



Australian Government

Department of Health and Ageing

**SCHEDULE OF PHARMACEUTICAL
BENEFITS**

SUMMARY OF CHANGES

EFFECTIVE 1 January 2012

PHARMACEUTICAL BENEFITS

These changes to the Schedule of Pharmaceutical Benefits are effective from 1 January 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 January 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

- 5054B **Apixaban**, Tablet 2.5 mg (*Eliquis*)
- 5061J **Apixaban**, Tablet 2.5 mg (*Eliquis*)
- 5043K **Glucose Indicator—blood**, Test strips, 50 (*Accu-Chek Aviva*)
- 5053Y **Glucose Indicator—blood**, Test strips, 50 (*Accu-Chek Aviva*)
- 5572G **Nicotine**, Transdermal patch releasing approximately 14 mg per 24 hours (*Nicotinell Step 2*)
- 5573H **Nicotine**, Transdermal patch releasing approximately 7 mg per 24 hours (*Nicotinell Step 3*)

Addition – Brand

- 1007B *Aciclovir GH, GQ* – **Aciclovir**, Tablet 200 mg
- 8594H *APO-Amisulpride, TX* – **Amisulpride**, Tablet 100 mg
- 8595J *APO-Amisulpride, TX* – **Amisulpride**, Tablet 200 mg
- 8596K *APO-Amisulpride, TX* – **Amisulpride**, Tablet 400 mg
- 1169M *Cefaclor GH, GQ* – **Cefaclor**, Tablet 375 mg (sustained release)
- 5045M *Cefaclor GH, GQ* – **Cefaclor**, Tablet 375 mg (sustained release) (**Dental**)
- 8506Q *APO-Exemestane, TX* – **Exemestane**, Tablet 25 mg
- 8878G *Fentanyl Sandoz, SZ* – **Fentanyl**, Transdermal patch 2.1 mg (releasing approximately 12 micrograms per hour)
- 8891Y *Fentanyl Sandoz, SZ* – **Fentanyl**, Transdermal patch 4.2 mg (releasing approximately 25 micrograms per hour)
- 8892B *Fentanyl Sandoz, SZ* – **Fentanyl**, Transdermal patch 8.4 mg (releasing approximately 50 micrograms per hour)
- 8893C *Fentanyl Sandoz, SZ* – **Fentanyl**, Transdermal patch 12.6 mg (releasing approximately 75 micrograms per hour)
- 8894D *Fentanyl Sandoz, SZ* – **Fentanyl**, Transdermal patch 16.8 mg (releasing approximately 100 micrograms per hour)
- 1434L *Fluoxetine Sandoz, SZ* – **Fluoxetine**, Capsule 20 mg (as hydrochloride)
- 8450R *Pharmacor Glimepiride 1, CR* – **Glimepiride**, Tablet 1 mg
- 8451T *Pharmacor Glimepiride 2, CR* – **Glimepiride**, Tablet 2 mg
- 8533D *Pharmacor Glimepiride 3, CR* – **Glimepiride**, Tablet 3 mg
- 8452W *Pharmacor Glimepiride 4, CR* – **Glimepiride**, Tablet 4 mg
- 8887R *APO-Meloxicam, TX* – **Meloxicam**, Capsule 7.5 mg
- 8887R *Chem mart Meloxicam, CH* – **Meloxicam**, Capsule 7.5 mg
- 8887R *Terry White Chemists Meloxicam, TW* – **Meloxicam**, Capsule 7.5 mg
- 8888T *APO-Meloxicam, TX* – **Meloxicam**, Capsule 15 mg
- 8888T *Chem mart Meloxicam, CH* – **Meloxicam**, Capsule 15 mg
- 8888T *Terry White Chemists Meloxicam, TW* – **Meloxicam**, Capsule 15 mg
- 1326T *APO-Omeprazole, TX* – **Omeprazole**, Capsule 20 mg
- 1326T *Omeprazole Sandoz, HX* – **Omeprazole**, Capsule 20 mg
- 1327W *APO-Omeprazole, TX* – **Omeprazole**, Capsule 20 mg
- 1327W *Omeprazole Sandoz, HX* – **Omeprazole**, Capsule 20 mg
- 8449Q *Perindopril/ Indapamide GH 4/1.25, GQ* – **Perindopril with Indapamide Hemihydrate**, Tablet containing 4 mg perindopril erbumine-1.25 mg indapamide hemihydrate
- 8694N *Pioglitazone-GA, GM* – **Pioglitazone**, Tablet 15 mg (as hydrochloride)

8695P	<i>Pioglitazone-GA, GM</i> – Pioglitazone , Tablet 30 mg (as hydrochloride)
8696Q	<i>Pioglitazone-GA, GM</i> – Pioglitazone , Tablet 45 mg (as hydrochloride)
2833D	<i>Pharmacor Pravastat 10, CR</i> – Pravastatin , Tablet containing pravastatin sodium 10 mg
9237E	<i>Pharmacor Pravastat 10, CR</i> – Pravastatin , Tablet containing pravastatin sodium 10 mg
2834E	<i>Pharmacor Pravastat 20, CR</i> – Pravastatin , Tablet containing pravastatin sodium 20 mg
9238F	<i>Pharmacor Pravastat 20, CR</i> – Pravastatin , Tablet containing pravastatin sodium 20 mg
8197K	<i>Pharmacor Pravastat 40, CR</i> – Pravastatin , Tablet containing pravastatin sodium 40 mg
9239G	<i>Pharmacor Pravastat 40, CR</i> – Pravastatin , Tablet containing pravastatin sodium 40 mg
2893G	<i>Pharmacor Prozine 5, CR</i> – Prochlorperazine , Tablet containing prochlorperazine maleate 5 mg
5205Y	<i>Pharmacor Prozine 5, CR</i> – Prochlorperazine , Tablet containing prochlorperazine maleate 5 mg (Dental)
2011W	<i>Simvacor 10, CR</i> – Simvastatin , Tablet 10 mg
9242K	<i>Simvacor 10, CR</i> – Simvastatin , Tablet 10 mg
2012X	<i>Simvacor 20, CR</i> – Simvastatin , Tablet 20 mg
9243L	<i>Simvacor 20, CR</i> – Simvastatin , Tablet 20 mg
8173E	<i>Simvacor 40, CR</i> – Simvastatin , Tablet 40 mg
9244M	<i>Simvacor 40, CR</i> – Simvastatin , Tablet 40 mg
8313M	<i>Simvacor 80, CR</i> – Simvastatin , Tablet 80 mg
9245N	<i>Simvacor 80, CR</i> – Simvastatin , Tablet 80 mg
8313M	<i>Simvastatin Sandoz, SZ</i> – Simvastatin , Tablet 80 mg
9245N	<i>Simvastatin Sandoz, SZ</i> – Simvastatin , Tablet 80 mg

