



Australian Government

Department of Health and Ageing

**SCHEDULE OF PHARMACEUTICAL
BENEFITS**

SUMMARY OF CHANGES

EFFECTIVE 1 FEBRUARY 2011

PHARMACEUTICAL BENEFITS

These changes to the Schedule of Pharmaceutical Benefits are effective from 1 February 2011. 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 February 2011 and are included, where applicable, in prices published in the Schedule —

Dispensing Fees:	Ready-prepared	\$6.42
	Dangerous drug fee	\$2.71
	Extemporaneously-prepared	\$8.46
	Allowable additional patient charge*	\$3.92
Additional Fees (for safety net prices):	Ready-prepared	\$1.07
	Extemporaneously-prepared	\$1.41
Patient Co-payments:	General	\$34.20
	Concessional	\$5.60
Safety Net Thresholds:	General	\$1317.20
	Concessional	\$336.00
Safety Net Card Issue Fee:		\$8.58

*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

5466Q	Amino Acid Synthetic Formula supplemented with Long Chain Polyunsaturated Fatty Acids and Medium Chain Triglycerides , Compound powder 400 g (<i>Neocate LCP+MCT</i>)
5467R	Amino Acid Synthetic Formula supplemented with Long Chain Polyunsaturated Fatty Acids and Medium Chain Triglycerides , Compound powder 400 g (<i>Neocate LCP+MCT</i>) (Diff. Max. Rpts)
5468T	Dutasteride , Capsule 500 micrograms (<i>Avodart</i>)
3414Q	Nicotine , Transdermal patch releasing approximately 21 mg per 24 hours (<i>Nicotinell Step 1</i>)
5465P	Nicotine , Transdermal patch releasing approximately 21 mg per 24 hours (<i>Nicabate P</i>)
5469W	Varenicline , Tablet 1 mg (as tartrate) (<i>Champix</i>)

Additions — Brands

2132F	<i>Ralozam, GM</i> — Alprazolam , Tablet 1 mg
8118G	<i>Ralozam, GM</i> — Alprazolam , Tablet 2 mg

8202Q	<i>Mayne Pharma Aspirin, YT</i> — Aspirin , Tablet 100 mg
8200N	<i>Zitrocin, GM</i> — Azithromycin , Tablet 500 mg (as dihydrate)
8336R	<i>Zitrocin, GM</i> — Azithromycin , Tablet 500 mg (as dihydrate) (Diff. Max. Rpts)
8115D	<i>Dostan, GM</i> — Cabergoline , Tablet 500 micrograms
8114C	<i>Dostan, GM</i> — Cabergoline , Tablet 500 micrograms (Diff. Max. Qty & Rpts)
8393R	<i>Cobasol, GM</i> — Cabergoline , Tablet 1 mg
8394T	<i>Cobasol, GM</i> — Cabergoline , Tablet 2 mg
8315P	<i>DBL Cefepime, HH</i> — Cefepime , Powder for injection 1 g (as hydrochloride) (solvent required) (code 7079N applies to above item with approved solvents)
8316Q	<i>DBL Cefepime, HH</i> — Cefepime , Powder for injection 2 g (as hydrochloride) (solvent required) (code 7085X applies to above item with approved solvents)
1370D	<i>Acetec, AL</i> — Enalapril , Tablet containing enalapril maleate 5 mg
1368B	<i>Acetec, AL</i> — Enalapril , Tablet containing enalapril maleate 10 mg
1369C	<i>Acetec, AL</i> — Enalapril , Tablet containing enalapril maleate 20 mg
1473M	<i>Fluconazole Sandoz, SZ</i> — Fluconazole , Solution for I.V. infusion 100 mg in 50 mL
8512B	<i>Fluvoxamine GA, GM</i> — Fluvoxamine , Tablet containing fluvoxamine maleate 50 mg
8174F	<i>Fluvoxamine GA, GM</i> — Fluvoxamine , Tablet containing fluvoxamine maleate 100 mg
8049P	<i>Gemplan, WQ</i> — Gemcitabine , Powder for I.V. infusion 200 mg (as hydrochloride)
8050Q	<i>Gemplan, WQ</i> — Gemcitabine , Powder for I.V. infusion 1 g (as hydrochloride)
8534E	<i>Lercadip, GM</i> — Lercanidipine Hydrochloride , Tablet 10 mg
8679T	<i>Lercadip, GM</i> — Lercanidipine Hydrochloride , Tablet 20 mg
2457H	<i>Lisinopril Sandoz, SZ</i> — Lisinopril , Tablet 10 mg
8607B	<i>APO-Metformin 1000, TX; Chem mart Metformin 1000, CH; Terry White Chemists Metformin 1000, TW</i> — Metformin Hydrochloride , Tablet 1 g
8224W	<i>Ondansetron-DRLA, RZ</i> — Ondansetron , Tablet 4 mg (as hydrochloride dihydrate)
1594X	<i>Ondansetron-DRLA, RZ</i> — Ondansetron , Tablet 4 mg (as hydrochloride dihydrate) (Diff. Max. Qty & Rpts)
8225X	<i>Ondansetron-DRLA, RZ</i> — Ondansetron , Tablet 8 mg (as hydrochloride dihydrate)
1595Y	<i>Ondansetron-DRLA, RZ</i> — Ondansetron , Tablet 8 mg (as hydrochloride dihydrate) (Diff. Max. Qty & Rpts)
9346X	<i>Reaptan 5/5, RX</i> — Perindopril with Amlodipine , Tablet containing 5 mg perindopril arginine with 5 mg amlodipine (as besylate)
9347Y	<i>Reaptan 5/10, RX</i> — Perindopril with Amlodipine , Tablet containing 5 mg perindopril arginine with 10 mg amlodipine (as besylate)
9348B	<i>Reaptan 10/5, RX</i> — Perindopril with Amlodipine , Tablet containing 10 mg perindopril arginine with 5 mg amlodipine (as besylate)
9349C	<i>Reaptan 10/10, RX</i> — Perindopril with Amlodipine , Tablet containing 10 mg perindopril arginine with 10 mg amlodipine (as besylate)
8869T	<i>Risperidone Sandoz, SZ</i> — Risperidone , Tablet 0.5 mg
8787L	<i>Risperidone Sandoz, SZ</i> — Risperidone , Tablet 0.5 mg (Diff. Max. Rpts)
3169T	<i>Risperidone Sandoz, SZ</i> — Risperidone , Tablet 1 mg
8789N	<i>Risperidone Sandoz, SZ</i> — Risperidone , Tablet 1 mg (Diff. Max. Rpts)
3170W	<i>Risperidone Sandoz, SZ</i> — Risperidone , Tablet 2 mg
9079W	<i>Risperidone Sandoz, SZ</i> — Risperidone , Tablet 2 mg (Diff. Max. Rpts)
3171X	<i>Risperidone Sandoz, SZ</i> — Risperidone , Tablet 3 mg
3172Y	<i>Risperidone Sandoz, SZ</i> — Risperidone , Tablet 4 mg

2236Q	<i>Sertracor 50, MI</i> — Sertraline , Tablet 50 mg (as hydrochloride)
2237R	<i>Sertracor 100, MI</i> — Sertraline , Tablet 100 mg (as hydrochloride)
8144P	<i>Sumatriptan-GA, GM</i> — Sumatriptan , Tablet 50 mg (as succinate)
8133C	<i>Zelitrex, RE</i> — Valaciclovir , Tablet 500 mg (as hydrochloride)
8064K	<i>Zelitrex, RE</i> — Valaciclovir , Tablet 500 mg (as hydrochloride) (Diff. Max. Qty)
8134D	<i>Zelitrex, RE</i> — Valaciclovir , Tablet 500 mg (as hydrochloride) (Diff. Max. Qty & Rpts)
3130R	<i>Vancomycin Alphapharm, AF</i> — Vancomycin , Powder for injection 500 mg (as hydrochloride) (500,000 i.u. vancomycin activity)
3131T	<i>Vancomycin Alphapharm, AF</i> — Vancomycin , Powder for injection 500 mg (as hydrochloride) (500,000 i.u. vancomycin activity) (Diff. Max. Qty)
2269K	<i>Vancomycin Alphapharm, AF</i> — Vancomycin , Powder for injection 1 g (as hydrochloride) (1,000,000 i.u. vancomycin activity)
2270L	<i>Vancomycin Alphapharm, AF</i> — Vancomycin , Powder for injection 1 g (as hydrochloride) (1,000,000 i.u. vancomycin activity) (Diff. Max. Qty)
3323X	<i>Vancomycin Alphapharm, AF</i> — Vancomycin , Powder for injection 500 mg (as hydrochloride) (500,000 i.u. vancomycin activity) (Dental)
5083M	<i>Vancomycin Alphapharm, AF</i> — Vancomycin , Powder for injection 1 g (as hydrochloride) (1,000,000 i.u. vancomycin activity) (Dental)

