Australian Government

Department of Health and Ageing

SCHEDULE OF PHARMACEUTICAL BENEFITS

SUMMARY OF CHANGES

EFFECTIVE 1 MARCH 2009

PHARMACEUTICAL BENEFITS

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

Fees, Patient Contributions and Safety Net Thresholds

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

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

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

SUMMARY OF CHANGES

ADDITIONS

Additions — Items

(see under 'RESTRICTIONS' below for full details)

9375K **Amlodipine with valsartan**, Tablet 5 mg (as besylate)-80 mg (*Exforge 5/80*)
9376L **Amlodipine with valsartan**, Tablet 5 mg (as besylate)-160 mg (*Exforge 5/160*)
9377M **Amlodipine with valsartan**, Tablet 10 mg (as besylate)-160 mg (*Exforge 10/160*)
9386B **Amylopectin, modified long chain**, Sachets 60 g, 30 (*Glycosade*)
5543R **Betaxolol hydrochloride**, Eye drops, suspension, 2.5 mg (base) per mL (0.25%), 5 mL (*Betoptic S*) **(Optometrical)**
5544T **Betaxolol hydrochloride**, Eye drops, solution, 5 mg (base) per mL (0.5%), 5 mL (*BetoQuin, Betoptic*) **(Optometrical)**
5551E **Bimatoprost**, Eye drops 300 micrograms per mL (0.03%), 3 mL (*Lumigan*) **(Optometrical)**
5534G **Brimonidine tartrate**, Eye drops 2 mg per mL (0.2%), 5 mL (*Enidin, Alphagan*) **(Optometrical)**
5535H **Brimonidine tartrate with timolol maleate**, Eye drops 2 mg-5 mg (base) per mL (0.2%-0.5%), 5 mL (*Combigan*) **(Optometrical)**
5540N **Brinzolamide**, Eye drops 10 mg per mL (1%), 5 mL (*BrinzoQuin, Azopt*) **(Optometrical)**
5541P **Dorzolamide hydrochloride**, Eye drops 20 mg (base) per mL (2%), 5 mL (*Trusopt*) **(Optometrical)**
5542Q **Dorzolamide hydrochloride with timolol maleate**, Eye drops 20 mg (base)-5 mg (base) per mL (2%-0.5%), 5 mL (*Cosopt*) **(Optometrical)**
9385Y **Essential amino acids formula with vitamins and minerals**, Sachets 12.5 g, 50 (*EAA Supplement*)
5552F **Latanoprost**, Eye drops 50 micrograms per mL (0.005%), 2.5 mL (*Xalatan*) **(Optometrical)**
5553G **Latanoprost with timolol maleate**, Eye drops 50 micrograms-5 mg (base) per mL (0.005%-0.5%), 2.5 mL (*Xalacom*) **(Optometrical)**
9384X **Phenylalanine with carbohydrate**, Sachets 4 g containing 50 mg phenylalanine, 30 (*Phenylalanine Amino Acid Supplement*)
5536J **Pilocarpine hydrochloride**, Eye drops 10 mg per mL (1%), 15 mL (*Isopto Carpine, Pilopt, P.V. Carpine*) **(Optometrical)**
5537K **Pilocarpine hydrochloride**, Eye drops 20 mg per mL (2%), 15 mL (*Isopto Carpine, Pilopt, P.V. Carpine*) **(Optometrical)**
5538L **Pilocarpine hydrochloride**, Eye drops 40 mg per mL (4%), 15 mL (*Isopto Carpine, Pilopt, P.V. Carpine*) **(Optometrical)**
5539M **Pilocarpine hydrochloride**, Eye drops 60 mg per mL (6%), 15 mL (*Pilopt, P.V. Carpine*) **(Optometrical)**
9381R **Telmisartan with hydrochlorothiazide**, Tablet 80 mg-25 mg (*Micardis Plus 80/25 mg*)
5546X **Timolol maleate**, Eye gel 1 mg (base) per g (0.1%), 5 g (*Nyogel*) **(Optometrical)**
5547Y **Timolol maleate**, Eye drops 2.5 mg (base) per mL (0.25%), 5 mL (*Tenopt, Timoptol*) **(Optometrical)**
5548B **Timolol maleate**, Eye drops 5 mg (base) per mL (0.5%), 5 mL (*Tenopt, Timoptol*) **(Optometrical)**
5549C **Timolol maleate**, Eye drops (gellan gum solution) 2.5 mg (base) per mL (0.25%), 2.5 mL (*Timoptol XE*) **(Optometrical)**
5550D **Timolol maleate**, Eye drops (gellan gum solution) 5 mg (base) per mL (0.5%), 2.5 mL (*Timoptol XE*) **(Optometrical)**
9387C **Trandolapril with verapamil hydrochloride**, Tablet 2 mg-180 mg (sustained release) (*Tarka 2/180*)
5554H **Travoprost**, Eye drops 40 micrograms per mL (0.004%), 2.5 mL (*Travatan*) **(Optometrical)**
5555J **Travoprost with timolol maleate**, Eye drops 40 micrograms-5 mg (base) per mL (0.004%-0.5%), 2.5 mL (*Duotrav*) **(Optometrical)**
9383W **Triglycerides—medium chain, formula**, Sachets 16 g, 25 (*MCT Pro-Cal*)
9368C **Valsartan**, Tablet 40 mg (*Diovan*)
9369D **Valsartan**, Tablet 80 mg (*Diovan*)

