Australian Government

Department of Health and Ageing

SCHEDULE OF PHARMACEUTICAL BENEFITS

SUMMARY OF CHANGES

EFFECTIVE 1 NOVEMBER 2008

PHARMACEUTICAL BENEFITS

These changes to the Schedule of Pharmaceutical Benefits are effective from 1 November 2008. 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 November 2008 and are included, where applicable, in prices published in the Schedule—

Dispensing Fees:	Ready-prepared	$5.99
	Dangerous drug fee	$2.71
	Extemporaneously-prepared	$8.03
	Allowable additional patient charge*	$3.63
Additional Fees (for safety net prices):	Ready-prepared	$1.03
	Extemporaneously-prepared	$1.39
Patient Co-payments:	General	$31.30
	Concessional	$5.00
Safety Net Thresholds:	General	$1141.80
	Concessional	$290.00
Safety Net Card Issue Fee:		$7.86

*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

(see under 'RESTRICTIONS' and 'NOTES' below for full details)

9210R **Carbomer 980**, Ocular lubricating gel 2 mg per g (0.2%), 10 g (*GelTears, PAA, Viscotears Liquid Gel*)
9211T **Carmellose sodium**, Eye drops 5 mg per mL (0.5%), 15 mL (*Refresh Tears Plus*)
9212W **Carmellose sodium**, Eye drops 10 mg per mL (1%), 15 mL (*Refresh Liquigel*)
9282M **Dasatinib**, Tablet 20 mg (*Sprycel*)
9283N **Dasatinib**, Tablet 50 mg (*Sprycel*)
9284P **Dasatinib**, Tablet 70 mg (*Sprycel*)
5533F **Fluorometholone acetate**, Eye drops 1 mg per mL (0.1%), 5 mL (*Flarex*) **(Optometrical)**
9213X **Hypromellose**, Eye drops 3 mg per mL (0.3%), 15 mL (contains sodium perborate as preservative) (*In a Wink Moisturising, Genteal*)
9214Y **Hypromellose**, Eye drops 5 mg per mL (0.5%), 15 mL (*Methopt*)
9215B **Hypromellose with carbomer 980**, Ocular lubricating gel 3 mg-2 mg per g (0.3%-0.2%), 10 g (*HPMC PAA, Genteal gel*)
9216C **Hypromellose with dextran**, Eye drops 3 mg-1 mg per mL (0.3%-0.1%), 15 mL (*Poly-Tears, Tears Naturale*)
9224L **Insulin glulisine**, Injection (human analogue) 100 units per mL, 10 mL (*Apidra*)
9206M **Mesalazine**, Sachet containing granules, 1.5 g per sachet (*Salofalk*)
9285Q **Nilotinib**, Capsule 200 mg (as hydrochloride monohydrate) (*Tasigna*)
9217D **Paraffin**, Compound eye ointment 3.5 g (*Poly Visc, Duratears*)
9218E **Paraffin**, Pack containing 2 tubes compound eye ointment 3.5 g (*Poly Visc, Ircal, Lacri-Lube*)
9197C **Paroxetine**, Tablet 20 mg (as mesilate) (*Paroxetine generichealth*)
9219F **Polyethylene glycol 400 with propylene glycol**, Eye drops 4 mg-3 mg per mL (0.4%-0.3%), 15 mL (*Systane*)
9220G **Polyvinyl alcohol**, Eye drops 14 mg per mL (1.4%), 15 mL (*PVA Tears, Liquifilm Tears*)
9221H **Polyvinyl alcohol**, Eye drops 14 mg per mL (1.4%), 15 mL (contains sodium chlorite/hydrogen peroxide as preservative) (*Vistil*)
9222J **Polyvinyl alcohol**, Eye drops 30 mg per mL (3%), 15 mL (*PVA Forte, Liquifilm Forte*)
9223K **Polyvinyl alcohol**, Eye drops 30 mg per mL (3%), 15 mL (contains sodium chlorite/hydrogen peroxide as preservative) (*Vistil Forte*)
9202H **Quetiapine fumarate**, Tablet (modified release) equivalent to 50 mg quetiapine (*Seroquel XR*)
9203J **Quetiapine fumarate**, Tablet (modified release) equivalent to 200 mg quetiapine (*Seroquel XR*)
9204K **Quetiapine fumarate**, Tablet (modified release) equivalent to 300 mg quetiapine (*Seroquel XR*)
9205L **Quetiapine fumarate**, Tablet (modified release) equivalent to 400 mg quetiapine (*Seroquel XR*)
9208P **Sulfasalazine**, Tablet 500 mg (*Salazopyrin*)
9209Q **Sulfasalazine**, Tablet 500 mg (enteric coated) (*Pyralin EN, Salazopyrin-EN*)
9199E **Tramadol hydrochloride**, Tablet 100 mg (once a day extended release) (*Durotram XR*)
5001F **Tramadol hydrochloride**, Tablet 100 mg (once a day extended release) (*Durotram XR*) **(Dental)**
9200F **Tramadol hydrochloride**, Tablet 200 mg (once a day extended release) (*Durotram XR*)
5002G **Tramadol hydrochloride**, Tablet 200 mg (once a day extended release) (*Durotram XR*) **(Dental)**
9201G **Tramadol hydrochloride**, Tablet 300 mg (once a day extended release) (*Durotram XR*)
5003H **Tramadol hydrochloride**, Tablet 300 mg (once a day extended release) (*Durotram XR*) **(Dental)**

Additions – Brands

8596K *Amipride 400, SI* — **Amisulpride**, Tablet 400 mg
2751T *Amlotrust 5, MI* — **Amlodipine**, Tablet 5 mg (as besylate)

2752W *Amlotrust 10, MI* — **Amlodipine**, Tablet 10 mg (as besylate)
8255L *GN-Carvedilol, GM* — **Carvedilol**, Tablet 3.125 mg
8256M *GN-Carvedilol, GM* — **Carvedilol**, Tablet 6.25 mg
8257N *GN-Carvedilol, GM* — **Carvedilol**, Tablet 12.5 mg
8258P *GN-Carvedilol, GM* — **Carvedilol**, Tablet 25 mg
8415X *Irinotecan-GA, GM* — **Irinotecan hydrochloride trihydrate**, I.V. injection 100 mg in 5 mL
2848X *Lamotrigine-GA, GN* — **Lamotrigine**, Tablet 25 mg
2849Y *Lamotrigine-GA, GN* — **Lamotrigine**, Tablet 50 mg
2850B *Lamotrigine-GA, GN* — **Lamotrigine**, Tablet 100 mg
2851C *Lamotrigine-GA, GN* — **Lamotrigine**, Tablet 200 mg

Additions – Notes

(see under 'NOTES' below for full details)

9092M **Atomoxetine hydrochloride**, Capsule 10 mg (base) (*Strattera*)
9093N **Atomoxetine hydrochloride**, Capsule 18 mg (base) (*Strattera*)
9094P **Atomoxetine hydrochloride**, Capsule 25 mg (base) (*Strattera*)
9095Q **Atomoxetine hydrochloride**, Capsule 40 mg (base) (*Strattera*)
9096R **Atomoxetine hydrochloride**, Capsule 60 mg (base) (*Strattera*)

DELETIONS

Deletions – Items

8395W **Cabergoline**, Tablet 4 mg (*Cabaser*)
9018P **Epirubicin hydrochloride**, Powder for injection 50 mg (*HH*)

Deletions – Brands

2456G *Lisinotrust 5, MI* — **Lisinopril**, Tablet 5 mg
2457H *Lisinotrust 10, MI* — **Lisinopril**, Tablet 10 mg
2458J *Lisinotrust 20, MI* — **Lisinopril**, Tablet 20 mg
2236Q *Sertratrust 50, MI* — **Sertraline hydrochloride**, Tablet 50 mg (base)
2237R *Sertratrust 100, MI* — **Sertraline hydrochloride**, Tablet 100 mg (base)
2011W *Simvatrust 10, MI* — **Simvastatin**, Tablet 10 mg
2012X *Simvatrust 20, MI* — **Simvastatin**, Tablet 20 mg
8173E *Simvatrust 40, MI* — **Simvastatin**, Tablet 40 mg
8313M *Simvatrust 80, MI* — **Simvastatin**, Tablet 80 mg

Deletions – Note

1377L **Epirubicin hydrochloride**, Solution for injection 50 mg in 25 mL (*Epirubicin Ebewe, Pharmorubicin Solution, HH*)