Deletions

Deletion – Item

8614J	Drotrecogin Alfa (activated) , Powder for I.V. infusion 5 mg (<i>Xigris</i>)
2101N	Testosterone Esters , Injection 250 mg (<i>Sustanon 250</i>)

Deletion – Brand

2013Y	<i>Simvasyn, CR</i> – Simvastatin , Tablet 5 mg
9241J	<i>Simvasyn, CR</i> – Simvastatin , Tablet 5 mg
2011W	<i>Simvasyn, CR</i> – Simvastatin , Tablet 10 mg
9242K	<i>Simvasyn, CR</i> – Simvastatin , Tablet 10 mg
2012X	<i>Simvasyn, CR</i> – Simvastatin , Tablet 20 mg
9243L	<i>Simvasyn, CR</i> – Simvastatin , Tablet 20 mg
8173E	<i>Simvasyn, CR</i> – Simvastatin , Tablet 40 mg
9244M	<i>Simvasyn, CR</i> – Simvastatin , Tablet 40 mg
8313M	<i>Simvasyn, CR</i> – Simvastatin , Tablet 80 mg
9245N	<i>Simvasyn, CR</i> – Simvastatin , Tablet 80 mg

Alterations

Alteration – Brand Name

From:

8522M *Optium glucose, MS – Glucose Indicator—blood*, Test strips, 100

To:

8522M *FreeStyle Optium, MS – Glucose Indicator—blood*, Test strips, 100

From:

9270X *Optium glucose, MS – Glucose Indicator—blood*, Test strips, 100

To:

9270X *FreeStyle Optium, MS – Glucose Indicator—blood*, Test strips, 100

From:

9325T *WaveSense Jazz, HE – Glucose Indicator—blood*, Test strips, 50

To:

9325T *AgaMatrix Jazz, HE – Glucose Indicator—blood*, Test strips, 50

From:

9324R *WaveSense Jazz, HE – Glucose Indicator—blood*, Test strips, 50

To:

9324R *AgaMatrix Jazz, HE – Glucose Indicator—blood*, Test strips, 50

Alteration – Item Description

From:

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

To:

8646C **Tacrolimus**, Capsule 0.5 mg (*Prograf, Tacrolimus Sandoz*)

Alteration – Number of Repeats

		<i>From</i>	<i>To</i>
3414Q	Nicotine , Transdermal patch releasing approximately 21 mg per 24 hours (<i>Nicotinell Step 1</i>)	2	0

Alteration – Note

3414Q **Nicotine**, Transdermal patch releasing approximately 21 mg per 24 hours (*Nicotinell Step 1*)

Alteration – Manufacturer's Code

		<i>From</i>	<i>To</i>
1434L	<i>Fluohexal, HX – Fluoxetine</i> , Capsule 20 mg (as hydrochloride)	SZ	HX
3416T	<i>your pharmacy Clear Laxative, OY – Macrogol 3350</i> , Powder for oral solution 510 g	TW	OY
5426N	<i>your pharmacy Clear Laxative, OY – Macrogol 3350</i> , Powder for oral solution 510 g (Palliative Care)	TW	OY
5427P	<i>your pharmacy Clear Laxative, OY – Macrogol 3350</i> , Powder for oral solution 510 g (Palliative Care)	TW	OY
5423K	<i>Relistor, LM – Methylnaltrexone</i> , Solution for injection containing methylnaltrexone bromide 12 mg in 0.6 mL (Palliative Care)	PF	LM
5424L	<i>Relistor, LM – Methylnaltrexone</i> , Solution for injection containing methylnaltrexone bromide 12 mg in 0.6 mL (Palliative Care)	PF	LM
1746X	<i>Chem mart Paracetamol, XS – Paracetamol</i> , Tablet 500 mg	CH	XS
5196L	<i>Chem mart Paracetamol, XS – Paracetamol</i> , Tablet 500 mg (Dental)	CH	XS
5224Y	<i>Chem mart Paracetamol, XS – Paracetamol</i> , Tablet 500 mg (Dental)	CH	XS
8784H	<i>Chem mart Paracetamol, XS – Paracetamol</i> , Tablet 500 mg	CH	XS

		From	To
1746X	Terry White Chemists Paracetamol, YS – Paracetamol , Tablet 500 mg	TW	YS
5196L	Terry White Chemists Paracetamol, YS – Paracetamol , Tablet 500 mg (Dental)	TW	YS
5224Y	Terry White Chemists Paracetamol, YS – Paracetamol , Tablet 500 mg (Dental)	TW	YS
8784H	Terry White Chemists Paracetamol, YS – Paracetamol , Tablet 500 mg	TW	YS
9197C	Pharmacor Paroxo 20, MI – Paroxetine , Tablet 20 mg (as mesilate)	CR	MI
9286R	Dibenzyliline, BZ – Phenoxybenzamine Hydrochloride , Capsules 10 mg, 100	GH	BZ
2833D	Pravastatin 10, MI – Pravastatin , Tablet containing pravastatin sodium 10 mg	CR	MI
9237E	Pravastatin 10, MI – Pravastatin , Tablet containing pravastatin sodium 10 mg	CR	MI
2834E	Pravastatin 20, MI – Pravastatin , Tablet containing pravastatin sodium 20 mg	CR	MI
9238F	Pravastatin 20, MI – Pravastatin , Tablet containing pravastatin sodium 20 mg	CR	MI
8197K	Pravastatin 40, MI – Pravastatin , Tablet containing pravastatin sodium 40 mg	CR	MI
9239G	Pravastatin 40, MI – Pravastatin , Tablet containing pravastatin sodium 40 mg	CR	MI
8313M	Simvahexal, HX – Simvastatin , Tablet 80 mg	SZ	HX
9245N	Simvahexal, HX – Simvastatin , Tablet 80 mg	SZ	HX
5480K	Valacor 500, QR – Valaciclovir , Tablet 500 mg (as hydrochloride)	CR	QR
8064K	Valacor 500, QR – Valaciclovir , Tablet 500 mg (as hydrochloride)	CR	QR
8134D	Valacor 500, QR – Valaciclovir , Tablet 500 mg (as hydrochloride)	CR	QR

SECTION 100 – HIGHLY SPECIALISED DRUGS PROGRAM

Additions

Addition – Item

5030R	Epoprostenol Sodium , Powder for I.V. infusion 500 micrograms (base) infusion administration set (<i>Flolan Kit</i>) (Public)
5036C	Epoprostenol Sodium , Powder for I.V. infusion 500 micrograms (base) infusion administration set (<i>Flolan Kit</i>) (Private)
5035B	Epoprostenol Sodium , Powder for I.V. infusion 1.5 mg (base) infusion administration set (<i>Flolan Kit</i>) (Public)
5042J	Epoprostenol Sodium , Powder for I.V. infusion 1.5 mg (base) infusion administration set (<i>Flolan Kit</i>) (Private)
5084N	Etravirine , Tablet 200 mg (<i>Intelence</i>) (Public)
5062K	Etravirine , Tablet 200 mg (<i>Intelence</i>) (Private)

