Australian Government

Department of Health and Ageing

SCHEDULE OF PHARMACEUTICAL BENEFITS

SUMMARY OF CHANGES

EFFECTIVE 1 December 2011

PHARMACEUTICAL BENEFITS

These changes to the Schedule of Pharmaceutical Benefits are effective from 1 December 2011. The Schedule is updated on the first day of each month and is available on the Internet at www.pbs.gov.au.

Fees, Patient Contributions and Safety Net Thresholds

The following fees, patient contributions and safety net thresholds apply as at 1 December 2011 and are included, where applicable, in prices published in the Schedule —

Dispensing Fees:	Ready-prepared	$6.42
	Dangerous drug fee	$2.71
	Extemporaneously-prepared	$8.46
	Allowable additional patient charge*	$3.92
Additional Fees (for safety net prices):	Ready-prepared	$1.09
	Extemporaneously-prepared	$1.44
Patient Co-payments:	General	$34.20
	Concessional	$5.60
Safety Net Thresholds:	General	$1317.20
	Concessional	$336.00
Safety Net Card Issue Fee:		$8.58

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

SUMMARY OF CHANGES

Additions

Addition – Item

5140M **Asenapine**, Sublingual wafer 5 mg (as maleate) *(Saphris)*

5141N **Asenapine**, Sublingual wafer 10 mg (as maleate) *(Saphris)*

8956J **Dalteparin Sodium (low Molecular Weight Heparin Sodium—porcine mucous)** , Injection 7,500 units (anti-Xa) in 0.75 mL single dose pre-filled syringe *(Fragmin)*

8957K **Dalteparin Sodium (low Molecular Weight Heparin Sodium—porcine mucous)** , Injection 10,000 units (anti-Xa) in 1 mL single dose pre-filled syringe *(Fragmin)*

8958L **Dalteparin Sodium (low Molecular Weight Heparin Sodium—porcine mucous)** , Injection 12,500 units (anti-Xa) in 0.5 mL single dose pre-filled syringe *(Fragmin)*

8959M **Dalteparin Sodium (low Molecular Weight Heparin Sodium—porcine mucous)** , Injection 15,000 units (anti-Xa) in 0.6 mL single dose pre-filled syringe *(Fragmin)*

8960N **Dalteparin Sodium (low Molecular Weight Heparin Sodium—porcine mucous)** , Injection 18,000 units (anti-Xa) in 0.72 mL single dose pre-filled syringe *(Fragmin)*

5110Y **Denosumab**, Injection 120 mg in 1 mL *(Xgeva)*

5134F **Indacaterol**, Capsule containing powder for oral inhalation 150 micrograms (as maleate) (for use in Breezhaler) *(Onbrez)*

5137J **Indacaterol**, Capsule containing powder for oral inhalation 300 micrograms (as maleate) (for use in Breezhaler) *(Onbrez)*

5452Y **Losartan**, Tablet containing losartan potassium 25 mg *(Cozavan)*

8203R **Losartan**, Tablet containing losartan potassium 50 mg *(Cozavan)*

5146W **Magnesium**, Tablet 37.4 mg (as aspartate dihydrate) *(Mag-Sup)*

8000C **Oxycodone Hydrochloride with Naloxone Hydrochloride**, Tablet 5 mg-2.5 mg (controlled release) *(Targin 5/2.5mg)*

8934F **Oxycodone Hydrochloride with Naloxone Hydrochloride**, Tablet 10 mg-5 mg (controlled release) *(Targin 10/5mg)*

8935G **Oxycodone Hydrochloride with Naloxone Hydrochloride**, Tablet 20 mg-10 mg (controlled release) *(Targin 20/10mg)*

8936H **Oxycodone Hydrochloride with Naloxone Hydrochloride**, Tablet 40 mg-20 mg (controlled release) *(Targin 40/20mg)*

5100K **Paliperidone**, I.M. injection (modified release) 25 mg (as palmitate) in pre-filled syringe *(Invega Sustenna)*

5102M **Paliperidone**, I.M. injection (modified release) 50 mg (as palmitate) in pre-filled syringe *(Invega Sustenna)*

5103N **Paliperidone**, I.M. injection (modified release) 75 mg (as palmitate) in pre-filled syringe *(Invega Sustenna)*

5107T **Paliperidone**, I.M. injection (modified release) 100 mg (as palmitate) in pre-filled syringe *(Invega Sustenna)*

5109X **Paliperidone**, I.M. injection (modified release) 150 mg (as palmitate) in pre-filled syringe *(Invega Sustenna)*

5143Q **Pramipexole Hydrochloride**, Tablet 2.25 mg (extended release) *(Sifrol ER)*

5145T **Pramipexole Hydrochloride**, Tablet 3.75 mg (extended release) *(Sifrol ER)*

Addition – Brand

8604W *Bisoprolol GH, GQ* – **Bisoprolol Fumarate**, Tablet 2.5 mg

8605X *Bisoprolol GH, GQ* – **Bisoprolol Fumarate**, Tablet 5 mg

8606Y *Bisoprolol GH, GQ* – **Bisoprolol Fumarate**, Tablet 10 mg

2509C *Dexmethsone, AS* – **Dexamethasone Sodium Phosphate**, Injection equivalent to 4 mg dexamethasone phosphate in 1 mL

3472R *Dexmethsone, AS* – **Dexamethasone Sodium Phosphate**, Injection equivalent to 4 mg dexamethasone phosphate in 1 mL **(Emergency Drug Supply)**

1291Y *Dexmethsone, AS* – **Dexamethasone Sodium Phosphate**, Injection equivalent to 8 mg dexamethasone phosphate in 2 mL

8897G *APO-Famciclovir, TX* – **Famciclovir**, Tablet 500 mg

8896F *APO-Famciclovir, TX* – **Famciclovir**, Tablet 500 mg

8896F *Chem mart Famciclovir, CH* – **Famciclovir**, Tablet 500 mg

8897G *Chem mart Famciclovir, CH* – **Famciclovir**, Tablet 500 mg

8896F *Terry White Chemists Famciclovir, TW* – **Famciclovir**, Tablet 500 mg

8897G *Terry White Chemists Famciclovir, TW* – **Famciclovir**, Tablet 500 mg

2321E *Medroxyprogesterone Sandoz, SZ* – **Medroxyprogesterone Acetate**, Tablet 10 mg

1653B *APOTEX-MORPHINE MR, TX* – **Morphine Sulfate**, Tablet 10 mg (controlled release)

1654C *APOTEX-MORPHINE MR, TX* – **Morphine Sulfate**, Tablet 30 mg (controlled release)

1655D *APOTEX-MORPHINE MR, TX* – **Morphine Sulfate**, Tablet 60 mg (controlled release)

1656E *APOTEX-MORPHINE MR, TX* – **Morphine Sulfate**, Tablet 100 mg (controlled release)

3050M *Perindopril generichealth, GQ* – **Perindopril**, Tablet containing 2 mg perindopril erbumine

3051N *Perindopril generichealth, GQ* – **Perindopril**, Tablet containing 4 mg perindopril erbumine

8704D *Perindopril generichealth, GQ* – **Perindopril**, Tablet containing 8 mg perindopril erbumine

8016X *Roxithromycin Sandoz, SZ* – **Roxithromycin**, Tablet 300 mg

5261X *Roxithromycin Sandoz, SZ* – **Roxithromycin**, Tablet 300 mg **(Dental)**

2236Q *Sertraline Sandoz, SZ* – **Sertraline**, Tablet 50 mg (as hydrochloride)

2237R *Sertraline Sandoz, SZ* – **Sertraline**, Tablet 100 mg (as hydrochloride)

8819E *Astromide, WQ* – **Temozolomide**, Capsule 5 mg

8820F *Astromide, WQ* – **Temozolomide**, Capsule 20 mg

8821G *Astromide, WQ* – **Temozolomide**, Capsule 100 mg

9361Q *Astromide, WQ* – **Temozolomide**, Capsule 140 mg

8378Y *Astromide, WQ* – **Temozolomide**, Capsule 5 mg

8379B *Astromide, WQ* – **Temozolomide**, Capsule 20 mg

8380C *Astromide, WQ* – **Temozolomide**, Capsule 100 mg

8381D *Astromide, WQ* – **Temozolomide**, Capsule 250 mg

9362R *Astromide, WQ* – **Temozolomide**, Capsule 140 mg

8819E *Temizole 5, QA* – **Temozolomide**, Capsule 5 mg

8820F *Temizole 20, QA* – **Temozolomide**, Capsule 20 mg

8821G *Temizole 100, QA* – **Temozolomide**, Capsule 100 mg

9361Q *Temizole 140, QA* – **Temozolomide**, Capsule 140 mg

8378Y *Temizole 5, QA* – **Temozolomide**, Capsule 5 mg

8379B *Temizole 20, QA* – **Temozolomide**, Capsule 20 mg

8380C *Temizole 100, QA* – **Temozolomide**, Capsule 100 mg

9362R *Temizole 140, QA* – **Temozolomide**, Capsule 140 mg

8381D *Temizole 250, QA* – **Temozolomide**, Capsule 250 mg

8163P *Topiramate generichealth, GQ* – **Topiramate**, Tablet 25 mg

8164Q *Topiramate generichealth, GQ* – **Topiramate**, Tablet 50 mg

8165R *Topiramate generichealth, GQ* – **Topiramate**, Tablet 100 mg

8166T *Topiramate generichealth, GQ* – **Topiramate**, Tablet 200 mg

8134D *Valaciclovir generichealth, GQ* – **Valaciclovir**, Tablet 500 mg (as hydrochloride)

