Australian Government

Department of Health and Ageing

SCHEDULE OF PHARMACEUTICAL BENEFITS

SUMMARY OF CHANGES

EFFECTIVE 1 July 2011

PHARMACEUTICAL BENEFITS

These changes to the Schedule of Pharmaceutical Benefits are effective from 1 July 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 July 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

5274N **Docetaxel**, Solution concentrate for I.V. infusion 140 mg in 7 mL *(Oncotaxel 140)*

5275P **Docetaxel**, Solution concentrate for I.V. infusion 140 mg in 7 mL *(Oncotaxel 140)*

8995K **Fluorouracil**, Injection 2500 mg in 50 mL *(Fluorouracil Ebewe)*

8996L **Fluorouracil**, Injection 5000 mg in 100 mL *(Fluorouracil Ebewe)*

8982R **Lacosamide**, Oral solution 15 mg per mL, 200 mL *(Vimpat)*

Additions – Brands

2344J *Amiodarone Sandoz, SZ* – **Amiodarone**, Tablet containing amiodarone hydrochloride 100 mg

2343H *Amiodarone Sandoz, SZ* – **Amiodarone**, Tablet containing amiodarone hydrochloride 200 mg

5462L *Oncotaxel 20, TA* – **Docetaxel**, Solution concentrate for I.V. infusion 20 mg in 1 mL

5463M *Oncotaxel 20, TA* – **Docetaxel**, Solution concentrate for I.V. infusion 20 mg in 1 mL

8986Y *Oncotaxel 20, TA* – **Docetaxel**, Solution concentrate for I.V. infusion 20 mg in 1 mL

5464N *Oncotaxel 80, TA* – **Docetaxel**, Solution concentrate for I.V. infusion 80 mg in 4 mL

8989D *Oncotaxel 80, TA* – **Docetaxel**, Solution concentrate for I.V. infusion 80 mg in 4 mL

8700X *Escitalopram generichealth, GQ* – **Escitalopram**, Tablet 10 mg (as oxalate)

8701Y *Escitalopram generichealth, GQ* – **Escitalopram**, Tablet 20 mg (as oxalate)

1968N *Aquinafil, GN* – **Quinapril**, Tablet 5 mg (as hydrochloride)

1969P *Aquinafil, GN* – **Quinapril**, Tablet 10 mg (as hydrochloride)

1970Q *Aquinafil, GN* – **Quinapril**, Tablet 20 mg (as hydrochloride)

8621R *Risedronate Sandoz, SZ* – **Risedronate Sodium**, Tablet 35 mg

8899J *Acris Combi, AF* – **Risedronate Sodium and Calcium Carbonate**, Pack containing 4 tablets risedronate sodium 35 mg and 24 tablets calcium carbonate 1.25 g (equivalent to 500 mg calcium)

8133C *Valvala, NV* – **Valaciclovir**, Tablet 500 mg (as hydrochloride)

8134D *Valvala, NV* – **Valaciclovir**, Tablet 500 mg (as hydrochloride)

8064K *Valvala, NV* – **Valaciclovir**, Tablet 500 mg (as hydrochloride)

3130R *Vycin IV, WQ* – **Vancomycin**, Powder for injection 500 mg (as hydrochloride) (500,000 i.u. vancomycin activity)

3131T *Vycin IV, WQ* – **Vancomycin**, Powder for injection 500 mg (as hydrochloride) (500,000 i.u. vancomycin activity)

2269K *Vycin IV, WQ* – **Vancomycin**, Powder for injection 1 g (as hydrochloride) (1,000,000 i.u. vancomycin activity)

2270L *Vycin IV, WQ* – **Vancomycin**, Powder for injection 1 g (as hydrochloride) (1,000,000 i.u. vancomycin activity)

5083M *Vycin IV, WQ* – **Vancomycin**, Powder for injection 1 g (as hydrochloride) (1,000,000 i.u. vancomycin activity)**(Dental)**

3323X *Vycin IV, WQ* – **Vancomycin**, Powder for injection 500 mg (as hydrochloride) (500,000 i.u. vancomycin activity)**(Dental)**

8280T *Vinorelbine Kabi, PK* – **Vinorelbine**, Solution for I.V. infusion 10 mg (as tartrate) in 1 mL

8281W *Vinorelbine Kabi, PK* – **Vinorelbine**, Solution for I.V. infusion 50 mg (as tartrate) in 5 mL

Additions – Bioequivalence Indicators

8899J *Actonel Combi, SW* – **Risedronate Sodium and Calcium Carbonate**, Pack containing 4 tablets risedronate sodium 35 mg and 24 tablets calcium carbonate 1.25 g (equivalent to 500 mg calcium)

Deletions

Deletions – Items

5023J **Hydromorphone Hydrochloride**, Tablet 4 mg (modified release) *(Jurnista)***(Dental)**

3357Q **Hydromorphone Hydrochloride**, Tablet 8 mg (modified release) *(Jurnista)***(Dental)**

3358R **Hydromorphone Hydrochloride**, Tablet 16 mg (modified release) *(Jurnista)***(Dental)**

3367F **Hydromorphone Hydrochloride**, Tablet 32 mg (modified release) *(Jurnista)***(Dental)**

3368G **Hydromorphone Hydrochloride**, Tablet 64 mg (modified release) *(Jurnista)***(Dental)**

5129Y **Hydromorphone Hydrochloride**, Injection 2 mg in 1 mL *(Dilaudid)***(Dental)**

5130B **Hydromorphone Hydrochloride**, Injection 10 mg in 1 mL *(Dilaudid-HP)***(Dental)**

5131C **Hydromorphone Hydrochloride**, Injection 50 mg in 5 mL *(Dilaudid-HP)***(Dental)**

1626N **Metronidazole**, Tablet 400 mg *(Metrogyl 400)*

5159M **Metronidazole**, Tablet 400 mg *(Metrogyl 400)***(Dental)**

5162Q **Morphine Sulfate**, Tablet 5 mg (controlled release) *(MS Contin)***(Dental)**

5164T **Morphine Sulfate**, Tablet 10 mg (controlled release) *(Momex SR 10, MS Contin)***(Dental)**

5161P **Morphine Sulfate**, Tablet 15 mg (controlled release) *(MS Contin)***(Dental)**

5165W **Morphine Sulfate**, Tablet 30 mg (controlled release) *(Momex SR 30, MS Contin)***(Dental)**

5166X **Morphine Sulfate**, Tablet 60 mg (controlled release) *(Momex SR 60, MS Contin)***(Dental)**

5167Y **Morphine Sulfate**, Tablet 100 mg (controlled release) *(Momex SR 100, MS Contin)***(Dental)**

5246D **Morphine Sulfate**, Capsule 10 mg (containing sustained release pellets) *(Kapanol)***(Dental)**

5240T **Morphine Sulfate**, Capsule 20 mg (containing sustained release pellets) *(Kapanol)***(Dental)**

5064M **Morphine Sulfate**, Capsule 30 mg (controlled release) *(MS Mono)* **(Dental)**

5241W **Morphine Sulfate**, Capsule 50 mg (containing sustained release pellets) *(Kapanol)***(Dental)**

5065N **Morphine Sulfate**, Capsule 60 mg (controlled release) *(MS Mono)***(Dental)**

5066P **Morphine Sulfate**, Capsule 90 mg (controlled release) *(MS Mono)***(Dental)**

5242X **Morphine Sulfate**, Capsule 100 mg (containing sustained release pellets) *(Kapanol)***(Dental)**

5067Q **Morphine Sulfate**, Capsule 120 mg (controlled release) *(MS Mono)***(Dental)**

5171E **Morphine Sulfate**, Sachet containing controlled release granules for oral suspension, 20 mg per sachet *(MS Contin Suspension 20 mg)***(Dental)**