Deletions

Deletion – Item

9517X	Peginterferon Alfa-2b , Powder for injection 50 micrograms with diluent in single use injection pen (<i>PEG-Intron Redipen</i>) (Public)
6411K	Peginterferon Alfa-2b , Powder for injection 50 micrograms with diluent in single use injection pen (<i>PEG-Intron Redipen</i>) (Private)
9518Y	Peginterferon Alfa-2b , Powder for injection 80 micrograms with diluent in single use injection pen (<i>PEG-Intron Redipen</i>) (Public)
6412L	Peginterferon Alfa-2b , Powder for injection 80 micrograms with diluent in single use injection pen (<i>PEG-Intron Redipen</i>) (Private)
9520C	Peginterferon Alfa-2b , Powder for injection 100 micrograms with diluent in single use injection pen (<i>PEG-Intron Redipen</i>) (Public)
6413M	Peginterferon Alfa-2b , Powder for injection 100 micrograms with diluent in single use injection pen (<i>PEG-Intron Redipen</i>) (Private)
9521D	Peginterferon Alfa-2b , Powder for injection 120 micrograms with diluent in single use injection pen (<i>PEG-Intron Redipen</i>) (Public)

- 6414N **Peginterferon Alfa-2b**, Powder for injection 120 micrograms with diluent in single use injection pen (*PEG-Intron Redipen*) **(Private)**
- 9522E **Peginterferon Alfa-2b**, Powder for injection 150 micrograms with diluent in single use injection pen (*PEG-Intron Redipen*) **(Public)**
- 6415P **Peginterferon Alfa-2b**, Powder for injection 150 micrograms with diluent in single use injection pen (*PEG-Intron Redipen*) **(Private)**

Alterations

Alteration – Item Description

From:

9558C **Tacrolimus**, Capsule 500 micrograms (*Prograf, Tacrolimus Sandoz*) **(Public)**

To:

9558C **Tacrolimus**, Capsule 0.5 mg (*Prograf, Tacrolimus Sandoz*) **(Public)**

From:

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

To:

6328C **Tacrolimus**, Capsule 0.5 mg (*Prograf, Tacrolimus Sandoz*) **(Private)**

REPATRIATION PHARMACEUTICAL BENEFITS

Deletions

Deletion – Item

4012E **Nystatin**, Cream pessaries 100,000 units, 15 (*Nilstat*)

Alterations

Alteration – Brand Name

From:

4945G *Hydrocoll 900938/1, HR – Dressing—hydrocolloid (superficial Wound—moderate Exudate)*, Dressings 10 cm x 10 cm, 10

To:

4945G *Hydrocoll 900744, HR – Dressing—hydrocolloid (superficial Wound—moderate Exudate)*, Dressings 10 cm x 10 cm, 10

From:

4946H *Hydrocoll 900939/1, HR – Dressing—hydrocolloid (superficial Wound—moderate Exudate)*, Dressings 15 cm x 15 cm, 10

To:

4946H *Hydrocoll 900936, HR – Dressing—hydrocolloid (superficial Wound—moderate Exudate)*, Dressings 15 cm x 15 cm, 10

From:

4947J *Hydrocoll Thin 900942/1, HR – Dressing—hydrocolloid (superficial Wound—light Exudate)*, Dressings 10 cm x 10 cm, 10

To:

4947J *Hydrocoll Thin 900758, HR – Dressing—hydrocolloid (superficial Wound—light Exudate)*, Dressings 10 cm x 10 cm, 10

Alteration – Item Description

From:

4342M **Mometasone Furoate**, Cream 1 mg per g (0.1%), 45 g (*Elocon*)

To:

4342M **Mometasone Furoate**, Cream 1 mg per g (0.1%), 50 g (*Elocon*)

From:

4343N **Mometasone Furoate**, Ointment 1 mg per g (0.1%), 45 g (*Elocon*)

To:

4343N **Mometasone Furoate**, Ointment 1 mg per g (0.1%), 50 g (*Elocon*)

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 *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

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—

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

2350Q *Karicare De-Lact, SB* – **Milk Powder—lactose Free Formula**, Lactose-predigested powder infant formula 900 g

2349P *Karicare De-Lact, SB* – **Milk Powder—lactose Free Formula**, Lactose-predigested powder infant formula 900 g

2833D *Pravastatin 10, MI* – **Pravastatin**, Tablet containing pravastatin sodium 10 mg

9237E *Pravastatin 10, MI* – **Pravastatin**, Tablet containing pravastatin sodium 10 mg

2834E *Pravastatin 20, MI* – **Pravastatin**, Tablet containing pravastatin sodium 20 mg

9238F *Pravastatin 20, MI* – **Pravastatin**, Tablet containing pravastatin sodium 20 mg

8197K *Pravastatin 40, MI* – **Pravastatin**, Tablet containing pravastatin sodium 40 mg

9239G *Pravastatin 40, MI* – **Pravastatin**, Tablet containing pravastatin sodium 40 mg

8259Q *Pepti-Junior Gold, SB* – **Protein Hydrolysate Formula with Medium Chain Triglycerides**, Compound powder 450 g

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

8016X *Roxide, HX* – **Roxithromycin**, Tablet 300 mg

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

5261X *Roxide, HX* – **Roxithromycin**, Tablet 300 mg (**Dental**)

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

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

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 – Deletion of Item

The following Items will be deleted from the Schedule of Pharmaceutical Benefits on 1 April 2012:

Item discontinued by the manufacturer—

6477X **Epoprostenol Sodium**, Powder for I.V. infusion 500 micrograms (base) with diluent (*Flolan*)(**Private**)

6478Y **Epoprostenol Sodium**, Powder for I.V. infusion 1.5 mg (base) with diluent (*Flolan*)(**Private**)

5731P **Epoprostenol Sodium**, Powder for I.V. infusion 500 micrograms (base) with diluent (*Flolan*)(**Public**)

5732Q **Epoprostenol Sodium**, Powder for I.V. infusion 1.5 mg (base) with diluent (*Flolan*)(**Public**)