5480K *Valaciclovir generichealth, GQ* – **Valaciclovir**, Tablet 500 mg (as hydrochloride)

8064K *Valaciclovir generichealth, GQ* – **Valaciclovir**, Tablet 500 mg (as hydrochloride)

Addition – Equivalence Indicator

1291Y *Hospira Pty Limited, HH* – **Dexamethasone Sodium Phosphate**, Injection equivalent to 8 mg dexamethasone phosphate in 2 mL

2509C *Hospira Pty Limited, HH* – **Dexamethasone Sodium Phosphate**, Injection equivalent to 4 mg dexamethasone phosphate in 1 mL

3472R *Hospira Pty Limited, HH* – **Dexamethasone Sodium Phosphate**, Injection equivalent to 4 mg dexamethasone phosphate in 1 mL **(Emergency Drug Supply)**

8819E *Temodal, MK* – **Temozolomide**, Capsule 5 mg

8820F *Temodal, MK* – **Temozolomide**, Capsule 20 mg

8821G *Temodal, MK* – **Temozolomide**, Capsule 100 mg

9361Q *Temodal, MK* – **Temozolomide**, Capsule 140 mg

8378Y *Temodal, MK* – **Temozolomide**, Capsule 5 mg

8379B *Temodal, MK* – **Temozolomide**, Capsule 20 mg

8380C *Temodal, MK* – **Temozolomide**, Capsule 100 mg

8381D *Temodal, MK* – **Temozolomide**, Capsule 250 mg

9362R *Temodal, MK* – **Temozolomide**, Capsule 140 mg

Deletions

Deletion of chemotherapy drugs used for the treatment of cancer and administered through infusion or injection

The items listed below have been removed from Section 2 of the Schedule of Pharmaceutical Benefits. The items continue to be pharmaceutical benefits but prescribing and dispensing arrangements for these chemotherapy drugs will operate under a new section 100 program from 1 December 2011. The new program is the "Revised Arrangements for the Efficient Funding of Chemotherapy Drugs initiative (Revised Arrangements)". Chemotherapy drugs used for the treatment of cancer and administered through infusion or injection are covered by these Revised Arrangements.

A separate "EFFICIENT FUNDING OF CHEMOTHERAPY – SECTION 100 ARRANGEMENTS" schedule provides the listing details for these items. The schedule, in PDF format, will be available on the PBS website, www.pbs.gov.au/browse/publications from 1 December 2011.

9453M **Arsenic Trioxide**, Injection concentrate 10 mg in 10 mL *(Phenasen)*

9442Y **Bevacizumab**, Solution for I.V. infusion 100 mg in 4 mL *(Avastin)*

9443B **Bevacizumab**, Solution for I.V. infusion 400 mg in 16 mL *(Avastin)*

2315W **Bleomycin Sulfate**, Powder for injection 15,000 i.u. (solvent required) *(Hospira Pty Limited)***(Special Pharmaceutical Benefits)**

1160C **Carboplatin**, Solution for I.V. injection 50 mg in 5 mL *(Hospira Pty Limited, Pfizer Australia Pty Ltd, Carboplatin Ebewe)*

1161D **Carboplatin**, Solution for I.V. injection 150 mg in 15 mL *(Hospira Pty Limited, Pfizer Australia Pty Ltd, Carboplatin Ebewe)*

1162E **Carboplatin**, Solution for I.V. injection 450 mg in 45 mL *(Hospira Pty Limited, Pfizer Australia Pty Ltd, Carboplatin Ebewe)*

5447Q **Cetuximab**, Solution for I.V. infusion 100 mg in 20 mL *(Erbitux)*

5448R **Cetuximab**, Solution for I.V. infusion 500 mg in 100 mL *(Erbitux)*

9136W **Cetuximab**, Solution for I.V. infusion 100 mg in 20 mL *(Erbitux)*

9137X **Cetuximab**, Solution for I.V. infusion 500 mg in 100 mL *(Erbitux)*

9138Y **Cetuximab**, Solution for I.V. infusion 100 mg in 20 mL *(Erbitux)*

9139B **Cetuximab**, Solution for I.V. infusion 500 mg in 100 mL *(Erbitux)*

2578Q **Cisplatin**, I.V. injection 10 mg in 10 mL *(Pfizer Australia Pty Ltd)*

2579R **Cisplatin**, I.V. injection 50 mg in 50 mL *(Hospira Pty Limited, Pfizer Australia Pty Ltd)*

2580T **Cisplatin**, I.V. injection 100 mg in 100 mL *(Hospira Pty Limited, Pfizer Australia Pty Ltd, Cisplatin Ebewe)*

1811H **Cladribine**, Solution for I.V. infusion 10 mg in 10 mL *(Leustatin)*

8800E **Cladribine**, Injection 10 mg in 5 mL *(Litak)*

1031G **Cyclophosphamide**, Powder for injection 2 g (solvent required) *(Endoxan)*

1079T **Cyclophosphamide**, Powder for injection 500 mg (solvent required) *(Endoxan)*

1080W **Cyclophosphamide**, Powder for injection 1 g (solvent required) *(Endoxan)*

2884T **Cytarabine**, Injection 100 mg in 5 mL *(Pfizer Australia Pty Ltd)*

5149B **Docetaxel**, Powder for I.V. infusion 20 mg with solvent *(Docetaxel SUN)*

5156J **Docetaxel**, Powder for I.V. infusion 80 mg with solvent *(Docetaxel SUN)*

5270J **Docetaxel**, Solution concentrate for I.V. infusion 20 mg in 1 mL *(Taxotere, Oncotaxel 20)*

5271K **Docetaxel**, Injection set containing 1 single use vial concentrate for I.V. infusion 20 mg (anhydrous) in 0.5 mL with solvent *(Taxotere)*

5272L **Docetaxel**, Solution concentrate for I.V. infusion 80 mg in 4 mL *(Taxotere, Oncotaxel 80)*

5273M **Docetaxel**, Injection set containing 1 single use vial concentrate for I.V. infusion 80 mg (anhydrous) in 2 mL with solvent *(Taxotere)*

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

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

5428Q **Docetaxel**, Solution concentrate for I.V. infusion 20 mg in 1 mL *(Taxotere, Oncotaxel 20)*

5429R **Docetaxel**, Solution concentrate for I.V. infusion 20 mg in 2 mL *(DBL Docetaxel Concentrated Injection, Docetaxel Ebewe, Docetaxel Sandoz)*

5430T **Docetaxel**, Injection set containing 1 single use vial concentrate for I.V. infusion 20 mg (anhydrous) in 0.5 mL with solvent *(Taxotere)*

5431W **Docetaxel**, Solution concentrate for I.V. infusion 80 mg in 4 mL *(Taxotere, Oncotaxel 80)*

5432X **Docetaxel**, Solution concentrate for I.V. infusion 80 mg in 8 mL *(DBL Docetaxel Concentrated Injection, Docetaxel Ebewe, Docetaxel Sandoz)*

5433Y **Docetaxel**, Injection set containing 1 single use vial concentrate for I.V. infusion 80 mg (anhydrous) in 2 mL with solvent *(Taxotere)*

5462L **Docetaxel**, Solution concentrate for I.V. infusion 20 mg in 1 mL *(Taxotere, Oncotaxel 20)*

5463M **Docetaxel**, Solution concentrate for I.V. infusion 20 mg in 1 mL *(Taxotere, Oncotaxel 20)*

5464N **Docetaxel**, Solution concentrate for I.V. infusion 80 mg in 4 mL *(Taxotere, Oncotaxel 80)*

5485Q **Docetaxel**, Solution concentrate for I.V. infusion 20 mg in 2 mL *(DBL Docetaxel Concentrated Injection, Docetaxel Ebewe, Docetaxel Sandoz)*

5486R **Docetaxel**, Solution concentrate for I.V. infusion 20 mg in 2 mL *(DBL Docetaxel Concentrated Injection, Docetaxel Ebewe, Docetaxel Sandoz)*

5487T **Docetaxel**, Solution concentrate for I.V. infusion 80 mg in 8 mL *(DBL Docetaxel Concentrated Injection, Docetaxel Ebewe, Docetaxel Sandoz)*

8071T **Docetaxel**, Injection set containing 1 single use vial concentrate for I.V. infusion 20 mg (anhydrous) in 0.5 mL with solvent *(Taxotere)*

8074Y **Docetaxel**, Injection set containing 1 single use vial concentrate for I.V. infusion 80 mg (anhydrous) in 2 mL with solvent *(Taxotere)*

8967Y **Docetaxel**, Solution concentrate for I.V. infusion 160 mg in 16 mL *(DBL Docetaxel Concentrated Injection)*

8986Y **Docetaxel**, Solution concentrate for I.V. infusion 20 mg in 1 mL *(Taxotere, Oncotaxel 20)*

8987B **Docetaxel**, Solution concentrate for I.V. infusion 20 mg in 2 mL *(DBL Docetaxel Concentrated Injection, Docetaxel Sandoz)*

8988C **Docetaxel**, Injection set containing 1 single use vial concentrate for I.V. infusion 20 mg (anhydrous) in 0.5 mL with solvent *(Taxotere)*

8989D **Docetaxel**, Solution concentrate for I.V. infusion 80 mg in 4 mL *(Taxotere, Oncotaxel 80)*

8990E **Docetaxel**, Solution concentrate for I.V. infusion 80 mg in 8 mL *(DBL Docetaxel Concentrated Injection, Docetaxel Sandoz)*

8991F **Docetaxel**, Injection set containing 1 single use vial concentrate for I.V. infusion 80 mg (anhydrous) in 2 mL with solvent *(Taxotere)*

