
 - (ii) details of prior biological treatment, including dosage, date and duration of treatment.*

Applications for patients who have demonstrated a response to PBS-subsidised infliximab treatment within this Treatment Cycle and who wish to re-commence infliximab treatment within the same Cycle following a break in

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therapy, will only be approved where evidence of the patient's response to their most recent course of PBS-subsidised infliximab treatment has been submitted to Medicare Australia within 1 month of cessation of treatment.

A maximum of 22 weeks of treatment with infliximab will be authorised under this restriction.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised.

Where fewer than 3 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 22 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period beyond 22 weeks.

A PASI assessment of the patient's response to this course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

It is recommended that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment.

Patients who fail to demonstrate a response to treatment with each of the biological agents, adalimumab, etanercept and infliximab, are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may re-commence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

Public and private hospital authority required

Continuing treatment (Whole body)

Continuing PBS-subsidised treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over:

- (a) who have a documented history of severe chronic plaque psoriasis; and*
- (b) whose most recent course of PBS-subsidised biological treatment for this condition in this Treatment Cycle was with infliximab; and*
- (c) who have demonstrated an adequate response to their most recent course of treatment with infliximab.*

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the pre-biological treatment baseline value for this Treatment Cycle.

This assessment must be provided to Medicare Australia no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with infliximab, the assessment of response must be after a minimum of 12 weeks of treatment with an initial course.

Applications for authorisation must be made in writing and must include:

- (a) a completed authority prescription form; and*
- (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:*
 - (i) the completed Psoriasis Area and Severity Index (PASI) calculation sheet along with the date of the assessment of the patient's condition.*

The most recent PASI assessment must be no more than 1 month old at the time of application.

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Approval will be based on the PASI assessment of response to the most recent course of treatment with infliximab.

A maximum of 24 weeks of treatment with infliximab will be authorised under this restriction.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for continuing authority applications, or for treatment that would otherwise extend the treatment period beyond 24 weeks.

A PASI assessment of the patient's response must be conducted within 4 weeks prior to completion of this course of treatment. This assessment, which will be used to determine eligibility for further continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

It is recommended that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment.

Patients who fail to demonstrate a response to treatment with each of the biological agents, adalimumab, etanercept and infliximab, are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may re-commence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

Public and private hospital authority required

- *Initial treatment [Initial 1, Face, hand, foot (New patients — No prior biological agent)]*
Initial treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over who:
- (a) have severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis; and*
 - (b) have not received any prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle; and*
 - (c) have signed a patient and prescriber acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment (face, hand, foot); and*
 - (d) have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 3 of the following 4 treatments:*
 - (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; and/or*
 - (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; and/or*
 - (iii) cyclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; and/or*
 - (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks.*

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity to necessitate permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of acceptable toxicities including severity, associated with phototherapy, methotrexate, cyclosporin and acitretin, can be found on the Medicare Australia website (www.medicareaustralia.gov.au).

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The following initiation criterion indicates failure to achieve an adequate response and must be demonstrated in all patients at the time of the application:

(a) Chronic plaque psoriasis classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where:

(i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment; or

(ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.

(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 1 month following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than 1 month old at the time of application.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy]; and

(iii) the signed patient and prescriber acknowledgements.

A maximum of 22 weeks of treatment with infliximab will be authorised under this restriction.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised.

Where fewer than 3 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 22 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period beyond 22 weeks.

A PASI assessment of the patient's response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

It is recommended that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

Public and private hospital authority required

➤ **Initial or re-Treatment [Initial 2, Face, hand, foot (Received prior biological agent under PBS)]**

Treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over who:

(a) have a documented history of severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot; and

(b) have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle;

and

continued ➤

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(c) have not failed PBS-subsidised therapy with infliximab for the treatment of this condition in the current Treatment Cycle.

Applications for authorisation must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
 - (i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and
 - (ii) details of prior biological treatment, including dosage, date and duration of treatment.

Applications for patients who have demonstrated a response to PBS-subsidised infliximab treatment within this Treatment Cycle and who wish to re-commence infliximab treatment within the same Cycle following a break in therapy, will only be approved where evidence of the patient's response to their most recent course of PBS-subsidised infliximab treatment has been submitted to Medicare Australia within 1 month of cessation of treatment.

A maximum of 22 weeks of treatment with infliximab will be authorised under this restriction.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised.

Where fewer than 3 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 22 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period beyond 22 weeks.

A PASI assessment of the patient's response to this course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

It is recommended that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

Patients who fail to demonstrate a response to treatment with each of the biological agents, adalimumab, etanercept and infliximab, are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may re-commence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

Public and private hospital authority required

Continuing treatment (Face, hand, foot)

Continuing PBS-subsidised treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over:

- (a) who have a documented history of severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot; and
- (b) whose most recent course of PBS-subsidised biological treatment for this condition in this Treatment Cycle was with infliximab; and
- (c) who have demonstrated an adequate response to treatment with infliximab.

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An adequate response to infliximab treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

- (i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the pre-biological treatment baseline values; or*
- (ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the pre-biological treatment baseline value.*

This assessment must be provided to Medicare Australia no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with infliximab, the assessment of response must be after a minimum of 12 weeks of treatment with an initial course.

Applications for authorisation must be made in writing and must include:

- (a) a completed authority prescription form; and*
- (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:*
 - (i) the completed Psoriasis Area and Severity Index (PASI) calculation sheet and face, hand, foot area diagrams along with the date of the assessment of the patient's condition [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].*

The most recent PASI assessment must be no more than 1 month old at the time of application.

A maximum of 24 weeks of treatment with infliximab will be authorised under this restriction.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for continuing authority applications, or for treatment that would otherwise extend the treatment period beyond 24 weeks.

A PASI assessment of the patient's response must be conducted within 4 weeks prior to completion of this course of treatment. This assessment, which will be used to determine eligibility for further continuing treatment must be submitted to Medicare Australia no later than 1 month from the date of completion of this course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

It is recommended that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment.

The PASI assessment for continuing treatment must be performed on the same affected area assessed at baseline.

Patients who fail to demonstrate a response to treatment with each of the biological agents, adalimumab, etanercept and infliximab, are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may re-commence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

9617E	Powder for I.V. infusion 100 mg	1	751.70	Remicade	SH

NOTE:

No applications for increased repeats will be authorised.

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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)(a) Abnormal serum ALT levels in conjunction with documented chronic hepatitis B infection; or</i>					
<i>(b) Elevated HBV DNA levels in conjunction with documented chronic hepatitis B infection;</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
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)(a) Abnormal serum ALT levels in conjunction with documented chronic hepatitis B infection; or</i>					
<i>(b) Elevated HBV DNA levels in conjunction with documented chronic hepatitis B infection;</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

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer \$	Proprietary Name and Manufacturer	
INTERFERON GAMMA-1b					
<u>Private hospital authority required</u>					
<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	6	1360.90	Imukin	BY
LAMIVUDINE					
<u>Private hospital authority required</u>					
<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)(a) Abnormal serum ALT levels in conjunction with documented chronic hepatitis B infection; or</i>					
<i>(b) Elevated HBV DNA levels in conjunction with documented chronic hepatitis B infection;</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	149.36	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
<u>Private hospital authority required</u>					
<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)(a) Abnormal serum ALT levels in conjunction with documented chronic hepatitis B infection; or</i>					
<i>(b) Elevated HBV DNA levels in conjunction with documented chronic hepatitis B infection;</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>					
6271C	Oral solution 5 mg per mL, 240 mL	1	69.91	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>					
6194B	Oral solution 10 mg per mL, 240 mL	1	86.48	3TC	GK

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer \$	Proprietary Name and Manufacturer	
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 a patient 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 while awaiting the effects of radiotherapy and where treatment with dopamine agonists has failed; or</i>					
<i>(c) if the patient is unfit for or unwilling to undergo surgery and where radiotherapy is contraindicated.</i>					
<i>In a patient treated with radiotherapy, treatment must cease if there is biochemical evidence of remission (normal IGF1) after lanreotide has been withdrawn for at least 4 weeks (6 weeks after the last dose). Lanreotide should be withdrawn every 2 years in the 10 years after radiotherapy for assessment of remission.</i>					
<i>Treatment must cease if IGF1 is not lower after 3 months treatment.</i>					
6332G	Powder for suspension for injection 30 mg (base) with diluent ampoule	1	750.00	Somatuline LA	IS
<u>Private hospital authority required</u>					
<i>Active acromegaly in a patient 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 while awaiting the effects of radiotherapy and where treatment with dopamine agonists has failed; or</i>					
<i>(c) if the patient is unfit for or unwilling to undergo surgery and where radiotherapy is contraindicated.</i>					
<i>In a patient treated with radiotherapy, treatment must cease if there is biochemical evidence of remission (normal IGF1) after lanreotide has been withdrawn for at least 4 weeks (8 weeks after the last dose). Lanreotide should be withdrawn every 2 years in the 10 years after radiotherapy for assessment of remission.</i>					
<i>Treatment must cease if IGF1 is not lower after 3 months treatment;</i>					
<i>Functional carcinoid tumour causing intractable symptoms. The patient must have experienced on average over 1 week, 3 or more episodes per day of diarrhoea and/or flushing, which persisted despite the use of anti-histamines, anti-serotonin agents and anti-diarrhoea agents, and surgery or antineoplastic therapy must have failed or be inappropriate.</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

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer \$	Proprietary Name and Manufacturer	
LANTHANUM CARBONATE HYDRATE					
<u>Private hospital authority required</u>					
<i>Management of hyperphosphataemia in a patient with chronic kidney disease on dialysis whose serum phosphate is not controlled on calcium and where:</i>					
<i>(a) serum phosphate is greater than 1.6 mmol per L; or</i>					
<i>(b) the serum calcium times phosphate product is greater than 4.0.</i>					
<i>at the commencement of therapy.</i>					
<i>Management includes initiation, stabilisation and review of therapy as required.</i>					
NOTE:					
<i>Not to be used in combination with sevelamer.</i>					
9635D	Chewable tablet 500 mg (base)	90	261.77	Fosrenol	ZI
9636E	Chewable tablet 750 mg (base)	90	395.28	Fosrenol	ZI
9637F	Chewable tablet 1000 mg (base)	90	445.01	Fosrenol	ZI
LENOGRASTIM					
<u>Private hospital authority required</u>					
<i>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;</i>					
<i>Mobilisation of peripheral blood progenitor cells, in normal volunteers, for use in allogeneic transplantation to facilitate harvest of such cells in healthy donors;</i>					
<i>Patients with non-myeloid malignancies receiving marrow-ablative chemotherapy and subsequent peripheral blood progenitor cell or bone marrow transplantation;</i>					
<i>Patients being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in:</i>					
<i>(a) acute lymphoblastic leukaemia; or</i>					
<i>(b) Ewing's sarcoma; or</i>					
<i>(c) germ cell tumours; or</i>					
<i>(d) infants and children with CNS tumours; or</i>					
<i>(e) neuroblastoma; or</i>					
<i>(f) non-Hodgkin's lymphoma (intermediate or high grade); or</i>					
<i>(g) osteosarcoma; or</i>					
<i>(h) relapsed Hodgkin's disease; or</i>					
<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>					
6337M	Powder for injection 13,400,000 i.u. (105 micrograms)	10	512.50	Granocyte 13	HH
6338N	Powder for injection 33,600,000 i.u. (263 micrograms)	10	1283.60	Granocyte 34	HH

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer \$	Proprietary Name and Manufacturer	
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>					
9633B	Tablet 100 mg-25 mg	60	171.25	Kaletra	AB
6495W	Tablet 200 mg-50 mg	120	685.00	Kaletra	AB
6341R	Oral liquid 400 mg-100 mg per 5 mL, 60 mL	1	129.00	Kaletra	AB

MYCOPHENOLATE MOFETIL**CAUTION:***Careful monitoring of patients is mandatory.***Private hospital authority required***Management of rejection, under the supervision and direction of a transplant unit, in patients receiving this drug for:**(a) prophylaxis of renal allograft rejection. Management includes initiation, stabilisation and review of therapy as required; or**(b) prophylaxis of cardiac allograft rejection. Management includes initiation, stabilisation and review of therapy as required.*

6208R	Capsule 250 mg	300	555.70	CellCept	RO
6209T	Tablet 500 mg	150	555.70	CellCept	RO
6364Y	Powder for oral suspension 1 g per 5 mL, 165 mL	1	244.51	CellCept	RO

MYCOPHENOLATE SODIUM**CAUTION:***Careful monitoring of patients is mandatory.***Private hospital authority required***Management of rejection, under the supervision and direction of a transplant unit, in patients receiving this drug for prophylaxis of renal allograft rejection. Management includes initiation, stabilisation and review of therapy as required.*

6369F	Tablet (enteric coated) 180 mg (mycophenolic acid)	120	222.28	Myfortic	NV
6370G	Tablet (enteric coated) 360 mg (mycophenolic acid)	120	444.56	Myfortic	NV

NATALIZUMAB**CAUTION:***Progressive multifocal leukoencephalopathy (PML) has been reported with this drug.***NOTE:***Neurologists prescribing natalizumab under the PBS listing must be registered with the Tysabri Australian Prescribing Program.***Private hospital authority required***Initial treatment, as monotherapy, by neurologists, of clinically definite relapsing-remitting multiple sclerosis in an ambulatory (without assistance or support) patient 18 years of age or older, who has experienced at least 2 documented attacks of neurological dysfunction, believed to be due to multiple sclerosis, in the preceding 2 years.**The diagnosis must be confirmed by magnetic resonance imaging of the brain and/or spinal cord and the date of the scan included in the authority application, unless the authority application is accompanied by written certification provided by a radiologist that an MRI scan is contraindicated because of the risk of physical (not psychological) injury to the patient.*

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Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer \$	Proprietary Name and Manufacturer	

A maximum quantity of 6 infusions will be issued with the initial authority.

Private hospital authority required

Continuing treatment, as monotherapy, of clinically definite relapsing-remitting multiple sclerosis in a patient previously issued with an authority prescription for this drug who does not show continuing progression of disability while on treatment with this drug, and who has demonstrated compliance with, and an ability to tolerate, this therapy.

A maximum quantity of 3 infusions will be issued with the continuing authority.

9624M	Solution concentrate for I.V. infusion 300 mg in 15 mL	1	2038.46	Tysabri	BD

NEVIRAPINE

Private hospital authority required

Treatment of HIV infection in patients with:

- (a) CD4 cell counts of less than 500 per cubic millimetre; or*
- (b) viral load of greater than 10,000 copies per mL.*

6215D	Tablet 200 mg	60	271.58	Viramune	BY

OCTREOTIDE ACETATE

Private hospital authority required

Active acromegaly in a patient with persistent elevation of mean growth hormone levels of greater than 2.5 micrograms per litre AND

- (a) after failure of other therapy including dopamine agonists; or*
- (b) as interim treatment while awaiting the effects of radiotherapy and where treatment with dopamine agonists has failed; or*

(c) if the patient is unfit for or unwilling to undergo surgery and where radiotherapy is contraindicated.

In a patient treated with radiotherapy, treatment must cease if there is biochemical evidence of remission (normal IGF1) after octreotide has been withdrawn for at least 4 weeks. Octreotide should be withdrawn every 2 years in the 10 years after radiotherapy for assessment of remission.

Treatment must cease if IGF1 is not lower after 3 months treatment at a dose of 100 micrograms 3 times daily;

Functional carcinoid tumour or vasoactive intestinal peptide secreting tumour (VIPoma) causing intractable symptoms. The patient must have experienced on average over 1 week, 3 or more episodes per day of diarrhoea and/or flushing, which persisted despite the use of anti-histamines, anti-serotonin agents and anti-diarrhoea agents, and surgery or antineoplastic therapy must have failed or be inappropriate.

Treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 2 months' therapy. Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose.

6227R	Injection 50 micrograms (base) in 1 mL	5	35.81	^a Sandostatin 0.05 ^a HH	NV
6228T	Injection 100 micrograms (base) in 1 mL	5	71.60	^a Sandostatin 0.1 ^a HH	NV
6229W	Injection 500 micrograms (base) in 1 mL	5	358.41	^a Sandostatin 0.5 ^a HH	NV

Private hospital authority required

Acromegaly in a patient controlled on Sandostatin subcutaneous injections.

In a patient treated with radiotherapy, treatment must cease if there is biochemical evidence of remission (normal IGF1) after octreotide has been withdrawn for at least 4 weeks (8 weeks after the last dose). Octreotide should be withdrawn every 2 years in the 10 years after radiotherapy for assessment of remission.

Treatment must cease if IGF1 is not lower after 3 months of treatment;

continued 

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer \$	Proprietary Name and Manufacturer	
	<i>Functional carcinoid tumour or vasoactive intestinal peptide secreting tumour (VIPoma) with symptom control on Sandostatin subcutaneous injections.</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 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.</i>				
6426F	Injection (modified release) 10 mg (base) vial and diluent syringe	1	1362.20	Sandostatin LAR	NV
6427G	Injection (modified release) 20 mg (base) vial and diluent syringe	1	1813.00	Sandostatin LAR	NV
6428H	Injection (modified release) 30 mg (base) vial and diluent syringe	1	2268.70	Sandostatin LAR	NV
	PEGFILGRASTIM				
	<u>Private hospital authority required</u>				
	<i>For use in a patient undergoing induction and consolidation therapy for acute myeloid leukaemia;</i> <i>A patient with breast cancer receiving standard dose adjuvant chemotherapy who has had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned;</i> <i>A patient receiving chemotherapy for B-cell chronic lymphocytic leukaemia with fludarabine and cyclophosphamide who has had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned;</i> <i>A patient receiving first-line chemotherapy for Hodgkin disease who has had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned;</i> <i>A patient receiving chemotherapy for myeloma who has had a prior episode of febrile neutropenia, and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned.</i>				
	<u>Private hospital authority required</u>				
	<i>A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in:</i> <i>(a) acute lymphoblastic leukaemia; or</i> <i>(b) breast cancer (adjuvant chemotherapy with docetaxel in combination with an anthracycline and cyclophosphamide); or</i> <i>(c) germ cell tumours; or</i> <i>(d) infants and children with CNS tumours; or</i> <i>(e) neuroblastoma; or</i> <i>(f) non-Hodgkin lymphoma (aggressive grades; or low grade receiving an anthracycline-containing regimen); or</i> <i>(g) relapsed Hodgkin disease; or</i> <i>(h) sarcoma.</i>				
6363X	Injection 6 mg in 0.6 mL single use pre-filled syringe	1	1925.00	Neulasta	AN

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer \$	Proprietary Name and Manufacturer	

PEGINTERFERON ALFA-2a**CAUTION:**

Treatment with peginterferon alfa has been associated with depression and suicide in some patients. Patients with a history of suicidal ideation or depressive illness should be warned of the risks. Psychiatric status during therapy should be monitored.

Private hospital authority required

Monotherapy in patients with chronic hepatitis B and compensated liver disease who satisfy all of the following criteria:

- (1) Histological evidence of chronic hepatitis on liver biopsy (except in patients with coagulation disorders considered severe enough to prevent liver biopsy);*
- (2)(a) Abnormal serum ALT levels in conjunction with documented chronic hepatitis B infection; or*
- (b) Elevated HBV DNA levels in conjunction with documented chronic hepatitis B infection;*
- (3) Have received no prior peginterferon alfa therapy for the treatment of hepatitis B;*
- (4) Female patients of child-bearing age are not pregnant, not breast-feeding, and are using an effective form of contraception;*
- (5) Are not persons with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L).*

Treatment is limited to 1 course of treatment for a duration of up to 48 weeks;

Treatment, managed by an accredited treatment centre, of chronic hepatitis C in patients 18 years or older who have compensated liver disease and who have received no prior interferon alfa or peginterferon alfa treatment for hepatitis C and have a contraindication to ribavirin, who satisfy all of the following criteria:

- (1) Documented chronic hepatitis C infection (repeatedly anti-HCV positive and HCV RNA positive);*
- (2) Female patients of child-bearing age are not pregnant, not breast-feeding, and are using an effective form of contraception.*

The treatment course is limited to up to 48 weeks.

Patients may only continue treatment after the first 12 weeks if the result of an HCV RNA quantitative assay (performed at the same laboratory using the same test) shows that the plasma HCV RNA has become undetectable or the viral load has decreased by at least a 2 log drop.

NOTE:

Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C:

- (a) a nurse educator/counsellor for patients; and*
- (b) 24 hour access by patients to medical advice; and*
- (c) an established liver clinic; and*
- (d) facilities for safe liver biopsy.*

6439X	Injection 135 micrograms in 0.5 mL single use pre-filled syringe	4	1165.90	Pegasys	RO
6449K	Injection 180 micrograms in 0.5 mL single use pre-filled syringe	4	1350.23	Pegasys	RO

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer \$	Proprietary Name and Manufacturer	
PEGINTERFERON ALFA-2b					
CAUTION:					
<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
RALTEGRAVIR POTASSIUM					
Private hospital authority required					
<i>Treatment, in combination with other antiretroviral agents, of HIV infection in an antiretroviral experienced patient with:</i>					
<i>(a) evidence of HIV replication (viral load greater than 10,000 copies per mL); and/or</i>					
<i>(b) CD4 cell counts of less than 500 per cubic millimetre.</i>					
<i>A patient must have failed previous treatment with, or have resistance to, 3 different antiretroviral regimens which have included:</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>					
9629T	Tablet 400 mg (base)	60	1146.90	Isentress	MK

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer \$	Proprietary Name and Manufacturer	
RIBAVIRIN and PEGINTERFERON ALFA-2a					
CAUTION:					
<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>Patients naive to interferon based therapies (non-pegylated or pegylated).</i>					
<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.</i>					
<i>(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	1295.60	Pegasys RBV	RO
6390H	Pack containing 112 tablets ribavirin 200 mg and 4 pre-filled syringes peginterferon alfa-2a injection 135 micrograms	± 1	1375.88	Pegasys RBV	RO
6391J	Pack containing 140 tablets ribavirin 200 mg and 4 pre-filled syringes peginterferon alfa-2a injection 135 micrograms	± 1	1456.14	Pegasys RBV	RO
6392K	Pack containing 168 tablets ribavirin 200 mg and 4 pre-filled syringes peginterferon alfa-2a injection 135 micrograms	± 1	1536.42	Pegasys RBV	RO
6393L	Pack containing 84 tablets ribavirin 200 mg and 4 pre-filled syringes peginterferon alfa-2a injection 180 micrograms	± 1	1462.37	Pegasys RBV	RO

continued ➡

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer \$	Proprietary Name and Manufacturer	
6394M	Pack containing 112 tablets ribavirin 200 mg and 4 pre-filled syringes peginterferon alfa-2a injection 180 micrograms	‡ 1	1542.64	Pegasys RBV	RO
6395N	Pack containing 140 tablets ribavirin 200 mg and 4 pre-filled syringes peginterferon alfa-2a injection 180 micrograms	‡ 1	1622.91	Pegasys RBV	RO
6396P	Pack containing 168 tablets ribavirin 200 mg and 4 pre-filled syringes peginterferon alfa-2a injection 180 micrograms	‡ 1	1703.18	Pegasys RBV	RO

RIBAVIRIN and PEGINTERFERON ALFA-2b

CAUTION:

Treatment with peginterferon alfa has been associated with depression and suicide in some patients. Patients with a history of suicidal ideation or depressive illness should be warned of the risks. Psychiatric status during therapy should be monitored.

CAUTION:

Ribavirin is a category X drug and must not be given to pregnant women. Pregnancy in female patients or in the partners of male patients must be avoided during treatment and during the 6 months period after cessation of treatment.

Private hospital authority required

Patients naive to interferon based therapies (non-pegylated or pegylated).

Treatment, managed by an accredited treatment centre, of chronic hepatitis C in patients 18 years or older who have compensated liver disease and who have received no prior interferon alfa or peginterferon alfa treatment for hepatitis C and who satisfy all of the following criteria:

- (1) Documented chronic hepatitis C infection (repeatedly anti-HCV positive and HCV RNA positive);*
- (2) Female patients of child-bearing age are not pregnant, not breast-feeding, and both patient and their partner are using effective forms of contraception (one for each partner). Male patients and their partners are using effective forms of contraception (one for each partner). Female partners of male patients are not pregnant.*

For patients with genotype 2 or 3 hepatitis C without hepatic cirrhosis or bridging fibrosis, the treatment course is limited to 24 weeks. For hepatitis C patients with genotype 1, 4, 5 or 6 and those genotype 2 or 3 patients with hepatic cirrhosis or bridging fibrosis, the treatment course is limited to 48 weeks.

Patients with genotype 1, 4, 5 or 6 who are eligible for 48 weeks of treatment may only continue treatment after the first 12 weeks if the result of an HCV RNA quantitative assay (performed at the same laboratory using the same test) shows that the plasma HCV RNA has become undetectable or the viral load has decreased by at least a 2 log drop. (An HCV RNA assay at week 12 is unnecessary for genotype 2 and 3 patients because of the high likelihood of early viral response by week 12).

Patients with genotype 1, 4, 5 or 6 who are viral positive at week 12 but have attained at least a 2 log drop in viral load may only continue treatment after the first 24 weeks of treatment if plasma HCV RNA is not detectable by an HCV RNA qualitative assay at week 24. Similarly, genotype 2 or 3 patients with hepatic cirrhosis or bridging fibrosis may only continue treatment after the first 24 weeks if plasma HCV RNA is not detectable by an HCV RNA qualitative assay at week 24. An HCV RNA qualitative assay at week 24 is unnecessary for those patients with genotype 1, 4, 5 or 6 who became viral negative at week 12.

NOTE:

Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C:

- (a) a nurse educator/counsellor for patients; and*
- (b) 24 hour access by patients to medical advice; and*
- (c) an established liver clinic; and*
- (d) facilities for safe liver biopsy.*

continued ➞

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer \$	Proprietary Name and Manufacturer	
Private hospital authority required					
<i>Patients who have failed one prior attempt at interferon based therapies (non-pegylated or pegylated).</i>					
<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 more than one prior treatment with interferon alfa or peginterferon alfa 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>The treatment course is limited to 48 weeks. Patients may only continue treatment after the first 12 weeks of treatment if plasma HCV RNA is not detectable by an HCV RNA qualitative assay at week 12.</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	917.38	Pegatron	SH
6400W	Pack containing 112 capsules ribavirin 200 mg and 4 single use injection pens containing peginterferon alfa-2b powder for injection 50 micrograms with diluent	± 1	1059.87	Pegatron	SH
6401X	Pack containing 84 capsules ribavirin 200 mg and 4 single use injection pens containing peginterferon alfa-2b powder for injection 80 micrograms with diluent	± 1	1211.36	Pegatron	SH
6402Y	Pack containing 140 capsules ribavirin 200 mg and 4 single use injection pens containing peginterferon alfa-2b powder for injection 80 micrograms with diluent	± 1	1353.83	Pegatron	SH
6403B	Pack containing 168 capsules ribavirin 200 mg and 4 single use injection pens containing peginterferon alfa-2b powder for injection 80 micrograms with diluent	± 1	1353.83	Pegatron	SH
6404C	Pack containing 84 capsules ribavirin 200 mg and 4 single use injection pens containing peginterferon alfa-2b powder for injection 100 micrograms with diluent	± 1	1407.33	Pegatron	SH
6405D	Pack containing 112 capsules ribavirin 200 mg and 4 single use injection pens containing peginterferon alfa-2b powder for injection 100 micrograms with diluent	± 1	1549.81	Pegatron	SH
6406E	Pack containing 84 capsules ribavirin 200 mg and 4 single use injection pens containing peginterferon alfa-2b powder for injection 120 micrograms with diluent	± 1	1603.31	Pegatron	SH
6407F	Pack containing 140 capsules ribavirin 200 mg and 4 single use injection pens containing peginterferon alfa-2b powder for injection 120 micrograms with diluent	± 1	1745.79	Pegatron	SH

continued ➞

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer \$	Proprietary Name and Manufacturer	
6408G	Pack containing 84 capsules ribavirin 200 mg and 4 single use injection pens containing peginterferon alfa-2b powder for injection 150 micrograms with diluent	‡ 1	1897.28	Pegatron	SH
6409H	Pack containing 140 capsules ribavirin 200 mg and 4 single use injection pens containing peginterferon alfa-2b powder for injection 150 micrograms with diluent	‡ 1	2039.76	Pegatron	SH
6410J	Pack containing 168 capsules ribavirin 200 mg and 4 single use injection pens containing peginterferon alfa-2b powder for injection 150 micrograms with diluent	‡ 1	2039.76	Pegatron	SH
9634C	Pack containing 196 capsules ribavirin 200 mg and 4 single use injection pens containing peginterferon alfa-2b powder for injection 150 micrograms with diluent	‡ 1	2182.24	Pegatron	SH

RIFABUTIN**Private hospital authority required**

Treatment of Mycobacterium avium complex infections in HIV-positive patients;

Prophylaxis against Mycobacterium avium complex infections in HIV-positive patients with CD4 cell counts of less than 75 per cubic millimetre.

6195C	Capsule 150 mg	30	147.00	Mycobutin	PH

RITONAVIR**Private hospital authority required**

Treatment of HIV infection in patients with:

(a) CD4 cell counts of less than 500 per cubic millimetre; or

(b) viral load of greater than 10,000 copies per mL.

6203L	Capsule 100 mg	84	106.17	Norvir	AB
6494T	Oral solution 600 mg per 7.5 mL (80 mg per mL), 90 mL	1	91.00	Norvir	AB

RITUXIMAB**NOTE:**

Any queries concerning the arrangements to prescribe rituximab may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written applications for authority to prescribe rituximab should be forwarded to:

Medicare Australia

Prior Written Approval of Specialised Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

Further prescribing information is on the Medicare Australia website at www.medicareaustralia.gov.au.

NOTE:**TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying anti-rheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, etanercept, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-1 inhibitor (anakinra) and the T-cell co-stimulation modulator (abatacept).

continued ➞

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer \$	Proprietary Name and Manufacturer

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

PBS-subsidised infliximab, anakinra, rituximab and abatacept must be used in combination with methotrexate at a dose of at least 7.5 mg weekly. Where a patient cannot tolerate 7.5 mg of methotrexate weekly, they are only eligible to receive PBS-subsidised etanercept and adalimumab.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.

From 1 March 2008, under the PBS, all patients will be able to commence a Treatment Cycle where they may trial PBS-subsidised bDMARD agents without having to experience a disease flare when swapping to an alternate agent. Under these interchangeability arrangements, within a single Treatment Cycle, a patient may continue to receive long-term treatment with a bDMARD while they continue to show a response to therapy.

A patient who received PBS-subsidised bDMARD treatment prior to 1 March 2008 is considered to be in their first Cycle as of 1 March 2008.

Within the same Treatment Cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a Treatment Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised bDMARD therapy before they are eligible to commence the next Cycle.

For patients who have failed PBS-subsidised treatment with 3 bDMARDs prior to 1 March 2008 please contact Medicare Australia on 1800 700 270.

The 5-year break is measured from the date of the last approval for PBS-subsidised bDMARD treatment in the most recent Cycle to the date of the first application for initial treatment with a bDMARD under the new Treatment Cycle.

A patient who has failed fewer than 3 bDMARDs in a Treatment Cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same Treatment Cycle.

A patient who has failed fewer than 3 bDMARDs in a Treatment Cycle and who has a break in therapy of more than 5 years, may commence a new Treatment Cycle.

There is no limit to the number of Treatment Cycles a patient may undertake in their lifetime.

If patients fail to respond to a particular bDMARD within a single Treatment Cycle, they are not eligible to receive further PBS-subsidised treatment with that drug until they commence the next Cycle.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 March 2008.

(a) Initial treatment.

Applications for initial treatment should be made where:

- (i) a patient has received no prior PBS-subsidised bDMARD treatment in this Treatment Cycle and wishes to commence such therapy, excluding rituximab (Initial 1); or*
- (ii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or*
- (iii) a patient wishes to re-commence treatment with a specific bDMARD following a break in PBS-subsidised therapy with that agent (Initial 2).*

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for etanercept, adalimumab, anakinra and abatacept, 22 weeks of therapy for infliximab and 2 infusions of rituximab.

From 1 March 2008, a patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to Medicare Australia within 4 weeks.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer \$	Proprietary Name and Manufacturer

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

Rituximab patients:

A further application may be submitted to Medicare Australia 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Rituximab patients:

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD within the same Treatment Cycle without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the same Treatment Cycle.

In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF- α antagonist treatment.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

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NOTE:**(3) Baseline measurements to determine response.**

Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a Treatment Cycle and Medicare Australia will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

The baseline joint and blood counts should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment.

(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent Treatment Cycle following a break in PBS-subsidised bDMARD therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have received treatment with at least 1 non-biological DMARD, at an adequate dose, for a minimum of 3 months at the time the ESR and/or CRP levels and the active joint count are measured.

(5) Patients 'grandfathered' onto PBS-subsidised treatment with rituximab or abatacept.

From 1 March 2008, a patient who commenced treatment with rituximab for severe rheumatoid arthritis prior to 7 March 2007 or abatacept for severe rheumatoid arthritis prior to 1 November 2007 and who was 'grandfathered' on to PBS-subsidised therapy, and who continues to receive treatment in the same Treatment Cycle, will have further applications for treatment with rituximab or abatacept assessed under the continuing treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment with abatacept will be authorised under this criterion.

'Grandfather' arrangements will only apply for the first Treatment Cycle. For the second and subsequent Cycles, a 'grandfather' patient must requalify for initial treatment under the criteria that applies to a new patient. See 'Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' above for further details.

Public and private hospital authority required**Initial 2 (change or re-commencement)**

Application for an initial course of PBS-subsidised treatment with rituximab, in combination with methotrexate at a dose of at least 7.5 mg weekly, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of an adult who:

- (a) has a documented history of severe active rheumatoid arthritis; and
- (b) has failed to respond to at least 1 PBS-subsidised TNF-alfa antagonist in this Treatment Cycle; and
- (c) has not previously failed to respond to PBS-subsidised rituximab in the current Treatment Cycle.

Applications for patients who have demonstrated a response to PBS-subsidised rituximab treatment within this Treatment Cycle and who wish to re-commence rituximab treatment within the same Cycle following a break in therapy, will only be approved where evidence of a response to the patient's most recent course of PBS-subsidised rituximab treatment has been submitted to Medicare Australia.

A patient may qualify to receive a further course of treatment (1 infusion at week 0 and 1 infusion at week 2) every 24 weeks with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction. The demonstration of response must be submitted to Medicare Australia within 4 weeks of assessment.

The same indices of disease severity used to establish baseline at the commencement of treatment with each initial application must be used for assessment of all continuing applications.

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The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form [www.medicareaustralia.gov.au].

Patients who fail to demonstrate a response to treatment with rituximab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug, in this Treatment Cycle. Patients may re-trial rituximab after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised bDMARD was approved in this Cycle and the date of the first application under the new Cycle.

Patients who fail to demonstrate a response to rituximab treatment and who qualify to trial an alternate bDMARD according to the interchangeability arrangements for bDMARDs for the treatment of severe rheumatoid arthritis, may do so without having to have a 22 week treatment-free period.

Patients who fail to demonstrate a response to treatment with 3 bDMARDs are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may re-commence a new bDMARD Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised bDMARD was approved in this Cycle and the date of the first application under the new Cycle.

Public and private hospital authority required

Initial 3 ('grandfather' patients)

Initial PBS-subsidised supply for continuing treatment with rituximab, in combination with methotrexate at a dose of at least 7.5 mg weekly, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of an adult who:

(a) has a documented history of severe active rheumatoid arthritis; and

(b) was receiving treatment with rituximab prior to 7 March 2007; and

(c) has demonstrated a response as specified in the criteria for continuing PBS-subsidised treatment with rituximab.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form [www.medicareaustralia.gov.au] which includes the signed patient acknowledgement form.

The same indices of disease severity used to establish baseline at the commencement of treatment with a bDMARD must be used for assessment of all continuing applications.

Patients who fail to demonstrate a response to treatment with 3 bDMARDs are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may re-commence a new bDMARD Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised bDMARD was approved in this Cycle and the date of the first application under the new Cycle.

Patients can qualify for PBS-subsidised treatment under this criteria once only.

Public and private hospital authority required

Continuing treatment

Continuing PBS-subsidised treatment with rituximab, in combination with methotrexate at a dose of at least 7.5 mg weekly, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of an adult:

(a) who has a documented history of severe active rheumatoid arthritis; and

(b) who has demonstrated an adequate response to treatment with rituximab; and

(c) whose most recent course of PBS-subsidised bDMARD treatment in this Treatment Cycle was with rituximab.

continued ➡

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	<i>An adequate response to treatment is defined as:</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 either of the following:</i> <i>(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</i> <i>(ii) a reduction in the number of the following major 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 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>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 Rheumatoid Arthritis PBS Authority Application - Supporting Information Form</i> <i>[www.medicareaustralia.gov.au].</i> <i>Patients may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction. The demonstration of response must be submitted to Medicare Australia within 4 weeks of assessment.</i> <i>The same indices of disease severity used to establish baseline at the commencement of treatment with each initial application must be used for assessment of all continuing applications.</i> <i>Patients who fail to demonstrate a response to treatment with 3 bDMARDs are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may re-commence a new bDMARD Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised bDMARD was approved in this Cycle and the date of the first application under the new Cycle.</i>				
9611W	Solution for I.V. infusion 500 mg in 50 mL	1	2263.57	Mabthera	RO
	SAQUINAVIR MESYLATE				
	<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>				
6498B	Tablet 500 mg (base)	120	505.56	Invirase	RO
	SEVELAMER HYDROCHLORIDE				
	<u>Private hospital authority required</u>				
	<i>Management of hyperphosphataemia in a patient with chronic kidney disease on dialysis whose serum phosphate is not controlled on calcium and where:</i>				
	<i>(a) serum phosphate is greater than 1.6 mmol per L; or</i>				
	<i>(b) the serum calcium times phosphate product is greater than 4.0.</i>				
	<i>at the commencement of therapy.</i>				
	<i>Management includes initiation, stabilisation and review of therapy as required.</i>				
	<u>NOTE:</u>				
	<i>Not to be used in combination with lanthanum.</i>				
9620H	Tablet 800 mg	180	310.00	Renagel	GZ

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SILDENAFIL CITRATE**NOTE:**

Any queries concerning the arrangements to prescribe sildenafil citrate may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written applications for authority to prescribe sildenafil citrate should be forwarded to:

Medicare Australia

Prior Written Approval of Specialised Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

NOTE:

Sildenafil citrate is not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with scleroderma, where the total lung capacity is less than 70% of that predicted.

Sildenafil citrate is not PBS-subsidised when used in combination with PBS-subsidised bosentan monohydrate, PBS-subsidised iloprost trometamol, PBS-subsidised epoprostenol sodium or PBS-subsidised sitaxentan sodium.

The following provides some explanatory notes regarding the availability of PBS-subsidised treatment with:

- (a) bosentan monohydrate, of primary pulmonary hypertension or pulmonary arterial hypertension secondary to scleroderma, in patients with disease of WHO Functional Class III or IV severity; AND*
- (b) iloprost trometamol, of primary pulmonary hypertension, drug-induced pulmonary arterial hypertension or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class III or IV severity; AND*
- (c) epoprostenol sodium, of primary pulmonary hypertension, in patients with disease of WHO Functional Class III or IV severity; AND*
- (d) sildenafil citrate, of primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class III severity; AND*
- (e) sitaxentan sodium, of primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class III severity.*

Adult patients:

From 1 April 2008, adult patients with primary pulmonary hypertension will be able to access, through the PBS, bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate (WHO Class III only) or sitaxentan sodium (WHO Class III only). Once these patients are approved initial treatment with 1 of these 5 drugs, they may swap between bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate and sitaxentan sodium at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary. (New baselines may be submitted where the patient has failed to respond to their current treatment.)

Patients may only swap to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate or sitaxentan sodium if they have not failed prior PBS-subsidised treatment with that drug.

Adult patients with pulmonary arterial hypertension secondary to scleroderma will be able to access, through the PBS, bosentan monohydrate, iloprost trometamol, sildenafil citrate (WHO Class III only) or sitaxentan sodium (WHO Class III only). Once these patients are approved initial treatment with 1 of these 4 drugs, they may swap between bosentan monohydrate, iloprost trometamol, sildenafil citrate and sitaxentan sodium at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary. (New baselines may be submitted where the patient has failed to respond to their current treatment.)

Patients may only swap to bosentan monohydrate, iloprost trometamol, sildenafil citrate or sitaxentan sodium if they have not failed prior PBS-subsidised treatment with that drug.

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Adult patients with pulmonary arterial hypertension secondary to connective tissue disease other than scleroderma will be able to access, through the PBS, iloprost trometamol, sildenafil citrate (WHO Class III only) or sitaxentan sodium (WHO Class III only). Once these patients are approved initial treatment with 1 of these 3 drugs, they may swap between iloprost trometamol, sildenafil citrate and sitaxentan sodium at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary. (New baselines may be submitted where the patient has failed to respond to their current treatment.)