ALTERATIONS

Alterations – Items

From:
2242B **Paroxetine hydrochloride**, Tablet 20 mg (base) (*Chem mart Paroxetine, Extine 20, GenRx Paroxetine, Paroxetine 20, Paroxetine-DP, Paroxetine Sandoz, Paroxetine Winthrop, Paxtine, Terry White Chemists Paroxetine, Aropax*)

To:
2242B **Paroxetine**, Tablet 20 mg (as hydrochloride) (*Chem mart Paroxetine, Extine 20, GenRx Paroxetine, Paroxetine 20, Paroxetine-DP, Paroxetine Sandoz, Paroxetine Winthrop, Paxtine, Terry White Chemists Paroxetine, Aropax*)

From:
9170P **Polyethylene glycol 400 with propylene glycol**, Eye drops 4 mg-3 mg per mL (0.4%-0.3%), single dose units 0.7 mL, 28 (*Systane*)

To:
9170P **Polyethylene glycol 400 with propylene glycol**, Eye drops 4 mg-3 mg per mL (0.4%-0.3%), single dose units 0.8 mL, 28 (*Systane*)

From:
5532E **Polyethylene glycol 400 with propylene glycol**, Eye drops 4 mg-3 mg per mL (0.4%-0.3%), single dose units 0.7 mL, 28 (*Systane*)

To:
5532E **Polyethylene glycol 400 with propylene glycol**, Eye drops 4 mg-3 mg per mL (0.4%-0.3%), single dose units 0.8 mL, 28 (*Systane*) **(Optometrical)**

From:
2527B **Tramadol hydrochloride**, Tablet 50 mg (sustained release) (*Tramal SR 50*)

To:
2527B **Tramadol hydrochloride**, Tablet 50 mg (twice daily sustained release) (*Tramal SR 50*)

From:
3338Q **Tramadol hydrochloride**, Tablet 50 mg (sustained release) (*Tramal SR 50*) **(Dental)**

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

From:
8523N **Tramadol hydrochloride**, Tablet 100 mg (sustained release) (*Tramahexal SR, Tramedo SR 100, Zydol SR 100, Tramal SR 100*)

To:
8523N **Tramadol hydrochloride**, Tablet 100 mg (twice daily sustained release) (*Tramahexal SR, Tramedo SR 100, Zydol SR 100, Tramal SR 100*)

From:
5234L **Tramadol hydrochloride**, Tablet 100 mg (sustained release) (*Tramahexal SR, Tramedo SR 100, Zydol SR 100, Tramal SR 100*) **(Dental)**

To:
5234L **Tramadol hydrochloride**, Tablet 100 mg (twice daily sustained release) (*Tramahexal SR, Tramedo SR 100, Zydol SR 100, Tramal SR 100*) **(Dental)**

From:
8524P **Tramadol hydrochloride**, Tablet 150mg (sustained release) (*Tramahexal SR, Tramedo SR 150, Zydol SR 150, Tramal SR 150*)

To:
8524P **Tramadol hydrochloride**, Tablet 150mg (twice daily sustained release) (*Tramahexal SR, Tramedo SR 150, Zydol SR 150, Tramal SR 150*)

From:

5235M **Tramadol hydrochloride**, Tablet 150 mg (sustained release) (*Tramahexal SR, Tramedo SR 150, Zydol SR 150, Tramal SR 150*) **(Dental)**

To:

5235M **Tramadol hydrochloride**, Tablet 150 mg (twice daily sustained release) (*Tramahexal SR, Tramedo SR 150, Zydol SR 150, Tramal SR 150*) **(Dental)**

From:

8525Q **Tramadol hydrochloride**, Tablet 200 mg (sustained release) (*Tramahexal SR, Tramedo SR 200, Zydol SR 200, Tramal SR 200*)

To:

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

From:

5236N **Tramadol hydrochloride**, Tablet 200 mg (sustained release) (*Tramahexal SR, Tramedo SR 200, Zydol SR 200, Tramal SR 200*) **(Dental)**

To:

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

Alterations – Maximum Quantity

		From	*To*
9170P	**Polyethylene glycol 400 with propylene glycol**, Eye drops 4 mg-3 mg per mL (0.4%-0.3%), single dose units 0.8 mL, 28 (*Systane*)	3	2
5532E	**Polyethylene glycol 400 with propylene glycol**, Eye drops 4 mg-3 mg per mL (0.4%-0.3%), single dose units 0.8 mL, 28 (*Systane*) **(Optometrical)**	3	2

Alterations – Proprietary Name

From:

8020D **Pancreatic extract**, Capsule (containing enteric coated minimicrospheres) providing not less than 10,000 BP units of lipase activity (*Creon*)

To:

8020D **Pancreatic extract**, Capsule (containing enteric coated minimicrospheres) providing not less than 10,000 BP units of lipase activity (*Creon 10,000*)

From:

8021E **Pancreatic extract**, Capsule (containing enteric coated minimicrospheres) providing not less than 25,000 BP units of lipase activity (*Creon Forte*)

To:

8021E **Pancreatic extract**, Capsule (containing enteric coated minimicrospheres) providing not less than 25,000 BP units of lipase activity (*Creon 25,000*)

Alterations – Manufacturer's Code

		From	*To*
8511Y	**Alendronate sodium**, Tablet equivalent to 70 mg alendronic acid (*Alendro Once Weekly*)	AW	SI
2130D	**Alprazolam**, Tablet 250 micrograms (*Alprax 0.25*)	AW	SI
2131E	**Alprazolam**, Tablet 500 micrograms (*Alprax 0.5*)	AW	SI
2132F	**Alprazolam**, Tablet 1 mg (*Alprax 1*)	AW	SI
8118G	**Alprazolam**, Tablet 2 mg (*Alprax 2*)	AW	SI
2343H	**Amiodarone hydrochloride**, Tablet 200 mg (*Rithmik 200*)	AW	SI
2344J	**Amiodarone hydrochloride**, Tablet 100 mg (*Rithmik 100*)	AW	SI
2687K	**Azathioprine**, Tablet 50 mg (*Azapin*)	AW	SI
2729P	**Baclofen**, Tablet 10 mg (*Stelax 10*)	AW	SI

