



Australian Government

Department of Health and Ageing

SCHEDULE OF PHARMACEUTICAL BENEFITS

SUMMARY OF CHANGES

EFFECTIVE 1 APRIL 2011

PHARMACEUTICAL BENEFITS

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

Fees, Patient Contributions and Safety Net Thresholds

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

Dispensing Fees:	Ready-prepared	\$6.42
	Dangerous drug fee	\$2.71
	Extemporaneously-prepared	\$8.46
	Allowable additional patient charge*	\$3.92
Additional Fees (for safety net prices):	Ready-prepared	\$1.07
	Extemporaneously-prepared	\$1.41
Patient Co-payments:	General	\$34.20
	Concessional	\$5.60
Safety Net Thresholds:	General	\$1317.20
	Concessional	\$336.00
Safety Net Card Issue Fee:		\$8.58

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

SUMMARY OF CHANGES

Additions

Additions – Items

8961P	Adalimumab , Injection 40 mg in 0.8 mL pre-filled syringe, 6 (<i>Humira</i>)
8962Q	Adalimumab , Injection 40 mg in 0.8 mL pre-filled pen, 6 (<i>Humira</i>)
8963R	Adalimumab , Injection 40 mg in 0.8 mL pre-filled syringe (<i>Humira</i>)
8964T	Adalimumab , Injection 40 mg in 0.8 mL pre-filled syringe (<i>Humira</i>) (Diff. Max. Rpts)
8965W	Adalimumab , Injection 40 mg in 0.8 mL pre-filled pen (<i>Humira</i>)
8966X	Adalimumab , Injection 40 mg in 0.8 mL pre-filled pen (<i>Humira</i>) (Diff. Max. Rpts)
8954G	Adapalene with Benzoyl Peroxide , Gel 1 mg-25 mg per g (0.1%-2.5%), 30 g (<i>Epiduo</i>)
8955H	Adapalene with Benzoyl Peroxide , Gel 1 mg-25 mg per g (0.1%-2.5%), 30 g (<i>Epiduo</i>)
8952E	Olanzapine , Wafer 15 mg (<i>Zyprexa Zydis</i>)
8953F	Olanzapine , Wafer 20 mg (<i>Zyprexa Zydis</i>)
5480K	Valaciclovir , Tablet 500 mg (as hydrochloride) (<i>APO-Valaciclovir, Chem mart Valaciclovir, Terry White Chemists Valaciclovir, Vaclovir, Valaciclovir GA, Valaciclovir RBX, Valaciclovir SZ, Valnir, Valtrex, Zelitrex</i>)
5474D	Vildagliptin with Metformin , Tablet containing 50 mg vildagliptin with 500 mg metformin hydrochloride (<i>Galvumet 50/500</i>)
5475E	Vildagliptin with Metformin , Tablet containing 50 mg vildagliptin with 850 mg metformin hydrochloride (<i>Galvumet 50/850</i>)
5476F	Vildagliptin with Metformin , Tablet containing 50 mg vildagliptin with 1000 mg metformin hydrochloride (<i>Galvumet 50/1000</i>)
9388D	Zonisamide , Capsule 25 mg (<i>Zonegran</i>)
9389E	Zonisamide , Capsule 50 mg (<i>Zonegran</i>)
9390F	Zonisamide , Capsule 100 mg (<i>Zonegran</i>)

Additions – Brands

1081X	<i>Atenolol generichealth, GQ</i> – Atenolol , Tablet 50 mg
8858F	<i>DBL Epirubicin Hydrochloride Injection, HH</i> – Epirubicin Hydrochloride , Solution for injection 200 mg in 100 mL
8559L	<i>Pharmacor Gabapentin 600, CR</i> – Gabapentin , Tablet 600 mg
8389M	<i>Pharmacor Gabapentin 800, CR</i> – Gabapentin , Tablet 800 mg
8530Y	<i>Idarubicin Ebewe, IT</i> – Idarubicin Hydrochloride , Solution for I.V. injection 5 mg in 5 mL
8531B	<i>Idarubicin Ebewe, IT</i> – Idarubicin Hydrochloride , Solution for I.V. injection 10 mg in 10 mL
2591J	<i>Rocta 10, SI</i> – Isotretinoin , Capsule 10 mg
2592K	<i>Rocta 20, SI</i> – Isotretinoin , Capsule 20 mg
3010K	<i>Norfloxacin Sandoz, SZ</i> – Norfloxacin , Tablet 400 mg
8694N	<i>Acpio 15, SI; APOTEX-Pioglitazone, TX; Chem mart Pioglitazone, CH; Pharmacor Pioglitazone 15, CR; Pioglitazone generichealth 15, GQ; Pizaccord, MI; Terry White Chemists Pioglitazone, TW</i> – Pioglitazone , Tablet 15 mg (as hydrochloride)
8695P	<i>Acpio 30, SI; APOTEX-Pioglitazone, TX; Chem mart Pioglitazone, CH; Pharmacor Pioglitazone 30, CR; Pioglitazone generichealth 30, GQ; Pizaccord, MI; Terry White Chemists Pioglitazone, TW</i> – Pioglitazone , Tablet 30 mg (as hydrochloride)
8696Q	<i>Acpio 45, SI; APOTEX-Pioglitazone, TX; Chem mart Pioglitazone, CH; Pharmacor Pioglitazone 45, CR; Pioglitazone generichealth 45, GQ; Pizaccord, MI; Terry White Chemists Pioglitazone, TW</i> – Pioglitazone , Tablet 45 mg (as hydrochloride)

8621R	<i>APO-Risedronate, TX; Chem mart Risedronate, CH; Terry White Chemists Risedronate, TW – Risedronate Sodium, Tablet 35 mg</i>
2236Q	<i>Sertraline-DRLA, RZ – Sertraline, Tablet 50 mg (as hydrochloride)</i>
2237R	<i>Sertraline-DRLA, RZ – Sertraline, Tablet 100 mg (as hydrochloride)</i>
8064K	<i>APO-Valaciclovir, TX; Chem mart Valaciclovir, CH; Terry White Chemists Valaciclovir, TW; Vaclovir, AF; Valaciclovir GA, GM; Valaciclovir RBX, RA; Valaciclovir Sandoz, SZ; Valnir, SI – Valaciclovir, Tablet 500 mg (as hydrochloride)</i>
8133C	<i>APO-Valaciclovir, TX; Chem mart Valaciclovir, CH; Terry White Chemists Valaciclovir, TW; Vaclovir, AF; Valaciclovir GA, GM; Valaciclovir Sandoz, SZ; Valnir, SI – Valaciclovir, Tablet 500 mg (as hydrochloride)</i>
8134D	<i>APO-Valaciclovir, TX; Chem mart Valaciclovir, CH; Terry White Chemists Valaciclovir, TW; Vaclovir, AF; Valaciclovir GA, GM; Valaciclovir RBX, RA; Valaciclovir Sandoz, SZ; Valaciclovir SZ, HX; Valnir, SI – Valaciclovir, Tablet 500 mg (as hydrochloride)</i>

Additions – Bioequivalence Indicators

8858F	<i>Epirubicin Ebewe, IT – Epirubicin Hydrochloride, Solution for injection 200 mg in 100 mL</i>
8530Y	<i>Zavedos Solution, PF – Idarubicin Hydrochloride, Solution for I.V. injection 5 mg in 5 mL</i>
8531B	<i>Zavedos Solution, PF – Idarubicin Hydrochloride, Solution for I.V. injection 10 mg in 10 mL</i>
8694N	<i>Actos, LY – Pioglitazone, Tablet 15 mg (as hydrochloride)</i>
8695P	<i>Actos, LY – Pioglitazone, Tablet 30 mg (as hydrochloride)</i>
8696Q	<i>Actos, LY – Pioglitazone, Tablet 45 mg (as hydrochloride)</i>
8621R	<i>Actonel Once-a-Week, SW – Risedronate Sodium, Tablet 35 mg</i>

Additions – PBS Authority Required Therapeutic Group Premium Exemption Codes

A therapeutic group premium applies to **Candesartan Cilexetil**, tablet 8 mg (*Atacand*), tablet 16 mg (*Atacand*) and tablet 32 mg.

The following codes were established to provide for cases where an authority has been obtained that grants exemption from the therapeutic group premium:

8997M	Candesartan , Tablet 8 mg (<i>Atacand</i>)
8998N	Candesartan , Tablet 16 mg (<i>Atacand</i>)
8999P	Candesartan , Tablet 32 mg (<i>Atacand</i>)

Deletions

Deletions – Items

1350C	Dydrogesterone , Tablet 10 mg (<i>Duphaston</i>)
2255Q	Flupenthixol Decanoate , Oily I.M. injection 20 mg in 1 mL (<i>Fluanxol Depot</i>)
2256R	Flupenthixol Decanoate , Oily I.M. injection 40 mg in 2 mL (<i>Fluanxol Depot</i>)
2917M	Glucose Indicator—blood , Test strips, 50 (<i>Glucostix</i>)
9280K	Glucose Indicator—blood , Test strips, 50 (<i>Glucostix</i>) (Diff. Max. Rpts)
2772X	Norethisterone with Ethinyloestradiol , Tablets 500 micrograms-35 micrograms, 21 (<i>Brevinor</i>)
2773Y	Norethisterone with Ethinyloestradiol , Tablets 1 mg-35 micrograms, 21 (<i>Brevinor-1</i>)
8556H	Pancreatic Extract , Capsule (containing enteric coated minimicrospheres) providing not less than 5,000 BP units of lipase activity (<i>Creon 5000</i>)
9225M	Pancreatic Extract , Capsule (containing enteric coated minimicrospheres) providing not less than 5,000 BP units of lipase activity (<i>Creon 5000</i>) (Diff. Max. Rpts)

