



Australian Government

Department of Health and Ageing

**SCHEDULE OF PHARMACEUTICAL
BENEFITS**

SUMMARY OF CHANGES

EFFECTIVE 1 March 2012

PHARMACEUTICAL BENEFITS

These changes to the Schedule of Pharmaceutical Benefits are effective from 1 March 2012. The Schedule is updated on the first day of each month and is available on the Internet at www.pbs.gov.au.

Fees, Patient Contributions and Safety Net Thresholds

The following fees, patient contributions and safety net thresholds apply as at 1 March 2012 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*	\$4.04
Additional Fees (for safety net prices):	Ready-prepared	\$1.09
	Extemporaneously-prepared	\$1.44
Patient Co-payments:	General	\$35.40
	Concessional	\$5.80
Safety Net Thresholds:	General	\$1363.30
	Concessional	\$348.00
Safety Net Card Issue Fee:		\$8.88

*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

3387G **Linagliptin**, Tablet 5 mg (*Trajenta*)

Addition – Brand

2751T *Auro-Amlodipine 5, DO* – **Amlodipine**, Tablet 5 mg (as besylate)

2752W *Auro-Amlodipine 10, DO* – **Amlodipine**, Tablet 10 mg (as besylate)

1081X *Atenolol-PS, FZ* – **Atenolol**, Tablet 50 mg

8604W *Bisoprolol Pfizer, FZ* – **Bisoprolol Fumarate**, Tablet 2.5 mg

8605X *Bisoprolol Pfizer, FZ* – **Bisoprolol Fumarate**, Tablet 5 mg

8606Y *Bisoprolol Pfizer, FZ* – **Bisoprolol Fumarate**, Tablet 10 mg

2502Q *Calciprox, GN* – **Calcitriol**, Capsule 0.25 microgram

2502Q *Calcitriol-PS, FZ* – **Calcitriol**, Capsule 0.25 microgram

3058Y *Cephalexin-PS, FZ* – **Cephalexin**, Capsule 250 mg

3317N *Cephalexin-PS, FZ* – **Cephalexin**, Capsule 250 mg (**Dental**)

3119E *Cephalexin-PS, FZ* – **Cephalexin**, Capsule 500 mg

3318P *Cephalexin-PS, FZ* – **Cephalexin**, Capsule 500 mg (**Dental**)

1209P *Ciprofloxacin-PS, FZ* – **Ciprofloxacin**, Tablet 500 mg

1210Q *Ciprofloxacin-PS, FZ* – **Ciprofloxacin**, Tablet 750 mg

8220P *Auro-Citalopram 20, DO* – **Citalopram Hydrobromide**, Tablet 20 mg (base)

8703C *Auro-Citalopram 40, DO* – **Citalopram Hydrobromide**, Tablet 40 mg (base)

8700X *Escitalopram GA, GN* – **Escitalopram**, Tablet 10 mg (as oxalate)

8701Y *Escitalopram GA, GN* – **Escitalopram**, Tablet 20 mg (as oxalate)

8506Q *Exemestane Sandoz, SZ* – **Exemestane**, Tablet 25 mg

1434L *Fluoxetine-PS, FZ* – **Fluoxetine**, Capsule 20 mg (as hydrochloride)

2848X *Lamotrigine-PS, FZ* – **Lamotrigine**, Tablet 25 mg

2849Y *Lamotrigine-PS, FZ* – **Lamotrigine**, Tablet 50 mg

2850B *Lamotrigine-PS, FZ* – **Lamotrigine**, Tablet 100 mg

2851C *Lamotrigine-PS, FZ* – **Lamotrigine**, Tablet 200 mg

2456G *Lisinopril-PS, FZ* – **Lisinopril**, Tablet 5 mg

2457H *Lisinopril-PS, FZ* – **Lisinopril**, Tablet 10 mg

2458J *Lisinopril-PS, FZ* – **Lisinopril**, Tablet 20 mg

8331L *Omeprazole-PS, FZ* – **Omeprazole**, Tablet 20 mg

8399C *Pantoprazole-PS, FZ* – **Pantoprazole Sodium Sesquihydrate**, Tablet (enteric coated), equivalent to 20 mg pantoprazole

8007K *Panthron, GN* – **Pantoprazole Sodium Sesquihydrate**, Tablet (enteric coated), equivalent to 40 mg pantoprazole

8007K *Pantoprazole-PS, FZ* – **Pantoprazole Sodium Sesquihydrate**, Tablet (enteric coated), equivalent to 40 mg pantoprazole

8008L *Panthron, GN* – **Pantoprazole Sodium Sesquihydrate**, Tablet (enteric coated), equivalent to 40 mg pantoprazole

8008L *Pantoprazole-PS, FZ* – **Pantoprazole Sodium Sesquihydrate**, Tablet (enteric coated), equivalent to 40 mg pantoprazole

2893G *Prochlorperazine-PS, FZ* – **Prochlorperazine**, Tablet containing prochlorperazine maleate 5 mg

5205Y *Prochlorperazine-PS, FZ* – **Prochlorperazine**, Tablet containing prochlorperazine maleate 5 mg (**Dental**)

8470T	<i>Ramipril-PS, FZ</i> – Ramipril , Capsule 10 mg
1978D	<i>Ranitidine-PS, FZ</i> – Ranitidine Hydrochloride , Tablet 150 mg (base)
8787L	<i>Risperidone Pfizer, FZ</i> – Risperidone , Tablet 0.5 mg
8869T	<i>Risperidone Pfizer, FZ</i> – Risperidone , Tablet 0.5 mg
8789N	<i>Risperidone Pfizer, FZ</i> – Risperidone , Tablet 1 mg
3169T	<i>Risperidone Pfizer, FZ</i> – Risperidone , Tablet 1 mg
3170W	<i>Risperidone Pfizer, FZ</i> – Risperidone , Tablet 2 mg
9079W	<i>Risperidone Pfizer, FZ</i> – Risperidone , Tablet 2 mg
3171X	<i>Risperidone Pfizer, FZ</i> – Risperidone , Tablet 3 mg
3172Y	<i>Risperidone Pfizer, FZ</i> – Risperidone , Tablet 4 mg
2236Q	<i>Auro-Sertraline 50, DO</i> – Sertraline , Tablet 50 mg (as hydrochloride)
8836C	<i>Auro-Sertraline 50, DO</i> – Sertraline , Tablet 50 mg (as hydrochloride)
2237R	<i>Auro-Sertraline 100, DO</i> – Sertraline , Tablet 100 mg (as hydrochloride)
8837D	<i>Auro-Sertraline 100, DO</i> – Sertraline , Tablet 100 mg (as hydrochloride)
2011W	<i>Auro-Simvastatin 10, DO</i> – Simvastatin , Tablet 10 mg
9242K	<i>Auro-Simvastatin 10, DO</i> – Simvastatin , Tablet 10 mg
2012X	<i>Auro-Simvastatin 20, DO</i> – Simvastatin , Tablet 20 mg
9243L	<i>Auro-Simvastatin 20, DO</i> – Simvastatin , Tablet 20 mg
8173E	<i>Auro-Simvastatin 40, DO</i> – Simvastatin , Tablet 40 mg
9244M	<i>Auro-Simvastatin 40, DO</i> – Simvastatin , Tablet 40 mg
8313M	<i>Auro-Simvastatin 80, DO</i> – Simvastatin , Tablet 80 mg
9245N	<i>Auro-Simvastatin 80, DO</i> – Simvastatin , Tablet 80 mg

Addition – Equivalence Indicator

8885P	<i>Imigran FDT, GK</i> – Sumatriptan , Tablet (fast disintegrating) 50 mg (as succinate)
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Addition - Note

5457F	Denosumab , Injection 60 mg in 1 mL pre-filled syringe (<i>Prolia</i>)
8144P	Sumatriptan , Tablet 50 mg (as succinate) (<i>Imigran, Sumatab, Sumagran 50, Pharmacor Sumatriptan 50, APO-Sumatriptan, Chem mart Sumatriptan, Terry White Chemists Sumatriptan, Sumatriptan-GA, Sumatriptan generichealth</i>)
8885P	Sumatriptan , Tablet (fast disintegrating) 50 mg (as succinate) (<i>Imigran FDT</i>)

Deletions

Deletion – Brand

2502Q	<i>Calcitriol-DP, GN</i> – Calcitriol , Capsule 0.25 microgram
1169M	<i>Douglas Cefaclor-CD, GM</i> – Cefaclor , Tablet 375 mg (sustained release)
5045M	<i>Douglas Cefaclor-CD, GM</i> – Cefaclor , Tablet 375 mg (sustained release) (Dental)
1209P	<i>Ascent Pharmaceuticals Limited, GN</i> – Ciprofloxacin , Tablet 500 mg
1210Q	<i>Ascent Pharmaceuticals Limited, GN</i> – Ciprofloxacin , Tablet 750 mg
1370D	<i>Enalapril-DP 5mg, GN</i> – Enalapril , Tablet containing enalapril maleate 5 mg
1368B	<i>Enalapril-DP 10mg, GN</i> – Enalapril , Tablet containing enalapril maleate 10 mg
1369C	<i>Enalapril-DP 20mg, GN</i> – Enalapril , Tablet containing enalapril maleate 20 mg
2487X	<i>Pepcidine M, MK</i> – Famotidine , Tablet 20 mg
2848X	<i>Lamotrigine-DP, GM</i> – Lamotrigine , Tablet 25 mg
2849Y	<i>Lamotrigine-DP, GM</i> – Lamotrigine , Tablet 50 mg