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
APIXABAN							
<u>Authority required</u>							
Prevention of venous thromboembolism in a patient undergoing total knee replacement.							
<u>Note</u>							
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.							
<u>Note</u>							
No applications for increased maximum quantities and/or repeats will be authorised.							
5054B NP	Tablet 2.5 mg	30	148.66	35.40	Eliquis BQ
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APIXABAN							
<u>Authority required</u>							
Prevention of venous thromboembolism in a patient undergoing total hip replacement.							
<u>Note</u>							
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.							
<u>Note</u>							
No applications for increased maximum quantities and/or repeats will be authorised.							
5061J NP	Tablet 2.5 mg	60	279.89	35.40	Eliquis BQ
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GLUCOSE INDICATOR—BLOOD							
5043K NP	Test strips, 50	2	5	..	*53.18	35.40	Accu-Chek Aviva RD
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GLUCOSE INDICATOR—BLOOD							
<u>Restricted benefit</u>							
For use in patients who are receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements.							
<u>Note</u>							
No applications for increased maximum quantities and/or repeats will be authorised.							
5053Y	Test strips, 50	2	11	..	*53.18	35.40	Accu-Chek Aviva RD
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NICOTINE							
<u>Authority required</u>							
Short-term sole PBS-subsidised therapy as an aid to achieving abstinence in a patient who has indicated they are ready to cease smoking and who has entered a comprehensive support and counselling program. Details of the program must be specified in the initial authority application;							
Short-term sole PBS-subsidised therapy as an aid to achieving abstinence in a patient who has indicated they are ready to cease smoking and who is entering a comprehensive support and counselling program during the consultation at which this authority is requested. Details of the program must be specified in the initial authority application.							
<u>Note</u>							
No applications for increased maximum quantities will be authorised. Applications for increased repeats, up to a maximum of 2, may be authorised. A maximum of 12 weeks of PBS-subsidised nicotine replacement therapy will be authorised per year.							
<u>Authority required</u>							
Nicotine dependence in an Aboriginal or a Torres Strait Islander person as the sole PBS-subsidised therapy.							
<u>Note</u>							
Only 2 courses of PBS-subsidised nicotine replacement therapy will be authorised per year. No applications for increased maximum quantities and/or repeats will be authorised. Benefit is improved if used in conjunction with a comprehensive support and counselling program.							

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	
3414Q NP	Transdermal patch releasing approximately 21 mg per 24 hours	28	55.22	35.40	Nicotinell Step 1	NC

NICOTINE

Authority required

Short-term sole PBS-subsidised therapy as an aid to achieving abstinence in a patient who has indicated they are ready to cease smoking and who has entered a comprehensive support and counselling program.

Details of the program must be specified in the initial authority application;

Short-term sole PBS-subsidised therapy as an aid to achieving abstinence in a patient who has indicated they are ready to cease smoking and who is entering a comprehensive support and counselling program during the consultation at which this authority is requested.

Details of the program must be specified in the initial authority application.

Note

No applications for increased maximum quantities will be authorised.

Applications for increased repeats, up to a maximum of 2, may be authorised.

A maximum of 12 weeks of PBS-subsidised nicotine replacement therapy will be authorised per year.

5572G NP	Transdermal patch releasing approximately 14 mg per 24 hours	28	55.22	35.40	Nicotinell Step 2	NC
5573H NP	Transdermal patch releasing approximately 7 mg per 24 hours	28	55.22	35.40	Nicotinell Step 3	NC

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
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EPOPROSTENOL SODIUM

Note

Any queries concerning the arrangements to prescribe epoprostenol sodium may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written applications for authority to prescribe PAH agents should be forwarded to:

Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001;

Note

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of agents for primary pulmonary hypertension and pulmonary arterial hypertension. Where the term PAH agents appears in the following notes and restrictions it refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate and ambrisentan.

Patients are eligible for PBS-subsidised treatment with only 1 of the above PAH agents at any 1 time. Eligible patients may only swap between PAH agents if they have not failed prior PBS-subsidised treatment with that agent.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with scleroderma or connective tissue disease, where the total lung capacity is less than 70% of that predicted.

The following provides some explanatory notes regarding the availability of PBS-subsidised treatment of adults with:

- (a) bosentan monohydrate, of primary pulmonary hypertension or pulmonary arterial hypertension secondary to scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology), in patients with disease of WHO Functional Class III or IV severity; AND
- (b) iloprost trometamol, of:
 - primary pulmonary hypertension, or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class III severity and who have failed to respond to prior PBS-subsidised treatment with an alternate PAH agent; AND
 - primary pulmonary hypertension, or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class IV severity; AND
 - drug-induced pulmonary arterial hypertension, in patients with disease of WHO Functional Class III and IV severity; AND
- (c) epoprostenol sodium, of:
 - primary pulmonary hypertension, in patients with disease of WHO Functional Class III severity and who have failed to respond to prior PBS-subsidised treatment with an alternate PAH agent; AND
 - primary pulmonary hypertension, in patients with disease of WHO Functional Class IV severity; AND
- (d) sildenafil citrate, of primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class III severity; AND
- (e) ambrisentan, of primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class III or IV severity.

From 1 December 2009, adult patients can access PAH agents through the PBS according to the relevant restrictions. Once these patients are approved initial treatment with 1 of these 5 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary. (New baselines may be submitted where the patient has failed to respond to their current treatment.)

The following provides some explanatory notes regarding the availability of PBS-subsidised treatment of patients under the age of 18 years with:

- (a) bosentan monohydrate, of primary pulmonary hypertension or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology), in patients with disease of WHO Functional Class III or IV severity; AND
- (b) iloprost trometamol, of:
 - primary pulmonary hypertension, in patients with disease of WHO Functional Class III severity and who have failed to respond to prior PBS-subsidised treatment with an alternate PAH agent; AND
 - primary pulmonary hypertension, in patients with disease of WHO Functional Class IV severity; AND
- (c) epoprostenol sodium, of:
 - primary pulmonary hypertension, in patients with disease of WHO Functional Class III severity and who have failed to respond to prior PBS-subsidised treatment with an alternate PAH agent; AND
 - primary pulmonary hypertension, in patients with disease of WHO Functional Class IV severity; AND
- (d) sildenafil citrate, of primary pulmonary hypertension in patients with disease of WHO Functional Class III severity; AND
- (e) ambrisentan, of primary pulmonary hypertension in patients with disease of WHO Functional Class III or IV severity.

From 1 December 2009, patients under the age of 18 years can access PAH agents through the PBS according to the relevant restrictions. Once these patients are approved initial treatment with 1 of these 5 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary. (New baselines may be submitted where the patient has failed to respond to their current treatment.)

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
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1. Definition of primary pulmonary hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease, including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology).

Primary pulmonary hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease, including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows:

- (i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary capillary wedge pressure (PCWP) less than 18 mmHg; or
- (ii) mPAP greater than 30 mmHg with exercise and PCWP less than 18 mmHg; or
- (iii) where a right heart catheter cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

2. Definition of WHO Functional Class III or IV disease severity.

(a) WHO Functional Class III disease severity is defined as follows:

Patients with pulmonary hypertension resulting in marked limitation of physical activity who are comfortable at rest and on ordinary physical activity experience dyspnoea or fatigue, chest pain or near syncope.