Patients may only swap to iloprost trometamol, sildenafil citrate or sitaxentan sodium if they have not failed prior PBS-subsidised treatment with that drug.

Patients with drug-induced pulmonary arterial hypertension are only eligible for treatment with iloprost trometamol. They may not swap to bosentan monohydrate, epoprostenol sodium, sildenafil citrate or sitaxentan sodium.

Patients under 18 years of age:

From 1 April 2008, patients aged less than 18 years with primary pulmonary hypertension are eligible to receive PBS-subsidised treatment with bosentan monohydrate, epoprostenol sodium, iloprost trometamol, sildenafil citrate (WHO Class III only) or sitaxentan sodium (WHO Class III only). Once these patients are approved initial treatment with 1 of these 5 drugs, they may swap between bosentan monohydrate, epoprostenol sodium, iloprost trometamol, sildenafil citrate and sitaxentan sodium at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary. (New baselines may be submitted where the patient has failed to respond to their current treatment.)

Patients may only swap to bosentan monohydrate, epoprostenol sodium, iloprost trometamol, sildenafil citrate or sitaxentan sodium if they have not failed prior PBS-subsidised treatment with that drug.

1. Definition of primary pulmonary hypertension, drug-induced pulmonary arterial hypertension or pulmonary arterial hypertension secondary to connective tissue disease, including scleroderma.

Primary pulmonary hypertension, drug-induced pulmonary arterial hypertension or pulmonary arterial hypertension secondary to connective tissue disease, including scleroderma, are defined as follows:

- (i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary capillary wedge pressure (PCWP) less than 18 mmHg; or*
- (ii) mPAP greater than 30 mmHg with exercise and PCWP less than 18 mmHg; or*
- (iii) where a right heart catheter cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.*

2. Definition of WHO Functional Class III or IV disease severity.

(a) WHO Functional Class III disease severity is defined as follows:

Patients with pulmonary hypertension resulting in marked limitation of physical activity who are comfortable at rest and on ordinary physical activity experience dyspnoea or fatigue, chest pain or near syncope.

(b) WHO Functional Class IV disease severity is defined as follows:

Patients with the inability to carry out any physical activity without symptoms. These patients manifest signs of right heart failure. Dyspnoea and/or fatigue may even be present at rest. Discomfort is increased by any physical activity.

3. Designated hospitals.

Refer to the Medicare Australia website at www.medicareaustralia.gov.au for a list of designated hospitals.

4. Test requirements to establish baseline for initiation of treatment and response to treatment for continuation of treatment.

(a) Initiation of treatment.

The first written application for PBS-subsidised treatment with the first of either bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate or sitaxentan sodium should be accompanied by the results of a right heart catheter (RHC) composite assessment, plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements.

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Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

- (1) RHC plus ECHO composite assessments;*
- (2) RHC composite assessment plus 6MWT;*
- (3) RHC composite assessment only.*

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted to Medicare Australia for consideration based on the results of the following test combinations, which are listed in descending order of preference:

- (1) ECHO composite assessment plus 6MWT;*
- (2) ECHO composite assessment only.*

Where fewer than 3 tests are able to be performed on clinical grounds, a reason outlining why the particular test/s could not be conducted must be provided with the authority application.

NOTE:

Where patients were initiated on PBS-subsidised treatment either with bosentan monohydrate on or after 1 March 2004, with iloprost trometamol on or after 1 April 2005, with epoprostenol sodium on or after 1 August 2006, with sildenafil citrate on or after 1 March 2007, with sitaxentan sodium on or after 1 April 2008, or with bosentan monohydrate (for PAH associated with congenital systemic-to-pulmonary shunt) on or after 1 August 2008, the test results provided with the initial application must be no more than 2 months old at the time of application. These results will form the baseline against which response assessments will be made.

Where patients received treatment with either bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate or sitaxentan sodium prior to being commenced on PBS-subsidised treatment with the first of either bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate or sitaxentan sodium, the test requirements above still apply. The results that will form the baseline against which response assessments will be made will be those measured at the time patients commenced non-PBS-subsidised treatment with either bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate or sitaxentan sodium, whichever of the 5 drugs the patient received first.

(b) Continuation of treatment.

The following list outlines the preferred test combination, in descending order, for the purposes of continuation of PBS-subsidised treatment:

- (1) RHC plus ECHO composite assessments plus 6MWT;*
- (2) RHC plus ECHO composite assessments;*
- (3) RHC composite assessment plus 6MWT;*
- (4) ECHO composite assessment plus 6MWT;*
- (5) RHC composite assessment only;*
- (6) ECHO composite assessment only.*

The results of the same tests as conducted at baseline should be provided with each written continuing treatment application (i.e. every 6 months), except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a reason why the test(s) could not be conducted must be provided with the application.

The test(s) results provided with the application for continuing treatment must be no more than 2 months old at the time of application.

5. Definition of response to sildenafil citrate, bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sitaxentan sodium or prior vasodilator treatment.

For adult patients with 2 or more baseline tests, response to treatment is defined as 2 or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For adult patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For adult patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

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For patients aged less than 18 years, response to treatment is defined as at least 1 of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

6. Authority approval requirements. *[The following 2 sections are only relevant to the PBS listing of sildenafil citrate. The requirements specific to bosentan monohydrate, iloprost trometamol, epoprostenol sodium and sitaxentan sodium are given in parts 6 and 7 of the NOTE included in the bosentan monohydrate, iloprost trometamol, epoprostenol sodium and sitaxentan sodium Schedule entry respectively.]*

(a) Initiation of PBS-subsidised treatment with sildenafil citrate, where the patient has not received prior PBS-subsidised treatment with bosentan monohydrate, iloprost trometamol, epoprostenol sodium or sitaxentan sodium.

All applications for initial treatment must be made in writing, must include an authority prescription and must be submitted to Medicare Australia for authorisation. The total duration of initial PBS-subsidised treatment that will be approved with this first written application is up to 6 months.

(b) Continuation of treatment.

Written applications for continuing treatment must be submitted to Medicare Australia for authorisation every 6 months. Approvals will be limited to provide sufficient supply for up to a maximum of 6 months of treatment, based on the dosage recommendations in the TGA-approved Product Information.

Applications for continuing treatment will only be approved for patients who have currently demonstrated a response to treatment with sildenafil citrate.

The assessment of the patient's response to the first and subsequent 6 month courses of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated. Applications for continuing treatment with sildenafil citrate should be made prior to the completion of the 6 month treatment course to ensure continuity for those patients who respond to treatment, as assessed by the treating physician.

(c) Swapping between bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate and sitaxentan sodium.

For eligible patients, applications to swap between these 5 drugs must be made under the relevant initial treatment restriction. Patients should be assessed for response to the treatment they are ceasing at the time the application to swap therapy is being made. Patients who fail to demonstrate a response or for whom no assessment results are submitted with the application to swap therapy may not re-commence PBS-subsidised treatment with the drug they are ceasing.

It is important that patients are assessed for response to every course of treatment approved within the timeframes specified in the relevant restriction, in order to maximise the choice of treatment.

To avoid confusion, applications for patients who wish to swap to an alternate treatment should be accompanied by the previously approved authority prescription, or remaining repeats, for the treatment the patient is ceasing.

(d) Cessation of treatment.

Patients who fail to demonstrate a response to PBS-subsidised sildenafil citrate treatment at the times where an assessment is required must cease PBS-subsidised sildenafil citrate therapy.

7. Re-treatment with sildenafil citrate.

Patients who do not respond to treatment are not eligible to receive further PBS-subsidised treatment with sildenafil citrate under any circumstances.

8. Further information.

A tabulated representation of the above information and the restriction can be obtained from the Medicare Australia website at www.medicareaustralia.gov.au.

Public and private hospital authority required

Initial (new patients)

Application for initial PBS-subsidised treatment with sildenafil citrate of patients who have not received prior PBS-subsidised treatment with bosentan monohydrate, iloprost trometamol, epoprostenol sodium or sitaxentan sodium and who have been assessed by a physician from a designated hospital to have:

(a) WHO Functional Class III primary pulmonary hypertension and a mean right atrial pressure of 8 mmHg or less, as measured by RHC, unless a RHC is contraindicated on clinical grounds; OR

(b) WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease and a mean right atrial pressure of 8 mmHg or less, as measured by RHC, unless a RHC is contraindicated on clinical grounds.

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Patients must have failed to respond [see Note for definition of response] to 6 or more weeks of appropriate vasodilator treatment unless intolerance or a contraindication to such treatment exists.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted to Medicare Australia for consideration based on the test results of the ECHO composite assessment plus 6MWT or the ECHO composite assessment only.

Applications for authorisation must be in writing and must include:

*(1) a completed authority prescription form [see Note for authority approval requirements]; and
(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form [www.medicareaustralia.gov.au] which includes results from the 3 tests below, where available:*

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6MWT; and

(3) a signed patient acknowledgment indicating that the patient understands and acknowledges that PBS-subsidised treatment with sildenafil citrate for primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, OR with epoprostenol sodium for primary pulmonary hypertension, OR with iloprost trometamol for primary pulmonary hypertension, drug-induced pulmonary arterial hypertension or pulmonary arterial hypertension secondary to connective tissue disease, OR with bosentan monohydrate for primary pulmonary hypertension or pulmonary arterial hypertension secondary to scleroderma, OR with sitaxentan sodium for primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, will cease if the treating physician determines that the patient has not achieved a response to treatment [see Note for definition of response].

Details of prior vasodilator treatment, including the dose and duration of treatment, must be provided at the time of application. Where the patient has an adverse event to a vasodilator or where vasodilator treatment is contraindicated, details on the nature of the adverse event or contraindication according to the TGA-approved Product Information must also be provided with the application.

Where fewer than 3 tests (see requirement 2 above) are able to be performed on clinical grounds, a reason outlining why the particular test/s could not be conducted must be provided with the authority application [see Note for test requirements].

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. A maximum of 5 repeats may be requested. Where fewer than 5 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 6 months of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Public and private hospital authority required

Initial (new patients)

Application for initial PBS-subsidised treatment with sildenafil citrate of patients who have not received prior PBS-subsidised treatment with bosentan monohydrate, iloprost trometamol, epoprostenol sodium or sitaxentan sodium and who have been assessed by a physician from a designated hospital to have:

(a) WHO Functional Class III primary pulmonary hypertension and a mean right atrial pressure greater than 8 mmHg, as measured by RHC, unless a RHC is contraindicated on clinical grounds; OR

(b) WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease and a mean right atrial pressure greater than 8 mmHg, as measured by RHC, unless a RHC is contraindicated on clinical grounds.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted to Medicare Australia for consideration based on the test results of the ECHO composite assessment plus 6MWT or the ECHO composite assessment only.

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer \$	Proprietary Name and Manufacturer

Applications for authorisation must be in writing and must include:

- (1) a completed authority prescription form [see Note for authority approval requirements]; and
- (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form [www.medicareaustralia.gov.au] which includes results from the 3 tests below, where available:

- (i) RHC composite assessment; and
- (ii) ECHO composite assessment; and
- (iii) 6MWT; and

(3) a signed patient acknowledgment indicating that the patient understands and acknowledges that PBS-subsidised treatment with sildenafil citrate for primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, OR with epoprostenol sodium for primary pulmonary hypertension, OR with iloprost trometamol for primary pulmonary hypertension, drug-induced pulmonary arterial hypertension or pulmonary arterial hypertension secondary to connective tissue disease, OR with bosentan monohydrate for primary pulmonary hypertension or pulmonary arterial hypertension secondary to scleroderma, OR with sitaxentan sodium for primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, will cease if the treating physician determines that the patient has not achieved a response to treatment [see Note for definition of response].

Where fewer than 3 tests (see requirement 2 above) are able to be performed on clinical grounds, a reason outlining why the particular test/s could not be conducted must be provided with the authority application [see Note for test requirements].

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. A maximum of 5 repeats may be requested. Where fewer than 5 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 6 months of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Public and private hospital authority required

Initial (change or re-commencement for all patients)

Application for initial PBS-subsidised treatment with sildenafil citrate of patients with either of the following:

- (a) WHO Class III primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease who wish to re-commence PBS-subsidised sildenafil citrate after a break in therapy and who have demonstrated a response to their most recent course of PBS-subsidised treatment with sildenafil citrate; OR
- (b) WHO Class III primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease and whose most recent course of PBS-subsidised treatment was with iloprost trometamol; OR
- (c) WHO Class III primary pulmonary hypertension or pulmonary arterial hypertension secondary to scleroderma and whose most recent course of PBS-subsidised treatment was with bosentan monohydrate; OR
- (d) WHO Class III primary pulmonary hypertension and whose most recent course of PBS-subsidised treatment was with epoprostenol sodium; OR
- (e) WHO Class III primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease and whose most recent course of PBS-subsidised treatment was with sitaxentan sodium.

Applications for authorisation must be in writing and must include:

- (1) a completed authority prescription form [see Note for authority approval requirements]; and
- (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form [www.medicareaustralia.gov.au] which includes the results on which approval for the first application for PBS-subsidised sildenafil citrate, epoprostenol sodium, iloprost trometamol, bosentan monohydrate or sitaxentan sodium, whichever was initiated first, was granted; and
- (3) the date of the first application for PBS-subsidised treatment with sildenafil citrate, epoprostenol sodium, iloprost trometamol, bosentan monohydrate or sitaxentan sodium, whichever was initiated first; and
- (4) the results of the patient's response to treatment with their last course of PBS-subsidised sildenafil citrate, epoprostenol sodium, iloprost trometamol, bosentan monohydrate or sitaxentan sodium.

continued ➞

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer \$	Proprietary Name and Manufacturer	
<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 treatment (all patients)</i> Continuing PBS-subsidised treatment with sildenafil citrate of patients who have received approval for initial PBS-subsidised treatment with sildenafil citrate, and who have been assessed by a physician from a designated hospital to have achieved a response to their most recent course of sildenafil citrate treatment [see Note for definition of response]. <i>Applications for authorisation must be in writing and must include:</i> (1) a completed authority prescription form; and (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form [www.medicareaustralia.gov.au] which includes results from the 3 tests below, where available: (i) RHC composite assessment; and (ii) ECHO composite assessment; and (iii) 6MWT. <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>					
9605M	Tablet 20 mg (base)	90	898.43	Revatio	PF
SIROLIMUS CAUTION: Careful monitoring of patients is mandatory. Private hospital authority required Management of rejection, under the supervision and direction of a transplant unit, in patients receiving this drug for prophylaxis of renal allograft rejection. Management includes initiation, stabilisation and review of therapy as required.					
6436R	Tablet 1 mg	100	723.33	Rapamune	WX
6457W	Tablet 2 mg	100	1446.67	Rapamune	WX
6437T	Oral solution 1 mg per mL, 60 mL	1	468.00	Rapamune	WX
SITAXENTAN SODIUM CAUTION: Sitaxentan sodium is a category X drug and must not be given to pregnant women. Pregnancy must be excluded before the start of treatment and avoided during treatment with this drug. NOTE: Any queries concerning the arrangements to prescribe sitaxentan sodium may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Written applications for authority to prescribe sitaxentan sodium should be forwarded to:					

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Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer \$	Proprietary Name and Manufacturer

Medicare Australia

Prior Written Approval of Specialised Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

NOTE:

Sitaxentan sodium is not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with scleroderma, where the total lung capacity is less than 70% of that predicted.

Sitaxentan sodium is not PBS-subsidised when used in combination with PBS-subsidised bosentan monohydrate, PBS-subsidised iloprost trometamol, PBS-subsidised epoprostenol sodium or PBS-subsidised sildenafil citrate.

The following provides some explanatory notes regarding the availability of PBS-subsidised treatment with:

(a) bosentan monohydrate, of primary pulmonary hypertension or pulmonary arterial hypertension secondary to scleroderma, in patients with disease of WHO Functional Class III or IV severity; AND

(b) iloprost trometamol, of primary pulmonary hypertension, drug-induced pulmonary arterial hypertension or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class III or IV severity; AND

(c) epoprostenol sodium, of primary pulmonary hypertension, in patients with disease of WHO Functional Class III or IV severity; AND

(d) sildenafil citrate, of primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class III severity; AND

(e) sitaxentan sodium, of primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class III severity.

Adult patients:

From 1 April 2008, adult patients with primary pulmonary hypertension will be able to access, through the PBS, bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate (WHO Class III only) or sitaxentan sodium (WHO Class III only). Once these patients are approved initial treatment with 1 of these 5 drugs, they may swap between bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate and sitaxentan sodium at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary. (New baselines may be submitted where the patient has failed to respond to their current treatment.)

Patients may only swap to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate or sitaxentan sodium if they have not failed prior PBS-subsidised treatment with that drug.

Adult patients with pulmonary arterial hypertension secondary to scleroderma will be able to access, through the PBS, bosentan monohydrate, iloprost trometamol, sildenafil citrate (WHO Class III only) or sitaxentan sodium (WHO Class III only). Once these patients are approved initial treatment with 1 of these 4 drugs, they may swap between bosentan monohydrate, iloprost trometamol, sildenafil citrate and sitaxentan sodium at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary. (New baselines may be submitted where the patient has failed to respond to their current treatment.)

Patients may only swap to bosentan monohydrate, iloprost trometamol, sildenafil citrate or sitaxentan sodium if they have not failed prior PBS-subsidised treatment with that drug.

Adult patients with pulmonary arterial hypertension secondary to connective tissue disease other than scleroderma will be able to access, through the PBS, iloprost trometamol, sildenafil citrate (WHO Class III only) or sitaxentan sodium (WHO Class III only). Once these patients are approved initial treatment with 1 of these 3 drugs, they may swap between iloprost trometamol, sildenafil citrate and sitaxentan sodium at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary. (New baselines may be submitted where the patient has failed to respond to their current treatment.)

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Patients may only swap to iloprost trometamol, sildenafil citrate or sitaxentan sodium if they have not failed prior PBS-subsidised treatment with that drug.

Patients with drug-induced pulmonary arterial hypertension are only eligible for treatment with iloprost trometamol. They may not swap to bosentan monohydrate, epoprostenol sodium, sildenafil citrate or sitaxentan sodium.

Patients under 18 years of age:

From 1 April 2008, patients aged less than 18 years with primary pulmonary hypertension are eligible to receive PBS-subsidised treatment with bosentan monohydrate, epoprostenol sodium, iloprost trometamol, sildenafil citrate (WHO Class III only) or sitaxentan sodium (WHO Class III only). Once these patients are approved initial treatment with 1 of these 5 drugs, they may swap between bosentan monohydrate, epoprostenol sodium, iloprost trometamol, sildenafil citrate and sitaxentan sodium at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary. (New baselines may be submitted where the patient has failed to respond to their current treatment.)

Patients may only swap to bosentan monohydrate, epoprostenol sodium, iloprost trometamol, sildenafil citrate or sitaxentan sodium if they have not failed prior PBS-subsidised treatment with that drug.

1. Definition of primary pulmonary hypertension, drug-induced pulmonary arterial hypertension or pulmonary arterial hypertension secondary to connective tissue disease, including scleroderma.

Primary pulmonary hypertension, drug-induced pulmonary arterial hypertension or pulmonary arterial hypertension secondary to connective tissue disease, including scleroderma, are defined as follows:

- (i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary capillary wedge pressure (PCWP) less than 18 mmHg; or*
- (ii) mPAP greater than 30 mmHg with exercise and PCWP less than 18 mmHg; or*
- (iii) where a right heart catheter cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.*

2. Definition of WHO Functional Class III or IV disease severity.

(a) WHO Functional Class III disease severity is defined as follows:

Patients with pulmonary hypertension resulting in marked limitation of physical activity who are comfortable at rest and on ordinary physical activity experience dyspnoea or fatigue, chest pain or near syncope.

(b) WHO Functional Class IV disease severity is defined as follows:

Patients with the inability to carry out any physical activity without symptoms. These patients manifest signs of right heart failure. Dyspnoea and/or fatigue may even be present at rest. Discomfort is increased by any physical activity.

3. Designated hospitals.

Refer to the Medicare Australia website at www.medicareaustralia.gov.au for a list of designated hospitals.

4. Test requirements to establish baseline for initiation of treatment and response to treatment for continuation of treatment.

(a) Initiation of treatment.

(i) New patients.

The first written application for PBS-subsidised treatment with the first of either bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate or sitaxentan sodium should be accompanied by the results of a right heart catheter (RHC) composite assessment, plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

- (1) RHC plus ECHO composite assessments;*
- (2) RHC composite assessment plus 6MWT;*
- (3) RHC composite assessment only.*

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In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted to Medicare Australia for consideration based on the results of the following test combinations, which are listed in descending order of preference:

- (1) ECHO composite assessment plus 6MWT;*
- (2) ECHO composite assessment only.*

Where fewer than 3 tests are able to be performed on clinical grounds, a reason outlining why the particular test/s could not be conducted must be provided with the authority application.

NOTE:

Where patients were initiated on PBS-subsidised treatment either with bosentan monohydrate on or after 1 March 2004, with iloprost trometamol on or after 1 April 2005, with epoprostenol sodium on or after 1 August 2006, with sildenafil citrate on or after 1 March 2007, with sitaxentan sodium on or after 1 April 2008, or with bosentan monohydrate (for PAH associated with congenital systemic-to-pulmonary shunt) on or after 1 August 2008, the test results provided with the initial application must be no more than 2 months old at the time of application. These results will form the baseline against which response assessments will be made.

Where patients received treatment with either bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate or sitaxentan sodium prior to being commenced on PBS-subsidised treatment with the first of either bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate or sitaxentan sodium, the test requirements above still apply. The results that will form the baseline against which response assessments will be made will be those measured at the time patients commenced non-PBS-subsidised treatment with either bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate or sitaxentan sodium, whichever of the 5 drugs the patient received first.

(ii) Patients who received non-PBS-subsidised treatment with sitaxentan sodium prior to 1 April 2008.

For patients with primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease who were commenced on sitaxentan sodium treatment prior to 1 April 2008 and who have received less than 6 months of treatment with sitaxentan sodium at the time of application, the first application for PBS-subsidised treatment must include, where available, all 3 test results at the time that the patient commenced treatment with sitaxentan sodium, sildenafil citrate, epoprostenol sodium, bosentan monohydrate or iloprost trometamol, whichever was initiated first.

For patients with primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease who were commenced on sitaxentan sodium treatment prior to 1 April 2008 and who have received 6 or more months of treatment at the time of application, the first application for PBS-subsidised treatment must include, where available, all 3 test results at the time that the patient commenced treatment with sitaxentan sodium, sildenafil citrate, epoprostenol sodium, bosentan monohydrate or iloprost trometamol, whichever was initiated first. The results at the time of application for initial PBS-subsidised treatment must also be provided and must be no older than 3 months.

(b) Continuation of treatment.

The following list outlines the preferred test combination, in descending order, for the purposes of continuation of PBS-subsidised treatment:

- (1) RHC plus ECHO composite assessments plus 6MWT;*
- (2) RHC plus ECHO composite assessments;*
- (3) RHC composite assessment plus 6MWT;*
- (4) ECHO composite assessment plus 6MWT;*
- (5) RHC composite assessment only;*
- (6) ECHO composite assessment only.*

The results of the same tests as conducted at baseline should be provided with each written continuing treatment application (i.e. every 6 months), except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a reason why the test(s) could not be conducted must be provided with the application.

The test(s) results provided with the application for continuing treatment must be no more than 2 months old at the time of application.

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	5. Definition of response to sitaxentan sodium, sildenafil citrate, bosentan monohydrate, iloprost trometamol, epoprostenol sodium or prior vasodilator treatment. <i>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.</i> <i>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.</i> <i>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.</i> <i>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.</i> 6. Authority approval requirements. [The following 2 sections are only relevant to the PBS listing of sitaxentan sodium. The requirements specific to bosentan monohydrate, iloprost trometamol, epoprostenol sodium and sildenafil citrate are given in parts 6 and 7 of the NOTE included in the bosentan monohydrate, iloprost trometamol, epoprostenol sodium and sildenafil citrate Schedule entry respectively.] <i>(a) Initiation of PBS-subsidised treatment with sitaxentan sodium, where the patient has not received prior PBS-subsidised treatment with bosentan monohydrate, iloprost trometamol, epoprostenol sodium or sildenafil citrate. All applications for initial treatment must be made in writing, must include an authority prescription and must be submitted to Medicare Australia for authorisation. The total duration of initial PBS-subsidised treatment that will be approved with this first written application is up to 6 months.</i> <i>Patients who commence PBS-subsidised sitaxentan sodium treatment after 1 April 2008 and patients who received 6 or more months of sitaxentan sodium treatment prior to 1 April 2008 are eligible to receive up to 6 months of treatment per authority application.</i> <i>Patients who commenced treatment with sitaxentan sodium prior to 1 April 2008 and who have received less than 6 months of treatment at the time of application are eligible to receive sufficient supply to allow the patient to complete a total of 6 months of combined PBS-subsidised and non-PBS-subsidised treatment.</i> <i>All patients with primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease who commenced treatment with sitaxentan sodium prior to 1 April 2008 will be eligible to commence PBS-subsidised treatment with sitaxentan sodium. Thereafter, to be eligible for further PBS-subsidised supply, these patients must demonstrate a response to sitaxentan sodium treatment, as defined above under definition of response.</i> <i>(b) Continuation of treatment.</i> <i>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.</i> <i>Applications for continuing treatment will only be approved for patients who have currently demonstrated a response to treatment with sitaxentan sodium.</i> <i>The assessment of the patient's response to the first and subsequent 6 month courses of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated. Applications for continuing treatment with sitaxentan sodium should be made prior to the completion of the 6 month treatment course to ensure continuity for those patients who respond to treatment, as assessed by the treating physician.</i> <i>(c) Swapping between bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate and sitaxentan sodium.</i> <i>For eligible patients, applications to swap between these 5 drugs must be made under the relevant initial treatment restriction. Patients should be assessed for response to the treatment they are ceasing at the time the application to swap therapy is being made. Patients who fail to demonstrate a response or for whom no assessment results are submitted with the application to swap therapy may not re-commence PBS-subsidised treatment with the drug they are ceasing.</i> <i>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.</i> <i>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.</i>			

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer \$	Proprietary Name and Manufacturer

(d) Cessation of treatment.

Patients who fail to demonstrate a response to PBS-subsidised sitaxentan sodium treatment at the times where an assessment is required must cease PBS-subsidised sitaxentan sodium therapy.

7. Re-treatment with sitaxentan sodium.

Patients who do not respond to treatment are not eligible to receive further PBS-subsidised treatment with sitaxentan sodium under any circumstances.

8. Further information.

A tabulated representation of the above information and the restriction can be obtained from the Medicare Australia website at www.medicareaustralia.gov.au.

Public and private hospital authority required

Initial (new patients)

Application for initial PBS-subsidised treatment with sitaxentan sodium of patients who have not received prior PBS-subsidised treatment with bosentan monohydrate, iloprost trometamol, epoprostenol sodium or sildenafil citrate and who have been assessed by a physician from a designated hospital to have:

- (a) WHO Functional Class III primary pulmonary hypertension and a mean right atrial pressure of 8 mmHg or less, as measured by RHC, unless a RHC is contraindicated on clinical grounds; OR*
- (b) WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease and a mean right atrial pressure of 8 mmHg or less, as measured by RHC, unless a RHC is contraindicated on clinical grounds.*

Patients must have failed to respond [see Note for definition of response] to 6 or more weeks of appropriate vasodilator treatment unless intolerance or a contraindication to such treatment exists.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted to Medicare Australia for consideration based on the test results of the ECHO composite assessment plus 6MWT or the ECHO composite assessment only.

Applications for authorisation must be in writing and must include:

- (1) a completed authority prescription form [see Note for authority approval requirements]; and*
- (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form [www.medicareaustralia.gov.au] which includes results from the 3 tests below, where available:*
 - (i) RHC composite assessment; and*
 - (ii) ECHO composite assessment; and*
 - (iii) 6MWT; and*
- (3) a signed patient acknowledgment indicating that the patient understands and acknowledges that PBS-subsidised treatment with sitaxentan sodium for primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, OR with sildenafil citrate for primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, OR with epoprostenol sodium for primary pulmonary hypertension, OR with iloprost trometamol for primary pulmonary hypertension, drug-induced pulmonary arterial hypertension or pulmonary arterial hypertension secondary to connective tissue disease, OR with bosentan monohydrate for primary pulmonary hypertension or pulmonary arterial hypertension secondary to scleroderma, will cease if the treating physician determines that the patient has not achieved a response to treatment [see Note for definition of response].*

Details of prior vasodilator treatment, including the dose and duration of treatment, must be provided at the time of application. Where the patient has an adverse event to a vasodilator or where vasodilator treatment is contraindicated, details on the nature of the adverse event or contraindication according to the TGA-approved Product Information must also be provided with the application.

Where fewer than 3 tests (see requirement 2 above) are able to be performed on clinical grounds, a reason outlining why the particular test/s could not be conducted must be provided with the authority application [see Note for test requirements].

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. A maximum of 5 repeats may be requested. Where fewer than 5 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 6 months of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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Public and private hospital authority required

Initial (new patients)

Application for initial PBS-subsidised treatment with sitaxentan sodium of patients who have not received prior PBS-subsidised treatment with bosentan monohydrate, iloprost trometamol, epoprostenol sodium or sildenafil citrate and who have been assessed by a physician from a designated hospital to have:

- (a) WHO Functional Class III primary pulmonary hypertension and a mean right atrial pressure greater than 8 mmHg, as measured by RHC, unless a RHC is contraindicated on clinical grounds; OR*
- (b) WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease and a mean right atrial pressure greater than 8 mmHg, as measured by RHC, unless a RHC is contraindicated on clinical grounds.*

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted to Medicare Australia for consideration based on the test results of the ECHO composite assessment plus 6MWT or the ECHO composite assessment only.

Applications for authorisation must be in writing and must include:

- (1) a completed authority prescription form [see Note for authority approval requirements]; and*
- (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form [www.medicareaustralia.gov.au] which includes results from the 3 tests below, where available:*
 - (i) RHC composite assessment; and*
 - (ii) ECHO composite assessment; and*
 - (iii) 6MWT; and*
- (3) a signed patient acknowledgment indicating that the patient understands and acknowledges that PBS-subsidised treatment with sitaxentan sodium for primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, OR with sildenafil citrate for primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, OR with epoprostenol sodium for primary pulmonary hypertension, OR with iloprost trometamol for primary pulmonary hypertension, drug-induced pulmonary arterial hypertension or pulmonary arterial hypertension secondary to connective tissue disease, OR with bosentan monohydrate for primary pulmonary hypertension or pulmonary arterial hypertension secondary to scleroderma, will cease if the treating physician determines that the patient has not achieved a response to treatment [see Note for definition of response].*

Where fewer than 3 tests (see requirement 2 above) are able to be performed on clinical grounds, a reason outlining why the particular test/s could not be conducted must be provided with the authority application [see Note for test requirements].

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. A maximum of 5 repeats may be requested. Where fewer than 5 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 6 months of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Public and private hospital authority required

Initial (grandfather patients)

Application for initial PBS-subsidised treatment with sitaxentan sodium of patients who were receiving treatment with sitaxentan sodium prior to 1 April 2008, who have not received prior PBS-subsidised treatment with bosentan monohydrate, iloprost trometamol, epoprostenol sodium or sildenafil citrate and who have been assessed by a physician from a designated hospital to have:

- (a) WHO Functional Class III primary pulmonary hypertension; OR*
- (b) WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease.*

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Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer \$	Proprietary Name and Manufacturer

Applications for authorisation must be in writing and must include:

*(1) a completed authority prescription form [see Note for authority approval requirements]; and
(2) (a) for patients who have received less than 6 months of sitaxentan sodium treatment at the time of application — a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form [www.medicareaustralia.gov.au] which includes results of the following 3 tests, where available, at the time treatment with sitaxentan sodium was commenced:*

- (i) RHC composite assessment; and*
- (ii) ECHO composite assessment; and*
- (iii) 6MWT; or*

(b) for patients who have received 6 or more months of sitaxentan sodium treatment at the time of application — a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form [www.medicareaustralia.gov.au] which includes results of the following 3 tests, both at the time treatment with sitaxentan sodium was commenced and at the time of application, where available:

- (i) RHC composite assessment; and*
- (ii) ECHO composite assessment; and*
- (iii) 6MWT; and*

(3) the date of commencement of sitaxentan sodium treatment; and

(4) a signed patient acknowledgment indicating that the patient understands and acknowledges that PBS-subsidised treatment with sitaxentan sodium for primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, OR with sildenafil citrate for primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, OR with epoprostenol sodium for primary pulmonary hypertension, OR with iloprost trometamol for primary pulmonary hypertension, drug-induced pulmonary arterial hypertension or pulmonary arterial hypertension secondary to connective tissue disease, OR with bosentan monohydrate for primary pulmonary hypertension or pulmonary arterial hypertension secondary to scleroderma, will cease if the treating physician determines that the patient has not achieved a response to treatment [see Note for definition of response].

Where fewer than 3 tests (see requirement 2 above) are able to be performed on clinical grounds, a reason outlining why the particular test/s could not be conducted must be provided with the authority application [see Note for test requirements].

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. The number of repeats authorised will be dependent on the duration of prior sitaxentan sodium therapy. Where patients have received less than 6 months of non-PBS-subsidised treatment with sitaxentan sodium, sufficient repeats to allow the patient to complete a total of 6 months of combined PBS-subsidised and non-PBS-subsidised therapy may be requested. Where patients have received 6 months or more of non-PBS-subsidised treatment with sitaxentan sodium, a maximum of 5 repeats may be requested. Where fewer than the maximum allowable number of repeats are requested at the time of application, authority approvals for the remainder of the allowable repeats may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Public and private hospital authority required

Initial (change or re-commencement for all patients)

Application for initial PBS-subsidised treatment with sitaxentan sodium of patients with either of the following:

- (a) WHO Class III primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease who wish to re-commence PBS-subsidised sitaxentan sodium after a break in therapy and who have demonstrated a response to their most recent course of PBS-subsidised treatment with sitaxentan sodium; OR*
- (b) WHO Class III primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease and whose most recent course of PBS-subsidised treatment was with iloprost trometamol; OR*
- (c) WHO Class III primary pulmonary hypertension or pulmonary arterial hypertension secondary to scleroderma and whose most recent course of PBS-subsidised treatment was with bosentan monohydrate; OR*
- (d) WHO Class III primary pulmonary hypertension and whose most recent course of PBS-subsidised treatment was with epoprostenol sodium; OR*
- (e) WHO Class III primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease and whose most recent course of PBS-subsidised treatment was with sildenafil citrate.*

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer \$	Proprietary Name and Manufacturer	

Applications for authorisation must be in writing and must include:

- (1) a completed authority prescription form [see Note for authority approval requirements]; and
- (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form [www.medicareaustralia.gov.au] which includes the results on which approval for the first application for PBS-subsidised sitaxentan sodium, sildenafil citrate, epoprostenol sodium, iloprost trometamol or bosentan monohydrate, whichever was initiated first, was granted; and
- (3) the date of the first application for PBS-subsidised treatment with sitaxentan sodium, sildenafil citrate, epoprostenol sodium, iloprost trometamol or bosentan monohydrate, whichever was initiated first; and
- (4) the results of the patient's response to treatment with their last course of PBS-subsidised sitaxentan sodium, sildenafil citrate, epoprostenol sodium, iloprost trometamol or bosentan monohydrate.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. A maximum of 5 repeats may be requested. Where fewer than 5 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 6 months of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Public and private hospital authority required

Continuing treatment (all patients)

Continuing PBS-subsidised treatment with sitaxentan sodium of patients who have received approval for initial PBS-subsidised treatment with sitaxentan sodium, and who have been assessed by a physician from a designated hospital to have achieved a response to their most recent course of sitaxentan sodium treatment [see Note for definition of response].

Applications for authorisation must be in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form [www.medicareaustralia.gov.au] which includes results from the 3 tests below, where available:
 - (i) RHC composite assessment; and
 - (ii) ECHO composite assessment; and
 - (iii) 6MWT.

Where fewer than 3 tests (see requirement 2 above) are able to be performed on clinical grounds, a reason outlining why the particular test/s could not be conducted must be provided with the authority application [see Note for test requirements].

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. A maximum of 5 repeats may be requested. Where fewer than 5 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 6 months of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

9622K	Tablet 100 mg	30	2743.80	Thelin	CS

STAVUDINE

Private hospital authority required

Treatment of HIV infection in patients with:

- (a) CD4 cell counts of less than 500 per cubic millimetre; or
- (b) viral load of greater than 10,000 copies per mL.

6186N	Capsule 20 mg	60	280.00	Zerit	BQ
6189R	Capsule 30 mg	60	333.68	Zerit	BQ
6190T	Capsule 40 mg	60	444.90	Zerit	BQ
6250Y	Powder for oral solution 1 mg per mL, 200 mL	1	116.68	Zerit	BQ

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer \$	Proprietary Name and Manufacturer	
TACROLIMUS					
CAUTION:					
<i>Careful monitoring of patients is mandatory.</i>					
Private hospital authority required					
<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>					
6328C	Capsule 500 micrograms	100	187.34	Prograf	JC
6216E	Capsule 1 mg	100	374.67	Prograf	JC
6217F	Capsule 5 mg	50	936.68	Prograf	JC
TELBIVUDINE					
Private hospital authority required					
<i>Treatment, as sole PBS-subsidised therapy, in a patient with chronic hepatitis B who is nucleoside analogue naive and satisfies all of the following criteria:</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)(a) Abnormal serum ALT levels in conjunction with documented chronic hepatitis B infection; or</i>					
<i>(b) Elevated HBV DNA levels in conjunction with documented chronic hepatitis B infection;</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>					
9630W	Tablet 600 mg	28	250.88	Sebivo	NV
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	483.10	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	765.10	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	CJ
TIPRANA VIR					
Private hospital authority required					
<i>Treatment, in combination with other antiretroviral agents, and co-administered with 200 mg ritonavir twice daily, of HIV infection in antiretroviral experienced adults with:</i>					
<i>(a) evidence of HIV replication (viral load greater than 10,000 copies per mL); and/or</i>					
<i>(b) CD4 cell counts of less than 500 per cubic millimetre.</i>					
<i>Patients must have failed previous treatment with, or have resistance to, 3 different antiretroviral regimens which have included:</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 2 protease inhibitors.</i>					
9610T	Capsule 250 mg	120	1071.00	Aptivus	BY
NOTE:					
<i>Special Pricing Arrangements apply.</i>					
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;</i>					
<i>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:</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>					
6153W	Capsule 100 mg	100	205.46	Retrovir	GK
6154X	Capsule 250 mg	60	308.19	Retrovir	GK

continued 

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer \$	Proprietary Name and Manufacturer	
6155Y	Syrup 10 mg per mL, 200 mL	1	44.88	Retrovir	GK

ZOLEDRONIC ACID**Private hospital authority required***Multiple myeloma;**Bone metastases from breast cancer;**Bone metastases from hormone-resistant prostate cancer, with demonstration of biochemical progression of disease despite maximal therapy with hormonal treatments;**Treatment of hypercalcaemia of malignancy refractory to anti-neoplastic therapy.*

6371H	Injection concentrate for I.V. infusion 4 mg (as monohydrate) in 5 mL	1	450.00	Zometa	NV

NOTE:*Special Pricing Arrangements apply.***BOTULINUM TOXIN PROGRAM****BOTULINUM TOXIN TYPE A PURIFIED NEUROTOXIN COMPLEX****NOTE:***Arrangements to prescribe this item should be made by medical practitioners with Medicare Australia, contact telephone number 1800 700 270.**Treatment of blepharospasm associated with dystonia, including benign blepharospasm and VIIth nerve disorders (hemifacial spasm) in patients 12 years and older;**Treatment of dynamic equinus foot deformity due to spasticity in an ambulant paediatric cerebral palsy patient aged from 2 to 17 years inclusive;**Continuing PBS-subsidised treatment of dynamic equinus foot deformity due to spasticity in an ambulant cerebral palsy patient 18 years of age or older who was commenced on PBS-subsidised treatment with botulinum toxin type A purified neurotoxin complex as a paediatric patient;**Treatment of spasmodic torticollis, either as monotherapy or as adjunctive therapy to current standard care;**Treatment of moderate to severe spasticity of the upper limbs in a cerebral palsy patient 2 years of age or older;**Treatment of moderate to severe spasticity [defined as MAS greater than or equal to 3 using modified Ashworth scale] of the upper limb in adults following a stroke, as second line therapy when standard management has failed (e.g. physiotherapy and/or oral spasticity agents) or as an adjunct to physical therapy.**Maximum number of treatments to be authorised is 4 (total Botox and Dysport) per upper limb per lifetime.**Treatment should not be initiated until 3 to 6 months post-stroke in patients who do not have established severe contracture. Treatment should be discontinued if the patient does not respond (decrease of MAS greater than 1 in at least one joint) after two treatments.**Contraindications to treatment include established severe contracture, known sensitivity to botulinum toxin.*

6103F	Lyophilised powder for I.M. injection 100 units	1	415.50	Botox	AG

NOTE:*The units used to express the potency of botulinum toxin preparations currently available for PBS subsidy are not equivalent.*

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer \$	Proprietary Name and Manufacturer	

CLOSTRIDIUM BOTULINUM TYPE A TOXIN—HAEMAGGLUTININ COMPLEX

NOTE:

Arrangements to prescribe this item should be made by medical practitioners with Medicare Australia, contact telephone number 1800 700 270.