Additions — Bioequivalence Indicators

8115D	<i>Dostinex, PF</i> — Cabergoline , Tablet 500 micrograms
9346X	<i>Coveram, SE</i> — Perindopril with Amlodipine , Tablet containing 5 mg perindopril arginine with 5 mg amlodipine (as besylate)
9347Y	<i>Coveram, SE</i> — Perindopril with Amlodipine , Tablet containing 5 mg perindopril arginine with 10 mg amlodipine (as besylate)
9348B	<i>Coveram, SE</i> — Perindopril with Amlodipine , Tablet containing 10 mg perindopril arginine with 5 mg amlodipine (as besylate)
9349C	<i>Coveram, SE</i> — Perindopril with Amlodipine , Tablet containing 10 mg perindopril arginine with 10 mg amlodipine (as besylate)
8133C	<i>Valtrex, GK</i> — Valaciclovir , Tablet 500 mg (as hydrochloride)
8064K	<i>Valtrex, GK</i> — Valaciclovir , Tablet 500 mg (as hydrochloride) (Diff. Max. Qty)
8134D	<i>Valtrex, GK</i> — Valaciclovir , Tablet 500 mg (as hydrochloride) (Diff. Max. Qty & Rpts)

DELETIONS

Deletions — Items

1497T	Hydrocortisone Acetate , Eye ointment 5 mg per g (0.5%), 5 g (<i>Hycor</i>)
5515G	Hydrocortisone Acetate , Eye ointment 5 mg per g (0.5%), 5 g (<i>Hycor</i>) (Optometrical)

Deletions — Brands

1368B	<i>Enahexal, HX</i> — Enalapril , Tablet containing enalapril maleate 10 mg
1369C	<i>Enahexal, HX</i> — Enalapril , Tablet containing enalapril maleate 20 mg
1370D	<i>Enahexal, HX</i> — Enalapril , Tablet containing enalapril maleate 5 mg
2487X	<i>Famohexal, HX</i> — Famotidine , Tablet 20 mg

ALTERATIONS

Alterations — Item Description

From:

8200N **Azithromycin**, Tablet 500 mg (*Zithromax, Azithromycin Sandoz, Zitrocin*)

To:

8200N **Azithromycin**, Tablet 500 mg (as dihydrate) (*Zithromax, Azithromycin Sandoz, Zitrocin*)

From:

8336R **Azithromycin**, Tablet 500 mg (*Zithromax, Azithromycin Sandoz, Zitrocin*)

To:

8336R **Azithromycin**, Tablet 500 mg (as dihydrate) (*Zithromax, Azithromycin Sandoz, Zitrocin*)

From:

8201P **Azithromycin**, Powder for oral suspension 200 mg per 5 mL, 15 mL (*Zithromax*)

To:

8201P **Azithromycin**, Powder for oral suspension 200 mg (as dihydrate) per 5 mL, 15 mL (*Zithromax*)

From:

8512B **Fluvoxamine Maleate**, Tablet 50 mg (*Luvox, Faverin 50, Movox 50, Voxam, APO-Fluvoxamine, Fluvoxamine GA*)

To:

8512B **Fluvoxamine**, Tablet containing fluvoxamine maleate 50 mg (*Luvox, Faverin 50, Movox 50, Voxam, APO-Fluvoxamine, Fluvoxamine GA*)

From:

8174F **Fluvoxamine Maleate**, Tablet 100 mg (*Luvox, Faverin 100, Movox 100, Voxam, APO-Fluvoxamine, Fluvoxamine GA*)

To:

8174F **Fluvoxamine**, Tablet containing fluvoxamine maleate 100 mg (*Luvox, Faverin 100, Movox 100, Voxam, APO-Fluvoxamine, Fluvoxamine GA*)

From:

8224W **Ondansetron**, Tablet 4 mg (*Zofran, Ondaz, Onsetron 4, APO-Ondansetron, Ondansetron-DRLA*)

To:

8224W **Ondansetron**, Tablet 4 mg (as hydrochloride dihydrate) (*Zofran, Ondaz, Onsetron 4, APO-Ondansetron, Ondansetron-DRLA*)

From:

1594X **Ondansetron**, Tablet 4 mg (*Zofran, Ondaz, Onsetron 4, APO-Ondansetron, Ondansetron-DRLA*) **(Diff. Max. Qty & Rpts)**

To:

1594X **Ondansetron**, Tablet 4 mg (as hydrochloride dihydrate) (*Zofran, Ondaz, Onsetron 4, APO-Ondansetron, Ondansetron-DRLA*) **(Diff. Max. Qty & Rpts)**

From:

8225X **Ondansetron**, Tablet 8 mg (*Zofran, Ondaz, Onsetron 8, APO-Ondansetron, Ondansetron-DRLA*)

To:

8225X **Ondansetron**, Tablet 8 mg (as hydrochloride dihydrate) (*Zofran, Ondaz, Onsetron 8, APO-Ondansetron, Ondansetron-DRLA*)

From:

1595Y **Ondansetron**, Tablet 8 mg (*Zofran, Ondaz, Onsetron 8, APO-Ondansetron, Ondansetron-DRLA*) **(Diff. Max. Qty & Rpts)**

To:
1595Y **Ondansetron**, Tablet 8 mg (as hydrochloride dihydrate) (*Zofran, Ondaz, Onsetron 8, APO-Ondansetron, Ondansetron-DRLA*) (**Diff. Max. Qty & Rpts**)

From:
1596B **Ondansetron**, I.V. injection 4 mg in 2 mL (*Zofran, Pfizer Australia Pty Ltd, Ondaz, Onsetron, Ondansetron-Claris*)

To:
1596B **Ondansetron**, I.V. injection 4 mg (as hydrochloride dihydrate) in 2 mL (*Zofran, Pfizer Australia Pty Ltd, Ondaz, Onsetron, Ondansetron-Claris*)

From:
1597C **Ondansetron**, I.V. injection 8 mg in 4 mL (*Zofran, Pfizer Australia Pty Ltd, Ondaz, Onsetron, Ondansetron-Claris*)

To:
1597C **Ondansetron**, I.V. injection 8 mg (as hydrochloride dihydrate) in 4 mL (*Zofran, Pfizer Australia Pty Ltd, Ondaz, Onsetron, Ondansetron-Claris*)

From:
8226Y **Ondansetron**, I.V. injection 4 mg in 2 mL (*Zofran, Pfizer Australia Pty Ltd, Ondaz, Onsetron, Ondansetron-Claris*)

To:
8226Y **Ondansetron**, I.V. injection 4 mg (as hydrochloride dihydrate) in 2 mL (*Zofran, Pfizer Australia Pty Ltd, Ondaz, Onsetron, Ondansetron-Claris*)

From:
8227B **Ondansetron**, I.V. injection 8 mg in 4 mL (*Zofran, Pfizer Australia Pty Ltd, Ondaz, Onsetron, Ondansetron-Claris*)

To:
8227B **Ondansetron**, I.V. injection 8 mg (as hydrochloride dihydrate) in 4 mL (*Zofran, Pfizer Australia Pty Ltd, Ondaz, Onsetron, Ondansetron-Claris*)

From:
8233H **Ondansetron**, Syrup 4 mg per 5 mL, 50 mL (*Zofran syrup 50 mL*)

To:
8233H **Ondansetron**, Syrup 4 mg (as hydrochloride dihydrate) per 5 mL, 50 mL (*Zofran syrup 50 mL*)

From:
9441X **Ondansetron**, Syrup 4 mg per 5 mL, 50 mL (*Zofran syrup 50 mL*)

To:
9441X **Ondansetron**, Syrup 4 mg (as hydrochloride dihydrate) per 5 mL, 50 mL (*Zofran syrup 50 mL*)

From:
2236Q **Sertraline Hydrochloride**, Tablet 50 mg (base) (*Zoloft, Xydep 50, Eleva 50, GenRx Sertraline, Chem mart Sertraline, Terry White Chemists Sertraline, Concorz, Setrona, Sertraline Winthrop, Sertraline 50, Sertraline generichealth, Sertra 50, Sertraline-GA, Sertracor 50*)

To:
2236Q **Sertraline**, Tablet 50 mg (as hydrochloride) (*Zoloft, Xydep 50, Eleva 50, GenRx Sertraline, Chem mart Sertraline, Terry White Chemists Sertraline, Concorz, Setrona, Sertraline Winthrop, Sertraline 50, Sertraline generichealth, Sertra 50, Sertraline-GA, Sertracor 50*)

From:
8836C **Sertraline Hydrochloride**, Tablet 50 mg (base) (*Zoloft, Xydep 50, Eleva 50*)

To:
8836C **Sertraline**, Tablet 50 mg (as hydrochloride) (*Zoloft, Xydep 50, Eleva 50*)

From:
8837D **Sertraline Hydrochloride**, Tablet 100 mg (base) (*Zoloft, Xydep 100, Eleva 100*)

To:
8837D **Sertraline**, Tablet 100 mg (as hydrochloride) (*Zoloft, Xydep 100, Eleva 100*)

From:
2237R **Sertraline Hydrochloride**, Tablet 100 mg (base) (*Zoloft, Xydep 100, Eleva 100, GenRx Sertraline, Chem mart Sertraline, Terry White Chemists Sertraline, Concorz, Setrona, Sertraline 100, Sertraline generichealth, Sertra 100, Sertraline-GA, Sertracor 100*)

To:
2237R **Sertraline**, Tablet 100 mg (as hydrochloride) (*Zoloft, Xydep 100, Eleva 100, GenRx Sertraline, Chem mart Sertraline, Terry White Chemists Sertraline, Concorz, Setrona, Sertraline 100, Sertraline generichealth, Sertra 100, Sertraline-GA, Sertracor 100*)

From:
8133C **Valaciclovir Hydrochloride**, Tablet 500 mg (base) (*Valtrex, Zelitrex*)