(b) WHO Functional Class IV disease severity is defined as follows:

Patients with the inability to carry out any physical activity without symptoms. These patients manifest signs of right heart failure. Dyspnoea and/or fatigue may even be present at rest. Discomfort is increased by any physical activity.

3. Designated hospitals.

Refer to the Medicare Australia website at www.medicareaustralia.gov.au for a list of designated hospitals.

Note

4. Test requirements to establish baseline for initiation of treatment and response to treatment for continuation of treatment.

(a) Initiation of treatment.

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment, plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

- (1) RHC plus ECHO composite assessments;
- (2) RHC composite assessment plus 6MWT;
- (3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted to Medicare Australia for consideration based on the results of the following test combinations, which are listed in descending order of preference:

- (1) ECHO composite assessment plus 6MWT;
- (2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test/s could not be conducted must be provided with the authority application.

(b) Continuation of treatment.

The following list outlines the preferred test combination, in descending order, for the purposes of continuation of PBS-subsidised treatment:

- (1) RHC plus ECHO composite assessments plus 6MWT;
- (2) RHC plus ECHO composite assessments;
- (3) RHC composite assessment plus 6MWT;
- (4) ECHO composite assessment plus 6MWT;
- (5) RHC composite assessment only;
- (6) ECHO composite assessment only.

The results of the same tests as conducted at baseline should be provided with each written continuing treatment application (i.e. every 6 months), except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be provided with the application.

The test(s) results provided with the application for continuing treatment must be no more than 2 months old at the time of application.

5. Definition of response to a PAH agent or prior vasodilator treatment.

For adult patients with 2 or more baseline tests, response to treatment is defined as 2 or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

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For adult patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For adult patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least 1 of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

6. Authority approval requirements.

(a) Initiation of PBS-subsidised treatment with a PAH agent, where the patient has not received prior PBS-subsidised treatment with that agent. All applications for initial treatment must be made in writing, must include a completed authority prescription and must be submitted to Medicare Australia for authorisation. The total duration of initial PBS-subsidised treatment that will be approved with this first written application is up to 6 months, based on the dosage recommendations in the TGA-approved Product Information.

Bosentan only:

Approvals for the first authority prescription will be limited to 1 month of therapy with the 62.5 mg strength tablet, with the quantity approved based on the dosage recommendations in the Therapeutic Goods Administration (TGA)-approved Product Information. No repeats will be authorised for this prescription. The second authority prescription may be written for either the 62.5 mg tablet or the 125 mg tablet strengths. Where the 62.5 mg tablet strength is required, please contact Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) for further advice. Approvals for the second authority prescription will be limited to 1 month of treatment, with the quantity approved based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 4 repeats. The approved second authority prescription will be returned to the prescriber by Medicare Australia 2 weeks after the date of the approval of the first authority prescription, to allow for the uninterrupted completion of the 6 month initial treatment course. Medicare Australia will contact prescribers prior to dispatch of the second authority prescription to confirm the tablet strength required for the patient.

(b) Continuation of treatment.

Written applications for continuing treatment for patients who have demonstrated an adequate response to their current treatment must be submitted to Medicare Australia for authorisation every 6 months. Approvals will be limited to provide sufficient supply for up to a maximum of 6 months of treatment, based on the dosage recommendations in the TGA-approved Product Information.

The assessment of the patient's response to the first and subsequent 6 month courses of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated. Applications for continuing treatment with a PAH agent should be made prior to the completion of the 6 month treatment course to ensure continuity for those patients who respond to treatment, as assessed by the treating physician.

(c) Swapping between PAH agents.

For eligible patients, applications to swap between these 5 drugs must be made under the relevant initial treatment restriction. Patients should be assessed for response to the treatment they are ceasing at the time the application to swap therapy is being made. Patients who fail to demonstrate a response or for whom no assessment results are submitted with the application to swap therapy may not re-commence PBS-subsidised treatment with the drug they are ceasing.

It is important that patients are assessed for response to every course of treatment approved within the timeframes specified in the relevant restriction, in order to maximise the choice of treatment.

To avoid confusion, applications for patients who wish to swap to an alternate treatment should be accompanied by the previously approved authority prescription, or remaining repeats, for the treatment the patient is ceasing.

(d) Cessation of treatment — bosentan patients only.

Patients who fail to demonstrate a response to PBS-subsidised bosentan monohydrate treatment at the time where an assessment is required must cease PBS-subsidised bosentan monohydrate therapy.

For patients ceasing treatment, approval will only be granted to provide sufficient supply of the 62.5 mg tablet strength to allow gradual dose reduction over a period of no more than 1 month duration. Prescribers should telephone Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) to receive authorisation for this final supply and to ensure no unintended break in treatment occurs.

7. Re-treatment with a PAH agent.

Patients who do not respond to treatment are not eligible to receive further PBS-subsidised treatment with that agent under any circumstances.

8. Further information.

A tabulated representation of the above information and the restriction can be obtained from the Medicare Australia website at www.medicareaustralia.gov.au.

Authority required

Initial (new adult patients)

Application for initial PBS-subsidised treatment with epoprostenol sodium of adult patients who have not received prior PBS-subsidised treatment

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with a PAH agent and who have been assessed by a physician from a designated hospital to have:
WHO Functional Class IV primary pulmonary hypertension.

Applications for authorisation must be in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form [www.medicareaustralia.gov.au] which includes results from the 3 tests below, where available:
 - (i) RHC composite assessment; and
 - (ii) ECHO composite assessment; and
 - (iii) 6MWT; and
- (3) a signed patient and prescriber acknowledgment indicating that the patient understands and acknowledges that PBS-subsidised treatment with a PAH agent will cease if the treating physician determines that the patient has not achieved a response to treatment [see Note for definition of response].

Where fewer than 3 tests (see requirement 2 above) are able to be performed on clinical grounds, a patient specific reason outlining why the particular test/s could not be conducted must be provided with the authority application [see Note for test requirements].

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. A maximum of 5 repeats may be requested. Where fewer than 5 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 6 months of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required

Initial (new patients under 18 years of age)

Application for initial PBS-subsidised treatment with epoprostenol sodium of patients aged less than 18 years who have not received prior PBS-subsidised treatment with a PAH agent and who have been assessed by a physician from a designated hospital to have:
WHO Functional Class IV primary pulmonary hypertension.