9370E **Valsartan**, Tablet 160 mg (*Diovan*)
9371F **Valsartan**, Tablet 320 mg (*Diovan*)
9372G **Valsartan with hydrochlorothiazide**, Tablet 80 mg-12.5 mg (*Co-Diovan 80/12.5*)
9373H **Valsartan with hydrochlorothiazide**, Tablet 160 mg-12.5 mg (*Co-Diovan 160/12.5*)
9374J **Valsartan with hydrochlorothiazide**, Tablet 160 mg-25 mg (*Co-Diovan 160/25*)

9382T **Whey protein formula supplemented with amino acids, long chain polyunsaturated fatty acids, vitamins and minerals, and low in protein, phosphate, potassium and lactose**, Sachets 100 g, 10 (*RenaStart*)

Additions — Brands

1887H *Amoxycillin Sandoz, SZ* — **Amoxycillin**, Powder for syrup 250 mg per 5 mL, 100 mL

3393N *Amoxycillin Sandoz, SZ* — **Amoxycillin**, Powder for syrup 250 mg per 5 mL, 100 mL **(Dental)**
1169M *Cefaclor-GA, GN* — **Cefaclor**, Tablet 375 mg (sustained release)
5045M *Cefaclor-GA, GN* — **Cefaclor**, Tablet 375 mg (sustained release) **(Dental)**
1299J *Diclofenac-GA, GN* — **Diclofenac sodium**, Tablet 25 mg (enteric coated)
5076E *Diclofenac-GA, GN* — **Diclofenac sodium**, Tablet 25 mg (enteric coated) **(Dental)**
5364H *Diclofenac-GA, GN* — **Diclofenac sodium**, Tablet 25 mg (enteric coated) **(Palliative Care)**
5361E *Diclofenac-GA, GN* — **Diclofenac sodium**, Tablet 25 mg (enteric coated) **(Palliative Care) (Diff. Max. Rpts)**
8280T *Vinorelbine 10 Link, LM* — **Vinorelbine tartrate**, Solution for I.V. infusion 10 mg (base) in 1 mL
8281W *Vinorelbine 50 Link, LM* — **Vinorelbine tartrate**, Solution for I.V. infusion 50 mg (base) in 5 mL

DELETIONS

Deletions — Items

2495H **Pancrelipase**, Capsule (containing enteric coated microspheres) providing not less than 10,000 BP units of lipase activity (*Cotazym-S Forte*)

9228Q **Pancrelipase**, Capsule (containing enteric coated microspheres) providing not less than 10,000 BP units of lipase activity (*Cotazym-S Forte*) **(Diff. Max. Rpts)**