To:
8133C **Valaciclovir**, Tablet 500 mg (as hydrochloride) (*Valtrex, Zelitrex*)

From:
8064K **Valaciclovir Hydrochloride**, Tablet 500 mg (base) (*Valtrex, Zelitrex*) (**Diff. Max. Qty**)

To:
8064K **Valaciclovir**, Tablet 500 mg (as hydrochloride) (*Valtrex, Zelitrex*) (**Diff. Max. Qty**)

From:
8134D **Valaciclovir Hydrochloride**, Tablet 500 mg (base) (*Valtrex, Zelitrex*) (**Diff. Max. Qty & Rpts**)

To:
8134D **Valaciclovir**, Tablet 500 mg (as hydrochloride) (*Valtrex, Zelitrex*) (**Diff. Max. Qty & Rpts**)

From:
3130R **Vancomycin**, Powder for injection 500 mg (500,000 i.u.) vancomycin activity (*Hospira Pty Limited, Vancocin CP, Vancomycin Alphapharm, Vancomycin Sandoz*)

To:
3130R **Vancomycin**, Powder for injection 500 mg (as hydrochloride) (500,000 i.u. vancomycin activity) (*Hospira Pty Limited, Vancocin CP, Vancomycin Alphapharm, Vancomycin Sandoz*)

From:
3131T **Vancomycin**, Powder for injection 500 mg (500,000 i.u.) vancomycin activity (*Hospira Pty Limited, Vancocin CP, Vancomycin Sandoz*)

To:
3131T **Vancomycin**, Powder for injection 500 mg (as hydrochloride) (500,000 i.u. vancomycin activity) (*Hospira Pty Limited, Vancocin CP, Vancomycin Sandoz, Vancomycin Alphapharm*)

From:
3323X **Vancomycin**, Powder for injection 500 mg (500,000 i.u.) vancomycin activity (*Hospira Pty Limited, Vancocin CP, Vancomycin Sandoz*) (**Dental**)

To:
3323X **Vancomycin**, Powder for injection 500 mg (as hydrochloride) (500,000 i.u. vancomycin activity) (*Hospira Pty Limited, Vancocin CP, Vancomycin Sandoz, Vancomycin Alphapharm*) (**Dental**)

From:
2269K **Vancomycin**, Powder for injection 1 g (1,000,000 i.u.) vancomycin activity (*Hospira Pty Limited, Vancomycin Alphapharm, Vancomycin Sandoz*)

To:
2269K **Vancomycin**, Powder for injection 1 g (as hydrochloride) (1,000,000 i.u. vancomycin activity) (*Hospira Pty Limited, Vancomycin Alphapharm, Vancomycin Sandoz*)

From:

2270L **Vancomycin**, Powder for injection 1 g (1,000,000 i.u.) vancomycin activity (*Hospira Pty Limited, Vancomycin Alphapharm, Vancomycin Sandoz*)

To:

2270L **Vancomycin**, Powder for injection 1 g (as hydrochloride) (1,000,000 i.u. vancomycin activity) (*Hospira Pty Limited, Vancomycin Sandoz, Vancomycin Alphapharm, Vancomycin Sandoz*)

From:

5083M **Vancomycin**, Powder for injection 1 g (1,000,000 i.u.) vancomycin activity (*Hospira Pty Limited, Vancomycin Alphapharm, Vancomycin Sandoz*) **(Dental)**

To:

5083M **Vancomycin**, Powder for injection 1 g (as hydrochloride) (1,000,000 i.u. vancomycin activity) (*Hospira Pty Limited, Vancomycin Alphapharm, Vancomycin Sandoz*) **(Dental)**

Alterations — Proprietary Name

From:

8525Q **Tramadol hydrochloride**, Tablet 200mg (twice daily sustained release) (*Tramahexal SR*)

To:

8525Q **Tramadol hydrochloride**, Tablet 200mg (twice daily sustained release) (*Tramadol Sandoz SR*)

From:

5236N **Tramadol hydrochloride**, Tablet 200mg (twice daily sustained release) (*Tramahexal SR*) **(Dental)**

To:

5236N **Tramadol hydrochloride**, Tablet 200mg (twice daily sustained release) (*Tramadol Sandoz SR*) **(Dental)**

Alterations — Manufacturer's Code

		<i>From:</i>	<i>To:</i>
2132F	Alprazolam , Tablet 1 mg (<i>Alprazolam-GA</i>)	GM	GN
8118G	Alprazolam , Tablet 2 mg (<i>Alprazolam-GA</i>)	GM	GN
8202Q	Aspirin , Tablet 100 mg (<i>DBL Aspirin 100 mg</i>)	YT	GY
1062X	Bethanechol Chloride , Tablet 10 mg (<i>Uro-Carb</i>)	HA	YN
8569B	Doxorubicin Hydrochloride, Pegylated Liposomal , Suspension for I.V. infusion 20 mg in 10 mL (<i>Caelyx</i>)	SH	JC
8570C	Doxorubicin Hydrochloride, Pegylated Liposomal , Suspension for I.V. infusion 50 mg in 25 mL (<i>Caelyx</i>)	SH	JC
1473M	Fluconazole , Solution for I.V. infusion 100 mg in 50 mL (<i>Fluconazole Hexal</i>)	SZ	HX

Alteration — Restriction

9198D **Nicotine**, Transdermal patch releasing approximately 15 mg per 16 hours (*Nicorette Patch*)

Alteration — Restriction and Note

9129L **Varenicline**, Tablet 1 mg (as tartrate) (*Champix*)

SECTION 100 — HIGHLY SPECIALISED DRUGS PROGRAM

ADDITIONS

Additions — Items

9597D	Azacididine , Powder for injection 100 mg (<i>Vidaza</i>) (Public)
9598E	Azacididine , Powder for injection 100 mg (<i>Vidaza</i>) (Public) (Diff. Max. Rpts)
6100C	Azacididine , Powder for injection 100 mg (<i>Vidaza</i>) (Private)
6138C	Azacididine , Powder for injection 100 mg (<i>Vidaza</i>) (Private) (Diff. Max. Rpts)

DELETIONS

Deletions — Items

9552R	Stavudine , Powder for oral solution 1 mg per mL, 200 mL (<i>Zerit</i>) (Public)
6250Y	Stavudine , Powder for oral solution 1 mg per mL, 200 mL (<i>Zerit</i>) (Private)

ALTERATIONS

Alterations — Item Description

From:

5616N **Azithromycin**, Tablet 600 mg (*Zithromax*) **(Public)**

To:

5616N **Azithromycin**, Tablet 600 mg (as dihydrate) (*Zithromax*) **(Public)**

From:

6221K **Azithromycin**, Tablet 600 mg (*Zithromax*) **(Private)**

To:

6221K **Azithromycin**, Tablet 600 mg (as dihydrate) (*Zithromax*) **(Private)**

From:

9568N **Valaciclovir Hydrochloride**, Tablet 500 mg (base) (*Valtrex*) **(Public)**

To:

9568N **Valaciclovir**, Tablet 500 mg (as hydrochloride) (*Valtrex*) **(Public)**

From:

6280M **Valaciclovir Hydrochloride**, Tablet 500 mg (base) (*Valtrex*) **(Private)**

To:

6280M **Valaciclovir**, Tablet 500 mg (as hydrochloride) (*Valtrex*) **(Private)**

Alterations — Proprietary Name

From:

5610G **Apomorphine hydrochloride**, Injection 50mg in 5mL (*APO-go*) **(Public)**

To:

5610G **Apomorphine hydrochloride**, Injection 50mg in 5mL (*Apomine*) **(Public)**

From:

9640J **Apomorphine hydrochloride**, Injection 50mg in 5mL (*APO-go*) **(Private)**

To:

9640J **Apomorphine hydrochloride**, Injection 50mg in 5mL (*Apomine*) **(Private)**

Alterations — Manufacturer's Code

		<i>From:</i>	<i>To:</i>
5705G	Doxorubicin Hydrochloride, Pegylated Liposomal , Suspension for I.V. infusion 20 mg in 10 mL (<i>Caelyx</i>) (Public)	SH	JC
6249X	Doxorubicin Hydrochloride, Pegylated Liposomal , Suspension for I.V. infusion 20 mg in 10 mL (<i>Caelyx</i>) (Private)	SH	JC

SECTION 100 — HUMAN GROWTH HORMONE PROGRAM**ADDITION****Addition — Item**

6311E **Somatropin**, Solution for injection 10 mg (30 i.u.) in 1.5 mL cartridge (with preservative) (*Omnitrope*)

SECTION 100 — SPECIAL AUTHORITY PROGRAM — TRASTUZUMAB**ADDITIONS****Additions — Items**

9690B **Trastuzumab**, Powder for I.V. infusion 60 mg (*Herceptin*) (**Public**)

9691C **Trastuzumab**, Powder for I.V. infusion 60 mg (*Herceptin*) (**Private**)

REPATRIATION PHARMACEUTICAL BENEFITS**Alterations****Alterations — Item Description**

From:

4115N **Azithromycin**, Tablet 500 mg (*Zithromax*)

To:

4115N **Azithromycin**, Tablet 500 mg (as dihydrate) (*Zithromax*)

ADVANCE NOTICES DELETIONS

Advance Notice – Deletion of Items

The following items will be deleted from the Schedule of Pharmaceutical Benefits on 1 April 2011:

Items discontinued by the manufacturer—

- 1350C **Dydrogesterone**, Tablet 10 mg, (*Duphaston*)
- 2772X **Norethisterone with ethinyloestradiol**, Tablets 500 micrograms-35 micrograms, 21 (Brevinor)
- 2773Y **Norethisterone with ethinyloestradiol**, Tablets 1 micrograms-35 micrograms, 21 (Brevinor)
- 8556H **Pancreatic Extract**, Capsule (containing enteric coated minimicrospheres) providing not less than 5,000 BP units of lipase activity (*Creon 5000*)
- 9225M **Pancreatic Extract**, Capsule (containing enteric coated minimicrospheres) providing not less than 5,000 BP units of lipase activity (*Creon 5000*) (*Diff.Max.Rpts*)

Advance Notice — Deletion of Brands

The following brands will be deleted from the Schedule of Pharmaceutical Benefits on 1 March 2011:

Brands discontinued by the manufacturer—

- 2315W *Blenoxane, BQ* — **Bleomycin sulfate**, Powder for injection 15,000 i.u. (solvent required) (with any determined brand of sodium chloride as the required solvent)
(Special Pharmaceutical Benefit)
- 1978D *Ranixhexal, SZ* — **Ranitidine hydrochloride**, Tablet 150 mg (base)

The following brands will be deleted from the Schedule of Pharmaceutical Benefits on 1 May 2011:

Brands discontinued by the manufacturer—

- 2132F *Alprazolam-GA, GN* — **Alprazolam**, Tablet 1 mg
- 8118G *Alprazolam-GA, GN* — **Alprazolam**, Tablet 2 mg
- 8202Q *DBL Aspirin 100 mg, GY* — **Aspirin**, Tablet 100 mg
- 2457H *Lisinopril Hexal, HX* — **Lisinopril**, Tablet 10 mg

GENERAL PHARMACEUTICAL BENEFITS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer
ALPRAZOLAM							
Authority required							
Panic disorder where other treatments have failed or are inappropriate.							
2132F NP	Tablet 1 mg	50	2	..	14.79	15.86	a Alprax 1 SI a Alprazolam-GA GN a Alprazolam Sandoz SZ a Chem mart CH Alprazolam a GenRx Alprazolam GX a Kalma 1 AF a Ralozam GM a Terry White TW Chemists Alprazolam
8118G NP	Tablet 2 mg	50	2	..	19.38	20.45	a Xanax PF a Alprax 2 SI a Alprazolam-GA GN a Alprazolam Sandoz SZ a Chem mart CH Alprazolam a GenRx Alprazolam GX a Kalma 2 AF a Ralozam GM a Terry White TW Chemists Alprazolam B1.26 a Xanax PF B1.52 a Xanax Tri-Score PF

AMINO ACID SYNTHETIC FORMULA supplemented with LONG CHAIN POLYUNSATURATED FATTY ACIDS and MEDIUM CHAIN TRIGLYCERIDES

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.

5466Q NP	Compound powder 400 g	8	5	..	*367.86	34.20	Neocate LCP+MCT SB
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AMINO ACID SYNTHETIC FORMULA supplemented with LONG CHAIN POLYUNSATURATED FATTY ACIDS and MEDIUM CHAIN TRIGLYCERIDES

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;

GENERAL PHARMACEUTICAL BENEFITS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer
	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.						
5467R NP	Compound powder 400 g	8	5	..	*367.86	34.20	Neocate LCP+MCT SB
	ASPIRIN						
8202Q NP	Tablet 100 mg	112	1	..	8.03	9.10	^a DBL Aspirin 100 mg GY
							^a Mayne Pharma YT Aspirin
				^B 1.29	9.32	9.10	^a Astrix YN
	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 NP	Tablet 500 mg (as dihydrate)	2	21.09	22.16	^a Azithromycin SZ Sandoz
							^a Zithromax PF
							^a Zitrocin GM
	AZITHROMYCIN						
	Restricted benefit						
	Trachoma.						
	Note						
	No applications for increased maximum quantities and/or repeats will be authorised.						
8336R NP	Tablet 500 mg (as dihydrate)	2	2	..	21.09	22.16	^a Azithromycin SZ Sandoz
							^a Zithromax PF
							^a Zitrocin GM
8201P NP	Powder for oral suspension 200 mg (as dihydrate) per 5 mL, 15 mL	‡1	#21.09	22.50	Zithromax PF
	BETHANECHOL CHLORIDE						
1062X NP	Tablet 10 mg	100	2	..	21.03	22.10	Uro-Carb YN
	CABERGOLINE						
	Restricted benefit						
	Prevention of the onset of lactation in the puerperium for medical reasons.						
8115D NP	Tablet 500 micrograms	2	23.72	24.79	^a Dostan GM
							^a Dostinex PF

CABERGOLINE

Authority required (STREAMLINED)

2659

Pathological hyperprolactinaemia where surgery is not indicated;

GENERAL PHARMACEUTICAL BENEFITS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	a	Brand Name and Manufacturer
	2660 Pathological hyperprolactinaemia where surgery has already been used with incomplete resolution;							
	2661 Pathological hyperprolactinaemia where radiotherapy is not indicated;							
	2662 Pathological hyperprolactinaemia where radiotherapy has already been used with incomplete resolution.							
8114C	Tablet 500 micrograms	8	5	..	65.07	34.20	a	Dostan GM Dostinex PF Tinexa SI
<hr/>								
CABERGOLINE								
<u>Restricted benefit</u> Parkinson's disease.								
<u>Note</u> Care should be taken when treating patients with advanced age and significant cognitive impairment with dopamine agonists.								
<u>Note</u> Continuing Therapy Only: For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.								
8393R NP	Tablet 1 mg	30	5	..	59.78	34.20	a	Bergoline 1 SI Cabaser PF Cobasol GM
8394T NP	Tablet 2 mg	30	5	..	77.94	34.20	a	Bergoline 2 SI Cabaser PF Cobasol GM
CEFEPIME								
<u>Authority required</u> Treatment of febrile neutropenia.								
<u>Note</u> Shared Care Model: For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.								
8315P NP	Powder for injection 1 g (as hydrochloride) (solvent required) (code 7079N applies to above item with approved solvent)	10	*161.62	34.20	a	DBL Cefepime HH Maxipime BQ Omegapharm Pty OE Ltd
8316Q NP	Powder for injection 2 g (as hydrochloride) (solvent required) (code 7085X applies to above item with approved solvent)	10	*293.22	34.20	a	DBL Cefepime HH Maxipime BQ Omegapharm Pty OE Ltd
DOXORUBICIN HYDROCHLORIDE, PEGYLATED LIPOSOMAL								
<u>Authority required</u> Advanced epithelial ovarian cancer in women who have failed a first-line platinum-based chemotherapy regimen; Metastatic breast cancer, as monotherapy, after failure of prior therapy which includes capecitabine and a taxane; Metastatic breast cancer, as monotherapy, where therapy with capecitabine and/or a taxane is contraindicated.								
8569B	Suspension for I.V. infusion 20 mg in 10 mL	1	703.05	34.20		Caelyx JC

GENERAL PHARMACEUTICAL BENEFITS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer
8570C	Suspension for I.V. infusion 50 mg in 25 mL	1	1621.79	34.20	Caelyx JC
DUTASTERIDE							
<u>Authority required (STREAMLINED)</u>							
3667							
Treatment, in combination with an alpha-antagonist, of lower urinary tract symptoms due to benign prostatic hyperplasia where treatment is initiated by a urologist.							
5468T	Capsule 500 micrograms	30	5	..	30.43	31.50	Avodart GK
ENALAPRIL							
1368B NP	Tablet containing enalapril maleate 10 mg	30	5	..	16.90	17.97	^a Acetec AL ^a Alphapril AF ^a Auspril SI ^a Chem mart CH Enalapril ^a Enalabell BF ^a Enalapril-DP 10mg GN ^a Enalapril-GA GM ^a Enalapril GQ generichealth ^a Enalapril Sandoz SZ ^a Enalapril Winthrop WA ^a GenRx Enalapril GX ^a Terry White Chemists Enalapril TW
1369C NP	Tablet containing enalapril maleate 20 mg	30	5	..	^B 4.65 21.55 19.76	17.97 20.83	^a Renitec MK ^a Acetec AL ^a Alphapril AF ^a Auspril SI ^a Chem mart CH Enalapril ^a Enalabell BF ^a Enalapril-DP 20mg GN ^a Enalapril-GA GM ^a Enalapril GQ generichealth ^a Enalapril Sandoz SZ ^a GenRx Enalapril GX ^a Terry White Chemists Enalapril TW
1370D NP	Tablet containing enalapril maleate 5 mg	30	5	..	^B 4.66 24.42 12.80	20.83 13.87	^a Renitec 20 MK ^a Acetec AL ^a Alphapril AF ^a Auspril SI ^a Chem mart CH Enalapril ^a Enalabell BF ^a Enalapril-DP 5mg GN ^a Enalapril-GA GM ^a Enalapril GQ generichealth ^a Enalapril Sandoz SZ ^a Enalapril Winthrop WA

GENERAL PHARMACEUTICAL BENEFITS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price	Maximum	Brand Name and Manufacturer
					for Max. Qty \$	Recordable Value for Safety Net \$	
							^a GenRx Enalapril GX
							^a Terry White Chemists TW Enalapril
				^B 4.66	17.46	13.87	^a Renitec M MK

FLUCONAZOLE

Authority required (STREAMLINED)

3615

Treatment of cryptococcal meningitis;

3616

Maintenance therapy in patients with cryptococcal meningitis and immunosuppression;

3613

Treatment of oropharyngeal candidiasis in immunosuppressed patients;

3614

Treatment of oesophageal candidiasis in immunosuppressed patients;

3617

Prophylaxis of oropharyngeal candidiasis in immunosuppressed patients;

3618

Treatment of serious and life-threatening candida infections.