8992G **Docetaxel**, Solution concentrate for I.V. infusion 160 mg in 16 mL *(DBL Docetaxel Concentrated Injection)*

9291B **Docetaxel**, Injection set containing 1 single use vial concentrate for I.V. infusion 20 mg (anhydrous) in 0.5 mL with solvent

(Taxotere)

1336H **Doxorubicin Hydrochloride**, Solution for I.V. injection or intravesical administration 10 mg in 5 mL *(Hospira Pty Limited, Adriamycin Solution, Doxorubicin Ebewe)*

1340M **Doxorubicin Hydrochloride**, Solution for I.V. injection or intravesical administration 20 mg in 10 mL *(Adriamycin Solution)*

1342P **Doxorubicin Hydrochloride**, Solution for I.V. injection or intravesical administration 50 mg in 25 mL *(Hospira Pty Limited, Adriamycin Solution, Doxorubicin Ebewe)*

8827N **Doxorubicin Hydrochloride**, Solution for I.V. injection or intravesical administration 100 mg in 50 mL *(Doxorubicin Ebewe)*

8828P **Doxorubicin Hydrochloride**, Solution for I.V. injection or intravesical administration 200 mg in 100 mL *(Doxorubicin Ebewe, Adriamycin)*

8569B **Doxorubicin Hydrochloride, Pegylated Liposomal**, Suspension for I.V. infusion 20 mg in 10 mL *(Caelyx)*

8570C **Doxorubicin Hydrochloride, Pegylated Liposomal**, Suspension for I.V. infusion 50 mg in 25 mL *(Caelyx)*

1375J **Epirubicin Hydrochloride**, Solution for injection 10 mg in 5 mL *(Pharmorubicin Solution, Epirubicin Ebewe)*

1376K **Epirubicin Hydrochloride**, Solution for injection 20 mg in 10 mL *(Pharmorubicin Solution)*

1377L **Epirubicin Hydrochloride**, Solution for injection 50 mg in 25 mL *(Pharmorubicin Solution, Hospira Pty Limited, Epirubicin Ebewe)*

8817C **Epirubicin Hydrochloride**, Solution for injection 100 mg in 50 mL *(Hospira Pty Limited, Epirubicin Ebewe)*

8858F **Epirubicin Hydrochloride**, Solution for injection 200 mg in 100 mL *(Epirubicin Ebewe, DBL Epirubicin Hydrochloride Injection)*

1390E **Etoposide**, Solution for I.V. infusion 100 mg in 5 mL *(Hospira Pty Limited, Etoposide Ebewe)*

8120J **Etoposide**, Powder for I.V. infusion 100 mg (as phosphate) *(Etopophos)*

8515E **Etoposide**, Powder for I.V. infusion 1 g (as phosphate) *(Etopophos)*

9185K **Fludarabine Phosphate**, Powder for I.V. injection 50 mg *(Fludara, Fludarabine Actavis, Farine)*

9207N **Fludarabine Phosphate**, Solution for I.V. injection 50 mg in 2 mL *(Fludarabine Ebewe)*

2528C **Fluorouracil**, Injection 500 mg in 10 mL *(Hospira Pty Limited, Fluorouracil Ebewe)*

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

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

9005Y **Fluorouracil**, Injection 1000 mg in 20 mL *(Fluorouracil Ebewe, DBL Fluorouracil Injection BP)*

8786K **Fotemustine**, Powder for injection 208 mg with solvent *(Muphoran)*

8049P **Gemcitabine**, Powder for I.V. infusion 200 mg (as hydrochloride) *(Gemzar, Gemcitabine Ebewe, DBL Gemcitabine for Injection, Gemcite, Gemcitabine Actavis, Gemcitabine Kabi, Gemcitabine Sun, Gemplan)*

8050Q **Gemcitabine**, Powder for I.V. infusion 1 g (as hydrochloride) *(Gemzar, Gemcitabine Ebewe, DBL Gemcitabine for Injection, Gemcite, Gemcitabine Actavis, Gemcitabine Kabi, Gemcitabine Sun, Gemplan)*

9401T **Gemcitabine**, Solution concentrate for I.V. infusion 200 mg (as hydrochloride) in 20 mL *(Gemcitabine Ebewe)*

9402W **Gemcitabine**, Solution concentrate for I.V. infusion 1000 mg (as hydrochloride) in 100 mL *(Gemcitabine Ebewe)*

9414L **Gemcitabine**, Powder for I.V. infusion 2 g (as hydrochloride) *(DBL Gemcitabine for Injection, Gemcitabine Kabi)*

9463C **Gemcitabine**, Solution concentrate for I.V. infusion 500 mg (as hydrochloride) in 50 mL *(Gemcitabine Ebewe)*

8530Y **Idarubicin Hydrochloride**, Solution for I.V. injection 5 mg in 5 mL *(Zavedos Solution, Idarubicin Ebewe)*

8531B **Idarubicin Hydrochloride**, Solution for I.V. injection 10 mg in 10 mL *(Zavedos Solution, Idarubicin Ebewe)*

8076C **Ifosfamide**, Powder for I.V. injection 1 g *(Holoxan)*

8077D **Ifosfamide**, Powder for I.V. injection 2 g *(Holoxan)*

8414W **Irinotecan Hydrochloride Trihydrate**, I.V. injection 40 mg in 2 mL *(Hospira Pty Limited, Camptosar, Omegapharm Irinotecan, Irinotecan Actavis, Irinotecan Alphapharm, Irinotecan Ebewe, Tecan, Irinotecan Kabi)*

8415X **Irinotecan Hydrochloride Trihydrate**, I.V. injection 100 mg in 5 mL *(Hospira Pty Limited, Camptosar, Omegapharm Irinotecan, Irinotecan Actavis, Irinotecan Alphapharm, Irinotecan Ebewe, Tecan, Irinotecan Kabi)*

9119Y **Irinotecan Hydrochloride Trihydrate**, I.V. injection 500 mg in 25 mL *(Hospira Pty Limited, Irinotecan Ebewe, Irinotecan Actavis 500)*

9410G **Irinotecan Hydrochloride Trihydrate**, I.V. injection 300 mg in 15 mL *(Camptosar, Irinotecan Ebewe)*

8851W **Methotrexate**, Solution concentrate for I.V. infusion 1000 mg in 10 mL *(Hospira Pty Limited, Methotrexate Ebewe)*

8852X **Methotrexate**, Solution concentrate for I.V. infusion 5000 mg in 50 mL *(Methotrexate Ebewe)*

8863L **Methotrexate**, Solution concentrate for I.V. infusion 500 mg in 20 mL *(Hospira Pty Limited)*

1929M **Mitozantrone Hydrochloride**, Injection 20 mg (base) in 10 mL *(Hospira Pty Limited, Onkotrone, Pfizer Australia Pty Ltd, Mitozantrone Ebewe)*

1930N **Mitozantrone Hydrochloride**, Injection 25 mg (base) in 12.5 mL *(Onkotrone, Pfizer Australia Pty Ltd)*

1932Q **Mitozantrone Hydrochloride**, Injection 10 mg (base) in 5 mL *(Pfizer Australia Pty Ltd)*

9415M **Nab Paclitaxel**, Powder for I.V. injection 100 mg (base) *(Abraxane)*

2310N **Oxaliplatin**, Solution concentrate for I.V. infusion 200 mg in 40 mL *(Eloxatin, Oxaliplatin SUN)*

8539K **Oxaliplatin**, Powder for I.V. infusion 50 mg *(Hospira Pty Limited, Oxaliplatin Ebewe, Oxalatin, Oxaliplatin Actavis, Oxaliplatin Alphapharm, Oxaliplatin Link, Xalox)*

8540L **Oxaliplatin**, Powder for I.V. infusion 100 mg *(Hospira Pty Limited, Oxaliplatin Ebewe, Winthrop Oxaliplatin, Oxalatin, Oxaliplatin Actavis, Oxaliplatin Alphapharm, Oxaliplatin Link, Xalox)*

8847P **Oxaliplatin**, Solution concentrate for I.V. infusion 50 mg in 10 mL *(Eloxatin, DBL Oxaliplatin Concentrate, Oxaliplatin Kabi, Oxaliplatin SUN)*

8848Q **Oxaliplatin**, Solution concentrate for I.V. infusion 100 mg in 20 mL *(Eloxatin, DBL Oxaliplatin Concentrate, Oxaliplatin Kabi, Oxaliplatin SUN)*

3017T **Paclitaxel**, Solution concentrate for I.V. infusion 150 mg in 25 mL *(Anzatax, Paclitaxel Ebewe, Paclitaxel Actavis, Plaxel)*

3026G **Paclitaxel**, Solution concentrate for I.V. infusion 30 mg in 5 mL *(Taxol, Anzatax, Paclitaxel Ebewe, Paclitaxel Actavis, Plaxel, Paclitaxel Kabi)*

8018B **Paclitaxel**, Solution concentrate for I.V. infusion 100 mg in 16.7 mL *(Taxol, Anzatax, Paclitaxel Ebewe, Paclitaxel Actavis, Plaxel, Paclitaxel Kabi)*

8360B **Paclitaxel**, Solution concentrate for I.V. infusion 300 mg in 50 mL *(Taxol, Anzatax, Paclitaxel Ebewe, Paclitaxel Actavis, Plaxel, Paclitaxel Kabi)*