Applications for authorisation must be in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form [www.medicareaustralia.gov.au] which includes results from the 3 tests below, where available:
 - (i) RHC composite assessment; and
 - (ii) ECHO composite assessment; and
 - (iii) 6MWT; and
- (3) a patient acknowledgment, signed by the parent or authorised guardian and the prescriber, indicating that they understand and acknowledge that PBS-subsidised treatment with PAH agents will cease if the treating physician determines that the patient has not achieved a response to treatment [see Note for definition of response].

Where fewer than 3 tests (see requirement 2 above) are able to be performed on clinical grounds, a patient specific reason outlining why the particular test/s could not be conducted must be provided with the authority application [see Note for test requirements].

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. A maximum of 5 repeats will be authorised under this criterion. Where fewer than 5 repeats are initially requested, authority approvals for sufficient repeats to complete a maximum of 6 months of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required

Initial (change or re-commencement for all adult patients)

Application for initial PBS-subsidised treatment with epoprostenol sodium of adult patients with one of the following:

- (a) primary pulmonary hypertension who wish to re-commence PBS-subsidised epoprostenol sodium after a break in therapy and who have demonstrated a response to their most recent course of PBS-subsidised treatment with epoprostenol sodium; OR
- (b) WHO Functional Class IV primary pulmonary hypertension and who have received prior treatment with a PBS-subsidised PAH agent other than epoprostenol sodium; OR
- (c) WHO Functional Class III primary pulmonary hypertension and who have failed to respond to a prior PBS-subsidised PAH agent.

Applications for authorisation must be in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form [www.medicareaustralia.gov.au] which includes the results on which approval for the first application for PBS-subsidised PAH agent was granted; and
- (3) the date of the first application for PBS-subsidised treatment with a PAH agent; and
- (4) the results of the patient's response to treatment with their last course of PBS-subsidised PAH agent; and
- (5) for WHO Functional Class III patients, where this is the first application for epoprostenol sodium, assessment details of the PBS-subsidised PAH agent they have failed to respond to.

Where fewer than 3 tests (see requirement 2 above) are able to be performed on clinical grounds, a patient specific reason outlining why the particular test/s could not be conducted must be provided with the authority application [see Note for test requirements].

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in

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the TGA-approved Product Information. A maximum of 5 repeats may be requested. Where fewer than 5 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 6 months of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required

Initial (change or re-commencement for all patients under 18 years of age)

Application for initial PBS-subsidised treatment with epoprostenol sodium of patients aged less than 18 years with one of the following:

- (a) primary pulmonary hypertension who wish to re-commence PBS-subsidised epoprostenol sodium after a break in therapy and who have demonstrated a response to their most recent course of PBS-subsidised treatment with epoprostenol sodium; OR
- (b) WHO Functional Class IV primary pulmonary hypertension and who have received prior treatment with a PBS-subsidised PAH agent other than epoprostenol sodium; OR
- (c) WHO Functional Class III primary pulmonary hypertension and who have failed to respond to a prior PBS-subsidised PAH agent.

Applications for authorisation must be in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form [www.medicareaustralia.gov.au] which includes the results on which approval for the first application for PBS-subsidised PAH agent was granted; and
- (3) the date of the first application for PBS-subsidised treatment with a PAH agent; and
- (4) the results of the patient's response to treatment with their last course of PBS-subsidised PAH agent; and
- (5) for WHO Functional Class III patients, where this is the first application for epoprostenol sodium, assessment details of the PBS-subsidised PAH agent they have failed to respond to.

Where fewer than 3 tests (see requirement 2 above) are able to be performed on clinical grounds, a patient specific reason outlining why the particular test/s could not be conducted must be provided with the authority application [see Note for test requirements].

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. A maximum of 5 repeats may be requested. Where fewer than 5 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 6 months of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required

Continuing treatment (all patients)

Continuing PBS-subsidised treatment with epoprostenol sodium of patients who have received approval for initial PBS-subsidised treatment with epoprostenol sodium, and who have been assessed by a physician from a designated hospital to have achieved a response to their most recent course of epoprostenol sodium treatment [see Note for definition of response].

Applications for authorisation must be in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form [www.medicareaustralia.gov.au] which includes results from the 3 tests below, where available:
 - (i) RHC composite assessment; and
 - (ii) ECHO composite assessment; and
 - (iii) 6MWT.

The results of the same tests as conducted at baseline should be provided with each written continuing treatment application (i.e. every 6 months), except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be provided with the application.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. A maximum of 5 repeats may be requested. Where fewer than 5 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 6 months of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

5030R	Powder for I.V. infusion 500 micrograms (base) infusion administration set	1	41.69	Flolan Kit	GK
5035B	Powder for I.V. infusion 1.5 mg (base) infusion administration set	1	83.37	Flolan Kit	GK

ETRAVIRINE

Authority required (STREAMLINED)

3597

Treatment of HIV infection, in addition to optimised background therapy in combination with other antiretroviral agents in an antiretroviral experienced patient who, after each of at least three different antiretroviral regimens that have included one drug from at least 3 different antiretroviral classes, 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.

5084N	Tablet 200 mg	120	5	..	*1233.00	Intelence	JC
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EPOPROSTENOL SODIUM

Note

Any queries concerning the arrangements to prescribe epoprostenol sodium may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written applications for authority to prescribe PAH agents should be forwarded to:

Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001;

Note

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of agents for primary pulmonary hypertension and pulmonary arterial hypertension. Where the term PAH agents appears in the following notes and restrictions it refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate and ambrisentan.

Patients are eligible for PBS-subsidised treatment with only 1 of the above PAH agents at any 1 time. Eligible patients may only swap between PAH agents if they have not failed prior PBS-subsidised treatment with that agent.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with scleroderma or connective tissue disease, where the total lung capacity is less than 70% of that predicted.

The following provides some explanatory notes regarding the availability of PBS-subsidised treatment of adults with:

- (a) bosentan monohydrate, of primary pulmonary hypertension or pulmonary arterial hypertension secondary to scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology), in patients with disease of WHO Functional Class III or IV severity; AND
- (b) iloprost trometamol, of:
 - primary pulmonary hypertension, or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class III severity and who have failed to respond to prior PBS-subsidised treatment with an alternate PAH agent; AND
 - primary pulmonary hypertension, or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class IV severity; AND
 - drug-induced pulmonary arterial hypertension, in patients with disease of WHO Functional Class III and IV severity; AND
- (c) epoprostenol sodium, of:
 - primary pulmonary hypertension, in patients with disease of WHO Functional Class III severity and who have failed to respond to prior PBS-subsidised treatment with an alternate PAH agent; AND
 - primary pulmonary hypertension, in patients with disease of WHO Functional Class IV severity; AND
- (d) sildenafil citrate, of primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class III severity; AND
- (e) ambrisentan, of primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class III or IV severity.

From 1 December 2009, adult patients can access PAH agents through the PBS according to the relevant restrictions. Once these patients are approved initial treatment with 1 of these 5 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary. (New baselines may be submitted where the patient has failed to respond to their current treatment.)