Deletions – Brands

2751T	<i>Perivasc, AL – Amlodipine, Tablet 5 mg (as besylate)</i>
2752W	<i>Perivasc, AL – Amlodipine, Tablet 10 mg (as besylate)</i>

1368B	<i>Alphapril, AF – Enalapril Maleate</i> , Tablet 10 mg
1369C	<i>Alphapril, AF – Enalapril Maleate</i> , Tablet 20 mg
1370D	<i>Alphapril, AF – Enalapril Maleate</i> , Tablet 5 mg
1835N	<i>Douglas Gabapentin 400mg, GN – Gabapentin</i> , Capsule 400 mg
2881P	<i>Cortef, VT – Hydrocortisone</i> , Cream 10 mg per g (1%), 50 g
5113D	<i>Cortef, VT – Hydrocortisone</i> , Cream 10 mg per g (1%), 50 g (Dental)
1761Q	<i>Protaphane NovoLet 3 mL, NL – Insulin Isophane (N.P.H.)</i> , Injections (human) 100 units per mL, 3 mL, 5
8097E	Zuclopenthixol Decanoate , Oily I.M. injection 200 mg in 1 mL (<i>Clopixol Depot</i>)

Deletions – Notes

2774B	Norethisterone with Ethinyloestradiol , Pack containing 21 tablets 500 micrograms-35 micrograms and 7 inert tablets (<i>Brevinor, Norimin 28 Day</i>)
2775C	Norethisterone with Ethinyloestradiol , Pack containing 21 tablets 1 mg-35 micrograms and 7 inert tablets (<i>Brevinor-1, Norimin-1 28 Day</i>)

Alterations

Alterations – Manufacturer's Code

		From:	To:
5333Q	Carmellose Sodium , Mouth spray 10 mg per mL, 25 mL (<i>Aquae</i>) (Palliative Care) (Diff. Max. Rpts)	HA	VT
5334R	Carmellose Sodium , Mouth spray 10 mg per mL, 100 mL (<i>Aquae</i>) (Palliative Care) (Diff. Max. Rpts)	HA	VT
5335T	Carmellose Sodium , Mouth spray 10 mg per mL, 25 mL (<i>Aquae</i>) (Palliative Care)	HA	VT
5336W	Carmellose Sodium , Mouth spray 10 mg per mL, 100 mL (<i>Aquae</i>) (Palliative Care)	HA	VT
3138E	Clindamycin , Capsule 150 mg (<i>Cleocin</i>)	KR	FZ
5057E	Clindamycin , Capsule 150 mg (<i>Cleocin</i>) (Dental)	KR	FZ
1834M	Gabapentin , Capsule 300 mg (<i>Gantin</i>)	AW	GN
1835N	Gabapentin , Capsule 400 mg (<i>Gantin</i>)	AW	GN
8389M	Gabapentin , Tablet 800 mg (<i>Gantin</i>)	AW	GN
2321E	Medroxyprogesterone Acetate , Tablet 10 mg (<i>Ralovera</i>)	KR	FZ
2323G	Medroxyprogesterone Acetate , Tablet 5 mg (<i>Ralovera</i>)	KR	FZ
2722G	Medroxyprogesterone Acetate , Tablet 10 mg (<i>Ralovera</i>)	KR	FZ
3118D	Medroxyprogesterone Acetate , Injection 150 mg in 1 mL (<i>Depo-Ralovera</i>)	KR	FZ
1928L	Methylprednisolone Acetate , Injection 40 mg in 1 mL (<i>Depo-Nisolone</i>)	KR	FZ
5148Y	Methylprednisolone Acetate , Injection 40 mg in 1 mL (<i>Depo-Nisolone</i>) (Dental)	KR	FZ
1900B	Moclobemide , Tablet 150 mg (<i>Aurorix</i>)	RO	VP
8003F	Moclobemide , Tablet 300 mg (<i>Aurorix 300 mg</i>)	RO	VP
1967M	Norethisterone , Tablets 350 micrograms, 28 (<i>Locilan 28 Day</i>)	KR	FZ
2774B	Norethisterone with Ethinyloestradiol , Pack containing 21 tablets 500 micrograms-35 micrograms and 7 inert tablets (<i>Norimin 28 Day</i>)	KR	FZ
2776D	Norethisterone with Ethinyloestradiol Pack containing 12 tablets 500 micrograms-35 micrograms, 9 tablets 1 mg-35 micrograms and 7 inert tablets (<i>Improvil 28 Day</i>)	KR	FZ
2775C	Norethisterone with Ethinyloestradiol , Pack containing 21 tablets 1 mg-35 micrograms and 7	KR	FZ

inert tablets (*Norimin-1 28 Day*)

3010K	Norfloxacin , Tablet 400 mg (<i>Norflohexal</i>)	SZ	HX
2096H	Sulfasalazine , Tablet 500 mg (enteric coated) (<i>Pyralin EN</i>)	KR	FZ
9209Q	Sulfasalazine , Tablet 500 mg (enteric coated) (<i>Pyralin EN</i>)	KR	FZ
1465D	Tinidazole , Tablet 500 mg (<i>Simplotan</i>)	GP	FZ

Alterations – Maximum Quantity

		From:	To:
8681X	Oxycodone Hydrochloride , Tablet 5 mg (controlled release) (<i>OxyContin</i>)	20	28
5227D	Oxycodone Hydrochloride , Tablet 5 mg (controlled release) (<i>OxyContin</i>) (Dental)	20	28
8385H	Oxycodone Hydrochloride , Tablet 10 mg (controlled release) (<i>OxyContin</i>)	20	28
5247E	Oxycodone Hydrochloride , Tablet 10 mg (controlled release) (<i>OxyContin</i>) (Dental)	20	28
9399Q	Oxycodone Hydrochloride , Tablet 15 mg (controlled release) (<i>OxyContin</i>)	20	28
5015Y	Oxycodone Hydrochloride , Tablet 15 mg (controlled release) (<i>OxyContin</i>) (Dental)	20	28
8386J	Oxycodone Hydrochloride , Tablet 20 mg (controlled release) (<i>OxyContin</i>)	20	28
5248F	Oxycodone Hydrochloride , Tablet 20 mg (controlled release) (<i>OxyContin</i>) (Dental)	20	28
9400R	Oxycodone Hydrochloride , Tablet 30 mg (controlled release) (<i>OxyContin</i>)	20	28
5016B	Oxycodone Hydrochloride , Tablet 30 mg (controlled release) (<i>OxyContin</i>) (Dental)	20	28
8387K	Oxycodone Hydrochloride , Tablet 40 mg (controlled release) (<i>OxyContin</i>)	20	28
5249G	Oxycodone Hydrochloride , Tablet 40 mg (controlled release) (<i>OxyContin</i>) (Dental)	20	28
8388L	Oxycodone Hydrochloride , Tablet 80 mg (controlled release) (<i>OxyContin</i>)	20	28
5250H	Oxycodone Hydrochloride , Tablet 80 mg (controlled release) (<i>OxyContin</i>) (Dental)	20	28

Alterations – Restrictions

1208N	Ciprofloxacin , Tablet 250 mg (<i>C-Flox 250, Cifran, Ciprofloxacin-DRLA, Ciprofloxacin Sandoz, Ciprol 250, Ciproxin 250, GenRx Ciprofloxacin, Profloxin</i>)
1209P	Ciprofloxacin , Tablet 500 mg (<i>Ascent Pharmaceuticals Limited, C-Flox 500, Cifran, Ciprofloxacin 500, Ciprofloxacin-BW, Ciprofloxacin-DRLA, Ciprofloxacin-GA, Ciprofloxacin Sandoz, Ciprol 500, Ciproxin 500, GenRx Ciprofloxacin</i>)
1210Q	Ciprofloxacin , Tablet 750 mg (<i>Ascent Pharmaceuticals Limited, C-Flox 750, Cifran, Ciprofloxacin 750, Ciprofloxacin-BW, Ciprofloxacin-DRLA, Ciprofloxacin-GA, Ciprofloxacin Sandoz, Ciprol 750, Ciproxin 750, GenRx Ciprofloxacin</i>)
8134D	Valaciclovir , Tablet 500 mg (as hydrochloride) (<i>APO-Valaciclovir, Chem mart Valaciclovir, Terry White Chemists Valaciclovir, Vaclovir, Valaciclovir GA, Valaciclovir RBX, Valaciclovir Sandoz, Valaciclovir SZ, Valnir, Valtrex, Zelitrex</i>)

SECTION 100 – HIGHLY SPECIALISED DRUGS PROGRAM

Additions

Additions – Items

9692D	Filgrastim , Injection 300 micrograms in 0.5 mL single use pre-filled syringe (<i>Nivestim</i>) (Public)
9693E	Filgrastim , Injection 300 micrograms in 0.5 mL single use pre-filled syringe (<i>Nivestim</i>) (Private)
9694F	Filgrastim , Injection 480 micrograms in 0.5 mL single use pre-filled syringe (<i>Nivestim</i>) (Public)
9695G	Filgrastim , Injection 480 micrograms in 0.5 mL single use pre-filled syringe (<i>Nivestim</i>) (Private)
9696H	Romiplostim , Powder for injection 375 micrograms (250 micrograms in 0.5 mL when reconstituted) (<i>Nplate</i>) (Public)

9697J **Romiplostim**, Powder for injection 375 micrograms (250 micrograms in 0.5 mL when reconstituted) (*Nplate*) **(Private)**

9698K **Romiplostim**, Powder for injection 625 micrograms (500 micrograms in 1 mL when reconstituted) (*Nplate*) **(Public)**

9699L **Romiplostim**, Powder for injection 625 micrograms (500 micrograms in 1 mL when reconstituted) (*Nplate*) **(Private)**