5243Y **Morphine Sulfate**, Sachet containing controlled release granules for oral suspension, 30 mg per sachet *(MS Contin Suspension 30 mg)***(Dental)**

5244B **Morphine Sulfate**, Sachet containing controlled release granules for oral suspension, 60 mg per sachet *(MS Contin Suspension 60 mg)***(Dental)**

5245C **Morphine Sulfate**, Sachet containing controlled release granules for oral suspension, 100 mg per sachet *(MS Contin Suspension 100 mg)***(Dental)**

5227D **Oxycodone Hydrochloride**, Tablet 5 mg (controlled release) *(OxyContin)***(Dental)**

5247E **Oxycodone Hydrochloride**, Tablet 10 mg (controlled release) *(OxyContin)***(Dental)**

5015Y **Oxycodone Hydrochloride**, Tablet 15 mg (controlled release) *(OxyContin)***(Dental)**

5248F **Oxycodone Hydrochloride**, Tablet 20 mg (controlled release) *(OxyContin)***(Dental)**

5016B **Oxycodone Hydrochloride**, Tablet 30 mg (controlled release) *(OxyContin)***(Dental)**

5249G **Oxycodone Hydrochloride**, Tablet 40 mg (controlled release) *(OxyContin)***(Dental)**

5250H **Oxycodone Hydrochloride**, Tablet 80 mg (controlled release) *(OxyContin)***(Dental)**

5198N **Oxycodone Hydrochloride**, Capsule 20 mg *(OxyNorm)***(Dental)**

3338Q **Tramadol Hydrochloride**, Tablet 50 mg (twice daily sustained release) *(Tramal SR 50)***(Dental)**

5001F **Tramadol Hydrochloride**, Tablet 100 mg (once a day extended release) *(Durotram XR)***(Dental)**

5234L **Tramadol Hydrochloride**, Tablet 100 mg (twice daily sustained release) *(Tramal SR 100, Zydol SR 100, Tramedo SR 100, APO-Tramadol SR, Chem mart Tramadol SR, Terry White Chemists Tramadol SR, Lodam SR 100, GA Tramadol SR 100mg, Tramadol Sandoz SR)***(Dental)**

5235M **Tramadol Hydrochloride**, Tablet 150 mg (twice daily sustained release) *(Tramal SR 150, Zydol SR 150, Tramedo SR 150, APO-Tramadol SR, Chem mart Tramadol SR, Terry White Chemists Tramadol SR, Lodam SR 150, GA Tramadol SR 150mg, Tramadol Sandoz SR)***(Dental)**

5002G **Tramadol Hydrochloride**, Tablet 200 mg (once a day extended release) *(Durotram XR)***(Dental)**

5236N **Tramadol Hydrochloride**, Tablet 200 mg (twice daily sustained release) *(Tramal SR 200, Zydol SR 200, Tramedo SR 200, APO-Tramadol SR, Chem mart Tramadol SR, Terry White Chemists Tramadol SR, Lodam SR 200, GA Tramadol SR 200mg, Tramadol Sandoz SR)***(Dental)**

5003H **Tramadol Hydrochloride**, Tablet 300 mg (once a day extended release) *(Durotram XR)***(Dental)**

Deletions – Brands

2315W *Blenamax, QA* – **Bleomycin Sulfate**, Powder for injection 15,000 i.u. (solvent required) (code 6896Y applies to above item with approved solvent)

8256M *Kredex, MD* – **Carvedilol**, Tablet 6.25 mg

8257N *Kredex, MD* – **Carvedilol**, Tablet 12.5 mg

8258P *Kredex, MD* – **Carvedilol**, Tablet 25 mg

1358L *Prothiaden, AB* – **Dothiepin Hydrochloride**, Tablet 75 mg

8487Q *Implanon, SH* – **Etonogestrel**, Subcutaneous implant 68 mg

8414W *Irinotecan Sandoz, SZ* – **Irinotecan Hydrochloride Trihydrate**, I.V. injection 40 mg in 2 mL

8415X *Irinotecan Sandoz, SZ* – **Irinotecan Hydrochloride Trihydrate**, I.V. injection 100 mg in 5 mL

3010K *Norflohexal, HX* – **Norfloxacin**, Tablet 400 mg

1479W *Chem mart Prazosin, CH* – **Prazosin Hydrochloride**, Tablet 1 mg (as hydrochloride)

1479W *GenRx Prazosin, GX* – **Prazosin Hydrochloride**, Tablet 1 mg (as hydrochloride)

1479W *Terry White Chemists Prazosin, TW* – **Prazosin Hydrochloride**, Tablet 1 mg (as hydrochloride)

1480X *Chem mart Prazosin, CH* – **Prazosin Hydrochloride**, Tablet 2 mg (as hydrochloride)

1480X *GenRx Prazosin, GX* – **Prazosin Hydrochloride**, Tablet 2 mg (as hydrochloride)

1480X *Terry White Chemists Prazosin, TW* – **Prazosin Hydrochloride**, Tablet 2 mg (as hydrochloride)

1478T *Chem mart Prazosin, CH* – **Prazosin Hydrochloride**, Tablet 5 mg (as hydrochloride)

1478T *GenRx Prazosin, GX* – **Prazosin Hydrochloride**, Tablet 5 mg (as hydrochloride)

1478T *Terry White Chemists Prazosin, TW* – **Prazosin Hydrochloride**, Tablet 5 mg (as hydrochloride)

1968N *Quinapril-DP, GN* – **Quinapril**, Tablet 5 mg (as hydrochloride)

1969P *Quinapril-DP, GN* – **Quinapril**, Tablet 10 mg (as hydrochloride)

Deletions – Bioequivalence Indicators

2315W *Hospira Pty Limited, HH* – **Bleomycin Sulfate**, Powder for injection 15,000 i.u. (solvent required) (code 6896Y applies to above item with approved solvent)

1358L *Dothep 75, AF* – **Dothiepin Hydrochloride**, Tablet 75 mg

8487Q *Implanon NXT, MK* – **Etonogestrel**, Subcutaneous implant 68 mg

1479W *Minipress, PF* – **Prazosin Hydrochloride**, Tablet 1 mg (as hydrochloride)

1480X *Minipress, PF* – **Prazosin Hydrochloride**, Tablet 2 mg (as hydrochloride)

1478T *Minipress, PF* – **Prazosin Hydrochloride**, Tablet 5 mg (as hydrochloride)

Alterations

Alterations – Brand Name

From:

5257Q *Aspen Pharmacare Australia Pty Limited, LN* – **Flucloxacillin**, Powder for oral liquid 125 mg (as sodium) per 5 mL, 100 mL **(Dental)**

To:

5257Q *Flucil, LN* – **Flucloxacillin**, Powder for oral liquid 125 mg (as sodium) per 5 mL, 100 mL **(Dental)**

From:

5258R *Aspen Pharmacare Australia Pty Limited, LN* – **Flucloxacillin**, Powder for oral liquid 250 mg (as sodium) per 5 mL, 100 mL **(Dental)**

To:

5258R *Flucil, LN* – **Flucloxacillin**, Powder for oral liquid 250 mg (as sodium) per 5 mL, 100 mL **(Dental)**

From:

9149M *Aspen Pharmacare Australia Pty Limited, LN* – **Flucloxacillin**, Powder for oral liquid 125 mg (as sodium) per 5 mL, 100 mL

To:

9149M *Flucil, LN* – **Flucloxacillin**, Powder for oral liquid 125 mg (as sodium) per 5 mL, 100 mL

From:

9150N *Aspen Pharmacare Australia Pty Limited, LN* – **Flucloxacillin**, Powder for oral liquid 250 mg (as sodium) per 5 mL, 100 mL

To:

9150N *Flucil, LN* – **Flucloxacillin**, Powder for oral liquid 250 mg (as sodium) per 5 mL, 100 mL