2850B	<i>Lamotrigine-DP, GM</i> – Lamotrigine , Tablet 100 mg
2851C	<i>Lamotrigine-DP, GM</i> – Lamotrigine , Tablet 200 mg
2456G	<i>Liprace, GM</i> – Lisinopril , Tablet 5 mg
2457H	<i>Liprace, GM</i> – Lisinopril , Tablet 10 mg
2458J	<i>Liprace, GM</i> – Lisinopril , Tablet 20 mg
2321E	<i>Medroxyhexal, HX</i> – Medroxyprogesterone Acetate , Tablet 10 mg
2430X	<i>Ascent Pharmaceuticals Limited, GN</i> – Metformin Hydrochloride , Tablet 500 mg
1801T	<i>Ascent Pharmaceuticals Limited, GN</i> – Metformin Hydrochloride , Tablet 850 mg
2350Q	<i>Karicare De-Lact, SB</i> – Milk Powder—lactose Free Formula , Lactose-predigested powder infant formula 900 g
2349P	<i>Karicare De-Lact, SB</i> – Milk Powder—lactose Free Formula , Lactose-predigested powder infant formula 900 g
2242B	<i>Paroxetine-DP, GM</i> – Paroxetine , Tablet 20 mg (as hydrochloride)
2833D	<i>Pravastatin 10, MI</i> – Pravastatin , Tablet containing pravastatin sodium 10 mg
9237E	<i>Pravastatin 10, MI</i> – Pravastatin , Tablet containing pravastatin sodium 10 mg
2834E	<i>Pravastatin 20, MI</i> – Pravastatin , Tablet containing pravastatin sodium 20 mg
9238F	<i>Pravastatin 20, MI</i> – Pravastatin , Tablet containing pravastatin sodium 20 mg
8197K	<i>Pravastatin 40, MI</i> – Pravastatin , Tablet containing pravastatin sodium 40 mg
9239G	<i>Pravastatin 40, MI</i> – Pravastatin , Tablet containing pravastatin sodium 40 mg
8259Q	<i>Pepti-Junior Gold, SB</i> – Protein Hydrolysate Formula with Medium Chain Triglycerides , Compound powder 450 g
9120B	<i>Ramipril-DP, GN</i> – Ramipril , Capsule 1.25 mg
9121C	<i>Ramipril-DP, GN</i> – Ramipril , Capsule 2.5 mg
9122D	<i>Ramipril-DP, GN</i> – Ramipril , Capsule 5 mg
8470T	<i>Ramipril-DP, GN</i> – Ramipril , Capsule 10 mg
1760P	<i>Roxide, HX</i> – Roxithromycin , Tablet 150 mg
5260W	<i>Roxide, HX</i> – Roxithromycin , Tablet 150 mg (Dental)
8016X	<i>Roxide, HX</i> – Roxithromycin , Tablet 300 mg
5261X	<i>Roxide, HX</i> – Roxithromycin , Tablet 300 mg (Dental)
2236Q	<i>Concorz, HX</i> – Sertraline , Tablet 50 mg (as hydrochloride)
2237R	<i>Concorz, HX</i> – Sertraline , Tablet 100 mg (as hydrochloride)

Deletion – Equivalence Indicator

2350Q	<i>Karicare Aptamil De-Lact, NU</i> – Milk Powder—lactose Free Formula , Lactose-predigested powder infant formula 900 g
2349P	<i>Karicare Aptamil De-Lact, NU</i> – Milk Powder—lactose Free Formula , Lactose-predigested powder infant formula 900 g
8259Q	<i>Karicare Aptamil Pepti-Junior Gold, NU</i> – Protein Hydrolysate Formula with Medium Chain Triglycerides , Compound powder 450 g

Alterations

Alteration – Item Description

From:

9329B **Essential Amino Acids Formula**, Powder 200 g, 2 (*Essential Amino Acid Mix*)

To:

9329B **Essential Amino Acids Formula**, Powder 200 g (*Essential Amino Acid Mix*)

This alteration of form results in the increase to the maximum quantity for this item from 3 to 6.

Alteration – Restriction

- 5457F **Denosumab**, Injection 60 mg in 1 mL pre-filled syringe (*Prolia*)
- 3423E **Exenatide**, Injection solution 5 micrograms per dose in pre-filled pen, 60 doses (*Byetta 5 microgram*)
- 3424F **Exenatide**, Injection solution 10 micrograms per dose in pre-filled pen, 60 doses (*Byetta 10 microgram*)

Alteration – Authorised Prescriber

The following items can now be prescribed by Nurse Practitioners.

- 5285E **Amlodipine with Valsartan and Hydrochlorothiazide**, Tablet 5 mg (as besylate)-160 mg-12.5 mg (*Exforge HCT 5/160/12.5*)
- 5286F **Amlodipine with Valsartan and Hydrochlorothiazide**, Tablet 5 mg (as besylate)-160 mg-25 mg (*Exforge HCT 5/160/25*)
- 5287G **Amlodipine with Valsartan and Hydrochlorothiazide**, Tablet 10 mg (as besylate)-160 mg-12.5 mg (*Exforge HCT 10/160/12.5*)
- 5288H **Amlodipine with Valsartan and Hydrochlorothiazide**, Tablet 10 mg (as besylate)-160 mg-25 mg (*Exforge HCT 10/160/25*)
- 5289J **Amlodipine with Valsartan and Hydrochlorothiazide**, Tablet 10 mg (as besylate)-320 mg-25 mg (*Exforge HCT 10/320/25*)

Alteration – Manufacturer's Code

- | | | | |
|-------|--|-------|-----|
| | | From: | To: |
| 8286D | <i>Sandrena, AS</i> – Oestradiol , Transdermal gel 1 mg in 1 g sachet, 28 | MK | AS |

SECTION 100 – HIGHLY SPECIALISED DRUGS PROGRAM

Additions

Addition – Item

- 3392M **Darunavir**, Tablet 600 mg (as ethanolate) (*Prezista*) **(Public)**
- 5000E **Darunavir**, Tablet 600 mg (as ethanolate) (*Prezista*) **(Private)**
- 1123D **Filgrastim**, Injection 300 micrograms in 0.5 mL single use pre-filled syringe (*TevaGrastim*) **(Public)**
- 1082Y **Filgrastim**, Injection 300 micrograms in 0.5 mL single use pre-filled syringe (*TevaGrastim*) **(Private)**
- 1126G **Filgrastim**, Injection 480 micrograms in 0.8 mL single use pre-filled syringe (*TevaGrastim*) **(Public)**
- 1113N **Filgrastim**, Injection 480 micrograms in 0.8 mL single use pre-filled syringe (*TevaGrastim*) **(Private)**

Alterations

Alteration – Restriction

- 5604Y **Abacavir with Lamivudine and Zidovudine**, Tablet containing abacavir 300 mg (as sulfate) with lamivudine 150 mg and zidovudine 300 mg (*Trizivir*) **(Public)**
- 6327B **Abacavir with Lamivudine and Zidovudine**, Tablet containing abacavir 300 mg (as sulfate) with lamivudine 150 mg and zidovudine 300 mg (*Trizivir*) **(Private)**
- 5606C **Adefovir Dipivoxil**, Tablet 10 mg (*Hepsera*) **(Public)**
- 6450L **Adefovir Dipivoxil**, Tablet 10 mg (*Hepsera*) **(Private)**
- 5711N **Entecavir Monohydrate**, Tablet 0.5 mg (*Baraclude*) **(Public)**
- 9602J **Entecavir Monohydrate**, Tablet 0.5 mg (*Baraclude*) **(Private)**
- 5712P **Entecavir Monohydrate**, Tablet 1 mg (*Baraclude*) **(Public)**
- 9603K **Entecavir Monohydrate**, Tablet 1 mg (*Baraclude*) **(Private)**
- 5759D **Interferon Alfa-2a**, Injection 3,000,000 i.u. in 0.5 mL single dose pre-filled syringe (*Roferon-A*) **(Public)**
- 6210W **Interferon Alfa-2a**, Injection 3,000,000 i.u. in 0.5 mL single dose pre-filled syringe (*Roferon-A*) **(Private)**