Additions – Brands

6280M *APO-Valaciclovir, TX* – **Valaciclovir**, Tablet 500 mg (as hydrochloride) **(Private)**

9568N *APO-Valaciclovir, TX* – **Valaciclovir**, Tablet 500 mg (as hydrochloride) **(Public)**

Additions – Bioequivalence Indicators

6280M *Valtrex, GK* – **Valaciclovir**, Tablet 500 mg (as hydrochloride) **(Private)**

9568N *Valtrex, GK* – **Valaciclovir**, Tablet 500 mg (as hydrochloride) **(Public)**

Additions – Notes

9654D **Infliximab**, Powder for I.V. infusion 100 mg (*Remicade*) **(Public)**

9674E **Infliximab**, Powder for I.V. infusion 100 mg (*Remicade*) **(Private)**

Deletions

Deletions – Items

9551Q **Sitaxentan Sodium**, Tablet 100 mg (*Thelin*) **(Public)**

9622K **Sitaxentan Sodium**, Tablet 100 mg (*Thelin*) **(Private)**

Alterations

Alterations – Restrictions

9654D **Infliximab**, Powder for I.V. infusion 100 mg (*Remicade*) **(Public)**

9674E **Infliximab**, Powder for I.V. infusion 100 mg (*Remicade*) **(Private)**

Alterations – Notes

5618Q **Bosentan Monohydrate**, Tablet 62.5 mg (base) (*Tracleer*) **(Public)**

6429J **Bosentan Monohydrate**, Tablet 62.5 mg (base) (*Tracleer*) **(Private)**

5619R **Bosentan Monohydrate**, Tablet 125 mg (base) (*Tracleer*) **(Public)**

6430K **Bosentan Monohydrate**, Tablet 125 mg (base) (*Tracleer*) **(Private)**

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

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

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

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

5751Q **Iloprost**, Solution for inhalation 20 micrograms (base) in 2 mL (*Ventavis*) **(Public)**

6456T **Iloprost**, Solution for inhalation 20 micrograms (base) in 2 mL (*Ventavis*) **(Private)**

9547L **Sildenafil**, Tablet 20 mg (base) (*Revatio*) **(Public)**

9605M **Sildenafil**, Tablet 20 mg (base) (*Revatio*) **(Private)**

Alterations – Restriction and Note

5607D **Ambrisentan**, Tablet 5 mg (*Volibris*) **(Public)**

5608E **Ambrisentan**, Tablet 10 mg (*Volibris*) **(Public)**

9648T **Ambrisentan**, Tablet 5 mg (*Volibris*) **(Private)**

9649W **Ambrisentan**, Tablet 10 mg (*Volibris*) **(Private)**

ADVANCE NOTICES DELETIONS

Advance Notice – Deletion of Items

The following items will be deleted from the Schedule of Pharmaceutical Benefits on 1 June 2011:
Items discontinued by the manufacturer—

2059J **Memantine Hydrochloride**, Oral drops 10 mg per g, 50 g (*Ebixa*)

Advance Notice — Deletion of Brands

The following brands will be deleted from the Schedule of Pharmaceutical Benefits on 1 May 2011:
Brands discontinued by the manufacturer—

2132F *Alprazolam-GA, GN* — **Alprazolam**, Tablet 1 mg

8118G *Alprazolam-GA, GN* — **Alprazolam**, Tablet 2 mg

8202Q *DBL Aspirin 100 mg, GY* — **Aspirin**, Tablet 100 mg

2457H *Lisinopril Hexal, HX* — **Lisinopril**, Tablet 10 mg

The following brands will be deleted from the Schedule of Pharmaceutical Benefits on 1 July 2011:
Brand deletion requested by the manufacturer—

1358L *Prothiaden, AB* — **Dothiepin Hydrochloride**, Tablet 75 mg

Brand discontinued by the manufacturer—

3010K *Norflohexal, HX* — **Norfloxacin**, Tablet 400 mg

SUMMARY OF CHANGES – REPATRIATION PHARMACEUTICAL BENEFITS SCHEME

Deletions

Deletions – Brands

4592Q	<i>Douglas Gabapentin 300mg, GN</i> – Gabapentin , Capsule 300 mg
4593R	<i>Douglas Gabapentin 400mg, GN</i> – Gabapentin , Capsule 400 mg

Alterations

Alterations – Manufacturer's Code

		From:	To:
4568K	Carmellose Sodium , Mouth spray 10 mg per mL, 25 mL (<i>Aquae</i>)	HA	VT
4569L	Carmellose Sodium , Mouth spray 10 mg per mL, 100 mL (<i>Aquae</i>)	HA	VT
4592Q	Gabapentin , Capsule 300 mg (<i>Gantin</i>)	AW	GN
4593R	Gabapentin , Capsule 400 mg (<i>Gantin</i>)	AW	GN
4595W	Gabapentin , Tablet 800 mg (<i>Gantin</i>)	AW	GN

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 \$	

ADALIMUMAB

Note:

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

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe adalimumab should be forwarded to:

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

TREATMENT OF COMPLEX REFRACTORY FISTULISING CROHN DISEASE

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab and infliximab for patients with complex refractory fistulising Crohn disease. Where the term 'tumour necrosis factor (TNF) alfa antagonist' appears in the following NOTES and restrictions, it refers to adalimumab and infliximab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 2 TNF-alfa antagonists at any 1 time.

From 1 April 2011, under the PBS, all patients will be able to commence a treatment cycle where they may trial each PBS-subsidised TNF-alfa antagonist without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a TNF-alfa antagonist while they continue to show a response to therapy.

A patient who received PBS-subsidised TNF-alfa antagonist treatment prior to 1 April 2011 is considered to be in their first cycle as of 1 April 2011.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised TNF-alfa antagonist more than twice.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised TNF-alfa antagonist therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised TNF-alfa antagonist treatment in the most recent cycle to the date of the first application for initial treatment with a TNF-alfa antagonist under the new treatment cycle.

A patient who has failed fewer than 3 trials of TNF-alfa antagonists in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of TNF-alfa antagonists in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised TNF-alfa antagonist therapy after 1 April 2011.

(a) Initial treatment.

Applications for initial treatment should be made where:

- (i) a patient has received no prior PBS-subsidised TNF-alfa antagonist treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
- (ii) a patient has received prior PBS-subsidised (initial or continuing) TNF-alfa antagonist therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
- (iii) a patient wishes to re-commence treatment with a specific TNF-alfa antagonist following a break in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and 14 weeks of therapy for infliximab.

From 1 April 2011, a patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.

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
					\$	\$	

For second and subsequent courses of PBS-subsidised TNF-alfa antagonist treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

Adalimumab only: Two completed authority prescriptions must be submitted with every initial application for adalimumab. One prescription must be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats. The second prescription must be written for 2 doses of 40 mg and 2 repeats.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific TNF-alfa antagonist, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing TNF-alfa antagonist treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted TNF-alfa antagonist supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised TNF-alfa antagonist is approved, a patient may swap if eligible to the alternate TNF-alfa antagonist within the same treatment cycle.

A patient may trial the alternate TNF-alfa antagonist at any time, regardless of whether they are receiving therapy (initial or continuing) with a TNF-alfa antagonist at the time of the application. However, they cannot swap to a particular TNF-alfa antagonist if they have failed to respond to prior treatment with that drug two times within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to the alternate TNF-alfa antagonist should be accompanied by the approved authority prescription or remaining repeats for the TNF-alfa antagonist the patient is ceasing.

(3) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements submitted with the first authority application for a TNF-alfa antagonist. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and Medicare Australia will assess response according to these revised baseline measurements.

(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised TNF-alfa antagonist therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity.

(5) Patients 'grandfathered' onto PBS-subsidised treatment with adalimumab or infliximab.

A patient who commenced treatment with adalimumab for complex refractory fistulising Crohn disease prior to 4 November 2010 or infliximab prior to 10 March 2010 and who continues to receive treatment at the time of application, may qualify for treatment under the initial 'grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment with adalimumab or infliximab will be authorised under this criterion.

Following completion of the initial PBS-subsidised course, further applications for treatment with adalimumab or infliximab will be assessed under the continuing treatment restriction.

'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must requalify for initial treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' above for further details.

Authority required

Initial 1

Initial treatment of complex refractory FISTULISING CROHN DISEASE.

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
					\$	\$	

Initial PBS-subsidised treatment with adalimumab by a gastroenterologist or a consultant physician as specified in the NOTE below, of a patient with complex refractory fistulising Crohn disease who:

- (a) has confirmed Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician as specified in the NOTE below; and
- (b) has an externally draining enterocutaneous or rectovaginal fistula; and
- (c) has signed a patient acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criteria for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

Authority applications must be made in writing and must include:

- (a) two completed authority prescription forms; and
- (b) a completed Fistulising Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
 - (i) a completed current Fistula Assessment Form including the date of assessment of the patient's condition; and
 - (ii) a signed patient acknowledgement.

The most recent fistula assessment must be no more than 1 month old at the time of application.

A maximum of 16 weeks treatment will be authorised under this criterion.

Two completed authority prescriptions must be submitted with every initial application for adalimumab. One prescription must be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats. The second prescription must be written for 2 doses of 40 mg and 2 repeats. Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment with adalimumab 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). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

An assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of therapy so that there is adequate time for a response to be demonstrated.

This assessment must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with adalimumab.

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised adalimumab treatment.

Authority required

Initial 2

Change or re-commencement of treatment of complex refractory FISTULISING CROHN DISEASE.