Alterations – Item Description

From:

2344J **Amiodarone Hydrochloride**, Tablet 100 mg *(Aratac 100, Cardinorm, Rithmik 100, Cordarone X 100)*

To:

2344J **Amiodarone**, Tablet containing amiodarone hydrochloride 100 mg *(Aratac 100, Cardinorm, Rithmik 100, Amiodarone Sandoz, Cordarone X 100)*

From:

2343H **Amiodarone Hydrochloride**, Tablet 200 mg *(Aratac 200, Cardinorm, GenRx Amiodarone, Chem mart Amiodarone, Terry White Chemists Amiodarone, Rithmik 200, Cordarone X 200)*

To:

2343H **Amiodarone**, Tablet containing amiodarone hydrochloride 200 mg *(Aratac 200, Cardinorm, GenRx Amiodarone, Chem mart Amiodarone, Terry White Chemists Amiodarone, Rithmik 200, Amiodarone Sandoz, Cordarone X 200)*

From:

8700X **Escitalopram Oxalate**, Tablet 10 mg (base) *(Lexapro, Esipram, Esitalo, Chem mart Escitalopram, APO-Escitalopram, Terry White Chemists Escitalopram, Lexam 10, LoxaLate, Escicor 10, Pharmacor Escitalopram 10)*

To:

8700X **Escitalopram**, Tablet 10 mg (as oxalate) *(Lexapro, Esipram, Esitalo, Chem mart Escitalopram, APO-Escitalopram, Terry White Chemists Escitalopram, Lexam 10, LoxaLate, Escicor 10, Pharmacor Escitalopram 10, Escitalopram generichealth)*

From:

8701Y **Escitalopram Oxalate**, Tablet 20 mg (base) *(Lexapro, Esipram, Esitalo, Chem mart Escitalopram, APO-Escitalopram, Terry White Chemists Escitalopram, Lexam 20, LoxaLate, Escicor 20, Pharmacor Escitalopram 20)*

To:

8701Y **Escitalopram**, Tablet 20 mg (as oxalate) *(Lexapro, Esipram, Esitalo, Chem mart Escitalopram, APO-Escitalopram, Terry*

White Chemists Escitalopram, Lexam 20, LoxaLate, Escicor 20, Pharmacor Escitalopram 20, Escitalopram generichealth)

From:

8849R **Escitalopram Oxalate**, Oral solution 10 mg (base) per mL, 28 mL *(Lexapro)*

To:

8849R **Escitalopram**, Oral solution 10 mg (as oxalate) per mL, 28 mL *(Lexapro)*

From:

9432K **Escitalopram Oxalate**, Tablet 10 mg (base) *(Lexapro, Esipram)*

To:

9432K **Escitalopram**, Tablet 10 mg (as oxalate) *(Lexapro, Esipram)*

From:

9433L **Escitalopram Oxalate**, Tablet 20 mg (base) *(Lexapro, Esipram)*

To:

9433L **Escitalopram**, Tablet 20 mg (as oxalate) *(Lexapro, Esipram)*

From:

1479W **Prazosin Hydrochloride**, Tablet 1 mg (base) *(Minipress)*

To:

1479W **Prazosin**, Tablet 1 mg (as hydrochloride) *(Minipress)*

From:

1480X **Prazosin Hydrochloride**, Tablet 2 mg (base) *(Minipress)*

To:

1480X **Prazosin**, Tablet 2 mg (as hydrochloride) *(Minipress)*

From:

1478T **Prazosin Hydrochloride**, Tablet 5 mg (base) *(Minipress)*

To:

1478T **Prazosin**, Tablet 5 mg (as hydrochloride) *(Minipress)*

From:

8280T **Vinorelbine Tartrate**, Solution for I.V. infusion 10 mg (base) in 1 mL *(Hospira Pty Limited, Navelbine, Vinorelbine Ebewe, Vinorelbine Link)*

To:

8280T **Vinorelbine**, Solution for I.V. infusion 10 mg (as tartrate) in 1 mL *(Hospira Pty Limited, Navelbine, Vinorelbine Ebewe, Vinorelbine Link, Vinorelbine Kabi)*

From:

8281W **Vinorelbine Tartrate**, Solution for I.V. infusion 50 mg (base) in 5 mL *(Hospira Pty Limited, Navelbine, Vinorelbine Ebewe, Vinorelbine Link)*

To:

8281W **Vinorelbine**, Solution for I.V. infusion 50 mg (as tartrate) in 5 mL *(Hospira Pty Limited, Navelbine, Vinorelbine Ebewe, Vinorelbine Link, Vinorelbine Kabi)*

From:

9009E **Vinorelbine Tartrate**, Capsule 20 mg (base) *(Navelbine)*

To:

9009E **Vinorelbine**, Capsule 20 mg (as tartrate) *(Navelbine)*

From:

9010F **Vinorelbine Tartrate**, Capsule 30 mg (base) *(Navelbine)*

To:

9010F **Vinorelbine**, Capsule 30 mg (as tartrate) *(Navelbine)*

Alterations – Authorised Prescriber

Items which can now be prescribed by Nurse Practitioners:

5468T **Dutasteride**, Capsule 500 micrograms *(Avodart)*

9388D **Zonisamide**, Capsule 25 mg *(Zonegran)*

9389E **Zonisamide**, Capsule 50 mg *(Zonegran)*

9390F **Zonisamide**, Capsule 100 mg *(Zonegran)*

Alterations – Number of Repeats

		From:	*To:*
8808N	**Aprepitant**, Pack containing 1 capsule 125 mg and 2 capsules 80 mg *(Emend)*	0	5

Alterations – Restriction

8757X **Ezetimibe**, Tablet 10 mg *(Ezetrol)*

9483D **Ezetimibe with Simvastatin**, Tablet 10 mg-10 mg *(Vytorin)*

9484E **Ezetimibe with Simvastatin**, Tablet 10 mg-20 mg *(Vytorin)*

8881K **Ezetimibe with Simvastatin**, Tablet 10 mg-40 mg *(Vytorin)*

8882L **Ezetimibe with Simvastatin**, Tablet 10 mg-80 mg *(Vytorin)*

8689H **Rosiglitazone**, Tablet 4 mg (as maleate) *(Avandia)*

8690J **Rosiglitazone**, Tablet 8 mg (as maleate) *(Avandia)*

9059T **Rosiglitazone with Metformin**, Tablet containing 2 mg rosiglitazone (as maleate) with 500 mg metformin hydrochloride *(Avandamet)*

9060W **Rosiglitazone with Metformin**, Tablet containing 2 mg rosiglitazone (as maleate) with 1 g metformin hydrochloride *(Avandamet)*

9061X **Rosiglitazone with Metformin**, Tablet containing 4 mg rosiglitazone (as maleate) with 500 mg metformin hydrochloride *(Avandamet)*

9062Y **Rosiglitazone with Metformin**, Tablet containing 4 mg rosiglitazone (as maleate) with 1 g metformin hydrochloride *(Avandamet)*

Alterations – Notes

8808N **Aprepitant**, Pack containing 1 capsule 125 mg and 2 capsules 80 mg *(Emend)*

8819E **Temozolomide**, Capsule 5 mg *(Temodal)*

8820F **Temozolomide**, Capsule 20 mg *(Temodal)*

8821G **Temozolomide**, Capsule 100 mg *(Temodal)*

9361Q **Temozolomide**, Capsule 140 mg *(Temodal)*

5469W **Varenicline**, Tablet 1 mg (as tartrate) *(Champix)*

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

9128K **Varenicline**, 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 *(Champix)*

Alterations – Manufacturer's Code

All items with the manufacturer code EX have changed to the code FR.

All items with the manufacturer code IT have changed to the code SZ, with the exception of the brand Docetaxel Ebewe in all available forms which will change from manufacturer code IT to code HX.