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

9131N **Pemetrexed Disodium**, Powder for I.V. infusion 100 mg (base) *(Alimta)*

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

8293L **Rituximab**, Solution for I.V. infusion 100 mg in 10 mL *(Mabthera)*

8294M **Rituximab**, Solution for I.V. infusion 500 mg in 50 mL *(Mabthera)*

8665C **Rituximab**, Solution for I.V. infusion 100 mg in 10 mL *(Mabthera)*

8666D **Rituximab**, Solution for I.V. infusion 500 mg in 50 mL *(Mabthera)*

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

2199R **Vinblastine Sulfate**, Solution for I.V. injection 10 mg in 10 mL *(Hospira Pty Limited)*

2374Y **Vincristine Sulfate**, I.V. injection 1 mg in 1 mL *(Hospira Pty Limited, Pfizer Australia Pty Ltd)*

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

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

Deletion – Item

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

3176E **Norethisterone with Mestranol**, Tablets 1 mg-50 micrograms, 21 *(Norinyl-1)*

2345K **Thiotepa**, Powder for injection 15 mg *(Aspen Pharma Pty Ltd)*

Deletion – Brand

1148K *Ascent Pharma Pty Ltd, GM* – **Captopril**, Tablet 25 mg

1149L *Ascent Pharma Pty Ltd, GM* – **Captopril**, Tablet 50 mg

1215Y *Dolaforte, CO* – **Codeine Phosphate with Paracetamol**, Tablet 30 mg-500 mg

3316M *Dolaforte, CO* – **Codeine Phosphate with Paracetamol**, Tablet 30 mg-500 mg **(Dental)**

8785J *Dolaforte, CO* – **Codeine Phosphate with Paracetamol**, Tablet 30 mg-500 mg

1312C *Dilzem CD, GM* – **Diltiazem Hydrochloride**, Capsule 180 mg (controlled delivery)

1313D *Dilzem CD, GM* – **Diltiazem Hydrochloride**, Capsule 240 mg (controlled delivery)

8607B *Glucohexal, HX* – **Metformin Hydrochloride**, Tablet 1 g

2430X *Glucohexal, HX* – **Metformin Hydrochloride**, Tablet 500 mg

1801T *Glucohexal, HX* – **Metformin Hydrochloride**, Tablet 850 mg

2776D *Synphasic, PF* – **Norethisterone with Ethinyloestradiol**, Pack containing 12 tablets 500 micrograms-35 micrograms, 9 tablets 1 mg-35 micrograms and 7 inert tablets

Deletion – Equivalence Indicator

2776D *Improvil 28 Day, FZ* – **Norethisterone with Ethinyloestradiol**, Pack containing 12 tablets 500 micrograms-35 micrograms, 9 tablets 1 mg-35 micrograms and 7 inert tablets

Deletion – Note

8780D **Risperidone**, Powder for I.M. injection 25 mg (modified release) with 2 mL diluent in pre-filled syringe *(Risperdal Consta)*

8781E **Risperidone**, Powder for I.M. injection 37.5 mg (modified release) with 2 mL diluent in pre-filled syringe *(Risperdal Consta)*

8782F **Risperidone**, Powder for I.M. injection 50 mg (modified release) with 2 mL diluent in pre-filled syringe *(Risperdal Consta)*

Alterations

Alteration – Brand Name

From:

2285G *Lamisil, NV* – **Terbinafine**, Tablet 250 mg (as hydrochloride)

To:

2285G *Lamisil (Novartis Pharmaceuticals Australia Pty Limited, NV* – **Terbinafine**, Tablet 250 mg (as hydrochloride)

From:

2804N *Lamisil, NV* – **Terbinafine**, Tablet 250 mg (as hydrochloride)

To:

2804N *Lamisil (Novartis Pharmaceuticals Australia Pty Limited, NV* – **Terbinafine**, Tablet 250 mg (as hydrochloride)

From:

9160D *Lamisil, NC* – **Terbinafine**, Cream containing terbinafine hydrochloride 10 mg per g (1%), 15 g

To:

9160D *Lamisil (Novartis Consumer Health Australasia Pty Ltd, NC* – **Terbinafine**, Cream containing terbinafine hydrochloride 10 mg per g (1%), 15 g

Alteration – Item Description

From:

2962X **Nafarelin Acetate**, Nasal spray (pump pack) 200 micrograms (base) per dose (60 doses) *(Synarel)*

To:

2962X **Nafarelin**, Nasal spray (pump pack) 200 micrograms (as acetate) per dose, 60 doses *(Synarel)*

Alteration – Restriction

8511Y **Alendronate Sodium**, Tablet equivalent to 70 mg alendronic acid *(Fosamax Once Weekly, Alendro Once Weekly, Alendrobell 70mg, Ossmax 70mg, APO-Alendronate, Chem mart Alendronate 70mg, Terry White Chemists Alendronate 70mg, Adronat, Alendronate Sandoz, Alendronate-GA)*

9012H **Alendronate Sodium with Colecalciferol**, Tablet equivalent to 70 mg alendronic acid with 70 micrograms colecalciferol *(Fosamax Plus)*

9183H **Alendronate Sodium with Colecalciferol**, Tablet equivalent to 70 mg alendronic acid with 140 micrograms colecalciferol *(Fosamax Plus 70 mg/140 mcg, Dronalen Plus)*

9351E **Alendronate Sodium with Colecalciferol and Calcium Carbonate**, Pack containing 4 tablets containing the equivalent of 70 mg alendronic acid with 140 micrograms colecalciferol and 48 tablets calcium carbonate 1.25 g (equivalent to 500 mg calcium) *(Fosamax Plus D-Cal, Dronalen Plus D-Cal)*

8750M **Budesonide with Eformoterol Fumarate Dihydrate**, Powder for oral inhalation in breath actuated devices 400 micrograms-12 micrograms per dose (60 doses), 2 *(Symbicort Turbuhaler 400/12)*

8361C **Capecitabine**, Tablet 150 mg *(Xeloda)*

8362D **Capecitabine**, Tablet 500 mg *(Xeloda)*

9288W **Zoledronic Acid**, Solution for I.V. infusion 5 mg (as monohydrate) in 100 mL *(Aclasta)*

Alteration – Manufacturer's Code

		From:	*To:*
2321E	*Medroxyhexal, HX* – **Medroxyprogesterone Acetate**, Tablet 10 mg	SZ	HX
2236Q	*Concorz, HX* – **Sertraline**, Tablet 50 mg (as hydrochloride)	SZ	HX
2237R	*Concorz, HX* – **Sertraline**, Tablet 100 mg (as hydrochloride)	SZ	HX
8016X	*Roxide, HX* – **Roxithromycin**, Tablet 300 mg	SZ	HX
5261X	*Roxide, HX* – **Roxithromycin**, Tablet 300 mg **(Dental)**	SZ	HX

SECTION 100 – HIGHLY SPECIALISED DRUGS PROGRAM

Additions

Addition – Item

5821J **Darunavir**, Tablet 400 mg (as ethanolate) *(Prezista)* **(Public)**

5823L **Darunavir**, Tablet 400 mg (as ethanolate) *(Prezista)* **(Private)**

Alterations

Alteration – Restriction

9530N **Ribavirin and Peginterferon Alfa-2b**, Pack containing 84 capsules ribavirin 200 mg and 4 single use injection pens containing peginterferon alfa-2b powder for injection 80 micrograms with diluent *(Pegatron)* **(Public)**

6401X **Ribavirin and Peginterferon Alfa-2b**, Pack containing 84 capsules ribavirin 200 mg and 4 single use injection pens containing peginterferon alfa-2b powder for injection 80 micrograms with diluent *(Pegatron)* **(Private)**

9529M **Ribavirin and Peginterferon Alfa-2b**, Pack containing 112 capsules ribavirin 200 mg and 4 single use injection pens containing peginterferon alfa-2b powder for injection 50 micrograms with diluent *(Pegatron)* **(Public)**

6400W **Ribavirin and Peginterferon Alfa-2b**, Pack containing 112 capsules ribavirin 200 mg and 4 single use injection pens containing peginterferon alfa-2b powder for injection 50 micrograms with diluent *(Pegatron)* **(Private)**

9534T **Ribavirin and Peginterferon Alfa-2b**, Pack containing 112 capsules ribavirin 200 mg and 4 single use injection pens containing peginterferon alfa-2b powder for injection 100 micrograms with diluent *(Pegatron)* **(Public)**

6405D **Ribavirin and Peginterferon Alfa-2b**, Pack containing 112 capsules ribavirin 200 mg and 4 single use injection pens containing peginterferon alfa-2b powder for injection 100 micrograms with diluent *(Pegatron)* **(Private)**

SECTION 100 – BOTULINUM TOXIN PROGRAM

Alterations

Alteration – Item Description

From:

6103F **Botulinum Toxin Type A Purified Neurotoxin Complex**, Lyophilised powder for I.M. injection 100 units *(Botox)*

To:

6103F **Botulinum Toxin Type A Purified Neurotoxin Complex**, Lyophilised powder for injection 100 units *(Botox)*

Alteration – Restriction

6103F **Botulinum Toxin Type A Purified Neurotoxin Complex**, Lyophilised powder for injection 100 units *(Botox)*

SECTION 100 – HUMAN GROWTH HORMONE

Additions

Addition – Item

5818F **Somatropin (recombinant human growth hormone)** , Solution for injection 5 mg (15 i.u.) in 1.5 mL cartridge (with preservative) *(Norditropin FlexPro)*

5819G **Somatropin (recombinant human growth hormone)** , Solution for injection 10 mg (30 i.u.) in 1.5 mL cartridge (with preservative) *(Norditropin FlexPro)*

5820H **Somatropin (recombinant human growth hormone)** , Solution for injection 15 mg (45 i.u.) in 1.5 mL cartridge (with preservative) *(Norditropin FlexPro)*

SECTION 100 – IVF/GIFT TREATMENT

Additions

Addition – Item

5816D **Corifollitropin Alfa**, Solution for injection 100 micrograms in 0.5 mL single dose pre-filled syringe *(Elonva)*

5817E **Corifollitropin Alfa**, Solution for injection 150 micrograms in 0.5 mL single dose pre-filled syringe *(Elonva)*

5815C **Nafarelin**, Nasal spray (pump pack) 200 micrograms (as acetate) per dose, 60 doses *(Synarel)*

SECTION 100 – SPECIAL AUTHORITY ITEMS

Deletions

Deletion of chemotherapy drugs used for the treatment of cancer and administered through infusion or injection

The items listed below have been removed from the Special Authority Program (trastuzumab) - private hospital. The items continue to be pharmaceutical benefits but prescribing and dispensing arrangements for these chemotherapy drugs will operate under a new section 100 program from 1 December 2011. The new program is the "Revised Arrangements for the Efficient Funding of Chemotherapy Drugs initiative (Revised Arrangements)". Chemotherapy drugs used for the treatment of cancer and administered through infusion or injection are covered by these Revised Arrangements.