Treatment of dynamic equinus foot deformity due to spasticity in an ambulant paediatric cerebral palsy patient aged from 2 to 17 years inclusive;

Continuing PBS-subsidised treatment of dynamic equinus foot deformity due to spasticity in an ambulant cerebral palsy patient 18 years of age or older who was commenced on PBS-subsidised treatment with clostridium botulinum type A toxin-haemagglutinin complex as a paediatric patient;

Treatment of spasmodic torticollis, either as monotherapy or as adjunctive therapy to current standard care;

Treatment of moderate to severe spasticity [defined as MAS greater than or equal to 3 using modified Ashworth scale] of the upper limb in adults following a stroke, as second line therapy when standard management has failed (e.g. physiotherapy and/or oral spasticity agents) or as an adjunct to physical therapy.

Maximum number of treatments to be authorised is 4 (total Botox and Dysport) per upper limb per lifetime.

Treatment should not be initiated until 3 to 6 months post-stroke in patients who do not have established severe contracture. Treatment should be discontinued if the patient does not respond (decrease of MAS greater than 1 in at least one joint) after two treatments.

Contraindications to treatment include established severe contracture, known sensitivity to botulinum toxin.

6293F	Lyophilised powder for I.M. injection 500 units	1	650.00	Dysport	IS

NOTE:

The units used to express the potency of botulinum toxin preparations currently available for PBS subsidy are not equivalent.

HUMAN GROWTH HORMONE PROGRAM

SOMATROPIN (Recombinant human growth hormone)

Short stature in accordance with the 'Guidelines for the Availability of Human Growth Hormone (hGH) as a Pharmaceutical Benefit'.

NOTE:

These guidelines may be obtained from the Department of Health and Ageing's internet site at <http://www.health.gov.au/internet/main/publishing.nsf/Content/pbs-hghguidelines-contents>, or from:

Growth Hormone Program

Access and Systems Branch

Department of Health and Ageing

GPO Box 9848

CANBERRA ACT 2601

Contact telephone number (02) 6289 7274

6266T	Injection 4 mg (12 i.u.) vial with 3.5 mL diluent (with preservative)	1	198.00	Zomacton	FP
6330E	Injection 5 mg (15 i.u.) in 1 mL cartridge (with preservative)	1	247.50	Genotropin	PH
6476W	Solution for injection 5 mg (15 i.u.) in 1.5 mL cartridge (with preservative)	1	247.50	Omnitrope	SZ
6295H	Solution for injection 5 mg (15 i.u.) in 1.5 mL cartridge (with preservative)	1	247.50	Norditropin SimpleXx	NO
6465G	Solution for injection 5 mg (15 i.u.) in 1.5 mL cartridge (with preservative)	1	315.50	Norditropin NordiFlex	NO

NOTE:

Special Pricing Arrangements apply.

continued 

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer \$	Proprietary Name and Manufacturer	
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: Special Pricing Arrangements apply.				
9604L	Solution for injection 10 mg (30 i.u.) in 2 mL cartridge (with preservative)	1	495.00	NutropinAq	IS
6170R	Injection 36 i.u. (12 mg) cartridge with 3.15 mL diluent (with preservative)	1	594.00	Humatrope	LY
6312F	Injection 12 mg (36 i.u.) in 1 mL cartridge (with preservative)	1	594.00	Genotropin	PH
6297K	Solution for injection 15 mg (45 i.u.) in 1.5 mL cartridge (with preservative)	1	742.50	Norditropin SimpleXx	NO
6467J	Solution for injection 15 mg (45 i.u.) in 1.5 mL cartridge (with preservative)	1	946.50	Norditropin NordiFlex	NO
	NOTE: Special Pricing Arrangements apply.				
6345Y	Injection 72 i.u. (24 mg) cartridge with 3.15 mL diluent (with preservative)	1	1188.00	Humatrope	LY
9628R	Injection 0.6 mg (1.8 i.u.) with diluent in single use syringe (without preservative)	7	207.90	Genotropin MiniQuick	PH
6313G	Injection 0.8 mg (2.4 i.u.) with diluent in single use syringe (without preservative)	7	277.20	Genotropin MiniQuick	PH
6314H	Injection 1 mg (3 i.u.) with diluent in single use syringe (without preservative)	7	346.50	Genotropin MiniQuick	PH
6315J	Injection 1.2 mg (3.6 i.u.) with diluent in single use syringe (without preservative)	7	415.80	Genotropin MiniQuick	PH
6316K	Injection 1.4 mg (4.2 i.u.) with diluent in single use syringe (without preservative)	7	485.10	Genotropin MiniQuick	PH
6317L	Injection 1.6 mg (4.8 i.u.) with diluent in single use syringe (without preservative)	7	554.40	Genotropin MiniQuick	PH
6318M	Injection 1.8 mg (5.4 i.u.) with diluent in single use syringe (without preservative)	7	623.70	Genotropin MiniQuick	PH
6319N	Injection 2 mg (6 i.u.) with diluent in single use syringe (without preservative)	7	693.00	Genotropin MiniQuick	PH

IVF/GIFT PROGRAM

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer \$	Proprietary Name and Manufacturer	

CHORIOGONADOTROPIN ALFA

Patients who are receiving medical treatment as described in items 13200 or 13203 of the Medicare Benefits Schedule.

NOTE:

Arrangements to prescribe this item should be made by medical practitioners with Medicare Australia, contact telephone number 1800 700 270.

9631X	Solution for injection 250 micrograms in 0.5 mL pre-filled syringe	1	54.80	Ovidrel	SG

NOTE:

Special Pricing Arrangements apply.

FOLLITROPIN ALFA

Patients who are receiving medical treatment as described in items 13200 or 13203 of the Medicare Benefits Schedule.

NOTE:

Arrangements to prescribe this item should be made by medical practitioners with Medicare Australia, contact telephone number 1800 700 270.

6373K	Injection set containing 1 vial powder for injection 75 i.u. and 1 pre-filled syringe solvent 1 mL	1	36.00	Gonal-f 75	SG
6374L	Injection set containing 10 vials powder for injection 75 i.u. and 10 pre-filled syringes solvent 1 mL	1	360.00	Gonal-f 75	SG
6431L	Injection 300 i.u. in 0.5 mL multi-dose cartridge	1	144.00	Gonal-f Pen	SG
6376N	Injection set containing 1 vial powder for injection 450 i.u. and 1 pre-filled syringe solvent 1 mL	1	216.00	Gonal-f	SG
6432M	Injection 450 i.u. in 0.75 mL multi-dose cartridge	1	216.00	Gonal-f Pen	SG
6433N	Injection 900 i.u. in 1.5 mL multi-dose cartridge	1	432.00	Gonal-f Pen	SG
6375M	Injection set containing 1 vial powder for injection 1,050 i.u. and 1 pre-filled syringe solvent 2 mL	1	504.00	Gonal-f	SG

FOLLITROPIN BETA

Patients who are receiving medical treatment as described in items 13200 or 13203 of the Medicare Benefits Schedule.

NOTE:

Arrangements to prescribe this item should be made by medical practitioners with Medicare Australia, contact telephone number 1800 700 270.

6335K	Solution for injection 300 i.u. in 0.36 mL multi-dose cartridge	1	144.04	Puregon 300 IU/ 0.36 mL	SH
6336L	Solution for injection 600 i.u. in 0.72 mL multi-dose cartridge	1	288.09	Puregon 600 IU/ 0.72 mL	SH
6464F	Solution for injection 900 i.u. in 1.08 mL multi-dose cartridge	1	432.11	Puregon 900 IU/ 1.08 mL	SH

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer \$	Proprietary Name and Manufacturer	

HUMAN CHORIONIC GONADOTROPHIN

Patients who are receiving medical treatment as described in items 13200 or 13203 of the Medicare Benefits Schedule.

NOTE:

Arrangements to prescribe this item should be made by medical practitioners with Medicare Australia, contact telephone number 1800 700 270.

6176C	Injection set containing 3 ampoules powder for injection 500 units and 3 ampoules solvent 1 mL	1	19.77	Pregnyl	SH
6178E	Injection set containing 3 ampoules powder for injection 1,500 units and 3 ampoules solvent 1 mL	1	28.06	Pregnyl	SH
6181H	Injection set containing 3 ampoules powder for injection 5,000 units and 3 ampoules solvent 1 mL	1	34.47	Pregnyl	SH

PROGESTERONE

For luteal phase support in patients who are receiving medical treatment as described in item 13200 of the Medicare Benefits Schedule. The luteal phase is defined as the time span from embryo transfer until implantation confirmed by positive B-hCG measurement.

NOTE:

Arrangements to prescribe this item should be made by medical practitioners with Medicare Australia, contact telephone number 1800 700 270.

6366C	Vaginal gel (prolonged release) 90 mg in single dose pre-filled applicator	15	148.50	Crinone 8%	SG
9608Q	Pessary 100 mg	15	43.50	ON	
9609R	Pessary 200 mg	15	48.00	ON	

NOTE:

Special Pricing Arrangements apply.

OPIATE DEPENDENCE TREATMENT PROGRAM

The Australian Government funds the cost of buprenorphine hydrochloride, buprenorphine hydrochloride with naloxone hydrochloride and methadone hydrochloride supplied as pharmaceutical benefits through clinics and pharmacies approved by State and Territory governments. For further information about this program, please contact your State or Territory Government.

BUPRENORPHINE HYDROCHLORIDE

Treatment of opiate dependence, including maintenance and detoxification (withdrawal), within a framework of medical, social and psychological treatment.

NOTE:

Treatment must be in accordance with the law of the relevant State or Territory.

6307Y	Sublingual tablet 400 micrograms (base)	7	6.16	Subutex	RC
6308B	Sublingual tablet 2 mg (base)	7	10.50	Subutex	RC
6309C	Sublingual tablet 8 mg (base)	7	30.10	Subutex	RC

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 SI	MW
6172W	Oral liquid 25 mg per 5 mL, 1 L	1	35.28	^a Biodone Forte ^a SI	MW

SPECIAL AUTHORITY PROGRAM

TRASTUZUMAB

NOTE:

Any queries concerning the arrangements to prescribe trastuzumab may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written applications for authority to prescribe trastuzumab should be forwarded to:

Medicare Australia

Prior Written Approval of Specialised Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

Further prescribing information is on the Medicare Australia website at www.medicareaustralia.gov.au.

Section 100 authority required

Initial treatment for HER2 positive early breast cancer commencing concurrently with adjuvant chemotherapy following surgery.

The total duration of PBS-subsidised treatment (initial plus continuing) that will be authorised is 52 weeks.

HER2 positivity must be demonstrated by in situ hybridisation (ISH).

Trastuzumab must not be used in patients with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure. Cardiac function must be tested by a suitable method including, for example, ECHO or MUGA, prior to seeking the initial authority approval and then at 3 monthly intervals during treatment.

Authority applications for initial treatment must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Early Breast Cancer - PBS Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes:

(i) a copy of the pathology report from an Approved Pathology Authority confirming the presence of HER2 gene amplification by in situ hybridisation (ISH); and

(ii) a copy of the signed patient acknowledgement form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].

continued ➞

Code	Item and Section 100 Restriction	Pack Size	Price ex Manufacturer \$	Proprietary Name and Manufacturer	
	<i>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).</i> Section 100 authority required <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> <i>Breaks in therapy.</i> <i>Where a patient has a break in trastuzumab therapy of more than 1 week but less than 6 weeks from when the last dose was due, authority approval will be granted for a new loading dose. Authority applications for new loading doses may be made by telephone on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).</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	\$0.75
Other Items	25 mL vial	\$0.29

(The 25 mL is the most commonly used size)

FEES:

Dispensing Fee for Ready Prepared Benefits	\$5.99
Dangerous Drug Fee	\$2.71
Additional Fee for Agreed Price Ready Prepared Benefits	\$1.03

NOTE -

Standard packs and prices (including mark-up, but without dispensing fee and dangerous drug fee) are for items against the price of which an asterisk () is shown in Section 2 of the Schedule.*

(APPLY WASTAGE FACTOR IN CALCULATING BROKEN QUANTITY PRICES)

Code	Name	Form/Strength	Pack and Price \$	Manufacturer

EMERGENCY DRUG (DOCTOR'S BAG) SUPPLIES

3486L	Benzylpenicillin	600 mg	1 @ 3.65	CS
3463G	Diphtheria and Tetanus Vaccine, Adsorbed, Diluted For Adult Use	0.5 mL	5 @ 67.15	CS
3470P	Hydrocortisone Sodium Succinate	100 mg with 2 mL solvent	1 @ 5.36	PH
3481F	Naloxone Hydrochloride	800 mcg in 2 mL	1 @ 22.42	CS
3482G		2 mg in 5 mL	1 @ 35.83	CS
3488N	Promethazine Hydrochloride	50 mg in 2 mL	5 @ 7.95	HH

SPECIAL PHARMACEUTICAL BENEFITS - FOR GENERAL USE

2315W	Bleomycin Sulfate	15,000 i.u.	1 @ 48.58	HH (for reimbursement price)
			1 @ 92.28	HH (for total dispensed price)
8298R	Naratriptan Hydrochloride	2.5 mg (base)	2 @ 9.74	GK (for reimbursement price)
			2 @ 11.13	GK (for total dispensed price)
9734H		2.5 mg (base)	2 @ 11.13	GK (for reimbursement price)
			2 @ 11.13	GK (for total dispensed price)
8266C	Zolmitriptan	2.5 mg	2 @ 9.71	AP (for reimbursement price)
			2 @ 11.09	AP (for total dispensed price)
9736K		2.5 mg	2 @ 11.09	AP (for reimbursement price)
			2 @ 11.09	AP (for total dispensed price)

GENERAL PHARMACEUTICAL BENEFITS

8048N	Abciximab	10 mg in 5 mL	1 @ 482.23	LY
8747J	Acetylcysteine	200 mg per mL, 5 mL	6 @ 28.11	BQ
1003T	Aciclovir	200 mg	25 @ 31.56	AF, GM, SZ
			25 @ 33.73	GK
2600W	Allopurinol	100 mg	100 @ 3.39	AF
2157M	Aluminium Hydroxide with Magnesium Hydroxide	200 mg-200 mg per 5 mL, 500 mL	1 @ 4.83	JT
2159P	Aluminium Hydroxide with Magnesium Trisilicate and Magnesium Hydroxide	250 mg-120 mg-120 mg per 5 mL, 500 mL	1 @ 4.01	FM
3109P	Amiloride Hydrochloride	5 mg	50 @ 2.28	AF
3079C	Amino Acid Formula without Methionine, Threonine and Valine and low in Isoleucine	200 g	1 @ 208.40	SB
8554F	Amino Acid Formula without Phenylalanine	500 mg, 200	1 @ 79.37	SB
8678R		1 g, 75	1 @ 59.19	SB
8706F		42 g, 20	1 @ 156.49	SB
2347M		20 g, 30	1 @ 208.07	SB
3072Q		250 g	1 @ 150.43	SB
2379F	Amino Acid Formula without Phenylalanine, Tyrosine and Methionine	500 g	1 @ 666.39	SB

(APPLY WASTAGE FACTOR IN CALCULATING BROKEN QUANTITY PRICES)

Code	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 @ 87.15	SB
2650L	Amino Acid Formula with Vitamins and Minerals without Lysine and low in Tryptophan	400 g	1 @ 83.41	SB
2646G		500 g	1 @ 202.28	SB
8417B	Amino Acid Formula with Vitamins and Minerals without Methionine	400 g	1 @ 95.36	SB
8677Q		20 g, 30	1 @ 448.00	VF
8744F		25 g, 30	1 @ 772.99	VF
8328H		500 g	1 @ 222.29	SB
8416Y		500 g	1 @ 337.29	SB
9133Q		130 mL, 30	1 @ 772.99	VF
8058D	Amino Acid Formula with Vitamins and Minerals without Methionine, Threonine and Valine and low in Isoleucine	400 g	1 @ 77.88	SB
8059E		500 g	1 @ 192.04	SB
8061G		500 g	1 @ 240.69	SB
1411G	Amino Acid Formula with Vitamins and Minerals without Phenylalanine	18.2 g, 60	1 @ 544.55	SB
8555G		20 g, 30	1 @ 221.15	VF
8591E		25 g, 30	1 @ 385.68	VF
8804J		27.8 g, 30	1 @ 514.34	SB
8613H		29 g, 30	1 @ 221.42	SB
8727H		50 g, 30	1 @ 501.88	SB
2737C		400 g	1 @ 75.00	SB
8467P		325 g	1 @ 85.54	AB
8545R		400 g	1 @ 105.27	AB
2738D		500 g	1 @ 109.70	SB
2739E		500 g	1 @ 168.25	SB
8746H		250 mL	18 @ 261.37	SB
9397N		62.5 mL, 60	1 @ 526.47	NU
2382J		87 mL, 30	1 @ 257.09	VF
9021T		125 mL, 30	1 @ 514.34	SB
9396M		125 mL, 36	1 @ 315.86	NU
8846N		130 mL, 30	1 @ 385.48	VF
2474F		174 mL, 30	1 @ 511.90	VF
8631G	Amino Acid Formula with Vitamins and Minerals without Phenylalanine and Tyrosine	20 g, 30	1 @ 448.00	VF
8667E		25 g, 30	1 @ 772.99	VF
9395L		29 g, 30	1 @ 448.51	NU
8445L		400 g	1 @ 95.36	SB
8446M		500 g	1 @ 222.29	SB
3078B		500 g	1 @ 337.29	SB
9132P		130 mL, 30	1 @ 772.99	VF
8592F	Amino Acid Formula with Vitamins and Minerals without Valine, Leucine and Isoleucine	20 g, 30	1 @ 448.00	VF
8632H		25 g, 30	1 @ 772.99	VF
8745G		29 g, 30	1 @ 448.51	SB
2380G		400 g	1 @ 95.36	SB

(APPLY WASTAGE FACTOR IN CALCULATING BROKEN QUANTITY PRICES)

Code	Name	Form/Strength	Pack and Price \$	Manufacturer
8310J		500 g	1 @ 666.39	SB
8260R		500 g	1 @ 222.29	SB
8057C		500 g	1 @ 337.29	SB
2375B		130 mL, 30	1 @ 772.99	VF
2250K	Amino Acids—Synthetic, Formula	400 g	1 @ 43.77	AB
8574G		400 g	1 @ 44.34	AB
8443J		400 g	1 @ 44.34	SB
8754R		400 g	1 @ 44.34	SB
2244D		400 g	1 @ 44.34	SB
8575H		400 g	1 @ 44.34	AB
3066J		400 g	1 @ 44.34	SB
8755T		400 g	1 @ 44.34	SB
2553J		400 g	1 @ 44.34	SB
2246F	Amino Acid Synthetic Formula supplemented with Long Chain Polyunsaturated Fatty Acids	400 g	1 @ 45.18	SB
2560R		400 g	1 @ 45.18	SB
8736T	Amisulpride	100 mg per mL, 60 mL	1 @ 71.16	SW
9386B	Amylopectin, Modified Long Chain	60 g, 30	1 @ 186.47	VF
9092M	Atomoxetine Hydrochloride	10 mg (base)	28 @ 107.38	LY
9093N		18 mg (base)	28 @ 107.38	LY
9094P		25 mg (base)	28 @ 107.38	LY
9095Q		40 mg (base)	28 @ 107.38	LY
9096R		60 mg (base)	28 @ 107.38	LY
1140B	Bcg Immunotherapeutic (bacillus Calmette-guérin/ Connaught Strain)	6.6 to 19.2 x 10 ⁸ CFU set	1 @ 151.15	SW
1775K	Benzylpenicillin	600 mg	1 @ 3.65	CS
2647H		3 g	1 @ 6.05	CS
2812B	Betamethasone Valerate	200 mcg (base) per g, 100 g	1 @ 9.45	EX, FM, SH
			1 @ 12.54	SI
2820K		200 mcg (base) per g, 100 g	1 @ 9.45	EX, SH
8066M	Bifonazole	10 mg per g, 15 g	1 @ 12.35	BN
2544X	Biperiden Hydrochloride	2 mg	100 @ 7.23	LM
1260H	Bisacodyl	10 mg, 10	1 @ 5.15	PP
			1 @ 5.53	BY
1258F		10 mg, 12	1 @ 4.21	FL, PP
9117W	Bortezomib	3.5 mg	1 @ 1748.99	JC
9118X		3.5 mg	1 @ 1748.99	JC
8560M	Calcium	250 mg	120 @ 7.89	BN
3116B		500 mg	60 @ 5.15	IA
8740B	Calcium Folate	equiv. to 50 mg folic acid in 5 mL	1 @ 29.68	HH
			10 @ 234.50	PF
8812T		equiv. to 100 mg folic acid in 10 mL	1 @ 26.70	IT
9041W		equiv. to 300 mg folic acid in 30 mL	1 @ 77.31	HH
1153Q	Carbimazole	5 mg	100 @ 12.31	LM
8576J	Carbohydrate, Fat, Vitamins, Minerals and Trace Elements	400 g	1 @ 31.76	AB
8369L		400 g	1 @ 35.63	SB
8578L	Carbomer	2 mg per g, 0.6 mL, 30	1 @ 10.51	NV
8514D	Carbomer 974	3 mg per g, 0.5 g, 30	1 @ 9.88	AQ

(APPLY WASTAGE FACTOR IN CALCULATING BROKEN QUANTITY PRICES)

Code	Name	Form/Strength	Pack and Price \$	Manufacturer
1160C	Carboplatin	50 mg in 5 mL	1 @ 30.94	HH, IT, PU
1161D		150 mg in 15 mL	1 @ 70.92	HH, IT, PU
1162E		450 mg in 45 mL	1 @ 136.98	BX, HH, IT, PU
8823J	Carmellose Sodium	2.5 mg per mL, 0.6 mL, 24	1 @ 8.50	CX
2338C		5 mg per mL, 0.4 mL, 30	1 @ 9.88	AG
2324H		10 mg per mL, 0.4 mL, 30	1 @ 9.88	AG
8824K		10 mg per mL, 0.6 mL, 28	1 @ 9.22	CX
8315P	Cefepime	1 g	1 @ 17.74	BQ
8316Q		2 g	1 @ 32.52	BQ
1085D	Cefotaxime	1 g	1 @ 4.64	SZ
1086E		2 g	1 @ 8.51	SZ
1783W	Ceftriaxone	500 mg	1 @ 4.07	IZ
1784X		1 g	1 @ 6.36	HH, IZ, RO, SZ
1785Y		2 g	1 @ 11.28	HH, IZ, RO, SZ
1256D	Cephazolin	500 mg	5 @ 19.57	HH
1257E		1 g	5 @ 30.05	HH
1163F	Chlorambucil	2 mg	25 @ 32.89	GK
1585K	Chlorthalidone	25 mg	50 @ 3.61	LM
2967E	Cholestyramine	4.7 g (equiv. to 4 g cholestyramine)	1 @ 25.52	BQ
9249T		4.7 g (equivalent to 4 g cholestyramine)	1 @ 25.52	BQ
1217C	Ciprofloxacin	3 mg per mL, 5 mL	1 @ 11.60	IQ
			1 @ 12.63	AQ
8800E	Cladribine	10 mg in 5 mL	1 @ 660.45	OA
1211R	Clomiphene Citrate	50 mg	5 @ 13.34	GX, HX, SI
1805B	Clonazepam	500 mcg	100 @ 6.89	AF
			100 @ 8.68	RO
1806C		2 mg	100 @ 12.96	AF
			100 @ 15.00	RO
1808E		2.5 mg per mL, 10 mL	1 @ 4.31	RO
1027C	Clotrimazole	10 mg per mL, 20 mL	1 @ 6.64	BN
8785J	Codeine Phosphate with Paracetamol	30 mg-500 mg	20 @ 1.66	AL, AV, CO, FM, SZ
			20 @ 4.46	SW
1228P	Copper Sulfate	Tablets, 36	1 @ 32.53	BN
9251X		Tablets, 36	1 @ 32.53	BN
1079T	Cyclophosphamide	500 mg	1 @ 11.67	BX
8657P	Cyclosporin	10 mg	60 @ 44.00	NV
8658Q		25 mg	30 @ 48.25	SZ
			30 @ 49.39	NV
8659R		50 mg	30 @ 100.26	SZ
			30 @ 101.38	NV
8660T		100 mg	30 @ 194.94	SZ
			30 @ 196.07	NV
8661W		100 mg per mL, 50 mL	1 @ 353.12	NV
1798P	Cyproheptadine Hydrochloride	4 mg	50 @ 3.89	AS
1270W	Cyproterone Acetate	50 mg	50 @ 100.65	AF, GM, GX, SY, SZ
			50 @ 102.15	SC
9164H	Cystine with Carbohydrate	4 g containing 500 mg cystine, 30	1 @ 127.40	VF
2884T	Cytarabine	100 mg in 5 mL	5 @ 44.55	PU
8641T	Dalteparin Sodium (low Molecular Weight Heparin Sodium—Porcine Mucous)	2,500 units (anti-Xa) in 0.2 mL	10 @ 49.16	PH

(APPLY WASTAGE FACTOR IN CALCULATING BROKEN QUANTITY PRICES)

Code	Name	Form/Strength	Pack and Price \$	Manufacturer
8642W		5,000 units (anti-Xa) in 0.2 mL	10 @ 51.23	PH
8643X		7,500 units (anti-Xa) in 0.75 mL	10 @ 77.23	PH
8662X	Desmopressin Acetate	200 mcg	30 @ 57.83	FP
2129C		100 mcg per mL, 2.5 mL	1 @ 30.95	FP
8711L		10 mcg per actuation, 60 actuations, 6 mL	1 @ 77.31	FP
1302M	Diclofenac Sodium	100 mg	20 @ 9.25	NV
1299J		25 mg (e.c.)	50 @ 3.32	AW, CH, GM, GN, GX, SZ, TW
			50 @ 4.30	NV
3164M	Digoxin	50 mcg per mL, 60 mL	1 @ 11.13	SI
8461H	Disodium Pamidronate	15 mg in 5 mL	1 @ 64.45	HH
8462J		30 mg in 10 mL	1 @ 128.90	HH
8071T	Docetaxel	20 mg (anhydrous) set	1 @ 327.33	SW
1336H	Doxorubicin Hydrochloride	10 mg in 5 mL	1 @ 34.11	HH, IT, PH
1340M		20 mg in 10 mL	1 @ 59.96	PH
1342P		50 mg in 25 mL	1 @ 137.11	HH, IT, PH
9107H	Doxycycline	100 mg (as monohydrate)	7 @ 2.05	CH, GX, SZ, TW
2702F		100 mg (as hydrochloride)	7 @ 2.05	AF, GM, SI
			7 @ 3.24	PF
2703G		100 mg (as hydrochloride)	7 @ 2.05	FA
			7 @ 3.20	HH
9108J		100 mg (as monohydrate)	7 @ 2.05	CH, SZ, TW
2714W		100 mg (as hydrochloride)	7 @ 2.05	AF, GM, SI
			7 @ 3.24	PF
3199J	Electrolyte Replacement Solution	1 L	1 @ 7.77	BX
8558K	Enoxaparin Sodium	20 mg (2,000 i.u. anti-Xa) in 0.2 mL	10 @ 49.16	SW
8510X		40 mg (4,000 i.u. anti-Xa) in 0.4 mL	10 @ 51.23	SW
9195Y		40 mg (4,000 i.u. anti-Xa) in 0.4 mL	10 @ 51.23	SW
8716R		20 mg (2,000 i.u. anti-Xa) in 0.2 mL	10 @ 49.16	SW
8639Q		40 mg (4,000 i.u. anti-Xa) in 0.4 mL	10 @ 51.23	SW
9196B		40 mg (4,000 i.u. anti-Xa) in 0.4 mL	10 @ 51.23	SW
8640R		60 mg (6,000 i.u. anti-Xa) in 0.6 mL	10 @ 73.26	SW
8367J	Entacapone	200 mg	100 @ 137.70	NV
1375J	Epirubicin Hydrochloride	10 mg in 5 mL	1 @ 53.34	IT, PH
1376K		20 mg in 10 mL	1 @ 98.77	PH
1377L		50 mg in 25 mL	1 @ 242.42	HH, IT, PH
8817C		100 mg in 50 mL	1 @ 478.33	HH, IT
8397Y	Eprosartan Mesylate	400 mg (base)	28 @ 13.09	SM
8951D		400 mg (base)	28 @ 13.09	SM
8683B	Eptifibatide Acetate	20 mg (base) in 10 mL	1 @ 128.06	SH
8684C		75 mg (base) in 100 mL	1 @ 337.98	SH
1397M	Erythromycin Lactobionate	1 g (base)	1 @ 8.99	LM
8001D	Essential Amino Acids Formula with Minerals and Vitamin C	200 g	1 @ 62.77	SB
2027Q		400 g	1 @ 125.55	SB
9385Y	Essential Amino Acids Formula with Vitamins and Minerals	12.5 g, 50	1 @ 377.52	VF
8778B	Etanercept	25 mg and 1 mL solvent, 4	1 @ 911.29	WX
8779C		25 mg and 1 mL solvent, 4	1 @ 911.29	WX
9035M		25 mg and 1 mL solvent, 4	1 @ 911.29	WX

(APPLY WASTAGE FACTOR IN CALCULATING BROKEN QUANTITY PRICES)

Code	Name	Form/Strength	Pack and Price \$	Manufacturer
9036N		25 mg and 1 mL solvent, 4	1 @ 911.29	WX
8637N		25 mg and 1 mL solvent, 4	1 @ 911.29	WX
8638P		25 mg and 1 mL solvent, 4	1 @ 911.29	WX
9037P		25 mg and 1 mL solvent, 4	1 @ 911.29	WX
9429G		25 mg and 1 mL solvent, 4	1 @ 911.29	WX
8748K	Ethacrynic Acid	25 mg	100 @ 95.44	FK
1390E	Etoposide	100 mg in 5 mL	1 @ 33.37	HH
8120J		100 mg (as phosphate)	1 @ 33.37	BQ
8842J	Everolimus	0.75 mg	60 @ 786.10	NV
1473M	Fluconazole	100 mg in 50 mL	1 @ 22.75	PF, SZ
1474N		200 mg in 100 mL	1 @ 41.47	BX, PF, SZ
1433K	Fludrocortisone Acetate	100 mcg	100 @ 8.94	BQ
2528C	Fluorouracil	500 mg in 10 mL	1 @ 5.13	HH
			5 @ 25.65	IT
9005Y		1000 mg in 20 mL	1 @ 8.83	IT
2958Q	Folic Acid	500 mcg	100 @ 3.68	AF
1437P		5 mg	100 @ 3.80	AF
8672K	Follitropin Alfa	75 i.u.	1 @ 48.23	SG
8713N		300 i.u.	1 @ 185.67	SG
8675N		450 i.u.	1 @ 278.49	SG
8714P		450 i.u.	1 @ 278.50	SG
8715Q		900 i.u.	1 @ 554.41	SG
8565T	Follitropin Beta	300 i.u. in 0.36 mL	1 @ 185.67	SH
8566W		600 i.u. in 0.72 mL	1 @ 371.33	SH
8871X		900 i.u. in 1.08 mL	1 @ 554.40	SH
2414C	Frusemide	20 mg	50 @ 1.30	FM
			50 @ 2.25	SW
8444K	Gelatin - Succinylated	20 g per 500 mL, 500 mL	1 @ 13.11	BR
8049P	Gemcitabine Hydrochloride	200 mg (base)	1 @ 50.77	HH, LY
9401T		200 mg (base) in 20 mL	1 @ 50.77	IT
8050Q		1 g (base)	1 @ 237.62	HH, LY
9402W		1000 mg (base) in 100 mL	1 @ 237.62	IT
2824P	Gentamicin Sulfate	80 mg (base) in 2 mL	5 @ 7.04	HH
2245E	Glucose	278 mmol per L, 1 L	1 @ 3.90	BX
3106L	Glucose and Ketone Indicator—Urine	Reagent strips, 50	1 @ 5.44	RD
3107M		Reagent strips, 50	1 @ 5.50	BN
9254C		Reagent strips, 50	1 @ 5.44	RD
9255D		Reagent strips, 50	1 @ 5.50	BN
9193W	Glucose Indicator—Blood	Electrode strips, 25	1 @ 11.69	PZ
2979T		Electrode strips, 50	1 @ 23.38	RD
2891E		Electrode strips, 50	1 @ 23.38	RD
9358M		Electrode strips, 50	1 @ 23.38	MS
8890X		Electrode strips, 50	1 @ 23.38	MS
1820T		Electrode strips, 50	1 @ 23.38	DB
9013J		Electrode strips, 50	1 @ 23.38	OZ
8749L		Electrode strips, 50	1 @ 23.38	OZ
8682Y		Electrode strips, 50	1 @ 23.38	WF
8723D		Electrode strips, 50	1 @ 23.38	BR
9063B		Electrode strips, 50	1 @ 23.38	BR
2263D		Electrode strips, 50	1 @ 23.38	MS
8825L		Electrode strips, 50	1 @ 23.38	DB
8190C		Reagent strips, 50	1 @ 23.38	RD
8739Y		Reagent strips, 50	1 @ 23.38	RD

(APPLY WASTAGE FACTOR IN CALCULATING BROKEN QUANTITY PRICES)

Code	Name	Form/Strength	Pack and Price \$	Manufacturer
8806L		Reagent strips, 51	1 @ 23.38	RD
2890D		Reagent strips, 50	1 @ 23.38	NA
2860M		Reagent strips, 50	1 @ 23.38	NA
8759B		Reagent strips, 50	1 @ 23.38	LB
2914J		Reagent strips, 50	1 @ 19.74	NA
2917M		Reagent strips, 50	1 @ 19.74	BN
8795X		Reagent strips, 50	1 @ 23.38	PX
9256E		Electrode strips, 25	1 @ 11.69	PZ
9257F		Electrode strips, 50	1 @ 23.38	RD
9258G		Electrode strips, 50	1 @ 23.38	RD
9359N		Electrode strips, 50	1 @ 23.38	MS
9259H		Electrode strips, 50	1 @ 23.38	MS
9260J		Electrode strips, 50	1 @ 23.38	DB
9261K		Electrode strips, 50	1 @ 23.38	OZ
9263M		Electrode strips, 50	1 @ 23.38	OZ
9264N		Electrode strips, 50	1 @ 23.38	WF
9265P		Electrode strips, 50	1 @ 23.38	BR
9266Q		Electrode strips, 50	1 @ 23.38	BR
9267R		Electrode strips, 50	1 @ 23.38	MS
9268T		Electrode strips, 50	1 @ 23.38	DB
9273C		Reagent strips, 50	1 @ 23.38	RD
9274D		Reagent strips, 50	1 @ 23.38	RD
9275E		Reagent strips, 51	1 @ 23.38	RD
9276F		Reagent strips, 50	1 @ 23.38	NA
9277G		Reagent strips, 50	1 @ 23.38	NA
9278H		Reagent strips, 50	1 @ 23.38	LB
9279J		Reagent strips, 50	1 @ 19.74	NA
9280K		Reagent strips, 50	1 @ 19.74	BN
9281L		Reagent strips, 50	1 @ 23.38	PX
2352T	Glucose Indicator—Urine	Reagent strips, 50	1 @ 6.70	BN
3104J		Reagent strips, 50	1 @ 6.21	BN
9252Y		Reagent strips, 50	1 @ 6.70	BN
9253B		Reagent strips, 50	1 @ 6.21	BN
2555L	Glycerol	700 mg, 12	1 @ 3.98	PP
2556M		1.4 g, 12	1 @ 4.12	PP
2557N		2.8 g, 12	1 @ 4.27	PP
8728J	Granisetron Hydrochloride	2 mg (base)	1 @ 26.28	HH
1076P	Heparin Sodium	35,000 units in 35 mL	1 @ 22.68	HH
1583H	Human Chorionic Gonadotrophin	500 units set	1 @ 23.51	SH
1640H	Hydralazine Hydrochloride	25 mg	100 @ 4.54	AF
1639G		50 mg	100 @ 5.50	AF
1486F	Hydrochlorothiazide with Amiloride Hydrochloride	50 mg-5 mg	50 @ 3.73	MK
1502C	Hydrocortisone Acetate	21.1 g	1 @ 16.28	AS
1501B	Hydrocortisone Sodium Succinate	100 mg with 2 mL solvent	1 @ 5.36	PH
1510L		100 mg with 2 mL solvent	1 @ 5.36	PH
1511M		250 mg with 2 mL solvent	1 @ 9.27	PH
8299T	Hypromellose with Dextran	3 mg-1 mg per mL, 0.4 mL, 28	1 @ 10.14	AQ
3198H	Ibuprofen	200 mg	50 @ 2.82	AF
3190X		400 mg	30 @ 2.77	AB
2446R	Idarubicin Hydrochloride	5 mg	1 @ 80.23	PH
2448W		10 mg	1 @ 148.40	PH
8076C	Ifosfamide	1 g	1 @ 51.03	BX

(APPLY WASTAGE FACTOR IN CALCULATING BROKEN QUANTITY PRICES)

Code	Name	Form/Strength	Pack and Price \$	Manufacturer
8077D		2 g	1 @ 94.15	BX
2757D	Indomethacin	100 mg	20 @ 8.04	AS
2454E		25 mg	50 @ 2.83	AF
			50 @ 3.29	AS
8571D	Insulin Aspart	100 units per mL, 10 mL	1 @ 30.57	NO
8435Y		100 units per mL, 3 mL, 5	1 @ 51.56	NF, NO
8609D	Insulin Aspart—Insulin Aspart Protamine Suspension	100 units (30 units-70 units) per mL, 3 mL, 5	1 @ 51.56	NF, NO
9040T	Insulin Detemir	100 units per mL, 3 mL, 5	1 @ 85.26	NF, NO
9039R	Insulin Glargine	100 units per mL, 3 mL, 5	1 @ 85.26	AV, SW
9224L	Insulin Glulisine	100 units per mL, 10 mL	1 @ 30.57	SW
1921D		100 units per mL, 3 mL, 5	1 @ 51.56	SW
1711C	Insulin Isophane (n.p.h.)	100 units per mL, 10 mL	1 @ 27.72	AS
1533Q		100 units per mL, 10 mL	1 @ 25.48	LY, NO
1761Q		100 units per mL, 3 mL, 5	1 @ 43.58	LY, NI, NL, NO
8084L	Insulin Lispro	100 units per mL, 10 mL	1 @ 30.57	LY
8212F		100 units per mL, 3 mL, 5	1 @ 51.56	LY
8390N	Insulin Lispro—Insulin Lispro Protamine Suspension	100 units (25 units-75 units) per mL, 3 mL, 5	1 @ 51.56	LY
8874C		100 units (50 units-50 units) per mL, 3 mL, 5	1 @ 51.56	LY
1713E	Insulin Neutral	100 units per mL, 10 mL	1 @ 27.72	AS
1531N		100 units per mL, 10 mL	1 @ 25.48	LY, NO
1762R		100 units per mL, 3 mL, 5	1 @ 43.58	LY, NO
1426C	Insulin Neutral—Insulin Isophane (n.p.h.), (mixed) (biphasic Isophane)	100 units (30 units-70 units) per mL, 10 mL	1 @ 25.48	LY
1763T		100 units (30 units-70 units) per mL, 3 mL, 5	1 @ 43.58	LY, NI, NO
2062M		100 units (50 units-50 units) per mL, 3 mL, 5	1 @ 43.58	NO
8180M	Interferon Alfa-2a	3,000,000 i.u. in 0.5 mL	1 @ 33.32	RO
8551C		4,500,000 i.u. in 0.5 mL	1 @ 51.66	RO
8552D		6,000,000 i.u. in 0.5 mL	1 @ 67.66	RO
8553E		9,000,000 i.u. in 0.5 mL	1 @ 99.94	RO
8181N		3,000,000 i.u. in 0.5 mL	1 @ 33.32	RO
8182P		4,500,000 i.u. in 0.5 mL	1 @ 51.66	RO
8183Q		6,000,000 i.u. in 0.5 mL	1 @ 67.66	RO
8184R		9,000,000 i.u. in 0.5 mL	1 @ 99.94	RO
8572E	Interferon Alfa-2b	18,000,000 i.u. in 1.2 mL	1 @ 199.87	SH
8348J		18,000,000 i.u. in 1.2 mL	1 @ 199.87	SH
8476D		30,000,000 i.u. in 1.2 mL	1 @ 333.11	SH
8671J	Ipratropium Bromide	21 mcg per dose (200 doses)	1 @ 14.43	BY
1542E		250 mcg (anhydrous) in 1 mL, 30	1 @ 15.43	AF, GM, PU, SI, TX
			1 @ 15.79	BY
8238N		500 mcg (anhydrous) in 1 mL, 30	1 @ 18.11	AF, GM, PU, SI, TX
			1 @ 18.42	BY
8415X	Irinotecan Hydrochloride Trihydrate	100 mg in 5 mL	1 @ 323.62	HH, OE, PU, SZ
9134R	Isoleucine with Carbohydrate	4 g containing 50 mg isoleucine, 30	1 @ 127.40	VF
2587E	Isosorbide Dinitrate	10 mg	100 @ 3.86	AF
2588F		5 mg	100 @ 4.31	SI
1588N	Ketoprofen	100 mg	20 @ 9.44	SW