5760E	Interferon Alfa-2a , Injection 4,500,000 i.u. in 0.5 mL single dose pre-filled syringe (<i>Roferon-A</i>)(Public)
6211X	Interferon Alfa-2a , Injection 4,500,000 i.u. in 0.5 mL single dose pre-filled syringe (<i>Roferon-A</i>)(Private)
5761F	Interferon Alfa-2a , Injection 6,000,000 i.u. in 0.5 mL single dose pre-filled syringe (<i>Roferon-A</i>)(Public)
6212Y	Interferon Alfa-2a , Injection 6,000,000 i.u. in 0.5 mL single dose pre-filled syringe (<i>Roferon-A</i>)(Private)
5762G	Interferon Alfa-2a , Injection 9,000,000 i.u. in 0.5 mL single dose pre-filled syringe (<i>Roferon-A</i>)(Public)
6213B	Interferon Alfa-2a , Injection 9,000,000 i.u. in 0.5 mL single dose pre-filled syringe (<i>Roferon-A</i>)(Private)
5766L	Interferon Alfa-2b , Solution for injection 18,000,000 i.u. in 3 mL single dose vial (<i>Intron A</i>)(Public)
6218G	Interferon Alfa-2b , Solution for injection 18,000,000 i.u. in 3 mL single dose vial (<i>Intron A</i>)(Private)
5767M	Interferon Alfa-2b , Solution for injection 25,000,000 i.u. in 2.5 mL single dose vial (<i>Intron A</i>)(Public)
6219H	Interferon Alfa-2b , Solution for injection 25,000,000 i.u. in 2.5 mL single dose vial (<i>Intron A</i>)(Private)
5768N	Interferon Alfa-2b , Solution for injection 10,000,000 i.u. in 1 mL single dose vial (<i>Intron A</i>)(Public)
6246R	Interferon Alfa-2b , Solution for injection 10,000,000 i.u. in 1 mL single dose vial (<i>Intron A</i>)(Private)
5763H	Interferon Alfa-2b , Solution for injection 18,000,000 i.u. in 1.2 mL multi-dose injection pen (<i>Intron A Redipen</i>)(Public)
6253D	Interferon Alfa-2b , Solution for injection 18,000,000 i.u. in 1.2 mL multi-dose injection pen (<i>Intron A Redipen</i>)(Private)
5764J	Interferon Alfa-2b , Solution for injection 30,000,000 i.u. in 1.2 mL multi-dose injection pen (<i>Intron A Redipen</i>)(Public)
6254E	Interferon Alfa-2b , Solution for injection 30,000,000 i.u. in 1.2 mL multi-dose injection pen (<i>Intron A Redipen</i>)(Private)
5765K	Interferon Alfa-2b , Solution for injection 60,000,000 i.u. in 1.2 mL multi-dose injection pen (<i>Intron A Redipen</i>)(Public)
6255F	Interferon Alfa-2b , Solution for injection 60,000,000 i.u. in 1.2 mL multi-dose injection pen (<i>Intron A Redipen</i>)(Private)
5770Q	Lamivudine , Tablet 100 mg (<i>Zeffix</i>)(Public)
6257H	Lamivudine , Tablet 100 mg (<i>Zeffix</i>)(Private)
5771R	Lamivudine , Oral solution 5 mg per mL, 240 mL (<i>Zeffix</i>)(Public)
6271C	Lamivudine , Oral solution 5 mg per mL, 240 mL (<i>Zeffix</i>)(Private)
9515T	Peginterferon Alfa-2a , Injection 135 micrograms in 0.5 mL single use pre-filled syringe (<i>Pegasys</i>)(Public)
6439X	Peginterferon Alfa-2a , Injection 135 micrograms in 0.5 mL single use pre-filled syringe (<i>Pegasys</i>)(Private)
9516W	Peginterferon Alfa-2a , Injection 180 micrograms in 0.5 mL single use pre-filled syringe (<i>Pegasys</i>)(Public)
6449K	Peginterferon Alfa-2a , Injection 180 micrograms in 0.5 mL single use pre-filled syringe (<i>Pegasys</i>)(Private)
9562G	Telbivudine , Tablet 600 mg (<i>Sebivo</i>)(Public)
9630W	Telbivudine , Tablet 600 mg (<i>Sebivo</i>)(Private)
9563H	Tenofovir , Tablet containing tenofovir disoproxil fumarate 300 mg (<i>Viread</i>)(Public)
6358P	Tenofovir , Tablet containing tenofovir disoproxil fumarate 300 mg (<i>Viread</i>)(Private)
9565K	Tenofovir with Emtricitabine and Efavirenz , Tablet containing tenofovir disoproxil fumarate 300 mg with emtricitabine 200 mg and efavirenz 600 mg (<i>Atripla</i>)(Public)
9650X	Tenofovir with Emtricitabine and Efavirenz , Tablet containing tenofovir disoproxil fumarate 300 mg with emtricitabine 200 mg and efavirenz 600 mg (<i>Atripla</i>)(Private)

Alteration – Manufacturer's Code

		From:	To:
5747L	<i>Foscavir, IX</i> – Foscarnet Sodium , I.V. infusion 24 mg per mL, 250 mL (Public)	AP	IX
6134W	<i>Foscavir, IX</i> – Foscarnet Sodium , I.V. infusion 24 mg per mL, 250 mL (Private)	AP	IX

SECTION 100 – HUMAN GROWTH HORMONE

Additions

Addition – Item

- 5822K **Somatropin (recombinant human growth hormone)**, Solution for injection 6 mg (18 i.u.) in 1.03 mL cartridge (with preservative) (*Saizen*)
- 5824M **Somatropin (recombinant human growth hormone)**, Solution for injection 12 mg (36 i.u.) in 1.5 mL cartridge (with preservative) (*Saizen*)
- 3388H **Somatropin (recombinant human growth hormone)**, Solution for injection 20 mg (60 i.u.) in 2.5 mL cartridge (with preservative) (*Saizen*)

SECTION 100 – IVF/GIFT TREATMENT

Additions

Addition – Item

- 6182J **Choriogonadotropin Alfa**, Solution for injection 250 micrograms in 0.5 mL pre-filled pen (*Ovidrel*)

REPATRIATION PHARMACEUTICAL BENEFITS

Additions

Addition – Item

- 4277D **Alfuzosin Hydrochloride**, Tablet 10 mg (*Xatral SR*)
- 4050E **Bandage—compression**, Bandage, two layer (*Coban*)
- 4286N **Codeine Phosphate with Aspirin**, Tablet 8 mg-300 mg (*Aspalgin 40*)
- 4275B **Codeine Phosphate with Paracetamol**, Tablet 8 mg-500 mg (*Panamax Co. 40*)
- 4252T **Dressing—foam—silver**, Dressings, adhesive, 7.5 cm x 7.5 cm, 10 (*Allevyn Ag Adhesive 66800073*)
- 4255Y **Dressing—foam—silver**, Dressings, adhesive, 10 cm x 10 cm, 10 (*Allevyn Ag Adhesive 66800075*)
- 4258D **Dressing—foam—silver**, Dressings, adhesive, 12.5 cm x 12.5 cm, 10 (*Allevyn Ag Adhesive 66800078*)
- 4259E **Dressing—foam—silver**, Dressings, non-adhesive, 10 cm x 10 cm, 10 (*Allevyn Ag Non-Adhesive 66800086*)
- 4263J **Dressing—foam—silver**, Dressings 7.5 cm x 7.5 cm, 10 (*Allevyn Ag Gentle 66800460*)
- 4266M **Dressing—foam—silver**, Dressings 10 cm x 10 cm, 10 (*Allevyn Ag Gentle 66800461*)
- 4270R **Dressing—foam—silver**, Dressings 12.5 cm x 12.5 cm, 10 (*Allevyn Ag Gentle 66800462*)
- 4196W **Dressing—foam with Silicone—heavy Exudate**, Dressings 10 cm x 10 cm, 10 (*Allevyn Gentle 66800248*)
- 4207K **Dressing—foam with Silicone—heavy Exudate**, Dressings 7.5 cm x 7.5 cm, 10 (*Allevyn Gentle Border 66800269*)
- 4230P **Dressing—foam with Silicone—heavy Exudate**, Dressings 10 cm x 10 cm, 10 (*Allevyn Gentle Border 66800270*)
- 4303L **Finasteride**, Tablet 5 mg (*Finpro*)
- 4306P **Lubricating Gel**, Tube 100 g (*Lubri-Gel*)
- 3400Y **Miconazole Nitrate**, Cream 40 g (2% miconazole) (*Resolve Thrush*)
- 4307Q **Sunscreens**, Cream 75 g (*Sunsense Sensitive SPF 30+*)
- 4290T **Vardenafil**, Tablet 10 mg (*Levitra*)
- 4302K **Vardenafil**, Tablet 20 mg (*Levitra*)