2730Q	**Baclofen**, Tablet 25 mg (*Stelax 25*)	AW	SI
2502Q	**Calcitriol**, Capsule 0.25 microgram (*Kosteo*)	AW	SI
1208N	**Ciprofloxacin**, Tablet 250 mg (*Ciprol 250*)	AW	SI
1209P	**Ciprofloxacin**, Tablet 500 mg (*Ciprol 500*)	AW	SI
1210Q	**Ciprofloxacin**, Tablet 750 mg (*Ciprol 750*)	AW	SI
8220P	**Citalopram hydrobromide**, Tablet 20 mg (base) (*Talam*)	AW	SI
8318T	**Clarithromycin**, Tablet 250 mg (*Clarithro 250*)	AW	SI
1211R	**Clomiphene citrate**, Tablet 50 mg (*Fermil*)	AW	SI
3161J	**Diazepam**, Tablet 2 mg (*Valpam 2*)	AW	SI
5071X	**Diazepam**, Tablet 2 mg (*Valpam 2*) **(Dental)**	AW	SI
5357Y	**Diazepam**, Tablet 2 mg (*Valpam 2*) **(Palliative Care)**	AW	SI
5355W	**Diazepam**, Tablet 2 mg (*Valpam 2*) **(Palliative Care) (Diff. Max. Rpts)**	AW	SI
3162K	**Diazepam**, Tablet 5 mg (*Valpam 5*)	AW	SI
5072Y	**Diazepam**, Tablet 5 mg (*Valpam 5*) **(Dental)**	AW	SI
5358B	**Diazepam**, Tablet 5 mg (*Valpam 5*) **(Palliative Care)**	AW	SI
5356X	**Diazepam**, Tablet 5 mg (*Valpam 5*) **(Palliative Care) (Diff. Max. Rpts)**	AW	SI
9106G	**Doxycycline**, Tablet 50 mg (as monohydrate) (*Frakas*)	AW	SI
2487X	**Famotidine**, Tablet 20 mg (*Ausfam 20*)	AW	SI
2488Y	**Famotidine**, Tablet 40 mg (*Ausfam 40*)	AW	SI
2366M	**Felodipine**, Tablet 5 mg (extended release) (*Felodil XR 5*)	AW	SI
2367N	**Felodipine**, Tablet 10 mg (extended release) (*Felodil XR 10*)	AW	SI
1471K	**Fluconazole**, Capsule 50 mg (*Fluconazole Hexal, Fluzole 50*)	HX	SZ
		AW	SI
1472L	**Fluconazole**, Capsule 100 mg (*Fluconazole Hexal*)	HX	SZ
1475P	**Fluconazole**, Capsule 200 mg (*Fluconazole Hexal, Fluzole 200*)	HX	SZ
		AW	SI
8512B	**Fluvoxamine maleate**, Tablet 50 mg (*Faverin 50*)	AW	SI
8174F	**Fluvoxamine maleate**, Tablet 100 mg (*Faverin 100*)	AW	SI
1182F	**Fosinopril sodium**, Tablet 10 mg (*Fosipril 10*)	AW	SI
1183G	**Fosinopril sodium**, Tablet 20 mg (*Fosipril 20*)	AW	SI
2449X	**Gliclazide**, Tablet 80 mg (*Nidem*)	AW	SI
8450R	**Glimepiride**, Tablet 1 mg (*Diapride 1*)	AW	SI
8451T	**Glimepiride**, Tablet 2 mg (*Diapride 2*)	AW	SI
8533D	**Glimepiride**, Tablet 3 mg (*Diapride 3*)	AW	SI
8452W	**Glimepiride**, Tablet 4 mg (*Diapride 4*)	AW	SI
1542E	**Ipratropium bromide**, Nebuliser solution single dose units 250 micrograms (anhydrous) in 1 mL, 30 (*Aeron 250*)	AW	SI
8238N	**Ipratropium bromide**, Nebuliser solution single dose units 500 micrograms (anhydrous) in 1 mL, 30 (*Aeron 500*)	AW	SI
8063J	**Lamotrigine**, Tablet 5 mg (*Seaze 5*)	AW	SI
2848X	**Lamotrigine**, Tablet 25 mg (*Seaze 25*)	AW	SI
2849Y	**Lamotrigine**, Tablet 50 mg (*Seaze 50*)	AW	SI
2850B	**Lamotrigine**, Tablet 100 mg (*Seaze 100*)	AW	SI
2851C	**Lamotrigine**, Tablet 200 mg (*Seaze 200*)	AW	SI
2456G	**Lisinopril**, Tablet 5 mg (*Fibsol 5*)	AW	SI
2457H	**Lisinopril**, Tablet 10 mg (*Fibsol 10*)	AW	SI
2458J	**Lisinopril**, Tablet 20 mg (*Fibsol 20*)	AW	SI
8561N	**Meloxicam**, Tablet 7.5 mg (*Movalis 7.5*)	AW	SI
8562P	**Meloxicam**, Tablet 15 mg (*Movalis 15*)	AW	SI
2430X	**Metformin hydrochloride**, Tablet 500 mg (*Formet 500*)	AW	SI
1801T	**Metformin hydrochloride**, Tablet 850 mg (*Formet 850*)	AW	SI
8607B	**Metformin hydrochloride**, Tablet 1 g (*Formet 1000*)	AW	SI
1324Q	**Metoprolol tartrate**, Tablet 50 mg (*Metrol 50*)	AW	SI

1325R	**Metoprolol tartrate**, Tablet 100 mg (*Metrol 100*)	AW	SI
8513C	**Mirtazapine**, Tablet 30 mg (*Mirtazon*)	AW	SI
8883M	**Mirtazapine**, Tablet 45 mg (*Mirtazon*)	AW	SI
1906H	**Nifedipine**, Tablet 30 mg (controlled release) (*Addos XR 30*)	AW	SI
1907J	**Nifedipine**, Tablet 60 mg (controlled release) (*Addos XR 60*)	AW	SI
3010K	**Norfloxacin**, Tablet 400 mg (*Roxin*)	AW	SI
8224W	**Ondansetron**, Tablet 4 mg (*Onsetron 4*)	AW	SI
1594X	**Ondansetron**, Tablet 4 mg (*Onsetron 4*) **(Diff. Max. Qty and Rpts)**	AW	SI
8225X	**Ondansetron**, Tablet 8 mg (*Onsetron 8*)	AW	SI
1595Y	**Ondansetron**, Tablet 8 mg (*Onsetron 8*) **(Diff. Max. Qty and Rpts)**	AW	SI
8226Y	**Ondansetron**, I.V. injection 4 mg in 2 mL (*Onsetron*)	AW	SI
1596B	**Ondansetron**, I.V. injection 4 mg in 2 mL (*Onsetron*) **(Diff. Restriction)**	AW	SI
8227B	**Ondansetron**, I.V. injection 8 mg in 4 mL (*Onsetron*)	AW	SI
1597C	**Ondansetron**, I.V. injection 8 mg in 4 mL (*Onsetron*) **(Diff. Restriction)**	AW	SI
1746X	**Paracetamol**, Tablet 500 mg (*Parmol*)	AW	SI
8784H	**Paracetamol**, Tablet 500 mg (*Parmol*) **(Diff. Max. Qty and Rpts)**	AW	SI
5196L	**Paracetamol**, Tablet 500 mg (*Parmol*) **(Dental)**	AW	SI
5224Y	**Paracetamol**, Tablet 500 mg (*Parmol*) **(Dental) (Diff. Max. Qty)**	AW	SI
2242B	**Paroxetine**, Tablet 20 mg (as hydrochloride) (*Extine 20*)	AW	SI
2833D	**Pravastatin sodium**, Tablet 10 mg (*Lipostat 10*)	AW	SI
2834E	**Pravastatin sodium**, Tablet 20 mg (*Lipostat 20*)	AW	SI
8197K	**Pravastatin sodium**, Tablet 40 mg (*Lipostat 40*)	AW	SI
8829Q	**Pravastatin sodium**, Tablet 80 mg (*Lipostat 80*)	AW	SI
1968N	**Quinapril hydrochloride**, Tablet 5 mg (base) (*Acquin 5*)	AW	SI
1969P	**Quinapril hydrochloride**, Tablet 10 mg (base) (*Acquin 10*)	AW	SI
1970Q	**Quinapril hydrochloride**, Tablet 20 mg (base) (*Acquin 20*)	AW	SI
1944H	**Ramipril**, Tablet 1.25 mg (*Prilace 1.25*)	AW	SI
1945J	**Ramipril**, Tablet 2.5 mg (*Prilace 2.5*)	AW	SI
1946K	**Ramipril**, Tablet 5 mg (*Prilace 5*)	AW	SI
8470T	**Ramipril**, Capsule 10 mg (*Prilace 10*)	AW	SI
1760P	**Roxithromycin**, Tablet 150 mg (*Roxar 150*)	AW	SI
8016X	**Roxithromycin**, Tablet 300 mg (*Roxar 300*)	AW	SI
2000G	**Salbutamol sulfate**, Nebuliser solution single dose units 2.5 mg (base) in 2.5 mL, 30 (*Butamol 2.5*)	AW	SI
2001H	**Salbutamol sulfate**, Nebuliser solution single dose units 5 mg (base) in 2.5 mL, 30 (*Butamol 5*)	AW	SI
3496B	**Salbutamol sulfate**, Nebuliser solution single dose units 2.5 mg (base) in 2.5 mL, 30 (*Butamol 2.5*) **(Doctor's Bag)**	AW	SI
3497C	**Salbutamol sulfate**, Nebuliser solution single dose units 5 mg (base) in 2.5 mL, 30 (*Butamol 5*) **(Doctor's Bag)**	AW	SI
8398B	**Sotalol hydrochloride**, Tablet 80 mg (*Solavert*)	AW	SI
2043M	**Sotalol hydrochloride**, Tablet 160 mg (*Solavert*)	AW	SI
8144P	**Sumatriptan succinate**, Tablet 50 mg (base) (*Sumagran 50*)	AW	SI
2285G	**Terbinafine hydrochloride**, Tablet 250 mg (base) (*Tamsil*)	AW	SI
2804N	**Terbinafine hydrochloride**, Tablet 250 mg (base) (*Tamsil*) **(Diff. Max. Rpts)**	AW	SI
2791X	**Trandolapril**, Capsule 500 micrograms (*Dolapril 0.5*)	AW	SI
2792Y	**Trandolapril**, Capsule 1 mg (*Dolapril 1*)	AW	SI
2793B	**Trandolapril**, Capsule 2 mg (*Dolapril 2*)	AW	SI
8758Y	**Trandolapril**, Capsule 4 mg (*Dolapril 4*)	AW	SI

Alterations – Restrictions

(see under 'RESTRICTIONS' below for full details)