The following provides some explanatory notes regarding the availability of PBS-subsidised treatment of patients under the age of 18 years with:

- (a) bosentan monohydrate, of primary pulmonary hypertension or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology), in patients with disease of WHO Functional Class III or IV severity; AND
- (b) iloprost trometamol, of:
 - primary pulmonary hypertension, in patients with disease of WHO Functional Class III severity and who have failed to respond to prior PBS-subsidised treatment with an alternate PAH agent; AND
 - primary pulmonary hypertension, in patients with disease of WHO Functional Class IV severity; AND
- (c) epoprostenol sodium, of:
 - primary pulmonary hypertension, in patients with disease of WHO Functional Class III severity and who have failed to respond to prior PBS-subsidised treatment with an alternate PAH agent; AND
 - primary pulmonary hypertension, in patients with disease of WHO Functional Class IV severity; AND
- (d) sildenafil citrate, of primary pulmonary hypertension in patients with disease of WHO Functional Class III severity; AND
- (e) ambrisentan, of primary pulmonary hypertension in patients with disease of WHO Functional Class III or IV severity.

From 1 December 2009, patients under the age of 18 years can access PAH agents through the PBS according to the relevant restrictions. Once these patients are approved initial treatment with 1 of these 5 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary. (New baselines may be submitted where the patient has failed to respond to their current treatment.)

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1. Definition of primary pulmonary hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease, including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology).

Primary pulmonary hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease, including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows:

- (i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary capillary wedge pressure (PCWP) less than 18 mmHg; or
- (ii) mPAP greater than 30 mmHg with exercise and PCWP less than 18 mmHg; or
- (iii) where a right heart catheter cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

2. Definition of WHO Functional Class III or IV disease severity.

(a) WHO Functional Class III disease severity is defined as follows:

Patients with pulmonary hypertension resulting in marked limitation of physical activity who are comfortable at rest and on ordinary physical activity experience dyspnoea or fatigue, chest pain or near syncope.

(b) WHO Functional Class IV disease severity is defined as follows:

Patients with the inability to carry out any physical activity without symptoms. These patients manifest signs of right heart failure. Dyspnoea and/or fatigue may even be present at rest. Discomfort is increased by any physical activity.

3. Designated hospitals.

Refer to the Medicare Australia website at www.medicareaustralia.gov.au for a list of designated hospitals.

Note

4. Test requirements to establish baseline for initiation of treatment and response to treatment for continuation of treatment.

(a) Initiation of treatment.

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment, plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

- (1) RHC plus ECHO composite assessments;
- (2) RHC composite assessment plus 6MWT;
- (3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted to Medicare Australia for consideration based on the results of the following test combinations, which are listed in descending order of preference:

- (1) ECHO composite assessment plus 6MWT;
- (2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test/s could not be conducted must be provided with the authority application.

(b) Continuation of treatment.

The following list outlines the preferred test combination, in descending order, for the purposes of continuation of PBS-subsidised treatment:

- (1) RHC plus ECHO composite assessments plus 6MWT;
- (2) RHC plus ECHO composite assessments;
- (3) RHC composite assessment plus 6MWT;
- (4) ECHO composite assessment plus 6MWT;
- (5) RHC composite assessment only;
- (6) ECHO composite assessment only.

The results of the same tests as conducted at baseline should be provided with each written continuing treatment application (i.e. every 6 months), except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be provided with the application.

The test(s) results provided with the application for continuing treatment must be no more than 2 months old at the time of application.

5. Definition of response to a PAH agent or prior vasodilator treatment.

For adult patients with 2 or more baseline tests, response to treatment is defined as 2 or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

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For adult patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For adult patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least 1 of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

6. Authority approval requirements.

(a) Initiation of PBS-subsidised treatment with a PAH agent, where the patient has not received prior PBS-subsidised treatment with that agent. All applications for initial treatment must be made in writing, must include a completed authority prescription and must be submitted to Medicare Australia for authorisation. The total duration of initial PBS-subsidised treatment that will be approved with this first written application is up to 6 months, based on the dosage recommendations in the TGA-approved Product Information.

Bosentan only:

Approvals for the first authority prescription will be limited to 1 month of therapy with the 62.5 mg strength tablet, with the quantity approved based on the dosage recommendations in the Therapeutic Goods Administration (TGA)-approved Product Information. No repeats will be authorised for this prescription. The second authority prescription may be written for either the 62.5 mg tablet or the 125 mg tablet strengths. Where the 62.5 mg tablet strength is required, please contact Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) for further advice. Approvals for the second authority prescription will be limited to 1 month of treatment, with the quantity approved based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 4 repeats. The approved second authority prescription will be returned to the prescriber by Medicare Australia 2 weeks after the date of the approval of the first authority prescription, to allow for the uninterrupted completion of the 6 month initial treatment course. Medicare Australia will contact prescribers prior to dispatch of the second authority prescription to confirm the tablet strength required for the patient.

(b) Continuation of treatment.

Written applications for continuing treatment for patients who have demonstrated an adequate response to their current treatment must be submitted to Medicare Australia for authorisation every 6 months. Approvals will be limited to provide sufficient supply for up to a maximum of 6 months of treatment, based on the dosage recommendations in the TGA-approved Product Information.

The assessment of the patient's response to the first and subsequent 6 month courses of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated. Applications for continuing treatment with a PAH agent should be made prior to the completion of the 6 month treatment course to ensure continuity for those patients who respond to treatment, as assessed by the treating physician.

(c) Swapping between PAH agents.

For eligible patients, applications to swap between these 5 drugs must be made under the relevant initial treatment restriction. Patients should be assessed for response to the treatment they are ceasing at the time the application to swap therapy is being made. Patients who fail to demonstrate a response or for whom no assessment results are submitted with the application to swap therapy may not re-commence PBS-subsidised treatment with the drug they are ceasing.

It is important that patients are assessed for response to every course of treatment approved within the timeframes specified in the relevant restriction, in order to maximise the choice of treatment.

To avoid confusion, applications for patients who wish to swap to an alternate treatment should be accompanied by the previously approved authority prescription, or remaining repeats, for the treatment the patient is ceasing.

(d) Cessation of treatment — bosentan patients only.

Patients who fail to demonstrate a response to PBS-subsidised bosentan monohydrate treatment at the time where an assessment is required must cease PBS-subsidised bosentan monohydrate therapy.

For patients ceasing treatment, approval will only be granted to provide sufficient supply of the 62.5 mg tablet strength to allow gradual dose reduction over a period of no more than 1 month duration. Prescribers should telephone Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) to receive authorisation for this final supply and to ensure no unintended break in treatment occurs.