Addition – Brand

4115N	<i>Zedd 500, QA</i> – Azithromycin , Tablet 500 mg (as dihydrate)
4594T	<i>Gabatine 600, QA</i> – Gabapentin , Tablet 600 mg
4595W	<i>Gabatine 800, QA</i> – Gabapentin , Tablet 800 mg
4419N	<i>Fibre Health Orange Smooth Sugar Free, PP</i> – Psyllium Hydrophilic Mucilloid , Oral powder (orange-flavoured, sugar-free) 283 g
4422R	<i>Fibre Health Natural Granular, PP</i> – Psyllium Hydrophilic Mucilloid , Oral powder (non-flavoured) 336 g
4462W	<i>Micolette, AE</i> – Sorbitol with Sodium Citrate and Sodium Lauryl Sulfoacetate , Enemas 3.125 g-450 mg-45 mg in 5 mL, 4

Alterations

Alteration – Item Description

From:

4481W **Tolnaftate**, Spray aerosol, 100 g (*Tinaderm*)

To:

4481W **Tolnaftate**, Spray aerosol 0.7 mg per g (0.07%), 100 g (*Tinaderm*)

Advance Notices

Advance Notices – Deletion of Item

The following items will be deleted from the Schedule of Pharmaceutical Benefits on 1 April 2012:
Item discontinued by the manufacturer—

8443J **Amino Acids—synthetic, Formula**, Compound powder 400 g (*Neocate*)

3066J **Amino Acids—synthetic, Formula**, Compound powder 400 g (*Neocate*)

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

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

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

1658G **Naproxen**, Oral suspension 125 mg per 5 mL, 474 mL (*Naprosyn*)

Advance Notices – Deletion of Brand

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

1434L *Fluohexal, HX* – **Fluoxetine**, Capsule 20 mg (as hydrochloride)

8313M *Simvahexal, HX* – **Simvastatin**, Tablet 80 mg

9245N *Simvahexal, HX* – **Simvastatin**, Tablet 80 mg

SECTION 100 – HIGHLY SPECIALISED DRUGS PROGRAM - Advance Notices**Advance Notices – Deletion of Item**

The following Items will be deleted from the Schedule of Pharmaceutical Benefits on 1 April 2012:
Item discontinued by the manufacturer—

- 5731P **Epoprostenol Sodium**, Powder for I.V. infusion 500 micrograms (base) with diluent (*Flolan*)(**Public**)
- 6477X **Epoprostenol Sodium**, Powder for I.V. infusion 500 micrograms (base) with diluent (*Flolan*)(**Private**)
- 5732Q **Epoprostenol Sodium**, Powder for I.V. infusion 1.5 mg (base) with diluent (*Flolan*)(**Public**)
- 6478Y **Epoprostenol Sodium**, Powder for I.V. infusion 1.5 mg (base) with diluent (*Flolan*)(**Private**)

GENERAL PHARMACEUTICAL BENEFITS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price	Maximum	Brand Name and Manufacturer
					for Max. Qty \$	Recordable Value for Safety Net \$	
	DENOSUMAB						
	<u>Authority required (STREAMLINED)</u>						
	2758						
	Treatment as the sole PBS-subsidised anti-resorptive agent for osteoporosis in a woman aged 70 years 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;						
	3987						
	Treatment as the sole PBS-subsidised anti-resorptive agent for established post-menopausal osteoporosis in a woman 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.						
	<u>Note</u>						
	Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, denosumab, disodium etidronate, raloxifene hydrochloride, strontium ranelate and zoledronic acid.						
	<u>Note</u>						
	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.						
5457F NP	Injection 60 mg in 1 mL pre-filled syringe	1	304.87	35.40	Prolia AN

EXENATIDE

Note

Exenatide is not PBS-subsidised as monotherapy or in combination with an insulin, a thiazolidinedione (glitazone) or a dipeptidyl peptidase 4 inhibitor (gliptin).

Authority required (STREAMLINED)

3540

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 dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone) or a glucagon-like peptide-1 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 qualifying HbA1c must be documented in the patient's medical records at the time treatment with a gliptin, a glitazone or a glucagon-like peptide-1 is initiated. The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone or a glucagon-like peptide-1 is initiated.

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 treatment with a gliptin, a glitazone or a glucagon-like peptide-1, must be documented in the patient's medical records.

Authority required (STREAMLINED)

3542

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 dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone) or a glucagon-like peptide-1 despite treatment with maximally tolerated doses of metformin and a sulfonylurea.

The date and level of the qualifying HbA1c must be documented in the patient's medical records at the time treatment with a gliptin, a glitazone or a glucagon-like peptide-1 is initiated. The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone or a glucagon-like peptide-1 is initiated.

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 treatment with a gliptin, a glitazone or a glucagon-like peptide-1, must be documented in the patient's medical records.

Note

Special Pricing Arrangements apply.

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
3423E NP	Injection solution 5 micrograms per dose in pre-filled pen, 60 doses	1	5	..	176.39	35.40	Byetta 5 microgram
3424F NP	Injection solution 10 micrograms per dose in pre-filled pen, 60 doses	1	5	..	176.39	35.40	Byetta 10 microgram

LINAGLIPTIN

Note

Linagliptin is not PBS-subsidised for use in combination with metformin and a sulfonylurea (triple oral therapy), as monotherapy or in combination with a thiazolidinedione (glitazone) or a glucagon-like peptide-1.

Authority required (STREAMLINED)

3540

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 dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone) or a glucagon-like peptide-1 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 qualifying HbA1c must be documented in the patient's medical records at the time treatment with a gliptin, a glitazone or a glucagon-like peptide-1 is initiated. The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone or a glucagon-like peptide-1 is initiated.

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 treatment with a gliptin, a glitazone or a glucagon-like peptide-1, must be documented in the patient's medical records.

3387G NP	Tablet 5 mg	30	5	..	96.62	35.40	Trajenta	BY
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SUMATRIPTAN

Caution

Sumatriptan is contraindicated in patients with known or suspected coronary artery disease. The drug should not be used within 24 hours of ergotamine or dihydroergotamine use.

Authority required (STREAMLINED)

3233

Migraine attack in a patient where attacks in the past have usually failed to respond to analgesics.

Note

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

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

Pharmaceutical benefits that have the form sumatriptan tablet 50 mg (as succinate) and pharmaceutical benefits that have the form sumatriptan tablet (fast disintegrating) 50 mg (as succinate) are equivalent for the purposes of substitution.

8144P NP	Tablet 50 mg (as succinate)	4	5	..	24.38	25.47	^a Pharmacor Sumatriptan 50	CR
							^a Sumatriptan-GA	GM
							^a Sumatriptan generichealth	GQ
				..	*24.38	25.47	^a APO Sumatriptan	TX
							^a Chem mart Sumatriptan	CH
							^a Sumagran 50	QA
							^a Sumatab	AF
							^a Terry White Chemists Sumatriptan	TW
				81.84	*26.22	25.47	^a Imigran	GK
8885P NP	Tablet (fast disintegrating) 50 mg (as succinate)	4	5	..	*24.38	25.47	^a Imigran FDT	GK

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
ABACAVIR with LAMIVUDINE and ZIDOVUDINE						
<u>Authority required (STREAMLINED)</u>						
3981 Initial treatment of HIV infection in a patient over 12 years of age, weighing 40 kg or more, with a CD4 count of less than 500 per cubic millimetre or symptomatic HIV disease;						
3982 Continuing treatment of HIV infection where the patient over 12 years of age, weighing 40 kg or more, has previously received PBS-subsidised therapy for HIV infection.						
5604Y	Tablet containing abacavir 300 mg (as sulfate) with lamivudine 150 mg and zidovudine 300 mg	120	5	..	*1704.00	Trizivir VI
ADEFOVIR DIPIVOXIL						
<u>Authority required (STREAMLINED)</u>						
3973 Chronic hepatitis B in a patient without cirrhosis who has failed antihepadnaviral therapy and who satisfies all of the following criteria: (a) Repeatedly elevated serum ALT levels while on concurrent antihepadnaviral therapy of greater than or equal to 6 months duration in conjunction with documented chronic hepatitis B infection; or (b) Repeatedly elevated HBV DNA levels one log greater than the nadir value or failure to achieve a 1 log reduction in HBV DNA within 3 months, whilst on previous antihepadnaviral therapy except in patients with evidence of poor compliance;						
3974 Chronic hepatitis B in a patient with cirrhosis who has failed antihepadnaviral therapy and who has detectable HBV DNA.						
Persons with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy.						
Note Patients may receive treatment in combination with lamivudine but not with other PBS-subsidised antihepadnaviral therapy.						
5606C	Tablet 10 mg	60	5	..	*1250.00	Hepsera GI
DARUNAVIR						
<u>Authority required (STREAMLINED)</u>						
3595 Treatment of HIV infection, in addition to optimised background therapy in combination with other antiretroviral agents, and co-administered with 100 mg ritonavir twice daily in an antiretroviral experienced patient who, after at least one antiretroviral regimen, has experienced virological failure or clinical failure or genotypic resistance. 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.						
3392M	Tablet 600 mg (as ethanolate)	120	5	..	*2097.42	Prezista JC
ENTECAVIR MONOHYDRATE						
<u>Authority required (STREAMLINED)</u>						
3961 Chronic hepatitis B in a patient without cirrhosis who satisfies all of the following criteria: (1) Elevated HBV DNA levels - greater than 20,000 IU/mL (100,000 copies/mL) if HBeAg positive, or greater than 2,000 IU/mL (10,000 copies/mL) if HBeAg negative - in conjunction with documented chronic hepatitis B infection; (2) Evidence of chronic liver injury as determined by: (a) Confirmed elevated serum ALT; or (b) Liver biopsy;						
3962 Chronic hepatitis B in a patient with cirrhosis who has detectable HBV DNA.						
Persons with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy.						
Note PBS-subsidised entecavir monohydrate must be used as monotherapy.						
5711N	Tablet 0.5 mg	60	5	..	*768.60	Baraclude BQ