A separate "EFFICIENT FUNDING OF CHEMOTHERAPY – SECTION 100 ARRANGEMENTS" schedule provides the listing details for these items. The schedule, in PDF format, will be available on the PBS website, www.pbs.gov.au/browse/publications from 1 December 2011.

6497Y **Trastuzumab**, Powder for I.V. infusion 150 mg *(Herceptin)***(Private)**

9691C **Trastuzumab**, Powder for I.V. infusion 60 mg *(Herceptin)***(Private)**

REPATRIATION PHARMACEUTICAL BENEFITS

Alterations

Alteration – Brand Name

From:

4011D *Lamisil, NV* – **Terbinafine**, Tablet 250 mg (as hydrochloride)

To:

4011D *Lamisil (Novartis Pharmaceuticals Australia Pty Limited, NV* – **Terbinafine**, Tablet 250 mg (as hydrochloride)

From:

4473K *Lamisil, NC* – **Terbinafine**, Cream containing terbinafine hydrochloride 10 mg per g (1%), 15 g

To:

4473K *Lamisil (Novartis Consumer Health Australasia Pty Ltd, NC* – **Terbinafine**, Cream containing terbinafine hydrochloride 10 mg per g (1%), 15 g

Alteration – Item Description

From:

4321K **Magnesium Aspartate**, Tablet 500 mg *(Magmin, Mag-Sup)*

To:

4321K **Magnesium**, Tablet 37.4 mg (as aspartate dihydrate) *(Magmin, Mag-Sup)*

Alteration – Manufacturer's Code

		From:	*To:*
4566H	*Condyline Paint, NQ* – **Podophyllotoxin**, Paint 5 mg per mL (0.5%), 3.5 mL (with 30 swabs)	HA	NQ

Advance Notices

Advance Notices – Deletion of Brand

The following brands will be deleted from the Schedule of Pharmaceutical Benefits on 1 March 2012:
Brand discontinued by the manufacturer—

2237R *Concorz, HX* – **Sertraline**, Tablet 100 mg (as hydrochloride)

2236Q *Concorz, HX* – **Sertraline**, Tablet 50 mg (as hydrochloride)

2321E *Medroxyhexal, HX* – **Medroxyprogesterone Acetate**, Tablet 10 mg

1760P *Roxide, HX* – **Roxithromycin**, Tablet 150 mg

5260W *Roxide, HX* – **Roxithromycin**, Tablet 150 mg **(Dental)**

The following brands will be deleted from the Schedule of Pharmaceutical Benefits on 1 May 2012:
Brand discontinued by the manufacturer—

5398D *Naprosyn, RO* – **Naproxen**, Oral suspension 125 mg per 5 mL, 474 mL **(Palliative Care)**

5397C *Naprosyn, RO* – **Naproxen**, Oral suspension 125 mg per 5 mL, 474 mL **(Palliative Care)**

1658G *Naprosyn, RO* – **Naproxen**, Oral suspension 125 mg per 5 mL, 474 mL

GENERAL PHARMACEUTICAL BENEFITS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
	ALENDRONATE SODIUM **Authority required (STREAMLINED)** ***3070*** Treatment as the sole PBS-subsidised anti-resorptive agent for corticosteroid-induced osteoporosis in a patient currently on long-term (at least 3 months), high-dose (at least 7.5 mg per day prednisolone or equivalent) corticosteroid therapy with a Bone Mineral Density (BMD) T-score of -1.5 or less. The duration and dose of corticosteroid therapy together with the date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated. **Authority required (STREAMLINED)** ***3933*** Treatment as the sole PBS-subsidised anti-resorptive agent for osteoporosis in a patient aged 70 years of age or older with a Bone Mineral Density (BMD) T-score of -2.5 or less. The date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated. **Authority required (STREAMLINED)** ***2646*** Treatment as the sole PBS-subsidised anti-resorptive agent for established osteoporosis in patients with fracture due to minimal trauma. The fracture must have been demonstrated radiologically and the year of plain x-ray or CT-scan or MRI scan must be documented in the patient's medical records when treatment is initiated. A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body. **Note** Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, denosumab, disodium etidronate, raloxifene hydrochloride, strontium ranelate and zoledronic acid.								
8511Y *NP*	Tablet equivalent to 70 mg alendronic acid	4	5	..	37.38	34.20	[a]	Adronat	AF
							[a]	Alendrobell 70mg	BF
							[a]	Alendronate-GA	GM
							[a]	Alendronate Sandoz	SZ
							[a]	Alendro Once Weekly	QA
							[a]	APO-Alendronate	TX
							[a]	Chem mart Alendronate 70mg	CH
							[a]	Ossmax 70mg	RA
							[a]	Terry White Chemists Alendronate 70mg	TW
				[B]3.00	40.38	34.20	[a]	Fosamax Once Weekly	MK
	ALENDRONATE SODIUM with COLECALCIFEROL **Authority required (STREAMLINED)** ***3070*** Treatment as the sole PBS-subsidised anti-resorptive agent for corticosteroid-induced osteoporosis in a patient currently on long-term (at least 3 months), high-dose (at least 7.5 mg per day prednisolone or equivalent) corticosteroid therapy with a Bone Mineral Density (BMD) T-score of -1.5 or less. The duration and dose of corticosteroid therapy together with the date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated. **Authority required (STREAMLINED)** ***3933*** Treatment as the sole PBS-subsidised anti-resorptive agent for osteoporosis in a patient aged 70 years of age or older with a Bone Mineral Density (BMD) T-score of -2.5 or less. The date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.								

GENERAL PHARMACEUTICAL BENEFITS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
	Authority required (STREAMLINED)								
	2646								
	Treatment as the sole PBS-subsidised anti-resorptive agent for established osteoporosis in patients with fracture due to minimal trauma. The fracture must have been demonstrated radiologically and the year of plain x-ray or CT-scan or MRI scan must be documented in the patient's medical records when treatment is initiated.								
	A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.								
	Note								
	Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, denosumab, disodium etidronate, raloxifene hydrochloride, strontium ranelate and zoledronic acid.								
	Note								
	Fosamax Plus provides a supplemental intake of vitamin D. The amount of colecalciferol present in Fosamax Plus is not sufficient to use as the sole treatment for correction of vitamin D deficiency.								
9012H *NP*	Tablet equivalent to 70 mg alendronic acid with 70 micrograms colecalciferol	4	5	..	45.16	34.20		Fosamax Plus	MK

ALENDRONATE SODIUM with COLECALCIFEROL

Authority required (STREAMLINED)

3070

Treatment as the sole PBS-subsidised anti-resorptive agent for corticosteroid-induced osteoporosis in a patient currently on long-term (at least 3 months), high-dose (at least 7.5 mg per day prednisolone or equivalent) corticosteroid therapy with a Bone Mineral Density (BMD) T-score of -1.5 or less.

The duration and dose of corticosteroid therapy together with the date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

Authority required (STREAMLINED)

3933

Treatment as the sole PBS-subsidised anti-resorptive agent for osteoporosis in a patient aged 70 years of age or older with a Bone Mineral Density (BMD) T-score of -2.5 or less.

The date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

Authority required (STREAMLINED)

2646

Treatment as the sole PBS-subsidised anti-resorptive agent for established osteoporosis in patients with fracture due to minimal trauma. The fracture must have been demonstrated radiologically and the year of plain x-ray or CT-scan or MRI scan must be documented in the patient's medical records when treatment is initiated.

A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

Note

Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, denosumab, disodium etidronate, raloxifene hydrochloride, strontium ranelate and zoledronic acid.

9183H *NP*	Tablet equivalent to 70 mg alendronic acid with 140 micrograms colecalciferol	4	5	..	45.16	34.20	[a]	Dronalen Plus	GM
				[B]2.50	47.66	34.20	[a]	Fosamax Plus 70 mg/140 mcg	MK

ALENDRONATE SODIUM with COLECALCIFEROL and CALCIUM CARBONATE

Authority required (STREAMLINED)

3070

Treatment as the sole PBS-subsidised anti-resorptive agent for corticosteroid-induced osteoporosis in a patient currently on long-term (at least 3 months), high-dose (at least 7.5 mg per day prednisolone or equivalent) corticosteroid therapy with a Bone Mineral Density (BMD) T-score of -1.5 or less.