9092M **Atomoxetine hydrochloride**, Capsule 10 mg (base) (*Strattera*)
9093N **Atomoxetine hydrochloride**, Capsule 18 mg (base) (*Strattera*)
9094P **Atomoxetine hydrochloride**, Capsule 25 mg (base) (*Strattera*)
9095Q **Atomoxetine hydrochloride**, Capsule 40 mg (base) (*Strattera*)
9096R **Atomoxetine hydrochloride**, Capsule 60 mg (base) (*Strattera*)
9118X **Bortezomib**, Powder for injection 3.5 mg (solvent required) (*Velcade*)
9117W **Bortezomib**, Powder for injection 3.5 mg (solvent required) (*Velcade*) **(Diff. Max. Rpts)**
2478K **Dasatinib**, Tablet 20 mg (*Sprycel*)
2482P **Dasatinib**, Tablet 50 mg (*Sprycel*)
2485T **Dasatinib**, Tablet 70 mg (*Sprycel*)
9176Y **Imatinib**, Tablet 100 mg (as mesylate) (*Glivec*)
9178C **Imatinib**, Tablet 100 mg (as mesylate) (*Glivec*) **(Diff. Restriction)**
9177B **Imatinib**, Tablet 400 mg (as mesylate) (*Glivec*)
9179D **Imatinib**, Tablet 400 mg (as mesylate) (*Glivec*) **(Diff. Restriction)**
9171Q **Nilotinib**, Capsule 200 mg (as hydrochloride monohydrate) (*Tasigna*)
8689H **Rosiglitazone maleate**, Tablet 4 mg (base) (*Avandia*)
8690J **Rosiglitazone maleate**, Tablet 8 mg (base) (*Avandia*)
9059T **Rosiglitazone maleate with metformin hydrochloride**, Tablet 2 mg (base)-500 mg (*Avandamet*)
9060W **Rosiglitazone maleate with metformin hydrochloride**, Tablet 2 mg (base)-1 g (*Avandamet*)
9061X **Rosiglitazone maleate with metformin hydrochloride**, Tablet 4 mg (base)-500 mg (*Avandamet*)
9062Y **Rosiglitazone maleate with metformin hydrochloride**, Tablet 4 mg (base)-1 g (*Avandamet*)
2700D **Thyrotropin alfa**, Powder for injection 0.9 mg, 2 (*Thyrogen*)

SECTION 100 – HIGHLY SPECIALISED DRUGS PROGRAM

ADDITION

Addition – Note

(see under 'NOTES' below for full details)

9624M **Natalizumab**, Solution concentrate for I.V. infusion 300 mg in 15 mL (*Tysabri*)

ADVANCE NOTICES

Advance Notices - Deletions

The following brand will be deleted from the Schedule of Pharmaceutical Benefits on 1 **December** 2008:
Brand discontinued by the manufacturer —

1147J *Capoten, BQ* — **Captopril**, Tablet 12.5 mg

The following item will be deleted from the Highly Specialised Drugs Program on 1 **December** 2008:
Item discontinued by the manufacturer —

6331F **Nelfinavir mesylate**, Tablet 250 mg (base) (*Viracept*)

The following brand will be deleted from the Schedule of Pharmaceutical Benefits on 1 **January** 2009:
Brand discontinued by the manufacturer —

2109B *Nolvadex, AP* — **Tamoxifen citrate**, Tablet 10 mg (base)

The following item will be deleted from the Schedule of Pharmaceutical Benefits on 1 **January** 2009:
Item discontinued by the manufacturer —

1036M **Aminoglutethimide**, Tablet 250 mg (*Cytadren 250*)

The following brand will be deleted from the Schedule of Pharmaceutical Benefits on 1 **February** 2009:
Brand discontinued by the manufacturer —

1081X *Anselol 50 mg, GM* — **Atenolol**, Tablet 50 mg

RESTRICTIONS

The text of restrictions mentioned above:

9092M **Atomoxetine hydrochloride**, Capsule 10 mg (base) (*Strattera*)

9093N **Atomoxetine hydrochloride**, Capsule 18 mg (base) (*Strattera*)
9094P **Atomoxetine hydrochloride**, Capsule 25 mg (base) (*Strattera*)
9095Q **Atomoxetine hydrochloride**, Capsule 40 mg (base) (*Strattera*)
9096R **Atomoxetine hydrochloride**, Capsule 60 mg (base) (*Strattera*)

Authority required

Initial sole PBS-subsidised treatment of attention-deficit hyperactivity disorder (ADHD) diagnosed between the ages of 6 and 18 years inclusive, by a paediatrician or psychiatrist according to the DSM-IV criteria, where

treatment with dexamphetamine sulfate or methylphenidate hydrochloride poses an unacceptable medical risk due to the following contraindications as specified in the TGA-approved product information:
(1) The patient has a history of substance abuse or misuse (other than alcohol); and/or
(2) The patient has comorbid motor tics or Tourette's Syndrome; and/or
(3) The patient has comorbid severe anxiety diagnosed according to the DSM-IV

Authority required

Initial sole PBS-subsidised treatment of attention-deficit hyperactivity disorder (ADHD) diagnosed between the ages of 6 and 18 years inclusive, by a paediatrician or psychiatrist according to the DSM-IV criteria, where

treatment with dexamphetamine sulfate or methylphenidate hydrochloride has resulted in the development or worsening of a comorbid mood disorder (diagnosed according to the DSM-IV criteria i.e. anxiety disorder, obsessive compulsive disorder, depressive disorder) of a severity necessitating permanent stimulant treatment withdrawal; or where the combination of stimulant treatment with another agent would pose an unacceptable medical risk of a severity necessitating permanent stimulant treatment withdrawal

Authority required

Initial sole PBS-subsidised treatment of attention-deficit hyperactivity disorder (ADHD) diagnosed between the ages of 6 and 18 years inclusive, by a paediatrician or psychiatrist according to the DSM-IV criteria, where

treatment with dexamphetamine sulfate AND methylphenidate hydrochloride has resulted in the development of adverse reactions of a severity necessitating permanent treatment withdrawal:
(1) Adverse effects on growth and weight; and/or
(2) Adverse effects on sleep including insomnia; and/or
(3) Adverse effects on appetite including anorexia

Authority required

Continuing sole PBS-subsidised treatment where the patient has previously been issued with an authority prescription for this drug

Bortezomib

NOTE:

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

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

Applications for authority to prescribe bortezomib should be forwarded to:

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

9118X **Bortezomib**, Powder for injection 3.5 mg (solvent required) (*Velcade*)

Authority required

Continuing PBS-subsidised treatment, as monotherapy or in combination with a corticosteroid and/or cyclophosphamide, of multiple myeloma in a patient who has previously received 8 treatment cycles with bortezomib and who, at the time of application, has demonstrated at least a partial response to bortezomib but who has not received 2 treatment cycles after first achieving a confirmed complete response.

If serum M protein and urine Bence-Jones protein levels are measurable, partial response (PR) compared with baseline (prior to treatment with bortezomib) is defined as:
(a) at least a 50% reduction in the level of serum M protein (monoclonal protein); or
(b) at least a 90% reduction in 24-hour urinary light chain M protein excretion or to less than 200 mg per 24 hours.

If serum M protein and urine Bence-Jones protein levels are unmeasurable as in non-secretory/oligo-secretory multiple myeloma, partial response compared with baseline is defined as:
(c) the difference between involved and uninvolved serum free light chain (FLC) levels, with at least a 50% reduction in this value.

If serum M protein and urine Bence-Jones protein levels and serum FLC are unmeasurable/unavailable, partial response compared with baseline is defined as:
(d) at least a 50% reduction in bone marrow plasma cells; or
(e) normalisation of corrected serum calcium to less than or equal to 2.65 mmol per L; or
(f) no increase in size or number of lytic bone lesions (development of compression fracture does not exclude response); or
(g) at least a 50% reduction in the size of soft tissue plasmacytoma (by clinical or applicable radiographic examination, i.e. MRI or CT-Scan).

The same parameters provided for the diagnosis of progressive disease are to be used to demonstrate at least a partial response to treatment.

Diagnostic reports must be within 1 month of the date of application.

For the purpose of assessing eligibility for continuing PBS-subsidised bortezomib treatment beyond 8 cycles, the patient must have achieved at least a partial response at the completion of cycle 8. The results of the response assessment must be included in a written application to Medicare Australia for further treatment. Where a response assessment is not submitted to Medicare Australia prior to cycle 9, patients will be deemed to have failed to respond to treatment with bortezomib. Continuing PBS-subsidised supply will not be approved if there is a gap of more than 10 months between the initial application and an application following completion of 8 treatment cycles.