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
ENTECAVIR MONOHYDRATE						
<u>Authority required (STREAMLINED)</u>						
3964						
Chronic hepatitis B in a patient without cirrhosis who has failed lamivudine and who satisfies all of the following criteria:						
(a) Repeatedly elevated serum ALT levels while on concurrent antihepadnaviral therapy of greater than or equal to 6 months duration in conjunction with documented chronic hepatitis B infection; or						
(b) Repeatedly elevated HBV DNA levels one log greater than the nadir value or failure to achieve a 1 log reduction in HBV DNA within 3 months, whilst on previous antihepadnaviral therapy except in patients with evidence of poor compliance;						
3966						
Chronic hepatitis B in a patient with cirrhosis who has failed lamivudine and who has detectable HBV DNA.						
Persons with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy.						
<u>Note</u>						
PBS-subsidised entecavir monohydrate must be used as monotherapy.						
5712P	Tablet 1 mg	60	5	..	*1250.00	Baraclude BQ

FILGRASTIM

Authority required (STREAMLINED)

3357

For use in a patient undergoing induction and consolidation therapy for acute myeloid leukaemia;

3358

Mobilisation of peripheral blood progenitor cells to facilitate harvest of such cells for autologous transplantation into a patient with a non-myeloid malignancy who has had myeloablative or myelosuppressive therapy;

3359

Mobilisation of peripheral blood progenitor cells, in a normal volunteer, for use in allogeneic transplantation;

3360

A patient receiving marrow-ablative chemotherapy and subsequent bone marrow transplantation;

3361

A patient with a non-myeloid malignancy receiving marrow-ablative chemotherapy and subsequent autologous peripheral blood progenitor cell transplantation;

3362

A patient with breast cancer receiving standard dose adjuvant chemotherapy who has had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned;

3363

A patient receiving chemotherapy for B-cell chronic lymphocytic leukaemia with fludarabine and cyclophosphamide who has had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned;

3364

A patient receiving first-line chemotherapy for Hodgkin disease who has had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned;

3365

A patient receiving chemotherapy for myeloma who has had a prior episode of febrile neutropenia, and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned;

3366

A patient with severe congenital neutropenia (absolute neutrophil count of less than 100 million cells per litre measured on 3 occasions, with readings at least 2 weeks apart, and in whom a bone marrow examination has shown evidence of maturational arrest of the neutrophil lineage);

3367

A patient with severe chronic neutropenia (absolute neutrophil count of less than 1,000 million cells per litre measured on 3 occasions, with readings at least 2 weeks apart, or evidence of neutrophil dysfunction, and, either having experienced a life-threatening infectious episode requiring hospitalisation and treatment with intravenous antibiotics in the previous 12 months, or having recurrent clinically significant infections (a minimum of 3 in the previous 12 months));

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	
3368	A patient with chronic cyclic neutropenia (absolute neutrophil count of less than 500 million cells per litre lasting for 3 days per cycle, measured over 3 separate cycles, and, either having experienced a life-threatening infectious episode requiring hospitalisation and treatment with intravenous antibiotics, or having recurrent clinically significant infections (a minimum of 3 in the previous 12 months));						
3369	A patient with inoperable Stage III, IVa or IVb squamous cell carcinoma of the oral cavity, larynx, oropharynx or hypopharynx receiving neoadjuvant treatment with docetaxel in combination with cisplatin and fluorouracil who has had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned.						
	Authority required (STREAMLINED)						
3370	A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in acute lymphoblastic leukaemia;						
3371	A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in breast cancer (adjuvant chemotherapy with docetaxel in combination with an anthracycline and cyclophosphamide);						
3372	A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in germ cell tumours;						
3373	A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in infants and children with CNS tumours;						
3374	A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in neuroblastoma;						
3375	A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in non-Hodgkin lymphoma (aggressive grades; or low grade receiving an anthracycline-containing regimen);						
3376	A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in relapsed Hodgkin disease;						
3377	A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in sarcoma;						
3834	A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in Hodgkin disease (first-line chemotherapy with escalated BEACOPP).						
1123D	Injection 300 micrograms in 0.5 mL single use pre-filled syringe	20	11	..	*2515.54	TevaGrastim	AS
1126G	Injection 480 micrograms in 0.8 mL single use pre-filled syringe	20	11	..	*4032.58	TevaGrastim	AS

INTERFERON ALFA-2a

Caution

Treatment with interferon 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.

Authority required (STREAMLINED)

3382

Use in the treatment of Philadelphia chromosome positive myelogenous leukaemia in the chronic phase;

3961

Chronic hepatitis B in a patient without cirrhosis who satisfies all of the following criteria:

- (1) Elevated HBV DNA levels - greater than 20,000 IU/mL (100,000 copies/mL) if HBeAg positive, or greater than 2,000 IU/mL (10,000 copies/mL) if HBeAg negative - in conjunction with documented chronic hepatitis B infection;
- (2) Evidence of chronic liver injury as determined by:
 - (a) Confirmed elevated serum ALT; or
 - (b) Liver biopsy;

3962

Chronic hepatitis B in a patient with cirrhosis who has detectable HBV DNA.

Persons with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy.

5759D	Injection 3,000,000 i.u. in 0.5 mL single dose pre-filled syringe	30	5	..	*894.00	Roferon-A	RO
5760E	Injection 4,500,000 i.u. in 0.5 mL single dose pre-filled syringe	30	5	..	*1341.00	Roferon-A	RO
5761F	Injection 6,000,000 i.u. in 0.5 mL single dose pre-filled syringe	30	5	..	*1787.40	Roferon-A	RO

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	
5762G	Injection 9,000,000 i.u. in 0.5 mL single dose pre-filled syringe	30	5	..	*2681.40	Roferon-A	RO

INTERFERON ALFA-2b

Caution

Treatment with interferon 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.

Authority required (STREAMLINED)

3384

Adjunctive therapy of malignant melanoma following surgery in patients with nodal involvement;

3382

Use in the treatment of Philadelphia chromosome positive myelogenous leukaemia in the chronic phase;

3961

Chronic hepatitis B in a patient without cirrhosis who satisfies all of the following criteria:

(1) Elevated HBV DNA levels - greater than 20,000 IU/mL (100,000 copies/mL) if HBeAg positive, or greater than 2,000 IU/mL (10,000 copies/mL) if HBeAg negative - in conjunction with documented chronic hepatitis B infection;

(2) Evidence of chronic liver injury as determined by:

- (a) Confirmed elevated serum ALT; or
- (b) Liver biopsy;

3962

Chronic hepatitis B in a patient with cirrhosis who has detectable HBV DNA.

Persons with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy.

5766L	Solution for injection 18,000,000 i.u. in 3 mL single dose vial	15	5	..	*2681.10	Intron A	MK
5767M	Solution for injection 25,000,000 i.u. in 2.5 mL single dose vial	15	5	..	*3723.75	Intron A	MK
5768N	Solution for injection 10,000,000 i.u. in 1 mL single dose vial	15	5	..	*1489.50	Intron A	MK
5763H	Solution for injection 18,000,000 i.u. in 1.2 mL multi-dose injection pen	2	5	..	*357.48	Intron A Redipen	MK
5764J	Solution for injection 30,000,000 i.u. in 1.2 mL multi-dose injection pen	2	5	..	*595.80	Intron A Redipen	MK
5765K	Solution for injection 60,000,000 i.u. in 1.2 mL multi-dose injection pen	2	5	..	*1191.60	Intron A Redipen	MK

LAMIVUDINE

Authority required (STREAMLINED)

3961

Chronic hepatitis B in a patient without cirrhosis who satisfies all of the following criteria:

(1) Elevated HBV DNA levels - greater than 20,000 IU/mL (100,000 copies/mL) if HBeAg positive, or greater than 2,000 IU/mL (10,000 copies/mL) if HBeAg negative - in conjunction with documented chronic hepatitis B infection;

(2) Evidence of chronic liver injury as determined by:

- (a) Confirmed elevated serum ALT; or
- (b) Liver biopsy;

3962

Chronic hepatitis B in a patient with cirrhosis who has detectable HBV DNA.