Initial PBS-subsidised treatment with adalimumab of complex refractory fistulising Crohn disease by a gastroenterologist or a consultant physician as specified in the NOTE below, of a patient with complex refractory fistulising Crohn disease who:

- (a) has a documented history of complex refractory fistulising Crohn disease; and
- (b) in this treatment cycle, has received prior PBS-subsidised treatment with adalimumab or infliximab for a draining enterocutaneous or rectovaginal fistula; and
- (c) has not failed PBS-subsidised therapy with adalimumab for this condition more than once in the current treatment cycle.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

To demonstrate a response to treatment the application must be accompanied by the results of the most recent course of TNF-alfa antagonist therapy within the time frames specified in the relevant restriction.

Where the most recent course of PBS-subsidised TNF-alfa antagonist treatment was approved under an initial treatment restriction, the patient must have been assessed for response to that course following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

If the response assessment to the previous course of TNF-alfa antagonist treatment is not submitted as detailed above, the patient will be deemed to have failed therapy with that particular course of TNF-alfa antagonist.

Authority applications must be made in writing and must include:

- (a) two completed authority prescription forms; and
- (b) a completed Fistulising Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
 - (i) a completed current Fistula Assessment Form including the date of assessment of the patient's condition; and
 - (ii) details of prior TNF-alfa antagonist treatment including details of date and duration of treatment.

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
					\$	\$	

The most recent fistula assessment must be no more than 1 month old at the time of application.

A maximum of 16 weeks treatment will be authorised under this criterion.

Two completed authority prescriptions must be submitted with every initial application for adalimumab. One prescription must be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats. The second prescription must be written for 2 doses of 40 mg and 2 repeats. Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment with adalimumab 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). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

An assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of therapy so that there is adequate time for a response to be demonstrated.

This assessment must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with adalimumab.

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised adalimumab treatment.

Note:

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

8961P	Injection 40 mg in 0.8 mL pre-filled syringe, 6	1	..		5036.36	34.20	Humira	AB
8962Q	Injection 40 mg in 0.8 mL pre-filled pen, 6	1	..		5036.36	34.20	Humira	AB
8963R	Injection 40 mg in 0.8 mL pre-filled syringe	2	2		1774.36	34.20	Humira	AB
8965W	Injection 40 mg in 0.8 mL pre-filled pen	2	2		1774.36	34.20	Humira	AB

ADALIMUMAB

Note:

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

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe adalimumab should be forwarded to:

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

TREATMENT OF COMPLEX REFRACTORY FISTULISING CROHN DISEASE

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab and infliximab for patients with complex refractory fistulising Crohn disease. Where the term 'tumour necrosis factor (TNF) alfa antagonist' appears in the following NOTES and restrictions, it refers to adalimumab and infliximab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 2 TNF-alfa antagonists at any 1 time.

From 1 April 2011, under the PBS, all patients will be able to commence a treatment cycle where they may trial each PBS-subsidised TNF-alfa antagonist without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a TNF-alfa antagonist while they continue to show a response to therapy.

A patient who received PBS-subsidised TNF-alfa antagonist treatment prior to 1 April 2011 is considered to be in their first cycle as of 1 April 2011.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised TNF-alfa antagonist more than twice.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must

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
					\$	\$	

have, at a minimum, a 5-year break in PBS-subsidised TNF-alfa antagonist therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised TNF-alfa antagonist treatment in the most recent cycle to the date of the first application for initial treatment with a TNF-alfa antagonist under the new treatment cycle.

A patient who has failed fewer than 3 trials of TNF-alfa antagonists in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of TNF-alfa antagonists in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised TNF-alfa antagonist therapy after 1 April 2011.

(a) Initial treatment.

Applications for initial treatment should be made where:

- (i) a patient has received no prior PBS-subsidised TNF-alfa antagonist treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
- (ii) a patient has received prior PBS-subsidised (initial or continuing) TNF-alfa antagonist therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
- (iii) a patient wishes to re-commence treatment with a specific TNF-alfa antagonist following a break in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and 14 weeks of therapy for infliximab.

From 1 April 2011, a patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.

For second and subsequent courses of PBS-subsidised TNF-alfa antagonist treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

Adalimumab only: Two completed authority prescriptions must be submitted with every initial application for adalimumab. One prescription must be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats. The second prescription must be written for 2 doses of 40 mg and 2 repeats.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific TNF-alfa antagonist, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing TNF-alfa antagonist treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted TNF-alfa antagonist supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised TNF-alfa antagonist is approved, a patient may swap if eligible to the alternate TNF-alfa antagonist within the same treatment cycle.

A patient may trial the alternate TNF-alfa antagonist at any time, regardless of whether they are receiving therapy (initial or continuing) with a TNF-alfa antagonist at the time of the application. However, they cannot swap to a particular TNF-alfa antagonist if they have failed to respond to prior treatment with that drug two times within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to the alternate TNF-alfa antagonist should be accompanied by the approved authority prescription or remaining repeats for the TNF-alfa antagonist the patient is ceasing.

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
					\$	\$	

(3) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements submitted with the first authority application for a TNF-alfa antagonist. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and Medicare Australia will assess response according to these revised baseline measurements.

(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised TNF-alfa antagonist therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity.

(5) Patients 'grandfathered' onto PBS-subsidised treatment with adalimumab or infliximab.

A patient who commenced treatment with adalimumab for complex refractory fistulising Crohn disease prior to 4 November 2010 or infliximab prior to 10 March 2010 and who continues to receive treatment at the time of application, may qualify for treatment under the initial 'grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment with adalimumab or infliximab will be authorised under this criterion.

Following completion of the initial PBS-subsidised course, further applications for treatment with adalimumab or infliximab will be assessed under the continuing treatment restriction.

'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must requalify for initial treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' above for further details.

Authority required

Initial 3 (grandfather)

Initial PBS-subsidised treatment of complex refractory FISTULISING CROHN DISEASE in a patient who has previously received non-PBS-subsidised therapy with adalimumab.

Initial PBS-subsidised supply for continuing treatment with adalimumab by a gastroenterologist, a consultant physician as specified in the NOTE below, or other consultant physician in consultation with a gastroenterologist of a patient who satisfies the following criteria:

- (a) has a documented history of complex refractory fistulising Crohn disease and was receiving treatment with adalimumab prior to 4 November 2010; and
- (b) had a draining enterocutaneous or rectovaginal fistula(e) prior to commencing treatment with adalimumab; and
- (c) has signed a patient acknowledgement indicating that they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criteria for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and
- (d) is receiving treatment with adalimumab at the time of application; and
- (e) has demonstrated or sustained an adequate response to treatment with adalimumab.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

An adequate response to adalimumab treatment is defined as:

- (a) a decrease from baseline in the number of open draining fistulae of greater than or equal to 50%; and/or
- (b) a marked reduction in drainage of all fistula(e) from baseline, together with less pain and induration as reported by the patient.

Applications for authorisation must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Fistulising Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
 - (i) a completed current and baseline Fistula Assessment form including the date of assessment of the patient's condition; and
 - (ii) a signed patient acknowledgement.

The current fistula assessment must be no more than 1 month old at the time of application.

The baseline fistula assessment must be from immediately prior to commencing treatment with adalimumab.

An assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criteria.

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with adalimumab.

A maximum of 24 weeks treatment will be approved under this criterion.

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
					\$	\$	

Where fewer than 5 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 24 weeks 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).

Patients may qualify for PBS-subsidised treatment under this restriction once only.

Authority required

Continuing treatment of complex refractory FISTULISING CROHN DISEASE.

Continuing PBS-subsidised treatment with adalimumab by a gastroenterologist, a consultant physician as specified in the NOTE below or other consultant physician in consultation with a gastroenterologist, of a patient who:

- (a) has a documented history of complex refractory fistulising Crohn disease; and
- (b) has demonstrated or sustained an adequate response to treatment with adalimumab.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

An adequate response is defined as:

- (a) a decrease from baseline in the number of open draining fistulae of greater than or equal to 50%; and/or
- (b) a marked reduction in drainage of all fistula(e) from baseline, together with less pain and induration as reported by the patient.

Authority applications must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Fistulising Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes a completed Fistula Assessment form including the date of the assessment of the patient's condition.

The fistula assessment must be no more than 1 month old at the time of application.

If the application is the first application for continuing treatment with adalimumab, an assessment of the patient's response must be made following a minimum of 12 weeks after the first dose so that there is adequate time for a response to be demonstrated.

An assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criteria.

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with adalimumab.

Patients are eligible to receive continuing adalimumab treatment in courses of up to 24 weeks providing they continue to sustain the response.

A maximum of 24 weeks treatment will be authorised under this criterion.

Where fewer than 5 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 24 weeks 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).

Note:

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

8964T	Injection 40 mg in 0.8 mL pre-filled syringe	2	5		1774.36	34.20	Humira	AB
8966X	Injection 40 mg in 0.8 mL pre-filled pen	2	5		1774.36	34.20	Humira	AB

ADAPALENE with BENZOYL PEROXIDE

Restricted benefit

Acute treatment, in combination with an oral antibiotic, of severe acne vulgaris.

8954G	Gel 1 mg-25 mg per g (0.1%-2.5%), 30 g	1	1		36.92	34.20	Epiduo	GA
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ADAPALENE with BENZOYL PEROXIDE

Restricted benefit

Maintenance treatment of severe acne vulgaris.