(APPLY WASTAGE FACTOR IN CALCULATING BROKEN QUANTITY PRICES)

Code	Name	Form/Strength	Pack and Price \$	Manufacturer
9148L	Lapatinib	250 mg (as ditosylate monohydrate)	70 @ 1690.52	GK
8797B	Levodopa with Carbidopa and Entacapone	50 mg-12.5 mg-200 mg	100 @ 152.73	NV
8798C		100 mg-25 mg-200 mg	100 @ 167.75	NV
8799D		150 mg-37.5 mg-200 mg	100 @ 182.77	NV
9292C		200 mg-50 mg-200 mg	100 @ 196.60	NV
8290H	Lithium Carbonate	450 mg (s.r.)	100 @ 13.94	GK
1598D	Mercaptopurine	50 mg	25 @ 61.38	GK
8731M	Mesalazine	500 mg (e.c.)	100 @ 145.51	OA
2214M		500 mg (p.r.)	100 @ 145.51	FP
8598M		500 mg	100 @ 145.51	OA
8753Q		1 g in 100 mL, 7	1 @ 82.45	FP
8616L		2 g in 60 mL, 7	1 @ 82.45	OA
8617M		4 g in 60 mL, 7	1 @ 109.87	OA
8768L		80 g	1 @ 82.45	OA
1606M	Methadone Hydrochloride	10 mg in 1 mL	10 @ 46.94	SI
2826R	Methysergide	1 mg	50 @ 19.27	LM
1638F	Metronidazole	500 mg in 100 mL	1 @ 5.11	BX
			10 @ 39.28	HH, SZ
9026C	Miconazole Nitrate	20 mg per g, 15 g	1 @ 4.74	JT
8282X	Milk Powder—Lactose Free Formula	900 g	1 @ 21.29	WX
2350Q		900 g	1 @ 16.50	NU
8283Y		900 g	1 @ 21.29	WX
2349P		900 g	1 @ 16.50	NU
2358D	Milk Powder—Lactose Modified	900 g	1 @ 22.13	SJ
2357C		900 g	1 @ 22.13	SJ
3092R	Milk Powder—Synthetic	400 g	1 @ 46.87	NU
8630F	Milk Protein and Fat Formula with Vitamins and Minerals—Carbohydrate Free	225 g	1 @ 26.75	SB
8816B	Modafinil	100 mg	60 @ 170.28	CS
1674D	Naproxen	250 mg	50 @ 3.65	AF
			50 @ 4.82	RO
9285Q	Nilotinib	200 mg (as hydrochloride monohydrate)	28 @ 1371.00	NV
9171Q		200 mg (as hydrochloride monohydrate)	28 @ 1371.00	NV
2732T	Nitrazepam	5 mg	25 @ 1.47	AF
			25 @ 3.00	VT
1967M	Norethisterone	350 mcg	1 @ 2.67	JC
			1 @ 2.67	KR
			1 @ 3.67	PH
2772X	Norethisterone with Ethinyloestradiol	500 mcg-35 mcg	1 @ 4.65	PH
2774B		Tablet-Pack	1 @ 2.67	KR
			1 @ 4.65	PH
2773Y		1 mg-35 mcg	1 @ 4.65	PH
2775C		Tablet-Pack	1 @ 2.67	KR
			1 @ 4.65	PH
2776D		Tablet-Pack	1 @ 2.67	KR
			1 @ 4.65	PH
3176E	Norethisterone with Mestranol	1 mg-50 mcg	1 @ 2.67	PH
3179H		Tablet-Pack	1 @ 2.67	PH
1698J	Nystatin	100,000 units per g, 15 g	1 @ 6.07	BQ
8383F	Ofloxacin	3 mg per mL, 5 mL	1 @ 12.86	AG

(APPLY WASTAGE FACTOR IN CALCULATING BROKEN QUANTITY PRICES)

Code	Name	Form/Strength	Pack and Price \$		Manufacturer
3134Y	Oxazepam	15 mg	25 @	1.28	AF
			25 @	3.06	SI
3135B		30 mg	25 @	1.47	AF, FM
			25 @	3.37	SI
8588B	Oxcarbazepine	60 mg per mL, 250 mL	1 @	65.85	NV
3026G	Paclitaxel	30 mg in 5 mL	1 @	192.73	BQ, BX, HH
8018B		100 mg in 16.7 mL	1 @	639.29	BQ, BX, HH, IT
3017T		150 mg in 25 mL	1 @	931.01	BQ, HH, IT
8556H	Pancreatic Extract	not less than 5,000 BP units lipase activity	100 @	22.56	SM
8020D		not less than 10,000 BP units lipase activity	100 @	32.87	SM
8021E		not less than 25,000 BP units lipase activity	100 @	65.74	SM
9412J		not less than 40,000 BP units lipase activity	100 @	104.60	SM
9225M		not less than 5,000 BP units lipase activity	100 @	22.56	SM
9226N	Pancrelipase	not less than 10,000 BP units lipase activity	100 @	32.87	SM
9227P		not less than 25,000 BP units lipase activity	100 @	65.74	SM
9413K		not less than 40,000 BP units lipase activity	100 @	104.60	SM
8366H		not less than 25,000 BP units lipase activity	100 @	65.74	TM
9229R		not less than 25,000 BP units lipase activity	100 @	65.74	TM
8784H	Paracetamol	500 mg	100 @	2.00	CH, FM, GM, HX, PC, SI, SW, SZ, TW, YM
8814X		665 mg (m.r.)	96 @	5.11	GC
1754H	Paraffin	3.5 g	1 @	7.87	IQ
			1 @	8.99	AQ
9217D		3.5 g	1 @	7.87	IQ
			1 @	8.99	AQ
1166J	Phenoxybenzamine Hydrochloride	10 mg, 30	1 @	66.16	GH
1787C	Phenoxymethylpenicillin	250 mg	25 @	2.58	SI
3028J		500 mg	25 @	3.82	SI
9143F		150 mg per 5 mL, 100 mL	1 @	7.99	FM, SI
1703P		250 mg	25 @	2.58	SI
9384X		4 g containing 50 mg phenylalanine, 30	1 @	127.40	VF
9170P	Polyethylene Glycol 400 with Propylene Glycol	4 mg-3 mg per mL, single dose units	1 @	13.83	AQ
		0.8 mL, 28			
2334W	Polygeline	17.5 g per 500 mL, 500 mL	1 @	13.11	AE
2642C	Potassium Chloride	600 mg	100 @	3.44	NM
			100 @	4.84	NV
1920C	Prednisolone Sodium Phosphate	equiv. to 20 mg prednisolone in 100 mL	7 @	53.69	SI
2554K		equiv. to 5 mg prednisolone, 10	1 @	10.80	SI
1948M	Promethazine Hydrochloride	50 mg in 2 mL	5 @	7.95	HH

(APPLY WASTAGE FACTOR IN CALCULATING BROKEN QUANTITY PRICES)

Code	Name	Form/Strength	Pack and Price \$	Manufacturer
1953T	Propantheline Bromide	15 mg	100 @ 10.02	SI
1955X	Propylthiouracil	50 mg	100 @ 21.61	PL
2676W	Protein Hydrolysate Formula with Medium Chain Triglycerides	400 g	1 @ 20.69	NT
8259Q		450 g	1 @ 12.93	NU
8284B	Raltitrexed	2 mg	1 @ 283.29	HH
1937Y	Ranitidine Hydrochloride	150 mg (base), effervescent	30 @ 7.37	GK
8162N		150 mg (base) per 10 mL, 300 mL	1 @ 8.75	GK
8903N		150 mg (base), effervescent	30 @ 7.37	GK
8905Q		150 mg (base) per 10 mL, 300 mL	1 @ 8.75	GK
8787L	Risperidone	0.5 mg	20 @ 10.17	JC, SI, TX
8788M		0.5 mg (orally disintegrating)	28 @ 14.23	JC
8790P		1 mg (orally disintegrating)	28 @ 27.21	JC
9080X		2 mg (orally disintegrating)	28 @ 54.68	JC
8792R		1 mg (orally disintegrating)	28 @ 27.21	JC
8794W		2 mg (orally disintegrating)	28 @ 54.68	JC
9075P		3 mg (orally disintegrating)	28 @ 81.28	JC
9076Q		4 mg (orally disintegrating)	28 @ 107.47	JC
8869T		0.5 mg	20 @ 10.17	JC, SI, TX
8870W		0.5 mg (orally disintegrating)	28 @ 14.23	JC
8780D		25 mg	1 @ 157.36	JC
8781E		37.5 mg	1 @ 201.99	JC
8782F		50 mg	1 @ 246.67	JC
1099W	Salbutamol Sulfate	200 mcg (base)	100 @ 6.04	GK
8288F		100 mcg (base) per dose (200 doses)	1 @ 4.40	AL, IA
			1 @ 4.99	GK
8354Q		100 mcg (base) per dose (200 doses)	1 @ 16.09	IA
2000G		2.5 mg (base) in 2.5 mL, 30	1 @ 6.26	AF, CR, GM, GX, PU, SI, SZ
			1 @ 6.99	GK
2001H		5 mg (base) in 2.5 mL, 30	1 @ 6.61	AF, CR, GM, GX, SI, SZ
			1 @ 7.34	GK
2003K		5 mg (base) per mL, 30 mL	1 @ 2.30	PU
1103C		2 mg (base) per 5 mL, 150 mL	1 @ 7.89	GK
2995P	Salcatonin	50 i.u. in 1 mL	5 @ 33.54	NV
2997R		100 i.u. in 1 mL	5 @ 51.57	NV
2014B	Sodium Alginate with Calcium Carbonate and Sodium Bicarbonate	1 g-320 mg-534 mg in 20 mL, 500 mL	1 @ 4.13	RC
2264E	Sodium Chloride	154 mmol per L, 1 L	1 @ 3.90	BX
2260Y		513 mmol per L, 1 L	1 @ 5.90	BX
2266G	Sodium Chloride Compound	1 L	1 @ 5.90	BX
2281C	Sodium Chloride with Glucose	31 mmol-222 mmol per L, 1 L	1 @ 3.90	BX
2279Y		19 mmol-104 mmol per 500 mL, 500 mL	1 @ 5.12	BX
2278X		39 mmol-69 mmol per 500 mL, 500 mL	1 @ 5.12	BX
9416N	Sodium Lactate Compound	500 mL	1 @ 2.73	BR
2286H		1 L	1 @ 3.90	BX
2294R	Sodium Valproate	100 mg	100 @ 12.79	SW
2289L		200 mg (e.c.)	100 @ 13.72	AF, SZ, WA
			100 @ 14.47	SW

(APPLY WASTAGE FACTOR IN CALCULATING BROKEN QUANTITY PRICES)

Code	Name	Form/Strength	Pack and Price \$	Manufacturer
2290M		500 mg (e.c.)	100 @ 25.98	AF, SZ, WA
2293Q		200 mg per 5 mL, 300 mL	100 @ 26.73	SW
2295T		200 mg per 5 mL, 300 mL	1 @ 14.25	SW
9380Q	Sorafenib	200 mg (as tosylate)	1 @ 14.25	SW
2091C	Sorbitol with Sodium Citrate and Sodium Lauryl Sulfoacetate	200 mg (as tosylate)	60 @ 3225.33	BN
8577K	Soy Protein and Fat Formula with Vitamins and Minerals—Carbohydrate Free	3.125 g-450 mg-45 mg in 5 mL, 12	1 @ 15.08	JT
2093E	Sulfasalazine	384 mL	1 @ 5.53	AB
2096H		500 mg	100 @ 23.16	PH
		500 mg (e.c.)	100 @ 25.31	KR
			100 @ 26.11	PH
9208P		500 mg	100 @ 23.16	PH
9209Q		500 mg (e.c.)	100 @ 25.31	KR
			100 @ 26.11	PH
2047R	Sulindac	100 mg	50 @ 4.96	AF
8144P	Sumatriptan Succinate	50 mg (base)	2 @ 9.55	AF, GK
8885P		50 mg (base) (fast disintegrating)	2 @ 9.55	GK
2248H	Tamarindus Indica Seed Polysaccharide	10 mg per mL, 0.5 mL, 20	1 @ 9.88	JT
2110C	Tamoxifen Citrate	20 mg (base)	30 @ 28.83	AP
2088X	Temazepam	10 mg	25 @ 1.47	AF, FM
			25 @ 2.85	SI
8819E	Temozolomide	5 mg	5 @ 67.21	SH
8820F		20 mg	5 @ 187.17	SH
8821G		100 mg	5 @ 794.29	SH
9361Q		140 mg	5 @ 1086.56	SH
9160D	Terbinafine Hydrochloride	10 mg per g, 15 g	1 @ 15.47	NC
1251W	Terbutaline Sulfate	5 mg in 2 mL, 30	1 @ 17.19	AP
8098F	Testosterone	100 mg	1 @ 33.86	SH
8099G		200 mg	1 @ 67.71	SH
2670M	Testosterone Esters	100 mg	1 @ 4.75	SH
2101N		250 mg	1 @ 9.02	SH
2832C	Tetracosactrin	1 mg in 1 mL	1 @ 12.97	NV
2345K	Thiotepa	15 mg	1 @ 74.62	SI
8221Q	Tiagabine Hydrochloride	5 mg (base)	50 @ 33.11	OA
8222R		10 mg (base)	50 @ 66.21	OA
8223T		15 mg (base)	50 @ 95.23	OA
1356J	Tobramycin Sulfate	80 mg (base) in 2 mL	5 @ 29.30	HH
8872Y		80 mg (base) in 2 mL (without preservative)	5 @ 29.30	PU
2117K	Triamcinolone Acetonide	200 mcg per g, 100 g	1 @ 4.23	FM
			1 @ 5.88	SI
2118L		200 mcg per g, 100 g	1 @ 4.23	FM
			1 @ 5.88	SI
3128P	Triglycerides, Medium Chain	500 mL	1 @ 22.98	SB
3136C	Triglycerides, Medium Chain and Long Chain with Glucose Polymer	400 g	1 @ 36.14	SB
8478F	Triglycerides—Medium Chain, Formula	400 g	1 @ 51.86	SB
8629E		420 g	1 @ 57.63	SB
9383W		16 g, 25	1 @ 52.30	VF
9165J	Tyrosine with Carbohydrate	4 g containing 1 g tyrosine, 30	1 @ 127.40	VF
8448P	Ursodeoxycholic Acid	250 mg	100 @ 183.09	OA
8133C	Valaciclovir Hydrochloride	500 mg (base)	10 @ 49.68	GK

(APPLY WASTAGE FACTOR IN CALCULATING BROKEN QUANTITY PRICES)

Code	Name	Form/Strength	Pack and Price \$	Manufacturer
9135T	Valine with Carbohydrate	4 g containing 50 mg valine, 30	1 @ 127.40	VF
3113W	Vancomycin	125 mg	20 @ 119.41	AS
3114X		250 mg	20 @ 229.81	AS
3130R		500 mg	1 @ 20.05	AS, HH, SZ
3131T		500 mg	1 @ 19.58	AS, HH, SZ
2270L		1 g	1 @ 39.14	HH, SZ
9129L	Varenicline	1 mg (as tartrate)	56 @ 113.32	PF
2374Y	Vincristine Sulfate	1 mg in 1 mL	5 @ 77.46	HH, PU
9009E	Vinorelbine Tartrate	20 mg (base)	1 @ 104.26	FB
9010F		30 mg (base)	1 @ 154.70	FB
8280T		10 mg (base) in 1 mL	1 @ 73.58	FB, HH, IT, LM
8281W		50 mg (base) in 5 mL	1 @ 307.06	FB, HH, IT, LM
9382T	Whey Protein Formula supplemented with Amino Acids, Long Chain Polyunsaturated Fatty Acids, Vitamins and Minerals, and low in Protein, Phosphate, Potassium and Lactose	100 g, 10	1 @ 165.36	VF
8587Y	Whey Protein Formula supplemented with Amino Acids, Vitamins and Minerals, and low in Protein, Phosphate, Potassium and Lactose	400 g	1 @ 66.22	SB

**PREPARATIONS WHICH MAY BE PRESCRIBED
FOR PATIENTS RECEIVING PALLIATIVE CARE**

5303D	Bisacodyl	10 mg, 10	1 @ 5.15	PP
			1 @ 5.53	BY
5304E		10 mg, 12	1 @ 4.21	FL, PP
5307H		10 mg, 10	1 @ 5.15	PP
			1 @ 5.53	BY
5308J		10 mg, 12	1 @ 4.21	FL, PP
5339B	Clonazepam	2.5 mg per mL, 10 mL	1 @ 4.31	RO
5342E		2.5 mg per mL, 10 mL	1 @ 4.31	RO
5361E	Diclofenac Sodium	25 mg (e.c.)	50 @ 3.32	AW, CH, GM, GN, GX, SZ, TW
			50 @ 4.30	NV
5363G		100 mg	20 @ 9.25	NV
5364H		25 mg (e.c.)	50 @ 3.32	AW, CH, GM, GN, GX, SZ, TW
			50 @ 4.30	NV
5366K		100 mg	20 @ 9.25	NV
5401G	Fentanyl	200 mcg, 3	1 @ 35.49	OA
5402H		400 mcg, 3	1 @ 35.49	OA
5403J		600 mcg, 3	1 @ 35.49	OA
5404K		800 mcg, 3	1 @ 35.49	OA
5405L		1200 mcg, 3	1 @ 35.49	OA
5406M		1600 mcg, 3	1 @ 35.49	OA
5407N		200 mcg, 3	1 @ 33.55	OA
5408P		400 mcg, 3	1 @ 33.55	OA
5409Q		600 mcg, 3	1 @ 33.55	OA
5410R		800 mcg, 3	1 @ 33.55	OA

(APPLY WASTAGE FACTOR IN CALCULATING BROKEN QUANTITY PRICES)

Code	Name	Form/Strength	Pack and Price \$	Manufacturer
5411T		1200 mcg, 3	1 @ 33.55	OA
5412W		1600 mcg, 3	1 @ 33.55	OA
5413X		200 mcg, 3	1 @ 33.55	OA
5414Y		400 mcg, 3	1 @ 33.55	OA
5415B		600 mcg, 3	1 @ 33.55	OA
5416C		800 mcg, 3	1 @ 33.55	OA
5417D		1200 mcg, 3	1 @ 33.55	OA
5418E		1600 mcg, 3	1 @ 33.55	OA
5311M	Glycerol	700 mg, 12	1 @ 3.98	PP
5312N		1.4 g, 12	1 @ 4.12	PP
5313P		2.8 g, 12	1 @ 4.27	PP
5314Q		700 mg, 12	1 @ 3.98	PP
5315R		1.4 g, 12	1 @ 4.12	PP
5316T		2.8 g, 12	1 @ 4.27	PP
5367L	Ibuprofen	200 mg	50 @ 2.82	AF
5368M		400 mg	30 @ 2.77	AB
5369N		200 mg	50 @ 2.82	AF
5370P		400 mg	30 @ 2.77	AB
5377B	Indomethacin	25 mg	50 @ 2.83	AF
			50 @ 3.29	AS
5378C		100 mg	20 @ 8.04	AS
5379D		25 mg	50 @ 2.83	AF
			50 @ 3.29	AS
5380E		100 mg	20 @ 8.04	AS
5345H	Naproxen	250 mg	50 @ 3.65	AF
			50 @ 4.82	RO
5349M		250 mg	50 @ 3.65	AF
			50 @ 4.82	RO
5359C	Nitrazepam	5 mg	25 @ 1.47	AF
			25 @ 3.00	VT
5360D		5 mg	25 @ 1.47	AF
			25 @ 3.00	VT
5371Q	Oxazepam	15 mg	25 @ 1.28	AF
			25 @ 3.06	SI
5372R		30 mg	25 @ 1.47	AF, FM
			25 @ 3.37	SI
5373T		15 mg	25 @ 1.28	AF
			25 @ 3.06	SI
5374W		30 mg	25 @ 1.47	AF, FM
			25 @ 3.37	SI
5343F	Paracetamol	665 mg (m.r.)	96 @ 5.11	GC
5344G		665 mg (m.r.)	96 @ 5.11	GC
5331N	Sorbitol with Sodium Citrate and Sodium Lauryl Sulfoacetate	3.125 g-450 mg-45 mg in 5 mL, 12	1 @ 15.08	JT
5332P		3.125 g-450 mg-45 mg in 5 mL, 12	1 @ 15.08	JT
5381F	Sulindac	100 mg	50 @ 4.96	AF
5383H		100 mg	50 @ 4.96	AF
5375X	Temazepam	10 mg	25 @ 1.47	AF, FM
			25 @ 2.85	SI
5376Y		10 mg	25 @ 1.47	AF, FM
			25 @ 2.85	SI

(APPLY WASTAGE FACTOR IN CALCULATING BROKEN QUANTITY PRICES)

Code	Name	Form/Strength	Pack and Price \$	Manufacturer
PREPARATIONS WHICH MAY BE PRESCRIBED BY PARTICIPATING DENTAL PRACTITIONERS FOR DENTAL TREATMENT ONLY				
3398W	Benzylpenicillin	600 mg	1 @ 3.65	CS
3399X		3 g	1 @ 6.05	CS
5048Q	Cefotaxime	1 g	1 @ 4.64	SZ
5049R		2 g	1 @ 8.51	SZ
5079H	Diclofenac Sodium	100 mg	20 @ 9.25	NV
5076E		25 mg (e.c.)	50 @ 3.32	AW, CH, GM, GN, GX, SZ, TW
			50 @ 4.30	NV
5088T	Erythromycin Lactobionate	1 g (base)	1 @ 8.99	LM
5106R	Glucose	278 mmol per L, 1 L	1 @ 3.90	BX
5118J	Hydrocortisone Sodium Succinate	100 mg with 2 mL solvent	1 @ 5.36	PH
5119K		250 mg with 2 mL solvent	1 @ 9.27	PH
5121M	Ibuprofen	200 mg	50 @ 2.82	AF
5123P		400 mg	30 @ 2.77	AB
5128X	Indomethacin	100 mg	20 @ 8.04	AS
5126T		25 mg	50 @ 2.83	AF
			50 @ 3.29	AS
5139L	Ketoprofen	100 mg	20 @ 9.44	SW
5154G	Metronidazole	500 mg in 100 mL	1 @ 5.11	BX
			10 @ 39.28	HH, SZ
5176K	Naproxen	250 mg	50 @ 3.65	AF
			50 @ 4.82	RO
5224Y	Paracetamol	500 mg	100 @ 2.00	CH, FM, GM, HX, PC, SI, SW, SZ, TW, YM
3360W	Phenoxymethylpenicillin	250 mg	25 @ 2.58	SI
3361X		500 mg	25 @ 3.82	SI
5012T		150 mg per 5 mL, 100 mL	1 @ 7.99	FM, SI
3374N	Promethazine Hydrochloride	50 mg in 2 mL	5 @ 7.95	HH
5212H	Sodium Chloride	154 mmol per L, 1 L	1 @ 3.90	BX
5213J		513 mmol per L, 1 L	1 @ 5.90	BX
5214K	Sodium Chloride with Glucose	31 mmol-222 mmol per L, 1 L	1 @ 3.90	BX
5215L		19 mmol-104 mmol per 500 mL, 500 mL	1 @ 5.12	BX
5216M		39 mmol-69 mmol per 500 mL, 500 mL	1 @ 5.12	BX
5217N	Sulindac	100 mg	50 @ 4.96	AF
3323X	Vancomycin	500 mg	1 @ 20.05	AS, HH, SZ

**PREPARATIONS WHICH MAY BE PRESCRIBED BY AUTHORISED
OPTOMETRISTS FOR OPTOMETRICAL TREATMENT ONLY**

5504Q	Carbomer	2 mg per g, 0.6 mL, 30	1 @ 10.51	NV
5502N	Carbomer 974	3 mg per g, 0.5 g, 30	1 @ 9.88	AQ
5509Y	Carmellose Sodium	2.5 mg per mL, 0.6 mL, 24	1 @ 8.50	CX
5506T		5 mg per mL, 0.4 mL, 30	1 @ 9.88	AG
5505R		10 mg per mL, 0.4 mL, 30	1 @ 9.88	AG
5510B		10 mg per mL, 0.6 mL, 28	1 @ 9.22	CX

(APPLY WASTAGE FACTOR IN CALCULATING BROKEN QUANTITY PRICES)

Code	Name	Form/Strength	Pack and Price		Manufacturer
				\$	
5521N	Hypromellose with Dextran	3 mg-1 mg per mL, 0.4 mL, 28	1 @	10.14	AQ
5523Q	Paraffin	3.5 g	1 @	7.87	IQ
			1 @	8.99	AQ
5532E	Polyethylene Glycol 400 with Propylene Glycol	4 mg-3 mg per mL, single dose units 0.8 mL, 28	1 @	13.83	AQ
5531D	Tamarindus Indica Seed Polysaccharide	10 mg per mL, 0.5 mL, 20	1 @	9.88	JT

Section 4

Drug Tariff

Container Prices

Standard Formulae Preparations

Table of Codes, Maximum Quantities, and Number of
Repeats for Extemporaneously Prepared
Pharmaceutical Benefits

Special Note:

Purified Water BP is the minimum requirement for water in all PBS extemporaneous preparations.

Drug Tariff

Drug	Standard	Recovery Prices			
		0.1 g/mL \$	1 g/mL \$	10 g/mL \$	100 g/mL \$
Acacia Mucilage (by weight)	APF 15	0.01	0.08	0.64	5.67
Acacia, powdered	BP	0.02	0.15	1.22	10.87
Acetic Acid (6 per cent)	BP	0.01	0.01	0.11	1.02
Acetic Acid (33 per cent)	BP	0.01	0.05	0.38	3.38
Acetone	BP	0.01	0.08	0.62	5.49
(use as additive only)					
Alum	BP	0.02	0.14	1.15	10.26
Aluminium Acetate Solution	BP	0.02	0.13	1.03	9.11
Anise Water Concentrated 1 in 40	BP	0.01	0.05	0.39	3.49
(use as additive only)					
Aqueous Cream	APF	0.01	0.07	0.56	5.02
(for use only as a base combined with active ingredients)					
Ascorbic Acid	BP	0.05	0.38	3.01	26.79
(for use only as an ingredient of ferrous sulfate mixtures)					
Aspirin	BP	0.08	0.65	5.21	46.29
Belladonna Tincture	BP	0.05	0.37	2.98	26.45
Benzocaine	BP	0.08	0.66	5.25	46.69
Benzoic Acid	BP	0.06	0.49	3.91	34.78
Benzoic Acid Compound Ointment	APF	0.01	0.10	0.79	6.99
Benzoic Acid Solution	BP	0.01	0.09	0.74	6.62
Benzoin Compound Tincture	BP	0.02	0.18	1.43	12.74
Boric Acid	BP	0.01	0.06	0.45	3.97
(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	0.17	1.35	11.98
Calcium Hydroxide Solution	BP	0.01	0.01	0.07	0.66
Castor Oil	BP	0.01	0.06	0.46	4.06
(use as additive only)					
Cetomacrogol Aqueous Cream	APF	0.01	0.03	0.20	1.79
(for use only as a base combined with active ingredients)					
Cetrimide Aqueous Cream	APF	0.02	0.12	0.98	8.70
(for use only as a base combined with active ingredients)					
Chlorhexidine Acetate	BP	0.45	3.56	28.50	253.30
(use as additive only)					
Chlorhexidine Aqueous Cream	APF	0.03	0.23	1.80	15.99
(for use only as a base combined with active ingredients)					
Chloroform	BP	0.02	0.15	1.18	10.48
(use as additive only)					
Chloroform Spirit	BP	0.01	0.03	0.25	2.26
Chloroform Water Concentrated 1 in 40	APF 15	0.01	0.03	0.25	2.26
Citric Acid Monohydrate	BP	0.01	0.06	0.51	4.57
Coal Tar	BP	0.10	0.82	6.53	58.00
Coal Tar Solution	BP	0.01	0.11	0.85	7.55
Cocaine Hydrochloride	BP	5.66	45.31	362.50	3222.22
Coconut Oil	BP	0.01	0.10	0.80	7.16

Drug	Standard	Recovery Prices			
		0.1 g/mL \$	1 g/mL \$	10 g/mL \$	100 g/mL \$
Codeine Linctus	APF	0.01	0.05	0.42	3.74
Codeine Phosphate (may only be prescribed in linctuses, mixtures or mixtures for children)	BP	1.40	11.18	89.45	795.07
Collodion Flexible	BP	0.05	0.39	3.13	27.79
Dithranol	BP	3.48	27.85	222.80	1980.45
Emulsifying Ointment (for use only as a base combined with active ingredients)	BP	0.01	0.06	0.51	4.52
Ephedrine Hydrochloride (may only be prescribed in nasal instillations)	BP	0.58	4.66	37.26	331.20
Ethanol (90 per cent) (use as additive only)	BP	0.01	0.02	0.19	1.69
Ethanol (96 per cent) (use as additive only)	BP	0.01	0.03	0.23	2.03
Ether Solvent (use as additive only)	BP	0.01	0.11	0.90	8.01
Eucalyptus Oil (use as additive only)	BP	0.01	0.11	0.88	7.83
Ferrous Sulfate	BP	0.10	0.81	6.47	57.50
Formaldehyde Solution	BP	0.03	0.20	1.56	13.90
Gentian Alkaline Mixture	APF	0.01	0.05	0.43	3.82
Glycerol	BP	0.01	0.05	0.40	3.53
Honey Purified (use as additive only)	BP 1993	0.01	0.02	0.16	1.42
Hydroxybenzoate Compound Solution	APF	0.06	0.50	4.00	35.58
Iodine	BP	0.39	3.13	25.01	222.33
Iodine Alcoholic Solution	BP	0.02	0.16	1.24	11.00
Iodine Aqueous Oral Solution	BP	0.02	0.19	1.50	13.29
Kaolin Mixture	BPC 1968	0.01	0.08	0.64	5.71
Kaolin and Opium Mixture	APF 14	0.01	0.09	0.69	6.10
Lactic Acid	BP	0.05	0.42	3.36	29.86
Lavender Spike Oil	BPC 1968	0.08	0.61	4.91	43.63
Liquorice Liquid Extract	BP	0.03	0.21	1.71	15.22
Magnesium Carbonate Light	BP	0.02	0.19	1.53	13.59
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	0.24	1.91	16.97
Menthol, Racemic or Levomenthol	BP	0.21	1.65	13.19	117.22
Methyl Hydroxybenzoate	BP	0.29	2.32	18.54	164.78
Methyl Hydroxybenzoate Solution	APF	0.03	0.23	1.81	16.09
Methylated Industrial Spirit (use as additive only)	BP	0.01	0.04	0.29	2.58
Olive Oil (use as additive only)	BP	0.01	0.10	0.80	7.07
Paraffin Hard	BP	0.01	0.06	0.49	4.32
Paraffin Liquid (may only be prescribed for other than oral use)	BP	0.01	0.03	0.23	2.07
Paraffin Light Liquid	BP	0.02	0.12	0.98	8.73
Paraffin Soft White	BP	0.01	0.03	0.26	2.28

Drug	Standard	Recovery Prices			
		0.1 g/mL \$	1 g/mL \$	10 g/mL \$	100 g/mL \$
Paraffin Soft Yellow	BP	0.01	0.05	0.43	3.82
Peppermint Oil (use as additive only)	BP	0.10	0.78	6.22	55.30
Peppermint Water Concentrated 1 in 40 (use as additive only)	APF 16	0.03	0.24	1.93	17.14
Phenobarbitone Sodium (may only be prescribed for the treatment of epilepsy)	BP	10.67	85.38	683.00	6071.11
Phenol Liquefied (not available for ear drops)	BP	0.06	0.44	3.49	31.05
Podophyllum Resin	BP	0.94	7.50	60.03	533.60
Potassium Citrate	BP	0.01	0.09	0.72	6.37
Potassium Iodide	BP	0.06	0.49	3.92	34.80
Potassium Permanganate	BP	0.02	0.15	1.21	10.75
Propyl Hydroxybenzoate	BP	0.25	1.96	15.69	139.43
Propylene Glycol	BP	0.01	0.07	0.57	5.04
Red Syrup	APF 15	0.02	0.12	0.92	8.17
Resorcinol	BP	0.12	0.97	7.72	68.64
Salicylic Acid	BP	0.02	0.19	1.54	13.68
Salicylic Acid Ointment	APF	0.01	0.09	0.74	6.59
Salicylic Acid Ointment	BP	0.01	0.09	0.74	6.59
Simple Ointment (white) (for use only as a base combined with active ingredients)	BP	0.02	0.14	1.13	10.09
Simple Ointment (yellow) (for use only as a base combined with active ingredients)	BP	0.02	0.17	1.34	11.92
Sodium Bicarbonate	BP	0.01	0.07	0.59	5.23
Sodium Chloride	BP	0.02	0.12	0.98	8.74
Sodium Chloride Solution	BP	0.01	0.01	0.07	0.61
Sodium Citrate	BP	0.02	0.12	0.95	8.44
Sodium Thiosulfate (use as additive only)	BP	0.03	0.20	1.60	14.25
Starch	BP	0.01	0.09	0.74	6.61
Sulfur Ointment (for use only as a base combined with active ingredients)	BP 1980	0.02	0.15	1.19	10.55
Sulfur Precipitated	BP 1980	0.03	0.24	1.91	17.01
Syrup	BP	0.01	0.03	0.24	2.17
Talc Purified, sterilised	BP	0.02	0.14	1.14	10.12
Thymol	BP	0.18	1.42	11.34	100.79
Thymol Compound Mouth Wash	APF 15	0.01	0.08	0.66	5.86
Tragacanth Compound Powder	BP 1980	0.07	0.54	4.35	38.63
Tragacanth Mucilage	APF 13	0.01	0.03	0.24	2.10
Tragacanth Mucilage	BPC 1973	0.01	0.02	0.17	1.55
Tragacanth, powdered	BP	0.10	0.79	6.29	55.89
Trichloroacetic Acid	BP 1980	0.26	2.05	16.41	145.82
Triethanolamine	BP	0.05	0.39	3.13	27.74
Water For Injections, sterilised (b) (extemporaneously prepared eye drops and eye lotions)	BP	0	0	0	8.45
Water Purified	BP	0.01	0.01	0.06	0.52
Wool Alcohols Ointment (white)	BP	0.02	0.13	1.04	9.25

Drug	Standard	Recovery Prices			
		0.1 g/mL \$	1 g/mL \$	10 g/mL \$	100 g/mL \$
(for use only as a base combined with active ingredients)					
Wool Alcohols Ointment (yellow)	BP	0.02	0.13	1.04	9.25
(for use only as a base combined with active ingredients)					
Wool Fat	BP	0.02	0.13	1.02	9.08
Wool Fat Hydrous	BP	0.01	0.10	0.82	7.29
Zinc Compound Paste	BP	0.02	0.15	1.21	10.76
Zinc Cream	BP	0.01	0.06	0.51	4.50
(for use only as a base combined with active ingredients)					
Zinc Oxide	BP	0.01	0.09	0.75	6.68
Zinc and Salicylic Acid Paste	BP	0.02	0.13	1.03	9.20
Zinc Sulfate	BP	0.02	0.19	1.54	13.68

Container Prices

\$

DISPENSING BOTTLES -

25mL	0.49
50mL	0.49
100mL	0.48
200mL	0.75
500mL	1.06

POISON BOTTLES -

25mL	0.45
50mL	0.43
100mL	0.47
200mL	0.66
500mL	1.20

SCREW CAP JARS -

25g	0.60
50g	0.66
100g	0.76
200g	0.79
500g	1.20

DROPPER CONTAINERS -

15mL polythene	0.78
15mL glass	0.76

Dispensing Fee for Extemporaneously Prepared Benefits	8.03
Additional Fee for Agreed Price Extemporaneously Prepared Benefits	1.39

Standard Formula Preparations

The following list is not intended to indicate in any way which particular formula an approved pharmacist should use in filling a prescription.

The prices shown in the column 'Dispensed Price for Max. Qty' are for the ingredients, the container and the dispensing fee. The prices shown in the column 'Maximum Recordable Value for Safety Net' are for the ingredients, the container and the dispensing fee and, where applicable, the additional fee for agreed price benefits.