All items with the manufacturer code SH have changed to the code MK, with the exception of the following drugs:

Simponi, **Golimumab**

Remicade, **Infliximab**

All items with the manufacturer code SM have changed to the code AB.

		From:	*To:*
2344J	*Cardinorm* – **Amiodarone**, Tablet containing amiodarone hydrochloride 100 mg	SZ	HX
2343H	*Cardinorm* – **Amiodarone**, Tablet containing amiodarone hydrochloride 200 mg	SZ	HX
1789E	*LPV* – **Phenoxymethylpenicillin**, Capsule 250 mg	AS	VT
1705R	*LPV* – **Phenoxymethylpenicillin**, Capsule 250 mg	AS	VT
3363B	*LPV* – **Phenoxymethylpenicillin**, Capsule 250 mg (**Dental**)	AS	VT
2965C	*LPV* – **Phenoxymethylpenicillin**, Capsule 500 mg	AS	VT
3364C	*LPV* – **Phenoxymethylpenicillin**, Capsule 500 mg (**Dental**)	AS	VT
1917X	*Solone* – **Prednisolone**, Tablet 5 mg	FM	VT
1916W	*Solone* – **Prednisolone**, Tablet 25 mg	FM	VT
1935W	*Sone* – **Prednisone**, Tablet 5 mg	FM	VT
1936X	*Sone* – **Prednisone**, Tablet 25 mg	FM	VT
8133C	*Valaciclovir GA* – **Valaciclovir**, Tablet 500 mg (as hydrochloride)	GM	GN
8134D	*Valaciclovir GA* – **Valaciclovir**, Tablet 500 mg (as hydrochloride)	GM	GN
5480K	*Valaciclovir GA* – **Valaciclovir**, Tablet 500 mg (as hydrochloride)	GM	GN
8064K	*Valaciclovir GA* – **Valaciclovir**, Tablet 500 mg (as hydrochloride)	GM	GN
8133C	*Zelitrex* – **Valaciclovir**, Tablet 500 mg (as hydrochloride)	RE	GM
8134D	*Zelitrex* – **Valaciclovir**, Tablet 500 mg (as hydrochloride)	RE	GM
5480K	*Zelitrex* – **Valaciclovir**, Tablet 500 mg (as hydrochloride)	RE	GM
8064K	*Zelitrex* – **Valaciclovir**, Tablet 500 mg (as hydrochloride)	RE	GM
8280T	*Vinorelbine Link* – **Vinorelbine**, Solution for I.V. infusion 10 mg (as tartrate) in 1 mL	PK	FU
8281W	*Vinorelbine Link* – **Vinorelbine**, Solution for I.V. infusion 50 mg (as tartrate) in 5 mL	PK	FU

SECTION 100 – HIGHLY SPECIALISED DRUGS PROGRAM

Additions

Additions – Items

9745X **Omalizumab**, Powder for injection 150 mg with diluent *(Xolair)* (**Public**)

9746Y **Omalizumab**, Powder for injection 150 mg with diluent *(Xolair)* (**Private**)

Additions – Brands

9568N *Valaciclovir RBX, RA* – **Valaciclovir**, Tablet 500 mg (as hydrochloride) (**Public**)

6280M *Valaciclovir RBX, RA* – **Valaciclovir**, Tablet 500 mg (as hydrochloride) (**Private**)

9568N *Valvala, NV* – **Valaciclovir**, Tablet 500 mg (as hydrochloride) (**Public**)

6280M *Valvala, NV* – **Valaciclovir**, Tablet 500 mg (as hydrochloride) (**Private**)

Alterations

Alterations – Manufacturer's Code

All items with the manufacturer code SH have changed to the code MK, with the exception of the following brand:

Remicade, **Infliximab**

		From:	*To:*
9568N	*Zelitrex* – **Valaciclovir**, Tablet 500 mg (as hydrochloride) (**Public**)	RE	GM
6280M	*Zelitrex* – **Valaciclovir**, Tablet 500 mg (as hydrochloride) (**Private**)	RE	GM

REPATRIATION PHARMACEUTICAL BENEFITS

Alterations

Alterations – Brand Name and Manufacturer

From:

4365R *Schering-Plough Pty Limited,* SH – **Oestradiol**, Implant 50 mg

To:

4365R *Merck Sharp & Dohme (Australia) Pty Ltd,* MK – **Oestradiol**, Implant 50 mg

From:

4366T *Schering-Plough Pty Limited,* SH – **Oestradiol**, Implant 100 mg

To:

4366T *Merck Sharp & Dohme (Australia) Pty Ltd,* MK – **Oestradiol**, Implant 100 mg

Alterations – Manufacturer's Code

All items with the manufacturer code SH have changed to the code MK.

All items with the manufacturer code SM have changed to the code AB.

		From:	*To:*
4011D	*Tinasil, AL* – **Terbinafine**, Tablet 250 mg (as hydrochloride)	AF	AL

Advance Notices

Advance Notices – Deletion of Brands

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

Brand discontinued by the manufacturer—

1446D *Parlodel, NV* – **Bromocriptine Mesylate**, Capsule 5 mg (base)

1445C *Parlodel, NV* – **Bromocriptine Mesylate**, Capsule 10 mg (base)

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

Brands discontinued by the manufacturer—

2344J *Cardinorm, HX* – **Amiodarone**, Tablet containing amiodarone hydrochloride 100mg

2343H *Cardinorm, HX* – **Amiodarone**, Tablet containing amiodarone hydrochloride 200mg

8280T *Vinorelbine Link, FU* – **Vinorelbine**, Solution for I.V. infusion 10 mg (as tartrate) in 1 mL

8281W *Vinorelbine Link, FU* – **Vinorelbine**, Solution for I.V. infusion 50 mg (as tartrate) in 5 mL

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	
	AMIODARONE								
	Caution								
	Amiodarone hydrochloride has been reported to cause frequent and potentially serious toxicity. Regular monitoring of hepatic and thyroid function is recommended.								
	Restricted benefit								
	Severe cardiac arrhythmias.								
	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.								
2344J *NP*	Tablet containing amiodarone hydrochloride 100 mg	30	5	..	14.60	15.67	[a]	Amiodarone Sandoz	SZ
							[a]	Aratac 100	AF
							[a]	Cardinorm	HX
							[a]	Cordarone X 100	SW
							[a]	Rithmik 100	QA
2343H *NP*	Tablet containing amiodarone hydrochloride 200 mg	30	5	..	20.96	22.03	[a]	Amiodarone Sandoz	SZ
							[a]	Aratac 200	AF
							[a]	Cardinorm	HX
							[a]	Chem mart Amiodarone	CH
							[a]	Cordarone X 200	SW
							[a]	GenRx Amiodarone	GX
							[a]	Rithmik 200	QA
							[a]	Terry White Chemists Amiodarone	TW
	APREPITANT								
	Note								
	Aprepitant is not PBS-subsidised for nausea and vomiting associated with radiotherapy being used to treat malignancy.								
	Authority required (STREAMLINED)								
	3619 Management of nausea and vomiting associated with cytotoxic chemotherapy being used to treat malignancy, in combination with a 5HT3 antagonist and dexamethasone, where any 1 of the following chemotherapy agents are to be administered: (a) altretamine; (b) carmustine; (c) cisplatin when a single dose constitutes a cycle of chemotherapy; (d) cyclophosphamide at a dose of 1500 mg per square metre per day or greater; (e) dacarbazine; (f) procarbazine when a single dose constitutes a cycle of chemotherapy; (g) streptozocin. No more than 1 pack containing 1 x 125 mg capsule and 2 x 80 mg capsules will be authorised per cycle of cytotoxic chemotherapy;								
	3620 Management of nausea and vomiting associated with cytotoxic chemotherapy being used to treat breast cancer, in combination with a 5HT3 antagonist and dexamethasone, where cyclophosphamide and an anthracycline are to be co-administered. No more than 1 pack containing 1 x 125 mg capsule and 2 x 80 mg capsules will be authorised per cycle of cytotoxic chemotherapy;								
	3621 Management of nausea and vomiting associated with moderately emetogenic cytotoxic chemotherapy being used to treat malignancy, in combination with a 5HT3 antagonist and dexamethasone on day 1, where the patient has had a prior episode of chemotherapy induced nausea or vomiting where any 1 of the following intravenous chemotherapy agents is to be administered: (a) arsenic trioxide; (b) azacitidine; (c) carboplatin; (d) cyclophosphamide at a dose of less than 1500 mg per square metre per day; (e) cytarabine at a dose of greater than 1 g per square metre per day; (f) dactinomycin; (g) daunorubicin; (h) doxorubicin; (i) epirubicin;								