GENERAL PHARMACEUTICAL BENEFITS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
Note 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.								
8955H NP	Gel 1 mg-25 mg per g (0.1%-2.5%), 30 g	±1	3		36.92	34.20	Epiduo	GA
ATENOLOL								
1081X NP	Tablet 50 mg	30	5		9.49	10.56	^a APO-Atenolol	TX
							^a Atenolol-GA	GN
							^a Atenolol generichealth	GQ
							^a Atenolol Sandoz	SZ
							^a Chem mart Atenolol	CH
							^a Noten	AF
							^a Tensig	SI
							^a Terry White Chemists Atenolol	TW
				^B 2.83	12.32	10.56	^a Tenormin	AP
CANDESARTAN CILEXETIL								
Authority required Adverse effects occurring with all of the base-priced drugs; Drug interactions occurring with all of the base-priced drugs; Drug interactions expected to occur with all of the base-priced drugs; Transfer to a base-priced drug would cause patient confusion resulting in problems with compliance.								
8997M NP	Tablet 8 mg	30	5		22.32	23.39	Atacand	AP
8998N NP	Tablet 16 mg	30	5		31.17	32.24	Atacand	AP
8999P NP	Tablet 32 mg	30	5		48.49	34.20	Atacand	AP
CARMELLOSE SODIUM								
Authority required (STREAMLINED) 3636 Initial supply, for up to 4 months, for a palliative care patient where dry mouth is a symptom.								
5333Q NP	Mouth spray 10 mg per mL, 25 mL (Palliative Care)	±1	3		10.79	11.86	Aquae	VT
5334R NP	Mouth spray 10 mg per mL, 100 mL (Palliative Care)	±1	3		12.46	13.53	Aquae	VT
CARMELLOSE SODIUM								
Authority required (STREAMLINED) 3637 Continuing supply for a palliative care patient where dry mouth is a symptom.								
Note Written or telephone authority applications for increased repeats may be approved where consultation with a palliative care specialist or service has occurred.								
5335T NP	Mouth spray 10 mg per mL, 25 mL (Palliative Care)	±1	..		10.79	11.86	Aquae	VT
5336W NP	Mouth spray 10 mg per mL, 100 mL (Palliative Care)	±1	..		12.46	13.53	Aquae	VT

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
CIPROFLOXACIN							
<u>Authority required</u>							
Respiratory tract infection proven or suspected to be caused by Pseudomonas aeruginosa in severely immunocompromised patients;							
Bacterial gastroenteritis in severely immunocompromised patients;							
Treatment of infections proven to be due to Pseudomonas aeruginosa or other gram-negative bacteria resistant to all other oral antimicrobials;							
Treatment of joint and bone infections, epididymo-orchitis, prostatitis or perichondritis of the pinna, suspected or proven to be caused by gram-negative bacteria or gram-positive bacteria resistant to all other appropriate antimicrobials;							
Gonorrhoea.							
1208N	Tablet 250 mg	14	..		25.33	26.40	^a C-Flox 250 AL
NP							^a Cifran RA
							^a Ciprofloxacin-DRLA RZ
							^a Ciprofloxacin Sandoz SZ
							^a Ciprol 250 SI
							^a GenRx Ciprofloxacin GX
							^a Profloxin HX
				^B 1.38	26.71	26.40	^a Ciproxin 250 BN

CIPROFLOXACIN

Authority required

Respiratory tract infection proven or suspected to be caused by *Pseudomonas aeruginosa* in severely immunocompromised patients;

Bacterial gastroenteritis in severely immunocompromised patients;

Treatment of infections proven to be due to *Pseudomonas aeruginosa* or other gram-negative bacteria resistant to all other oral antimicrobials;

Treatment of joint and bone infections, epididymo-orchitis, prostatitis or perichondritis of the pinna, suspected or proven to be caused by gram-negative bacteria or gram-positive bacteria resistant to all other appropriate antimicrobials.

GENERAL PHARMACEUTICAL BENEFITS

					Dispensed Price for Max. Qty	Maximum Recordable Value for Safety Net		
Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	\$	\$	Brand Name and Manufacturer	
1209P NP	Tablet 500 mg	14	..		43.06	34.20	^a Ascent Pharmaceuticals Limited	GN
							^a C-Flox 500	AL
							^a Cifran	RA
							^a Ciprofloxacin 500	CR
							^a Ciprofloxacin-BW	BF
							^a Ciprofloxacin-DRLA	RZ
							^a Ciprofloxacin-GA	GM
							^a Ciprofloxacin Sandoz	SZ
							^a Ciprol 500	SI
							^a GenRx	GX
				^B 1.20	44.26	34.20	^a Ciprofloxacin Ciproxin 500	BN
1210Q NP	Tablet 750 mg	14	..		59.69	34.20	^a Ascent Pharmaceuticals Limited	GN
							^a C-Flox 750	AL
							^a Cifran	RA
							^a Ciprofloxacin 750	CR
							^a Ciprofloxacin-BW	BF
							^a Ciprofloxacin-DRLA	RZ
							^a Ciprofloxacin-GA	GM
							^a Ciprofloxacin Sandoz	SZ
							^a Ciprol 750	SI
							^a GenRx	GX
				^B 1.31	61.00	34.20	^a Ciprofloxacin Ciproxin 750	BN

CLINDAMYCIN

Restricted benefit

Gram-positive coccal infections where these cannot be safely and effectively treated with a penicillin.

3138E NP,MW	Capsule 150 mg	24	..		19.75	20.82 ^a	Cleocin	FZ
				^B 1.37	21.12	20.82 ^a	Dalacin C	PF
5057E	Capsule 150 mg (Dental)	24	..		19.75	20.82 ^a	Cleocin	FZ
				^B 1.37	21.12	20.82 ^a	Dalacin C	PF

EPIRUBICIN HYDROCHLORIDE

8858F	Solution for injection 200 mg in 100 mL	1	..		751.43	34.20 ^a	DBL Epirubicin Hydrochloride Injection Epirubicin Ebewe	HH IT
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GABAPENTIN

Authority required (STREAMLINED)

2664

Treatment of partial epileptic seizures which are not controlled satisfactorily by other anti-epileptic drugs.

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.

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
8559L NP	Tablet 600 mg	100	5	^B 0.95	121.70	34.20	^a	Neurontin PF
					120.75	34.20	^a	Gabaran RA
							^a	Gabatine 600 SI
							^a	GenRx Gabapentin GX
							^a	Pharmacor Gabapentin 600 CR
8389M NP	Tablet 800 mg	100	5	^B 0.94	159.78	34.20	^a	Neurontin PF
					158.84	34.20	^a	Gabaran RA
							^a	Gabatine 800 SI
							^a	Gantin GN
							^a	GenRx Gabapentin GX
							^a	Pharmacor Gabapentin 800 CR
1834M NP	Capsule 300 mg	100	5	^B 0.95	60.18	34.20	^a	Neurontin PF
					59.23	34.20	^a	DBL Gabapentin HH
							^a	Gabapentin 300 CR
							^a	Gabapentin-GA GM
							^a	Gabapentin Sandoz SZ
							^a	Gabatine 300 SI
							^a	Gantin GN
							^a	GenRx Gabapentin GX
							^a	Nupentin 300 AF
1835N NP	Capsule 400 mg	100	5	^B 0.96	79.41	34.20	^a	Neurontin PF
					78.45	34.20	^a	DBL Gabapentin HH
							^a	Gabapentin 400 CR
							^a	Gabapentin Sandoz SZ
							^a	Gabatine 400 SI
							^a	Gantin GN
							^a	GenRx Gabapentin GX
							^a	Nupentin 400 AF

IDARUBICIN HYDROCHLORIDE

Restricted benefit

Acute myelogenous leukaemia.

8530Y	Solution for I.V. injection 5 mg in 5 mL	3	..		478.89	34.20	^a	Zavedos Solution PF
					*478.89	34.20	^a	Idarubicin Ebewe IT
8531B	Solution for I.V. injection 10 mg in 10 mL	6	..		*1778.40	34.20	^a	Idarubicin Ebewe IT
					1778.41	34.20	^a	Zavedos Solution PF

ISOTRETINOIN

Note

This drug causes birth defects. Isotretinoin has been reported to cause other frequent and potentially serious toxicity.

Note

Care must be taken to comply with the provisions of State/Territory law when prescribing isotretinoin.

Authority required (STREAMLINED)

1354

Severe cystic acne not responsive to other therapy.

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	
2591J	Capsule 10 mg	60	3		76.09	34.20	^a Oratane	GM
							^a Roaccutane	RO
							^a Rocta 10	SI
2592K	Capsule 20 mg	60	3		115.02	34.20	^a GenRx Isotretinoin	GX
							^a Oratane	GM
							^a Rocta 20	SI
				^B 1.88	116.90	34.20	^a Roaccutane	RO

MEDROXYPROGESTERONE ACETATE

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.

2321E NP	Tablet 10 mg	30	2		15.30	16.37	^a Medroxyhexal	SZ
							^a Ralovera	FZ
				^B 1.64	16.94	16.37	^a Provera	PF
2323G NP	Tablet 5 mg	56	2		14.69	15.76	^a Ralovera	FZ
				^B 1.64	16.33	15.76	^a Provera	PF

MEDROXYPROGESTERONE ACETATE

3118D NP	Injection 150 mg in 1 mL	1	1		21.29	22.36	^a Depo-Ralovera	FZ
				^B 3.20	24.49	22.36	^a Depo-Provera	PF

MEDROXYPROGESTERONE ACETATE

Restricted benefit

Endometriosis.

2722G	Tablet 10 mg	100	2		30.70	31.77	^a Ralovera	FZ
				^B 1.53	32.23	31.77	^a Provera	PF

METHYLPREDNISOLONE ACETATE

Restricted benefit

For local intra-articular or peri-articular infiltration.

1928L NP	Injection 40 mg in 1 mL	5	..	^B 0.72	24.95	25.30	^a Depo-Medrol	PF
					24.23	25.30	^a Depo-Nisolone	FZ
5148Y	Injection 40 mg in 1 mL (Dental)	5	..	^B 0.72	24.95	25.30	^a Depo-Medrol	PF
					24.23	25.30	^a Depo-Nisolone	FZ

MOCLOBEMIDE

Restricted benefit

Major depressive disorders.