Deletions — Brands

1891M *Clamohexal Duo 500 mg/125 mg, HX* — **Amoxycillin with clavulanic acid**, Tablet 500 mg-125 mg
5008N *Clamohexal Duo 500 mg/125 mg, HX* — **Amoxycillin with clavulanic acid**, Tablet 500 mg-125 mg **(Dental)**
8254K *Clamohexal Duo Forte 875 mg/125 mg, HX* — **Amoxycillin with clavulanic acid**, Tablet 875 mg-125 mg
5006L *Clamohexal Duo Forte 875 mg/125 mg, HX* — **Amoxycillin with clavulanic acid**, Tablet 875 mg-125 mg **(Dental)**
1892N *Clamohexal 125 mg/31.25 mg/5 mL, HX* — **Amoxycillin with clavulanic acid**, Powder for syrup 125 mg-31.25 mg per 5 mL, 75 mL
5009P *Clamohexal 125 mg/31.25 mg/5 mL, HX* — **Amoxycillin with clavulanic acid**, Powder for syrup 125 mg-31.25 mg per 5 mL, 75 mL **(Dental)**
8319W *Clamohexal Duo 400 mg/57 mg/5 mL, HX* — **Amoxycillin with clavulanic acid**, Powder for syrup 400 mg-57 mg per 5 mL, 60 mL
5011R *Clamohexal Duo 400 mg/57 mg/5 mL, HX* — **Amoxycillin with clavulanic acid**, Powder for syrup 400 mg-57 mg per 5 mL, 60 mL **(Dental)**
2729P *Baclohexal, HX* — **Baclofen**, Tablet 10 mg
2730Q *Baclohexal, HX* — **Baclofen**, Tablet 25 mg
8415X *Irinotecan-GA, GM* — **Irinotecan hydrochloride trihydrate**, I.V. injection 100 mg in 5 mL
8288F *Epaq, AW* — **Salbutamol sulfate**, Oral pressurised inhalation 100 micrograms (base) per dose (200 doses), CFC-free formulation

3495Y *Epaq, AW* — **Salbutamol sulfate**, Oral pressurised inhalation 100 micrograms (base) per dose (200 doses), CFC-free formulation **(Doctor's Bag)**

ALTERATIONS

Alterations — Restrictions

(see under 'RESTRICTIONS' below for full details)

Restrictions have been amended in respect of the following:

8844L **Bivalirudin trifluoroacetate**, Powder for I.V. injection 250 mg (base) (*Angiomax*)

9282M **Dasatinib**, Tablet 20 mg (*Sprycel*)
9283N **Dasatinib**, Tablet 50 mg (*Sprycel*)
9284P **Dasatinib**, Tablet 70 mg (*Sprycel*)
9285Q **Nilotinib**, Capsule 200 mg (as hydrochloride monohydrate) (*Tasigna*)
8787L **Risperidone**, Tablet 0.5 mg (*Risperidone-GA, Rixadone, APO-Risperidone, Rispa, Risperdal*)
8788M **Risperidone**, Tablet 0.5 mg (orally disintegrating) (*Risperdal Quicklet*)
8789N **Risperidone**, Tablet 1 mg (*APO-Risperidone, Rispa, Risperdal, Risperidone-GA, Risperidone generichealth, Rixadone*)
8790P **Risperidone**, Tablet 1 mg (orally disintegrating) (*Risperdal Quicklet*)
9079W **Risperidone**, Tablet 2 mg (*APO-Risperidone, Rispa, Risperdal, Risperidone-GA, Risperidone generichealth, Rixadone*)
9080X **Risperidone**, Tablet 2 mg (orally disintegrating) (*Risperdal Quicklet*)
9293D **Risperidone**, Oral solution 1 mg per mL, 100 mL (*Risperdal*)
8646C **Tacrolimus**, Capsule 500 micrograms (*Prograf*)
8647D **Tacrolimus**, Capsule 1 mg (*Prograf*)
8648E **Tacrolimus**, Capsule 5 mg (*Prograf*)

2857J **Trandolapril with verapamil hydrochloride**, Tablet 4 mg-240 mg (sustained release) (*Tarka 4/240*)

Alterations — Notes

(see under 'NOTES' below for full details)

The note has been deleted in respect of the following:

8844L **Bivalirudin trifluoroacetate**, Powder for I.V. injection 250 mg (base) (*Angiomax*)

The note has been amended in respect of the following:

8712M **Desmopressin acetate**, Nasal spray (pump pack) 10 micrograms per actuation, 60 actuations, 6 mL (*Minirin Nasal Spray*)

Alterations — Maximum Quantity

		From	*To*
2214M	**Mesalazine**, Tablet 500 mg (prolonged release) (*Pentasa*)	100	200
8448P	**Ursodeoxycholic acid**, Capsule 250 mg (*Ursofalk*)	100	200

Alterations — Number of Repeats

		From	*To*
9355J	**Carmellose sodium with glycerin**, Eye drops 5 mg-9 mg per mL (0.5%-0.9%), 15 mL (*Optive*)	2	3
9356K	**Carmellose sodium with glycerin**, Eye drops 5 mg-9 mg per mL (0.5%-0.9%), 15 mL (*Optive*) **(Diff. Max. Rpts)**	5	7
5556K	**Carmellose sodium with glycerin**, Eye drops 5 mg-9 mg per mL (0.5%-0.9%), 15 mL (*Optive*) **(Optometrical)**	2	3

Alterations — Manufacturer's Code

		From	*To*
2502Q	**Calcitriol**, Capsule 0.25 microgram (*Citrihexal*)	HX	SZ
1585K	**Chlorthalidone**, Tablet 25 mg (*Hygroton 25*)	NV	LM
2826R	**Methysergide**, Tablet 1 mg (*Deseril*)	NV	LM

SECTION 100 — HIGHLY SPECIALISED DRUGS PROGRAM

ALTERATIONS

Alterations — Restrictions

(see under 'RESTRICTIONS' below for full details)

6328C **Tacrolimus**, Capsule 500 micrograms (*Prograf*)

6216E **Tacrolimus**, Capsule 1 mg (*Prograf*)

6217F **Tacrolimus**, Capsule 5 mg (*Prograf*)

ADVANCE NOTICES

Advance Notice — Deletion of Item

The following item will be deleted from the Schedule of Pharmaceutical Benefits on 1 June 2009:
Deletion requested by the manufacturer —

8818D **Metoprolol succinate**, Pack containing 15 tablets 23.75 mg (controlled release), 15 tablets 47.5 mg (controlled release) and 15 tablets 95 mg (controlled release) (*Toprol-XL Titration Pack*)

Advance Notice — Deletion of Brands

The following brand will be deleted from the Schedule of Pharmaceutical Benefits on 1 April 2009:
Deletion requested by the manufacturer —

8839F *Attenta, AF* — **Methylphenidate hydrochloride**, Tablet 10 mg

The following brands will be deleted from the Schedule of Pharmaceutical Benefits on 1 June 2009:
Deletions requested by the manufacturer —

2592K *Chem mart Isotretinoin, CH; Terry White Chemists Isotretinoin, TW* — **Isotretinoin**, Capsule 20 mg

RESTRICTIONS

The text of restrictions mentioned above:

9377M **Amlodipine with valsartan**, Tablet 10 mg (as besylate)-160 mg (*Exforge 10/160*)

9376L **Amlodipine with valsartan**, Tablet 5 mg (as besylate)-160 mg (*Exforge 5/160*)

9375K **Amlodipine with valsartan**, Tablet 5 mg (as besylate)-80 mg (*Exforge 5/80*)

Restricted benefit

Hypertension in patients who are not adequately controlled with either amlodipine or valsartan monotherapy

9386B **Amylopectin, modified long chain**, Sachets 60 g, 30 (*Glycosade*)

Restricted benefit

Glycogen storage disease

8844L **Bivalirudin trifluoroacetate**, Powder for I.V. injection 250 mg (base) (*Angiomax*)

Authority required (STREAMLINED)

3075

A patient undergoing percutaneous coronary intervention

5535H **Brimonidine tartrate with timolol maleate**, Eye drops 2 mg-5 mg (base) per mL (0.2%-0.5%), 5 mL (*Combigan*)

5542Q **Dorzolamide hydrochloride with timolol maleate**, Eye drops 20 mg (base)-5 mg (base) per mL (2%-0.5%), 5 mL (*Cosopt*)