Persons with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy.

5770Q	Tablet 100 mg	56	5	..	*298.72	Zeffix	GK
5771R	Oral solution 5 mg per mL, 240 mL	5	5	..	*349.55	Zeffix	GK

PEGINTERFERON ALFA-2a

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.

Authority required (STREAMLINED)

3977

Treatment, as sole PBS-subsidised therapy, in a patient with chronic hepatitis B without cirrhosis who satisfies all of the following criteria:

(1) Elevated HBV DNA levels - greater than 20,000 IU/mL (100,000 copies/mL) if HBeAg positive, or greater than 2,000 IU/mL (10,000 copies/mL) if HBeAg negative - in conjunction with documented chronic hepatitis B infection;

(2) Evidence of chronic liver injury as determined by:

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
	(a) Confirmed elevated serum ALT; or (b) Liver biopsy; (3) Has received no prior peginterferon alfa therapy for the treatment of hepatitis B;					
	3978 Treatment, as sole PBS-subsidised therapy, in a patient with chronic hepatitis B with cirrhosis who has detectable HBV DNA. Persons with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy. Treatment is limited to 1 course of treatment for a duration of up to 48 weeks;					
	3412 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 prior interferon alfa or peginterferon alfa treatment for hepatitis C and have a contraindication to ribavirin, 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 are using an effective form of contraception. The treatment course is limited to up to 48 weeks. Patients 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.					
	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.					
9515T	Injection 135 micrograms in 0.5 mL single use pre-filled syringe	8	5	..	*2331.80	Pegasys RO
9516W	Injection 180 micrograms in 0.5 mL single use pre-filled syringe	8	5	..	*2700.46	Pegasys RO

TELBIVUDINE

Authority required (STREAMLINED)

3969

Treatment, as sole PBS-subsidised therapy, in a patient with chronic hepatitis B without cirrhosis who is nucleoside analogue naive and satisfies all of the following criteria:

- (1) Elevated HBV DNA levels - greater than 20,000 IU/mL (100,000 copies/mL) if HBeAg positive, or greater than 2,000 IU/mL (10,000 copies/mL) if HBeAg negative - in conjunction with documented hepatitis B infection;
- (2) Evidence of chronic liver injury as determined by:

- (a) Confirmed elevated serum ALT; or
- (b) Liver biopsy;

3970

Treatment, as sole PBS-subsidised therapy, in a patient with chronic hepatitis B with cirrhosis who is nucleoside analogue naive and who has detectable HBV DNA.

Persons with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy.

9562G	Tablet 600 mg	56	5	..	*501.76	Sebivo NV
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TENOFOVIR

Authority required (STREAMLINED)

3588

Initial treatment of HIV infection in combination with other antiretroviral agents in a patient with a CD4 count of less than 500 per cubic millimetre or symptomatic HIV disease;

3589

Continuing treatment of HIV infection in combination with other antiretroviral agents where the patient has previously received PBS-subsidised therapy for HIV infection.

Authority required (STREAMLINED)

3969

Treatment, as sole PBS-subsidised therapy, in a patient with chronic hepatitis B without cirrhosis who is nucleoside analogue naive and satisfies all of the following criteria:

- (1) Elevated HBV DNA levels - greater than 20,000 IU/mL (100,000 copies/mL) if HBeAg positive, or greater than 2,000 IU/mL (10,000 copies/mL) if HBeAg negative - in conjunction with documented hepatitis B infection;
- (2) Evidence of chronic liver injury as determined by:

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	
	(a) Confirmed elevated serum ALT; or (b) Liver biopsy;						
	3970 Treatment, as sole PBS-subsidised therapy, in a patient with chronic hepatitis B with cirrhosis who is nucleoside analogue naive and who has detectable HBV DNA.						
	Persons with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy.						
	Note Patients may receive treatment in combination with lamivudine but not with other PBS-subsidised antihepadnaviral therapy.						
	Authority required (STREAMLINED) 3973 Chronic hepatitis B in a patient without cirrhosis who has failed antihepadnaviral therapy and who satisfies all of the following criteria: (a) Repeatedly elevated serum ALT levels while on concurrent antihepadnaviral therapy of greater than or equal to 6 months duration in conjunction with documented chronic hepatitis B infection; or (b) Repeatedly elevated HBV DNA levels one log greater than the nadir value or failure to achieve a 1 log reduction in HBV DNA within 3 months, whilst on previous antihepadnaviral therapy except in patients with evidence of poor compliance;						
	3974 Chronic hepatitis B in a patient with cirrhosis who has failed antihepadnaviral therapy and who has detectable HBV DNA.						
	Persons with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy.						
	Note Patients may receive treatment in combination with lamivudine but not with other PBS-subsidised antihepadnaviral therapy.						
9563H	Tablet containing tenofovir disoproxil fumarate 300 mg	60	5	..	*966.20	Viread	GI
	TENOFOVIR with EMTRICITABINE and EFAVIRENZ Authority required (STREAMLINED) 3985 Initial treatment of HIV infection in a patient with a CD4 count of less than 500 per cubic millimetre or symptomatic HIV disease;						
	3986 Continuing treatment of HIV infection where the patient has previously received PBS-subsidised therapy for HIV infection.						
9565K	Tablet containing tenofovir disoproxil fumarate 300 mg with emtricitabine 200 mg and efavirenz 600 mg	60	5	..	*2435.48	Atripla	GI

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
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ABACAVIR with LAMIVUDINE and ZIDOVUDINE

Authority required

Initial treatment of HIV infection in a patient over 12 years of age, weighing 40 kg or more, with a CD4 count of less than 500 per cubic millimetre or symptomatic HIV disease;

Continuing treatment of HIV infection where the patient over 12 years of age, weighing 40 kg or more, has previously received PBS-subsidised therapy for HIV infection.

6327B	Tablet containing abacavir 300 mg (as sulfate) with lamivudine 150 mg and zidovudine 300 mg	120	5	..	*1750.42	Trizivir	VI
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ADEFOVIR DIPIVOXIL

Authority required

Chronic hepatitis B in a patient without cirrhosis who has failed antihepadnaviral therapy and who satisfies all of the following criteria:

(a) Repeatedly elevated serum ALT levels while on concurrent antihepadnaviral therapy of greater than or equal to 6 months duration in conjunction with documented chronic hepatitis B infection; or

(b) Repeatedly elevated HBV DNA levels one log greater than the nadir value or failure to achieve a 1 log reduction in HBV DNA within 3 months, whilst on previous antihepadnaviral therapy except in patients with evidence of poor compliance;

Chronic hepatitis B in a patient with cirrhosis who has failed antihepadnaviral therapy and who has detectable HBV DNA.

Persons with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy.

Note

Patients may receive treatment in combination with lamivudine but not with other PBS-subsidised antihepadnaviral therapy.

6450L	Tablet 10 mg	60	5	..	*1296.42	Hepsera	GI
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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 twice daily in an antiretroviral experienced patient who, after at least one antiretroviral regimen, has experienced virological failure or clinical failure or genotypic resistance.

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.

5000E	Tablet 600 mg (as ethanolate)	120	5	..	*2143.84	Prezista	JC
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ENTECAVIR MONOHYDRATE

Authority required

Chronic hepatitis B in a patient without cirrhosis who satisfies all of the following criteria:

(1) Elevated HBV DNA levels - greater than 20,000 IU/mL (100,000 copies/mL) if HBeAg positive, or greater than 2,000 IU/mL (10,000 copies/mL) if HBeAg negative - in conjunction with documented chronic hepatitis B infection;

(2) Evidence of chronic liver injury as determined by:

(a) Confirmed elevated serum ALT; or

(b) Liver biopsy;

Chronic hepatitis B in a patient with cirrhosis who has detectable HBV DNA.

Persons with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy.

Note

PBS-subsidised entecavir monohydrate must be used as monotherapy.

9602J	Tablet 0.5 mg	60	5	..	*805.76	Baraclude	BQ
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ENTECAVIR MONOHYDRATE

Authority required

Chronic hepatitis B in a patient without cirrhosis who has failed lamivudine and who satisfies all of the following criteria:

(a) Repeatedly elevated serum ALT levels while on concurrent antihepadnaviral therapy of greater than or equal to 6 months duration in conjunction with documented chronic hepatitis B infection; or

(b) Repeatedly elevated HBV DNA levels one log greater than the nadir value or failure to achieve a 1 log reduction in HBV DNA within 3 months, whilst on previous antihepadnaviral therapy except in patients with evidence of poor compliance;

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium \$	Dispensed		Brand Name and Manufacturer
					Price for Max. Qty	\$	
9603K	Tablet 1 mg	60	5	..	*1296.42		Baraclude BQ

Chronic hepatitis B in a patient with cirrhosis who has failed lamivudine and who has detectable HBV DNA.