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.

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	
1900B NP	Tablet 150 mg	60	5	^B 0.69	18.83	19.21	^a	Aurorix	VP
					18.14	19.21	^a	Amira 150	AF
							^a	Chem mart	CH
							^a	Moclobemide	
							^a	Clobemix	GM
							^a	GenRx	GX
							^a	Moclobemide	
							^a	Moclobemide	SZ
							^a	Sandoz	
							^a	Mohexal	HX
							^a	Terry White Chemists	TW
							^a	Moclobemide	
8003F NP	Tablet 300 mg	60	5		28.99	30.06	^a	Amira 300	AF
							^a	Chem mart	CH
							^a	Moclobemide	
							^a	Clobemix	GM
							^a	GenRx	GX
							^a	Moclobemide	
							^a	Moclobemide	SZ
							^a	Sandoz	
							^a	Terry White Chemists	TW
							^a	Moclobemide	
				^B 1.37	30.36	30.06	^a	Aurorix 300 mg	VP
NORETHISTERONE									
1967M NP	Tablets 350 micrograms, 28	4	2		*16.46	17.53	^a	Locilan 28 Day	FZ
								Micronor	JC
				^B 3.88	*20.34	17.53	^a	Noriday 28 Day	PF
NORETHISTERONE with ETHINYLOESTRADIOL									
2774B NP	Pack containing 21 tablets 500 micrograms- 35 micrograms and 7 inert tablets	4	2		*16.46	17.53	^a	Norimin 28 Day	FZ
				^B 7.68	*24.14	17.53	^a	Brevinor	PF
2776D NP	Pack containing 12 tablets 500 micrograms- 35 micrograms, 9 tablets 1 mg-35 micrograms and 7 inert tablets	4	2		*16.46	17.53	^a	Improvil 28 Day	FZ
				^B 7.68	*24.14	17.53	^a	Synphasic	PF
2775C NP	Pack containing 21 tablets 1 mg-35 micrograms and 7 inert tablets	4	2		*16.46	17.53	^a	Norimin-1 28 Day	FZ
				^B 7.68	*24.14	17.53	^a	Brevinor-1	PF

NORFLOXACIN

Authority required

Acute bacterial enterocolitis;

Complicated urinary tract infection.

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	
3010K NP	Tablet 400 mg	14	1		17.16	18.23	^a Chem mart	CH
							^a Norfloxacin	
							^a GenRx Norfloxacin	GX
							^a Norflohexal	HX
							^a Norfloxacin-GA	GM
							^a Norfloxacin Sandoz	SZ
							^a Nufloxib	AF
							^a Roxin	SI
							^a Terry White Chemists	TW
							^a Norfloxacin	
				^B 3.91	21.07	18.23	^a Noroxin	MK

OLANZAPINE

Authority required (STREAMLINED)

1589

Schizophrenia;

2044

Maintenance treatment of bipolar I disorder.

Note

Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

8952E NP	Wafer 15 mg	28	5		280.22	34.20	Zyprexa Zydys	LY
8953F NP	Wafer 20 mg	28	5		365.47	34.20	Zyprexa Zydys	LY

OXYCODONE HYDROCHLORIDE

Note

The risk of drug dependence is high.

Restricted benefit

Chronic severe disabling pain not responding to non-narcotic analgesics.

Note

Authorities for increased maximum quantities and/or repeats will be granted only for:

(i) chronic severe disabling pain associated with proven malignant neoplasia; or

(ii) chronic severe disabling pain not responding to non-narcotic analgesics where the total duration of narcotic analgesic treatment is less than 12 months; or

(iii) first application for treatment beyond 12 months of chronic severe disabling pain not responding to non-narcotic analgesics where the patient's pain management has been reviewed through consultation by the patient with another medical practitioner, and the clinical need for continuing narcotic analgesic treatment has been confirmed. The date of the consultation must be no more than 3 months prior to the application for a PBS authority. The full name of the medical practitioner consulted and the date of consultation are to be provided at the time of application; or

(iv) subsequent application for treatment of chronic severe disabling pain not responding to non-narcotic analgesics where a PBS authority prescription for treatment beyond 12 months has previously been issued for this patient.

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
8385H NP	Tablet 10 mg (controlled release)	28	..		27.09	28.16	OxyContin MF
8386J NP	Tablet 20 mg (controlled release)	28	..		40.97	34.20	OxyContin MF
8387K NP	Tablet 40 mg (controlled release)	28	..		62.60	34.20	OxyContin MF
8388L NP	Tablet 80 mg (controlled release)	28	..		96.72	34.20	OxyContin MF
8681X NP	Tablet 5 mg (controlled release)	28	..		26.00	27.07	OxyContin MF
9399Q NP	Tablet 15 mg (controlled release)	28	..		35.47	34.20	OxyContin MF
9400R NP	Tablet 30 mg (controlled release)	28	..		52.69	34.20	OxyContin MF

OXYCODONE HYDROCHLORIDE

Note

The risk of drug dependence is high.

Restricted benefit

Chronic severe disabling pain not responding to non-narcotic analgesics.

Note

Prescribing of drugs of addiction by dentists is not permitted in some States/Territories.

5015Y	Tablet 15 mg (controlled release) (Dental)	28	..		35.47	34.20	OxyContin MF
5016B	Tablet 30 mg (controlled release) (Dental)	28	..		52.69	34.20	OxyContin MF
5227D	Tablet 5 mg (controlled release) (Dental)	28	..		26.00	27.07	OxyContin MF
5247E	Tablet 10 mg (controlled release) (Dental)	28	..		27.09	28.16	OxyContin MF
5248F	Tablet 20 mg (controlled release) (Dental)	28	..		40.97	34.20	OxyContin MF
5249G	Tablet 40 mg (controlled release) (Dental)	28	..		62.60	34.20	OxyContin MF
5250H	Tablet 80 mg (controlled release) (Dental)	28	..		96.72	34.20	OxyContin MF

PIOGLITAZONE

Note

Pioglitazone hydrochloride is not PBS-subsidised as monotherapy or in combination with a dipeptidyl peptidase 4 inhibitor (gliptin) 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.

Authority required (STREAMLINED)

3541

Combination therapy with insulin

Type 2 diabetes, in combination with insulin, in a patient whose HbA1c is greater than 7% prior to initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone) or a glucagon-like peptide-1 despite treatment with insulin and oral anti-diabetic agents, or insulin alone

GENERAL PHARMACEUTICAL BENEFITS

					Dispensed Price for Max. Qty	Maximum Recordable Value for Safety Net	
Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	\$	\$	Brand Name and Manufacturer
where metformin is contraindicated.							

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.

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
8694N NP	Tablet 15 mg (as hydrochloride)	28	5		53.00	34.20	^a Acpio 15 SI
							^a Actos LY
							^a APOTEX- Pioglitazone TX
							^a Chem mart Pioglitazone CH
							^a Pharmacor Pioglitazone 15 CR
							^a Pioglitazone generichealth 15 GQ
							^a Pizaccord MI
							^a Terry White Chemists Pioglitazone TW
8695P NP	Tablet 30 mg (as hydrochloride)	28	5		77.62	34.20	^a Acpio 30 SI
							^a Actos LY
							^a APOTEX- Pioglitazone TX
							^a Chem mart Pioglitazone CH
							^a Pharmacor Pioglitazone 30 CR
							^a Pioglitazone generichealth 30 GQ
							^a Pizaccord MI
							^a Terry White Chemists Pioglitazone TW
8696Q NP	Tablet 45 mg (as hydrochloride)	28	5		99.01	34.20	^a Acpio 45 SI
							^a Actos LY
							^a APOTEX- Pioglitazone TX
							^a Chem mart Pioglitazone CH
							^a Pharmacor Pioglitazone 45 CR
							^a Pioglitazone generichealth 45 GQ
							^a Pizaccord MI
							^a Terry White Chemists Pioglitazone TW

RISEDRONATE SODIUM

Authority required (STREAMLINED)

3070

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

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

Authority required (STREAMLINED)

2645

Treatment as the sole PBS-subsidised anti-resorptive agent for osteoporosis in a patient aged 70 years of age or older with a Bone Mineral Density (BMD) T-score of -3.0 or less.

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

Authority required (STREAMLINED)

2646

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

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	
	A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.							
	Note Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, denosumab, disodium etidronate, raloxifene hydrochloride, strontium ranelate and zoledronic acid.							
8621R NP	Tablet 35 mg	4	5		46.55	34.20	^a Actonel Once-a-Week ^a APO-Risedronate ^a Chem mart Risedronate ^a Terry White Chemists Risedronate	SW TX CH TW
	SERTRALINE Restricted benefit Major depressive disorders.							
2236Q NP	Tablet 50 mg (as hydrochloride)	30	5		23.75	24.82	^a Chem mart Sertraline ^a Concorz ^a Eleva 50 ^a GenRx Sertraline ^a Sertra 50 ^a Sertracor 50 ^a Sertraline 50 ^a Sertraline-DRLA ^a Sertraline-GA ^a Sertraline generichealth ^a Sertraline Winthrop ^a Setrona ^a Terry White Chemists Sertraline ^a Xydep 50	CH SZ AF GX SI MI CR RZ GM GQ WA RA TW GN
				^B 1.42	25.17	24.82	^a Zoloft	PF
2237R NP	Tablet 100 mg (as hydrochloride)	30	5		23.75	24.82	^a Chem mart Sertraline ^a Concorz ^a Eleva 100 ^a GenRx Sertraline ^a Sertra 100 ^a Sertracor 100 ^a Sertraline 100 ^a Sertraline-DRLA ^a Sertraline-GA ^a Sertraline generichealth ^a Setrona ^a Terry White Chemists Sertraline ^a Xydep 100	CH SZ AF GX SI MI CR RZ GM GQ RA TW GN
				^B 1.42	25.17	24.82	^a Zoloft	PF

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
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SULFASALAZINE

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.