KEY TO REFERENCES:

APF	Australian Pharmaceutical Formulary
BP	British Pharmacopoeia
BPC	British Pharmaceutical Codex
QHF	Queensland Hospital Formulary

Code	Item	Reference	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$
CREAMS (Maximum Quantity 100 g and 1 Repeat)				
7502W	Salicylic Acid and Sulfur Aqueous	APF	14.48	15.87
DUSTING POWDERS (Maximum Quantity 100 g and 1 Repeat)				
7458M	Zinc, Starch and Talc	APF 15 & BPC 1973	19.47	20.86
EAR DROPS (Maximum Quantity 15 mL and 2 Repeats)				
7642F	Aluminium Acetate	APF	9.85	11.24
7643G	Aluminium Acetate	BP	10.35	11.74
7314Y	Sodium Bicarbonate	APF & BP	9.17	10.56
7313X	Spirit	APF	9.05	10.44
INHALATIONS (Maximum Quantity 50 mL and 1 Repeat)				
7484X	Benzoin and Menthol	APF	17.28	18.67
7308P	Menthol	APF	11.06	12.45
7310R	Menthol and Eucalyptus	BP 1980	11.59	12.98
LINCTUSES CONTAINING CODEINE PHOSPHATE (Maximum Quantity 100 mL and 0 Repeats)				
7530H	Codeine	APF	12.25	13.64
LOTIONS (Maximum Quantity 200 mL and 2 Repeats)				
7709R	Aluminium Acetate Aqueous	APF	10.70	12.09
MIXTURES, OTHER (Maximum Quantity 200 mL and 4 Repeats)				
7604F	Gentian Alkaline	APF	16.43	17.82
7348R	Kaolin	BPC 1968	20.21	21.60
7301G	Kaolin and Opium	APF 14	20.97	22.36
7342K	Magnesium Trisilicate	BPC 1968	15.03	16.42
7343L	Magnesium Trisilicate and Belladonna	BPC 1968	17.90	19.29
MOUTH WASHES (Maximum Quantity 200 mL and 1 Repeat)				
7457L	Thymol Compound	APF 15	20.41	21.80
OINTMENTS (Maximum Quantity 100 g and 1 Repeat)				
7914M	Benzoic Acid Compound	APF	15.78	17.17
7914M	Benzoic Acid Compound (extemporaneous formula)	BP	15.78	17.17
7902X	Boric Acid, Olive Oil and Zinc Oxide	QHF	12.96	14.35

—CONTAINER RATES ARE INCLUDED—

Code	Item	Reference	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$
7926E	Salicylic Acid	APF	15.38	16.77
7928G	Salicylic Acid (extemporaneous formula)	BP	15.38	16.77
PAINTS (Maximum Quantity 25 mL and 1 Repeat)				
7567G	Podophyllin Compound	APF 16 & BP	40.20	32.90
7568H	Salicylic Acid	APF	16.78	18.17
PASTES, OTHER (Maximum Quantity 100 g and 1 Repeat)				
7558T	Zinc	APF	19.55	20.94
7558T	Zinc Compound (extemporaneous formula)	BP	19.55	20.94
POWDER FOR INTERNAL USE (Maximum Quantity 100 g and 2 Repeats)				
7545D	Magnesium Trisilicate	BP	25.79	27.18

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 JUNE 2009

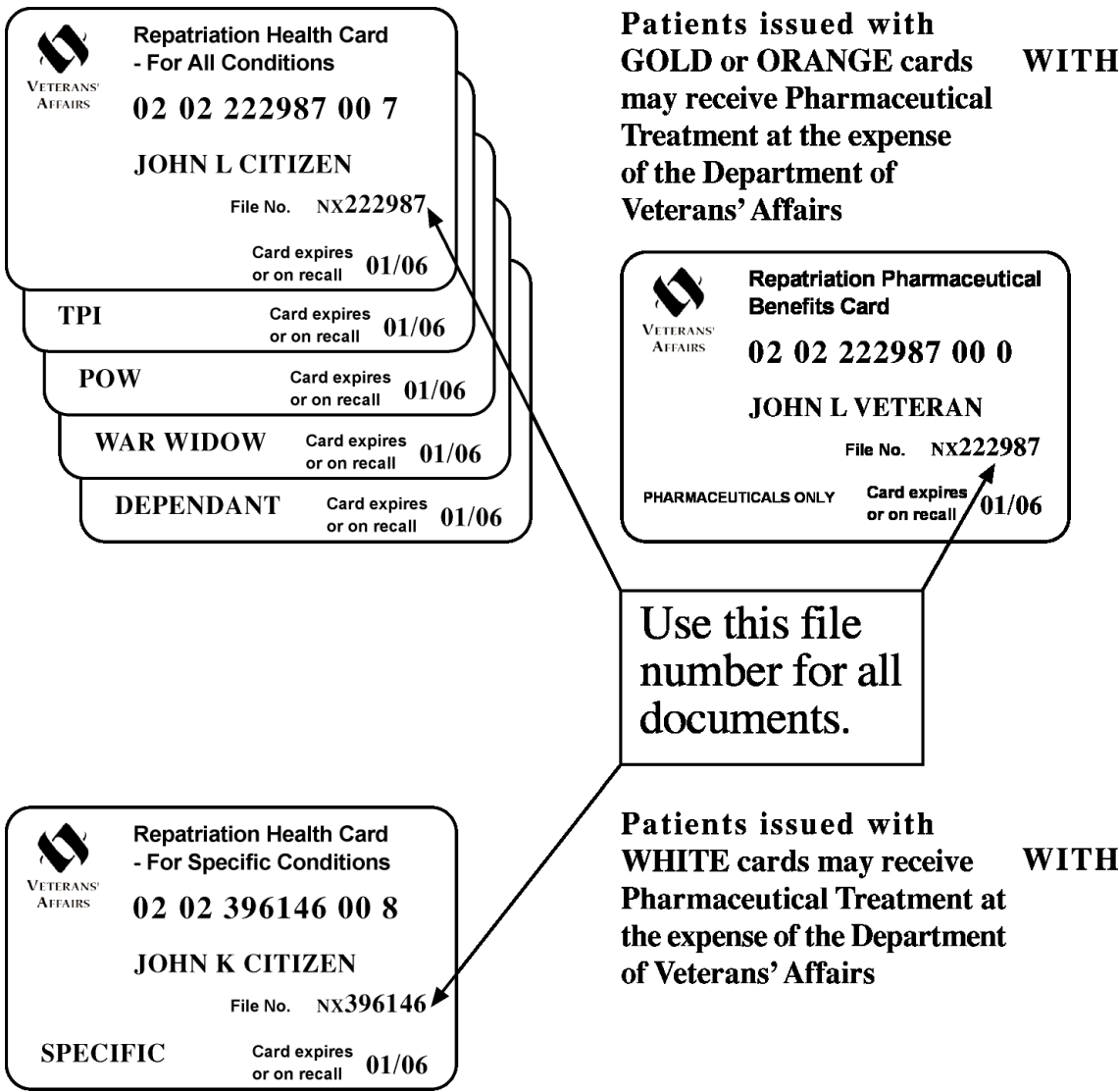
The benefits listed in this Schedule may only be prescribed to Department of Veterans' Affairs beneficiaries holding a:

- Repatriation Health Card For All Conditions (gold); or
- Repatriation Health Card For Specific Conditions (white); or
- Repatriation Pharmaceutical Benefits Card (orange);

BENEFICIARIES' ENTITLEMENT CARDS AND ELIGIBILITY

The diagram below outlines the drug eligibility of Department of Veterans' Affairs

REPATRIATION PHARMACEUTICAL BENEFITS



FOR REPATRIATION PHARMACEUTICAL BENEFITS

beneficiaries in accordance with their treatment entitlement.

PBS Schedule listings written on the common PBS/RPBS prescription form, ticked as 'RPBS' (restrictions apply)	+	Repatriation Schedule listings written on the common PBS/RPBS prescription form, ticked as 'RPBS'	+	Items for which prescribing approval has been authorised on the common PBS/RPBS authority prescription form for: (i) PBS and Repatriation Schedules 'Authority required' items; (ii) greater quantities/repeats of drugs listed in PBS and Repatriation Schedules; or (iii) items not listed in PBS or Repatriation Schedules.

Only for disabilities that have been accepted for treatment by the Department of Veterans' Affairs

PBS Schedule listings written on the common PBS/RPBS prescription form, ticked as 'RPBS' (restrictions apply)	+	Repatriation Schedule listings written on the common PBS/RPBS prescription form, ticked as 'RPBS'	+	Items for which prescribing approval has been authorised on a common PBS/RPBS authority prescription form for: (i) PBS and Repatriation Schedules 'Authority required' items; (ii) greater quantities/repeats of drugs listed in PBS and Repatriation Schedules; or (iii) items not listed in PBS or Repatriation Schedules.

RPBS Explanatory Notes

Introduction

The Australian Repatriation System

1. The Australian Repatriation system is based primarily on the principle of compensation to veterans and eligible dependants for injury or death related to war service. In certain cases, treatment is also provided for accepted injuries or conditions that are not service-related or have occurred as a result of other than war service.
2. Through the *Veterans' Entitlements Act 1986* the Department of Veterans' Affairs provides programs of compensation, income support and treatment for eligible veterans and their dependants. One of the defined benefits for eligible veterans is the Repatriation Pharmaceutical Benefits Scheme. This range of medications and dressings is more comprehensive than is available through the Pharmaceutical Benefits Scheme.

RPBS prescribing provisions

3. Unless otherwise stated, Repatriation Pharmaceutical Benefits Scheme (RPBS) prescriptions must conform with the requirements of Pharmaceutical Benefits Scheme (PBS) prescriptions, as detailed in Section 1 – Explanatory Notes in the *Schedule of Pharmaceutical Benefits* book. The prescriber shall ensure that a prescription contains the following details:
 - the category of benefit, i.e., RPBS, by placing a cross in the relevant box;
 - the patient's full name and address;
 - the prescription date;
 - the DVA file number of the patient as evidence of entitlement;
 - in the case of authority prescriptions, the Authority approval number or the four digit streamlined authority code;
 - the item, form, strength, quantity and directions;
 - the number of repeats, if applicable;
 - indicate when brand substitution is not permitted; and
 - the name, signature, the prescriber number and address of the prescriber.

Prior Approval Arrangements

4. The prior approval of the Department is required to prescribe the following:
 - 'Authority required' items (excluding 'Authority required (STREAMLINED)' items) listed in either the PBS or RPBS Schedule;
 - increased quantities and/or repeats of items listed in either the PBS or RPBS Schedule;
 - items listed under section 100 of the *National Health Act 1953*; and
 - other items not listed in either Schedule (non-Schedule items).
5. The above items are to be prescribed on the common PBS/RPBS authority prescription form in accordance with the directions stated in the Explanatory Notes in the *Schedule of Pharmaceutical Benefits* (See also information regarding dental prescribing and prescribing by optometrists under the RPBS in these Notes.)

6. All Authority required prescriptions and requests for non-Schedule items must receive prior approval from the Department. This can be achieved by either:
 - using the Department's national free call number 1800 552 580; or
 - by mailing the written authority prescription to the Veterans' Affairs Pharmaceutical Advisory Centre (VAPAC) at the reply paid address shown at the end of these RPBS Explanatory Notes.

Prior approval is not required from DVA to prescribe an Authority required (STREAMLINED) item (except where increased quantities and/or repeats are required). Instead the authority prescription form must include a four digit streamlined authority code.

7. Some requests for prior approval (including some non-Schedule items) need to be referred by VAPAC to the Repatriation Pharmaceutical Reference Committee for consideration. In such cases a VAPAC pharmacist will advise the prescriber to submit a request in writing that provides the following information:
 - A current clinical report on the patient's condition (such as age, co-morbidities, renal, liver failure) and clinical reports including pathology, biochemistry, diagnostic and other investigations if appropriate.
 - Details of past and current therapy for the condition. Include details of PBS, RPBS and non-Schedule items utilised, and the results of those therapies.
 - Details of the proposed treatment regimen. Include intended dose and duration of treatment and objective measures of response.
 - When the proposed use of the item is outside the TGA-approved indications for use in Australia, provide copies of articles from peer reviewed publications supporting the proposed treatment.
 - Signed, informed patient consent where the item is to be used for a non-TGA-approved indication.
 - For items without Australian marketing approval, a copy of the TGA Special Access Scheme approval to prescribe the drug.
8. Requests for prior approval to prescribe a non-Schedule (PBS or RPBS) item that is of the same therapeutic class (ATC level 3) as an item that is listed on the Schedule, will not be approved unless unequivocal clinical evidence is presented to demonstrate that the requested item is essential for effective treatment of the nominated patient.
9. A pharmacist should not supply an item prescribed on an RPBS Authority Prescription Form unless the form has been approved and stamped by VAPAC, or has been endorsed by the prescriber with a telephone Authority approval number provided by VAPAC. Medicare Australia will not accept RPBS Authority prescriptions that have not been approved by the Department of Veterans' Affairs for payment.

Palliative Care Drugs

10. The following medications may be available, or made available in increased quantities or doses under prior approval arrangements for use only in the palliative care of terminal disease:
 - clonazepam
 - cyclizine
 - dexamethasone
 - disodium pamidronate
 - fentanyl
 - glycopyrrolate
 - hyoscine butylbromide
 - hyoscine hydrobromide
 - ketamine
 - midazolam
 - octreotide

For further information telephone VAPAC on 1800 552 580.

Dental Prescribing

11. Under Department of Veterans' Affairs arrangements, financial responsibility for pharmaceutical benefits prescribed by a Local Dental Officer (LDO) is limited to treatment to which holders of the following cards are entitled:
 - a Gold Repatriation Health Card – For All Conditions; or
 - a White Repatriation Health Card – For Specific Conditions; or
 - an Orange Repatriation Pharmaceutical Benefits Card.

Where possible the LDO shall prescribe in accordance with the provisions governing dental prescribing under the Pharmaceutical Benefits Scheme (PBS).
12. Prescriptions for PBS Dental Schedule items for Gold, White and Orange Card holders are to be dispensed at the PBS concessional rate. Claims for payment by the dispensing pharmacist are to be included with other Repatriation prescriptions. The card holder is required to meet the cost of any applicable brand premium.
13. When a non-PBS Dental Schedule item is prescribed for an eligible card holder, the LDO's private prescription form should be used. The dispensing pharmacist may charge the patient the full cost of the prescription. The patient may claim a refund for the full cost of a non-Schedule item from the Department if an itemised receipt (not a cash register receipt) and a copy of the prescription are provided.

Prescribing by optometrists

14. Optometrists approved as 'PBS prescribers' may write RPBS prescriptions as outlined in Section 1 for medicines listed in Section 2 of the PBS Schedule as pharmaceutical benefits for optometrical use.
15. Medicines in the optometrist list include non-Authority and Authority required items. Procedures for obtaining VAPAC approval to prescribe 'Authority required' optometrist items or increased quantities and/or repeats of optometrist items under the RPBS are the same as indicated under prior approval arrangements above.

16. The list of medicines for prescribing by optometrists under the RPBS is the same as applies under the PBS. There are no optometrist listings in the RPBS Schedule for prescribing for veterans only. There is no provision for optometrist prescribers to request approval to prescribe items that are not included in the PBS optometrist list (non-Schedule items).
17. Optometrist PBS/RPBS prescription forms are for use for prescribing non-Authority or Authority required optometrist items under the RPBS with one item per form only.

Provisions governing pricing and payment for RPBS benefits

Introduction

18. Unless otherwise stated, the pricing and payment principles and arrangements for approved pharmacists supplying pharmaceutical benefits under the RPBS will be the same as those arrangements applying under the PBS.
19. Where a pharmaceutical benefit that is not listed on the PBS or RPBS Schedule is dispensed on an RPBS Authority prescription, a pharmacist will price the benefit and enter the serial number, prescription identifying number and price on the sticker or stamp imprint affixed to the prescription.

Pricing of Schedule Items

20. Items supplied under the RPBS from the PBS Schedule, both ready-prepared and extemporaneously-prepared, will be paid on the same basis as benefits supplied under the PBS. Items supplied under the RPBS from the Repatriation Schedule, including wound dressings, will be paid on the basis of the price as given in the Repatriation Pharmaceutical Benefits section (Section 1 – RPBS Schedule, Drugs, Medicines and Dressings) of the *Schedule of Pharmaceutical Benefits*.

Pricing of Non-Schedule Ready Prepared Items

21. Non-Schedule ready-prepared items are to be priced on the basis of the invoiced, GST-exclusive wholesale price to pharmacists plus the appropriate PBS mark-up and the PBS dispensing fee. Where the item price to pharmacists is greater than \$100.00, a copy of the invoice pertaining to the supply of that item is to be submitted together with the appropriate copy of the authority prescription as part of the claim for payment.

Pricing of Non-Schedule Extemporaneously Prepared Items

22. When an ingredient drug is not listed in the PBS Drug Tariff, the recovery price will be based on the invoiced wholesale price to pharmacists, increased by a mark-up of 100%, calculated in accordance with the directions contained in the pricing instructions for pricing of PBS extemporaneously-prepared benefits in this Schedule. The price paid by the pharmacist for the commercial pack from which the ingredient is used shall be endorsed on the prescription form.

Miscellaneous Pricing Rules

23. The price to pharmacists used as the basis of pricing will be the invoiced, GST-exclusive price from the wholesaler.
24. If multiple quantities of a manufacturer's original pack are supplied, the PBS mark-up is applied to the price to pharmacist of each pack and then totalled. The PBS dispensing fee, and the PBS dangerous drug fee if applicable, are then added to the total of the marked-up prices.
25. When the quantity prescribed corresponds with the quantity of a manufacturer's original pack, in no circumstances will the price payable for one pack exceed that payable for multiples or combinations of packs to supply the quantity prescribed.
26. The list of ingredient drugs and prices included in the PBS Drug Tariff are common to both the PBS and RPBS. Certain restrictions apply regarding the prescribing and dispensing of some of these ingredient drugs as pharmaceutical benefits, e.g., use as additive only.

27. For items prescribed generically, including non-Schedule and wound dressings, the pharmacist should indicate on the prescription the quantity and brand supplied. If prescriptions are not endorsed, the Department will pay the lowest priced acceptable product available.

General

Packaging Material, Postage or Freight

28. Payment to a pharmacist for the costs of packaging materials, postage or freight required to supply a pharmaceutical benefit is to be paid by the patient, who may then claim reimbursement from the Department through the provision of a pharmacist's itemised receipt.

Payment for Items Supplied at Short Intervals

29. For all items dispensed at specific short intervals of time, the Department will pay a separate PBS dispensing fee for each occasion that the drug is supplied and which is acknowledged on receipt by the patient or agent.
30. The price payable on the items supplied will be based on the individual dose quantity supplied. Where applicable, a PBS dangerous drug fee and a minimum container charge will be payable for each supply.

Receipts for Patient Charges

31. Where a charge is paid by a patient in any of the circumstances of paragraphs 13 or 24, the pharmacist is required to provide a printed receipt to the patient with the details of the items or services provided, the amount paid, date of supply and the patient's name and address. The patient may apply for reimbursement from the Department.

Special Patient Contributions

32. The Special Patient Contribution for items listed as Special Pharmaceutical Benefits in the PBS Schedule is not payable by veterans entitled to pharmaceutical benefits under the RPBS. Eligible veterans receiving Special Pharmaceutical Benefits under the RPBS are required to pay only the concessional patient contribution and any applicable brand premium. If a Safety Net Entitlement card is held, the veteran should receive a Special Pharmaceutical Benefit free of charge, subject to any brand premium applicable. Medicare Australia will reimburse the dispensing pharmacist the total dispensed price, less the concessional patient contribution and/or brand premium if applicable.

Therapeutic Group Premiums — Authority Processing

33. Items attracting a therapeutic group premium are dual listed. Dispensing pharmacists are therefore required to select the appropriate code for those items that are dual listed as authority and non-authority items, in order to correctly charge the patient and claim from Medicare Australia. Those authority prescriptions that grant exemption from a therapeutic group premium will have the letters 'TPX' at the beginning of the telephone Authority approval number, or, in the case of a written approval, will be stamped with the words "This prescription does not attract a therapeutic group premium".

DEPARTMENT OF VETERANS' AFFAIRS

Authority Prescription Applications

Applications for authority to prescribe under the Repatriation Pharmaceutical Benefits Scheme (RPBS) should be sent to the Veterans' Affairs Pharmaceutical Advisory Centre (VAPAC) using the free postal service:

REPLY PAID 9998
VAPAC (Veterans' Affairs Pharmaceutical Advisory Centre)
Department of Veterans' Affairs
GPO Box 9998
BRISBANE QLD 4001

For RPBS enquiries and telephone approvals 24 hours a day the Freecall number is:

1800 552 580

Departmental pharmacists answer applications for prior approval for non-Schedule items and Authority application calls.

REPATRIATION PHARMACEUTICAL BENEFITS

These changes to the Repatriation Pharmaceutical Benefits Schedule are effective from 1 June 2009. The Schedule is updated on the first day of each month and is available on the Internet at www.pbs.gov.au.

SUMMARY OF CHANGES

ADDITIONS

Additions — Items

- 4390C **Podophyllotoxin**, Cream 1.5 mg per g (0.15%), 5 g (*Wartec Cream*)
- 4380M **Risedronate sodium and calcium carbonate with colecalciferol**, Pack containing 4 tablets risedronate sodium 35 mg and 24 sachets containing granules of calcium carbonate 2.5 g (equivalent to 1 g calcium) with colecalciferol 22 micrograms (*Actonel Combi D*)
- 4389B **Salicylic acid**, Gel 270 mg per g (27%), 15 g (*Duofilm Gel*)
- 4386W **Salicylic acid with lactic acid**, Liquid 167 mg-167 mg per g (16.7%-16.7%), 15 mL (*Duofilm Solution*)

Additions — Brands

- 4591P *Gabatine 100, SI* — **Gabapentin**, Capsule 100 mg
- 4592Q *Gabatine 300, SI* — **Gabapentin**, Capsule 300 mg
- 4593R *Gabatine 400, SI* — **Gabapentin**, Capsule 400 mg

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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								
• Antiinfectives and antiseptics for local oral treatment								
CHLORHEXIDINE GLUCONATE								
4161B	Mouth wash 2 mg per mL (0.2%), 250 mL	‡ 1	..	..	11.46 11.98	5.30 5.30	Plaqacide Savacol Mouth and Throat Rinse	OB OM
4160Y	Mouth wash 2 mg per mL (0.2%), 250 mL	‡ 1	..	..	13.34	5.30	Periogard (Chlorohex) Mouth Rinse	OM
• Other agents for local oral treatment								
CARMELLOSE SODIUM								
4568K	Mouth spray 10 mg per mL, 25 mL	‡ 1	1	..	10.36	5.30	Aquae	HA
4569L	Mouth spray 10 mg per mL, 100 mL	‡ 1	..	..	12.03	5.30	Aquae	HA
DRUGS FOR ACID RELATED DISORDERS								
Antacids								
• Calcium compounds								
CALCIUM CARBONATE with GLYCINE								
NOTE: For patients with chronic renal failure.								
4055K	Tablet 420 mg-180 mg	200	5	..	* 22.75	5.30	Titralac	MM
• Combinations and complexes of aluminium, calcium and magnesium compounds								
ALUMINIUM HYDROXIDE with MAGNESIUM HYDROXIDE and SIMETHICONE								
4453J	Tablet 400 mg-400 mg-40 mg	200	5	..	* 45.69	5.30	Mylanta Double Strength	JT
4118R	Oral suspension 400 mg-400 mg-30 mg per 5 mL, 500 mL	2	5	..	* 22.21	5.30	Mylanta Double Strength	JT
DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS								
Drugs for functional bowel disorders								
• Synthetic anticholinergics, esters with tertiary amino group								
MEBEVERINE HYDROCHLORIDE								
4328T	Tablet 135 mg	90	..	..	27.69 30.98	5.30 5.30	^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								
• <i>Belladonna alkaloids semisynthetic, quaternary ammonium compounds</i>								
HYOSCINE BUTYLBROMIDE								
4279F	Injection 20 mg in 1 mL	5	..	..	22.31	5.30	Buscopan	BY
LAXATIVES								
Laxatives								
• <i>Softeners, emollients</i>								
DOCUSATE SODIUM								
4200C	Tablet 50 mg	100	2	..	12.30	5.30	Coloxyl 50	FM
• <i>Contact laxatives</i>								
DOCUSATE SODIUM with SENNA								
4198Y	Tablet 50 mg-8 mg	90	2	..	13.98	5.30	Coloxyl with Senna	FM
4028B	Tablet 50 mg-8 mg	100	2	..	13.98	5.30	Soflax	GM
SENNA STANDARDISED								
4455L	Tablet 7.5 mg	100	1	..	13.43	5.30	Senokot	RC
• <i>Bulk producers</i>								
ISPAGHULA HUSK								
4285M	Sachets 3.5 g, 30	± 1	1	..	17.21	5.30	Fybogel	RC
PSYLLIUM HYDROPHILIC MUCILLOID								
4419N	Oral powder (orange-flavoured, sugar-free) 283 g	± 1	1	..	21.24	5.30	Metamucil Smooth Texture Orange	PY
4422R	Oral powder (non-flavoured) 336 g	± 1	1	..	21.24	5.30	Metamucil Regular	PY
PSYLLIUM HYDROPHILIC MUCILLOID with HIGH AMYLOSE MAIZE STARCH								
4416K	Oral powder 2.7 g-0.7 g per 7.5 g, 440 g	± 1	1	..	20.84	5.30	Nucolox	SI
STERCULIA with FRANGULA BARK								
4558X	Granules 620 mg-80 mg per g (62%-8%), 500 g	± 1	1	..	24.52	5.30	Normacol Plus	NE
• <i>Enemas</i>								
SORBITOL with SODIUM CITRATE and SODIUM LAURYL SULFOACETATE								
4462W	Enemas 3.125 g-450 mg-45 mg in 5 mL, 4	± 1	..	..	11.67	5.30	Micro lax	JT

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

Short-term use when oral laxative therapy has failed or is inappropriate.

4246L	Suppositories 2.8 g (for adults), 12	3	..	..	* 18.80	5.30	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	..	128.21	5.30	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	..	10.39	5.30	Betamin	SW

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	..	12.91	5.30	Accomin Adult Tonic	WT

MINERAL SUPPLEMENTS

Calcium

• Calcium

CALCIUM

Restricted Benefit

Hypocalcaemia;

Osteoporosis;

Proven calcium malabsorption.

4332B	Tablet 250 mg (as citrate)	120	1	..	13.88	5.30	Citracal	BN
4333C	Tablet (chewable) 500 mg (as carbonate)	120	1	..	* 16.29	5.30	Cal-Sup	IA
4082W	Tablet 600 mg (as carbonate)	120	1	..	13.88	5.30	CAL-600	PP

Restricted Benefit

Hyperphosphataemia in chronic renal failure.

4093K	Tablet 250 mg (as citrate)	240	1	..	* 21.77	5.30	Citracal	BN
4094L	Tablet (chewable) 500 mg (as carbonate)	240	1	..	* 26.59	5.30	Cal-Sup	IA
4142B	Tablet 600 mg (as carbonate)	240	1	..	* 21.77	5.30	CAL-600	PP

Other mineral supplements

• Magnesium

MAGNESIUM ASPARTATE

Restricted Benefit

Patients with documented hypomagnesaemia.

4321K	Tablet 500 mg	50	..	..	13.96	5.30	Magmin Mag-Sup	BB PP

BLOOD AND BLOOD FORMING ORGANS

ANTITHROMBOTIC AGENTS

Antithrombotic agents

• Platelet aggregation inhibitors excl. heparin

ASPIRIN

4076M	Tablet 100 mg (with glycine)	90	1	..	15.24	5.30	Cardiprin 100	RC

continued ➞

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	
4077N	Tablet 100 mg (enteric coated)	84	1	..	13.28	5.30	Cartia	GK
4078P	Capsule 100 mg (containing enteric coated pellets)	84	1	..	14.19	5.30	Astrix	HH

NOTE:

The enteric coated preparations are for patients with a significant risk of gastrointestinal bleeding.

CLOPIDOGREL HYDROGEN SULFATE

Authority Required

For use in patients pre- and post-angioplasty.

4179Y	Tablet 75 mg (base)	28	3	..	80.49	5.30	^a Iscover ^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	..	9.90	5.30	BX	
4461T	Irrigation solution 9 mg per mL (0.9%), 1 L	± 1	2	..	10.22	5.30	BX	

CARDIOVASCULAR SYSTEM

VASOPROTECTIVES

Agents for treatment of hemorrhoids and anal fissures for topical use

• **Corticosteroids**

HYDROCORTISONE with CINCHOCAINE

HYDROCHLORIDE

CAUTION:

Long-term use may lead to skin atrophy.

4036K	Ointment 5 mg-5 mg per g (0.5%-0.5%), 30 g	± 1	..	..	19.61	5.30	Proctosedyl	SW
4038M	Suppositories 5 mg-5 mg, 12	± 1	..	..	18.51	5.30	Proctosedyl	SW

• **Other agents for treatment of hemorrhoids and anal fissures for topical use**

ZINC OXIDE

4039N	Compound ointment 50 g	± 1	1	..	14.01	5.30	Anusol	JT
4040P	Compound suppositories, 12	± 1	1	..	12.92	5.30	Anusol	JT

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	
DERMATOLOGICALS								
ANTIFUNGALS FOR DERMATOLOGICAL USE								
Antifungals for topical use								
• Antibiotics								
NYSTATIN								
4001N	Cream 100,000 units per g, 15 g	‡ 1	1	..	12.06	5.30	Mycostatin	BQ
• Imidazole and triazole derivatives								
BIFONAZOLE								
4003Q	Cream 10 mg per g (1%), 15 g	‡ 1	..	..	18.34	5.30	Mycospor	BN
CLOTRIMAZOLE								
4004R	Cream 10 mg per g (1%), 20 g	‡ 1	1	..	8.54	5.30	Clonea	AF
4005T	Lotion 10 mg per mL (1%), 20 mL	‡ 1	1	..	12.63	5.30	Canesten	BN
KETOCONAZOLE								
Restricted Benefit								
<i>Severe seborrhoeic dermatitis.</i>								
4008Y	Shampoo 20 mg per g (2%), 60 mL	‡ 1	..	..	17.88	5.30	Nizoral 2%	JT
4007X	Shampoo 20 mg per g (2%), 100 mL	‡ 1	..	..	18.94	5.30	Sebizole	GM
				..	18.96	5.30	Hexal Konazol 2% Shampoo	HX
MICONAZOLE								
4341L	Tincture 20 mg per mL (2%), 30 mL	‡ 1	1	..	19.04	5.30	Daktarin	JT
MICONAZOLE NITRATE								
4454K	Cream 20 mg per g (2%), 30 g	‡ 1	1	..	14.36	5.30	Daktarin	JT
• Other antifungals for topical use								
AMOROLFINE HYDROCHLORIDE								
Restricted Benefit								
<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	..	93.95	5.30	Loceryl	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	
CICLOPIROX OLAMINE								
<u>Restricted Benefit</u> <i>Severe seborrheic dermatitis.</i>								
44106D	Shampoo 15 mg per g (1.5%), 60 mL	‡ 1	..	..	16.13	5.30	Stieprox Liquid	SX
TERBINAFINE								
<u>Restricted Benefit</u> <i>Tinea pedis.</i>								
4463X	Gel 10 mg per g (1%), 15 g	‡ 1	..	..	22.92	5.30	Lamisil DermGel	NC
TERBINAFINE HYDROCHLORIDE								
<u>Restricted Benefit</u> <i>Tinea pedis.</i>								
4473K	Cream 10 mg per g (1%), 15 g	‡ 1	1	..	21.46	5.30	Lamisil	NC
TOLNAFTATE								
4481W	Spray aerosol 10 mg per g (1%), 100 g	‡ 1	..	..	14.25	5.30	Tinaderm	SH
Antifungals for systemic use								
• Antifungals for systemic use								
TERBINAFINE HYDROCHLORIDE								
<u>Authority Required</u> <i>Onychomycosis due to dermatophyte infection proven by microscopy or culture and confirmed by an approved pathology provider.</i>								
4011D	Tablet 250 mg (base)	42	1	..	102.39	5.30	^a Tamsil	SI
							^a Terbihexal	SZ
							^a Terbinafine-DP	GM
							^a Zabel	AF
				..	103.85	5.30	^a Lamisil	NV

EMOLLIENTS AND PROTECTIVES

Emollients and protectives

• **Silicone products**
DIMETHICONE with GLYCEROL
Restricted Benefit
For colostomy and ileostomy use;
For use by paraplegic and quadriplegic patients;
For use with surgical appliances.

4556T	Cream 150 mg-20 mg per g (15%-2%), 75 g	‡ 1	..	..	11.71	5.30	Silic 15	EO

continued ➞

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	
4551M	<i>Cream 150 mg-20 mg per g (15%-2%), 500 g</i>	± 1	..	..	24.68	5.30	<i>Silic 15</i>	<i>EO</i>
	• <i>Soft paraffin and fat products</i> WOOL ALCOHOLS							
4041Q	Ointment 100 g	± 1	1	..	12.37	5.30	Eucerin	BE
	• <i>Carbamide products</i> UREA							
4042R	Cream 100 mg per g (10%), 100 g	± 1	2	..	11.65	5.30	Aquacare H.P.	AG
				..	11.73	5.30	Urederm	HA
				..	12.34	5.30	Calmurid	OL
							Nutraplus	GA
	• <i>Other emollients and protectives</i> CARMELLOSE SODIUM with PECTIN and GELATIN							
4518T	Paste 167 mg-167 mg-167 mg per g (16.7%-16.7%- 16.7%), 5 g	± 1	..	..	11.42	5.30	Orabase	BQ
	SKIN EMOLLIENT							
4122Y	Bath oil 500 mL	± 1	2	..	16.92	5.30	Alpha Keri Bath Oil	MT
				..	19.33	5.30	QV Bath Oil	EO
				..	19.42	5.30	Hamilton Skin Therapy Oil	HA
4107E	Lotion 500 mL	± 1	2	..	16.92	5.30	Alpha Keri Lotion	MT
	Protectives against UV-radiation • <i>Protectives against UV-radiation for topical use</i> SUNSCREENS							
4543D	Solid stick 4.5 g	± 1	2	..	11.68	5.30	Hamilton Solastick 30+	HA
4544E	Cream 100 g	± 1	2	..	15.09	5.30	Hamilton Sunscreen Family Sunscreen Cream SPF 15	HA
				..	16.69	5.30	SunSense Cream SPF 30+	EO

continued ➞

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	
4546G	Lotion (non-alcoholic) 125 mL	‡ 1	2	..	15.09	5.30	Hamilton Sunscreen Family Sunscreen Milk SPF 15	HA
				..	15.55	5.30	Aquasun Lotion SPF 18	PF
				..	16.56	5.30	SunSense Ultra SPF 30+	EO

ANTIPRURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC.

Antipruritics, incl. antihistamines, anesthetics, etc.

- **Anesthetics for topical use**

LIGNOCAINE HYDROCHLORIDE with
CARBOXYMETHYLCELLULOSE

4308R	Mucilage 20 mg-25 mg per mL (2%-2.5%), 200 mL	‡ 1	..	..	78.92	5.30	Xylocaine Viscous	AP

- **Other antipruritics**

PINE TAR with TRIETHANOLAMINE LAURYL SULFATE

NOTE:

For patients who have failed to respond to simple moisturising agents.

4408B	Solution 23 mg-60 mg per mL (2.3%-6%), 500 mL	‡ 1	2	..	19.87	5.30	Hamilton Pine Tar Solution	HA
				..	20.50	5.30	Pinetarsol	EO

ANTIPSORIATICS

Antipsoriatics for topical use

- **Tars**

ALLANTOIN with SULFUR, PHENOL, COAL TAR
SOLUTION and MENTHOL

4505D	Gel 25 mg-5 mg-5 mg-0.05 mL-7.5 mg per g (2.5%-0.5%-0.5%-5%-0.75%), 30 g	‡ 1	2	..	14.64	5.30	Egopsoryl-TA	EO

ANTIBIOTICS AND CHEMOTHERAPEUTICS FOR DERMATOLOGICAL USE

Antibiotics for topical use

- **Other antibiotics for topical use**

MUPIROCIN

Restricted Benefit

For the topical treatment of secondarily infected traumatic skin lesions.

4348W	Cream 20 mg (as calcium) per g (2%), 15 g	‡ 1	..	..	15.85	5.30	Bactroban	GK

continued ➞

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	
4350Y	Ointment 20 mg per g (2%), 15 g	± 1	..	..	15.85	5.30	Bactroban	GK

Chemotherapeutics for topical use

- **Antivirals**

PODOPHYLLOTOXIN

Authority Required

For the treatment of ano-genital warts.

4390C	Cream 1.5 mg per g (0.15%), 5 g	± 1	..	..	52.23	5.30	Wartec Cream	SX
4566H	Paint 5 mg per mL (0.5%), 3.5 mL (with 30 swabs)	± 1	..	..	38.03	5.30	Condyline Paint	HA

- **Other chemotherapeutics**

METRONIDAZOLE

4030D	Gel 7.5 mg per g (0.75%), 50 g	± 1	..	..	31.42	5.30	Rozex	GA
4340K	Cream 7.5 mg per g (0.75%), 30 g	± 1	1	..	22.23	5.30	Rozex	GA

CORTICOSTEROIDS, DERMATOLOGICAL PREPARATIONS

Corticosteroids, plain

- **Corticosteroids, potent (group III)**

BETAMETHASONE VALERATE

4131K	Cream 1 mg (base) per g (0.1%), 30 g	± 1	2	..	22.00	5.30	Betnovate	SI
4132L	Ointment 1 mg (base) per g (0.1%), 30 g	± 1	2	..	22.00	5.30	Betnovate	SI

MOMETASONE FUROATE

4342M	Cream 1 mg per g (0.1%), 45 g	± 1	..	..	26.38	5.30	Elocon	SH
4343N	Ointment 1 mg per g (0.1%), 45 g	± 1	..	..	26.38	5.30	Elocon	SH

NOTE:

Application to large areas of skin for longer than four weeks is not recommended.

Corticosteroids, combinations with antibiotics

- **Corticosteroids, moderately potent, combinations with antibiotics**

TRIAMCINOLONE ACETONIDE with NEOMYCIN

SULFATE, GRAMICIDIN and NYSTATIN

4482X	Ointment 1 mg-2.5 mg (base)-250 micrograms- 100,000 units per g (0.1%-0.25% (base)-0.025%-100,000 units in 1 g), 15 g	± 1	..	..	18.66	5.30	Kenacomb	BQ

CAUTION:

For the short-term treatment of localised infective eczema only.

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	
ANTISEPTICS AND DISINFECTANTS								
Antiseptics and disinfectants								
• Iodine products								
POVIDONE-IODINE								
4411E	Solution 100 mg per mL (10%), 100 mL	‡ 1	..	..	20.39	5.30	Betadine Antiseptic Liquid	FH
OTHER DERMATOLOGICAL PREPARATIONS								
Other dermatological preparations								
• Antihidrotics								
DIPHEMANIL METHYLSULFATE								
4191N	Dusting powder 20 mg per g (2%), 50 g	‡ 1	1	..	16.93	5.30	Prantal	SH
• Medicated shampoos								
PINE TAR with CADE OIL, COAL TAR SOLUTION, ARACHIS OIL EXTRACT OF CRUDE COAL TAR and OLEYL ALCOHOL								
4405W	Scalp cleanser 3 mg-3 mg-1 mg-3 mg-10 mg per mL (0.3%-0.3%-0.1%-0.3%-1%), 300 mL	‡ 1	2	..	20.60	5.30	Polytar	SX
SALICYLIC ACID with COAL TAR SOLUTION								
4560B	Scalp cleanser 20 mg-50 mg per mL (2%-5%), 200 mL	‡ 1	2	..	19.28	5.30	Ionil-T	GA
SALICYLIC ACID with COAL TAR SOLUTION and PINE TAR								
4447C	Scalp cleanser 20 mg-10 mg-10 mg per mL (2%-1%-1%), 250 mL	‡ 1	2	..	17.28	5.30	Sebitar	EO
SELENIUM SULFIDE								
4452H	Shampoo 25 mg per mL (2.5%), 125 mL	‡ 1	..	..	13.71	5.30	Selsun	AB
• Wart and anti-corn preparations								
SALICYLIC ACID								
4389B	Gel 270 mg per g (27%), 15 g	‡ 1	..	..	19.11	5.30	Duofilm Gel	SX
SALICYLIC ACID with LACTIC ACID								
4386W	Liquid 167 mg-167 mg per g (16.7%-16.7%), 15 mL	‡ 1	..	..	17.72	5.30	Duofilm Solution	SX

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	
SALICYLIC ACID with PODOPHYLLIN RESIN								
4450F	Paint 100 mg-200 mg per mL (10%-20%), 6 mL	‡ 1	1	..	14.88	5.30	Posalfilin	NE
• Other dermatologicals ALLANTOIN with GLYCEROL and ICHTHAMMOL NOTE: For patients who have failed to respond to simple moisturising agents.								
4281H	Cream 5 mg-10 mg-10 mg per g (0.5%-1%-1%), 50 g	‡ 1	2	..	16.92	5.30	Egoderm Cream	EO
4280G	Ointment 5 mg-10 mg-10 mg per g (0.5%-1%-1%), 50 g	‡ 1	2	..	16.92	5.30	Egoderm Ointment	EO
CATIONIC CONDITIONER with PANTHENOL								
NOTE: To be used in conjunction with the scalp cleanser salicylic acid with coal tar solution and pine tar (code 4447C).								
4510J	Cream 200 g	‡ 1	2	..	13.82	5.30	SebiRinse	EO
IMIQUIMOD								
Authority Required <i>Primary treatment of histopathologically confirmed superficial basal cell carcinoma where other standard treatments are inappropriate and topical drug therapy is required.</i>								
4559Y	Cream 50 mg per g (5%), 250 mg single use sachets, 12	1	1	..	159.52	5.30	Aldara	IA
Authority Required <i>Treatment of solar keratosis on the face and scalp in patients where other standard treatments are inappropriate and topical drug therapy is required as field treatment for clinically visible and subclinical lesions.</i>								
4134N	Cream 50 mg per g (5%), 250 mg single use sachets, 12	1	1	..	159.52	5.30	Aldara	IA
SKIN CLEANSER								
4549K	Lotion 500 mL	‡ 1	2	..	20.31	5.30	Hamilton Skin Therapy Wash	HA
ZINC OXIDE with STARCH and CHLORPHENESIN								
4497Q	Dusting powder 100 g	‡ 1	1	..	11.83	5.30	Z.S.C.	SI

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	
GENITO URINARY SYSTEM AND SEX HORMONES								
GYNECOLOGICAL ANTIINFECTIVES AND ANTISEPTICS								
Antiinfectives and antiseptics, excl. comb. with corticosteroids								
• Antibiotics								
NYSTATIN								
4012E	Cream pessaries 100,000 units, 15	‡ 1	1	..	13.36	5.30	Nilstat	SI
4013F	Vaginal cream 100,000 units per dose, 15 doses, 75 g	‡ 1	1	..	13.36	5.30	Nilstat	SI
• Imidazole derivatives								
CLOTRIMAZOLE								
4014G	Pessaries 100 mg, 6	‡ 1	..	..	14.65	5.30	Clofeme	HX
4015H	Pessary 500 mg	1	..	..	15.25	5.30	Clofeme	HX
4016J	Vaginal cream 50 mg per 5 g (1%), 35 g	‡ 1	..	..	14.65	5.30	Chem mart Clotrimazole 6 Day Cream GenRx Clotrimazole 6 Day Cream healthsense Clotrimazole 6 Day Cream Terry White Chemists Clotrimazole 6 Day Cream	CH GX HS TW
				..	14.76	5.30	Hexal Clofeme 6 Day Cream	HX
4017K	Vaginal cream 100 mg per 5 g (2%), 20 g	‡ 1	..	..	14.65	5.30	Chem mart Clotrimazole 3 Day Cream Femizol Vaginal Cream GenRx Clotrimazole 3 Day Cream healthsense Clotrimazole 3 Day Cream Terry White Chemists Clotrimazole 3 Day Cream	CH GM GX HS TW
				..	14.76	5.30	Hexal Clofeme 3 Day Cream	HX

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	
MICONAZOLE NITRATE								
4020N	Pessaries 100 mg, 7	‡ 1	..	..	14.42	5.30	Monistat 7	JC
4021P	Vaginal cream 100 mg per 5 g (2%), 40 g	‡ 1	..	..	14.42	5.30	Monistat 7	JC

OTHER GYNECOLOGICALS

Other gynecologicals

• Other gynecologicals

RICINOLEIC ACID with ACETIC ACID and
HYDROXYQUINOLINE SULFATE

4434J	Vaginal jelly 7 mg-9.4 mg-250 micrograms per g (0.7%-0.94%-0.025%), 100 g	‡ 1	..	..	32.47	5.30	Aci-Jel	JC

SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM

Estrogens

• Natural and semisynthetic estrogens, plain

OESTRADIOL

Restricted Benefit

Post-menopausal symptoms in women who have failed to respond using oral or topical oestrogens.