Note

Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

1473M NP	Solution for I.V. infusion 100 mg in 50 mL	7	*156.29	34.20	^a Diflucan PF
							^a Fluconazole-Claris AE
							^a Fluconazole Hexal HX
							^a Fluconazole Sandoz SZ

FLUVOXAMINE

Restricted benefit

Major depressive disorders;

Obsessive-compulsive disorder.

8174F NP	Tablet containing fluvoxamine maleate 100 mg	30	5	..	26.49	27.56	^a APO-Fluvoxamine TX
							^a Faverin 100 SI
							^a Fluvoxamine GA GM
							^a Movox 100 AF
							^a Voxam SZ
				^B 2.80	29.29	27.56	^a Luvox SM
8512B NP	Tablet containing fluvoxamine maleate 50 mg	30	5	..	19.67	20.74	^a APO-Fluvoxamine TX
							^a Faverin 50 SI
							^a Fluvoxamine GA GM
							^a Movox 50 AL
							^a Voxam SZ
				^B 2.82	22.49	20.74	^a Luvox SM

GEMCITABINE

Authority required

Advanced breast cancer in combination with paclitaxel after failure of prior therapy which includes an anthracycline;

Advanced epithelial ovarian cancer, in combination with carboplatin, in patients who relapse more than 6 months after platinum-based therapy;

Locally advanced or metastatic non-small cell lung cancer;

Locally advanced or metastatic adenocarcinoma of the pancreas;

Locally advanced or metastatic bladder cancer, in combination with cisplatin.

GENERAL PHARMACEUTICAL BENEFITS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	a	Brand Name and Manufacturer
Note								
The powder for I.V. infusion 200 mg (as hydrochloride) (after reconstitution) and the solution concentrate for I.V. infusion 200 mg (as hydrochloride) are bioequivalent.								
8049P	Powder for I.V. infusion 200 mg (as hydrochloride)	4	2	..	*201.90	34.20	a	DBL Gemcitabine for Injection HH
							a	Gemcitabine Actavis GQ
							a	Gemcitabine Ebewe IT
							a	Gemcitabine Kabi PK
							a	Gemcitabine Sun ZF
							a	Gemcitate ZP
							a	Gemplan WQ
							a	Gemzar LY
<hr/>								
GEMCITABINE								
Authority required								
Advanced breast cancer in combination with paclitaxel after failure of prior therapy which includes an anthracycline;								
Advanced epithelial ovarian cancer, in combination with carboplatin, in patients who relapse more than 6 months after platinum-based therapy;								
Locally advanced or metastatic non-small cell lung cancer;								
Locally advanced or metastatic adenocarcinoma of the pancreas;								
Locally advanced or metastatic bladder cancer, in combination with cisplatin.								
Note								
The powder for I.V. infusion 1 g (as hydrochloride) (after reconstitution) and the solution concentrate for I.V. infusion 1000 mg (as hydrochloride) are bioequivalent.								
8050Q	Powder for I.V. infusion 1 g (as hydrochloride)	2	2	..	*463.28	34.20	a	DBL Gemcitabine for Injection HH
							a	Gemcitabine Actavis GQ
							a	Gemcitabine Ebewe IT
							a	Gemcitabine Kabi PK
							a	Gemcitabine Sun ZF
							a	Gemcitate ZP
							a	Gemplan WQ
							a	Gemzar LY
LERCANIDIPINE HYDROCHLORIDE								
8534E NP	Tablet 10 mg	28	5	..	15.70	16.77	a	APO-Lercanidipine TX
							a	Chem mart Lercanidipine CH
							a	Lercadip GM
							a	Lercan SI
							a	Terry White Chemists Lercanidipine TW
				^B 1.84	17.54	16.77	a	Zanidip SM
					15.70	16.77	a	Lercanidipine Sandoz SZ
8679T NP	Tablet 20 mg	28	5	..	21.92	22.99	a	APO-Lercanidipine TX
							a	Chem mart Lercanidipine CH
							a	Lercadip GM
							a	Lercan SI
							a	Terry White Chemists TW

GENERAL PHARMACEUTICAL BENEFITS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer
				^B 3.27	25.19	22.99	^a Lercanidipine Zanidip SM
					21.92	22.99	^a Lercanidipine Sandoz SZ
2457H <i>NP</i>	LISINAPRIL Tablet 10 mg	30	5	..	17.41	18.48	^a APO-Lisinopril TX ^a Chem mart CH Lisinopril ^a Fibsol 10 SI ^a GenRx Lisinopril GX ^a Liprace GM ^a Lisinopril 10 CR ^a Lisinopril-DRLA RZ ^a Lisinopril-GA GN ^a Lisinopril GQ generichealth ^a Lisinopril Hexal HX ^a Lisinopril Ranbaxy RA ^a Lisinopril Sandoz SZ ^a Lisinopril Winthrop WA ^a Lisodur AF ^a Terry White TW Chemists Lisinopril
				^B 1.98	19.39	18.48	^a Zestril AP
				^B 3.76	21.17	18.48	^a Prinivil 10 MK
8607B <i>NP</i>	METFORMIN HYDROCHLORIDE Tablet 1 g	90	5	..	17.46	18.53	^a APO-Metformin TX 1000 ^a Chem mart CH Metformin 1000 ^a Diaformin 1000 AF ^a Formet 1000 SI ^a Glucohexal HX ^a Metformin-GA GM ^a Metformin GQ generichealth 1000 ^a Metformin RA Ranbaxy 1000 ^a Metformin Sandoz SZ ^a Pharmacor CR Metformin 1000 ^a Terry White TW Chemists Metformin 1000
				^B 1.71	19.17	18.53	^a Diabex 1000 AL

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.

GENERAL PHARMACEUTICAL BENEFITS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer
<u>Authority required</u>							
Short-term sole PBS-subsidised therapy as an aid to achieving abstinence in a patient who has indicated they are ready to cease smoking and who has entered a comprehensive support and counselling program. Details of the program must be specified in the initial authority application;							
Short-term sole PBS-subsidised therapy as an aid to achieving abstinence in a patient who has indicated they are ready to cease smoking and who is entering a comprehensive support and counselling program during the consultation at which this authority is requested. Details of the program must be specified in the initial authority application.							
<u>Note</u>							
A maximum of 12 weeks of PBS-subsidised nicotine replacement therapy will be authorised per year. No applications for increased maximum quantities and/or repeats will be authorised.							
9198D NP	Transdermal patch releasing approximately 15 mg per 16 hours	28	2	..	55.22	34.20	Nicorette Patch JT
NICOTINE							
<u>Authority required</u>							
Short-term sole PBS-subsidised therapy as an aid to achieving abstinence in a patient who has indicated they are ready to cease smoking and who has entered a comprehensive support and counselling program. Details of the program must be specified in the initial authority application;							
Short-term sole PBS-subsidised therapy as an aid to achieving abstinence in a patient who has indicated they are ready to cease smoking and who is entering a comprehensive support and counselling program during the consultation at which this authority is requested. Details of the program must be specified in the initial authority application.							
<u>Note</u>							
A maximum of 12 weeks of PBS-subsidised nicotine replacement therapy will be authorised per year. No applications for increased maximum quantities and/or repeats will be authorised.							
3414Q NP	Transdermal patch releasing approximately 21 mg per 24 hours	28	2	..	55.22	34.20	Nicotinell Step 1 NC
5465P NP	Transdermal patch releasing approximately 21 mg per 24 hours	28	2	..	55.22	34.20	Nicabate P GC
ONDANSETRON							
<u>Restricted benefit</u>							
Management of nausea and vomiting associated with cytotoxic chemotherapy being used to treat malignancy which occurs within 48 hours of chemotherapy administration.							
Increased maximum quantities will be limited to a maximum of 7 days per chemotherapy cycle.							
8224W NP	Tablet 4 mg (as hydrochloride dihydrate)	4	38.78	34.20	^a APO-Ondansetron TX ^a Ondansetron-DRLA RZ ^a Ondaz SZ ^a Onsetron 4 ZP ^a Zofran GK
8225X NP	Tablet 8 mg (as hydrochloride dihydrate)	4	54.99	34.20	^a APO-Ondansetron TX ^a Ondansetron-DRLA RZ ^a Ondaz SZ ^a Onsetron 8 ZP ^a Zofran GK
8226Y NP	I.V. injection 4 mg (as hydrochloride dihydrate) in 2 mL	1	19.93	21.00	^a Ondansetron-Claris AE ^a Ondaz SZ ^a Onsetron ZP ^a Pfizer Australia Pty Ltd PF ^a Zofran GK
8227B NP	I.V. injection 8 mg (as hydrochloride dihydrate) in 4 mL	1	27.90	28.97	^a Ondansetron-Claris AE ^a Ondaz SZ ^a Onsetron ZP