The authority application must be made in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Multiple Myeloma Authority Application - Supporting Information Form; and
(3) diagnostic reports demonstrating the patient has achieved at least a partial response.

No more than 2 cycles of treatment beyond the cycle at which the complete response was first achieved will be authorised. Confirmation requires 2 determinations a minimum of 6 weeks apart.

Applications for PBS-subsidised treatment with bortezomib that extends beyond 11 cycles will not be approved

Authority required

Initial PBS-subsidised treatment of multiple myeloma in patients receiving treatment with bortezomib prior to 1 November 2007.

Patients who fail to demonstrate at least a partial response after 4 cycles will not be eligible to receive further PBS-subsidised treatment with bortezomib.

Diagnostic reports demonstrating at least a partial response must be within 1 month of the date of application.

Patients may qualify for PBS-subsidised treatment under this restriction for a maximum of 3 cycles. To receive further treatment the patient must qualify under the continuing treatment criteria.

The authority application must be made in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Multiple Myeloma Authority Application - Supporting Information Form; and
(3) a signed patient acknowledgment; and
(4) details including relevant reports of the basis of the diagnosis of progressive disease and nomination of which disease activity parameters will be used to assess response; and
(5) if relevant, details including relevant reports for patients who have demonstrated a partial response and who have received 4 or more cycles

9117W **Bortezomib**, Powder for injection 3.5 mg (solvent required) (*Velcade*)

Authority required

Initial PBS-subsidised treatment, as monotherapy or in combination with a corticosteroid and/or cyclophosphamide, of multiple myeloma in a patient with a WHO performance status of 2 or less, who has progressive disease, who has received at least 1 prior therapy (other than thalidomide), who has undergone or is ineligible for a primary stem cell transplant and who has experienced treatment failure after a trial of at least four (4) weeks of thalidomide at a dose of at least 100 mg daily.

If the dosing requirement for thalidomide cannot be met, the application must state the reasons why this criterion cannot be satisfied.

Thalidomide treatment failure is defined as:
(1) confirmed disease progression during or within 6 months of discontinuing thalidomide treatment; or
(2) severe intolerance or toxicity unresponsive to clinically appropriate dose adjustment.

Progressive disease is defined as at least 1 of the following:
(a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or
(b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or
(c) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or
(d) an increase in the size or number of lytic bone lesions (not including compression fractures); or
(e) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or
(f) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Severe intolerance due to thalidomide is defined as unacceptable somnolence or sedation interfering with activities of daily living.

Toxicity from thalidomide is defined as peripheral neuropathy (Grade 2 or greater, interfering with function), drug-related seizures, serious Grade 3 or Grade 4 drug-related dermatological reactions, such as Stevens-Johnson Syndrome, or other Grade 3 or 4 toxicity.

The authority application must be made in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Multiple Myeloma Authority Application - Supporting Information Form,

which includes details of prior treatments including name(s) of drug(s) and date of most recent treatment cycle and record of prior stem cell transplant or ineligibility for prior stem cell transplant; the patient's WHO performance status; details of thalidomide treatment failure; details of the basis of the diagnosis of progressive disease; and nomination of which disease activity parameters will be used to assess response.

To enable confirmation by Medicare Australia of response, current diagnostic reports of the following are required:
(a) the level of serum monoclonal protein; and
(b) if Bence-Jones proteinuria is present, the results of 24-hour urinary light chain M protein excretion.

If neither serum M protein or urine Bence-Jones protein are present in measurable quantities, additional diagnostic reports are required, including:
(c) bone marrow aspirate and trephine; and
(d) if present, the size and location of lytic bone lesions (not including compression fractures); or
(e) if present, the size and location of all soft tissue plasmacytomas by clinical or radiographic examination i.e. MRI or CT-scan; or
(f) if present, the level of hypercalcaemia, corrected for albumin concentration; or
(g) if present, the serum free light chain levels.

As these parameters will be used to determine response, results for (a) and (b) should be provided for all patients. Where the patient has oligo-secretory or non-secretory multiple myeloma, (c) must be provided and if relevant (d), (e) or (f). Where the prescriber plans to assess response in patients with oligo-secretory or non-secretory multiple myeloma with free light chain assays, (g) must be provided. Where 1 or more results cannot be provided, the application must state the reason(s) these cannot be provided; and
(3) duration of thalidomide and daily dose prescribed; and
(4) a signed patient acknowledgment

Authority required

Continuing PBS-subsidised treatment, as monotherapy or in combination with a corticosteroid and/or cyclophosphamide, of multiple myeloma in a patient who has previously received 4 treatment cycles of bortezomib and who, at the time of application, has demonstrated at least a partial response to bortezomib.

If serum M protein and urine Bence-Jones protein levels are measurable, partial response (PR) compared with baseline (prior to treatment with bortezomib) is defined as:
(a) at least a 50% reduction in the level of serum M protein (monoclonal protein); or
(b) at least a 90% reduction in 24-hour urinary light chain M protein excretion or to less than 200 mg per 24 hours.

If serum M protein and urine Bence-Jones protein levels are unmeasurable as in non-secretory/oligo-secretory multiple myeloma, partial response compared with baseline is defined as:
(c) at least a 50% reduction in the difference between involved and uninvolved serum free light chain (FLC) levels.

If serum M protein and urine Bence-Jones protein and serum FLC are unmeasurable/unavailable, partial response compared with baseline is defined as:
(d) at least a 50% reduction in bone marrow plasma cells; or
(e) normalisation of corrected serum calcium to less than or equal to 2.65 mmol per L; or
(f) no increase in size or number of lytic bone lesions (development of compression fracture does not exclude response); or
(g) at least a 50% reduction in the size of soft tissue plasmacytoma (by clinical or applicable radiographic examination, i.e. MRI or CT-Scan).

For the purpose of assessing eligibility for continuing PBS-subsidised bortezomib treatment beyond 4 cycles, the patient must have achieved at least a partial response at the completion of cycle 4. The results of the response assessment must be included in a written application to Medicare Australia for further treatment. Where a response assessment is not submitted to Medicare Australia prior to cycle 5, patients will be deemed to have failed to respond to treatment with bortezomib. Continuing PBS-subsidised supply

will not be approved if there is a gap of more than 6 months between the initial application and subsequent applications.

The same parameters provided for the diagnosis of progressive disease are to be used to demonstrate at least a partial response to treatment.

The authority application must be made in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Multiple Myeloma Authority Application - Supporting Information Form; and
(3) diagnostic reports demonstrating the patient has achieved at least a partial response.

Diagnostic reports must be no more than 1 month old at the time of application.

Patients who fail to demonstrate at least a partial response after 8 cycles will not be eligible to receive further PBS-subsidised treatment with bortezomib.

No more than 2 cycles of treatment beyond the cycle at which a confirmed complete response was first achieved will be authorised. Confirmation requires 2 determinations a minimum of 6 weeks apart

9210R **Carbomer 980**, Ocular lubricating gel 2 mg per g (0.2%), 10 g (*GelTears, PAA, Viscotears Liquid Gel*)
9212W **Carmellose sodium**, Eye drops 10 mg per mL (1%), 15 mL (*Refresh Liquigel*)
9211T **Carmellose sodium**, Eye drops 5 mg per mL (0.5%), 15 mL (*Refresh Tears Plus*)
9213X **Hypromellose**, Eye drops 3 mg per mL (0.3%), 15 mL (contains sodium perborate as preservative) (*In a Wink Moisturising, Genteal*)
9214Y **Hypromellose**, Eye drops 5 mg per mL (0.5%), 15 mL (*Methopt*)
9215B **Hypromellose with carbomer 980**, Ocular lubricating gel 3 mg-2 mg per g (0.3%-0.2%), 10 g (*HPMC PAA, Genteal gel*)
9216C **Hypromellose with dextran**, Eye drops 3 mg-1 mg per mL (0.3%-0.1%), 15 mL (*Poly-Tears, Tears Naturale*)
9219F **Polyethylene glycol 400 with propylene glycol**, Eye drops 4 mg-3 mg per mL (0.4%-0.3%), 15 mL (*Systane*)
9221H **Polyvinyl alcohol**, Eye drops 14 mg per mL (1.4%), 15 mL (contains sodium chlorite/hydrogen peroxide as preservative) (*Vistil*)
9220G **Polyvinyl alcohol**, Eye drops 14 mg per mL (1.4%), 15 mL (*PVA Tears, Liquifilm Tears*)
9223K **Polyvinyl alcohol**, Eye drops 30 mg per mL (3%), 15 mL (contains sodium chlorite/hydrogen peroxide as preservative) (*Vistil Forte*)
9222J **Polyvinyl alcohol**, Eye drops 30 mg per mL (3%), 15 mL (*PVA Forte, Liquifilm Forte*)

Restricted benefit

For use in patients who have severe dry eye syndrome, including Sjogren's syndrome, and who are receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements.