2096H NP	Tablet 500 mg (enteric coated)	200	5		*54.24	34.20 ^a	Pyralin EN	FZ
				^B 1.84	*56.08	34.20 ^a	Salazopyrin-EN	PF

SULFASALAZINE

Restricted benefit

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.

Note

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

9209Q	Tablet 500 mg (enteric coated)	200	11		*54.24	34.20 ^a	Pyralin EN	FZ
				^B 1.84	*56.08	34.20 ^a	Salazopyrin-EN	PF

TINIDAZOLE

1465D NP	Tablet 500 mg	4	..		10.79	11.86 ^a	Simplotan	FZ
				^B 2.42	13.21	11.86 ^a	Fasigyn	PF

VALACICLOVIR

Authority required (STREAMLINED)

3632

Moderate to severe initial genital herpes. Microbiological confirmation of diagnosis (viral culture, antigen detection or nucleic acid amplification by PCR) is desirable but need not delay treatment.

Note

Valaciclovir 500 mg is not PBS-subsidised for chickenpox or herpes simplex infections other than genital herpes.

Note

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

8133C NP	Tablet 500 mg (as hydrochloride)	20	..		*105.78	34.20 ^a	APO-Valaciclovir	TX
						^a	Chem mart	CH
						^a	Valaciclovir	
						^a	Terry White	TW
							Chemists	
						^a	Valaciclovir	
						^a	Vaclovir	AF
						^a	Valaciclovir GA	GM
						^a	Valaciclovir Sandoz	SZ
						^a	Valnir	SI
						^a	Valtrex	GK
						^a	Zelitrex	RE

VALACICLOVIR

Authority required (STREAMLINED)

3624

Episodic treatment of moderate to severe recurrent genital herpes. Microbiological confirmation of diagnosis (viral culture, antigen detection or nucleic acid amplification by PCR) is required but need not delay treatment.

Note

Valaciclovir 500 mg is not PBS-subsidised for chickenpox or herpes simplex infections other than genital herpes.

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	
8134D NP	Tablet 500 mg (as hydrochloride)	30	5		155.43	34.20	^a	APO-Valaciclovir	TX
							^a	Chem mart	CH
							^a	Valaciclovir	
							^a	Terry White	TW
								Chemists	
							^a	Valaciclovir	
							^a	Vaclovir	AF
							^a	Valaciclovir GA	GM
							^a	Valaciclovir RBX	RA
							^a	Valaciclovir Sandoz	SZ
							^a	Valaciclovir SZ	HX
							^a	Valnir	SI
							^a	Valtrex	GK
							^a	Zelitrex	RE

VALACICLOVIR

Authority required (STREAMLINED)

3623

Suppressive therapy of moderate to severe recurrent genital herpes. Microbiological confirmation of diagnosis (viral culture, antigen detection or nucleic acid amplification by PCR) is required but need not delay treatment.

Note

Valaciclovir 500 mg is not PBS-subsidised for chickenpox or herpes simplex infections other than genital herpes.

5480K NP	Tablet 500 mg (as hydrochloride)	30	5		155.43	34.20	^a	APO-Valaciclovir	TX
							^a	Chem mart	CH
								Valaciclovir	
							^a	Terry White	TW
								Chemists	
							^a	Valaciclovir	
							^a	Vaclovir	AF
							^a	Valaciclovir GA	GM
							^a	Valaciclovir RBX	RA
							^a	Valaciclovir SZ	HX
							^a	Valnir	SI
							^a	Valtrex	GK
							^a	Zelitrex	RE

VALACICLOVIR

Authority required (STREAMLINED)

3622

Treatment of patients with herpes zoster within 72 hours of the onset of the rash;

3631

Herpes zoster ophthalmicus.

Note

Valaciclovir is effective only if commenced within 72 hours of onset of rash.

Valaciclovir 500 mg is not PBS-subsidised for chickenpox or herpes simplex infections other than genital herpes.

Note

No applications for repeats will be authorised.

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	
8064K NP	Tablet 500 mg (as hydrochloride)	42	..		214.06	34.20	^a APO-Valaciclovir	TX
							^a Chem mart	CH
							^a Valaciclovir	
							^a Terry White	TW
							^a Chemists	
							^a Valaciclovir	
							^a Vavlovir	AF
							^a Valaciclovir GA	GM
							^a Valaciclovir RBX	RA
							^a Valaciclovir Sandoz	SZ
							^a Valnir	SI
							^a Valtrex	GK
							^a Zelitrex	RE

VILDAGLIPTIN with METFORMIN

Note

Vildagliptin with metformin fixed dose combination tablet is not PBS-subsidised for use in combination with a sulfonylurea (triple oral therapy), as initial therapy or in combination with a thiazolidinedione (glitazone) or a glucagon-like peptide-1.

Authority required (STREAMLINED)

3543

Type 2 diabetes 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 metformin 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;

3686

Continuation of therapy in type 2 diabetes mellitus in a patient who has previously received and been stabilised on a PBS-subsidised regimen of oral diabetic medicines which includes metformin and vildagliptin.

5474D NP	Tablet containing 50 mg vildagliptin with 500 mg metformin hydrochloride	60	5		97.79	34.20	Galvumet 50/500	NV
5475E NP	Tablet containing 50 mg vildagliptin with 850 mg metformin hydrochloride	60	5		100.22	34.20	Galvumet 50/850	NV
5476F NP	Tablet containing 50 mg vildagliptin with 1000 mg metformin hydrochloride	60	5		101.20	34.20	Galvumet 50/1000	NV

ZONISAMIDE

Authority required (STREAMLINED)

2664

Treatment of partial epileptic seizures which are not controlled satisfactorily by other anti-epileptic drugs.

9388D	Capsule 25 mg	56	5		22.80	23.87	Zonegran	SA
9389E	Capsule 50 mg	56	5		33.72	34.20	Zonegran	SA
9390F	Capsule 100 mg	112	5		*93.46	34.20	Zonegran	SA

HIGHLY SPECIALISED DRUGS PROGRAM

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 \$	

AMBRISENTAN

Note:

Ambrisentan is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 3 months following cessation of treatment with this drug.

Any queries concerning the arrangements to prescribe ambrisentan 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;

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

HIGHLY SPECIALISED DRUGS PROGRAM

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
					\$	\$	

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.)

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.

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.

HIGHLY SPECIALISED DRUGS PROGRAM

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					\$	\$	

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.

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.

HIGHLY SPECIALISED DRUGS PROGRAM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty	Maximum Recordable Value for Safety Net	Brand Name and Manufacturer
					\$	\$	

Authority required

Initial (new patients)

Application for initial PBS-subsidised treatment with ambrisentan of patients 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:

- (a) WHO Functional Class III primary pulmonary hypertension and a mean right atrial pressure of 8 mmHg or less, as measured by RHC, or, where a RHC cannot be performed on clinical grounds, right ventricular function as assessed by ECHO; OR
- (b) WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease and a mean right atrial pressure of 8 mmHg or less, as measured by RHC, or, where a RHC cannot be performed on clinical grounds, right ventricular function as assessed by ECHO.

Patients must have failed to respond [see Note for definition of response] to 6 or more weeks of appropriate vasodilator treatment unless intolerance or a contraindication to such treatment exists.

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].

Details of prior vasodilator treatment, including the dose and duration of treatment, must be provided at the time of application. Where the patient has an adverse event to a vasodilator or where vasodilator treatment is contraindicated, details on the nature of the adverse event or contraindication according to the TGA-approved Product Information must also be provided with the application.

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)

Application for initial PBS-subsidised treatment with ambrisentan of patients 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:

- (a) WHO Functional Class III primary pulmonary hypertension and a mean right atrial pressure greater than 8 mmHg, as measured by RHC, or, where a RHC cannot be performed on clinical grounds, right ventricular function as assessed by ECHO; OR
- (b) WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease and a mean right atrial pressure greater than 8 mmHg, as measured by RHC, or, where a RHC cannot be performed on clinical grounds, right ventricular function as assessed by ECHO; OR
- (c) WHO Functional Class IV primary pulmonary hypertension; OR
- (d) WHO Functional Class IV pulmonary arterial hypertension secondary to connective tissue disease.

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 (change or re-commencement for all patients)

Application for initial treatment with ambrisentan of patients with one of the following:

- (a) primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease who wish to re-commence PBS-subsidised ambrisentan after a break in therapy and who have demonstrated a response to their most recent course of PBS-subsidised treatment

HIGHLY SPECIALISED DRUGS PROGRAM

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
					\$	\$	

with ambrisentan; OR

(b) primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease and whose most recent course of PBS-subsidised treatment was with an alternate PAH agent other than ambrisentan.

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.

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 ambrisentan of patients who have received approval for initial PBS-subsidised treatment with ambrisentan and who have been assessed by a physician from a designated hospital to have achieved a response to their most recent course of ambrisentan 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 will be authorised. Where fewer than 5 repeats are initially requested under this criterion, 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).

Note:

Special Pricing Arrangements apply.

5607D	Tablet 5 mg (Public)	30	..	4035.00	Volibris	GK
5608E	Tablet 10 mg (Public)	30	..	4035.00	Volibris	GK
9648T	Tablet 5 mg (Private)	30	..	4081.42	Volibris	GK
9649W	Tablet 10 mg (Private)	30	..	4081.42	Volibris	GK

BOSENTAN MONOHYDRATE

Note:

Bosentan monohydrate is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 3 months following cessation of treatment with this drug.