GENERAL PHARMACEUTICAL BENEFITS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer
							^a Pfizer Australia Pty PF Ltd
							^a Zofran GK
9441X NP	Syrup 4 mg (as hydrochloride dihydrate) per 5 mL, 50 mL	‡1	85.38	34.20	Zofran syrup 50mL GK
ONDANSETRON							
Authority required (STREAMLINED)							
3611							
Management of nausea and vomiting associated with radiotherapy being used to treat malignancy.							
1594X NP	Tablet 4 mg (as hydrochloride dihydrate)	10	1	..	83.79	34.20	^a APO-Ondansetron TX ^a Ondansetron-DRLA RZ ^a Ondaz SZ ^a Onsetron 4 ZP ^a Zofran GK
1595Y NP	Tablet 8 mg (as hydrochloride dihydrate)	10	1	..	127.64	34.20	^a APO-Ondansetron TX ^a Ondansetron-DRLA RZ ^a Ondaz SZ ^a Onsetron 8 ZP ^a Zofran GK
1596B NP	I.V. injection 4 mg (as hydrochloride dihydrate) in 2 mL	1	19.93	21.00	^a Ondansetron-Claris AE ^a Ondaz SZ ^a Onsetron ZP ^a Pfizer Australia Pty PF Ltd ^a Zofran GK
1597C NP	I.V. injection 8 mg (as hydrochloride dihydrate) in 4 mL	1	27.90	28.97	^a Ondansetron-Claris AE ^a Ondaz SZ ^a Onsetron ZP ^a Pfizer Australia Pty PF Ltd ^a Zofran
8233H NP	Syrup 4 mg (as hydrochloride dihydrate) per 5 mL, 50 mL	‡1	1	..	85.38	34.20	Zofran syrup 50mL GK

PERINDOPRIL with AMLODIPINE

Note

Treatment should not be initiated with this combination.

Restricted benefit

Hypertension in a patient who is not adequately controlled with either of the drugs in the combination;

Stable coronary heart disease in a patient who is stabilised on treatment with perindopril and amlodipine at the same doses.

9346X NP	Tablet containing 5 mg perindopril arginine with 5 mg amlodipine (as besylate)	30	5	..	27.11	28.18	^a Coveram SE ^a Reaptan 5/5 RX
9347Y NP	Tablet containing 5 mg perindopril arginine with 10 mg amlodipine (as besylate)	30	5	..	34.45	34.20	^a Coveram SE ^a Reaptan 5/10 RX
9348B NP	Tablet containing 10 mg perindopril arginine with 5 mg amlodipine (as besylate)	30	5	..	32.94	34.01	^a Coveram SE ^a Reaptan 10/5 RX
9349C NP	Tablet containing 10 mg perindopril arginine with 10 mg amlodipine (as besylate)	30	5	..	40.26	34.20	^a Coveram SE ^a Reaptan 10/10 RX

GENERAL PHARMACEUTICAL BENEFITS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price	Maximum		Brand Name and Manufacturer
					for Max. Qty \$	Recordable Value for Safety Net \$		
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.								
<u>Caution</u>								
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.								
<u>Note</u>								
Shared Care Model:								
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.								
8787L NP	Tablet 0.5 mg	60	2	..	30.34	31.41	^a	Ozidal RA
							^a	Resdone 0.5 CR
							^a	Rispa SI
							^a	Risperidone-DRLA RZ
							^a	Risperidone-GA GM
							^a	Risperidone Sandoz SZ
							^a	Rixadone AF
					*30.36	31.43	^a	APO-Risperidone TX
							^a	Risperdal JC
8789N NP	Tablet 1 mg	60	2	..	51.07	34.20	^a	APO-Risperidone TX
							^a	Ozidal RA
							^a	Resdone 1 CR
							^a	Rispa SI
							^a	Risperdal JC
							^a	Risperidone-DRLA RZ
							^a	Risperidone-GA GM
							^a	Risperidone generichealth GQ
							^a	Risperidone Sandoz SZ
							^a	Rixadone AF
<hr/>								
RISPERIDONE								
<u>Authority required (STREAMLINED)</u>								
1589								
Schizophrenia.								
<u>Note</u>								
Shared Care Model:								
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.								
8869T NP	Tablet 0.5 mg	60	5	..	30.34	31.41	^a	Ozidal RA

GENERAL PHARMACEUTICAL BENEFITS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price	Maximum	Brand Name and Manufacturer
					for Max. Qty \$	Recordable Value for Safety Net \$	
							^a Resdone 0.5 CR
							^a Rispa SI
							^a Risperidone-DRLA RZ
							^a Risperidone-GA GM
							^a Risperidone Sandoz SZ
							^a Rixadone AF
					*30.36	31.43	^a APO-Risperidone TX
							^a Risperdal JC
RISPERIDONE							
<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.							
Note							
Shared Care Model:							
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.							
3169T NP	Tablet 1 mg	60	5	..	51.07	34.20	^a APO-Risperidone TX
							^a Ozidal RA
							^a Resdone 1 CR
							^a Rispa SI
							^a Risperdal JC
							^a Risperidone-DRLA RZ
							^a Risperidone-GA GM
							^a Risperidone generichealth GQ
							^a Risperidone Sandoz SZ
							^a Rixadone AF
3170W NP	Tablet 2 mg	60	5	..	107.42	34.20	^a APO-Risperidone TX
							^a Ozidal RA
							^a Resdone 2 CR
							^a Rispa SI
							^a Risperdal JC
							^a Risperidone-DRLA RZ
							^a Risperidone-GA GM
							^a Risperidone generichealth GQ
							^a Risperidone Sandoz SZ
							^a Rixadone AF
3171X NP	Tablet 3 mg	60	5	..	162.16	34.20	^a APO-Risperidone TX
							^a Ozidal RA
							^a Resdone 3 CR
							^a Rispa SI
							^a Risperdal JC
							^a Risperidone-DRLA RZ
							^a Risperidone-GA GM
							^a Risperidone generichealth GQ
							^a Risperidone Sandoz SZ

GENERAL PHARMACEUTICAL BENEFITS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer
3172Y NP	Tablet 4 mg	60	5	..	215.55	34.20	^a Rixadone AF
							^a APO-Risperidone TX
							^a Ozidal RA
							^a Resdone 4 CR
							^a Rispa SI
							^a Risperdal JC
							^a Risperidone-DRLA RZ
							^a Risperidone-GA GM
							^a Risperidone generichealth GQ
							^a Risperidone Sandoz SZ
^a Rixadone AF							

RISPERIDONE

Authority required (STREAMLINED)

3083

Treatment under the supervision of a paediatrician or psychiatrist, in combination with non-pharmacological measures, of severe behavioural disturbances in a patient aged less than 18 years with autism.

Continuing PBS-subsidised treatment under the supervision of a paediatrician or psychiatrist, in combination with non-pharmacological measures, of severe behavioural disturbances in a patient 18 years of age or older with autism who was commenced on PBS-subsidised treatment with risperidone prior to turning 18 years of age.

Behaviour disturbances are defined as severe aggression and injuries to self or others where non-pharmacological methods alone have been unsuccessful.

The diagnosis of autism must be made based on the Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV) or ICD-10 international classification of mental and behavioural disorders.

Note

Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

9079W NP	Tablet 2 mg	60	2	..	107.42	34.20	^a APO-Risperidone TX
							^a Ozidal RA
							^a Resdone 2 CR
							^a Rispa SI
							^a Risperdal JC
							^a Risperidone-DRLA RZ
							^a Risperidone-GA GM
							^a Risperidone generichealth GQ
							^a Risperidone Sandoz SZ
							^a Rixadone AF

SERTRALINE

Restricted benefit

Major depressive disorders.

2236Q NP	Tablet 50 mg (as hydrochloride)	30	5	..	23.75	24.82	^a Chem mart Sertraline CH
							^a Concorz SZ
							^a Eleva 50 AF
							^a GenRx Sertraline GX
							^a Sertra 50 SI
							^a Sertracor 50 MI
^a Sertraline 50 CR							

GENERAL PHARMACEUTICAL BENEFITS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer
							^a Sertraline-GA GM
							^a Sertraline GQ
							^a Sertraline generichealth WA
							^a Winthrop RA
							^a Setrona RA
							^a Terry White Chemists TW
							^a Sertraline GN
				^B 1.42	25.17	24.82	^a Xydep 50 PF
2237R NP	Tablet 100 mg (as hydrochloride)	30	5	..	23.75	24.82	^a Zoloft PF
							^a Chem mart CH
							^a Sertraline Sertraline CH
							^a Concorz SZ
							^a Eleva 100 AF
							^a GenRx Sertraline GX
							^a Sertra 100 SI
							^a Sertracor 100 MI
							^a Sertraline 100 CR
							^a Sertraline-GA GM
							^a Sertraline GQ
							^a generichealth RA
							^a Setrona RA
							^a Terry White Chemists TW
							^a Sertraline Sertraline GN
				^B 1.42	25.17	24.82	^a Xydep 100 GN
							^a Zoloft PF

SERTRALINE

Restricted benefit

Obsessive-compulsive disorder;

Panic disorder where other treatments have failed or are inappropriate.

8836C NP	Tablet 50 mg (as hydrochloride)	30	5	..	23.75	24.82	^a Eleva 50 AF
							^a Xydep 50 GN
				^B 1.42	25.17	24.82	^a Zoloft PF
8837D NP	Tablet 100 mg (as hydrochloride)	30	5	..	23.75	24.82	^a Eleva 100 AF
							^a Xydep 100 GN
				^B 1.42	25.17	24.82	^a Zoloft PF

SUMATRIPTAN

Caution

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

Authority required (STREAMLINED)

3233

Migraine attack in a patient where attacks in the past have usually failed to respond to analgesics.

