



Australian Government

Department of Health and Ageing

**SCHEDULE OF PHARMACEUTICAL
BENEFITS**

SUMMARY OF CHANGES

EFFECTIVE 1 SEPTEMBER 2009

PHARMACEUTICAL BENEFITS

These changes to the Schedule of Pharmaceutical Benefits are effective from 1 September 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 September 2009 and are included, where applicable, in prices published in the Schedule—

Dispensing Fees:	Ready-prepared	\$6.42
	Dangerous drug fee	\$2.71
	Extemporaneously-prepared	\$8.46
	Allowable additional patient charge*	\$3.79
Additional Fees (for safety net prices):	Ready-prepared	\$1.05
	Extemporaneously-prepared	\$1.38
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 and NOTES' below for full details of items where a restriction and/or note applies)

- 1017M **Clotrimazole**, Cream 10 mg per g (1%), 20 g (*Clonea*)
 9477T **Lansoprazole**, Tablet 30 mg (orally disintegrating) (*Zoton FasTabs*)
 9478W **Lansoprazole**, Tablet 30 mg (orally disintegrating) (*Zoton FasTabs*) (**Diff. Max. Rpts**)
 9476R **Poly-l-lactic acid**, Powder for injection 150 mg (*Sculpra*)
 9475Q **Poly-l-lactic acid**, Powder for injection 150 mg (*Sculpra*) (**Diff. Max. Rpts**)
 9479X **Silver sulfadiazine**, Cream 10 mg per g (1%), 50 g (*Flamazine*)
 9470K **Sodium bicarbonate**, Capsule 840 mg (*Sodibic*)

Additions — Brands

- 3119E *Cephalexin generichealth, GQ* — **Cephalexin**, Capsule 500 mg
 3318P *Cephalexin generichealth, GQ* — **Cephalexin**, Capsule 500 mg (**Dental**)
 8700X *LoxaLate, AF* — **Escitalopram oxalate**, Tablet 10 mg (base)
 8701Y *LoxaLate, AF* — **Escitalopram oxalate**, Tablet 20 mg (base)
 9185K *Fludarabine Actavis, GQ* — **Fludarabine phosphate**, Powder for I.V. injection 50 mg
 8535F *APO-Gliclazide MR, TX; Chem mart Gliclazide MR, CH; Terry White Chemists Gliclazide MR, TW* — **Gliclazide**, Tablet 30 mg (modified release)
 8450R *APO-Glimepiride, TX* — **Glimepiride**, Tablet 1 mg
 8451T *APO-Glimepiride, TX* — **Glimepiride**, Tablet 2 mg
 8533D *APO-Glimepiride, TX* — **Glimepiride**, Tablet 3 mg
 8452W *APO-Glimepiride, TX* — **Glimepiride**, Tablet 4 mg
 2245E *PK* — **Glucose**, I.V. infusion 278 mmol (anhydrous) per L (5%), 1 L
 5106R *PK* — **Glucose**, I.V. infusion 278 mmol (anhydrous) per L (5%), 1 L (**Dental**)
 9435N *Diaformin XR, AF; Metex XR, SI* — **Metformin hydrochloride**, Tablets 500 mg (extended release), 120
 2833D *APO-Pravastatin, TX* — **Pravastatin sodium**, Tablet 10 mg
 9237E *APO-Pravastatin, TX* — **Pravastatin sodium**, Tablet 10 mg (**Diff. Max. Rpts**)
 1760P *Roxithromycin-GA, GM* — **Roxithromycin**, Tablet 150 mg
 8016X *Roxithromycin-GA, GM* — **Roxithromycin**, Tablet 300 mg
 2264E *PK* — **Sodium chloride**, I.V. infusion 154 mmol per L (0.9%), 1 L
 5212H *PK* — **Sodium chloride**, I.V. infusion 154 mmol per L (0.9%), 1 L (**Dental**)
 2286H *PK* — **Sodium lactate compound**, I.V. infusion 1 L
 8455B *Lodam 50, ZP* — **Tramadol hydrochloride**, Capsule 50 mg
 8611F *Lodam 50, ZP* — **Tramadol hydrochloride**, Capsule 50 mg (**Diff. Max. Rpts**)
 5232J *Lodam 50, ZP* — **Tramadol hydrochloride**, Capsule 50 mg (**Dental**)
 8523N *Lodam SR 100, ZP* — **Tramadol hydrochloride**, Tablet 100 mg (twice daily sustained release)
 5234L *Lodam SR 100, ZP* — **Tramadol hydrochloride**, Tablet 100 mg (twice daily sustained release) (**Dental**)
 8524P *Lodam SR 150, ZP* — **Tramadol hydrochloride**, Tablet 150 mg (twice daily sustained release)
 5235M *Lodam SR 150, ZP* — **Tramadol hydrochloride**, Tablet 150 mg (twice daily sustained release) (**Dental**)
 8525Q *Lodam SR 200, ZP* — **Tramadol hydrochloride**, Tablet 200 mg (twice daily sustained release)
 5236N *Lodam SR 200, ZP* — **Tramadol hydrochloride**, Tablet 200 mg (twice daily sustained release) (**Dental**)

