Australian Government

Department of Health and Ageing

SCHEDULE OF PHARMACEUTICAL BENEFITS

SUMMARY OF CHANGES

EFFECTIVE 1 FEBRUARY 2008

PHARMACEUTICAL BENEFITS

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

Dispensing Fees:	Ready-prepared	$5.44
	Dangerous drug fee	$2.71
	Extemporaneously-prepared	$7.48
	Allowable additional patient charge*	$3.63
Additional Fees (for safety net prices):	Ready-prepared	$1.01
	Extemporaneously-prepared	$1.40
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 - Item

(see under 'RESTRICTIONS' below for full details)

5531D **Tamarindus indica seed polysaccharide**, Eye drops 10 mg per mL (1%), 0.5 mL, 20 (*Visine Professional*) **(Optometrical)**

Additions - Brands

1182F *Fosinopril Winthrop, BG* — **Fosinopril sodium**, Tablet 10 mg

1183G *Fosinopril Winthrop, BG* — **Fosinopril sodium**, Tablet 20 mg

8400D *Fosinopril/HCT Winthrop 10 mg/12.5 mg, BG* — **Fosinopril sodium with hydrochlorothiazide**, Tablet 10 mg-12.5 mg

8401E *Fosinopril/HCT Winthrop 20 mg/12.5 mg, BG* — **Fosinopril sodium with hydrochlorothiazide**, Tablet 20 mg-12.5 mg

8559L *GenRx Gabapentin, GX* — **Gabapentin**, Tablet 600 mg

8389M *GenRx Gabapentin, GX* — **Gabapentin**, Tablet 800 mg

8331L *GenRx Omeprazole, GX* — **Omeprazole**, Tablet 20 mg

8333N *GenRx Omeprazole, GX* — **Omeprazole**, Tablet 20 mg **(Diff. Max. Rpts)**

8039D *Oxybutynin Winthrop, WA* — **Oxybutynin hydrochloride**, Tablet 5 mg

1968N *APO-Quinapril, GX; Pharmacor Quinapril 5, CR; Quinapril-DP, GM* — **Quinapril hydrochloride**, Tablet 5 mg (base)

1969P *APO-Quinapril, GX; Pharmacor Quinapril 10, CR; Quinapril-DP, GM* — **Quinapril hydrochloride**, Tablet 10 mg (base)

1970Q *APO-Quinapril, GX; Pharmacor Quinapril 20, CR; Quinapril-DP, GM* — **Quinapril hydrochloride**, Tablet 20 mg (base)

8144P *Sumagran 50, AW* — **Sumatriptan succinate**, Tablet 50 mg (base)

DELETIONS

Deletions - Brands

2852D *Fluarix, GK* — **Influenza vaccine**, Injection (trivalent) 0.5 mL (containing A/New Caledonia/20/99, A/Wisconsin/67/2005 and B/Malaysia/2506/2004 like strains)

2592K *Isohexal, HX* — **Isotretinoin**, Capsule 20 mg

2949F *Septrin, SI* — **Trimethoprim with sulfamethoxazole**, Tablet 80 mg-400 mg

3389J *Septrin, SI* — **Trimethoprim with sulfamethoxazole**, Tablet 80 mg-400 mg **(Dental)**

Deletions - Bioequivalence Indicators

The bioequivalence indicator ([a]) has been removed from the following brands:

2949F *Resprim, AF* — **Trimethoprim with sulfamethoxazole**, Tablet 80 mg-400 mg

3389J *Resprim, AF* — **Trimethoprim with sulfamethoxazole**, Tablet 80 mg-400 mg **(Dental)**