Persons with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy.

Note

PBS-substituted entecavir monohydrate must be used as monotherapy.

FILGRASTIM

Authority required

For use in a patient undergoing induction and consolidation therapy for acute myeloid leukaemia;

Mobilisation of peripheral blood progenitor cells to facilitate harvest of such cells for autologous transplantation into a patient with a non-myeloid malignancy who has had myeloablative or myelosuppressive therapy;

Mobilisation of peripheral blood progenitor cells, in a normal volunteer, for use in allogeneic transplantation;

A patient receiving marrow-ablative chemotherapy and subsequent bone marrow transplantation;

A patient with a non-myeloid malignancy receiving marrow-ablative chemotherapy and subsequent autologous peripheral blood progenitor cell transplantation;

A patient with breast cancer receiving standard dose adjuvant chemotherapy who has had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned;

A patient receiving chemotherapy for B-cell chronic lymphocytic leukaemia with fludarabine and cyclophosphamide who has had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned;

A patient receiving first-line chemotherapy for Hodgkin disease who has had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned;

A patient receiving chemotherapy for myeloma who has had a prior episode of febrile neutropenia, and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned;

A patient with severe congenital neutropenia (absolute neutrophil count of less than 100 million cells per litre measured on 3 occasions, with readings at least 2 weeks apart, and in whom a bone marrow examination has shown evidence of maturational arrest of the neutrophil lineage);

A patient with severe chronic neutropenia (absolute neutrophil count of less than 1,000 million cells per litre measured on 3 occasions, with readings at least 2 weeks apart, or evidence of neutrophil dysfunction, and, either having experienced a life-threatening infectious episode requiring hospitalisation and treatment with intravenous antibiotics in the previous 12 months, or having recurrent clinically significant infections (a minimum of 3 in the previous 12 months));

A patient with chronic cyclic neutropenia (absolute neutrophil count of less than 500 million cells per litre lasting for 3 days per cycle, measured over 3 separate cycles, and, either having experienced a life-threatening infectious episode requiring hospitalisation and treatment with intravenous antibiotics, or having recurrent clinically significant infections (a minimum of 3 in the previous 12 months));

A patient with inoperable Stage III, IVa or IVb squamous cell carcinoma of the oral cavity, larynx, oropharynx or hypopharynx receiving neoadjuvant treatment with docetaxel in combination with cisplatin and fluorouracil who has had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned.

Authority required

A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in acute lymphoblastic leukaemia;

A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in breast cancer (adjuvant chemotherapy with docetaxel in combination with an anthracycline and cyclophosphamide);

A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in germ cell tumours;

A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in infants and children with CNS tumours;

A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in neuroblastoma;

A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in non-Hodgkin lymphoma (aggressive grades; or low grade receiving an anthracycline-containing regimen);

A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in relapsed Hodgkin disease;

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	
A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in sarcoma;							
A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in Hodgkin disease (first-line chemotherapy with escalated BEACOPP).							
1082Y	Injection 300 micrograms in 0.5 mL single use pre-filled syringe	20	11	..	*2561.96	TevaGrastim	AS
1113N	Injection 480 micrograms in 0.8 mL single use pre-filled syringe	20	11	..	*4079.00	TevaGrastim	AS

INTERFERON ALFA-2a

Caution

Treatment with interferon 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.

Authority required

Use in the treatment of Philadelphia chromosome positive myelogenous leukaemia in the chronic phase;

Chronic hepatitis B in a patient without cirrhosis who satisfies all of the following criteria:

(1) Elevated HBV DNA levels - greater than 20,000 IU/mL (100,000 copies/mL) if HBeAg positive, or greater than 2,000 IU/mL (10,000 copies/mL) if HBeAg negative - in conjunction with documented chronic hepatitis B infection;

(2) Evidence of chronic liver injury as determined by:

- (a) Confirmed elevated serum ALT; or
- (b) Liver biopsy;

Chronic hepatitis B in a patient with cirrhosis who has detectable HBV DNA.

Persons with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy.

6210W	Injection 3,000,000 i.u. in 0.5 mL single dose pre-filled syringe	30	5	..	*936.12	Roferon-A	RO
6211X	Injection 4,500,000 i.u. in 0.5 mL single dose pre-filled syringe	30	5	..	*1387.32	Roferon-A	RO
6212Y	Injection 6,000,000 i.u. in 0.5 mL single dose pre-filled syringe	30	5	..	*1833.72	Roferon-A	RO
6213B	Injection 9,000,000 i.u. in 0.5 mL single dose pre-filled syringe	30	5	..	*2727.72	Roferon-A	RO

INTERFERON ALFA-2b

Caution

Treatment with interferon 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.

Authority required

Adjunctive therapy of malignant melanoma following surgery in patients with nodal involvement;

Use in the treatment of Philadelphia chromosome positive myelogenous leukaemia in the chronic phase;

Chronic hepatitis B in a patient without cirrhosis who satisfies all of the following criteria:

(1) Elevated HBV DNA levels - greater than 20,000 IU/mL (100,000 copies/mL) if HBeAg positive, or greater than 2,000 IU/mL (10,000 copies/mL) if HBeAg negative - in conjunction with documented chronic hepatitis B infection;

(2) Evidence of chronic liver injury as determined by:

- (a) Confirmed elevated serum ALT; or
- (b) Liver biopsy;

Chronic hepatitis B in a patient with cirrhosis who has detectable HBV DNA.

Persons with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy.

6218G	Solution for injection 18,000,000 i.u. in 3 mL single dose vial	15	5	..	*2727.57	Intron A	MK
6219H	Solution for injection 25,000,000 i.u. in 2.5 mL single dose vial	15	5	..	*3770.22	Intron A	MK
6246R	Solution for injection 10,000,000 i.u. in 1 mL single dose vial	15	5	..	*1535.91	Intron A	MK
6253D	Solution for injection 18,000,000 i.u. in 1.2 mL multi-dose injection pen	2	5	..	*378.20	Intron A Redipen	MK
6254E	Solution for injection 30,000,000 i.u. in 1.2 mL multi-dose injection pen	2	5	..	*626.06	Intron A Redipen	MK
6255F	Solution for injection 60,000,000 i.u. in 1.2 mL multi-dose injection pen	2	5	..	*1238.02	Intron A Redipen	MK

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
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LAMIVUDINE

Authority required

Chronic hepatitis B in a patient without cirrhosis who satisfies all of the following criteria:

- (1) Elevated HBV DNA levels - greater than 20,000 IU/mL (100,000 copies/mL) if HBeAg positive, or greater than 2,000 IU/mL (10,000 copies/mL) if HBeAg negative - in conjunction with documented chronic hepatitis B infection;
- (2) Evidence of chronic liver injury as determined by:
 - (a) Confirmed elevated serum ALT; or
 - (b) Liver biopsy;

Chronic hepatitis B in a patient with cirrhosis who has detectable HBV DNA.

Persons with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy.

6257H	Tablet 100 mg	56	5	..	*317.08	Zeffix	GK
6271C	Oral solution 5 mg per mL, 240 mL	5	5	..	*369.97	Zeffix	GK

PEGINTERFERON ALFA-2a

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.

Authority required

Treatment, as sole PBS-subsidised therapy, in a patient with chronic hepatitis B without cirrhosis who satisfies all of the following criteria:

- (1) Elevated HBV DNA levels - greater than 20,000 IU/mL (100,000 copies/mL) if HBeAg positive, or greater than 2,000 IU/mL (10,000 copies/mL) if HBeAg negative - in conjunction with documented chronic hepatitis B infection;
- (2) Evidence of chronic liver injury as determined by:
 - (a) Confirmed elevated serum ALT; or
 - (b) Liver biopsy;
- (3) Has received no prior peginterferon alfa therapy for the treatment of hepatitis B;

Treatment, as sole PBS-subsidised therapy, in a patient with chronic hepatitis B with cirrhosis who has detectable HBV DNA.

Persons with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy.

Treatment is limited to 1 course of treatment for a duration of up to 48 weeks;

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 prior interferon alfa or peginterferon alfa treatment for hepatitis C and have a contraindication to ribavirin, 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 are using an effective form of contraception.

The treatment course is limited to up to 48 weeks.

Patients 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.

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.