NOTE:

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

Dasatinib

NOTE:

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

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

Any queries concerning patients who are enrolled on the Dasatinib Compassionate Program may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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

Medicare Australia

Prior Written Approval of Specialised Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

9282M **Dasatinib**, Tablet 20 mg (*Sprycel*)
9283N **Dasatinib**, Tablet 50 mg (*Sprycel*)
9284P **Dasatinib**, Tablet 70 mg (*Sprycel*)

Authority required

Initial treatment, as the sole PBS-subsidised therapy, of a patient with chronic myeloid leukaemia in any disease phase bearing the Philadelphia chromosome or expressing the transcript, BCR-ABL, who has active leukaemia (as defined by presence on current pathology assessments of either the Philadelphia chromosome on cytogenetic or FISH analysis, or the presence of the transcript BCR-ABL greater than 1% on the international scale) and who has failed an adequate trial of imatinib.

Failure of an adequate trial of imatinib is defined as:

(i) Lack of response to initial imatinib therapy, defined as either:

— failure to achieve a haematological response after a minimum of 3 months therapy with imatinib for patients initially treated in chronic phase; or

— failure to achieve any cytogenetic response after a minimum of 6 months therapy with imatinib for patients initially treated in chronic phase as demonstrated on bone marrow biopsy by presence of greater than 95% Philadelphia chromosome positive cells; or

— failure to achieve a major cytogenetic response or a peripheral blood BCR-ABL level of less than 1% after a minimum of 12 months therapy with imatinib; OR

(ii) Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph positive cells on bone marrow biopsy), during ongoing imatinib therapy; OR

(iii) Loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing in value by at least 5 fold to a level of greater than 1% confirmed on a subsequent test); OR

(iv) Development of accelerated phase or blast crisis in a patient previously prescribed imatinib for any phase of chronic myeloid leukaemia.

Accelerated phase is defined by the presence of 1 or more of the following:

(1) Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 15% but less than 30%; or

(2) Percentage of blasts plus promyelocytes in the peripheral blood or bone marrow greater than or equal to 30%; or

(3) Peripheral basophils greater than or equal to 20%; or

(4) Progressive splenomegaly to a size greater than or equal to 10 cm below the left costal margin to be confirmed on 2 occasions at least 4 weeks apart, or a greater than or equal to 50% increase in size below the left costal margin over 4 weeks; or

(5) Karyotypic evolution (chromosomal abnormalities in addition to a single Philadelphia chromosome).

Blast crisis is defined as either:

(1) Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 30%; or

(2) Extramedullary involvement other than spleen and liver; OR

(v) Disease progression (defined as a greater than or equal to 50% increase in peripheral white blood cell count, blast count, basophils or platelets) during first-line imatinib therapy in patients with accelerated phase or blast crisis chronic myeloid leukaemia; OR

(vi) Grade 3 or 4 non-haematological toxicity that is imatinib related and necessitates permanent cessation of imatinib. For patients with imatinib related toxicities, leukaemia activity does not need to be demonstrated.

Applications for authorisation must be in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Chronic Myeloid Leukaemia Dasatinib/Nilotinib PBS Authority Application - Supporting Information Form; and

(c) a signed patient acknowledgement; and

(d) a bone marrow biopsy pathology report demonstrating the patient has active chronic myeloid leukaemia, either manifest as cytogenetic evidence of the Philadelphia chromosome, or RT-PCR level of BCR-ABL transcript greater than 1% on the international scale. (The date of the relevant pathology report needs to be provided); and

(e) where there has been a loss of response to imatinib, a copy of the current confirming pathology report(s) from an Approved Pathology Authority or details of the dates of assessment in the case of progressive splenomegaly or extramedullary involvement; or

(f) details of Grade 3 or 4 non-haematological toxicity

NOTE:

Dasatinib will only be subsidised for patients with chronic myeloid leukaemia who are not receiving concomitant PBS-subsidised imatinib mesylate, nilotinib or interferon alfa therapy.

Patients should be commenced on a dose of dasatinib of at least 100 mg (base) daily. Continuing therapy is dependent on patients demonstrating a major cytogenetic response to dasatinib therapy or a peripheral blood BCR-ABL level of less than 1% at 18 months and thereafter at 12 monthly intervals, irrespective of the daily dasatinib dose received.

From 1 November 2008, under the PBS, a patient will be able to trial either dasatinib and/or nilotinib within the initial 18 month treatment period, providing the patient's CML is not resistant to the first second-line agent.

Dasatinib is not PBS-subsidised for patients with CML that is resistant to nilotinib.

2478K **Dasatinib**, Tablet 20 mg (*Sprycel*)
2482P **Dasatinib**, Tablet 50 mg (*Sprycel*)
2485T **Dasatinib**, Tablet 70 mg (*Sprycel*)

Authority required

Continuing treatment, as the sole PBS-subsidised therapy, of a patient who has received initial treatment with dasatinib as a pharmaceutical benefit for chronic myeloid leukaemia, and who has demonstrated either a major cytogenetic response, or less than 1% BCR-ABL level in the blood, to dasatinib in the preceding 18 months and thereafter at 12 monthly intervals.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Chronic Myeloid Leukaemia Dasatinib/Nilotinib Authority Application Form for continuing treatment; and

(3) demonstration of continued response to treatment as evidenced by either:

(a) major cytogenetic response [see Note explaining definitions of response]. Where this has been supplied within the previous 12 months (or 18 months for the initial supply), only the date of the relevant pathology report needs to be provided; or

(b) a peripheral blood level of BCR-ABL of less than 1% on the international scale [see Note explaining definitions of response]. Where this has been supplied within the previous 12 months (or 18 months for the initial supply), only the date of the relevant pathology report needs to be provided

NOTE:

Definitions of response.

A major cytogenetic response is defined as less than 35% Philadelphia positive bone marrow cells.

A bone marrow or peripheral blood BCR-ABL level of less than 1% on the international scale (Blood 108: 28-37, 2006) also indicates a response, at least the biological equivalent of a major cytogenetic response.

Authority approval requirements.

For the purposes of assessing response to PBS-subsidised treatment with dasatinib, either cytogenetic analysis indicating the number of Philadelphia positive [t (9;22)] cells in the bone marrow measured by standard karyotyping, or quantitative PCR indicating the relative level of BCR-ABL transcript in the peripheral blood using the international scale, must be submitted. For bone marrow analyses, where the standard karyotyping is not informative for technical reasons, a cytogenetic analysis performed on the bone marrow by the use of fluorescence in situ hybridisation (FISH) with BCR-ABL specific probe must be submitted. The cytogenetic or peripheral blood quantitative PCR analyses must be submitted as follows:

(i) between 10 and 18 months of the commencement of treatment with dasatinib, at which time patients in whom a major cytogenetic response or peripheral blood BCR-ABL level of less than 1% has been demonstrated may receive authorisation for a further 12 months of treatment; and

(ii) at no greater than 12 month intervals thereafter, to demonstrate that the major cytogenetic response or peripheral blood BCR-ABL level of less than 1% has been sustained.

For each authority application where eligibility for continuing PBS-subsidised treatment is to be demonstrated, a copy of the cytogenetic analysis indicating the number of Philadelphia positive [t (9;22)] cells in the bone marrow measured by standard karyotyping, or a copy of the quantitative PCR indicating the relative level of BCR-ABL transcript in the peripheral blood using the international scale, must be submitted as described in (i) and (ii) above. For bone marrow analyses, where the standard karyotyping conducted at the time of application is not informative, a copy of a cytogenetic analysis conducted on the bone marrow using FISH with BCR-ABL specific probe must be submitted with the authority application. A copy of the non-informative standard karyotype analysis must be included with the authority application.

Where a patient has previously received PBS-subsidised treatment with dasatinib, no approval will be granted for PBS-subsidised re-treatment where that patient has at any time failed to meet the criteria for continuing treatment.