Note

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

Note

Continuing Therapy Only:

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

8144P NP	Tablet 50 mg (as succinate)	4	5	..	*24.38	25.45	^a Imigran GK
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GENERAL PHARMACEUTICAL BENEFITS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price	Maximum	Brand Name and Manufacturer
					for Max. Qty \$	Recordable Value for Safety Net \$	
							^a Pharmacor Sumatriptan 50 CR
							^a Sumagran 50 SI
							^a Sumatab AF
							^a Sumatriptan-GA GM
							^a APO-Sumatriptan TX
							^a Chem mart Sumatriptan CH
							^a Terry White Chemists Sumatriptan TW

TRAMADOL HYDROCHLORIDE

Restricted benefit

For pain where aspirin and/or paracetamol alone are inappropriate or have failed.

Note

Authorities for increased maximum quantities and/or repeats will be granted only for severe disabling pain not responding to non-narcotic analgesics.

8525Q NP	Tablet 200 mg (twice daily sustained release)	20	18.02	19.09	^a APO-Tramadol SR TX
							^a Chem mart Tramadol SR CH
							^a GA Tramadol SR 200mg GM
							^a Lodam SR 200 ZP
							^a Terry White Chemists Tramadol SR TW
							^a Tramadol Sandoz SR SZ
							^a Tramedo SR 200 AF
							^a Zydol SR 200 SI
				^b 5.78	23.80	19.09	^a Tramal SR 200 CS

VALACICLOVIR

Authority required (STREAMLINED)

3632

Moderate to severe initial genital herpes. Microbiological confirmation of diagnosis (viral culture, antigen detection or nucleic acid amplification by PCR) is desirable but need not delay treatment.

Note

Valaciclovir 500 mg is not PBS-subsidised for chickenpox or herpes simplex infections other than genital herpes.

Note

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

8133C NP	Tablet 500 mg (as hydrochloride)	20	*105.78	34.20	^a Valtrex GK
							^a Zelitrex RE

VALACICLOVIR

Authority required (STREAMLINED)

3633

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 NP	Tablet 500 mg (as hydrochloride)	30	5	..	155.43	34.20	^a Valtrex GK
							^a Zelitrex RE

GENERAL PHARMACEUTICAL BENEFITS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	a	Brand Name and Manufacturer
VALACICLOVIR								
<u>Authority required (STREAMLINED)</u>								
3622								
Treatment of patients with herpes zoster within 72 hours of the onset of the rash;								
3631								
Herpes zoster ophthalmicus.								
<u>Note</u>								
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.								
<u>Note</u>								
No applications for repeats will be authorised.								
8064K NP	Tablet 500 mg (as hydrochloride)	42	214.06	34.20	a	Valtrex GK
							a	Zelitrex RE
VANCOMYCIN								
<u>Restricted benefit</u>								
Prophylaxis of endocarditis in patients hypersensitive to penicillin.								
2269K	Powder for injection 1 g (as hydrochloride) (1,000,000 i.u. vancomycin activity)	1	17.95	19.02	a	Hospira Pty Limited HH
							a	Vancomycin Alphapharm AF
							a	Vancomycin Sandoz SZ
3130R	Powder for injection 500 mg (as hydrochloride) (500,000 i.u. vancomycin activity)	2	*17.96	19.03	a	Hospira Pty Limited HH
							a	Vancocin CP AS
							a	Vancomycin Alphapharm AF
							a	Vancomycin Sandoz SZ
VANCOMYCIN								
<u>Restricted benefit</u>								
Endophthalmitis;								
Use initiated in a hospital for infections where vancomycin is an appropriate antibiotic.								
2270L	Powder for injection 1 g (as hydrochloride) (1,000,000 i.u. vancomycin activity)	3	*41.01	34.20	a	Hospira Pty Limited HH
							a	Vancomycin Alphapharm AF
							a	Vancomycin Sandoz SZ
3131T	Powder for injection 500 mg (as hydrochloride) (500,000 i.u. vancomycin activity)	5	*35.27	34.20	a	Hospira Pty Limited HH
							a	Vancocin CP AS
							a	Vancomycin Alphapharm AF
							a	Vancomycin Sandoz SZ
VARENICLINE								
<u>Note</u>								
The period between commencing varenicline tartrate and bupropion hydrochloride must be at least 6 months. A course of treatment with varenicline tartrate is 12 weeks or up to 24 weeks, if initial treatment of 12 weeks has been successful. No increased maximum quantities or repeats will be authorised. Clinical review is recommended within 2 to 3 weeks of the initial prescription being requested.								
<u>Authority required</u>								
Continuation of short-term sole PBS-subsidised therapy as an aid to achieving abstinence in a patient who has previously been issued with an authority prescription for this drug and who is enrolled in a comprehensive support and counselling program.								
9129L NP	Tablet 1 mg (as tartrate)	112	*231.70	34.20		Champix PF

GENERAL PHARMACEUTICAL BENEFITS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer
VARENICLINE							
Note							
The period between commencing varenicline tartrate and bupropion hydrochloride must be at least 6 months. A course of treatment with varenicline tartrate is 12 weeks or up to 24 weeks, if initial treatment of 12 weeks has been successful. No increased maximum quantities or repeats will be authorised. Clinical review is recommended within 2 to 3 weeks of the initial prescription being requested.							
Authority required							
Completion of short-term sole PBS-subsidised therapy as an aid to achieving long-term abstinence after completion of an initial 12-week PBS-subsidised course in a patient who has ceased smoking, and who is enrolled in a comprehensive support and counselling program.							
5469W NP	Tablet 1 mg (as tartrate)	56	2	..	120.42	34.20	Champix PF

**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 \$	Brand Name and Manufacturer
TRAMADOL HYDROCHLORIDE							
<u>Restricted benefit</u>							
For pain where aspirin and/or paracetamol alone are inappropriate or have failed.							
5236N	Tablet 200 mg (twice daily sustained release) (Dental)	20	18.02	19.09	^a APO-Tramadol SR TX
							^a Chem mart CH
							^a Tramadol SR GM
							^a GA Tramadol SR 200mg GM
							^a Lodam SR 200 ZP
							^a Terry White Chemists TW
							^a Tramadol SR SZ
							^a Tramadol Sandoz SR SZ
							^a Tramedo SR 200 AF
							^a Zydol SR 200 SI
				^B 5.78	23.80	19.09	^a Tramal SR 200 CS
VANCOMYCIN							
<u>Restricted benefit</u>							
Prophylaxis of endocarditis in patients hypersensitive to penicillin.							
5083M	Powder for injection 1 g (as hydrochloride) (1,000,000 i.u. vancomycin activity) (Dental)	1	17.95	19.02	^a Hospira Pty Limited HH
							^a Vancomycin AF
							^a Alphapharm SZ
							^a Vancomycin Sandoz SZ
3323X	Powder for injection 500 mg (as hydrochloride) (500,000 i.u. vancomycin activity) (Dental)	2	*17.96	19.03	^a Hospira Pty Limited HH
							^a Vancocin CP AS
							^a Vancomycin Alphapharm AF
							^a Vancomycin Sandoz SZ

SECTION 100 – HIGHLY SPECIALISED DRUGS PROGRAM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Brand Name and Manufacturer
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APOMORPHINE HYDROCHLORIDE

Authority required (STREAMLINED)

3314

Parkinson's disease in patients severely disabled by motor fluctuations which do not respond to other therapy.

5610G	Injection 50 mg in 5 mL (Public)	5	194.65	Apomine	HH
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APOMORPHINE HYDROCHLORIDE

Authority required

Parkinson's disease in patients severely disabled by motor fluctuations which do not respond to other therapy.

9640J	Injection 50 mg in 5 mL (Private)	5	208.86	Apomine	HH
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AZACITIDINE

Note

Any queries concerning the arrangements to prescribe azacitidine may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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

Written applications for authority to prescribe azacitidine should be forwarded to:

Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001.

Authority required

Initial PBS-subsidised treatment of a patient with:

- (1) Myelodysplastic syndrome classified as Intermediate-2 or high risk according to the International Prognostic Scoring System (IPSS); OR
- (2) Chronic Myelomonocytic Leukaemia (10% to 29% marrow blasts without Myeloproliferative Disorder); OR
- (3) Acute Myeloid Leukaemia with 20 to 30% marrow blasts and multi-lineage dysplasia, according to World Health Organisation (WHO) Classification.

Classification of a patient as Intermediate-2 requires a score of 1.5 to 2.0 on the IPSS, achieved with the possible combinations:

1. 11% to 30% marrow blasts with good karyotypic status (normal, -Y alone, del(5q) alone, del(20q) alone), and 0 to 1 cytopenias; OR
2. 11% to 20% marrow blasts with intermediate karyotypic status (other abnormalities), and 0 to 1 cytopenias; OR
3. 11% to 20% marrow blasts with good karyotypic status (normal, -Y alone, del(5q) alone, del(20q) alone), and 2 to 3 cytopenias; OR
4. 5% to 10% marrow blasts with poor karyotypic status (3 or more abnormalities or chromosome 7 anomalies), regardless of cytopenias; OR
5. 5% to 10% marrow blasts with intermediate karyotypic status (other abnormalities), and 2 to 3 cytopenias; OR
6. less than 5% marrow blasts with poor karyotypic status (3 or more abnormalities or chromosome 7 anomalies), and 2 to 3 cytopenias.