6439X	Injection 135 micrograms in 0.5 mL single use pre-filled syringe	8	5	..	*2378.22	Pegasys	RO
6449K	Injection 180 micrograms in 0.5 mL single use pre-filled syringe	8	5	..	*2746.88	Pegasys	RO

TELBIVUDINE

Authority required

Treatment, as sole PBS-subsidised therapy, in a patient with chronic hepatitis B without cirrhosis who is nucleoside analogue naive and satisfies all of the following criteria:

- (1) Elevated HBV DNA levels - greater than 20,000 IU/mL (100,000 copies/mL) if HBeAg positive, or greater than 2,000 IU/mL (10,000 copies/mL) if HBeAg negative - in conjunction with documented hepatitis B infection;
- (2) Evidence of chronic liver injury as determined by:
 - (a) Confirmed elevated serum ALT; or
 - (b) 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	
	Treatment, as sole PBS-subsidised therapy, in a patient with chronic hepatitis B with cirrhosis who is nucleoside analogue naive and who has detectable HBV DNA.						
	Persons with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy.						
9630W	Tablet 600 mg	56	5	..	*528.26	Sebivo	NV
TENOFOVIR							
<u>Authority required</u>							
Initial treatment of HIV infection in combination with other antiretroviral agents in a patient with a CD4 count of less than 500 per cubic millimetre or symptomatic HIV disease;							
Continuing treatment of HIV infection in combination with other antiretroviral agents where the patient has previously received PBS-subsidised therapy for HIV infection.							
<u>Authority required</u>							
Treatment, as sole PBS-subsidised therapy, in a patient with chronic hepatitis B without cirrhosis who is nucleoside analogue naive and satisfies all of the following criteria:							
(1) Elevated HBV DNA levels - greater than 20,000 IU/mL (100,000 copies/mL) if HBeAg positive, or greater than 2,000 IU/mL (10,000 copies/mL) if HBeAg negative - in conjunction with documented hepatitis B infection;							
(2) Evidence of chronic liver injury as determined by:							
(a) Confirmed elevated serum ALT; or							
(b) Liver biopsy;							
Treatment, as sole PBS-subsidised therapy, in a patient with chronic hepatitis B with cirrhosis who is nucleoside analogue naive and who has detectable HBV DNA.							
Persons with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy.							
<u>Note</u>							
Patients may receive treatment in combination with lamivudine but not with other PBS-subsidised antihepadnaviral therapy.							
<u>Authority required</u>							
Chronic hepatitis B in a patient without cirrhosis who has failed antihepadnaviral therapy and who satisfies all of the following criteria:							
(a) Repeatedly elevated serum ALT levels while on concurrent antihepadnaviral therapy of greater than or equal to 6 months duration in conjunction with documented chronic hepatitis B infection; or							
(b) Repeatedly elevated HBV DNA levels one log greater than the nadir value or failure to achieve a 1 log reduction in HBV DNA within 3 months, whilst on previous antihepadnaviral therapy except in patients with evidence of poor compliance;							
Chronic hepatitis B in a patient with cirrhosis who has failed antihepadnaviral therapy and who has detectable HBV DNA.							
Persons with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy.							
<u>Note</u>							
Patients may receive treatment in combination with lamivudine but not with other PBS-subsidised antihepadnaviral therapy.							
6358P	Tablet containing tenofovir disoproxil fumarate 300 mg	60	5	..	*1011.26	Viread	GI
TENOFOVIR with EMTRICITABINE and EFAVIRENZ							
<u>Authority required</u>							
Initial treatment of HIV infection in a patient with a CD4 count of less than 500 per cubic millimetre or symptomatic HIV disease;							
Continuing treatment of HIV infection where the patient has previously received PBS-subsidised therapy for HIV infection.							
9650X	Tablet containing tenofovir disoproxil fumarate 300 mg with emtricitabine 200 mg and efavirenz 600 mg	60	5	..	*2481.90	Atripla	GI

SECTION 100 (HUMAN GROWTH HORMONE)

Code	Name, Restriction, Manner of Administration and Form	Pack Size	Price ex manufacturer \$	Brand Name and Manufacturer
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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

5822K	Solution for injection 6 mg (18 i.u.) in 1.03 mL cartridge (with preservative)	1	297.00	Saizen	SG
5824M	Solution for injection 12 mg (36 i.u.) in 1.5 mL cartridge (with preservative)	1	594.00	Saizen	SG
3388H	Solution for injection 20 mg (60 i.u.) in 2.5 mL cartridge (with preservative)	1	990.00	Saizen	SG

SECTION 100 (IVF/GIFT TREATMENT)

Code	Name, Restriction, Manner of Administration and Form	Pack Size	Price ex manufacturer \$	Brand Name and Manufacturer
CHORIOGONADOTROPIN ALFA				
<u>Criteria for availability</u>				
Patients who are receiving medical treatment as described in items 13200, 13201, 13202 or 13203 of the Medicare Benefits Schedule.				
<u>Note</u>				
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.				
<u>Note</u>				
Special Pricing Arrangements apply.				
6182J	Solution for injection 250 micrograms in 0.5 mL pre-filled pen	1	54.80	Ovidrel SG

REPATRIATION 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
ALFUZOSIN HYDROCHLORIDE							
<u>Authority required</u>							
Treatment of benign prostatic hyperplasia where surgery is inappropriate, or where other drug treatment has failed or is contraindicated.							
4277D	Tablet 10 mg	30	5	..	63.36	5.80	Xatral SR SW
BANDAGE—COMPRESSION							
<u>Note</u>							
Treatment of varices and oedema associated with venous disease and lymphoedema; contraindicated in arterial disease.							
<u>Restricted benefit</u>							
Initial treatment of venous ulcers.							
<u>Restricted benefit</u>							
Continuation of treatment of venous ulcers where patient's ability to tolerate dressing has been demonstrated.							
<u>Note</u>							
Bandage can be left in situ for up to 7 days as per manufacturer's instructions.							
4050E	Bandage, two layer	1	42.68	5.80	Coban MM
CODEINE PHOSPHATE with ASPIRIN							
4286N	Tablet 8 mg-300 mg	40	2	..	14.18	5.80	Aspalgin 40 QA
CODEINE PHOSPHATE with PARACETAMOL							
4275B	Tablet 8 mg-500 mg	40	2	..	10.69	5.80	Panamax Co. 40 SW
DRESSING—FOAM—SILVER							
<u>Authority required</u>							
For wounds where there is evidence of critical colonisation and for well-assessed chronic wounds that have not responded to conventional dressings.							
<u>Note</u>							
Smith & Nephew products are distributed via the three major wholesalers, API, Sigma & Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS pricing from distributors other than those aforementioned.							
4252T	Dressings, adhesive, 7.5 cm x 7.5 cm, 10	#1	134.89	5.80	Allevyn Ag Adhesive 66800073 SN
4255Y	Dressings, adhesive, 10 cm x 10 cm, 10	#1	200.58	5.80	Allevyn Ag Adhesive 66800075 SN
4258D	Dressings, adhesive, 12.5 cm x 12.5 cm, 10	#1	245.05	5.80	Allevyn Ag Adhesive 66800078 SN
4259E	Dressings, non-adhesive, 10 cm x 10 cm, 10	#1	204.42	5.80	Allevyn Ag Non-Adhesive 66800086 SN
4263J	Dressings 7.5 cm x 7.5 cm, 10	#1	134.89	5.80	Allevyn Ag Gentle 66800460 SN
4266M	Dressings 10 cm x 10 cm, 10	#1	200.58	5.80	Allevyn Ag Gentle 66800461 SN
4270R	Dressings 12.5 cm x 12.5 cm, 10	#1	245.05	5.80	Allevyn Ag Gentle 66800462 SN
DRESSING—FOAM with SILICONE—HEAVY EXUDATE							
<u>Note</u>							
Smith & Nephew products are distributed via the three major wholesalers, API, Sigma & Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS pricing from distributors other than those aforementioned.							
4196W	Dressings 10 cm x 10 cm, 10	#1	62.87	5.80	Allevyn Gentle 66800248 SN
4207K	Dressings 7.5 cm x 7.5 cm, 10	#1	43.48	5.80	Allevyn Gentle Border 66800269 SN

REPATRIATION 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	
4230P	Dressings 10 cm x 10 cm, 10	#1	60.87	5.80	Allevyn Gentle Border 66800270	SN
FINASTERIDE								
<u>Authority required</u>								
Treatment of benign prostatic hyperplasia where surgery is inappropriate, or where other drug treatment has failed or is contraindicated.								
4303L	Tablet 5 mg	28	5	..	91.27	5.80	Finpro	RZ
LUBRICATING GEL								
4306P	Tube 100 g	1	12.64	5.80	Lubri-Gel	PP
MICONAZOLE NITRATE								
3400Y	Cream 40 g (2% miconazole)	#1	1	..	13.68	5.80	Resolve Thrush	EO
SUNSCREENS								
4307Q	Cream 75 g	#1	2	..	17.02	5.80	Sunsense Sensitive SPF 30+	EO
WARDENAFIL								
<u>Authority required</u>								
Specific accepted war-caused or service-related disabilities for males with vasculogenic, psychogenic or neurogenic erectile dysfunction.								
Authorisation will not be given for any additional prescriptions within 6 months or for any increased quantities or repeats.								
4290T	Tablet 10 mg	4	5	..	72.79	5.80	Levitra	BN
4302K	Tablet 20 mg	4	5	..	83.52	5.80	Levitra	BN