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	
	(j) fotemustine; (k) idarubicin; (l) ifosfamide; (m) irinotecan; (n) melphalan; (o) methotrexate at a dose of 250 mg to 1 g per square metre; (p) oxaliplatin; (q) raltitrexed. No more than one pack containing 1 x 125 mg capsule and 2 x 80 mg capsules will be authorised per cycle of cytotoxic chemotherapy. Concomitant use of a 5HT3 antagonist should not occur with aprepitant on days 2 and 3 of any chemotherapy cycle. **Note** No applications for increased maximum quantities and/or repeats will be authorised.							
8808N *NP*	Pack containing 1 capsule 125 mg and 2 capsules 80 mg	‡1	5	..	138.89	34.20	Emend	MK
	DOCETAXEL **Authority required** Neoadjuvant treatment of a patient with a WHO performance status of 1 or less, with inoperable Stage III, IVa or IVb squamous cell carcinoma of the oral cavity, larynx, oropharynx or hypopharynx, in combination with cisplatin and fluorouracil. **Note** The carcinoma can be considered inoperable for technical or organ preservation reasons. **Authority required** Adjuvant treatment of node-positive breast cancer in combination with an anthracycline and cyclophosphamide; Advanced breast cancer after failure of prior therapy; Advanced metastatic ovarian cancer after failure of prior therapy which includes a platinum compound; Locally advanced or metastatic non-small cell lung cancer. **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.							
5274N	Solution concentrate for I.V. infusion 140 mg in 7 mL	1	..	..	2159.66	34.20	Oncotaxel 140	TA
	DOCETAXEL **Authority required** Treatment of HER2 positive early breast cancer in combination with trastuzumab. **Authority required** Adjuvant treatment of operable breast cancer in combination with cyclophosphamide. **Note** A maximum of four cycles of treatment will be authorised under this restriction.							
5275P	Solution concentrate for I.V. infusion 140 mg in 7 mL	1	..	..	2159.66	34.20	Oncotaxel 140	TA
	DUTASTERIDE **Authority required (STREAMLINED)** ***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. **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.							
5468T *NP*	Capsule 500 micrograms	30	5	..	30.43	31.50	Avodart	GK

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	
	ESCITALOPRAM								
	Restricted benefit								
	Major depressive disorders.								
8700X *NP*	Tablet 10 mg (as oxalate)	28	5	..	28.06	29.13	[a]	APO-Escitalopram	TX
							[a]	Chem mart Escitalopram	CH
							[a]	Escicor 10	MI
							[a]	Escitalopram generichealth	GQ
							[a]	Esipram	GM
							[a]	Esitalo	SZ
							[a]	Lexam 10	QA
							[a]	LoxaLate	AF
							[a]	Pharmacor Escitalopram 10	CR
							[a]	Terry White Chemists Escitalopram	TW
				[B]4.70	32.76	29.13	[a]	Lexapro	LU
8701Y *NP*	Tablet 20 mg (as oxalate)	28	5	..	28.19	29.26	[a]	APO-Escitalopram	TX
							[a]	Chem mart Escitalopram	CH
							[a]	Escicor 20	MI
							[a]	Escitalopram generichealth	GQ
							[a]	Esipram	GM
							[a]	Esitalo	SZ
							[a]	Lexam 20	QA
							[a]	LoxaLate	AF
							[a]	Pharmacor Escitalopram 20	CR
							[a]	Terry White Chemists Escitalopram	TW
				[B]6.85	35.04	29.26	[a]	Lexapro	LU

ESCITALOPRAM

Restricted benefit

Moderate to severe generalised anxiety disorder (GAD), as defined by Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV) criteria, in a patient who has not responded to non-pharmacological therapy and:
(a) for whom a GP Mental Health Care Plan, as described under item 2710 of the Medicare Benefits Schedule, has been prepared; or

(b) who has been assessed by a psychiatrist;

Continuing PBS-subsidised treatment, for moderate to severe generalised anxiety disorder (GAD), of a patient commenced on escitalopram prior to 1 March 2008.

Restricted benefit

Moderate to severe social anxiety disorder (social phobia, SAD), as described by Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV) criteria, in a patient who has not responded to non-pharmacological therapy and:
(a) for whom a GP Mental Health Care Plan, as described under item 2710 of the Medicare Benefits Schedule, has been prepared; or

(b) who has been assessed by a psychiatrist;

Continuing PBS-subsidised treatment, for moderate to severe social anxiety disorder (social phobia, SAD), of a patient commenced on escitalopram prior to 1 March 2008.

9432K *NP*	Tablet 10 mg (as oxalate)	28	5	..	28.06	29.13	[a]	Esipram	GM
				[B]4.70	32.76	29.13	[a]	Lexapro	LU
9433L *NP*	Tablet 20 mg (as oxalate)	28	5	..	28.19	29.26	[a]	Esipram	GM

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]6.85	35.04	29.26 [a]	Lexapro	LU

ESCITALOPRAM

Restricted benefit

Major depressive disorders.

Restricted benefit

Moderate to severe generalised anxiety disorder (GAD), as defined by Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV) criteria, in a patient who has not responded to non-pharmacological therapy and:
(a) for whom a GP Mental Health Care Plan, as described under item 2710 of the Medicare Benefits Schedule, has been prepared; or

(b) who has been assessed by a psychiatrist;

Continuing PBS-subsidised treatment, for moderate to severe generalised anxiety disorder (GAD), of a patient commenced on escitalopram prior to 1 November 2008.

Restricted benefit

Moderate to severe social anxiety disorder (social phobia, SAD), as described by Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV) criteria, in a patient who has not responded to non-pharmacological therapy and:
(a) for whom a GP Mental Health Care Plan, as described under item 2710 of the Medicare Benefits Schedule, has been prepared; or

(b) who has been assessed by a psychiatrist;

Continuing PBS-subsidised treatment, for moderate to severe social anxiety disorder (social phobia, SAD), of a patient commenced on escitalopram prior to 1 November 2008.

8849R *NP*	Oral solution 10 mg (as oxalate) per mL, 28 mL	‡1	5	..	34.30	34.20	Lexapro	LU

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:
3724
(a) coronary heart disease; or

3725
(b) diabetes mellitus; or

3726
(c) peripheral vascular disease; or

3727
(d) heterozygous familial hypercholesterolaemia; or

3728
(e) symptomatic cerebrovascular disease; or

3729
(f) family history of coronary heart disease; or

3730
(g) hypertension.

Inadequate control with a statin is defined as follows:
(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or
(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

Authority required (STREAMLINED)

1989
Patients eligible for PBS-subsidised lipid-lowering medication (according to the criteria set out in the General Statement for Lipid-Lowering Drugs) where treatment with an HMG CoA reductase inhibitor (statin) is contraindicated;

3731
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 because the patient developed a clinically important product-related adverse event during treatment with a statin.