Restricted benefit

Reduction of elevated intra-ocular pressure in patients with open-angle glaucoma who are not adequately controlled with timolol maleate 5 mg (base) per mL (0.5%) eye drops

Restricted benefit

Reduction of elevated intra-ocular pressure in patients with ocular hypertension who are not adequately controlled with timolol maleate 5 mg (base) per mL (0.5%) eye drops

DASATINIB

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), during ongoing imatinib therapy; OR

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

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

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

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

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

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

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

Blast crisis is defined as either:

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

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

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

(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

9385Y **Essential amino acids formula with vitamins and minerals**, Sachets 12.5 g, 50 (*EAA Supplement*)

Restricted benefit

Gyrate atrophy of the choroid and retina

Restricted benefit

Urea cycle disorders

5553G **Latanoprost with timolol maleate**, Eye drops 50 micrograms-5 mg (base) per mL (0.005%-0.5%), 2.5 mL (*Xalacom*)

Restricted benefit

Reduction of elevated intra-ocular pressure in patients with open-angle glaucoma who are not adequately controlled with timolol maleate 5 mg (base) per mL (0.5%) eye drops or latanoprost eye drops

Restricted benefit

Reduction of elevated intra-ocular pressure in patients with ocular hypertension who are not adequately controlled with timolol maleate 5 mg (base) per mL (0.5%) eye drops or latanoprost eye drops

NILOTINIB

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), during ongoing imatinib therapy; 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

9384X **Phenylalanine with carbohydrate**, Sachets 4 g containing 50 mg phenylalanine, 30 (*Phenylalanine Amino Acid Supplement*)

Restricted benefit

Tyrosinaemia

9293D **Risperidone**, Oral solution 1 mg per mL, 100 mL (*Risperdal*)
8788M **Risperidone**, Tablet 0.5 mg (orally disintegrating) (*Risperdal Quicklet*)
8787L **Risperidone**, Tablet 0.5 mg (*Risperidone-GA, Rixadone, APO-Risperidone, Rispa, Risperdal*)
8789N **Risperidone**, Tablet 1 mg (*APO-Risperidone, Rispa, Risperdal, Risperidone-GA, Risperidone generichealth, Rixadone*)
8790P **Risperidone**, Tablet 1 mg (orally disintegrating) (*Risperdal Quicklet*)

Authority required (STREAMLINED)

2061

Behavioural disturbances characterised by psychotic symptoms and aggression in patients with dementia where non-pharmacological methods have been unsuccessful

CAUTION:

In placebo controlled trials in elderly patients with dementia there was a significantly higher incidence of cerebrovascular adverse events, such as stroke (including fatalities) and transient ischaemic attacks, in patients treated with risperidone compared with patients treated with placebo.

Authority required (STREAMLINED)

3083

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

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

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

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

9079W **Risperidone**, Tablet 2 mg (*APO-Risperidone, Rispa, Risperdal, Risperidone-GA, Risperidone generichealth, Rixadone*)

9080X **Risperidone**, Tablet 2 mg (orally disintegrating) (*Risperdal Quicklet*)

Authority required (STREAMLINED)

3083

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

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

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

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

TACROLIMUS

CAUTION:

Careful monitoring of patients is mandatory

8647D **Tacrolimus**, Capsule 1 mg (*Prograf*)

8646C **Tacrolimus**, Capsule 500 micrograms (*Prograf*)

8648E **Tacrolimus**, Capsule 5 mg (*Prograf*)

Authority required

Maintenance therapy, following initiation and stabilisation of treatment with tacrolimus, of patients with organ or tissue transplants. Therapy must remain under the supervision and direction of the transplant unit reviewing the patient. The name of the specialised transplant unit reviewing treatment and the date of the latest review at the specialised transplant unit must be included in the authority application

6216E **Tacrolimus**, Capsule 1 mg (*Prograf*)

6328C **Tacrolimus**, Capsule 500 micrograms (*Prograf*)

6217F **Tacrolimus**, Capsule 5 mg (*Prograf*)