ALTERATIONS

Alterations - Item

From:
2265F **Influenza vaccine**, Injection (trivalent) 0.25 mL (containing A/New Caledonia/20/99, A/Wisconsin/67/2005 and B/Malaysia/2506/2004 like strains) (*Vaxigrip Junior*)
To:
2265F **Influenza vaccine**, Injection (trivalent) 0.25 mL (containing A/Solomon Islands/3/2006, A/Brisbane/10/2007 and B/Florida/4/2006 like strains) (*Vaxigrip Junior*)
From:
2852D **Influenza vaccine**, Injection (trivalent) 0.5 mL (containing A/New Caledonia/20/99, A/Wisconsin/67/2005 and B/Malaysia/2506/2004 like strains) (*Fluvax, Influvac, Vaxigrip*)
To:
2852D **Influenza vaccine**, Injection (trivalent) 0.5 mL (containing A/Solomon Islands/3/2006, A/Brisbane/10/2007 and B/Florida/4/2006 like strains) (*Fluvax, Influvac, Vaxigrip*)

Alterations - Maximum Quantities

		From	*To*
9097T	**Cetuximab**, Solution for I.V. infusion 100 mg in 50 mL (*Erbitux*)	6	1
9098W	**Cetuximab**, Solution for I.V. infusion 100 mg in 50 mL (*Erbitux*) **(Diff. Max. Rpts)**	4	1

Alterations - Brands

From:
3058Y **Cephalexin**, Capsule 250 mg (*Cephalexin-Lupin*)
To:
3058Y **Cephalexin**, Capsule 250 mg (*Cephalexin Max*)
From:
3317N **Cephalexin**, Capsule 250 mg (*Cephalexin-Lupin*) **(Dental)**
To:
3317N **Cephalexin**, Capsule 250 mg (*Cephalexin Max*) **(Dental)**
From:
3119E **Cephalexin**, Capsule 500 mg (*Cephalexin-Lupin*)
To:
3119E **Cephalexin**, Capsule 500 mg (*Cephalexin Max*)
From:
3318P **Cephalexin**, Capsule 500 mg (*Cephalexin-Lupin*) **(Dental)**
To:
3318P **Cephalexin**, Capsule 500 mg (*Cephalexin Max*) **(Dental)**

Alterations - Manufacturer's Codes

		From	*To*
2344J	**Amiodarone hydrochloride**, Tablet 100 mg (*Cardinorm*)	HX	SZ
2343H	**Amiodarone hydrochloride**, Tablet 200 mg (*Cardinorm*)	HX	SZ
8594H	**Amisulpride**, Tablet 100 mg (*Amisulpride Sandoz*)	AV	SZ

8595J	**Amisulpride**, Tablet 200 mg (*Amisulpride Sandoz*)	AV	SZ
8596K	**Amisulpride**, Tablet 400 mg (*Amisulpride Sandoz*)	AV	SZ
1215Y	**Codeine phosphate with paracetamol**, Tablet 30 mg-500 mg (*Comfarol Forte*)	WA	SZ
8785J	**Codeine phosphate with paracetamol**, Tablet 30 mg-500 mg (*Comfarol Forte*) **(Diff. Max. Qty)**	WA	SZ
3316M	**Codeine phosphate with paracetamol**, Tablet 30 mg-500 mg (*Comfarol Forte*) **(Dental)**	WA	SZ
1269T	**Cyproterone acetate**, Tablet 50 mg (*Cyprohexal*)	HX	SZ
1270W	**Cyproterone acetate**, Tablet 50 mg (*Cyprohexal*) **(Diff. Max. Qty)**	HX	SZ
8019C	**Cyproterone acetate**, Tablet 100 mg (*Cyprohexal*)	HX	SZ
1312C	**Diltiazem hydrochloride**, Capsule 180 mg (controlled delivery) (*Diltahexal CD*)	WA	SZ
1313D	**Diltiazem hydrochloride**, Capsule 240 mg (controlled delivery) (*Diltahexal CD*)	WA	SZ
8480H	**Diltiazem hydrochloride**, Capsule 360 mg (controlled delivery) (*Diltahexal CD*)	WA	SZ
2436F	**Indapamide hemihydrate**, Tablet 2.5 mg (*Indahexal*)	HX	SZ
1558B	**Isosorbide mononitrate**, Tablet 60 mg (sustained release) (*Isomonit*)	HX	SZ
2289L	**Sodium valproate**, Tablet 200 mg (enteric coated) (*Sodium Valproate Sandoz*)	AV	SZ
2290M	**Sodium valproate**, Tablet 500 mg (enteric coated) (*Sodium Valproate Sandoz*)	AV	SZ