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 clinically important product-related adverse event is defined as follows: (i) Severe myalgia (muscle symptoms without creatine kinase elevation) which is proven to be temporally associated with statin treatment; or (ii) Myositis (clinically important creatine kinase elevation, with or without muscle symptoms) demonstrated by results twice the upper limit of normal on a single reading or a rising pattern on consecutive measurements and which is unexplained by other causes; or (iii) Unexplained, persistent elevations of serum transaminases (greater than 3 times the upper limit of normal) during treatment with a statin. **Authority required (STREAMLINED)** ***1991*** Homozygous sitosterolaemia; ***2438*** Patients with homozygous familial hypercholesterolaemia who are eligible for PBS-subsidised lipid-lowering medication (according to the criteria set out in the General Statement for Lipid-Lowering Drugs), in combination with an HMG CoA reductase inhibitor (statin). **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.							
8757X *NP*	Tablet 10 mg	30	5	..	70.97	34.20	Ezetrol	MK
	EZETIMIBE with SIMVASTATIN **Authority required (STREAMLINED)** ***2431*** Patients with homozygous familial hypercholesterolaemia who are eligible for PBS-subsidised lipid-lowering medication (according to the criteria set out in the General Statement for Lipid-Lowering Drugs); ***3739*** 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 reduced because the patient developed a clinically important product-related adverse event during treatment with a statin. A clinically important product-related adverse event is defined as follows: (i) Severe myalgia (muscle symptoms without creatine kinase elevation) which is proven to be temporally associated with statin treatment; or (ii) Myositis (clinically important creatine kinase elevation, with or without muscle symptoms) demonstrated by results twice the upper limit of normal on a single reading or a rising pattern on consecutive measurements and which is unexplained by other causes; or (iii) Unexplained, persistent elevations of serum transaminases (greater than 3 times the upper limit of normal) during treatment with a statin. **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.							
9483D *NP*	Tablet 10 mg-10 mg	30	5	..	88.79	34.20	Vytorin	MK
9484E *NP*	Tablet 10 mg-20 mg	30	5	..	96.59	34.20	Vytorin	MK

EZETIMIBE with SIMVASTATIN
Authority required (STREAMLINED)
Treatment, in conjunction with dietary therapy and exercise, in patients whose cholesterol levels are inadequately controlled with an HMG CoA reductase inhibitor (statin) and who have:
3732
(a) coronary heart disease; or

3733
(b) diabetes mellitus; or

3734
(c) peripheral vascular disease; or

3735
(d) heterozygous familial hypercholesterolaemia; or

3736
(e) cerebrovascular disease which has become symptomatic; or

3737
(f) family history of coronary heart disease; or

3738
(g) hypertension;

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	
	Inadequate control with a statin is defined as follows: (1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when the ezetimibe component is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when the ezetimibe component is initiated; or (2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when the ezetimibe component is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when the ezetimibe component is initiated. ***2431*** Patients with homozygous familial hypercholesterolaemia who are eligible for PBS-subsidised lipid-lowering medication (according to the criteria set out in the General Statement for Lipid-Lowering Drugs).							
	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.							
8881K *NP*	Tablet 10 mg-40 mg	30	5	..	107.85	34.20	Vytorin	MK
8882L *NP*	Tablet 10 mg-80 mg	30	5	..	123.97	34.20	Vytorin	MK
	FLUOROURACIL							
8995K	Injection 2500 mg in 50 mL	2	..	..	*48.22	34.20	Fluorouracil Ebewe	SZ
8996L	Injection 5000 mg in 100 mL	1	..	..	48.22	34.20	Fluorouracil Ebewe	SZ
	LACOSAMIDE **Authority required** Treatment, initiated by a neurologist, in combination with two or more anti-epileptic drugs which includes one second-line adjunctive agent, of partial epileptic seizures which are not controlled satisfactorily by other anti-epileptic drugs in a patient aged 16 years or older with intractable epilepsy. A patient must have trialled and failed to achieve satisfactory seizure control with: (i) at least one first-line anti-epileptic agent; and (ii) at least two second-line adjunctive anti-epileptic agents; Continuing treatment, in combination with two or more anti-epileptic drugs which includes one second-line adjunctive agent, of partial epileptic seizures in a patient aged 16 years or older, who has previously been treated with PBS-subsidised lacosamide.							
	Note No applications for increased maximum quantities will be authorised for the 56 tablet packs of the 150 mg and 200 mg strengths.							
	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.							
8982R *NP*	Oral solution 15 mg per mL, 200 mL	2	5	..	*201.46	34.20	Vimpat	UC
	PRAZOSIN							
1479W *NP*	Tablet 1 mg (as hydrochloride)	100	5	..	12.31	13.38	Minipress	PF
1480X *NP*	Tablet 2 mg (as hydrochloride)	100	5	..	14.50	15.57	Minipress	PF
1478T *NP*	Tablet 5 mg (as hydrochloride)	100	5	..	20.13	21.20	Minipress	PF
	ROSIGLITAZONE **Note** Rosiglitazone maleate is not PBS-subsidised as monotherapy or in combination with metformin and a sulfonylurea (triple oral therapy) or an insulin or a dipeptidyl peptidase 4 inhibitor (gliptin) or a glucagon-like peptide-1. **Authority required** 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							

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	
	dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone) or a glucagon-like peptide-1 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 treatment with a gliptin, a glitazone or a glucagon-like peptide-1 is initiated. The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone or a glucagon-like peptide-1 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 treatment with a gliptin, a glitazone or a glucagon-like peptide-1, must be documented in the patient's medical records.							
8689H *NP*	Tablet 4 mg (as maleate)	28	5	..	61.52	34.20	Avandia	GK
8690J *NP*	Tablet 8 mg (as maleate)	28	5	..	91.19	34.20	Avandia	GK
	ROSIGLITAZONE with METFORMIN **Note** Rosiglitazone with metformin fixed dose combination tablet is not PBS-subsidised when used in combination with a sulfonylurea (triple oral therapy) or an insulin or a dipeptidyl peptidase 4 inhibitor (gliptin) or a glucagon-like peptide-1. **Authority required** Type 2 diabetes in a patient whose HbA1c is greater than 7% prior to initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone) or a glucagon-like peptide-1 despite treatment with metformin and where 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 treatment with a gliptin, a glitazone or a glucagon-like peptide-1 is initiated. The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone or a glucagon-like peptide-1 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 treatment with a gliptin, a glitazone or a glucagon-like peptide-1, must be documented in the patient's medical records.							
9059T *NP*	Tablet containing 2 mg rosiglitazone (as maleate) with 500 mg metformin hydrochloride	56	5	..	64.92	34.20	Avandamet	GK
9060W *NP*	Tablet containing 2 mg rosiglitazone (as maleate) with 1 g metformin hydrochloride	56	5	..	68.09	34.20	Avandamet	GK
9061X *NP*	Tablet containing 4 mg rosiglitazone (as maleate) with 500 mg metformin hydrochloride	56	5	..	94.59	34.20	Avandamet	GK
9062Y *NP*	Tablet containing 4 mg rosiglitazone (as maleate) with 1 g metformin hydrochloride	56	5	..	97.75	34.20	Avandamet	GK
	TEMOZOLOMIDE **Authority required** Glioblastoma multiforme concomitantly with radiotherapy. **Note** Temozolomide is not PBS-subsidised for use in conjunction with PBS-subsidised carmustine. **Note** No applications for increased repeats will be authorised.							
8819E	Capsule 5 mg	15	2	..	*208.05	34.20	Temodal	MK
8820F	Capsule 20 mg	15	2	..	*567.93	34.20	Temodal	MK
8821G	Capsule 100 mg	15	2	..	*2389.29	34.20	Temodal	MK
9361Q	Capsule 140 mg	15	2	..	*3266.10	34.20	Temodal	MK