Private hospital authority required

Management of rejection in patients following organ or tissue transplantation, under the supervision and direction of a transplant unit. Management includes initiation, stabilisation and review of therapy as required

9381R **Telmisartan with hydrochlorothiazide**, Tablet 80 mg-25 mg (*Micardis Plus 80/25 mg*)

Restricted benefit

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

TRANDOLAPRIL WITH VERAPAMIL HYDROCHLORIDE

CAUTION:

The myocardial depressant effects of verapamil hydrochloride and of beta-blocking drugs are additive

9387C **Trandolapril with verapamil hydrochloride**, Tablet 2 mg-180 mg (sustained release) (*Tarka 2/180*)
2857J **Trandolapril with verapamil hydrochloride**, Tablet 4 mg-240 mg (sustained release) (*Tarka 4/240*)

Restricted benefit

Hypertension in a patient who is not adequately controlled with either trandolapril or verapamil hydrochloride sustained release monotherapy

5555J **Travoprost with timolol maleate**, Eye drops 40 micrograms-5 mg (base) per mL (0.004%-0.5%), 2.5 mL (*Duotrav*)

Restricted benefit

Reduction of elevated intra-ocular pressure in patients with open-angle glaucoma who are not adequately controlled with timolol maleate 5 mg (base) per mL (0.5%) eye drops or latanoprost eye drops or travoprost eye drops

Restricted benefit

Reduction of elevated intra-ocular pressure in patients with ocular hypertension who are not adequately controlled with timolol maleate 5 mg (base) per mL (0.5%) eye drops or latanoprost eye drops or travoprost eye drops

TRIGLYCERIDES—MEDIUM CHAIN, FORMULA

NOTE:

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

9383W **Triglycerides—medium chain, formula**, Sachets 16 g, 25 (*MCT Pro-Cal*)

Authority required

Chylous ascites

Authority required

Chylothorax

Authority required

Fat malabsorption due to liver disease, short gut syndrome, cystic fibrosis and gastrointestinal disorders

Authority required

Hyperlipoproteinaemia type 1

Authority required

Long chain fatty acid oxidation disorders

NOTE:

Monogen is not indicated for the treatment of intractable childhood epilepsy or cerebrospinal fluid glucose transporter defect requiring a ketogenic diet

9373H **Valsartan with hydrochlorothiazide**, Tablet 160 mg-12.5 mg (*Co-Diovan 160/12.5*)
9374J **Valsartan with hydrochlorothiazide**, Tablet 160 mg-25 mg (*Co-Diovan 160/25*)

9372G **Valsartan with hydrochlorothiazide**, Tablet 80 mg-12.5 mg (*Co-Diovan 80/12.5*)

Restricted benefit

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

9382T **Whey protein formula supplemented with amino acids, long chain polyunsaturated fatty acids, vitamins and minerals, and low in protein, phosphate, potassium and lactose**, Sachets 100 g, 10 (*RenaStart*)

Authority required

Infants and young children with chronic renal failure requiring treatment with a low protein and a low phosphorus diet, or a low protein, a low phosphorus and a low potassium diet

NOTES

The text of notes mentioned above:

8712M **Desmopressin**, Nasal spray (pump pack) 10 micrograms per actuation, 60 actuations, 6 mL

NOTE:

Not to be used in preference to enuresis alarms

Desmopressin nasal spray may be associated with an increased risk of hyponatraemia compared to the tablet formulation

Valsartan

NOTE:

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

REPATRIATION PHARMACEUTICAL BENEFITS

This Schedule is effective from 1 March 2009 and all previous issues are cancelled.

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

SUMMARY OF CHANGES

ALTERATIONS

Alteration — Note

(The note for Infliximab has been amended to reflect the change of address details for VAPAC)

4284L **Infliximab**, Powder for I.V. infusion 100 mg (*Remicade*)

Alteration — Proprietary Name

From:

4695D *(Tielle MT2440)* **Dressing—hydroactive (superficial wound—high exudate)**, Dressings, island, 11 cm x 11 cm, 10

To:

4695D *(Tielle MTL101E)* **Dressing—hydroactive (superficial wound—high exudate)**, Dressings, island, 11 cm x 11 cm, 10