Alterations - Restrictions

(see under 'RESTRICTIONS' below for full details)

9130M	**Pemetrexed disodium**, Powder for I.V. infusion 500 mg (base) (*Alimta*)
8694N	**Pioglitazone hydrochloride**, Tablet 15 mg (base) (*Actos*)
8695P	**Pioglitazone hydrochloride**, Tablet 30 mg (base) (*Actos*)
8696Q	**Pioglitazone hydrochloride**, Tablet 45 mg (base) (*Actos*)

NOTES

Alterations - Notes

(see under 'NOTES' below for full details)

The notes have been **amended** in respect of the following:

8694N	**Pioglitazone hydrochloride**, Tablet 15 mg (base) (*Actos*)
8695P	**Pioglitazone hydrochloride**, Tablet 30 mg (base) (*Actos*)
8696Q	**Pioglitazone hydrochloride**, Tablet 45 mg (base) *(Actos)*

ADVANCE NOTICES

Advance Notices - Deletion of Items

The following items will be deleted from the Schedule of Pharmaceutical Benefits on 1 **March** 2008:
Items discontinued by the manufacturer -

6283Q **Efavirenz**, Capsule 200 mg (*Stocrin*)
8513C **Mirtazapine**, Tablet 30 mg *(Remeron)*

The following item will be deleted from the Schedule of Pharmaceutical Benefits on 1 **April** 2008:
Item discontinued by the manufacturer -

8645B **Oestradiol hemihydrate**, Nasal spray 150 micrograms per actuation, 60 actuations, 4.2 mL (*Aerodiol*)

The following item will be deleted from the Schedule of Pharmaceutical Benefits on 1 **May** 2008:
Item discontinued by the manufacturer -

3027H **Salmeterol xinafoate**, Oral pressurised inhalation 25 micrograms (base) per dose (120 doses) (*Serevent*)

RESTRICTIONS

The text of restrictions mentioned above:

9130M **Pemetrexed disodium**, Powder for I.V. infusion 500 mg (base) (*Alimta*)

Authority required

Mesothelioma in combination with cisplatin.

8694N **Pioglitazone hydrochloride**, Tablet 15 mg (base) (*Actos*)
8695P **Pioglitazone hydrochloride**, Tablet 30 mg (base) (*Actos*)
8696Q **Pioglitazone hydrochloride**, Tablet 45 mg (base) (*Actos*)

Authority required (STREAMLINED)

2635

Dual oral combination therapy with metformin or a sulfonylurea

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

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

Authority required (STREAMLINED)

2638

Combination therapy with insulin

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

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

Authority required (STREAMLINED)

2648

Triple oral combination therapy with metformin and a sulfonylurea

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

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

5531D **Tamarindus indica seed polysaccharide**, Eye drops 10 mg per mL (1%), 0.5 mL, 20 (*Visine Professional*) **(Optometrical)**

Authority required

Severe dry eye syndrome in patients who are sensitive to preservatives in multi-dose eye drops.

NOTES

The text of notes mentioned above:

8694N **Pioglitazone hydrochloride**, Tablet 15 mg (base) (*Actos*)

8695P **Pioglitazone hydrochloride**, Tablet 30 mg (base) (*Actos*)

8696Q **Pioglitazone hydrochloride**, Tablet 45 mg (base) (*Actos*)

Note:

Pioglitazone hydrochloride is not PBS-subsidised as monotherapy.