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** A course of treatment with varenicline tartrate is 12 weeks or up to 24 weeks, if initial treatment of 12 weeks has been successful. Only one course of 12 or up to 24 weeks of PBS-subsidised varenicline tartrate will be authorised per year. The period between commencing varenicline tartrate and bupropion hydrochloride must be at least 6 months. 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** 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 *NP*	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	..	..	103.12	34.20		Champix	PF
	VARENICLINE **Note** A course of treatment with varenicline tartrate is 12 weeks or up to 24 weeks, if initial treatment of 12 weeks has been successful. Only one course of 12 or up to 24 weeks of PBS-subsidised varenicline tartrate will be authorised per year. The period between commencing varenicline tartrate and bupropion hydrochloride must be at least 6 months. 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** 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
	VARENICLINE **Note** A course of treatment with varenicline tartrate is 12 weeks or up to 24 weeks, if initial treatment of 12 weeks has been successful. Only one course of 12 or up to 24 weeks of PBS-subsidised varenicline tartrate will be authorised per year. The period between commencing varenicline tartrate and bupropion hydrochloride must be at least 6 months. 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
	VINORELBINE **Authority required** Locally advanced or metastatic non-small cell lung cancer.								
9009E	Capsule 20 mg (as tartrate)	20	2	..	*1973.02	34.20		Navelbine	FB
9010F	Capsule 30 mg (as tartrate)	16	2	..	*2340.02	34.20		Navelbine	FB
	VINORELBINE **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 (as tartrate) in 1 mL	16	2	..	*1114.42	34.20	[a]	Hospira Pty Limited	HH
							[a]	Navelbine	FB
							[a]	Vinorelbine Ebewe	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	
							[a]	Vinorelbine Kabi	PK
							[a]	Vinorelbine Link	FU
8281W	Solution for I.V. infusion 50 mg (as tartrate) in 5 mL	4	2	..	*1162.46	34.20	[a]	Hospira Pty Limited	HH
							[a]	Navelbine	FB
							[a]	Vinorelbine Ebewe	SZ
							[a]	Vinorelbine Kabi	PK
							[a]	Vinorelbine Link	FU

ZONISAMIDE

Authority required (STREAMLINED)

2664

Treatment of partial epileptic seizures which are not controlled satisfactorily by other anti-epileptic drugs.

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.

9388D *NP*	Capsule 25 mg	56	5	..	22.80	23.87	Zonegran	SA
9389E *NP*	Capsule 50 mg	56	5	..	33.72	34.20	Zonegran	SA
9390F *NP*	Capsule 100 mg	112	5	..	*93.46	34.20	Zonegran	SA

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

OMALIZUMAB

Note

Any queries concerning the arrangements to prescribe omalizumab 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 omalizumab 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 AND ADOLESCENT PATIENTS WITH UNCONTROLLED SEVERE ALLERGIC ASTHMA

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

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

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

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

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

Initial treatment authorisations will be limited to provide for a maximum of 28 weeks of therapy with omalizumab.

A patient must be assessed for response to a course of Initial PBS-subsidised treatment following a minimum of 24 weeks of therapy with omalizumab, and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date of assessment.

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 omalizumab.

For second and subsequent courses of PBS-subsidised omalizumab 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 the initial treatment course with omalizumab, a patient may qualify to receive up to a further 24 weeks of continuing treatment with omalizumab providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing omalizumab treatment in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted omalizumab supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia within 4 weeks of the date of assessment, and no later than 2 weeks prior to the patient completing their current treatment course, to avoid an interruption to supply.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with omalizumab.

(2) Baseline measurements to determine response.

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

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

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

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

(4) Patients 'grandfathered' onto PBS-subsidised treatment with omalizumab.

A patient who commenced treatment with omalizumab for uncontrolled severe allergic asthma prior to 1 November 2010 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 omalizumab will be authorised under this criterion.

Following completion of the Initial PBS-subsidised course, further applications for treatment with omalizumab will be assessed under the continuing treatment restriction.

'Grandfather' arrangements will only apply for the first treatment cycle (initial treatment course with or without continuing treatment course/s). For the second and subsequent cycles, a 'Grandfathered' patient must re-qualify for Initial treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 6 month break in PBS-subsidised therapy' above for further details.

(5) Monitoring of patients.

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

Authority required

Initial treatment of uncontrolled severe allergic asthma

Initial PBS-subsidised treatment with omalizumab by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma, of a patient aged 12 years or older with uncontrolled severe allergic asthma who has been under the care of this physician for at least 12 months, and satisfies the following criteria:

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

(b) duration of asthma of at least 1 year; and

(c) FEV1 less than or equal to 80% predicted, documented on 3 or more occasions in the previous 12 months; and

(d) past or current evidence of atopy, documented by skin prick testing or RAST; and

(e) total serum human immunoglobulin E (IgE) greater than or equal to 76 IU/mL; and

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

(g) has failed to achieve adequate control with optimised asthma therapy, despite formal assessment of and adherence to correct inhaler technique, which has been documented (see NOTE). Optimised asthma therapy includes:
(i) adherence to maximal inhaled therapy, including high dose inhaled corticosteroid (budesonide 1600 micrograms per day or fluticasone propionate 1000 micrograms per day or equivalent), plus long-acting beta-2 agonist therapy (at least salmeterol 50 micrograms bd or eformoterol 12 micrograms bd) for at least 12 months, unless contraindicated or not tolerated, AND
(ii) oral corticosteroids (at least 10 mg per day prednisolone (or equivalent)) for at least 6 weeks, unless contraindicated or not tolerated.

If the requirement for treatment with optimised asthma therapy cannot be met because of contraindications according to the relevant TGA-approved Product Information and/or intolerances of a severity necessitating permanent treatment withdrawal, details of the contraindication and/or intolerance must be provided in the authority application. Details of the accepted toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement of treatment with optimised asthma therapy can be found on the Medicare Australia website [www.medicareaustralia.gov.au].

The initial IgE assessment must be no more than 12 months old at the time of application. A re-assessment of free IgE can only be made at least 12

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

months after the last dose of omalizumab. For patients re-commencing omalizumab within 12 months of the last dose the previous pre-omalizumab IgE level should be used.

The IgE pathology report must be provided with the authority application.

The following initiation criteria indicate failure to achieve adequate control and must be demonstrated in all patients at the time of the application:
(a) an Asthma Control Questionnaire (ACQ-5) score of at least 2.0, as assessed in the previous month, AND
(b) while on oral corticosteroids and in the past 12 months, experienced at least 1 admission to hospital for a severe asthma exacerbation, OR 1 severe asthma exacerbation, requiring documented use of systemic corticosteroids (oral corticosteroids initiated or increased for at least 3 days, or parenteral corticosteroids) prescribed/supervised by a physician.

The authority application must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Severe Allergic Asthma PBS Authority Application - Supporting Information Form (may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)) which includes the following:
(i) details of prior optimised asthma drug therapy (dosage, date of commencement and duration of therapy); and
(ii) details of severe exacerbation/s experienced while on oral corticosteroids (date and treatment); and
(iii) the signed patient acknowledgement; and
(c) a completed Asthma Control Questionnaire (ACQ-5) calculation sheet including the date of assessment of the patient's symptoms. (For copies of the ACQ please contact Novartis Medical Information on 1800 671 203 or medinfo.phauno@novartis.com)

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

Where fewer than the required number of repeats to complete 28 weeks of treatment are requested at the time of the application, authority approvals for sufficient repeats to complete 28 weeks of omalizumab therapy 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 28 weeks.

The Asthma Control Questionnaire (5 item version) assessment of the patient's response to this initial course of treatment, and the assessment of oral corticosteroid dose, must be made at around 24 to 26 weeks after the first dose so that there is adequate time for a response to be demonstrated and for the application for continuing therapy to be processed.