Imatinib

NOTE:

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

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

Written applications for authority to prescribe imatinib mesylate should be forwarded to:

Medicare Australia

Prior Written Approval of Specialised Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

For the following diseases, written authority is required at initiation and for continuation:

Chronic myeloid leukaemia (chronic phase);

Dermatofibrosarcoma protuberans;

Hypereosinophilic syndrome;

Chronic eosinophilic leukaemia;

Myelodysplastic or myeloproliferative disorder;

Aggressive systemic mastocytosis with eosinophilia.

9176Y **Imatinib**, Tablet 100 mg (as mesylate) (*Glivec*)
9177B **Imatinib**, Tablet 400 mg (as mesylate) (*Glivec*)

Authority required

Initial PBS-subsidised treatment of a patient with a myelodysplastic or myeloproliferative disorder where:

(1) there is confirmed evidence of a platelet-derived growth factor receptor (PDGFR) gene re-arrangement either by standard karyotyping, or FISH or PDGFRB fusion gene transcript; and

(2) the patient has previously failed an adequate trial of one or more of the following conventional therapies:

— cytarabine;

— etoposide;

— hydroxyurea.

Maximum dose: 400 mg per day.

Applications for authorisation for initial treatment must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Rare Diseases Imatinib PBS Authority Application - Supporting Information Form; and

(c) a copy of the pathology report confirming the platelet-derived growth factor receptor (PDGFR) gene re-arrangement; and

(d) a copy of the bone marrow biopsy report which demonstrates the presence of a myelodysplastic or myeloproliferative disorder; and

(e) details of the prior therapy trialled and the response; and

(f) a signed patient acknowledgement

Authority required

Continuing PBS-subsidised treatment of a patient with a PDGFRB fusion gene-positive myelodysplastic or myeloproliferative disorder who has previously been issued with an authority prescription for imatinib and who has demonstrated a complete haematological response.

Maximum dose: 400 mg per day.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Rare Diseases Imatinib PBS Authority Application - Supporting Information Form; and

(c) a copy of the full blood examination report which demonstrates a complete haematological response; and

(d) a statement that the disease has not progressed on imatinib therapy

NOTE:

No applications for increased repeats will be authorised.

9178C **Imatinib**, Tablet 100 mg (as mesylate) (*Glivec*)
9179D **Imatinib**, Tablet 400 mg (as mesylate) (*Glivec*)

Authority required

Initial PBS-subsidised treatment of a patient with aggressive systemic mastocytosis with eosinophilia where:

(1) there is confirmed evidence of the FIP1L1-PDGFRA fusion gene; and

(2) the patient has previously failed an adequate trial of one or more of the following conventional therapies:

— corticosteroids;

— hydroxyurea.

Maximum dose: 400 mg per day.

Applications for authorisation for initial treatment must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Rare Diseases Imatinib PBS Authority Application - Supporting Information Form; and

(c) a copy of the pathology report confirming the presence of the FIP1L1-PDGFRA fusion gene; and

(d) a copy of the bone marrow biopsy report and/or other tissue biopsy report confirming the diagnosis of aggressive systemic mastocytosis and a copy of the full blood examination report demonstrating eosinophilia; and

(e) details of symptomatic organ involvement requiring treatment, including a copy of the radiology, nuclear medicine, respiratory function or anatomical pathology reports as appropriate; and

(f) details of prior treatment trialled and the response; and

(g) a signed patient acknowledgement

Authority required

Continuing PBS-subsidised treatment of a patient with aggressive systemic mastocytosis confirmed to carry the FIP1L1-PDGFRA fusion gene, who has previously been issued with an authority prescription for imatinib and who has demonstrated a complete haematological response.

Maximum dose: 400 mg per day.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Rare Diseases Imatinib PBS Authority Application - Supporting Information Form; and

(c) a copy of the full blood examination report which demonstrates a complete haematological response; and

(d) a statement that the disease has not progressed on imatinib therapy

NOTE:

No applications for increased repeats will be authorised.

9206M **Mesalazine**, Sachet containing granules, 1.5 g per sachet (*Salofalk*)

Authority required (STREAMLINED)

1708

Ulcerative colitis where hypersensitivity to sulfonamides exists.

Authority required (STREAMLINED)

1709

Ulcerative colitis where intolerance to sulfasalazine exists.

NOTE:

Not for the treatment of Crohn disease.

Nilotinib

NOTE:

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

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

Any queries concerning patients who are enrolled on the Nilotinib Compassionate Program may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Applications for authority to prescribe nilotinib should be forwarded to:

Medicare Australia

Prior Written Approval of Specialised Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

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

Authority required

Initial treatment, as the sole PBS-subsidised therapy, of a patient with chronic myeloid leukaemia in chronic or accelerated phase bearing the Philadelphia chromosome or expressing the transcript, BCR-ABL, who has active leukaemia (as defined by presence on current pathology assessments of either the Philadelphia chromosome on cytogenetic or FISH analysis, or the presence of the transcript BCR-ABL greater than 1% on the international scale) and who has failed an adequate trial of imatinib.

Failure of an adequate trial of imatinib is defined as:

(i) Lack of response to initial imatinib therapy, defined as either:

— failure to achieve a haematological response after a minimum of 3 months therapy with imatinib for patients initially treated in chronic phase; or

— failure to achieve any cytogenetic response after a minimum of 6 months therapy with imatinib for patients initially treated in chronic phase as demonstrated on bone marrow biopsy by presence of greater than 95% Philadelphia chromosome positive cells; or

— failure to achieve a major cytogenetic response or a peripheral blood BCR-ABL level of less than 1% after a minimum of 12 months therapy with imatinib; OR

(ii) Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph positive cells on bone marrow biopsy), during ongoing imatinib therapy; OR

(iii) Loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing in value by at least 5 fold to a level of greater than 1% confirmed on a subsequent test); OR

(iv) Development of accelerated phase in a patient previously prescribed imatinib for the chronic phase of chronic myeloid leukaemia.

Accelerated phase is defined by the presence of 1 or more of the following:

(1) Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 15% but less than 30%; or

(2) Percentage of blasts plus promyelocytes in the peripheral blood or bone marrow greater than or equal to 30%, provided that blast count is less than 30%; or

(3) Peripheral basophils greater than or equal to 20%; or

(4) Progressive splenomegaly to a size greater than or equal to 10 cm below the left costal margin to be confirmed on 2 occasions at least 4 weeks apart, or a greater than or equal to 50% increase in size below the left costal margin over 4 weeks; or

(5) Karyotypic evolution (chromosomal abnormalities in addition to a single Philadelphia chromosome); OR

(v) Disease progression (defined as a greater than or equal to 50% increase in peripheral white blood cell count, blast count, basophils or platelets) during first-line imatinib therapy in patients with accelerated phase chronic myeloid leukaemia, provided that blast crisis has been excluded on bone marrow biopsy; OR

(vi) Grade 3 or 4 non-haematological toxicity that is imatinib related and necessitates permanent cessation of imatinib. For patients with imatinib related toxicities, leukaemia activity does not need to be demonstrated.

Applications for authorisation must be in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Chronic Myeloid Leukaemia Dasatinib/Nilotinib PBS Authority Application - Supporting Information Form; and

(c) a signed patient acknowledgement; and

(d) a bone marrow biopsy pathology report demonstrating the patient has active chronic myeloid leukaemia, either manifest as cytogenetic evidence of the Philadelphia chromosome, or RT-PCR level of BCR-ABL transcript greater than 1% on the international scale. (The date of the relevant pathology report needs to be provided); and

(e) where there has been a loss of response to imatinib, a copy of the current confirming pathology report(s) from an Approved Pathology Authority; or

(f) details of Grade 3 or 4 non-haematological imatinib related toxicity

NOTE:

Nilotinib will only be subsidised for patients with chronic myeloid leukaemia who are not receiving concomitant PBS-subsidised imatinib mesylate, dasatinib or interferon alfa therapy.

Patients should be commenced on a dose of nilotinib of 400 mg twice daily. Continuing therapy is dependent on patients demonstrating a major cytogenetic response to nilotinib therapy or a peripheral blood BCR-ABL level of less than 1% at 18 months and thereafter at 12 monthly intervals, irrespective of the daily nilotinib dose received.

Nilotinib is not PBS-subsidised for patients with CML that is resistant to dasatinib.

Nilotinib is not TGA-registered and not PBS-subsidised for patients with CML in blast crisis.

Requests for doses of greater than nilotinib 400 mg twice daily will not be approved.

From 1 November 2008, under the PBS, a patient will be able to trial either dasatinib and/or nilotinib within the initial 18 month treatment period, providing the patient's CML is not resistant to the first second-line agent.