The duration and dose of corticosteroid therapy together with the date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

Authority required (STREAMLINED)

3933

Treatment as the sole PBS-subsidised anti-resorptive agent for osteoporosis in a patient aged 70 years of age or older with a Bone Mineral Density (BMD) T-score of -2.5 or less.

The date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

GENERAL PHARMACEUTICAL BENEFITS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
	Authority required (STREAMLINED)								
	2646								
	Treatment as the sole PBS-subsidised anti-resorptive agent for established osteoporosis in patients with fracture due to minimal trauma. The fracture must have been demonstrated radiologically and the year of plain x-ray or CT-scan or MRI scan must be documented in the patient's medical records when treatment is initiated. A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.								
	Note								
	Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, denosumab, disodium etidronate, raloxifene hydrochloride, strontium ranelate and zoledronic acid.								
9351E *NP*	Pack containing 4 tablets containing the equivalent of 70 mg alendronic acid with 140 micrograms colecalciferol and 48 tablets calcium carbonate 1.25 g (equivalent to 500 mg calcium)	‡1	5	..	45.16	34.20	[a]	Dronalen Plus D-Cal	FR
							[a]	Fosamax Plus D-Cal	MK
	ASENAPINE								
	Authority required (STREAMLINED)								
	1589								
	Schizophrenia;								
	3935								
	Treatment, for up to 6 months, of an episode of acute mania or mixed episodes associated with bipolar I disorder;								
	3936								
	Maintenance treatment, as monotherapy, of bipolar I disorder.								
	Note								
	Shared Care Model: For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.								
5140M *NP*	Sublingual wafer 5 mg (as maleate)	60	5	..	157.07	34.20		Saphris	LU
5141N *NP*	Sublingual wafer 10 mg (as maleate)	60	5	..	252.72	34.20		Saphris	LU
	BUDESONIDE with EFORMOTEROL FUMARATE DIHYDRATE								
	Restricted benefit								
	Patients who previously had frequent episodes of asthma while receiving treatment with oral corticosteroids and who have been stabilised on concomitant inhaled eformoterol fumarate dihydrate and budesonide;								
	Patients who previously had frequent episodes of asthma while receiving treatment with optimal doses of inhaled corticosteroids and who have been stabilised on concomitant inhaled eformoterol fumarate dihydrate and budesonide.								
	Note								
	Symbicort 400/12 is not recommended nor PBS-subsidised for use as 'maintenance and reliever' therapy.								
	Restricted benefit								
	Symptomatic treatment of chronic obstructive pulmonary disease (COPD), where the FEV1 is less than 50% predicted normal and there is a history of repeated exacerbations with significant symptoms despite regular beta-2 agonist bronchodilator therapy.								
	Note								
	Budesonide with eformoterol fumarate dihydrate is not indicated for the initiation of bronchodilator therapy in COPD.								
8750M *NP*	Powder for oral inhalation in breath actuated devices 400 micrograms-12 micrograms per dose (60 doses), 2	1	5	..	90.55	34.20		Symbicort Turbuhaler 400/12	AP
	CAPECITABINE								
	Authority required								
	Advanced breast cancer after failure of prior therapy which includes a taxane and an anthracycline;								
	Advanced breast cancer where therapy with a taxane and/or an anthracycline is contraindicated;								
	Advanced breast cancer in combination with docetaxel after failure of prior anthracycline-containing chemotherapy;								
	Treatment of advanced or metastatic colorectal cancer;								

GENERAL PHARMACEUTICAL BENEFITS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	
	Adjuvant treatment of stage III (Dukes C) colon cancer, following complete resection of the primary tumour either as: (a) monotherapy; or (b) in combination with oxaliplatin; Advanced (Stage III or IV) oesophago-gastric cancer, previously untreated, in combination with a cisplatin-based regimen, in a patient with a WHO performance status of 2 or less. **Note** In the adjuvant setting, the recommended treatment duration is 24 weeks. Capecitabine is not PBS-subsidised for the treatment of patients with stage II (Dukes B) colon cancer. Capecitabine is not PBS-subsidised for the adjuvant treatment of patients with rectal cancer.							
8361C	Tablet 150 mg	60	2	..	123.93	34.20	Xeloda	RO
8362D	Tablet 500 mg	120	2	..	695.17	34.20	Xeloda	RO
	DALTEPARIN SODIUM (Low Molecular Weight Heparin Sodium—porcine mucous) **Restricted benefit** Management of symptomatic venous thromboembolism in a patient with a solid tumour(s). **Note** No applications for increased maximum quantities will be authorised.							
8956J *NP*	Injection 7,500 units (anti-Xa) in 0.75 mL single dose pre-filled syringe	30	5	..	*192.30	34.20	Fragmin	PF
8957K *NP*	Injection 10,000 units (anti-Xa) in 1 mL single dose pre-filled syringe	30	5	..	*255.06	34.20	Fragmin	PF
8958L *NP*	Injection 12,500 units (anti-Xa) in 0.5 mL single dose pre-filled syringe	30	5	..	*349.71	34.20	Fragmin	PF
8959M *NP*	Injection 15,000 units (anti-Xa) in 0.6 mL single dose pre-filled syringe	30	5	..	*414.75	34.20	Fragmin	PF
8960N *NP*	Injection 18,000 units (anti-Xa) in 0.72 mL single dose pre-filled syringe	30	5	..	*493.59	34.20	Fragmin	PF
	DENOSUMAB **Authority required** Bone metastases from breast cancer; Bone metastases from hormone-resistant prostate cancer. **Note** **Continuing Therapy Only:** For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.							
5110Y *NP*	Injection 120 mg in 1 mL	1	5	..	531.97	34.20	Xgeva	AN
	INDACATEROL **Restricted benefit** Chronic obstructive pulmonary disease. **Note** Indacaterol is not PBS-subsidised for the treatment of asthma.							
5134F *NP*	Capsule containing powder for oral inhalation 150 micrograms (as maleate) (for use in Breezhaler)	30	5	..	73.44	34.20	Onbrez	NV
5137J *NP*	Capsule containing powder for oral inhalation 300 micrograms (as maleate) (for use in Breezhaler)	30	5	..	73.44	34.20	Onbrez	NV
	LOSARTAN							
5452Y *NP*	Tablet containing losartan potassium 25 mg	30	5	..	13.92	15.01	Cozavan	AF
8203R *NP*	Tablet containing losartan potassium 50 mg	60	5	..	*27.84	28.93	Cozavan	AF

GENERAL PHARMACEUTICAL BENEFITS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	
	MAGNESIUM							
	Authority required							
	Hypomagnesaemia in an Aboriginal or a Torres Strait Islander person;							
	Chronic renal disease in an Aboriginal or a Torres Strait Islander person.							
5146W *NP*	Tablet 37.4 mg (as aspartate dihydrate)	50	5	..	13.70	14.79	Mag-Sup	PP
	OXYCODONE HYDROCHLORIDE with NALOXONE HYDROCHLORIDE							
	Caution							
	The risk of drug dependence is high.							
	Restricted benefit							
	Chronic severe disabling pain not responding to non-narcotic analgesics.							
	Note							
	Authorities for increased maximum quantities and/or repeats will be granted only for: (i) chronic severe disabling pain associated with proven malignant neoplasia; or (ii) chronic severe disabling pain not responding to non-narcotic analgesics where the total duration of narcotic analgesic treatment is less than 12 months; or (iii) first application for treatment beyond 12 months of chronic severe disabling pain not responding to non-narcotic analgesics where the patient's pain management has been reviewed through consultation by the patient with another medical practitioner, and the clinical need for continuing narcotic analgesic treatment has been confirmed. The date of the consultation must be no more than 3 months prior to the application for a PBS authority. The full name of the medical practitioner consulted and the date of consultation are to be provided at the time of application; or (iv) subsequent application for treatment of chronic severe disabling pain not responding to non-narcotic analgesics where a PBS authority prescription for treatment beyond 12 months has previously been issued for this patient.							
	Note **Shared Care Model:** For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.							
8000C *NP*	Tablet 5 mg-2.5 mg (controlled release)	28	..	..	29.37	30.46	Targin 5/2.5mg	MF
8934F *NP*	Tablet 10 mg-5 mg (controlled release)	28	..	..	30.67	31.76	Targin 10/5mg	MF
8935G *NP*	Tablet 20 mg-10 mg (controlled release)	28	..	..	46.85	34.20	Targin 20/10mg	MF
8936H *NP*	Tablet 40 mg-20 mg (controlled release)	28	..	..	73.28	34.20	Targin 40/20mg	MF
	PALIPERIDONE							
	Authority required (STREAMLINED)							
	1589							
	Schizophrenia.							
	Note **Shared Care Model:** For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.							
5100K *NP*	I.M. injection (modified release) 25 mg (as palmitate) in pre-filled syringe	1	5	..	149.63	34.20	Invega Sustenna	JC
5102M *NP*	I.M. injection (modified release) 50 mg (as palmitate) in pre-filled syringe	1	5	..	284.80	34.20	Invega Sustenna	JC
5103N *NP*	I.M. injection (modified release) 75 mg (as palmitate) in pre-filled syringe	1	5	..	363.14	34.20	Invega Sustenna	JC
5107T *NP*	I.M. injection (modified release) 100 mg (as palmitate) in pre-filled syringe	1	5	..	440.69	34.20	Invega Sustenna	JC
5109X *NP*	I.M. injection (modified release) 150 mg (as palmitate) in pre-filled syringe	1	5	..	440.69	34.20	Invega Sustenna	JC
	PRAMIPEXOLE HYDROCHLORIDE							
	Caution							
	Episodes of sudden onset of sleep without warning, during activity, have been reported with this drug.							