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

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 24 to 26 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised omalizumab treatment.

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

Note

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

Authority required

Continuing treatment

Continuing PBS-subsidised treatment with omalizumab, by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma, of a patient who:
(a) has a documented history of severe allergic asthma; and
(b) has demonstrated or sustained an adequate response to treatment with omalizumab.

An adequate response to omalizumab treatment is defined as:
(a) a reduction in the Asthma Control Questionnaire (ACQ-5) score of at least 0.5 from baseline, OR
(b) maintenance oral corticosteroid dose reduced by at least 25% from baseline, and no deterioration in ACQ-5 score from baseline.

The authority application must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Severe Allergic Asthma PBS Authority Application - Supporting Information Form (may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)) which includes details of maintenance oral corticosteroid dose; and
(c) a completed Asthma Control Questionnaire (ACQ-5) calculation sheet including the date of assessment of the patient's symptoms. (For copies of the ACQ please contact Novartis Medical Information on 1800 671 203 or medinfo.phauno@novartis.com)

All applications for continuing treatment with omalizumab must include a measurement of response to the prior course of therapy. The Asthma

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

Control Questionnaire (5 item version) assessment of the patient's response to the prior course of treatment, and the assessment of oral corticosteroid dose, must be made at around 20 to 22 weeks after the first dose so that there is adequate time for a response to be demonstrated and for the application for continuing therapy to be processed.

The first assessment should, where possible, be completed by the same physician who initiated treatment with omalizumab. If the same physician cannot assess the patient please call Medicare Australia on 1800 700 270.

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

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 20 to 22 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised omalizumab treatment.

Patients are eligible to receive continuing courses of omalizumab treatment of up to 24 weeks providing they continue to demonstrate an adequate response to treatment.

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

Where fewer than the required number of repeats to complete 24 weeks of treatment are requested at the time of the application, authority approvals for sufficient repeats to complete 24 weeks of omalizumab therapy 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).

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

Authority required

Initial PBS-subsidised treatment of severe allergic asthma in a patient who has previously received non-PBS-subsidised therapy with omalizumab (grandfather patients)

Initial PBS-subsidised supply for continuing treatment with omalizumab by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma, of a patient aged 12 years or older with severe allergic asthma who satisfies the following criteria:

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

(b) duration of asthma of at least 1 year; and

(c) past or current evidence of atopy, documented by skin prick testing or RAST; 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 criteria for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment for grandfathered patients; and

(e) prior to omalizumab therapy had failed to achieve adequate control with optimised asthma therapy. Optimised asthma therapy includes:
(i) adherence to maximal inhaled therapy, including high dose inhaled corticosteroid (budesonide 1600 micrograms per day or fluticasone propionate 1000 micrograms per day or equivalent), plus long-acting beta-2 agonist therapy (at least salmeterol 50 micrograms bd or eformoterol 12 micrograms bd) for at least 12 months, and
(ii) may have included maintenance dose oral corticosteroids; and

(f) has demonstrated an adequate response to treatment with omalizumab.

A review of the patient's records should be conducted to extract pre- and post-omalizumab data on symptoms, quality of life, medication doses, exacerbations and hospitalisations. Examples of parameters to establish response include:
(i) a reduction in Asthma Control Questionnaire (ACQ-5) score of at least 0.5;
(ii) an improvement of at least 0.5 in the Asthma Quality of Life Questionnaire (AQLQ or mini-AQLQ);
(iii) maintenance oral corticosteroid dose reduced by at least 25% from baseline; and/or
(iv) a reduction in the number of hospitalisations or severe exacerbations requiring use of systemic corticosteroids, compared to the 12 months prior to commencement of omalizumab.

HIGHLY SPECIALISED DRUGS PROGRAM

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	Where baseline assessments are not available, please call Medicare Australia on 1800 700 270 to discuss. If the requirement for treatment with optimised asthma therapy cannot be met because of contraindications according to the relevant TGA-approved Product Information and/or intolerances of a severity necessitating permanent treatment withdrawal, details of the contraindication and/or intolerance must be provided in the authority application. Details of the accepted contraindications and toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement of treatment with optimised asthma therapy can be found on the Medicare Australia website [www.medicareaustralia.gov.au]. The authority application must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Severe Allergic Asthma PBS Authority Application - Supporting Information Form (may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)) which includes the following: (i) details of prior optimised asthma drug therapy (dosage, date of commencement and duration of therapy); and (ii) details of pre- and post-omalizumab data on symptoms, quality of life, medication doses, exacerbations and hospitalisations; and (iii) the signed patient acknowledgement. At the time of the authority application, medical practitioners should request the appropriate maximum quantity and number of repeats to provide for an initial course of omalizumab consisting of the recommended number of doses for the baseline IgE level and body weight of the patient (refer to the TGA-approved Product Information) to be administered every 2 or 4 weeks. Where fewer than the required number of repeats to complete 24 weeks of treatment are requested at the time of the application, authority approvals for sufficient repeats to complete 24 weeks of omalizumab therapy 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. An assessment of the patient's continued response to this course of PBS-subsidised treatment must be made at around 20 to 22 weeks after the first dose so that there is adequate time for a response to be demonstrated and for the application for continuing therapy to be processed. The same parameters used to establish response to non-PBS-subsidised therapy with omalizumab should be used for the assessment. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia within 4 weeks of the date of assessment, and no later than 2 weeks prior to the patient completing their current treatment course, to avoid an interruption to supply. Where a response assessment is not undertaken and submitted to Medicare Australia within this timeframe, the patient will be deemed to have failed to respond to treatment with omalizumab. It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 20 to 22 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised omalizumab treatment. Patients are eligible to receive continuing courses of omalizumab treatment of up to 24 weeks providing they continue to demonstrate an adequate response to treatment. Patients may qualify for PBS-subsidised treatment under this restriction once only. A patient who fails to respond to a course of PBS-subsidised omalizumab for the treatment of uncontrolled severe allergic asthma will not be eligible to receive further PBS-subsidised treatment with omalizumab for this condition within 6 months of the date on which treatment was ceased. **Note** Special Pricing Arrangements apply.								
9745X	Powder for injection 150 mg with diluent **(Public)**	1	..	..	425.00		Xolair	NV
9746Y	Powder for injection 150 mg with diluent **(Private)**	1	..	..	448.42		Xolair	NV
	VALACICLOVIR **Authority required (STREAMLINED)** ***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	[a]	APO-Valaciclovir	TX
						[a]	Valaciclovir RBX	RA
						[a]	Valtrex	GK
						[a]	Valvala	NV
						[a]	Zelitrex	GM

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	
	VALACICLOVIR							
	Authority required							
	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	[a]	APO-Valaciclovir	TX
						[a]	Valaciclovir RBX	RA
						[a]	Valtrex	GK
						[a]	Valvala	NV
						[a]	Zelitrex	GM

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	
	OESTRADIOL								
	Restricted benefit								
	Post-menopausal symptoms in women who have failed to respond using oral or topical oestrogens.								
4365R	Implant 50 mg	1	..	..	83.34	5.60		Merck Sharp & Dohme (Australia) Pty Ltd	MK
4366T	Implant 100 mg	1	..	..	121.58	5.60		Merck Sharp & Dohme (Australia) Pty Ltd	MK
	TERBINAFINE								
	Authority required								
	Onychomycosis due to dermatophyte infection proven by microscopy or culture and confirmed by an approved pathology provider.								
4011D	Tablet 250 mg (as hydrochloride)	42	1	..	98.01	5.60	[a]	Lamisil	NV
							[a]	Tamsil	QA
							[a]	Terbihexal	SZ
							[a]	Terbinafine-DP	GN
							[a]	Tinasil	AL