9171Q **Nilotinib**, Capsule 200 mg (as hydrochloride monohydrate) (*Tasigna*)

Authority required

Continuing treatment, as the sole PBS-subsidised therapy, of a patient who has received initial treatment with nilotinib as a pharmaceutical benefit for chronic myeloid leukaemia, and who has demonstrated either a major cytogenetic response, or less than 1% BCR-ABL level in the blood, to nilotinib in the preceding 18 months and thereafter at 12 monthly intervals.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Chronic Myeloid Leukaemia Dasatinib/Nilotinib Authority Application Form for continuing treatment; and

(3) demonstration of continued response to treatment as evidenced by either:

(a) major cytogenetic response [see Note explaining definitions of response]. Where this has been supplied within the previous 12 months (or 18 months for the initial supply), only the date of the relevant pathology report needs to be provided; or

(b) a peripheral blood level of BCR-ABL of less than 1% on the international scale [see Note explaining definitions of response]. Where this has been supplied within the previous 12 months (or 18 months for the initial supply), only the date of the relevant pathology report needs to be provided

NOTE:

Definitions of response.

A major cytogenetic response is defined as less than 35% Philadelphia positive bone marrow cells.

A bone marrow or peripheral blood BCR-ABL level of less than 1% on the international scale (Blood 108: 28-37, 2006) also indicates a response, at least the biological equivalent of a major cytogenetic response.

Authority approval requirements.

For the purposes of assessing response to PBS-subsidised treatment with nilotinib, either cytogenetic analysis indicating the number of Philadelphia positive [t (9;22)] cells in the bone marrow measured by standard karyotyping, or quantitative PCR indicating the relative level of BCR-ABL transcript in the peripheral blood using the international scale, must be submitted. For bone marrow analyses, where the standard karyotyping is not informative for technical reasons, a cytogenetic analysis performed on the bone marrow by the use of fluorescence in situ hybridisation (FISH) with BCR-ABL specific probe must be submitted. The cytogenetic or peripheral blood quantitative PCR analyses must be submitted as follows:

(i) between 10 and 18 months of the commencement of treatment with nilotinib, at which time patients in whom a major cytogenetic response or peripheral blood BCR-ABL level of less than 1% has been demonstrated may receive authorisation for a further 12 months of treatment; and

(ii) at no greater than 12 month intervals thereafter, to demonstrate that the major cytogenetic response or peripheral blood BCR-ABL level of less than 1% has been sustained.

For each authority application where eligibility for continuing PBS-subsidised treatment is to be demonstrated, a copy of the cytogenetic analysis indicating the number of Philadelphia positive [t (9;22)] cells in the bone marrow measured by standard karyotyping, or a copy of the quantitative PCR indicating the relative level of BCR-ABL transcript in the peripheral blood using the international scale, must be submitted as described in (i) and (ii) above. For bone marrow analyses, where the standard karyotyping conducted at the time of application is not informative, a copy of a cytogenetic analysis conducted on the bone marrow using FISH with BCR-ABL specific probe must be submitted with the authority application. A copy of the non-informative standard karyotype analysis must be included with the authority application.

Where a patient has previously received PBS-subsidised treatment with nilotinib, no approval will be granted for PBS-subsidised re-treatment where that patient has at any time failed to meet the criteria for continuing treatment.

9217D **Paraffin**, Compound eye ointment 3.5 g (*Poly Visc, Duratears*)

9218E **Paraffin**, Pack containing 2 tubes compound eye ointment 3.5 g (*Poly Visc, Ircal, Lacri-Lube*)

9209Q **Sulfasalazine**, Tablet 500 mg (enteric coated) (*Pyralin EN, Salazopyrin-EN*)

9208P **Sulfasalazine**, Tablet 500 mg (*Salazopyrin*)

Restricted benefit

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

NOTE:

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

9197C **Paroxetine**, Tablet 20 mg (as mesilate) (*Paroxetine generichealth*)

Restricted benefit

Major depressive disorders

Restricted benefit

Obsessive-compulsive disorder

Restricted benefit

Panic disorder

NOTE:

Bioequivalence has been demonstrated between paroxetine tablet 20 mg (as hydrochloride) and paroxetine tablet 20 mg (as mesilate).

9203J **Quetiapine fumarate**, Tablet (modified release) equivalent to 200 mg quetiapine (*Seroquel XR*)
9204K **Quetiapine fumarate**, Tablet (modified release) equivalent to 300 mg quetiapine (*Seroquel XR*)
9205L **Quetiapine fumarate**, Tablet (modified release) equivalent to 400 mg quetiapine (*Seroquel XR*)
9202H **Quetiapine fumarate**, Tablet (modified release) equivalent to 50 mg quetiapine (*Seroquel XR*)

Authority required (STREAMLINED)

1589

Schizophrenia

8689H **Rosiglitazone maleate**, Tablet 4 mg (base) (*Avandia*)
8690J **Rosiglitazone maleate**, Tablet 8 mg (base) (*Avandia*)

Authority required (STREAMLINED)

3037

Continuation of therapy in type 2 diabetes mellitus in a patient who has previously received and been stabilised on a PBS-subsidised regimen of oral anti-diabetic medicines which includes rosiglitazone maleate.

NOTE:

This restriction will be removed from the Schedule of Pharmaceutical Benefits on 1 February 2009.

Rosiglitazone maleate with metformin hydrochloride

NOTE:

Rosiglitazone with metformin fixed dose combination tablet is not PBS-subsidised when used in combination with insulin.

9060W **Rosiglitazone maleate with metformin hydrochloride**, Tablet 2 mg (base)-1 g (*Avandamet*)
9059T **Rosiglitazone maleate with metformin hydrochloride**, Tablet 2 mg (base)-500 mg (*Avandamet*)
9062Y **Rosiglitazone maleate with metformin hydrochloride**, Tablet 4 mg (base)-1 g (*Avandamet*)
9061X **Rosiglitazone maleate with metformin hydrochloride**, Tablet 4 mg (base)-500 mg (*Avandamet*)

Authority required (STREAMLINED)

3037

Continuation of therapy in type 2 diabetes mellitus in a patient who has previously received and been stabilised on a PBS-subsidised regimen of oral anti-diabetic medicines which includes rosiglitazone maleate.

NOTE:

This restriction will be removed from the Schedule of Pharmaceutical Benefits on 1 February 2009.

2700D **Thyrotropin alfa**, Powder for injection 0.9 mg, 2 (*Thyrogen*)

Authority required

Ablation of thyroid remnant tissue, in combination with radioactive iodine, in a post thyroidectomy patient without known metastatic disease

9199E **Tramadol hydrochloride**, Tablet 100 mg (once a day extended release) (*Durotram XR*)
9200F **Tramadol hydrochloride**, Tablet 200 mg (once a day extended release) (*Durotram XR*)
9201G **Tramadol hydrochloride**, Tablet 300 mg (once a day extended release) (*Durotram XR*)

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.

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

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

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

Restricted benefit

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

NOTES

The text of notes mentioned above:

9092M **Atomoxetine hydrochloride**, Capsule 10 mg (base) (*Strattera*)

9093N **Atomoxetine hydrochloride**, Capsule 18 mg (base) (*Strattera*)
9094P **Atomoxetine hydrochloride**, Capsule 25 mg (base) (*Strattera*)
9095Q **Atomoxetine hydrochloride**, Capsule 40 mg (base) (*Strattera*)
9096R **Atomoxetine hydrochloride**, Capsule 60 mg (base) (*Strattera*)

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

5533F **Fluorometholone acetate**, Eye drops 1 mg per mL (0.1%), 5 mL (*Flarex*)

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

9624M **Natalizumab**, Solution concentrate for I.V. infusion 300 mg in 15 mL (*Tysabri*)

Neurologists prescribing natalizumab under the PBS listing must be registered with the Tysabri Australian Prescribing Program.

Paroxetine

Bioequivalence has been demonstrated between paroxetine tablet 20 mg (as hydrochloride) and paroxetine tablet 20 mg (as mesilate).

REPATRIATION PHARMACEUTICAL BENEFITS

This Schedule is effective from 1 November 2008 and all previous issues are cancelled.

New Schedules take effect on the first day of each month.

SUMMARY OF CHANGES

DELETION

Deletion – Item

4420P **Pseudoephedrine hydrochloride**, Tablet 60 mg (*Sudafed Sinus & Nasal Decongestant*)

ALTERATION

Alteration – Manufacturer's Code

		From	*To*
4011D	**Terbinafine hydrochloride**, Tablet 250 mg (base) (*Tamsil*)	AW	SI