7. Re-treatment with a PAH agent.

Patients who do not respond to treatment are not eligible to receive further PBS-subsidised treatment with that agent under any circumstances.

8. Further information.

A tabulated representation of the above information and the restriction can be obtained from the Medicare Australia website at www.medicareaustralia.gov.au.

Authority required

Initial (new adult patients)

Application for initial PBS-subsidised treatment with epoprostenol sodium of adult patients who have not received prior PBS-subsidised treatment

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

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with a PAH agent and who have been assessed by a physician from a designated hospital to have:
WHO Functional Class IV primary pulmonary hypertension.

Applications for authorisation must be in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form [www.medicareaustralia.gov.au] which includes results from the 3 tests below, where available:
 - (i) RHC composite assessment; and
 - (ii) ECHO composite assessment; and
 - (iii) 6MWT; and
- (3) a signed patient and prescriber acknowledgment indicating that the patient understands and acknowledges that PBS-subsidised treatment with a PAH agent will cease if the treating physician determines that the patient has not achieved a response to treatment [see Note for definition of response].

Where fewer than 3 tests (see requirement 2 above) are able to be performed on clinical grounds, a patient specific reason outlining why the particular test/s could not be conducted must be provided with the authority application [see Note for test requirements].

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. A maximum of 5 repeats may be requested. Where fewer than 5 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 6 months of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required

Initial (new patients under 18 years of age)

Application for initial PBS-subsidised treatment with epoprostenol sodium of patients aged less than 18 years who have not received prior PBS-subsidised treatment with a PAH agent and who have been assessed by a physician from a designated hospital to have:
WHO Functional Class IV primary pulmonary hypertension.

Applications for authorisation must be in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form [www.medicareaustralia.gov.au] which includes results from the 3 tests below, where available:
 - (i) RHC composite assessment; and
 - (ii) ECHO composite assessment; and
 - (iii) 6MWT; and
- (3) a patient acknowledgment, signed by the parent or authorised guardian and the prescriber, indicating that they understand and acknowledge that PBS-subsidised treatment with PAH agents will cease if the treating physician determines that the patient has not achieved a response to treatment [see Note for definition of response].

Where fewer than 3 tests (see requirement 2 above) are able to be performed on clinical grounds, a patient specific reason outlining why the particular test/s could not be conducted must be provided with the authority application [see Note for test requirements].

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. A maximum of 5 repeats will be authorised under this criterion. Where fewer than 5 repeats are initially requested, authority approvals for sufficient repeats to complete a maximum of 6 months of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required

Initial (change or re-commencement for all adult patients)

Application for initial PBS-subsidised treatment with epoprostenol sodium of adult patients with one of the following:

- (a) primary pulmonary hypertension who wish to re-commence PBS-subsidised epoprostenol sodium after a break in therapy and who have demonstrated a response to their most recent course of PBS-subsidised treatment with epoprostenol sodium; OR
- (b) WHO Functional Class IV primary pulmonary hypertension and who have received prior treatment with a PBS-subsidised PAH agent other than epoprostenol sodium; OR
- (c) WHO Functional Class III primary pulmonary hypertension and who have failed to respond to a prior PBS-subsidised PAH agent.

Applications for authorisation must be in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form [www.medicareaustralia.gov.au] which includes the results on which approval for the first application for PBS-subsidised PAH agent was granted; and
- (3) the date of the first application for PBS-subsidised treatment with a PAH agent; and
- (4) the results of the patient's response to treatment with their last course of PBS-subsidised PAH agent; and
- (5) for WHO Functional Class III patients, where this is the first application for epoprostenol sodium, assessment details of the PBS-subsidised PAH agent they have failed to respond to.

Where fewer than 3 tests (see requirement 2 above) are able to be performed on clinical grounds, a patient specific reason outlining why the particular test/s could not be conducted must be provided with the authority application [see Note for test requirements].

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

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the TGA-approved Product Information. A maximum of 5 repeats may be requested. Where fewer than 5 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 6 months of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required

Initial (change or re-commencement for all patients under 18 years of age)

Application for initial PBS-subsidised treatment with epoprostenol sodium of patients aged less than 18 years with one of the following:

- (a) primary pulmonary hypertension who wish to re-commence PBS-subsidised epoprostenol sodium after a break in therapy and who have demonstrated a response to their most recent course of PBS-subsidised treatment with epoprostenol sodium; OR
- (b) WHO Functional Class IV primary pulmonary hypertension and who have received prior treatment with a PBS-subsidised PAH agent other than epoprostenol sodium; OR
- (c) WHO Functional Class III primary pulmonary hypertension and who have failed to respond to a prior PBS-subsidised PAH agent.

Applications for authorisation must be in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form [www.medicareaustralia.gov.au] which includes the results on which approval for the first application for PBS-subsidised PAH agent was granted; and
- (3) the date of the first application for PBS-subsidised treatment with a PAH agent; and
- (4) the results of the patient's response to treatment with their last course of PBS-subsidised PAH agent; and
- (5) for WHO Functional Class III patients, where this is the first application for epoprostenol sodium, assessment details of the PBS-subsidised PAH agent they have failed to respond to.

Where fewer than 3 tests (see requirement 2 above) are able to be performed on clinical grounds, a patient specific reason outlining why the particular test/s could not be conducted must be provided with the authority application [see Note for test requirements].

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. A maximum of 5 repeats may be requested. Where fewer than 5 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 6 months of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required

Continuing treatment (all patients)

Continuing PBS-subsidised treatment with epoprostenol sodium of patients who have received approval for initial PBS-subsidised treatment with epoprostenol sodium, and who have been assessed by a physician from a designated hospital to have achieved a response to their most recent course of epoprostenol sodium treatment [see Note for definition of response].

Applications for authorisation must be in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form [www.medicareaustralia.gov.au] which includes results from the 3 tests below, where available:
 - (i) RHC composite assessment; and
 - (ii) ECHO composite assessment; and
 - (iii) 6MWT.

The results of the same tests as conducted at baseline should be provided with each written continuing treatment application (i.e. every 6 months), except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be provided with the application.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. A maximum of 5 repeats may be requested. Where fewer than 5 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 6 months of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

5036C	Powder for I.V. infusion 500 micrograms (base) infusion administration set	1	52.11	Flolan Kit	GK
5042J	Powder for I.V. infusion 1.5 mg (base) infusion administration set	1	93.79	Flolan Kit	GK

ETRAVIRINE

Authority required

Treatment of HIV infection, in addition to optimised background therapy in combination with other antiretroviral agents in an antiretroviral experienced patient who, after each of at least three different antiretroviral regimens that have included one drug from at least 3 different antiretroviral classes, 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.

5062K	Tablet 200 mg	120	5	..	*1279.42	Intelence	JC
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