Classification of a patient as high risk requires a score of 2.5 or more on the IPSS, achieved with the possible combinations:

1. 21% to 30% marrow blasts with good karyotypic status (normal, -Y alone, del(5q) alone, del(20q) alone), and 2 to 3 cytopenias; OR
2. 21% to 30% marrow blasts with intermediate (other abnormalities) or poor karyotypic status (3 or more abnormalities or chromosome 7 anomalies), regardless of cytopenias; OR
3. 11% to 20% marrow blasts with poor karyotypic status (3 or more abnormalities or chromosome 7 anomalies), regardless of cytopenias; OR
4. 11% to 20% marrow blasts with intermediate karyotypic status (other abnormalities), and 2 to 3 cytopenias.

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

- (a) a completed authority prescription form; and
- (b) a completed Azacitidine PBS Authority Application - Supporting Information Form; and
- (c) a copy of the bone marrow biopsy report demonstrating that the patient has myelodysplastic syndrome, chronic myelomonocytic leukaemia or acute myeloid leukaemia; and
- (d) a copy of the full blood examination report; and
- (e) for myelodysplastic syndrome, a copy of the pathology report detailing the cytogenetics demonstrating intermediate-2 or high risk disease according to the International Prognostic Scoring System (IPSS); and
- (f) a signed patient acknowledgment form.

No more than three cycles will be authorised.

Note

Special Pricing Arrangements apply.

6100C	Powder for injection 100 mg	14	2	..	*7746.46	Vidaza	CJ
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SECTION 100 – HIGHLY SPECIALISED DRUGS PROGRAM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium \$	Dispensed Price for		Brand Name and Manufacturer
					Max. Qty \$		
9597D	(Private) Powder for injection 100 mg (Public)	14	2	..	*7700.00		Vidaza CJ

AZACITIDINE

Note

Any queries concerning the arrangements to prescribe azacitidine may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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

Written applications for authority to prescribe azacitidine should be forwarded to:

Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001.

Authority required

Continuing treatment of a patient with:

- (1) Myelodysplastic syndrome classified as Intermediate-2 or high risk according to the International Prognostic Scoring System (IPSS); OR
- (2) Chronic Myelomonocytic Leukaemia (10% to 29% marrow blasts without Myeloproliferative Disorder); OR
- (3) Acute Myeloid Leukaemia with 20 to 30% blasts and multi-lineage dysplasia, according to World Health Organisation (WHO) Classification; who has previously been issued with an authority prescription for azacitidine and does not have progressive disease.

Authority applications for continuing treatment may be made by telephone on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Up to six cycles will be authorised.

Note

Special Pricing Arrangements apply.

6138C	Powder for injection 100 mg (Private)	14	5	..	*7746.46		Vidaza CJ
9598E	Powder for injection 100 mg (Public)	14	5	..	*7700.00		Vidaza CJ

AZITHROMYCIN

Authority required (STREAMLINED)

3317

Prophylaxis against Mycobacterium avium complex infections in HIV-positive patients with CD4 cell counts of less than 75 per cubic millimetre.

5616N	Tablet 600 mg (as dihydrate) (Public)	16	5	..	*113.96		Zithromax PF
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AZITHROMYCIN

Authority required

Prophylaxis against Mycobacterium avium complex infections in HIV-positive patients with CD4 cell counts of less than 75 per cubic millimetre.

6221K	Tablet 600 mg (as dihydrate) (Private)	16	5	..	*124.94		Zithromax PF
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DOXORUBICIN HYDROCHLORIDE, PEGYLATED LIPOSOMAL

Authority required (STREAMLINED)

3348

Treatment of AIDS-related Kaposi's sarcoma in patients with CD4 cell counts of less than 200 per cubic millimetre and extensive mucocutaneous involvement;

3349

Treatment of AIDS-related Kaposi's sarcoma in patients with CD4 cell counts of less than 200 per cubic millimetre and extensive visceral involvement.

5705G	Suspension for I.V. infusion 20 mg in 10 mL (Public)	4	5	..	*2491.96		Caelyx JC
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SECTION 100 – HIGHLY SPECIALISED DRUGS PROGRAM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Brand Name and Manufacturer
DOXORUBICIN HYDROCHLORIDE, PEGYLATED LIPOSOMAL						
<u>Authority required</u>						
Treatment of AIDS-related Kaposi's sarcoma in patients with CD4 cell counts of less than 200 per cubic millimetre and extensive mucocutaneous involvement;						
Treatment of AIDS-related Kaposi's sarcoma in patients with CD4 cell counts of less than 200 per cubic millimetre and extensive visceral involvement.						
6249X	Suspension for I.V. infusion 20 mg in 10 mL (Private)	4	5	..	*2538.38	Caelyx JC
VALACICLOVIR						
<u>Authority required</u>						
Prophylaxis of cytomegalovirus (CMV) infection and disease following renal transplantation in patients at risk of CMV disease.						
6280M	Tablet 500 mg (as hydrochloride) (Private)	500	2	..	*2162.32	Valtrex GK
VALACICLOVIR						
<u>Authority required (STREAMLINED)</u>						
3419						
Prophylaxis of cytomegalovirus (CMV) infection and disease following renal transplantation in patients at risk of CMV disease.						
9568N	Tablet 500 mg (as hydrochloride) (Public)	500	2	..	*2115.90	Valtrex GK

SECTION 100 – HUMAN GROWTH HORMONE PROGRAM

Code	Name, Restriction, Manner of Administration and Form	Pack Size	Price ex manufacturer \$	Brand Name and Manufacturer
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SOMATROPIN (Recombinant human growth hormone)

Criteria for availability

Short stature in accordance with the 'Guidelines for the Availability of Human Growth Hormone (hGH) as a Pharmaceutical Benefit'.

Genotropin branded products (including MiniQuick) are also available for the treatment of Prader-Willi Syndrome in accordance with the 'Guidelines for the Availability of Human Growth Hormone (hGH) as a Pharmaceutical Benefit for the treatment of Prader-Willi Syndrome'.

Note

These guidelines may be obtained from the Department of Health and Ageing's internet site at <http://www.health.gov.au/hGH>, or from:

Growth Hormone Program
Access and Systems Branch
Department of Health and Ageing
GPO Box 9848
CANBERRA ACT 2601
Contact telephone number (02) 6289 7274

6311E	Solution for injection 10 mg (30 i.u.) in 1.5 mL cartridge (with preservative)	1	495.00	Omnitrope	SZ
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SECTION 100 – SPECIAL AUTHORITY PROGRAM – TRASTUZUMAB

Code	Name, Restriction, Manner of Administration and Form	Pack Size	Price ex manufacturer \$	Brand Name and Manufacturer
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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.

Authority required

Initial treatment for HER2 positive early breast cancer commencing concurrently with adjuvant chemotherapy following surgery.

The total duration of PBS-subsidised treatment (initial plus continuing) that will be authorised is 52 weeks.

HER2 positivity must be demonstrated by in situ hybridisation (ISH).

Trastuzumab must not be used in patients with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure. Cardiac function must be tested by a suitable method including, for example, ECHO or MUGA, prior to seeking the initial authority approval and then at 3 monthly intervals during treatment.

Authority applications for initial treatment must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Early Breast Cancer - PBS Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes:
 - (i) a copy of the pathology report from an Approved Pathology Authority confirming the presence of HER2 gene amplification by in situ hybridisation (ISH); and
 - (ii) a copy of the signed patient acknowledgement form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].

The medical practitioner should request sufficient quantity based on the weight of the patient to provide for a maximum of 3 weeks' treatment (equivalent to the loading dose for the 3 weekly regimen, and the loading dose and 2 weekly doses for the once weekly regimen).

Authority required

Continuing treatment for HER2 positive early breast cancer where the patient has previously received treatment with PBS-subsidised trastuzumab.

The patient is eligible to receive sufficient trastuzumab to complete 52 weeks of combined PBS-subsidised and non-PBS-subsidised therapy.

Trastuzumab must not be used in patients with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure. Cardiac function must be tested by a suitable method including, for example, ECHO or MUGA, at 3 monthly intervals during treatment.

Authority applications for continuing treatment may be made by telephone on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

The medical practitioner should request sufficient quantity based on the weight of the patient for 3 weeks' supply (equivalent to 1 dose for the 3 weekly dosing regimen, or 3 doses for the once weekly dosing regimen). Up to a maximum of 3 repeats may be authorised.

Breaks in therapy.

Where a patient has a break in trastuzumab therapy of more than 1 week but less than 6 weeks from when the last dose was due, authority approval will be granted for a new loading dose. Authority applications for new loading doses may be made by telephone on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

9690B	Powder for I.V. infusion 60 mg (Public)	1	412.08	Herceptin	RO
9691C	Powder for I.V. infusion 60 mg (Private)	1	434.98	Herceptin	RO

REPATRIATION PHARMACEUTICAL BENEFITS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
AZITHROMYCIN								
<u>Restricted benefit</u>								
Upper and lower respiratory tract infections.								
4115N	Tablet 500 mg (as dihydrate)	3	31.51	5.60	Zithromax	PF