Additions — Bioequivalence Indicators

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

- 9435N *Diabex XR, AL* — **Metformin hydrochloride**, Tablets 500 mg (extended release), 120

DELETIONS

Deletions — Items

- 8861J **Etanercept**, Injection set containing 4 vials powder for injection 50 mg and 4 pre-filled syringes solvent 1 mL (*Enbrel*)
- 8862K **Etanercept**, Injection set containing 4 vials powder for injection 50 mg and 4 pre-filled syringes solvent 1 mL (*Enbrel*) (**Diff. Max. Rpts**)
- 9081Y **Etanercept**, Injection set containing 4 vials powder for injection 50 mg and 4 pre-filled syringes solvent 1 mL (*Enbrel*) (**Diff. Restr**)
- 9082B **Etanercept**, Injection set containing 4 vials powder for injection 50 mg and 4 pre-filled syringes solvent 1 mL (*Enbrel*) (**Diff. Restr**) (**Diff. Max. Rpts**)
- 9083C **Etanercept**, Injection set containing 4 vials powder for injection 50 mg and 4 pre-filled syringes solvent 1 mL (*Enbrel*) (**Diff. Restr**)
- 9084D **Etanercept**, Injection set containing 4 vials powder for injection 50 mg and 4 pre-filled syringes solvent 1 mL (*Enbrel*) (**Diff. Restr**) (**Diff. Max. Rpts**)
- 9038Q **Etanercept**, Injection set containing 4 vials powder for injection 50 mg and 4 pre-filled syringes solvent 1 mL (*Enbrel*) (**Diff. Restr**)
- 9430H **Etanercept**, Injection set containing 4 vials powder for injection 50 mg and 4 pre-filled syringes solvent 1 mL (*Enbrel*) (**Diff. Restr**) (**Diff. Max. Rpts**)

Deletions — Brands

- 1884E *Amohexal, HX* — **Amoxicillin**, Capsule 250 mg
- 3301R *Amohexal, HX* — **Amoxicillin**, Capsule 250 mg (**Dental**)
- 1162E *Baxter Carboplatin, BX* — **Carboplatin**, Solution for I.V. injection 450 mg in 45 mL
- 9432K *Esitalo, SZ; Lexam 10, SI* — **Escitalopram oxalate**, Tablet 10 mg (base)
- 9433L *Esitalo, SZ; Lexam 20, SI* — **Escitalopram oxalate**, Tablet 20 mg (base)
- 3026G *Baxter Paclitaxel, BX* — **Paclitaxel**, Solution concentrate for I.V. infusion 30 mg in 5 mL
- 8018B *Baxter Paclitaxel, BX* — **Paclitaxel**, Solution concentrate for I.V. infusion 100 mg in 16.7 mL
- 8360B *Baxter Paclitaxel, BX* — **Paclitaxel**, Solution concentrate for I.V. infusion 300 mg in 50 mL
- 2011W *GN* — **Simvastatin**, Tablet 10 mg
- 9242K *GN* — **Simvastatin**, Tablet 10 mg (**Diff. Max. Rpts**)
- 2012X *GN* — **Simvastatin**, Tablet 20 mg
- 9243L *GN* — **Simvastatin**, Tablet 20 mg (**Diff. Max. Rpts**)
- 8173E *GN* — **Simvastatin**, Tablet 40 mg
- 9244M *GN* — **Simvastatin**, Tablet 40 mg (**Diff. Max. Rpts**)
- 8313M *GN* — **Simvastatin**, Tablet 80 mg
- 9245N *GN* — **Simvastatin**, Tablet 80 mg (**Diff. Max. Rpts**)

ALTERATIONS

Alterations — Proprietary Name

From:

1891M **Amoxicillin with clavulanic acid**, Tablet 500 mg-125 mg (*Curam 500/125*)

To:

1891M **Amoxicillin with clavulanic acid**, Tablet 500 mg-125 mg (*Curam Duo 500/125*)

From:

5008N **Amoxicillin with clavulanic acid**, Tablet 500 mg-125 mg (*Curam 500/125*) (**Dental**)

To:

5008N **Amoxicillin with clavulanic acid**, Tablet 500 mg-125 mg (*Curam Duo 500/125*) (**Dental**)

From:

8254K **Amoxicillin with clavulanic acid**, Tablet 875 mg-125 mg (*Curam 875/125*)

To:	
8254K	Amoxicillin with clavulanic acid , Tablet 875 mg-125 mg (<i>Curam Duo Forte 875/125</i>)
From:	
5006L	Amoxicillin with clavulanic acid , Tablet 875 mg-125 mg (<i>Curam 875/125</i>) (Dental)
To:	
5006L	Amoxicillin with clavulanic acid , Tablet 875 mg-125 mg (<i>Curam Duo Forte 875/125</i>) (Dental)

Alterations — Manufacturer's Code

		<i>From</i>	<i>To</i>
8773R	Anakinra , Injection 100 mg in 0.67 mL single use pre-filled syringe (<i>Kineret</i>)	AN	FK
8774T	Anakinra , Injection 100 mg in 0.67 mL single use pre-filled syringe (<i>Kineret</i>) (Diff. Max. Rpts)	AN	FK
8700X	Escitalopram oxalate , Tablet 10 mg (base) (<i>Esipram</i>)	CF	GM
9432K	Escitalopram oxalate , Tablet 10 mg (base) (<i>Esipram</i>) (Diff. Restriction)	CF	GM
8701Y	Escitalopram oxalate , Tablet 20 mg (base) (<i>Esipram</i>)	CF	GM
9433L	Escitalopram oxalate , Tablet 20 mg (base) (<i>Esipram</i>) (Diff. Restriction)	CF	GM

Alterations — Restrictions

The following are now "Authority required (STREAMLINED)" items:

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

8800E	Cladribine , Injection 10 mg in 5 mL (<i>Litak</i>)
1811H	Cladribine , Solution for I.V. infusion 10 mg in 10 mL (<i>Leustatin</i>)
8786K	Fotemustine , Powder for injection 208 mg with solvent (<i>Muphoran</i>)
8414W	Irinotecan hydrochloride trihydrate , I.V. injection 40 mg in 2 mL (<i>Camptosar, Irinotecan Actavis, Irinotecan Sandoz, Omegapharm Irinotecan, HH</i>)
8415X	Irinotecan hydrochloride trihydrate , I.V. injection 100 mg in 5 mL (<i>Camptosar, Irinotecan Actavis, Irinotecan Sandoz, Omegapharm Irinotecan, HH</i>)
9410G	Irinotecan hydrochloride trihydrate , I.V. injection 300 mg in 15 mL (<i>Camptosar</i>)
9119Y	Irinotecan hydrochloride trihydrate , I.V. injection 500 mg in 25 mL (<i>HH</i>)
8284B	Raltitrexed , Powder for I.V. infusion 2 mg (<i>Tomudex</i>)
8199M	Topotecan hydrochloride , Powder for I.V. infusion 4 mg (base) (<i>Hycamtin</i>)

SECTION 100

HIGHLY SPECIALISED DRUGS PROGRAM

ALTERATIONS

Alteration — Restriction and Note

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

6469L	Thalidomide , Capsule 50 mg (<i>Thalidomide Pharmion</i>)
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ADVANCE NOTICES

Advance Notice — Deletion of Items

The following item will be deleted from the Schedule of Pharmaceutical Benefits on 1 October 2009:

Deletion requested by the manufacturer—

6393L **Ribavirin and peginterferon alfa-2a**, Pack containing 84 tablets ribavirin 200 mg and 4 pre-filled syringes peginterferon alfa-2a injection 180 micrograms (*Pegasys RBV*)

The following item will be deleted from the Schedule of Pharmaceutical Benefits on 1 November 2009:

Deletion requested by the manufacturer—

1251W **Terbutaline sulfate**, Nebuliser solution single dose units 5 mg in 2 mL, 30 (*Bricanyl Respules*)

Advance Notice — Deletion of Brands

The following brands will be deleted from the Schedule of Pharmaceutical Benefits on 1 December 2009:

Deletions requested by the manufacturer—

8884N *Metex SR, SI* — **Metformin hydrochloride**, Tablet 500 mg (extended release)

1975Y *Quinsul, LN* — **Quinine sulfate**, Tablet 300 mg

The following brand will be deleted from the Schedule of Pharmaceutical Benefits on 1 April 2010:

Deletion requested by the manufacturer—

3012M *K-Sol, LN* — **Potassium chloride with potassium bicarbonate**, Effervescent tablet 14 mmol potassium and 8 mmol chloride

RETENTION OF ITEM

Contrary to previous advice, the following item will not be deleted from the Schedule of Pharmaceutical Benefits on 1 November 2009:

9012H **Alendronate sodium with colecalciferol**, Tablet equivalent to 70 mg alendronic acid with 70 micrograms colecalciferol