GENERAL PHARMACEUTICAL BENEFITS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	
	Note Care should be taken when treating patients with advanced age and significant cognitive impairment with dopamine agonists.							
	Restricted benefit Parkinson disease.							
	Note **Continuing Therapy Only:** For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.							
	Note No applications for increased maximum quantities and/or repeats will be approved for extended release pramipexole formulations.							
5143Q *NP*	Tablet 2.25 mg (extended release)	30	5	..	96.57	34.20	Sifrol ER	BY
5145T *NP*	Tablet 3.75 mg (extended release)	30	5	..	167.61	34.20	Sifrol ER	BY
	ZOLEDRONIC ACID **Authority required (STREAMLINED)** ***3945*** Treatment as the sole PBS-subsidised anti-resorptive agent for corticosteroid-induced osteoporosis in a patient currently on long-term (at least 3 months), high-dose (at least 7.5 mg per day prednisolone or equivalent) corticosteroid therapy with a Bone Mineral Density (BMD) T-score of -1.5 or less. The duration and dose of corticosteroid therapy together with the date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated. Only 1 treatment each year per patient will be PBS-subsidised.							
	Authority required (STREAMLINED) ***3947*** Treatment as the sole PBS-subsidised anti-resorptive agent for osteoporosis in a patient aged 70 years of age or older with a Bone Mineral Density (BMD) T-score of -3.0 or less. The date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated. Only 1 treatment each year per patient will be PBS-subsidised.							
	Authority required (STREAMLINED) ***3946*** Treatment as the sole PBS-subsidised anti-resorptive agent for established osteoporosis in a patient with fracture due to minimal trauma. A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body. In all cases, the fracture must have been demonstrated radiologically and the year of plain x-ray or CT-scan or MRI scan must be documented in the patient's medical records when treatment is initiated. Only 1 treatment each year per patient will be PBS-subsidised.							
	Note Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, denosumab, disodium etidronate, raloxifene hydrochloride, strontium ranelate and zoledronic acid.							
9288W	Solution for I.V. infusion 5 mg (as monohydrate) in 100 mL	1	..	..	589.17	34.20	Aclasta	NV

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Brand Name and Manufacturer	
	DARUNAVIR						
	Authority required						
	Treatment of HIV infection, in addition to optimised background therapy in combination with other antiretroviral agents, and co-administered with 100 mg ritonavir in an antiretroviral experienced patient who, after at least one antiretroviral regimen, has experienced virological failure or clinical failure or genotypic resistance, and who has not demonstrated darunavir resistance associated mutations detected on resistance testing. Virological failure is defined as a viral load greater than 400 copies per mL on two consecutive occasions, while clinical failure is linked to emerging signs and symptoms of progressing HIV infection or treatment-limiting toxicity.						
5823L	Tablet 400 mg (as ethanolate)	120	5	..	*1444.70	Prezista	JC
	RIBAVIRIN and PEGINTERFERON ALFA-2b						
	Caution						
	Treatment with peginterferon alfa has been associated with depression and suicide in some patients. Patients with a history of suicidal ideation or depressive illness should be warned of the risks. Psychiatric status during therapy should be monitored.						
	Caution						
	Ribavirin is a category X drug and must not be given to pregnant women. Pregnancy in female patients or in the partners of male patients must be avoided during treatment and during the 6 months period after cessation of treatment.						
	Authority required						
	Patients naive to interferon based therapies (non-pegylated or pegylated)						
	Treatment, managed by an accredited treatment centre, of chronic hepatitis C in patients weighing at least 27 kg who have compensated liver disease and who have received no prior interferon alfa or peginterferon alfa treatment for hepatitis C and who satisfy all of the following criteria: (1) Documented chronic hepatitis C infection (repeatedly anti-HCV positive and HCV RNA positive); (2) Female patients of child-bearing age are not pregnant, not breast-feeding, and both patient and their partner are using effective forms of contraception (one for each partner). Male patients and their partners are using effective forms of contraception (one for each partner). Female partners of male patients are not pregnant. For patients with genotype 2 or 3 hepatitis C without hepatic cirrhosis or bridging fibrosis, the treatment course is limited to 24 weeks. For hepatitis C patients with genotype 1, 4, 5 or 6 and those genotype 2 or 3 patients with hepatic cirrhosis or bridging fibrosis, the treatment course is limited to 48 weeks. Patients with genotype 1, 4, 5 or 6 who are eligible for 48 weeks of treatment may only continue treatment after the first 12 weeks if the result of an HCV RNA quantitative assay (performed at the same laboratory using the same test) shows that the plasma HCV RNA has become undetectable or the viral load has decreased by at least a 2 log drop. (An HCV RNA assay at week 12 is unnecessary for genotype 2 and 3 patients because of the high likelihood of early viral response by week 12). Patients with genotype 1, 4, 5 or 6 who are viral positive at week 12 but have attained at least a 2 log drop in viral load may only continue treatment after the first 24 weeks of treatment if plasma HCV RNA is not detectable by an HCV RNA qualitative assay at week 24. Similarly, genotype 2 or 3 patients with hepatic cirrhosis or bridging fibrosis may only continue treatment after the first 24 weeks if plasma HCV RNA is not detectable by an HCV RNA qualitative assay at week 24. An HCV RNA qualitative assay at week 24 is unnecessary for those patients with genotype 1, 4, 5 or 6 who became viral negative at week 12.						
	Note						
	Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C: (a) a nurse educator/counsellor for patients; and (b) 24 hour access by patients to medical advice; and (c) an established liver clinic; and (d) facilities for safe liver biopsy.						
	Authority required						
	Patients who have failed one prior attempt at interferon based therapies (non-pegylated or pegylated)						
	Treatment, managed by an accredited treatment centre, of chronic hepatitis C in patients 18 years or older who have compensated liver disease and who have received no more than one prior treatment with interferon alfa or peginterferon alfa for hepatitis C and who satisfy all of the following criteria: (1) Documented chronic hepatitis C infection (repeatedly anti-HCV positive and HCV RNA positive); (2) Female patients of child-bearing age are not pregnant, not breast-feeding, and both patient and their partner are using effective forms of contraception (one for each partner). Male patients and their partners are using effective forms of contraception (one for each partner). Female partners of male patients are not pregnant. The treatment course is limited to 48 weeks. Patients may only continue treatment after the first 12 weeks of treatment if plasma HCV RNA is not detectable by an HCV RNA qualitative assay at week 12.						
	Note						
	Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C: (a) a nurse educator/counsellor for patients; and (b) 24 hour access by patients to medical advice; and (c) an established liver clinic; and (d) facilities for safe liver biopsy.						

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Brand Name and Manufacturer	
6401X	Pack containing 84 capsules ribavirin 200 mg and 4 single use injection pens containing peginterferon alfa-2b powder for injection 80 micrograms with diluent	2	5	..	*2469.14	Pegatron	MK
6400W	Pack containing 112 capsules ribavirin 200 mg and 4 single use injection pens containing peginterferon alfa-2b powder for injection 50 micrograms with diluent	2	5	..	*2166.16	Pegatron	MK
6405D	Pack containing 112 capsules ribavirin 200 mg and 4 single use injection pens containing peginterferon alfa-2b powder for injection 100 micrograms with diluent	2	5	..	*3146.04	Pegatron	MK

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Brand Name and Manufacturer	
	DARUNAVIR						
	Authority required (STREAMLINED)						
	3941						
	Treatment of HIV infection, in addition to optimised background therapy in combination with other antiretroviral agents, and co-administered with 100 mg ritonavir in an antiretroviral experienced patient who, after at least one antiretroviral regimen, has experienced virological failure or clinical failure or genotypic resistance, and who has not demonstrated darunavir resistance associated mutations detected on resistance testing. Virological failure is defined as a viral load greater than 400 copies per mL on two consecutive occasions, while clinical failure is linked to emerging signs and symptoms of progressing HIV infection or treatment-limiting toxicity.						
5821J	Tablet 400 mg (as ethanolate)	120	5	..	*1398.28	Prezista	JC
	RIBAVIRIN and PEGINTERFERON ALFA-2b						
	Caution						
	Treatment with peginterferon alfa has been associated with depression and suicide in some patients. Patients with a history of suicidal ideation or depressive illness should be warned of the risks. Psychiatric status during therapy should be monitored.						
	Caution						
	Ribavirin is a category X drug and must not be given to pregnant women. Pregnancy in female patients or in the partners of male patients must be avoided during treatment and during the 6 months period after cessation of treatment.						
	Authority required (STREAMLINED)						
	3949						
	Patients naive to interferon based therapies (non-pegylated or pegylated)						
	Treatment, managed by an accredited treatment centre, of chronic hepatitis C in patients weighing at least 27 kg who have compensated liver disease and who have received no prior interferon alfa or peginterferon alfa treatment for hepatitis C and who satisfy all of the following criteria: (1) Documented chronic hepatitis C infection (repeatedly anti-HCV positive and HCV RNA positive); (2) Female patients of child-bearing age are not pregnant, not breast-feeding, and both patient and their partner are using effective forms of contraception (one for each partner). Male patients and their partners are using effective forms of contraception (one for each partner). Female partners of male patients are not pregnant. For patients with genotype 2 or 3 hepatitis C without hepatic cirrhosis or bridging fibrosis, the treatment course is limited to 24 weeks. For hepatitis C patients with genotype 1, 4, 5 or 6 and those genotype 2 or 3 patients with hepatic cirrhosis or bridging fibrosis, the treatment course is limited to 48 weeks. Patients with genotype 1, 4, 5 or 6 who are eligible for 48 weeks of treatment may only continue treatment after the first 12 weeks if the result of an HCV RNA quantitative assay (performed at the same laboratory using the same test) shows that the plasma HCV RNA has become undetectable or the viral load has decreased by at least a 2 log drop. (An HCV RNA assay at week 12 is unnecessary for genotype 2 and 3 patients because of the high likelihood of early viral response by week 12). Patients with genotype 1, 4, 5 or 6 who are viral positive at week 12 but have attained at least a 2 log drop in viral load may only continue treatment after the first 24 weeks of treatment if plasma HCV RNA is not detectable by an HCV RNA qualitative assay at week 24. Similarly, genotype 2 or 3 patients with hepatic cirrhosis or bridging fibrosis may only continue treatment after the first 24 weeks if plasma HCV RNA is not detectable by an HCV RNA qualitative assay at week 24. An HCV RNA qualitative assay at week 24 is unnecessary for those patients with genotype 1, 4, 5 or 6 who became viral negative at week 12.						
	Note						
	Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C: (a) a nurse educator/counsellor for patients; and (b) 24 hour access by patients to medical advice; and (c) an established liver clinic; and (d) facilities for safe liver biopsy.						
	Authority required (STREAMLINED)						
	3414						
	Patients who have failed one prior attempt at interferon based therapies (non-pegylated or pegylated)						
	Treatment, managed by an accredited treatment centre, of chronic hepatitis C in patients 18 years or older who have compensated liver disease and who have received no more than one prior treatment with interferon alfa or peginterferon alfa for hepatitis C and who satisfy all of the following criteria: (1) Documented chronic hepatitis C infection (repeatedly anti-HCV positive and HCV RNA positive); (2) Female patients of child-bearing age are not pregnant, not breast-feeding, and both patient and their partner are using effective forms of contraception (one for each partner). Male patients and their partners are using effective forms of contraception (one for each partner). Female partners of male patients are not pregnant. The treatment course is limited to 48 weeks. Patients may only continue treatment after the first 12 weeks of treatment if plasma HCV RNA is not detectable by an HCV RNA qualitative assay at week 12.						
	Note						
	Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C: (a) a nurse educator/counsellor for patients; and						