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

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

and/or

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

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

REPATRIATION PHARMACEUTICAL BENEFITS

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

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

SUMMARY OF CHANGES

ADDITIONS

Additions - Items

(see under 'RESTRICTIONS' and 'NOTES' below for items where a restriction and/or note applies)

4510J **Cationic conditioner with panthenol**, Cream 200 g (*SebiRinse*)

4028B **Docusate sodium with senna**, Tablet 50 mg-8 mg (*DP soflax*)
4322L **Pregabalin**, Capsule 75 mg (*Lyrica*)
4323M **Pregabalin**, Capsule 150 mg (*Lyrica*)
4324N **Pregabalin**, Capsule 300 mg (*Lyrica*)
4029C **Pseudoephedrine hydrochloride**, Tablet 60 mg (*Logicin Sinus*)
4059P **Risedronate sodium and calcium carbonate**, Pack containing 4 tablets risedronate sodium 35 mg and 24 tablets calcium carbonate 1.25 g (equivalent to 500 mg calcium) (*Actonel Combi*)
4070F **Tamsulosin hydrochloride**, Tablet 400 micrograms (prolonged release) (*Flomaxtra*)

Additions - Brands

4175R *Alzene, AF* — **Cetirizine hydrochloride**, Tablet 10 mg

4017K *Femizol Vaginal Cream, GM* — **Clotrimazole**, Vaginal cream 100 mg per 5 g (2%), 20 g
4237B *Xergic, AF* — **Fexofenadine hydrochloride**, Tablet 60 mg
4313B *Allereze, AF; Lorano, HX* — **Loratadine**, Tablet 10 mg
4049D *Uracol, GM* — **Sodium citro-tartrate**, Sachets containing oral effervescent powder 4 g, 28
4011D *Terbihexal, SZ* — **Terbinafine hydrochloride**, Tablet 250 mg (base)

Addition - Bioequivalence Indicator

The bioequivalence indicator ([a]) has been added to the following brand:

4237B *Telfast, SW* — **Fexofenadine hydrochloride**, Tablet 60 mg

DELETIONS

Deletions - Items

4334D **Calcium**, Tablet 600 mg (as carbonate) (*Caltrate*)
4519W **Cationic conditioner with panthenol**, Solution 250 mL (*SebiRinse Conditioner*)

Deletion - Brand

4420P *Logicin Sinus, SI* — **Pseudoephedrine hydrochloride**, Tablet 60 mg

ALTERATIONS

Alteration - Drug name and form and strength description

From:
4447C **Salicylic acid with coal tar solution, pine tar and undecylenamide**, Scalp cleanser 20 mg-10 mg-10 mg-10 mg per mL (2%- 1%-1%-1%), 250 mL (*Sebitar*)

To:
4447C **Salicylic acid with coal tar solution and pine tar**, Scalp cleanser 20 mg-10 mg-10 mg per mL (2%-1%-1%), 250 mL (*Sebitar*)

RESTRICTIONS

The text of restrictions mentioned above:

4322L **Pregabalin**, Capsule 75 mg *(Lyrica)*

4323M **Pregabalin**, Capsule 150 mg *(Lyrica)*

4324N **Pregabalin**, Capsule 300 mg *(Lyrica)*

Authority required

For the treatment of refractory neuropathic pain not controlled by other drugs.

4059P **Risedronate sodium and calcium carbonate**, Pack containing 4 tablets risedronate sodium 35 mg and 24 tablets calcium carbonate 1.25 g (equivalent to 500 mg calcium) *(Actonel Combi)*

Authority required

For preservation of bone mineral density in patients on long-term glucocorticoid therapy where patients are undergoing continuous treatment with a dose equal to or greater than 7.5 mg of prednisone or equivalent per day. Prescribers need to demonstrate that the patient has been on continuous therapy for 3 months or more and demonstrate that the patient is osteopenic (bone mineral density t-score of less than -1.0).

4070F **Tamsulosin hydrochloride**, Tablet 400 micrograms (prolonged release) *(Flomaxtra)*

Authority required

Treatment of benign prostatic hyperplasia where surgery is inappropriate, or where other drug treatment has failed or is contraindicated.

NOTES

The text of notes mentioned above:

4510J **Cationic conditioner with panthenol**, Cream 200 g *(SebiRinse)*

Note:

To be used in conjunction with the scalp cleanser salicylic acid with coal tar solution and pine tar (code 4447C).