4365R	Implant 50 mg	1	..	..	75.93	5.30	SH	
4366T	Implant 100 mg	1	..	..	115.66	5.30	SH	

UROLOGICALS

Other urologicals, incl. antispasmodics

• Drugs used in erectile dysfunction

ALPROSTADIL

Authority Required

Specific accepted war-caused or service-related disabilities for males with vasculogenic, psychogenic or neurogenic erectile dysfunction.

Authorisation will not be given for any additional prescriptions within 6 months or for any increased quantities or repeats.

4579B	Intracavernosal injection 10 micrograms with diluent in single use syringe	6	3	..	* 82.19	5.30	Caverject Impulse	PH
4580C	Intracavernosal injection 20 micrograms with diluent in single use syringe	6	3	..	* 103.19	5.30	Caverject Impulse	PH

SILDENAFIL CITRATE

Authority Required

Specific accepted war-caused or service-related disabilities for males with vasculogenic, psychogenic or neurogenic erectile dysfunction.

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>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	..	57.67	5.30	Viagra	PF
4585H	Tablet 50 mg (base)	4	5	..	71.77	5.30	Viagra	PF
4586J	Tablet 100 mg (base)	4	5	..	77.14	5.30	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	..	76.82	5.30	Cialis	LY
4597Y	Tablet 20 mg	4	5	..	82.59	5.30	Cialis	LY
• Other urologicals SODIUM BICARBONATE								
4458P	Capsule 840 mg CAUTION: For use in the treatment of renal disease.	100	2	..	13.57	5.30	Sodibic	AS
SODIUM CITRO-TARTRATE								
Restricted Benefit								
<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	..	13.12	5.30	Uracol Ural Sachets	GM SI
Drugs used in benign prostatic hypertrophy								
• Alpha-adrenoreceptor antagonists TAMSULOSIN HYDROCHLORIDE								
Authority Required								
<i>Treatment of benign prostatic hyperplasia where surgery is inappropriate, or where other drug treatment has failed or is contraindicated.</i>								
4070F	Tablet 400 micrograms (prolonged release)	30	5	..	62.93	5.30	Flomaxtra	CS

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	
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	..	..	19.62	5.30	Hytrin	AB
4397K	Tablet 2 mg	28	5	..	41.26	5.30	Hytrin	AB
4398L	Tablet 5 mg	28	5	..	57.76	5.30	Hytrin	AB
4399M	Tablet 10 mg	28	5	..	85.63	5.30	Hytrin	AB

• **Testosterone-5-alpha reductase inhibitors**

FINASTERIDE

Authority Required

Treatment of benign prostatic hyperplasia where surgery is inappropriate, or where other drug treatment has failed or is contraindicated.

4233T	Tablet 5 mg	30	5	..	101.69	5.30	^a Finasta	SZ
				..	111.26	5.30	^a Proscar	MK

ANTIINFECTIVES FOR SYSTEMIC USE

ANTIBACTERIALS FOR SYSTEMIC USE

Macrolides, lincosamides and streptogramins

• **Macrolides**

AZITHROMYCIN

Restricted Benefit

Upper and lower respiratory tract infections.

4115N	Tablet 500 mg	3	..	..	34.67	5.30	Zithromax	PF

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

ANTINEOPLASTIC AGENTS

Antimetabolites

• **Pyrimidine analogues**

FLUOROURACIL

4222F	Cream 50 mg per g (5%), 20 g	± 1	..	..	50.45	5.30	Efudix	VT

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
IMMUNOSUPPRESSANTS							
Immunosuppressants							
• Tumor necrosis factor alpha (TNF-alpha) inhibitors							
INFLIXIMAB							
NOTE:							
<i>Any queries concerning the arrangements to prescribe infliximab may be directed to the Veterans' Affairs Pharmaceutical Advisory Centre (VAPAC) on 1800 552 580.</i>							
<i>Written applications for authority to prescribe infliximab should be forwarded to:</i>							
<i>Reply Paid 9998</i>							
<i>Veterans' Affairs Pharmaceutical Advisory Centre (VAPAC)</i>							
<i>Department of Veterans' Affairs</i>							
<i>GPO Box 9998</i>							
<i>BRISBANE QLD 4001</i>							
Authority Required							
<i>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:</i>							
<i>(1) (a) Proven raised erythrocyte sedimentation rate (ESR) and/or C-reactive protein (CRP); and</i>							
<i>(1) (b) Proven erosive rheumatoid arthritis without end-stage disease;</i>							
<i>(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;</i>							
<i>(3) No history of active tuberculosis requiring treatment in the last 3 years;</i>							
<i>(4) No history of opportunistic infection in the last 2 months;</i>							
<i>(5) Female patients of child-bearing age are not pregnant, not breast-feeding, and are using an effective form of contraception.</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>							
Authority Required							
<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	..	846.55	5.30	Remicade 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	

MUSCULO-SKELETAL SYSTEM

ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS

Antiinflammatory and antirheumatic products, non-steroids

- **Acetic acid derivatives and related substances**

DICLOFENAC SODIUM with MISOPROSTOL

Authority Required

Patients requiring an NSAID in whom a risk of upper gastrointestinal complications is high or with a history of peptic ulcer disease.

4190M	Tablet 50 mg-200 micrograms	60	2	..	37.35	5.30	Arthrotec 50	PH

TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN

Topical products for joint and muscular pain

- **Preparations with salicylic acid derivatives**

METHYL SALICYLATE

4022Q	Compound cream APF, 100 g	± 1	1	..	13.59	5.30	Gold Cross	BI
4023R	Ointment BP, 100 g	± 1	1	..	11.74	5.30	Gold Cross	BI
4025W	Compound ointment APF 1934, 100 g	± 1	1	..	10.38	5.30	Gold Cross	BI
4026X	Liniment APF, 100 mL	± 1	1	..	9.51	5.30	Gold Cross	BI
4027Y	Compound liniment APF, 100 mL	± 1	1	..	11.08	5.30	Gold Cross	BI

DRUGS FOR TREATMENT OF BONE DISEASES

Drugs affecting bone structure and mineralization

- **Bisphosphonates**

RISEDRONATE SODIUM

Authority Required

For preservation of bone mineral density in patients on long-term glucocorticoid therapy where patients are undergoing continuous treatment with a dose equal to or greater than 7.5 mg of prednisone or equivalent per day. Prescribers need to demonstrate that the patient has been on continuous therapy for 3 months or more and demonstrate that the patient is osteopenic (bone mineral density t-score of less than -1.0).

4443W	Tablet 5 mg	28	5	..	52.91	5.30	Actonel	SW
4444X	Tablet 35 mg	4	5	..	52.91	5.30	Actonel Once-a-Week	SW

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	
• Bisphosphonates, combinations RISEDRONATE SODIUM and CALCIUM CARBONATE								
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>								
4059P	Pack containing 4 tablets risedronate sodium 35 mg and 24 tablets calcium carbonate 1.25 g (equivalent to 500 mg calcium)	± 1	5	..	52.91	5.30	Actonel Combi	SW

RISEDRONATE SODIUM and CALCIUM CARBONATE with COLECALCIFEROL

Authority Required

For preservation of bone mineral density in patients on long-term glucocorticoid therapy where patients are undergoing continuous treatment with a dose equal to or greater than 7.5 mg of prednisone or equivalent per day. Prescribers need to demonstrate that the patient has been on continuous therapy for 3 months or more and demonstrate that the patient is osteopenic (bone mineral density T-score of less than -1.0).

4380M	Pack containing 4 tablets risedronate sodium 35 mg and 24 sachets containing granules of calcium carbonate 2.5 g (equivalent to 1 g calcium) with colecalciferol 22 micrograms	± 1	5	..	52.91	5.30	Actonel Combi D	SW

NERVOUS SYSTEM

ANALGESICS

Opioids

• Natural opium alkaloids

MORPHINE SULFATE

CAUTION:

The risk of drug dependence is high.

Restricted Benefit

Chronic severe disabling pain not responding to non-narcotic analgesics.

NOTE:

Authorities for increased maximum quantities and/or repeats will be granted only for

(i) chronic severe disabling pain associated with proven malignant neoplasia; or

(ii) chronic severe disabling pain where treatment has been initiated by a specialist with appropriate expertise in pain management.

4349X	Tablet 200 mg (controlled release)	20	..	..	104.50	5.30	MS Contin	MF

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	
• Diphenylpropylamine derivatives DEXTROPROPOXYPHENE NAPSYLATE CAUTION: Chronic use of this preparation is likely to cause drug dependence.								
4081T	Capsule 100 mg	50	..	..	* 18.19	5.30	Doloxene	AS
Other analgesics and antipyretics • Salicylic acid and derivatives CODEINE PHOSPHATE with ASPIRIN								
4061R	Tablet soluble 8 mg-300 mg	50	2	..	13.14	5.30	Aspalgin	FM
• Anilides CODEINE PHOSPHATE with PARACETAMOL								
4171M	Tablet 8 mg-500 mg	50	2	..	11.31	5.30	Panamax Co.	SW
				..	12.43	5.30	Codalgin	FM
4170L	Tablet 15 mg-500 mg	20	2	..	8.80	5.30	Prodeine 15	SW
• Other analgesics and antipyretics GABAPENTIN Authority Required <i>To be approved for the treatment of refractory neuropathic pain not controlled by other drugs.</i>								
4591P	Capsule 100 mg	100	5	..	23.38	5.30	^a Gabatine 100	SI
							^a Gantin	AW
				..	24.38	5.30	^a Nupentin 100	AF
							^a Neurontin	PF
4592Q	Capsule 300 mg	100	5	..	61.58	5.30	^a DBL Gabapentin	HH
							^a Douglas	GM
							^a Gabapentin	
							^a Gabahexal 300mg	SZ
							^a Gabatine 300	SI
							^a Gantin	AW
							^a GenRx Gabapentin	GX
							^a Nupentin 300	AF
				..	62.57	5.30	^a Neurontin	PF

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	
4593R	Capsule 400 mg	100	5	..	81.81	5.30	^a DBL Gabapentin	HH
							^a Douglas	GM
							Gabapentin	
							400mg	
							^a Gabahexal 400mg	SZ
							^a Gabatine 400	SI
							^a Gantin	AW
							^a GenRx Gabapentin	GX
							^a Nupentin 400	AF
				..	82.81	5.30	^a Neurontin	PF
4594T	Tablet 600 mg	100	5	..	127.34	5.30	Neurontin	PF
4595W	Tablet 800 mg	100	5	..	166.43	5.30	^a Gantin	AW
				..	167.43	5.30	^a Neurontin	PF

PREGABALIN

Authority Required

For the treatment of refractory neuropathic pain not controlled by other drugs.

4322L	Capsule 75 mg	56	5	..	84.53	5.30	Lyrica	PF
4323M	Capsule 150 mg	56	5	..	123.81	5.30	Lyrica	PF
4324N	Capsule 300 mg	56	5	..	182.71	5.30	Lyrica	PF

PSYCHOLEPTICS

Anxiolytics

• Benzodiazepine derivatives

BROMAZEPAM

Authority Required

Patients with terminal disease;

Patients with refractory phobic or anxiety states.

NOTE:

For short-term use and palliative care. This drug should not be used as the first line of treatment. Other PBS-listed benzodiazepines should have been adequately tried and found to be ineffective or inappropriate. Authorities for increased quantities and/or repeats may be granted to patients with terminal disease, and other patients who have been shown to be dependent on this item by an unsuccessful attempt at gradual withdrawal.

4150K	Tablet 3 mg	60	..	..	* 26.95	5.30	Lexotan	RO
4151L	Tablet 6 mg	60	..	..	* 32.97	5.30	Lexotan	RO

• Azaspirodecanedione derivatives

BUSPIRONE HYDROCHLORIDE

Authority Required

For the short-term treatment of anxiety.

4144D	Tablet 5 mg	50	..	..	37.56	5.30	Buspar	BQ
4145E	Tablet 10 mg	50	..	..	54.41	5.30	Buspar	BQ

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	
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	..	..	13.08	5.30	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	..	..	21.33	5.30	^a Imrest	AF
				..	22.91	5.30	^a Imovane	SW
OTHER NERVOUS SYSTEM DRUGS								
Drugs used in addictive disorders								
• Drugs used in nicotine dependence								
NICOTINE								
<u>Authority Required</u>								
<i>Patients who have indicated that they are ready to cease smoking and who have entered a support and counselling program.</i>								
<u>NOTE:</u>								
<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	..	..	* 50.39	5.30	Nicorette Patch	JT
4571N	Transdermal patches releasing approximately 7 mg per 24 hours, 7	2	..	..	* 45.77	5.30	QuitX	AF
				..	* 73.89	5.30	Nicabate CQ 7	GK
4577X	Transdermal patches releasing approximately 10 mg per 16 hours, 7	2	..	..	* 54.35	5.30	Nicorette Patch	JT
4572P	Transdermal patches releasing approximately 14 mg per 24 hours, 7	2	..	..	* 49.09	5.30	QuitX	AF
				..	* 73.89	5.30	Nicabate CQ 14	GK
4578Y	Transdermal patches releasing approximately 15 mg per 16 hours, 7	2	2	..	* 59.53	5.30	Nicorette Patch	JT
4573Q	Transdermal patches releasing approximately 21 mg per 24 hours, 7	2	2	..	* 53.09	5.30	QuitX	AF
				..	* 73.89	5.30	Nicabate CQ 21	GK

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	
ANTIPARASITIC PRODUCTS, INSECTICIDES AND REPELLENTS								
ANTHELMINTICS								
Antinematodal agents								
• Benzimidazole derivatives								
MEBENDAZOLE								
4325P	Tablet 100 mg	6	..	..	19.62	5.30	Vermox	JC
RESPIRATORY SYSTEM								
NASAL PREPARATIONS								
Decongestants and other nasal preparations for topical use								
• Sympathomimetics, plain								
OXYMETAZOLINE HYDROCHLORIDE								
4378K	Nasal spray 500 micrograms per mL (0.05%), 15 mL	‡ 1	..	..	16.20	5.30	Drixine	SH
4379L	Nasal spray 500 micrograms per mL (0.05%), 18 mL	‡ 1	..	..	16.33	5.30	Logicin Rapid Relief	SI
• Antiallergic agents, excl. corticosteroids								
LEVOCABASTINE HYDROCHLORIDE								
4311X	Nasal spray 500 micrograms per mL (0.05%), 10 mL (100 doses)	‡ 1	2	..	17.81	5.30	Livostin	JT
SODIUM CROMOGLYCATE								
4468E	Nasal spray metered dose pump 20 mg per mL (2%), 26 mL	‡ 1	5	..	19.93	5.30	Rynacrom	SW
• Corticosteroids								
BUDESONIDE								
Restricted Benefit								
<i>Severe intractable rhinitis.</i>								
4092J	Aqueous nasal spray (pump pack) 64 micrograms per dose (120 doses)	‡ 1	..	..	31.30	5.30	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	..	22.03	5.30	Atrovent Nasal Aqueous	BY

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	
4090G	Aqueous nasal spray (pump pack) 42 micrograms (anhydrous) per dose (180 doses)	‡ 1	5	..	28.46	5.30	Atrovent Nasal Forte	BY
Nasal decongestants for systemic use								
• Sympathomimetics								
PSEUDOEPHEDRINE HYDROCHLORIDE								
4029C	Tablet 60 mg	12	..	..	10.59	5.30	Logicin Sinus	SI
COUGH AND COLD PREPARATIONS								
Expectorants, excl. combinations with cough suppressants								
• Expectorants								
SENEGA and AMMONIA								
4074K	Mixture 200 mL	‡ 1	4	..	8.75	5.30	Gold Cross	BI
Cough suppressants, excl. combinations with expectorants								
• Opium alkaloids and derivatives								
PHOLCODINE								
4071G	Linctus 1 mg per mL (0.1%), 100 mL	‡ 1	2	..	8.59	5.30	Gold Cross	BI
				..	13.47	5.30	Duro-Tuss	IA
ANTIHISTAMINES FOR SYSTEMIC USE								
Antihistamines for systemic use								
• Phenothiazine derivatives								
PROMETHAZINE HYDROCHLORIDE								
4072H	Tablet 10 mg	50	2	..	14.24	5.30	Phenergan	SW
4073J	Tablet 25 mg	50	2	..	16.33	5.30	Phenergan	SW
CAUTION: Significant side effects may occur.								
• Piperazine derivatives								
CETIRIZINE HYDROCHLORIDE								
4175R	Tablet 10 mg	30	..	..	32.44	5.30	Alzene	AF
				..	39.02	5.30	Zilarex	SZ
				..			Zyrtec	JT
• Other antihistamines for systemic use								
FEXOFENADINE HYDROCHLORIDE								
4237B	Tablet 60 mg	60	..	..	* 40.70	5.30	^a Fexal	SZ
				..			^a Xergic	AF
				..	* 47.75	5.30	^a Telfast	SW

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	
4238C	Tablet 120 mg	30	..	..	34.28	5.30	^a Fexal	SZ
				..	41.09	5.30	^a Xergic	AF
							^a Telfast 120	SW
	LORATADINE							
4313B	Tablet 10 mg	30	..	..	43.22	5.30	^a Lorano	SZ
				..	44.31	5.30	^a Allereze	AF
							^a Claratyne	SH

SENSORY ORGANS

OPHTHALMOLOGICALS

Decongestants and antiallergics

• *Sympathomimetics used as decongestants*

ANTAZOLINE with NAPHAZOLINE

4031E	Eye drops 5 mg (sulfate)-250 micrograms (nitrate) per mL (0.5%-0.025%), 10 mL	‡ 1	1	..	13.43	5.30	Antistine-Privine	NV
4032F	Eye drops 5 mg (phosphate)-500 micrograms (hydrochloride) per mL (0.5%-0.05%), 15 mL	‡ 1	1	..	13.38	5.30	Albalon-A	AG

NAPHAZOLINE HYDROCHLORIDE

4035J	Eye drops 1 mg per mL (0.1%), 15 mL	‡ 1	1	..	12.59	5.30	Naphcon Forte	AQ
				..	13.44	5.30	Albalon Liquifilm	AG

NAPHAZOLINE HYDROCHLORIDE with PHENIRAMINE MALEATE

4355F	Eye drops 250 micrograms-3 mg per mL (0.025%-0.3%), 15 mL	‡ 1	1	..	13.71	5.30	Naphcon-A	AQ

ZINC SULFATE with PHENYLEPHRINE HYDROCHLORIDE

4034H	Eye drops 2.5 mg-1.2 mg per mL (0.25%-0.12%), 15 mL	‡ 1	5	..	12.59	5.30	Zincfrin	AQ

• *Other antiallergics*

LEVOCABASTINE HYDROCHLORIDE

4310W	Eye drops 500 micrograms per mL (0.05%), 4 mL (120 doses)	‡ 1	1	..	17.81	5.30	Livostin	JT

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	
OTOLOGICALS								
Corticosteroids and antiinfectives in combination								
• Corticosteroids and antiinfectives in combination								
CIPROFLOXACIN HYDROCHLORIDE with								
HYDROCORTISONE								
Authority Required								
<i>Indicated where first-line treatment has not been successful or is inappropriate.</i>								
4528H	Ear drops 2 mg (base)-10 mg per mL (0.2%-1%), 10 mL	± 1	2	..	29.37	5.30	Ciproxin HC	AQ
Other otologicals								
• Indifferent preparations								
CARBAMIDE PEROXIDE								
4176T	Ear drops 65 mg per mL (6.5%), 12 mL	± 1	..	..	13.97	5.30	Ear Clear for Ear Wax Removal	KY
DICHLOROBENZENE with CHLORBUTOL and TURPENTINE OIL								
4180B	Ear drops 20 mg-50 mg-0.1 mL per mL (2%-5%-10%), 11 mL	± 1	..	..	13.65	5.30	Cerumol	AC
DOCUSATE SODIUM								
4199B	Ear drops 5 mg per mL (0.5%), 10 mL	± 1	..	..	14.04	5.30	Waxsol	NE
VARIOUS								
ALL OTHER THERAPEUTIC PRODUCTS								
All other therapeutic products								
• Drugs for treatment of hyperkalemia and hyperphosphatemia								
SODIUM POLYSTYRENE SULFONATE								
4470G	Oral powder 454 g	± 1	2	..	65.13	5.30	Resonium-A	SW

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)

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

RED GRANULATING WOUND

Aims: (1) to protect the granulating tissue; (2) to encourage epithelialisation; (3) to absorb excess exudate.

LIGHT EXUDATE:

(A) Absorbing

Superficial

- Foam (Light Exudate);
- Hydroactive (Superficial Wound—Light Exudate);
- Hydrocolloid (Superficial Wound—Light Exudate)

Cavity

- Hydrocolloid (Cavity Wound)

(B) Moisture donating

- Hydrogel—Amorphous;
- Hydrogel—Sheet

- Hydrogel—Amorphous

HIGH EXUDATE:

(A) Absorbing

Superficial

- Alginate (Superficial Wound);
- Foam—Heavy Exudate;
- Hydroactive (Superficial Wound—Moderate Exudate);
- Hydrocolloid (Superficial Wound—Moderate/High Exudate)

Cavity

- Alginate (Cavity Wound);
- Foam—Moderate Exudate (see “cavity conforming” product);
- Hydroactive (Cavity Wound);
- Hydrocolloid (Cavity Wound)

(B) Moisture donating

NOT APPROPRIATE

continued ➞

REPATRIATION

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 \$	

YELLOW SLOUGHY WOUND

Aims: (1) to remove slough; (2) to encourage granulation; (3) to absorb excess exudate.

LIGHT EXUDATE:

(A) Absorbing

Superficial

- Cadexomer Iodine;
- Foam—Light Exudate;
- Foam with Charcoal;
- Hydroactive (Superficial Wound—Moderate Exudate);
- Hydrocolloid (Superficial Wound—Moderate Exudate)

Cavity

- Cadexomer Iodine;
- Hydrocolloid (Cavity Wound)

(B) Moisture Donating

- Hydrogel—Amorphous;
- Hydrogel—Sheet

- Hydrogel—Amorphous

HIGH EXUDATE:

(A) Absorbing

Superficial

- Alginate (Superficial Wound);
- Cadexomer Iodine;
- Foam—Heavy Exudate;
- Hydroactive (Superficial Wound—Moderate/High Exudate);
- Hydrocolloid (Superficial Wound—Moderate/High Exudate)

Cavity

- Alginate (Cavity Wound);
- Cadexomer Iodine;
- Hydrocolloid (Cavity Wound)

(B) Moisture donating

NOT APPROPRIATE

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

BLACK NECROTIC WOUND

Aim: To remove eschar by — (1) sharp debridement, e.g., scissor/scalpel and/or (2) rehydration and autolytic debridement. (These wounds usually produce a LIGHT EXUDATE.)

DRY / LIGHT EXUDATE:	Superficial	Cavity
(A) Absorbing	- Hydroactive (Superficial Wound—Light Exudate); - Hydrocolloid (Superficial Wound—Light/Moderate Exudate)	Hydrocolloid (Cavity Wound)
(B) Moisture donating	- Hydrogel—Amorphous; - Hydrogel—Sheet	- Hydrogel—Amorphous; - Hydrogel—Sheet

INFECTED WOUNDS

Aims: (1) to clear the infection with systemic antibiotics; (2) to absorb excess exudate; (3) to remove slough if present; (4) to decrease bacterial burden - by applying a Silver dressing or Cadexomer Iodine dressing.

MALODOROUS WOUNDS

Aims: (1) to clear infection if present; (2) to remove slough if present; (3) to clear colonising odour-producing bacteria in slough — by applying metronidazole gel, a Silver dressing or a Cadexomer Iodine dressing; (4) to absorb excess exudate.

Products: Activated Charcoal; Alginate with Charcoal; Foam with Charcoal; Silver dressing; Cadexomer Iodine dressing.

MINOR SKIN TRAUMA

Aims: (1) to stop bleeding; (2) to prevent infection; (3) to minimise the surface defect; (4) to promote epithelialisation.

ORDERING HARTMANN PRODUCTS

Hartmann wound dressings are available through the Hartmann Alliance only. If you would like to order Hartmann Wound Care products, please call Hartmann National Customer Care on 1800 805 839.

BANDAGE—ABSORBENT WOOL

4651T	Bandage (natural, non-sterile) 10 cm x 2.7 m	6	..	..	* 34.01	5.30	Soffban 7224	BV
4653X	Bandage 10 cm x 3 m	6	..	..	19.89	5.30	Surepress 650948	CC

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—CALICO								
4717G	Bandage, triangular, large	‡ 1	..	..	13.06	5.30	Handy 5608	BV
BANDAGE—COMPRESSION								
NOTE:								
<i>Treatment of varices and oedema associated with venous disease and lymphoedema; contraindicated in arterial disease.</i>								
4654Y	Bandage, short stretch, 8 cm x 5 m	5	..	..	* 71.99	5.30	Comprilan 1027	BV
4736G	Bandage, high stretch, 7.5 cm x 3 m	5	..	..	* 88.94	5.30	Tensopress 66004347	BV
4656C	Bandage, high stretch, 7.5 cm x 3.5 m	5	..	..	* 67.94	5.30	Setopress 3504	SS
4748X	Bandage, high stretch, 10 cm x 3 m	5	..	..	* 72.49	5.30	Surepress 650947	CC
				..	* 116.39	5.30	Tensopress 66004348	BV
4657D	Bandage, high stretch, 10 cm x 3.5 m	5	..	..	* 55.24	5.30	Eloflex 2480	BV
				..	* 78.14	5.30	Setopress 3505	SS
4658E	Bandage, four layer	5	..	..	* 208.64	5.30	Profore 66050016	SN
4598B	Bandage, four layer	5	..	..	* 140.94	5.30	Profore Lite 66050415	SN

BANDAGE—COMPRESSION

NOTE:

Treatment of varices and oedema associated with venous disease and lymphoedema; contraindicated in arterial disease.

Restricted Benefit

Initial treatment of venous ulcers.

4938X	Bandage, two layer, 18 cm-22 cm (red)	1	..	..	47.43	5.30	ProGuide 66000780	SN
4939Y	Bandage, two layer, 22 cm-28 cm (yellow)	1	..	..	47.43	5.30	ProGuide 66000781	SN
4940B	Bandage, two layer, 28 cm-32 cm (green)	1	..	..	47.43	5.30	ProGuide 66000782	SN

Restricted Benefit

Continuation of treatment of venous ulcers where patient's ability to tolerate dressing has been demonstrated.

4941C	Bandage, two layer, 18 cm-22 cm (red)	4	..	..	* 168.51	5.30	ProGuide 66000780	SN

continued ➞

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Proprietary Name and Manufacturer	
4942D	Bandage, two layer, 22 cm-28 cm (yellow)	4	..	..	* 168.51	5.30	ProGuide 66000781	SN
4943E	Bandage, two layer, 28 cm-32 cm (green)	4	..	..	* 168.51	5.30	ProGuide 66000782	SN
	BANDAGE—RETENTION—COHESIVE—HEAVY							
4811F	Bandage 5 cm x 1.3 m	2	..	..	* 13.59	5.30	Peg 7420	BK
4812G	Bandage 7.5 cm x 1.3 m	2	..	..	* 16.87	5.30	Peg 7422	BK
4659F	Bandage 7.5 cm x 3 m	2	..	..	* 19.63	5.30	Coplus 3629	BV
4813H	Bandage 10 cm x 1.3 m	2	..	..	* 20.61	5.30	Peg 7423	BK
4660G	Bandage 10 cm x 2 m	2	..	..	* 18.93	5.30	Coban 1584	MM
4814J	Bandage 15 cm x 1.3 m	2	..	..	* 27.75	5.30	Peg 7425	BK
	BANDAGE—RETENTION—COHESIVE—LIGHT							
4718H	Bandages 2.5 cm x 4 m, 2	‡ 1	..	..	12.09	5.30	Handygauze Cohesive 8631	BV
4719J	Bandage 6 cm x 4 m	2	..	..	* 14.27	5.30	Handygauze Cohesive 8633	BV
4662J	Bandage 10 cm x 4 m	2	..	..	* 16.71	5.30	Handygauze Cohesive 8635	BV
	BANDAGE—RETENTION—COTTON CREPE							
4727T	Bandage 5 cm x 2.3 m	2	..	..	* 17.01	5.30	Telfa 8252F	KE
				..	* 17.85	5.30	Elastocrepe 36102520	BV
4728W	Bandage 7.5 cm x 2.3 m	2	..	..	* 21.79	5.30	Telfa 8253F	KE
				..	* 21.97	5.30	Elastocrepe 36102420	BV
4729X	Bandage 10 cm x 2.3 m	2	..	..	* 24.95	5.30	Telfa 8254F	KE
				..	* 27.39	5.30	Elastocrepe 36102320	BV
	BANDAGE—TUBULAR							
4855M	Bandage 6.25 cm x 1 m	‡ 1	..	..	17.74	5.30	Tubigrip B 1520	SS
4856N	Bandage 6.75 cm x 1 m	‡ 1	..	..	17.74	5.30	Tubigrip C 1545	SS
4857P	Bandage 7.5 cm x 1 m	‡ 1	..	..	17.74	5.30	Tubigrip D 1546	SS
4858Q	Bandage 8.75 cm x 1 m	‡ 1	..	..	17.74	5.30	Tubigrip E 1547	SS
4859R	Bandage 10 cm x 1 m	‡ 1	..	..	17.74	5.30	Tubigrip F 1548	SS
4663K	Bandage, straight, size C	‡ 1	..	..	14.68	5.30	Elastoplast 2225	BE

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	
4664L	Bandage, straight, size D	‡ 1	..	..	14.68	5.30	Elastoplast 2226	BE
4665M	Bandage, straight, size E	‡ 1	..	..	14.68	5.30	Elastoplast 2227	BE
4667P	Bandage, lightweight, 8.75 cm x 1 m	‡ 1	..	..	16.64	5.30	Tensogrip 36361259	BV
BANDAGE—TUBULAR (FINGER)								
4798M	Complete pack including applicator	‡ 1	..	..	17.34	5.30	Tubegauz 0501633	SS
4726R	Refill	‡ 1	..	..	13.30	5.30	Tubegauz 0501658	SS
BANDAGE—TUBULAR (LIGHTWEIGHT)								
4671W	Bandage, small limb size (red), 10 m	‡ 1	..	..	27.93	5.30	Tubifast 2434	SS
4672X	Bandage, medium limb size (green), 10 m	‡ 1	..	..	31.59	5.30	Tubifast 2436	SS
4673Y	Bandage, large limb size (blue), 10 m	‡ 1	..	..	35.15	5.30	Tubifast 2438	SS
BANDAGE—TUBULAR (LONG STOCKING)								
4674B	Bandage, small size	2	..	..	* 39.75	5.30	Tubigrip 1482	SS
4797L	Bandage, medium size	2	..	..	* 39.75	5.30	Tubigrip 1483	SS
4799N	Bandage, large size	2	..	..	* 39.75	5.30	Tubigrip 1484	SS
4675C	Bandage, XX/large size	2	..	..	* 39.75	5.30	Tubigrip 1486	SS
BANDAGE—TUBULAR (SHORT STOCKING)								
4661H	Bandage, small B/C size	2	..	..	* 30.01	5.30	Tubigrip 1479	SS
4815K	Bandage, medium C/D size	2	..	..	* 30.01	5.30	Tubigrip 1480	SS
4816L	Bandage, large D/E size	2	..	..	* 30.01	5.30	Tubigrip 1481	SS
BANDAGE—ZINC PASTE								
NOTE: Used as an adjunct in the management of leg ulceration and associated eczema and skin conditions.								
4668Q	Bandage 7.5 cm x 6 m	2	..	..	* 28.77	5.30	Zincaband 3604	SS
4669R	Bandage 7.5 cm x 6 m	2	3	..	* 29.23	5.30	Steripaste 3610	XP
4750B	Bandage 7.5 cm x 6 m	2	3	..	* 63.11	5.30	Viscopaste 4948	SN
4749Y	Bandage 8 cm x 5 m (compression)	2	3	..	* 38.13	5.30	Gelocast Elastic 1080	BV
4670T	Bandage 10 cm x 9.1 m	2	3	..	* 28.35	5.30	Flexidress 650941	CC
4760M	Bandages 80 cm (stockings), 4	‡ 1	3	..	72.69	5.30	ZipZoc 66051550	SN

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	
COTTON WOOL ROLL								
4701K	Roll 100 g	‡ 1	2	..	10.08	5.30	JJ 02013	JJ
DRESSING—ACTIVATED CHARCOAL (MALODOROUS WOUND)								
4742N	Dressings 10 cm x 10 cm, 10	‡ 1	..	..	78.55	5.30	CarboFLEX 403202	CC
4681J	Dressing 10.5 cm x 10.5 cm	10	..	..	* 100.49	5.30	Actisorb Plus MAC031	JJ
4743P	Dressings 15 cm x 20 cm, 5	‡ 1	..	..	89.44	5.30	CarboFLEX 403204	CC
DRESSING—ALGINATE (CAVITY WOUND)								
NOTE: This dressing should be used only on moderately to heavily exuding wounds and should remain in place until saturated or for a maximum of 3 days.								
4832H	Rope 2 g	10	..	..	* 108.69	5.30	Sorbsan 1411	UM
				..	* 114.83	5.30	Kaltostat 168117	CC
4685N	Ropes 2 g (30 cm), 5	2	..	..	* 81.69	5.30	Restore CalciCare 9940	HO
4682K	Ropes 2 g (40 cm), 6	2	..	..	* 137.29	5.30	Comfeel SeaSorb Filler 3740	CT
DRESSING—ALGINATE (SUPERFICIAL WOUND)								
NOTE: This dressing should be used only on moderately to heavily exuding wounds and should remain in place until saturated or for a maximum of 3 days.								
4699H	Dressings 5 cm x 5 cm, 10	‡ 1	1	..	40.09	5.30	Restore CalciCare 9938	HO
				..	44.68	5.30	Algisite M 66000519	SN
				..	48.97	5.30	Kaltostat 168210	CC
4684M	Dressing 5 cm x 5 cm	10	1	..	* 46.49	5.30	Comfeel SeaSorb Dressing 3705	CT
4683L	Dressings 7.5 cm x 12 cm, 10	‡ 1	1	..	90.65	5.30	Kaltostat 168212	CC
4831G	Dressing 10 cm x 10 cm	10	1	..	* 83.99	5.30	Sorbsan 1410	UM
				..	* 89.69	5.30	Comfeel SeaSorb Dressing 3710	CT
4700J	Dressings 10 cm x 10 cm, 10	‡ 1	1	..	71.21	5.30	Restore CalciCare 9937	HO
				..	83.93	5.30	Algisite M 66000520	SN

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	
4691X	Dressings 15 cm x 20 cm, 10	‡ 1	1	..	203.20	5.30	Algisite M 66000521	SN
	DRESSING—FILM							
4686P	Dressings 6 cm x 7 cm, 8	‡ 1	..	..	15.21	5.30	Nexcare Tegaderm Transparent H1624	MM
4687Q	Dressings 10 cm x 12 cm, 4	‡ 1	..	..	19.22	5.30	Nexcare Tegaderm Transparent H1626	MM
4893M	Dressings 10 cm x 12 cm, 10	‡ 1	..	..	30.06	5.30	Op-Site Flexigrid 4629	SN
4688R	Dressing 15 cm x 20 cm	6	..	..	* 30.23	5.30	Tegaderm Transparent 1628	MM
	DRESSING—FILM ISLAND							
4689T	Dressing 5 cm x 7 cm	10	..	..	* 15.79	5.30	Tegaderm Transparent Island 3582	MM
4898T	Dressings 5 cm x 7.2 cm, 5	2	..	..	* 24.99	5.30	Cutifilm Plus 76309	SN
4899W	Dressings 8 cm x 10 cm, 5	2	..	..	* 39.57	5.30	Cutifilm Plus 76308	SN
4690W	Dressing 9 cm x 10 cm	10	..	..	* 27.29	5.30	Tegaderm Transparent Island 3586	MM
	DRESSING—FOAM—HEAVY EXUDATE							
	NOTE: This dressing should remain in place until saturated or up to a maximum of 7 days. Allow a minimum of 2 cm to 3 cm in excess of the wound size of the dressing around the wound.							
4795J	Dressings 10 cm x 10 cm, 10	‡ 1	1	..	74.63	5.30	Lyof foam Extra 603088	XP
				..	117.01	5.30	Allevyn 66007637	SN
4880W	Dressings 20 cm x 15 cm, 10	‡ 1	1	..	188.68	5.30	Lyof foam Extra 603090	XP
	DRESSING—FOAM—MODERATE EXUDATE							
	NOTE: This dressing should remain in place until saturated or up to a maximum of 7 days. Allow a minimum of 2 cm to 3 cm in excess of the wound size of the dressing around the wound.							
4890J	Dressings 7.5 cm x 7.5 cm, 10	‡ 1	1	..	42.41	5.30	Lyof foam Flat 603092	XP

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REPATRIATION

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Proprietary Name and Manufacturer	
4891K	Dressings 10 cm x 10 cm, 10	‡ 1	1	..	49.05	5.30	Lyof foam Flat 603093	XP
4590N	Dressings 12.5 cm x 12.5 cm, 10	‡ 1	..	..	104.94	5.30	Allevyn Adhesive 66000044	SN
NOTE: Care should be taken when changing <i>Allevyn Adhesive</i> dressings to avoid skin tears.								
4878R	Dressings 20 cm x 15 cm, 10	‡ 1	1	..	101.43	5.30	Lyof foam Flat 603095	XP
4694C	Dressing, cavity, conforming, 20 g	1	1	..	75.72	5.30	Cavicare 4563	SN
DRESSING—FOAM with CHARCOAL (MALODOROUS WOUND)								
NOTE: This dressing should remain in place on wounds with odour until saturated or up to a maximum of 7 days. Allow a minimum of 2 cm to 3 cm in excess of the wound size of the dressing around the wound.								
4892L	Dressings 10 cm x 10 cm, 10	2	..	..	* 173.63	5.30	Lyof foam C 603025	SS
DRESSING—FOAM with SILICONE—HEAVY EXUDATE								
4642H	Dressings 7.5 cm x 7.5 cm, 5	‡ 1	..	..	30.34	5.30	Mepilex Border 295200	MH
4643J	Dressings 10 cm x 10 cm, 5	‡ 1	..	..	42.25	5.30	Mepilex Border 295300	MH
DRESSING—FOAM with SILICONE—LIGHT EXUDATE								
4644K	Dressings 6 cm x 8.5 cm, 5	‡ 1	..	..	27.63	5.30	Mepilex Lite 284000	MH
4645L	Dressings 10 cm x 10 cm, 5	‡ 1	..	..	37.78	5.30	Mepilex Lite 284100	MH
DRESSING—FOAM with SILICONE—MODERATE EXUDATE								
4626L	Dressings 10 cm x 10 cm, 5	‡ 1	..	..	42.25	5.30	Mepilex 294100	MH
DRESSING—GAUZE (ABSORBENT PAD)								
4707R	Pads 5 cm x 5 cm, 100	‡ 1	..	..	13.45	5.30	Handy 5672	BV
4708T	Pads 10 cm x 10 cm, 100	‡ 1	..	..	26.97	5.30	Handy 5674	BV
DRESSING—GAUZE—EYE PAD								
4768Y	Pads, 12	‡ 1	..	..	12.40	5.30	Curity 4112	KE
DRESSING—GAUZE—PARAFFIN								
4759L	Dressings 10 cm x 10 cm, 10	‡ 1	..	..	17.43	5.30	Jelonet 7404	SN