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Brand Name and Manufacturer	
	(b) 24 hour access by patients to medical advice; and (c) an established liver clinic; and (d) facilities for safe liver biopsy.						
9530N	Pack containing 84 capsules ribavirin 200 mg and 4 single use injection pens containing peginterferon alfa-2b powder for injection 80 micrograms with diluent	2	5	..	*2422.72	Pegatron	MK
9529M	Pack containing 112 capsules ribavirin 200 mg and 4 single use injection pens containing peginterferon alfa-2b powder for injection 50 micrograms with diluent	2	5	..	*2119.74	Pegatron	MK
9534T	Pack containing 112 capsules ribavirin 200 mg and 4 single use injection pens containing peginterferon alfa-2b powder for injection 100 micrograms with diluent	2	5	..	*3099.62	Pegatron	MK

SECTION 100 (BOTULINUM TOXIN PROGRAM)

Code	Name, Restriction, Manner of Administration and Form	Pack Size	Price ex manufacturer $	Brand Name and Manufacturer	
	BOTULINUM TOXIN TYPE A PURIFIED NEUROTOXIN COMPLEX				
	Note				
	Arrangements to prescribe this item should be made by medical practitioners with Medicare Australia, contact telephone number 1800 700 270.				
	Criteria for availability				
	Treatment of blepharospasm associated with dystonia, including benign blepharospasm and VIIth nerve disorders (hemifacial spasm) in patients 12 years and older;				
	Treatment of dynamic equinus foot deformity due to spasticity in an ambulant paediatric cerebral palsy patient aged from 2 to 17 years inclusive;				
	Continuing PBS-subsidised treatment of dynamic equinus foot deformity due to spasticity in an ambulant cerebral palsy patient 18 years of age or older who was commenced on PBS-subsidised treatment with botulinum toxin type A purified neurotoxin complex as a paediatric patient;				
	Treatment of spasmodic torticollis, either as monotherapy or as adjunctive therapy to current standard care.				
	Criteria for availability				
	Treatment of moderate to severe spasticity of the upper limb in a cerebral palsy patient aged from 2 to 17 years inclusive;				
	Continuing PBS-subsidised treatment of moderate to severe spasticity of the upper limb in a cerebral palsy patient 18 years of age or older who was commenced on PBS-subsidised treatment with botulinum toxin type A purified neurotoxin complex as a paediatric patient.				
	Note				
	Contact Medicare Australia before commencing PBS-subsidised treatment in cerebral palsy patients who have been treated for moderate to severe spasticity of the upper limb with non-PBS-subsidised botulinum toxin prior to the age of 18.				
	Criteria for availability				
	Treatment of moderate to severe spasticity [defined as MAS greater than or equal to 3 using modified Ashworth scale] of the upper limb in adults following a stroke, as second line therapy when standard management has failed (e.g. physiotherapy and/or oral spasticity agents) or as an adjunct to physical therapy. Maximum number of treatments to be authorised is 4 (total Botox and Dysport) per upper limb per lifetime. Treatment should not be initiated until 3 months post-stroke in patients who do not have established severe contracture. Treatment should be discontinued if the patient does not respond (decrease of MAS greater than 1 in at least one joint) after two treatments. The date of the stroke must be provided. Contraindications to treatment include established severe contracture and known sensitivity to botulinum toxin.				
	Criteria for availability				
	Treatment of severe primary axillary hyperhidrosis in a patient 12 years or older who has failed or is intolerant to topical aluminium chloride hexahydrate after one to two months of treatment. Maximum number of treatments per year is 3, with no less than 4 months to elapse between treatments.				
	Note				
	The units used to express the potency of botulinum toxin preparations currently available for PBS subsidy are not equivalent.				
6103F	Lyophilised powder for injection 100 units	1	415.50	Botox	AG

SECTION 100 (HUMAN GROWTH HORMONE)

Code	Name, Restriction, Manner of Administration and Form	Pack Size	Price ex manufacturer $	Brand Name and Manufacturer	
	SOMATROPIN (Recombinant human growth hormone)				
	Criteria for availability				
	Short stature in accordance with the 'Guidelines for the Pharmaceutical Benefits Scheme Growth Hormone Program. The program also aims to correct neonatal hypoglycaemia due to biochemical growth hormone deficiency and improve body composition for children with Prader-Willi Syndrome.				
	The Guidelines specify the eligibility criteria for the conditions that are eligible for treatment through the program which include:				
	(i) short stature and slow growth; (ii) short stature associated with biochemical growth hormone deficiency; (iii) growth retardation secondary to intracranial lesion or cranial irradiation; (iv) neonates/infants at risk of hypoglycaemia secondary to growth hormone deficiency; (v) short stature associated with Turner Syndrome; (vi) short stature due to short stature homeobox (SHOX) gene disorders; (vii) short stature associated with chronic renal insufficiency; (viii) biochemical growth hormone deficiency and precocious puberty; (ix) Prader-Willi syndrome.				
	Genotropin branded products are available for the treatment of Prader-Willi Syndrome in accordance with the Guidelines.				
	Note				
	Growth hormone (Somatropin) for adults is currently not subsidised through the Pharmaceutical Benefits Scheme.				
	These guidelines may be obtained from the Department of Health and Ageing's internet site at http://www.health.gov.au/hGH, or from:				
	Growth Hormone Program Access and Systems Branch Department of Health and Ageing GPO Box 9848 CANBERRA ACT 2601 Contact telephone number (02) 6289 7274				
	Note				
	Special Pricing Arrangements apply.				
5818F	Solution for injection 5 mg (15 i.u.) in 1.5 mL cartridge (with preservative)	1	315.50	Norditropin FlexPro	NO
5819G	Solution for injection 10 mg (30 i.u.) in 1.5 mL cartridge (with preservative)	1	631.00	Norditropin FlexPro	NO
5820H	Solution for injection 15 mg (45 i.u.) in 1.5 mL cartridge (with preservative)	1	946.50	Norditropin FlexPro	NO

SECTION 100 (IVF/GIFT TREATMENT)

Code	Name, Restriction, Manner of Administration and Form	Pack Size	Price ex manufacturer $	Brand Name and Manufacturer	
	CORIFOLLITROPIN ALFA				
	Criteria for availability				
	A patient who is receiving treatment as described in items 13200, 13201 or 13202 of the Medicare Benefits Schedule and who: (i) Has an antral follicle count of 20 or less; and (ii) Weighs 90 kg or less; and (iii) Is undergoing a gonadotrophin releasing hormone antagonist cycle.				
	Note				
	Supply of these items is through an accredited IVF/GIFT clinic. For enquiries relating to the IVF/GIFT Program, medical practitioners should contact Medicare Australia on 1800 700 270.				
5816D	Solution for injection 100 micrograms in 0.5 mL single dose pre-filled syringe	1	410.14	Elonva	MK
5817E	Solution for injection 150 micrograms in 0.5 mL single dose pre-filled syringe	1	621.24	Elonva	MK
	NAFARELIN				
	Criteria for availability				
	For the prevention of premature luteinisation and ovulation in patients undergoing controlled ovarian stimulation, followed by oocyte pick-up and assisted reproductive techniques as described in items 13200, 13201, 13202 or 13203 of the Medicare Benefits Schedule.				
	Note				
	Supply of this item is through an accredited IVF/GIFT clinic. For enquiries relating to the IVF/GIFT Program, medical practitioners should contact Medicare Australia on 1800 700 270.				
5815C	Nasal spray (pump pack) 200 micrograms (as acetate) per dose, 60 doses	1	75.33	Synarel	PF