RESTRICTIONS and NOTES

The text of restrictions and notes mentioned above:

- 8800E **Cladribine**, Injection 10 mg in 5 mL (*Litak*)
- 1811H **Cladribine**, Solution for I.V. infusion 10 mg in 10 mL (*Leustatin*)
Authority required (STREAMLINED)
3180
 Hairy cell leukaemia.
- 1017M **Clotrimazole**, Cream 10 mg per g (1%), 20 g (*Clonea*)
Authority required (STREAMLINED)
2354
 Treatment of a fungal or a yeast infection in an Aboriginal or a Torres Strait Islander person.
- 8786K **Fotemustine**, Powder for injection 208 mg with solvent (*Muphoran*)
Authority required (STREAMLINED)
3181
 Metastatic malignant melanoma.
- 8414W **Irinotecan hydrochloride trihydrate**, I.V. injection 40 mg in 2 mL (*Camptosar, Irinotecan Actavis, Irinotecan Sandoz, Omegapharm Irinotecan, HH*)
- 8415X **Irinotecan hydrochloride trihydrate**, I.V. injection 100 mg in 5 mL (*Camptosar, Irinotecan Actavis, Irinotecan Sandoz, Omegapharm Irinotecan, HH*)
- 9410G **Irinotecan hydrochloride trihydrate**, I.V. injection 300 mg in 15 mL (*Camptosar*)
- 9119Y **Irinotecan hydrochloride trihydrate**, I.V. injection 500 mg in 25 mL (*HH*)
Authority required (STREAMLINED)
3184
 Metastatic colorectal cancer in patients with a WHO performance status of 2 or less.
NOTE:
 In first-line usage, effectiveness and tolerance may be improved when irinotecan is combined with an infusional 5-fluorouracil regimen.
- 9477T **Lansoprazole**, Tablet 30 mg (orally disintegrating) (*Zoton FasTabs*)
Restricted benefit
 Initial treatment of peptic ulcer.
NOTE:
Helicobacter pylori eradication therapy should be considered.
 No applications for increased repeats will be authorised.
- 9478W **Lansoprazole**, Tablet 30 mg (orally disintegrating) (*Zoton FasTabs*)
Restricted benefit
 Gastro-oesophageal reflux disease.
Restricted benefit
 Scleroderma oesophagus.

Poly-l-lactic acid**NOTE:**

Authority applications to prescribe poly-l-lactic acid may be made by telephone to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

9476R **Poly-l-lactic acid**, Powder for injection 150 mg (*Sculptra*)

Authority required

Maintenance PBS-subsidised treatment, for facial administration only, of severe facial lipoatrophy caused by therapy for HIV infection.

Accreditation following completion of injection administration training with Sanofi-Aventis is required to prescribe poly-l-lactic acid under the PBS. Patients must be referred from the HIV physician to the accredited injector.

NOTE:

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

Maintenance treatment is limited to one re-treatment (maximum 2 vials) every 2 years.

9475Q **Poly-l-lactic acid**, Powder for injection 150 mg (*Sculptra*)

Authority required

Initial PBS-subsidised treatment, for facial administration only, of severe facial lipoatrophy caused by therapy for HIV infection.

Accreditation following completion of injection administration training with Sanofi-Aventis is required to prescribe poly-l-lactic acid under the PBS. Patients must be referred from the HIV physician to the accredited injector.

NOTE:

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

8284B **Raltitrexed**, Powder for I.V. infusion 2 mg (*Tomudex*)

Authority required (STREAMLINED)**3185**

For use as a single agent in the treatment of advanced colorectal cancer.

9479X **Silver sulfadiazine**, Cream 10 mg per g (1%), 50 g (*Flamazine*)

Restricted benefit

Prevention and treatment of infection in partial or full skin thickness loss due to burns.

Restricted benefit

Prevention and treatment of infection in partial or full skin thickness loss due to epidermolysis bullosa.

Restricted benefit

Stasis ulcers.

6469L **Thalidomide**, Capsule 50 mg (*Thalidomide Pharmion*)

Private hospital authority required

Multiple myeloma.

NOTE:

Patients receiving thalidomide under the PBS listing must be registered in the Thalidomide Risk Management Program.

8199M **Topotecan hydrochloride**, Powder for I.V. infusion 4 mg (base) (*Hycamtin*)

Authority required (STREAMLINED)

3186

Advanced metastatic ovarian cancer after failure of prior therapy which includes a platinum compound.

REPATRIATION PHARMACEUTICAL BENEFITS

There are no changes to the Repatriation Pharmaceutical Benefits Schedule listings effective from 1 September 2009. The Schedule is updated on the first day of each month and is available on the Internet at www.pbs.gov.au.