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—GAUZE—PARAFFIN with CHLORHEXIDINE ACETATE								
4845B	Dressings 10 cm x 10 cm, 10	‡ 1	2	..	25.01	5.30	Bactigras 7457	SN
DRESSING—GAUZE—POVIDONE-IODINE PAD								
4779M	Pads 22.5 cm x 7.5 cm, 12	‡ 1	2	..	33.11	5.30	Betadine	FH
DRESSING—HYDROACTIVE (CAVITY WOUND)								
4918W	Dressings 5 cm x 6 cm, 10	‡ 1	1	..	75.52	5.30	Allevyn Plus Cavity 66047571	SN
4919X	Dressings 10 cm x 10 cm, 5	2	1	..	* 158.91	5.30	Allevyn Plus Cavity 66047573	SN
DRESSING—HYDROACTIVE (DEBRIDEMENT)								
4949L	Dressings 4 cm, 8	‡ 1	..	..	67.47	5.30	TenderWet 24 Active	HR
4948K	Dressings 5.5 cm, 8	‡ 1	..	..	68.23	5.30	TenderWet Active Cavity	HR
4950M	Dressings 7.5 cm x 7.5 cm, 8	‡ 1	..	..	91.76	5.30	TenderWet 24 Active	HR
NOTE: Hartmann products are not available through pharmacy wholesalers. To order please contact the Hartmann Alliance (refer to 'Ordering Hartmann Products' at the foot of the 'Wound Assessment and Dressing Identification' chart at the beginning of this section).								
DRESSING—HYDROACTIVE (SUPERFICIAL WOUND—HIGH EXUDATE)								
4692Y	Dressings (foam alternative) 10 cm x 10 cm, 10	‡ 1	..	..	54.47	5.30	CombiDERM 651031	CC
4693B	Dressings (foam alternative) 15 cm x 18 cm, 5	‡ 1	..	..	71.29	5.30	CombiDERM 651027	CC
4695D	Dressings, island, 11 cm x 11 cm, 10	‡ 1	..	..	110.81	5.30	Tielle MTL101E	JJ
4696E	Dressings, island, 18 cm x 18 cm, 5	‡ 1	..	..	135.41	5.30	Tielle MT2442	JJ
4927H	Non-adhesive waterproof semi-permeable absorbent foam pads 10 cm x 10 cm, 10	‡ 1	1	..	87.50	5.30	Biatain Non- adhesive 3410	CT
4928J	Non-adhesive waterproof semi-permeable absorbent foam pads 15 cm x 15 cm, 5	‡ 1	2	..	86.02	5.30	Biatain Non- adhesive 3413	CT
4929K	Adhesive waterproof semi-permeable absorbent foam pads 12 cm x 12 cm, 10	‡ 1	1	..	96.52	5.30	Biatain Adhesive 3420	CT
4930L	Adhesive waterproof semi-permeable absorbent foam pads 18 cm x 18 cm, 5	‡ 1	2	..	93.39	5.30	Biatain Adhesive 3423	CT

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—HYDROACTIVE (SUPERFICIAL WOUND—LIGHT EXUDATE)								
4905E	Dressings 5 cm x 6 cm, 10	‡ 1	1	..	54.77	5.30	Allevyn Thin 66047576	SN
4906F	Dressings 10 cm x 10 cm, 5	2	1	..	* 100.09	5.30	Allevyn Thin 66047578	SN
DRESSING—HYDROACTIVE (SUPERFICIAL WOUND—MODERATE EXUDATE)								
4885D	Dressings 5 cm x 6 cm, 10	‡ 1	1	..	41.81	5.30	Cutinova Hydro 66047441	SN
4886E	Dressings 10 cm x 10 cm, 5	2	1	..	* 67.85	5.30	Cutinova Hydro 66047443	SN
DRESSING—HYDROCOLLOID (CAVITY WOUND)								
<u>NOTE:</u> This dressing should remain in place until saturated or strike through occurs for a maximum of 7 days.								
4896Q	Paste 30 g	10	..	..	* 144.69	5.30	DuoDERM Paste H7930	CC
4895P	Paste 50 g	2	3	..	* 42.79	5.30	Comfeel Paste 4701	CT
4697F	Powder 6 g	5	2	..	* 46.99	5.30	Comfeel Powder 4706	CT
DRESSING—HYDROCOLLOID (SUPERFICIAL WOUND—LIGHT EXUDATE)								
<u>NOTE:</u> This dressing should be applied to a thickness of 3 mm to 5 mm. It should be covered with a hydrocolloid dressing and may be left in place for up to 7 days.								
4888G	Dressings 5 cm x 7 cm, 10	‡ 1	1	..	41.29	5.30	Comfeel Plus Transparent 3530	CT
4889H	Dressings 9 cm x 14 cm, 10	‡ 1	1	..	84.09	5.30	Comfeel Plus Transparent 3536	CT
4908H	Dressings 10 cm x 10 cm, 5	2	1	..	* 52.85	5.30	Restore Extra Thin 9921	HO
4907G	Dressings 10 cm x 10 cm, 10	‡ 1	1	..	71.29	5.30	DuoDERM Extra Thin H7955	CC
4924E	Dressings 10 cm x 10 cm, 10	‡ 1	1	..	69.35	5.30	Comfeel Plus Transparent 3533	CT
4947J	Dressings 10 cm x 10 cm, 10	‡ 1	1	..	47.72	5.30	Hydrocoll Thin 900942/1	HR

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Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Proprietary Name and Manufacturer	
NOTE: Hartmann products are not available through pharmacy wholesalers. To order please contact the Hartmann Alliance (refer to 'Ordering Hartmann Products' at the foot of the 'Wound Assessment and Dressing Identification' chart at the beginning of this section).								
DRESSING—HYDROCOLLOID (SUPERFICIAL WOUND—MODERATE EXUDATE)								
NOTE: This dressing should remain in place until saturated or strike through occurs for a maximum of 7 days.								
4897R	Dressings 10 cm x 10 cm, 5	2	1	..	* 58.39	5.30	Restore Plus 9956	HO
				..	* 80.97	5.30	DuoDERM CGF H7660	CC
4921B	Dressings 10 cm x 10 cm, 10	‡ 1	1	..	68.57	5.30	Repicare Ultra 66000434	SN
4945G	Dressings 10 cm x 10 cm, 10	‡ 1	1	..	47.72	5.30	Hydrocoll 900938/1	HR
NOTE: Hartmann products are not available through pharmacy wholesalers. To order please contact the Hartmann Alliance (refer to 'Ordering Hartmann Products' at the foot of the 'Wound Assessment and Dressing Identification' chart at the beginning of this section).								
4678F	Butterfly shape 7 cm	5	..	..	* 54.74	5.30	Comfeel Plus Pressure Relieving 3350	CT
4679G	Round 10 cm	5	..	..	* 59.19	5.30	Comfeel Plus Pressure Relieving 3353	CT
4946H	Dressings 15 cm x 15 cm, 10	‡ 1	1	..	89.48	5.30	Hydrocoll 900939/1	HR
NOTE: Hartmann products are not available through pharmacy wholesalers. To order please contact the Hartmann Alliance (refer to 'Ordering Hartmann Products' at the foot of the 'Wound Assessment and Dressing Identification' chart at the beginning of this section).								
4853K	Dressings 15 cm x 20 cm, 3	3	1	..	* 132.83	5.30	Restore Plus 9957	HO
4854L	Dressings 20 cm x 20 cm, 3	3	1	..	* 158.00	5.30	Restore Plus 9958	HO
4920Y	Dressings 20 cm x 20 cm, 5	2	1	..	* 221.89	5.30	DuoDERM CGF H7662	CC
4923D	Dressings with alginate 10 cm x 10 cm, 10	‡ 1	1	..	81.56	5.30	Comfeel Plus Ulcer Dressing 3110	CT
4842W	Dressings, sacral, 5	2	1	..	* 99.17	5.30	Restore Plus Sacral 9959	HO
DRESSING—HYDROFIBRE (ALTERNATE TO ALGINATES)								
4698G	Ropes 2 g (30 cm), 5	‡ 1	1	..	83.28	5.30	Aquacel 177904	CC
4649Q	Dressings 10 cm x 10 cm, 10	‡ 1	1	..	100.55	5.30	Aquacel 177902	CC

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	
4922C	Dressings 15 cm x 15 cm, 5	2	1	..	* 208.27	5.30	Aquacel 177903	CC
DRESSING—HYDROGEL—AMORPHOUS								
NOTE:								
This dressing should be applied to a thickness of 3 mm to 5 mm and remain in situ in infected wounds for 24 hours and in clean wounds for up to 3 days. It should be covered with a secondary dressing such as foam or film. It should not be covered with gauze or combine.								
4912M	Tubes 15 g, 10	‡ 1	1	..	64.05	5.30	DuoDERM Gel H7990	CC
				..	71.66	5.30	Comfeel Purilon Gel 3900	CT
4894N	Tube 25 g	4	3	..	* 53.43	5.30	Intrasite Gel 7313	SN
4913N	Tubes 30 g, 3	3	1	..	* 96.68	5.30	DuoDERM Gel H7987	CC
4914P	Tube 50 g	3	3	..	* 32.69	5.30	Solugel 10336	JJ
4599C	Tube 50 g	3	3	..	* 27.32	5.30	SoloSite Gel 36361338	SN

DRESSING—HYDROGEL—SHEET

NOTE:

This dressing should be applied to a thickness of 3 mm to 5 mm and remain in situ in infected wounds for 24 hours and in clean wounds for up to 3 days. It should be covered with a secondary dressing such as foam or film. It should not be covered with gauze or combine.

4911L	Dressings 9.5 cm x 10.2 cm, 5	2	..	..	* 82.77	5.30	Nu-Gel 2497	JJ
4806Y	Dressings 10 cm x 10 cm, 5	2	..	..	* 52.85	5.30	Aquaclear 900796	HR

NOTE:

Hartmann products are not available through pharmacy wholesalers. To order please contact the Hartmann Alliance (refer to 'Ordering Hartmann Products' at the foot of the 'Wound Assessment and Dressing Identification' chart at the beginning of this section).

DRESSING—NON-ADHERENT

4860T	Dressings 5 cm x 5 cm, 5	2	..	..	* 14.63	5.30	Melolin 36361357	SN
4819P	Dressings 5 cm x 5 cm, 5	2	..	..	* 13.93	5.30	Cutilin Non-Stick Wound Pad 76301	SN
4755G	Dressings 5 cm x 7.5 cm, 10	‡ 1	..	..	10.59	5.30	Telfa 1970C	KE
4758K	Dressings 7.5 cm x 10 cm, 6	‡ 1	..	..	10.80	5.30	Telfa 2140C	KE
4944F	Dressings 7.5 cm x 10 cm, 10	‡ 1	..	..	14.81	5.30	Atrauman 499513	HR

NOTE:

Hartmann products are not available through pharmacy wholesalers. To order please contact the Hartmann Alliance (refer to 'Ordering Hartmann Products' at the foot of the 'Wound Assessment and Dressing Identification' chart at the beginning of this section).

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Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Proprietary Name and Manufacturer	
4862X	Dressings 10 cm x 10 cm, 5	2	..	..	* 22.03	5.30	Cutilin Non-Stick Wound Pad 76300	SN
4861W	Dressings 10 cm x 10 cm, 10	‡ 1	..	..	29.09	5.30	Melolin 66974933	SN
4844Y	Dressings, self-adhesive, 7.5 cm x 10 cm, 6	‡ 1	2	..	11.59	5.30	Telfa 7650C	KE
DRESSING—TULLE NON-GAUZE—PARAFFIN								
4909J	Dressing 7.6 cm x 7.6 cm	10	1	..	* 15.29	5.30	Adaptic 2012	JJ
DRESSING with CADEXOMER IODINE								
<u>NOTE:</u> Suitable for yellow sloughy infected and malodorous wounds.								
4931M	Sachets 3 g, 7	‡ 1	2	..	62.26	5.30	Iodosorb Powder 66051070	SN
4932N	Tubes 10 g, 4	‡ 1	2	..	100.29	5.30	Iodosorb Ointment 66051240	SN
4933P	Tubes 20 g, 2	‡ 1	2	..	99.36	5.30	Iodosorb Ointment 66051230	SN
4935R	Sachets 5 g (6 cm x 4 cm), 5	‡ 1	2	..	94.79	5.30	Iodosorb 66051330	SN
4936T	Sachets 10 g (8 cm x 6 cm), 3	‡ 1	2	..	137.02	5.30	Iodosorb 66051340	SN
4937W	Sachets 17 g (10 cm x 8 cm), 2	‡ 1	..	..	144.41	5.30	Iodosorb 66051360	SN
DRESSING with SILVER								
<u>Authority Required</u> <i>For wounds where there is evidence of critical colonisation and for well-assessed chronic wounds that have not responded to conventional dressings.</i>								
4646M	Hydroactive dressings non-adhesive 10 cm x 10 cm, 5	‡ 1	..	..	175.46	5.30	Contreet Foam Non-Adhesive 9622	CT
4647N	Hydroactive dressings adhesive 12.5 cm x 12.5 cm, 5	‡ 1	..	..	190.86	5.30	Contreet Foam Adhesive 9632	CT
4648P	Tulle dressings 10 cm x 10 cm, 3	‡ 1	..	..	43.35	5.30	Atrauman Ag 499572	HR
<u>NOTE:</u> <i>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).</i>								
GAUZE and COTTON TISSUE (COMBINE ROLL)								
4767X	Wrapped pack 9 cm x 10 m	‡ 1	..	..	14.96	5.30	BSN 2902165	BV

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REPATRIATION

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 \$		
4848E	Roll (dispenser) 1.9 cm x 5.4 m	‡ 1	..	..	10.62	5.30	Nexcare Durable Cloth First Aid Tape 799	MM
4849F	Roll (dispenser) 1.9 cm x 7.3 m	‡ 1	..	..	10.62	5.30	Nexcare Gentle Paper First Aid Tape 789	MM

Section 2

Standard Packs and Prices

NOTE—

Standard packs and prices (including mark-up, but without dispensing fee and dangerous drug fee) are for items against the price of which an asterisk () is shown in Section 1 of the Schedule.*

(APPLY WASTAGE FACTOR IN CALCULATING BROKEN QUANTITY PRICES)

Code	Name	Form/Strength	Pack and Price \$	Manufacturer
4579B	Alprostadil	10 mcg	2 @ 25.40	PH
4580C		20 mcg	2 @ 32.40	PH
4453J	Aluminium Hydroxide with Magnesium Hydroxide and Simethicone	400 mg-400 mg-40 mg	100 @ 19.85	JT
4118R		400 mg-400 mg-30 mg per 5 mL, 500 mL	1 @ 8.11	JT
4651T	Bandage—Absorbent Wool	10 cm x 2.7 m	1 @ 4.67	BV
4654Y	Bandage—Compression	8 cm x 5 m	1 @ 13.20	BV
4736G		7.5 cm x 3 m	1 @ 16.59	BV
4656C		7.5 cm x 3.5 m	1 @ 12.39	SS
4748X		10 cm x 3 m	1 @ 13.30	CC
			1 @ 22.08	BV
4657D		10 cm x 3.5 m	1 @ 9.85	BV
			1 @ 14.43	SS
4658E		Four layer	1 @ 40.53	SN
4598B		Four layer	1 @ 26.99	SN
4941C		Two layer, 18 cm-22 cm	1 @ 40.63	SN
4942D		Two layer, 22 cm-28 cm	1 @ 40.63	SN
4943E		Two layer, 28 cm-32 cm	1 @ 40.63	SN
4811F	Bandage—Retention—Cohesive—Heavy	5 cm x 1.3 m	1 @ 3.80	BK
4812G		7.5 cm x 1.3 m	1 @ 5.44	BK
4659F		7.5 cm x 3 m	1 @ 6.82	BV
4813H		10 cm x 1.3 m	1 @ 7.31	BK
4660G		10 cm x 2 m	1 @ 6.47	MM
4814J		15 cm x 1.3 m	1 @ 10.88	BK
4719J	Bandage—Retention—Cohesive—Light	6 cm x 4 m	1 @ 4.14	BV
4662J		10 cm x 4 m	1 @ 5.36	BV
4727T	Bandage—Retention—Cotton Crepe	5 cm x 2.3 m	1 @ 5.51	KE
			1 @ 5.93	BV
4728W		7.5 cm x 2.3 m	1 @ 7.90	KE
			1 @ 7.99	BV
4729X		10 cm x 2.3 m	1 @ 9.48	KE
			1 @ 10.70	BV
4674B	Bandage—Tubular (long Stocking)	Small	1 @ 16.88	SS
4797L		Medium	1 @ 16.88	SS
4799N		Large	1 @ 16.88	SS
4675C		XX/large	1 @ 16.88	SS
4661H	Bandage—Tubular (short Stocking)	Small B/C	1 @ 12.01	SS
4815K		Medium C/D	1 @ 12.01	SS
4816L		Large D/E	1 @ 12.01	SS
4668Q	Bandage—Zinc Paste	7.5 cm x 6 m	1 @ 11.39	SS
4669R		7.5 cm x 6 m	1 @ 11.62	XP
4750B		7.5 cm x 6 m	1 @ 28.56	SN
4749Y		8 cm x 5 m	1 @ 16.07	BV
4670T		10 cm x 9.1 m	1 @ 11.18	CC
4150K	Bromazepam	3 mg	30 @ 10.48	RO
4151L		6 mg	30 @ 13.49	RO
4333C	Calcium	500 mg	60 @ 5.15	IA
4093K		250 mg	120 @ 7.89	BN
4094L		500 mg	60 @ 5.15	IA
4142B		600 mg	120 @ 7.89	PP
4055K	Calcium Carbonate with Glycine	420 mg-180 mg	100 @ 8.38	MM
4081T	Dextropropoxyphene Napsylate	100 mg	10 @ 2.44	AS

(APPLY WASTAGE FACTOR IN CALCULATING BROKEN QUANTITY PRICES)

Code	Name	Form/Strength	Pack and Price \$	Manufacturer
4681J	Dressing—Activated Charcoal (malodorous Wound)	10.5 cm x 10.5 cm	1 @ 9.45	JJ
4832H	Dressing—Alginate (cavity Wound)	2 g	1 @ 10.27	UM
4685N		2 g (30 cm), 5	5 @ 54.42	CC
4682K		2 g (40 cm), 6	1 @ 37.85	HO
4684M	Dressing—Alginate (superficial Wound)	5 cm x 5 cm	1 @ 65.65	CT
4831G		10 cm x 10 cm	1 @ 4.05	CT
4688R	Dressing—Film	15 cm x 20 cm	1 @ 7.80	UM
4689T	Dressing—Film Island	5 cm x 7 cm	1 @ 8.37	CT
4898T		5 cm x 7.2 cm, 5	1 @ 4.04	MM
4899W		8 cm x 10 cm, 5	1 @ 0.98	MM
4690W		9 cm x 10 cm	1 @ 9.50	SN
4892L	Dressing—Foam with Charcoal (malodorous Wound)	10 cm x 10 cm, 10	1 @ 16.79	SN
4919X	Dressing—Hydroactive (cavity Wound)	10 cm x 10 cm, 5	1 @ 2.13	MM
4906F	Dressing—Hydroactive (superficial Wound—Light Exudate)	10 cm x 10 cm, 5	1 @ 83.82	SS
4886E	Dressing—Hydroactive (superficial Wound—Moderate Exudate)	10 cm x 10 cm, 5	1 @ 76.46	SN
4896Q	Dressing—Hydrocolloid (cavity Wound)	30 g	1 @ 47.05	SN
4895P		50 g	1 @ 30.93	SN
4697F		6 g	1 @ 13.87	CC
4908H	Dressing—Hydrocolloid (superficial Wound—Light Exudate)	10 cm x 10 cm, 5	1 @ 18.40	CT
4897R	Dressing—Hydrocolloid (superficial Wound—Moderate Exudate)	10 cm x 10 cm, 5	1 @ 8.20	CT
4678F		7 cm	1 @ 23.43	HO
4679G		10 cm	1 @ 26.20	HO
4853K		15 cm x 20 cm, 3	1 @ 37.49	CC
4854L		20 cm x 20 cm, 3	1 @ 9.75	CT
4920Y		20 cm x 20 cm, 5	1 @ 10.64	CT
4842W		5	1 @ 42.28	HO
4922C	Dressing—Hydrofibre (alternate To Alginates)	15 cm x 15 cm, 5	1 @ 50.67	HO
4894N	Dressing—Hydrogel—Amorphous	25 g	1 @ 107.95	CC
4913N		30 g, 3	1 @ 46.59	HO
4914P		50 g	1 @ 101.14	CC
4599C		50 g	1 @ 11.86	SN
4911L	Dressing—Hydrogel—Sheet	9.5 cm x 10.2 cm, 5	1 @ 30.23	CC
4806Y		10 cm x 10 cm, 5	1 @ 8.90	JJ
4860T	Dressing—Non-adherent	5 cm x 5 cm, 5	1 @ 7.11	SN
4819P		5 cm x 5 cm, 5	1 @ 38.39	JJ
4862X		10 cm x 10 cm, 5	1 @ 23.43	HR
4909J	Dressing—Tulle Non-gauze—Paraffin	7.6 cm x 7.6 cm	1 @ 4.32	SN
4237B	Fexofenadine Hydrochloride	60 mg	1 @ 3.97	SN
4246L	Glycerol	2.8 g, 12	1 @ 8.02	SN
4576W	Nicotine	Approx. 5 mg per 16 hours, 7	1 @ 0.93	JJ
4571N		Approx. 7 mg per 24 hours, 7	20 @ 11.57	AF, SZ
			20 @ 13.92	SW
			1 @ 4.27	PP
			1 @ 22.20	JT
			1 @ 19.89	AF
			1 @ 33.95	GK

(APPLY WASTAGE FACTOR IN CALCULATING BROKEN QUANTITY PRICES)

Code	Name	Form/Strength	Pack and Price \$	Manufacturer
4577X		Approx. 10 mg per 16 hours, 7	1 @ 24.18	JT
4572P		Approx. 14 mg per 24 hours, 7	1 @ 21.55	AF
			1 @ 33.95	GK
4578Y		Approx. 15 mg per 16 hours, 7	1 @ 26.77	JT
4573Q		Approx. 21 mg per 24 hours, 7	1 @ 23.55	AF
			1 @ 33.95	GK
4676D	Pressure Reducing Products	10 cm x 10 cm x 3 mm	1 @ 11.04	KC
4677E		10 cm x 10 cm x 12 mm	1 @ 21.45	KC

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THERAPEUTIC GROUP PREMIUM POLICY

PHARMACEUTICAL BENEFIT ITEMS WHICH HAVE A THERAPEUTIC GROUP PREMIUM WITH EFFECT FROM 1 JUNE 2009

The Schedule of Pharmaceutical Benefits shows differences in price in some therapeutic groups where alternative drugs may have a therapeutic group premium.

The Therapeutic Group Premium Policy applies within narrowly defined therapeutic sub-groups where the drugs concerned are of similar safety and health outcomes.

The Australian Government, through the PBS, subsidises up to the price of the lowest priced drug in the group. This means that consumers may have to pay for more expensive drugs (those with a therapeutic group premium). This extra amount does not count towards their PBS safety net threshold.

Therapeutic group premiums apply where a prescriber has prescribed a drug within a therapeutic group that attracts a therapeutic group premium and has not sought an exemption from Medicare Australia on clinical grounds.

The exemption provisions are:

- adverse effects occurring with all of the base-priced drugs; or
- drug interactions occurring with all of the base-priced drugs; or
- drug interactions expected to occur with all of the base-priced drugs; or
- transfer to a base-priced drug would cause patient confusion resulting in problems with compliance.

The premiums are not a Government charge but reflect the fact that the supplier(s) of the drug charge a price higher than the Government is willing to subsidise.

Under the Therapeutic Group Premium Policy drug substitution by pharmacists is not permitted.

For ease of prescribing and dispensing, and in the interests of your patients, the following list shows those PBS drugs that attract a therapeutic group premium.

Premium Priced Brand	Form and Strength	Max. Qty	Therapeutic Group Premium \$

H₂-RECEPTOR ANTAGONISTS

<i>Zantac</i>	Effervescent tablet 150 mg (base)	60	3.26
<i>Zantac Syrup</i>	Syrup 150 mg (base) per 10 mL, 300 mL	2	2.20

The base-priced drugs in this therapeutic group are cimetidine, famotidine, nizatidine, and ranitidine hydrochloride (except ranitidine hydrochloride effervescent tablet 150 mg (base) and syrup 150 mg (base) per 10 mL, 300 mL).

DIHYDROPYRIDINE-DERIVATIVE CALCIUM CHANNEL BLOCKERS

<i>Adalat Oros 20mg</i>	Tablet 20 mg (controlled release)	30	2.26
<i>Zanidip</i>	Tablet 10 mg	30	2.01
<i>Zanidip</i>	Tablet 20 mg	30	4.02

The base-priced drugs in this therapeutic group are amlodipine, felodipine and nifedipine (except nifedipine controlled release tablet 20 mg).

PROTON PUMP INHIBITORS

<i>Zoton</i>	Sachet containing granules for oral suspension, 30 mg per sachet	28	3.62

The base-priced drugs in this therapeutic group are esomeprazole magnesium trihydrate, omeprazole, pantoprazole sodium sesquihydrate, rabeprazole sodium and lansoprazole (except lansoprazole sachet containing granules for oral suspension, 30 mg per sachet).

ANGIOTENSIN II ANTAGONISTS

<i>Teveten</i>	Tablet 400 mg (base)	56	1.52

The base-priced drugs in this therapeutic group are candesartan cilexetil, irbesartan, olmesartan medoxomil, telmisartan, valsartan and eprosartan mesylate (except eprosartan mesylate tablet 400 mg (base)).

BRAND PREMIUM POLICY

BRANDS OF PHARMACEUTICAL BENEFIT ITEMS WHICH HAVE A BRAND PREMIUM AND THAT MAY BE SUBSTITUTED WITH EFFECT FROM 1 JUNE 2009

The Schedule of Pharmaceutical Benefits shows differences in price between some alternative brands of the same drug product.

Manufacturers can develop generic equivalents and apply to have them listed on the PBS. In doing this, manufacturers need to ensure that they comply with the relevant legislation applicable to patents. These brands are clinically equivalent and must undergo the same strict quality controls. Although these brands are designed to act on the body in exactly the same way, they are usually cheaper than the originator brands.

The Australian Government, through the PBS, subsidises up to the price of the lowest priced brand (except in those instances where the lowest priced brand has, as part of its price, a therapeutic group premium). This means that consumers may have to pay extra for more expensive brands (those with a brand premium). This extra amount does not count towards their PBS safety net threshold.

Brand substitution by pharmacists without reference to the prescriber is permitted for PBS prescriptions where:

- the patient agrees to the substitution;
- the brands are identified in the Schedule of Pharmaceutical Benefits as being interchangeable;
- the prescriber has not indicated on the prescription form that substitution is not to occur; and
- substitution is permitted under the relevant State or Territory legislation.

Prescription forms supplied by Medicare Australia contain a box to be ticked where brand substitution is not to take place.

Prescribers not using these prescription forms should endorse the prescription if brand substitution is not permitted. Where a stamp is used for this purpose, the prescriber will be required to initial the stamped statement.

For ease of prescribing and dispensing, and in the interests of your patients, the following list shows those PBS drugs that attract a brand premium and that can be substituted where permitted. They are listed alphabetically, by brand name, with the brand premium and benchmark brand(s) cited in the last column.

Premium Priced Brand	Form and Strength	Max. Qty	Brand Premium \$	Benchmark Priced Brands
<i>Accupril</i>	Tablet 5 mg (base)	30	0.49	<i>Acquin 5; APO-Quinapril; Filpril; Pharmacor Quinapril 5; Quinapril-DP; Quinapril generichealth; Quinapril Sandoz</i>
	Tablet 10 mg (base)	30	0.66	<i>Acquin 10; APO-Quinapril; Filpril; Pharmacor Quinapril 10; Quinapril-DP; Quinapril generichealth</i>
	Tablet 20 mg (base)	30	0.99	<i>Acquin 20; APO-Quinapril; Filpril; Pharmacor Quinapril 20; Quinapril-DP; Quinapril generichealth; Quinapril Sandoz</i>
<i>Adalat Oros 30</i>	Tablet 30 mg (controlled release)	30	2.54	<i>Addos XR 30; Adefin XL 30</i>
<i>Adalat Oros 60</i>	Tablet 60 mg (controlled release)	30	2.81	<i>Addos XR 60; Adefin XL 60</i>
<i>Adalat 10</i>	Tablet 10 mg	60	1.17	<i>Adefin 10; Nypine 10</i>
<i>Adalat 20</i>	Tablet 20 mg	60	2.21	<i>Adefin 20; GenRx Nifedipine; Nifexhexal; Nyefax 20 mg; Nypine 20</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	2.24	<i>Hydopa</i>
<i>Alphagan</i>	Eye drops 2 mg per mL (0.2%), 5 mL	1	1.74	<i>Enidin</i>
<i>Amaryl</i>	Tablet 1 mg	30	2.81	<i>Aylide 1; Diapride 1; Dimirel; Glimepiride Sandoz</i>
	Tablet 2 mg	30	2.81	<i>Aylide 2; Diapride 2; Dimirel; Glimepiride Sandoz</i>
	Tablet 3 mg	30	2.80	<i>Aylide 3; Diapride 3; Dimirel; Glimepiride Sandoz</i>
	Tablet 4 mg	30	2.80	<i>Aylide 4; Diapride 4; Dimirel; Glimepiride Sandoz</i>
<i>Amoxil</i>	Capsule 250 mg	20	0.79	<i>Alphamox 250; Amohexal; Amoxycillin-DP; Amoxycillin Ranbaxy; Amoxycillin Sandoz; APO-Amoxycillin; Chem mart Amoxycillin; Cilamox; GenRx Amoxycillin; Terry White Chemists Amoxycillin</i>
	Capsule 500 mg	20	0.80	<i>Alphamox 500; Amohexal; Amoxycillin-DP; Amoxycillin Ranbaxy; Amoxycillin Sandoz; APO-Amoxycillin; Chem mart Amoxycillin; Cilamox; GenRx Amoxycillin; Moxacin; Terry White Chemists Amoxycillin</i>
	Powder for syrup 125 mg per 5 mL, 100 mL	1	0.95	<i>Alphamox 125; Amoxycillin Sandoz; Bgramin; Chem mart Amoxycillin; GenRx Amoxycillin; Ranmoxy; Terry White Chemists Amoxycillin</i>
<i>Amoxil Forte</i>	Powder for syrup 250 mg per 5 mL, 100 mL	1	0.79	<i>Alphamox 250; Amohexal; Amoxycillin Sandoz; Bgramin; Chem mart Amoxycillin; Cilamox; GenRx Amoxycillin; Ranmoxy; Terry White Chemists Amoxycillin</i>

Premium Priced Brand	Form and Strength	Max. Qty	Brand Premium \$	Benchmark Priced Brands
<i>Amprace 10</i>	Tablet 10 mg	30	2.46	<i>Alphapril; Auspril; Chem mart Enalapril; Enahexal; Enalabell; Enalapril-DP 10mg; Enalapril generichealth; Enalapril Winthrop; GenRx Enalapril; Terry White Chemists Enalapril</i>
<i>Amprace 20</i>	Tablet 20 mg	30	2.47	<i>Alphapril; Auspril; Chem mart Enalapril; Enahexal; Enalabell; Enalapril-DP 20mg; Enalapril generichealth; GenRx Enalapril; Terry White Chemists Enalapril</i>
<i>Anafranil 25</i>	Tablet 25 mg	50	3.26	<i>Chem mart Clomipramine; GenRx Clomipramine; Placil; Terry White Chemists Clomipramine</i>
<i>Anaprox 550</i>	Tablet 550 mg	50	2.29	<i>Crysanal</i>
<i>Androcur</i>	Tablet 50 mg	20	3.13	<i>Cyprohexal; Cyprone; Cyprostat; GenRx Cyproterone Acetate; Procur</i>
	Tablet 50 mg	100	3.00	<i>Cyprohexal; Cyprone; Cyprostat; GenRx Cyproterone Acetate; Procur</i>
<i>Androcur-100</i>	Tablet 100 mg	50	1.65	<i>Cyprohexal; Cyprostat-100; GenRx Cyproterone Acetate; Procur 100</i>
<i>Anginine Stabilised</i>	Tablets 600 micrograms, 100	1	1.64	<i>Lycinate</i>
<i>Aristocort 0.02%</i>	Cream 200 micrograms per g (0.02%), 100 g	2	3.30	<i>Tricortone</i>
	Ointment 200 micrograms per g (0.02%), 100 g	2	3.30	<i>Tricortone</i>
<i>Aropax</i>	Tablet 20 mg (as hydrochloride)	30	0.86	<i>Chem mart Paroxetine; Extine 20; GenRx Paroxetine; Paroxetine 20; Paroxetine-DP; Paroxetine generichealth; Paroxetine Sandoz; Paroxetine Winthrop; Paxtine; Terry White Chemists Paroxetine</i>
<i>Astrix</i>	Tablet 100 mg	112	1.36	<i>DBL Aspirin 100 mg</i>
<i>Atrovent</i>	Nebuliser solution single dose units 250 micrograms (anhydrous) in 1 mL, 30	2	0.72	<i>Aeron 250; APO-Ipratropium; Apoven 250; Ipratrin; Ipravent</i>
<i>Atrovent Adult</i>	Nebuliser solution single dose units 500 micrograms (anhydrous) in 1 mL, 30	2	0.62	<i>Aeron 500; APO-Ipratropium; Apoven 500; Ipratrin Adult; Ipravent</i>
<i>Augmentin</i>	Powder for syrup 125 mg-31.25 mg per 5 mL, 75 mL	1	1.51	<i>Clamoxyl</i>
<i>Augmentin Duo</i>	Tablet 500 mg-125 mg	10	1.55	<i>Clamoxyl Duo; Curam 500/125; GA-Amclav 500/125; Moxiclav Duo 500/125</i>
<i>Augmentin Duo forte</i>	Tablet 875 mg-125 mg	10	2.04	<i>Chem mart Amoxycillin and Clavulanic Acid; Clamoxyl Duo forte; Clavycillin 875/125; Curam 875/125; GA-Amclav Forte 875/125; GenRx Amoxycillin and Clavulanic Acid; Moxiclav Duo Forte 875/125; Terry White Chemists Amoxycillin and Clavulanic Acid</i>
<i>Augmentin Duo 400</i>	Powder for syrup 400 mg-57 mg per 5 mL, 60 mL	1	1.54	<i>Clamoxyl Duo 400</i>
<i>Aurorix</i>	Tablet 150 mg	60	0.72	<i>Amira 150; Chem mart Moclobemide; Clobemix; GenRx Moclobemide; Mohexal; 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	1.45	<i>Amira 300; Chem mart Moclobemide; Clobemix; GenRx Moclobemide; Maosig; Mohexal; Terry White Chemists Moclobemide</i>
<i>Avanza</i>	Tablet 30 mg	30	1.70	<i>Axit 30; Chem mart Mirtazapine; GenRx Mirtazapine; Mirtazapine-DP; Mirtazapine Sandoz; Mirtazon; Terry White Chemists Mirtazapine</i>
	Tablet 45 mg	30	1.49	<i>APO-Mirtazapine; Chem mart Mirtazapine; Mirtazapine Sandoz; Mirtazon; Terry White Chemists Mirtazapine</i>
<i>Azopt</i>	Eye drops 10 mg per mL (1%), 5 mL	1	1.23	<i>BrinzoQuin</i>
<i>Betaloc</i>	Tablet 100 mg	60	3.25	<i>Chem mart Metoprolol; GenRx Metoprolol; Metohexal; Metolol; Metrol 100; Minax 100; Terry White Chemists Metoprolol</i>
	Tablet 50 mg	100	3.25	<i>Chem mart Metoprolol; GenRx Metoprolol; Metohexal; Metolol; Metrol 50; Minax 50; Terry White Chemists Metoprolol</i>
<i>Betnovate 1/2</i>	Cream 500 micrograms (base) per g (0.05%), 15 g	1	1.91	<i>Cortival 1/2</i>
	Ointment 500 micrograms (base) per g (0.05%), 15 g	1	1.91	<i>Cortival 1/2</i>
<i>Betnovate 1/5</i>	Cream 200 micrograms (base) per g (0.02%), 100 g	2	6.18	<i>Cortival 1/5</i>
<i>Betoptic</i>	Eye drops, solution, 5 mg (base) per mL (0.5%), 5 mL	1	2.18	<i>BetoQuin</i>
<i>Blenoxane</i>	Powder for injection 15,000 i.u. (solvent required)	10	75.30	<i>Blenamax; HH brand</i>
<i>Brevinor</i>	Tablets 500 micrograms-35 micrograms, 21	4	7.92	<i>Norimin 28 Day</i>
	Pack containing 21 tablets	4	7.92	<i>Norimin 28 Day</i>
<i>Brevinor-1</i>	500 micrograms-35 micrograms and 7 inert tablets			
	Tablets 1 mg-35 micrograms, 21	4	7.92	<i>Norimin-1 28 Day</i>
	Pack containing 21 tablets 1 mg-35 micrograms and 7 inert tablets	4	7.92	<i>Norimin-1 28 Day</i>
<i>Capoten</i>	Tablet 25 mg	90	3.67	<i>Acenorm 25 mg; Captophexal; GenRx Captopril; GM brand</i>
	Tablet 50 mg	90	3.66	<i>Acenorm 50 mg; Captophexal; GenRx Captopril; GM brand</i>
<i>Carafate</i>	Tablet equivalent to 1 g anhydrous sucralfate	120	2.18	<i>UlcYTE</i>
<i>Ceclor</i>	Powder for oral suspension 125 mg per 5 mL, 100 mL	1	4.18	<i>Aclor 125; Cefaclor Sandoz; Chem mart Cefaclor; GenRx Cefaclor; Keflor; Ozcef; Terry White Chemists Cefaclor</i>
	Powder for oral suspension 250 mg per 5 mL, 75 mL	1	4.37	<i>Aclor 250; Cefaclor Sandoz; Chem mart Cefaclor; GenRx Cefaclor; Keflor; Ozcef; Terry White Chemists Cefaclor</i>
<i>Ceclor CD</i>	Tablet 375 mg (sustained release)	10	5.20	<i>Cefaclor-GA; Chem mart Cefaclor CD; Douglas Cefaclor-CD; GenRx Cefaclor CD; Karlor CD; Keflor CD; Ozcef; Terry White Chemists Cefaclor CD</i>
<i>Cefotaxime Sandoz</i>	Powder for injection 1 g	10	25.10	<i>HH brand</i>
	Powder for injection 2 g	10	46.50	<i>HH brand</i>
<i>Chlorvescent</i>	Effervescent tablet 14 mmol potassium and 8 mmol chloride	60	2.61	<i>K-Sol</i>

Premium Priced Brand	Form and Strength	Max. Qty	Brand Premium \$	Benchmark Priced Brands
<i>Ciloxan</i>	Eye drops 3 mg per mL (0.3%), 5 mL	2	2.06	<i>CiloQuin</i>
<i>Cipramil</i>	Tablet 20 mg (base)	28	4.45	<i>Celapram</i> ; <i>Celica</i> ; <i>Chem mart</i> <i>Citalopram</i> ; <i>Ciazil</i> ; <i>Citalobell</i> ; <i>Citalopram 20</i> ; <i>GenRx Citalopram</i> ; <i>Talam</i> ; <i>Talohexal</i> ; <i>Terry White</i> <i>Chemists Citalopram</i>
<i>Ciproxin 250</i>	Tablet 250 mg	14	1.45	<i>C-Flox 250</i> ; <i>Cifran</i> ; <i>Ciprol 250</i> ; <i>GenRx Ciprofloxacin</i> ; <i>Profloxin</i>
<i>Ciproxin 500</i>	Tablet 500 mg	14	1.26	<i>C-Flox 500</i> ; <i>Cifran</i> ; <i>Ciprofloxacin</i> <i>500</i> ; <i>Ciprofloxacin-BW</i> ; <i>Ciprol 500</i> ; <i>GenRx Ciprofloxacin</i> ; <i>Profloxin</i> ; <i>Proquin</i> ; <i>GN brand</i>
<i>Ciproxin 750</i>	Tablet 750 mg	14	1.37	<i>C-Flox 750</i> ; <i>Cifran</i> ; <i>Ciprofloxacin</i> <i>750</i> ; <i>Ciprofloxacin-BW</i> ; <i>Ciprol 750</i> ; <i>GenRx Ciprofloxacin</i> ; <i>Profloxin</i> ; <i>Proquin</i> ; <i>GN brand</i>
<i>Clomid</i>	Tablet 50 mg	10	3.90	<i>Clomhexal</i> ; <i>Fermil</i> ; <i>GenRx</i> <i>Clomiphene</i>
<i>Colgout</i>	Tablet 500 micrograms	100	0.91	<i>Lengout</i>
<i>Dalacin C</i>	Capsule 150 mg	24	1.45	<i>Cleocin</i>
<i>Daonil</i>	Tablet 5 mg	100	1.51	<i>Glimel</i>
<i>Depo-Medrol</i>	Injection 40 mg in 1 mL	5	0.76	<i>Depo-Nisolone</i>
<i>Depo-Provera</i>	Injection 150 mg in 1 mL	1	3.34	<i>Depo-Ralovera</i>
<i>Diabex</i>	Tablet 500 mg	100	1.79	<i>Chem mart Metformin</i> ; <i>Diaformin</i> ; <i>Formet 500</i> ; <i>GenRx Metformin</i> ; <i>Glucohexal</i> ; <i>Glucomet 500 mg</i> ; <i>Metforbell</i> ; <i>Metformin 500</i> ; <i>Metformin</i> <i>generichealth</i> ; <i>Metformin Ranbaxy</i> ; <i>Terry White Chemists Metformin</i> ; <i>GN</i> <i>brand</i>
<i>Diabex 850</i>	Tablet 850 mg	60	1.79	<i>Chem mart Metformin</i> ; <i>Diaformin</i> <i>850</i> ; <i>Formet 850</i> ; <i>GenRx Metformin</i> ; <i>Glucohexal</i> ; <i>Glucomet 850 mg</i> ; <i>Metforbell</i> ; <i>Metformin 850</i> ; <i>Metformin</i> <i>generichealth</i> ; <i>Metformin Ranbaxy</i> ; <i>Terry White Chemists Metformin</i> ; <i>GN</i> <i>brand</i>
<i>Diabex 1000</i>	Tablet 1 g	90	1.80	<i>Diaformin 1000</i> ; <i>Formet 1000</i> ; <i>Glucohexal</i> ; <i>Metformin-GA</i>
<i>Diamicron</i>	Tablet 80 mg	100	2.03	<i>Chem mart Gliclazide</i> ; <i>GenRx</i> <i>Gliclazide</i> ; <i>Glyade</i> ; <i>Mellihexal</i> ; <i>Nidem</i> ; <i>Terry White Chemists Gliclazide</i>
<i>Doryx</i>	Capsule 100 mg (as hydrochloride)	7	1.15	<i>DBL Doxycycline</i>
	Capsule 50 mg (as hydrochloride)	25	1.31	<i>DBL Doxycycline</i>
	Capsule 100 mg (as hydrochloride)	28	4.60	<i>DBL Doxycycline</i>
	Capsule 100 mg (as hydrochloride)	21	2.09	<i>DBL Doxycycline</i>
<i>Dulcolax</i>	Suppositories 10 mg, 10	3	1.14	<i>Petrus Bisacodyl Suppositories</i>
<i>Duphalac</i>	Mixture 3.34 g per 5 mL, 500 mL	1	1.67	<i>Actilax</i> ; <i>Genlac</i> ; <i>GenRx Lactulose</i> ; <i>Lac-Dol</i> ; <i>Lactocur</i>
<i>Duratears</i>	Compound eye ointment 3.5 g	2	2.24	<i>Poly Visc</i>
<i>E.E.S. Granules</i>	Powder for oral liquid 400 mg (base) per 5 mL, 100 mL	1	2.89	<i>E-Mycin 400</i>
<i>E.E.S. 200</i>	Powder for oral liquid 200 mg (base) per 5 mL, 100 mL	1	2.86	<i>E-Mycin 200</i>
<i>E.E.S. 400 Filmtab</i>	Tablet 400 mg (base)	25	2.80	<i>E-Mycin</i>

Premium Priced Brand	Form and Strength	Max. Qty	Brand Premium \$	Benchmark Priced Brands
<i>Epilim EC</i>	Tablet 200 mg (enteric coated)	200	1.50	<i>Sodium Valproate Sandoz; Valpro 200; Valproate Winthrop EC 200</i>
	Tablet 500 mg (enteric coated)	200	1.50	<i>Sodium Valproate Sandoz; Valpro 500; Valproate Winthrop EC 500</i>
<i>Eryc</i>	Capsule 250 mg	25	1.35	<i>DBL Erythromycin</i>
<i>Fasigyn</i>	Tablet 500 mg	4	2.51	<i>Simplotan</i>
<i>Feldene</i>	Capsule 10 mg	50	2.66	<i>Chem mart Piroxicam; GenRx Piroxicam; Mobilis 10; Terry White Chemists Piroxicam</i>
	Capsule 20 mg	25	2.64	<i>Chem mart Piroxicam; GenRx Piroxicam; Mobilis 20; Terry White Chemists Piroxicam</i>
<i>Feldene-D</i>	Dispersible tablet 20 mg	25	2.64	<i>Mobilis D-20</i>
<i>Flagyl</i>	Tablet 200 mg	21	2.30	<i>Metrogyl 200; Metronide 200</i>
	Tablet 400 mg	21	2.30	<i>Metrogyl 400; Metronide 400</i>
<i>Fosamax Once Weekly</i>	Tablet equivalent to 70 mg alendronic acid	4	1.42	<i>Adronat; Alendrobell 70mg; Alendronate-GA; Alendronate Sandoz; Alendro Once Weekly; APO-Alendronate; Chem mart Alendronate 70mg; Ossmax 70mg; Terry White Chemists Alendronate 70mg</i>
<i>Genteal</i>	Eye drops 3 mg per mL (0.3%), 15 mL (contains sodium perborate as preservative)	1	1.86	<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	1.86	<i>HPMC PAA</i>
<i>Glucophage</i>	Tablet 500 mg	100	1.10	<i>Chem mart Metformin; Diaformin; Formet 500; GenRx Metformin; Glucohexal; Glucomet 500 mg; Metforbell; Metformin 500; Metformin generichealth; Metformin Ranbaxy; Terry White Chemists Metformin; GN brand</i>
	Tablet 850 mg	60	1.10	<i>Chem mart Metformin; Diaformin 850; Formet 850; GenRx Metformin; Glucohexal; Glucomet 850 mg; Metforbell; Metformin 850; Metformin generichealth; Metformin Ranbaxy; Terry White Chemists Metformin; GN brand</i>
<i>Gopten</i>	Capsule 500 micrograms	28	1.57	<i>APO-Trandolapril; Dolapril 0.5; Tranalpha; Trandolapril-DP</i>
	Capsule 1 mg	28	1.57	<i>APO-Trandolapril; Dolapril 1; Tranalpha; Trandolapril-DP</i>
	Capsule 2 mg	28	1.58	<i>APO-Trandolapril; Dolapril 2; Tranalpha; Trandolapril-DP</i>
	Capsule 4 mg	28	1.57	<i>APO-Trandolapril; Dolapril 4; Tranalpha; Trandolapril-DP</i>
<i>Imdur 120 mg</i>	Tablet 120 mg (sustained release)	30	3.00	<i>Monodur 120 mg</i>
<i>Imdur Durule</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>Imodium</i>	Capsule 2 mg	12	0.94	<i>Gastro-Stop Loperamide</i>

Premium Priced Brand	Form and Strength	Max. Qty	Brand Premium \$	Benchmark Priced Brands
<i>Indocid</i>	Capsule 25 mg	100	0.92	<i>Arthrexin</i>
<i>Isoptin</i>	Tablet 40 mg	100	0.76	<i>Anpec 40</i>
	Tablet 80 mg	100	0.76	<i>Anpec 80</i>
	Tablet 240 mg (sustained release)	30	2.26	<i>Anpec SR; Cordilox SR</i>
<i>Isoptin 180 SR</i>	Tablet 180 mg (sustained release)	30	2.27	<i>Cordilox 180 SR</i>
<i>Keflex</i>	Capsule 250 mg	20	3.30	<i>Cefalexin Sandoz; Cephabell; Cephalexin Max; Cephatrust 250; Chem mart Cephalexin; Cilex; GenRx Cephalexin; Ialex; Ibilex 250; Rancef; Sporahexal; Terry White Chemists Cephalexin</i>
	Capsule 500 mg	20	4.41	<i>Cefalexin Sandoz; Cephabell; Cephalexin Max; Cephatrust 500; Chem mart Cephalexin; Cilex; GenRx Cephalexin; Ialex; Ibilex 500; Rancef; Sporahexal; Terry White Chemists Cephalexin</i>
	Granules for syrup 125 mg per 5 mL, 100 mL	1	3.55	<i>Cefalexin Sandoz; 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	4.38	<i>Cefalexin Sandoz; Chem mart Cephalexin; Cilex; GenRx Cephalexin; Ialex; Ibilex 250; Terry White Chemists Cephalexin</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	1.07	<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	1.08	<i>Otocomb Otic</i>
<i>Klacid</i>	Tablet 250 mg	14	1.96	<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	2.24	<i>Ircal</i>
<i>Lamictal</i>	Tablet 5 mg	56	0.76	<i>Lamogine; Seaze 5</i>
	Tablet 25 mg	56	0.77	<i>GenRx Lamotrigine; Lamidus; Lamogine; Lamotrigine-DP; Lamotrigine-GA; Lamotrigine generichealth; Lamotrigine Sandoz; Lamotrust 25; Seaze 25</i>
	Tablet 50 mg	56	0.66	<i>GenRx Lamotrigine; Lamidus; Lamogine; Lamotrigine-DP; Lamotrigine-GA; Lamotrigine generichealth; Lamotrigine Sandoz; Lamotrust 50; Seaze 50</i>
	Tablet 100 mg	56	0.73	<i>GenRx Lamotrigine; Lamidus; Lamogine; Lamotrigine-DP; Lamotrigine-GA; Lamotrigine generichealth; Lamotrigine Sandoz; Lamotrust 100; Seaze 100</i>

Premium Priced Brand	Form and Strength	Max. Qty	Brand Premium \$	Benchmark Priced Brands
	Tablet 200 mg	56	0.72	GenRx Lamotrigine; Lamidus; Lamogine; Lamotrigine-DP; Lamotrigine-GA; Lamotrigine generichealth; Lamotrigine Sandoz; Lamotruster 200; Seaze 200
Lamisil	Tablet 250 mg (base)	42	1.46	GenRx Terbinafine; Sebifin 250; Tamsil; Terbihexal; Terbinafine 250; Terbinafine-DP; Zabel
Lanoxin	Tablet 250 micrograms	100	1.80	Sigmaxin
Lanoxin-PG	Tablet 62.5 micrograms	200	1.79	Sigmaxin-PG
Lasix	Tablet 40 mg	100	2.40	Chem mart Frusemide; Frusehexal 40 mg; Frusid; GenRx Frusemide; Terry White Chemists Frusemide; Uremide
Lasix-M	Tablet 20 mg	100	1.90	Chem mart Frusemide; Frusid; GenRx Frusemide; Terry White Chemists Frusemide
Lexapro	Tablet 10 mg (base)	28	4.89	Esipram; Esitalo
	Tablet 20 mg (base)	28	7.16	Esipram; Esitalo
Lioresal 10	Tablet 10 mg	100	2.26	Baclo; Chem mart Baclofen; Clofen 10; GenRx Baclofen; Stelax 10; Terry White Chemists Baclofen
Lioresal 25	Tablet 25 mg	100	2.18	Baclo; Chem mart Baclofen; Clofen 25; GenRx Baclofen; Stelax 25; Terry White Chemists Baclofen
Lipex 10	Tablet 10 mg	30	2.95	APO-Simvastatin; Chem mart Simvastatin; GenRx Simvastatin; Ransim; Simvabell; Simvahexal; Simvar 10; Simvastatin-DP; Simvastatin generichealth; Simvastatin-Spirit 10; Simvastatin Winthrop; Simvasyn; Terry White Chemists Simvastatin; Zimstat; GN brand
Lipex 20	Tablet 20 mg	30	2.95	APO-Simvastatin; Chem mart Simvastatin; GenRx Simvastatin; Ransim; Simvabell; Simvahexal; Simvar 20; Simvastatin-DP; Simvastatin generichealth; Simvastatin-Spirit 20; Simvastatin Winthrop; Simvasyn; Terry White Chemists Simvastatin; Zimstat; GN brand
Lipex 40	Tablet 40 mg	30	2.95	APO-Simvastatin; Chem mart Simvastatin; GenRx Simvastatin; Ransim; Simvabell; Simvahexal; Simvar 40; Simvastatin-DP; Simvastatin generichealth; Simvastatin-Spirit 40; Simvastatin Winthrop; Simvasyn; Terry White Chemists Simvastatin; Zimstat; GN brand

Premium Priced Brand	Form and Strength	Max. Qty	Brand Premium \$	Benchmark Priced Brands
<i>Lipex 80</i>	Tablet 80 mg	30	2.95	APO-Simvastatin; Chem mart Simvastatin; GenRx Simvastatin; Ransim; Simvabell; Simvahexal; Simvar 80; Simvastatin-DP; Simvastatin generichealth; Simvastatin-Spirit 80; Simvastatin Winthrop; Simvasyn; Terry White Chemists Simvastatin; Zimstat; GN brand
<i>Liquifilm Forte</i>	Eye drops 30 mg per mL (3%), 15 mL	1	5.94	PVA Forte
<i>Liquifilm Tears</i>	Eye drops 14 mg per mL (1.4%), 15 mL	1	1.71	PVA Tears
<i>Lomotil</i>	Tablet 2.5 mg-25 micrograms	20	1.83	Lofenoxal
<i>Lopid</i>	Tablet 600 mg	60	2.95	Ausgem; Chem mart Gemfibrozil; Gemhexal; GenRx Gemfibrozil; Jezil; Lipazil 600 mg; Pharmacor Gemfibrozil 600; Terry White Chemists Gemfibrozil
<i>Losec Tablets</i>	Tablet 20 mg (as magnesium)	30	2.75	Acimax Tablets; APO-Omeprazole; Chem mart Omeprazole; GenRx Omeprazole; Meprazol; Omepral; Omeprazole-GA; Omeprazole Ranbaxy; Omeprazole Winthrop; Terry White Chemists Omeprazole
<i>Luvox</i>	Tablet 50 mg	30	2.96	APO-Fluvoxamine; Faverin 50; Movox 50; Voxam
	Tablet 100 mg	30	2.95	APO-Fluvoxamine; Faverin 100; Movox 100; Voxam
<i>Maxamox</i>	Tablet 1 g	14	1.17	Amoxycillin Sandoz
<i>Microgynon 30</i>	Tablets 150 micrograms-30 micrograms, 21	4	12.69	Levlen ED
<i>Microgynon 30 ED</i>	Pack containing 21 tablets 150 micrograms-30 micrograms and 7 inert tablets	4	12.69	Levlen ED
<i>Minidiab</i>	Tablet 5 mg	100	4.07	Melizide
<i>Minipress</i>	Tablet 1 mg (base)	100	2.95	Chem mart Prazosin; GenRx Prazosin; Pressin 1; Terry White Chemists Prazosin
	Tablet 2 mg (base)	100	3.04	Chem mart Prazosin; GenRx Prazosin; Pressin 2; Terry White Chemists Prazosin
	Tablet 5 mg (base)	100	3.29	Chem mart Prazosin; GenRx Prazosin; Pressin 5; Terry White Chemists Prazosin
<i>Minomycin-50</i>	Tablet 50 mg	60	0.85	Akamin 50
<i>Mobic</i>	Tablet 7.5 mg	30	1.61	Chem mart Meloxicam 7.5 mg; GenRx Meloxicam; Meloxibell; Meloxicam-GA; Meloxicam Ranbaxy; Meloxicam Sandoz; Meloxicam Winthrop; Movalis 7.5; Moxicam 7.5; Pharmacor Meloxicam 7.5; Terry White Chemists Meloxicam 7.5 mg

Premium Priced Brand	Form and Strength	Max. Qty	Brand Premium \$	Benchmark Priced Brands
	Tablet 15 mg	30	1.63	Chem mart Meloxicam 15 mg; GenRx Meloxicam; Meloxicabell; Meloxicam-GA; Meloxicam Ranbaxy; Meloxicam Sandoz; Meloxicam Winthrop; Movalis 15; Moxicam 15; Pharmacor Meloxicam 15; Terry White Chemists Meloxicam 15 mg
Mogadon	Tablet 5 mg	50	3.06	Alodorm
	Tablet 5 mg	25	1.53	Alodorm
Naprosyn	Tablet 250 mg	100	2.34	Inza 250
	Tablet 500 mg	50	1.36	Inza 500
Naprosyn SR1000	Tablet 1 g (sustained release)	28	1.34	Proxen SR 1000
Naprosyn SR750	Tablet 750 mg (sustained release)	28	1.27	Proxen SR 750
Natrilix	Tablet 2.5 mg	90	2.56	Chem mart Indapamide; Dapa-Tabs; GenRx Indapamide; Indahexal; Insig; Napamide 2.5 mg; Terry White Chemists Indapamide
Neoral 25	Capsule 25 mg	60	2.28	Cicloral
Neoral 50	Capsule 50 mg	60	2.24	Cicloral
Neoral 100	Capsule 100 mg	60	2.26	Cicloral
Neurontin	Capsule 100 mg	100	1.00	DBL Gabapentin; Gabatine 100; Gantin; Nupentin 100
	Capsule 300 mg	100	0.99	DBL Gabapentin; Douglas Gabapentin 300mg; Gabahexal 300mg; Gabapentin 300; Gabatine 300; Gantin; GenRx Gabapentin; Nupentin 300; Pendine 300
	Capsule 400 mg	100	1.00	DBL Gabapentin; Douglas Gabapentin 400mg; Gabahexal 400mg; Gabapentin 400; Gabatine 400; Gantin; GenRx Gabapentin; Nupentin 400; Pendine 400
	Tablet 600 mg	100	1.00	Gabahexal 600mg; Gabaran; GenRx Gabapentin
	Tablet 800 mg	100	1.00	Gabaran; Gantin; GenRx Gabapentin; Pendine 800
Nolvadex-D	Tablet 20 mg (base)	60	3.82	Chem mart Tamoxifen; Genox 20; GenRx Tamoxifen; Tamosin; Tamoxen 20 mg; Tamoxifen Sandoz; Terry White Chemists Tamoxifen
Nordette 28	Pack containing 21 tablets 150 micrograms-30 micrograms and 7 inert tablets	4	12.25	Monofeme 28
Noriday 28 Day	Tablets 350 micrograms, 28	4	4.00	Locilan 28 Day
Normison	Tablet 10 mg	25	1.38	Temaze; Temtabs
	Tablet 10 mg	50	2.76	Temaze; Temtabs
Noroxin	Tablet 400 mg	14	3.62	Chem mart Norfloxacin; GenRx Norfloxacin; Norfloxacin; Nufloxib; Roxin; Terry White Chemists Norfloxacin; GM brand
Norvasc	Tablet 5 mg (as besylate)	30	3.91	Amlo 5; Amlodipine-GA; Amlodipine generichealth; Amlodipine Sandoz; APO-Amlodipine; Chem mart Amlodipine; Ozlodip; Perivasc; Pharmacor Amlodipine 5; Terry White Chemists Amlodipine

Premium Priced Brand	Form and Strength	Max. Qty	Brand Premium \$	Benchmark Priced Brands
	Tablet 10 mg (as besylate)	30	5.68	<i>Amlor 10; Amlodipine-GA; Amlodipine generichealth; Amlodipine Sandoz; APO-Amlodipine; Chem mart Amlodipine; Ozlodip; Perivasc; Pharmacor Amlodipine 10; Terry White Chemists Amlodipine</i>
<i>Oroxine</i>	Tablet equivalent to 50 micrograms anhydrous thyroxine sodium	200	1.30	<i>Eutroxsig</i>
	Tablet equivalent to 75 micrograms anhydrous thyroxine sodium	200	1.46	<i>Eutroxsig</i>
	Tablet equivalent to 100 micrograms anhydrous thyroxine sodium	200	1.31	<i>Eutroxsig</i>
	Tablet equivalent to 200 micrograms anhydrous thyroxine sodium	200	1.29	<i>Eutroxsig</i>
<i>Orudis SR 200</i>	Capsule 200 mg (sustained release)	28	2.30	<i>Oruvail SR</i>
<i>Panadeine Forte</i>	Tablet 30 mg-500 mg	20	2.80	<i>Codalgin Forte; Codapane Forte; Comfarol Forte; Dolaforte; Prodeine Forte</i>
	Tablet 30 mg-500 mg	60	8.40	<i>Codalgin Forte; Codapane Forte; Comfarol Forte; Dolaforte; Prodeine Forte</i>
<i>Panafcort</i>	Tablet 1 mg	100	0.65	<i>Predsone</i>
<i>Panafcortelone</i>	Tablet 1 mg	100	0.46	<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; Famohexal; GenRx Famotidine; Pamacid 40; Pepzan; Terry White Chemists Famotidine</i>
<i>Pepcidine M</i>	Tablet 20 mg	60	4.25	<i>Ausfam 20; Chem mart Famotidine; Famohexal; GenRx Famotidine; Pamacid 20; Pepzan; Terry White Chemists Famotidine</i>
<i>Plendil ER</i>	Tablet 2.5 mg (extended release)	30	5.00	<i>Felodur ER 2.5 mg</i>
	Tablet 5 mg (extended release)	30	5.00	<i>Felodil XR 5; Felodur ER 5 mg</i>
	Tablet 10 mg (extended release)	30	5.00	<i>Felodil XR 10; Felodur ER 10 mg</i>
<i>Pravachol</i>	Tablet 10 mg	30	3.52	<i>Chem mart Pravastatin; Cholstat 10; GenRx Pravastatin; Lipostat 10; Liprachol; Pravastatin 10; Pravastatin-DP; Pravastatin-GA 10; Pravastatin generichealth; Pravastatin Winthrop; Terry White Chemists Pravastatin</i>
	Tablet 20 mg	30	3.52	<i>APO-Pravastatin; Chem mart Pravastatin; Cholstat 20; GenRx Pravastatin; Lipostat 20; Liprachol; Pravastatin 20; Pravastatin-DP; Pravastatin-GA 20; Pravastatin generichealth; Pravastatin Winthrop; Terry White Chemists Pravastatin; Vastoran</i>

Premium Priced Brand	Form and Strength	Max. Qty	Brand Premium \$	Benchmark Priced Brands
	Tablet 40 mg	30	3.07	APO-Pravastatin; Chem mart Pravastatin; Cholstat 40; GenRx Pravastatin; Lipostat 40; Liprachol; Pravastatin 40; Pravastatin-DP; Pravastatin-GA 40; Pravastatin generichealth; Pravastatin Winthrop; Terry White Chemists Pravastatin; Vastoran
	Tablet 80 mg	30	3.37	APO-Pravastatin; Chem mart Pravastatin; Lipostat 80; Pravastatin-GA 80; Pravastatin generichealth; Terry White Chemists Pravastatin
Prinivil 5	Tablet 5 mg	30	3.35	APO-Lisinopril; Chem mart Lisinopril; Fibsol 5; GenRx Lisinopril; Liprace; Lisinobell; Lisinopril 5; Lisinopril generichealth; Lisinopril Hexal; Lisinopril Ranbaxy; Lisinopril Winthrop; Lisodur; Terry White Chemists Lisinopril
Prinivil 10	Tablet 10 mg	30	3.35	APO-Lisinopril; Chem mart Lisinopril; Fibsol 10; GenRx Lisinopril; Liprace; Lisinobell; Lisinopril 10; Lisinopril generichealth; Lisinopril Hexal; Lisinopril Ranbaxy; Lisinopril Winthrop; Lisodur; Terry White Chemists Lisinopril
Prinivil 20	Tablet 20 mg	30	3.35	APO-Lisinopril; Chem mart Lisinopril; Fibsol 20; GenRx Lisinopril; Liprace; Lisinobell; Lisinopril 20; Lisinopril generichealth; Lisinopril Hexal; Lisinopril Ranbaxy; Lisinopril Winthrop; Lisodur; Terry White Chemists Lisinopril
Prothiaden	Capsule 25 mg	50	1.58	Dothep 25
	Tablet 75 mg	30	0.81	Dothep 75
Provera	Tablet 5 mg	56	1.74	Ralovera
	Tablet 10 mg	30	1.75	Medroxyhexal; Ralovera
	Tablet 10 mg	100	1.64	Ralovera
Prozac Tab	Tablet 20 mg (base) (dispersible)	28	4.13	Lovan 20 Tab
Prozac 20	Capsule 20 mg (base)	28	4.13	Auscap; Chem mart Fluoxetine; Fluohexal; Fluoxebell; Fluoxetine 20; Fluoxetine-DP; GenRx Fluoxetine; Lovan; Terry White Chemists Fluoxetine; Zactin
Quinate	Tablet 300 mg	50	2.17	Quinsul
Redipred	Oral solution equivalent to 5 mg prednisolone per mL, 30 mL	1	1.86	PredMix
Renitec	Tablet 10 mg	30	4.30	Alphapril; Auspril; Chem mart Enalapril; Enahexal; Enalabell; Enalapril-DP 10mg; Enalapril generichealth; Enalapril Winthrop; GenRx Enalapril; Terry White Chemists Enalapril

Premium Priced Brand	Form and Strength	Max. Qty	Brand Premium \$	Benchmark Priced Brands
<i>Renitec M</i>	Tablet 5 mg	30	4.30	<i>Alphapril; Auspril; Chem mart Enalapril; Enahexal; Enalabell; Enalapril-DP 5mg; Enalapril generichealth; Enalapril Winthrop; GenRx Enalapril; Terry White Chemists Enalapril</i>
<i>Renitec 20</i>	Tablet 20 mg	30	4.30	<i>Alphapril; Auspril; Chem mart Enalapril; Enahexal; Enalabell; Enalapril-DP 20mg; Enalapril generichealth; GenRx Enalapril; Terry White Chemists Enalapril</i>
<i>Rivotril</i>	Tablet 500 micrograms	200	3.58	<i>Paxam 0.5</i>
	Tablet 2 mg	200	4.08	<i>Paxam 2</i>
	Tablet 500 micrograms	100	1.79	<i>Paxam 0.5</i>
	Tablet 2 mg	100	2.04	<i>Paxam 2</i>
<i>Roaccutane</i>	Capsule 20 mg	60	2.37	<i>GenRx Isotretinoin; Oratane</i>
<i>Rulide</i>	Tablet 150 mg	10	2.60	<i>APO-Roxithromycin; Biaxsig; Chem mart Roxithromycin; Roxar 150; Roxide; Roximycin; Terry White Chemists Roxithromycin</i>
	Tablet 300 mg	5	2.60	<i>APO-Roxithromycin; Biaxsig; Chem mart Roxithromycin; Roxar 300; Roxide; Roximycin; Terry White Chemists Roxithromycin</i>
<i>Salazopyrin-EN</i>	Tablet 500 mg (enteric coated)	200	1.60	<i>Pyralin EN</i>
<i>Septrin Forte</i>	Tablet 160 mg-800 mg	10	1.10	<i>Bactrim DS; Resprim Forte</i>
<i>Serepax</i>	Tablet 15 mg	25	1.78	<i>Alepam 15</i>
	Tablet 30 mg	25	1.90	<i>Alepam 30; Murelax</i>
	Tablet 15 mg	50	3.56	<i>Alepam 15</i>
	Tablet 30 mg	50	3.80	<i>Alepam 30; Murelax</i>
<i>Serophene</i>	Tablet 50 mg	10	0.14	<i>Clomhexal; Fermil; GenRx Clomiphene</i>
<i>Sigmacort</i>	Cream 10 mg per g (1%), 50 g	1	1.91	<i>Cortic-DS 1%</i>
	Cream 10 mg per g (1%), 50 g	1	1.91	<i>Cortic-DS 1%</i>
	Cream 10 mg per g (1%), 30 g	1	1.90	<i>Cortic-DS 1%</i>
	Topical ointment 10 mg per g (1%), 30 g	1	1.90	<i>Cortic-DS 1%</i>
	Topical ointment 10 mg per g (1%), 50 g	1	1.91	<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	2.80	<i>Duro-K</i>
<i>Sofradex</i>	Ear drops 500 micrograms-5 mg-50 micrograms per mL, 8 mL	1	2.00	<i>Otodex</i>
<i>Sotacor</i>	Tablet 80 mg	60	4.50	<i>GenRx Sotalol; Solavert; Sotahexal</i>
	Tablet 160 mg	60	4.50	<i>Cardol; Chem mart Sotalol; GenRx Sotalol; Solavert; Sotab; Sotahexal; Terry White Chemists Sotalol</i>
<i>Stemetil</i>	Tablet containing prochlorperazine maleate 5 mg	25	2.50	<i>Stemzine</i>
<i>Synphasic</i>	Pack containing 12 tablets	4	7.92	<i>Improvil 28 Day</i>
	500 micrograms-35 micrograms, 9 tablets			
	1 mg-35 micrograms and 7 inert tablets			
<i>Tagamet</i>	Tablet 200 mg	120	1.94	<i>Magicul 200</i>
	Tablet 400 mg	60	1.94	<i>GenRx Cimetidine; Magicul 400</i>
<i>Tazac</i>	Capsule 150 mg	60	5.60	<i>Nizac; Tacidine</i>
	Capsule 300 mg	30	5.60	<i>Nizac; Tacidine</i>
<i>Tears Naturale</i>	Eye drops 3 mg-1 mg per mL (0.3%-0.1%), 15 mL	1	1.87	<i>Poly-Tears</i>

Premium Priced Brand	Form and Strength	Max. Qty	Brand Premium \$	Benchmark Priced Brands
<i>Tegretol 100</i>	Tablet 100 mg	200	2.55	<i>Carbamazepine Sandoz</i>
<i>Tegretol 200</i>	Tablet 200 mg	200	2.74	<i>Carbamazepine Sandoz; Teril</i>
<i>Tenormin</i>	Tablet 50 mg	30	3.54	<i>Atehexal; Atenolol-GA; Chem mart Atenolol; GenRx Atenolol; Noten; Tensig; Terry White Chemists Atenolol</i>
<i>Timoptol</i>	Eye drops 2.5 mg (base) per mL (0.25%), 5 mL	1	2.95	<i>Tenopt</i>
	Eye drops 5 mg (base) per mL (0.5%), 5 mL	1	2.95	<i>Tenopt</i>
<i>Tofranil 10</i>	Tablet 10 mg	50	2.97	<i>Tolerade 10</i>
<i>Tofranil 25</i>	Tablet 25 mg	50	2.97	<i>Tolerade 25</i>
<i>Tolvon</i>	Tablet 10 mg	50	1.99	<i>Lumin 10</i>
	Tablet 20 mg	50	2.97	<i>Lumin 20</i>
<i>Tramal</i>	Capsule 50 mg	20	2.42	<i>Chem mart Tramadol; GenRx Tramadol; Terry White Chemists Tramadol; Tramedo; Zydol</i>
<i>Tramal SR 100</i>	Tablet 100 mg (twice daily sustained release)	20	4.51	<i>Tramahexal SR; Tramedo SR 100; Zydol SR 100</i>
<i>Tramal SR 150</i>	Tablet 150 mg (twice daily sustained release)	20	5.37	<i>Tramahexal SR; Tramedo SR 150; Zydol SR 150</i>
<i>Tramal SR 200</i>	Tablet 200 mg (twice daily sustained release)	20	6.09	<i>Tramahexal SR; Tramedo SR 200; Zydol SR 200</i>
<i>Trandate</i>	Tablet 100 mg	100	2.99	<i>Presolol 100</i>
	Tablet 200 mg	100	2.97	<i>Presolol 200</i>
<i>Triphasil 28</i>	Pack containing 6 tablets	4	12.25	<i>Trifeme 28</i>
	50 micrograms-30 micrograms, 5 tablets			
	75 micrograms-40 micrograms, 10 tablets			
	125 micrograms-30 micrograms and 7 inert tablets			
<i>Triprim</i>	Tablet 300 mg	7	1.03	<i>Alprim</i>
<i>Triquilar ED</i>	Pack containing 6 tablets	4	12.69	<i>Logynon ED</i>
	50 micrograms-30 micrograms, 5 tablets			
	75 micrograms-40 micrograms, 10 tablets			
	125 micrograms-30 micrograms and 7 inert tablets			
<i>Valium</i>	Tablet 2 mg	50	0.86	<i>Antenex 2; Valpam 2</i>
	Tablet 5 mg	50	0.88	<i>Antenex 5; Diazepam-DP; Ranzepam; Valpam 5</i>
<i>Vastin</i>	Capsule 20 mg (fluvastatin)	28	3.28	<i>Lescol</i>
	Capsule 40 mg (fluvastatin)	28	3.58	<i>Lescol</i>
<i>Ventolin CFC-free</i>	Oral pressurised inhalation 100 micrograms (base) per dose (200 doses), CFC-free formulation	2	1.18	<i>Airomir; Asmol CFC-free</i>
<i>Ventolin Nebules</i>	Nebuliser solution single dose units 2.5 mg (base) in 2.5 mL, 30	2	1.46	<i>Asmol 2.5 uni-dose; Butamol 2.5; GenRx Salbutamol; Pharmacor Salbutamol 2.5; Salbutamol-GA; Salbutamol Sandoz; PU brand</i>
	Nebuliser solution single dose units 5 mg (base) in 2.5 mL, 30	2	1.46	<i>Asmol 5 uni-dose; Butamol 5; GenRx Salbutamol; Pharmacor Salbutamol 5; Salbutamol-GA; Salbutamol Sandoz</i>
<i>Vibramycin</i>	Tablet 100 mg (as hydrochloride)	7	1.19	<i>Chem mart Doxycycline; Doxsig; Doxy-100; Doxyhexal; Doxylin 100; GenRx Doxycycline; Terry White Chemists Doxycycline</i>
	Tablet 100 mg (as hydrochloride)	28	4.76	<i>Chem mart Doxycycline; Doxsig; Doxy-100; Doxyhexal; Doxylin 100; GenRx Doxycycline; Terry White Chemists Doxycycline</i>

Premium Priced Brand	Form and Strength	Max. Qty	Brand Premium \$	Benchmark Priced Brands
	Tablet 100 mg (as hydrochloride)	21	3.57	<i>Chem mart Doxycycline; Doxig; Doxy-100; Doxyhexal; Doxylin 100; GenRx Doxycycline; Terry White Chemists Doxycycline</i>
<i>Vibra-Tabs</i>	Tablet 50 mg (as hydrochloride)	25	1.25	<i>Chem mart Doxycycline; Doxy-50; Doxyhexal; Doxylin 50; Frakas; GenRx Doxycycline; Terry White Chemists Doxycycline</i>
<i>Viscotears</i>	Eye gel 2 mg per g (0.2%), 10 g	1	1.00	<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>
<i>Voltaren 25</i>	Tablet 25 mg (enteric coated)	100	1.96	<i>Chem mart Diclofenac; Clonac 25; Diclofenac-GA; Diclohexal; Dinac; Fenac 25; GenRx Diclofenac; Terry White Chemists Diclofenac</i>
<i>Voltaren 50</i>	Tablet 50 mg (enteric coated)	50	1.96	<i>Chem mart Diclofenac; Clonac 50; Diclohexal; Dinac; Fenac; GenRx Diclofenac; Terry White Chemists Diclofenac</i>
<i>Xanax</i>	Tablet 250 micrograms	50	1.04	<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	1.71	<i>Ausran; Chem mart Ranitidine; GenRx Ranitidine; Rani 2; Ranihexal; Ranoxyl; Terry White Chemists Ranitidine; Ulcaid</i>
	Tablet 300 mg (base)	30	1.71	<i>Ausran; Chem mart Ranitidine; GenRx Ranitidine; Rani 2; Ranihexal; Ranoxyl; Terry White Chemists Ranitidine; Ulcaid</i>
<i>Zestril</i>	Tablet 5 mg	30	2.08	<i>APO-Lisinopril; Chem mart Lisinopril; Fibsol 5; GenRx Lisinopril; Liprace; Lisinobell; Lisinopril 5; Lisinopril generichealth; Lisinopril Hexal; Lisinopril Ranbaxy; Lisinopril Winthrop; Lisodur; Terry White Chemists Lisinopril</i>
	Tablet 10 mg	30	2.08	<i>APO-Lisinopril; Chem mart Lisinopril; Fibsol 10; GenRx Lisinopril; Liprace; Lisinobell; Lisinopril 10; Lisinopril generichealth; Lisinopril Hexal; Lisinopril Ranbaxy; Lisinopril Winthrop; Lisodur; Terry White Chemists Lisinopril</i>

Premium Priced Brand	Form and Strength	Max. Qty	Brand Premium \$	Benchmark Priced Brands
Zocor	Tablet 20 mg	30	2.08	APO-Lisinopril; Chem mart Lisinopril; Fibsol 20; GenRx Lisinopril; Liprace; Lisinobell; Lisinopril 20; Lisinopril generichealth; Lisinopril Hexal; Lisinopril Ranbaxy; Lisinopril Winthrop; Lisodur; Terry White Chemists Lisinopril
	Tablet 10 mg	30	2.95	APO-Simvastatin; Chem mart Simvastatin; GenRx Simvastatin; Ransim; Simvabell; Simvahexal; Simvar 10; Simvastatin-DP; Simvastatin generichealth; Simvastatin-Spirit 10; Simvastatin Winthrop; Simvasyn; Terry White Chemists Simvastatin; Zimstat; GN brand
	Tablet 20 mg	30	2.95	APO-Simvastatin; Chem mart Simvastatin; GenRx Simvastatin; Ransim; Simvabell; Simvahexal; Simvar 20; Simvastatin-DP; Simvastatin generichealth; Simvastatin-Spirit 20; Simvastatin Winthrop; Simvasyn; Terry White Chemists Simvastatin; Zimstat; GN brand
	Tablet 40 mg	30	2.95	APO-Simvastatin; Chem mart Simvastatin; GenRx Simvastatin; Ransim; Simvabell; Simvahexal; Simvar 40; Simvastatin-DP; Simvastatin generichealth; Simvastatin-Spirit 40; Simvastatin Winthrop; Simvasyn; Terry White Chemists Simvastatin; Zimstat; GN brand
	Tablet 80 mg	30	2.95	APO-Simvastatin; Chem mart Simvastatin; GenRx Simvastatin; Ransim; Simvabell; Simvahexal; Simvar 80; Simvastatin-DP; Simvastatin generichealth; Simvastatin-Spirit 80; Simvastatin Winthrop; Simvasyn; Terry White Chemists Simvastatin; Zimstat; GN brand
Zofran	Tablet 5 mg	30	2.95	Simvabell; Simvahexal; Simvasyn; Zimstat
	Tablet 4 mg	4	0.62	APO-Ondansetron; Ondansetron-RL; Ondaz; Onsetron 4
	Tablet 8 mg	4	0.69	APO-Ondansetron; Ondansetron-RL; Ondaz; Onsetron 8
	I.V. injection 4 mg in 2 mL	1	0.70	Ondansetron-RL; Ondaz; Onsetron; PF brand
	I.V. injection 8 mg in 4 mL	1	0.69	Ondansetron-RL; Ondaz; Onsetron; PF brand
	Tablet 4 mg	10	0.69	APO-Ondansetron; Ondansetron-RL; Ondaz; Onsetron 4

Premium Priced Brand	Form and Strength	Max. Qty	Brand Premium \$	Benchmark Priced Brands
Zofran Zydis	Tablet 8 mg	10	0.67	APO-Ondansetron; Ondansetron-RL; Ondaz; Onsetron 8
	Wafer 4 mg	4	0.62	Ondansetron-RL Zydis; Ondaz Zydis
	Wafer 8 mg	4	0.69	Ondansetron-RL Zydis; Ondaz Zydis
	Wafer 4 mg	10	0.69	Ondansetron-RL Zydis; Ondaz Zydis
Zoloft	Wafer 8 mg	10	0.67	Ondansetron-RL Zydis; Ondaz Zydis
	Tablet 50 mg (base)	30	1.49	Chem mart Sertraline; Concorz; Eleva 50; GenRx Sertraline; Sertra 50; Sertraline 50; Sertraline-GA; Sertraline generichealth; Sertraline Winthrop; Setrona; Terry White Chemists Sertraline; Xydep 50
	Tablet 100 mg (base)	30	1.49	Chem mart Sertraline; Concorz; Eleva 100; GenRx Sertraline; Sertra 100; Sertraline 100; Sertraline-GA; Sertraline generichealth; Sertraline Winthrop; Setrona; Terry White Chemists Sertraline; Xydep 100
Zovirax 200 mg	Tablet 200 mg	50	4.34	Acihexal; Acyclo-V 200; GenRx Aciclovir; Lovir
	Tablet 200 mg	90	3.21	Aciclovir 200; Acihexal; Acyclo-V 200; Chem mart Aciclovir; GenRx Aciclovir; Lovir; Ozvir; Terry White Chemists Aciclovir
Zovirax 800 mg	Tablet 800 mg	35	1.56	Aciclovir 800; Acihexal; Acyclo-V 800; GenRx Aciclovir; Lovir
Zyban	Tablet 800 mg	120	5.19	Acihexal; Acyclo-V 800; Lovir
	Tablet 150 mg (sustained release)	30	0.85	Clorprax; Prexaton
Zyloprim	Tablet 150 mg (sustained release)	90	0.86	Clorprax; Prexaton
	Tablet 100 mg	200	1.91	Allohexal; Allosig; Chem mart Allopurinol; GenRx Allopurinol; Progout 100; Terry White Chemists Allopurinol
	Tablet 300 mg	60	1.80	Allohexal; Allosig; Chem mart Allopurinol; GenRx Allopurinol; Progout 300; Terry White Chemists Allopurinol