Any queries concerning the arrangements to prescribe bosentan monohydrate 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

HIGHLY SPECIALISED DRUGS PROGRAM

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
					\$	\$	
	GPO Box 9826 HOBART TAS 7001;						

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.)

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

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					Dispensed Price for Max. Qty	Maximum Recordable Value for Safety Net	
Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	\$	\$	Brand Name and Manufacturer
	(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.

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.

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.

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Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for	Maximum Recordable Value for	Brand Name and Manufacturer
					Max. Qty \$	Safety Net \$	

(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 bosentan monohydrate of adult patients 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:

- (a) WHO Functional Class III primary pulmonary hypertension and a mean right atrial pressure of 8 mmHg or less, as measured by RHC, or, where a RHC cannot be performed on clinical grounds, right ventricular function as assessed by ECHO; OR
- (b) WHO Functional Class III pulmonary arterial hypertension secondary to scleroderma and a mean right atrial pressure of 8 mmHg or less, as measured by RHC, or, where a RHC cannot be performed on clinical grounds, right ventricular function as assessed by ECHO.

Patients must have failed to respond [see Note for definition of response] to 6 or more weeks of appropriate vasodilator treatment unless intolerance or a contraindication to such treatment exists.

Applications for authorisation must be in writing and must include:

- (1) two completed authority prescription forms [see Note for authority approval requirements]; and
- (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form [www.medicareaustralia.gov.au] which

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					\$	\$	

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].

Details of prior vasodilator treatment, including the dose and duration of treatment, must be provided at the time of application. Where the patient has an adverse event to a vasodilator or where vasodilator treatment is contraindicated, details on the nature of the adverse event or contraindication according to the TGA-approved Product Information must also be provided with the application.

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. No repeats will be authorised for the first authority prescription issued under this criterion [see Note for full details of authority approval requirements]. A maximum of 4 repeats will be authorised for the second authority prescription issued under this criterion. Where fewer than 4 repeats are initially requested with the second authority prescription, 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 adult patients)

Application for initial PBS-subsidised treatment with bosentan monohydrate of adult patients 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:

(a) WHO Functional Class III primary pulmonary hypertension and a mean right atrial pressure greater than 8 mmHg, as measured by RHC, or, where a RHC cannot be performed on clinical grounds, right ventricular function as assessed by ECHO; OR

(b) WHO Functional Class III pulmonary arterial hypertension secondary to scleroderma and a mean right atrial pressure greater than 8 mmHg, as measured by RHC, or, where a RHC cannot be performed on clinical grounds, right ventricular function as assessed by ECHO; OR

(c) WHO Functional Class IV primary pulmonary hypertension; OR

(d) WHO Functional Class IV pulmonary arterial hypertension secondary to scleroderma.

Applications for authorisation must be in writing and must include:

(1) two completed authority prescription forms [see Note for authority approval requirements]; 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. No repeats will be authorised for the first authority prescription issued under this criterion [see Note for full details of authority approval requirements]. A maximum of 4 repeats will be authorised for the second authority prescription issued under this criterion. Where fewer than 4 repeats are initially requested with the second authority prescription, 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 bosentan monohydrate 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 III primary pulmonary hypertension and either a mean right atrial pressure of 8 mmHg or less, as measured by RHC, or, where a RHC cannot be performed on clinical grounds, right ventricular function as assessed by ECHO.

Patients must have failed to respond [see Note for definition of response] to 6 or more weeks of appropriate prior vasodilator treatment unless intolerance or a contraindication to such treatment exists.

Applications for authorisation must be in writing and must include:

(1) two completed authority prescription forms [see Note for authority approval requirements]; 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

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					\$	\$	

(iii) 6MWT; and

(3) a patient and prescriber acknowledgment, signed by the parent or authorised guardian, indicating that they understand and acknowledge 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].

Details of prior vasodilator treatment, including the dose and duration of treatment, must be provided at the time of application. Where the patient has an adverse event to a vasodilator or where vasodilator treatment is contraindicated, details on the nature of the adverse event or contraindication according to the TGA-approved Product Information must also be provided with the application.

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. No repeats will be authorised for the first authority prescription issued under this criterion [see Note for full details of authority approval requirements]. A maximum of 4 repeats will be authorised for the second authority prescription issued under this criterion. Where fewer than 4 repeats are initially requested with the second authority prescription, 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 bosentan monohydrate 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:

- (a) WHO Functional Class III primary pulmonary hypertension and either a mean right atrial pressure greater than 8 mmHg, as measured by RHC, or, where a RHC cannot be performed on clinical grounds, right ventricular function as assessed by ECHO; OR
- (b) WHO Functional Class IV primary pulmonary hypertension.

Applications for authorisation must be in writing and must include:

- (1) two completed authority prescription forms [see Note for authority approval requirements]; 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 and prescriber acknowledgment, signed by the parent or authorised guardian, indicating that they understand and acknowledge 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. No repeats will be authorised for the first authority prescription issued under this criterion [see Note for full details of authority approval requirements]. A maximum of 4 repeats will be authorised for the second authority prescription issued under this criterion. Where fewer than 4 repeats are initially requested with the second authority prescription, 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)

Application for initial PBS-subsidised treatment with bosentan monohydrate of a patient who has been assessed by a physician from a designated hospital to have WHO Functional Class III or IV pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology).

Applications for authorisation must be in writing and must include:

- (1) two completed authority prescription forms [see Note for authority approval requirements]; 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 (and signed by the parent or authorised guardian for patients under 18 years of age) indicating that the patient understands and acknowledges that PBS-subsidised treatment with bosentan monohydrate 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. No repeats will be authorised for the first authority prescription issued under this criterion [see Note for full details of authority approval requirements].

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					\$	\$	

details of authority approval requirements]. A maximum of 4 repeats will be authorised for the second authority prescription issued under this criterion. Where fewer than 4 repeats are initially requested with the second authority prescription, 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 adult patients)

Application for initial treatment with bosentan monohydrate of adult patients with one of the following:

- (a) 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), who wish to re-commence PBS-subsidised bosentan monohydrate after a break in therapy and who have demonstrated a response to their most recent course of PBS-subsidised treatment with bosentan monohydrate; OR
- (b) primary pulmonary hypertension or pulmonary arterial hypertension secondary to scleroderma and whose most recent course of PBS-subsidised treatment was with an alternate PAH agent other than bosentan monohydrate.

Applications for authorisation must be in writing and must include:

- (1) two completed authority prescription forms [see Note for authority approval requirements]; 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.

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. No repeats will be authorised for the first authority prescription issued under this criterion [see Note for full details of authority approval requirements]. A maximum of 4 repeats will be authorised for the second authority prescription issued under this criterion. Where fewer than 4 repeats are initially requested with the second authority prescription, 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 patients under 18 years of age)

Application for initial treatment with bosentan monohydrate of patients aged less than 18 years with one of the following:

- (a) primary pulmonary hypertension, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology), who wish to re-commence PBS-subsidised bosentan monohydrate after a break in therapy and who have demonstrated a response to their most recent course of PBS-subsidised treatment with bosentan monohydrate; OR
- (b) primary pulmonary hypertension and whose most recent course of PBS-subsidised treatment was with a PAH agent other than bosentan monohydrate.

Applications for authorisation must be in writing and must include:

- (1) two completed authority prescription forms [see Note for authority approval requirements]; 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.

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. No repeats will be authorised for the first authority prescription issued under this criterion [see Note for full details of authority approval requirements]. A maximum of 4 repeats will be authorised for the second authority prescription issued under this criterion. Where fewer than 4 repeats are initially requested with the second authority prescription, 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 bosentan monohydrate of patients who have received approval for initial PBS-subsidised treatment with bosentan monohydrate and who have been assessed by a physician from a designated hospital to have achieved a response to their most recent course of bosentan monohydrate 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

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							Maximum Recordable Value for Safety Net
	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty		
Code					\$	\$	Brand Name and Manufacturer
	(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 will be authorised.

Where fewer than 5 repeats are initially requested under this criterion, 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

Cessation of treatment (all patients)

Final PBS-subsidised supply for patients with WHO Functional Class III or IV primary pulmonary hypertension or WHO Functional Class III or IV pulmonary arterial hypertension secondary to scleroderma or WHO Functional Class III or IV pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology), who have not responded to bosentan monohydrate therapy [see Note for definition of response], to allow for gradual cessation of treatment.

Applications for authorisation under this criterion should be made on the telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) [see Note on authority approval requirements].

Approval will only be granted for the 62.5 mg tablet strength. The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment.

Under no circumstances will telephone approvals be granted for treatment that would extend the final treatment period beyond 1 month.

Note:

Special Pricing Arrangements apply.

5618Q	Tablet 62.5 mg (base) (Public)	60	..	4035.00	Tracleer	AT
6429J	Tablet 62.5 mg (base) (Private)	60	..	4081.42	Tracleer	AT
5619R	Tablet 125 mg (base) (Public)	60	..	4035.00	Tracleer	AT
6430K	Tablet 125 mg (base) (Private)	60	..	4081.42	Tracleer	AT

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;

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

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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
					\$	\$	
	(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.)

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.

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

HIGHLY SPECIALISED DRUGS PROGRAM

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
					\$	\$	

(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.

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

HIGHLY SPECIALISED DRUGS PROGRAM

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					\$	\$	

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 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

HIGHLY SPECIALISED DRUGS PROGRAM

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					\$	\$	

(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 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).

HIGHLY SPECIALISED DRUGS PROGRAM

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
<u>Authority required</u>							
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).							
5731P	Powder for I.V. infusion 500 micrograms (base) with diluent (Public)	1	..		41.69	Flolan	GK
6477X	Powder for I.V. infusion 500 micrograms (base) with diluent (Private)	1	..		52.11	Flolan	GK
5732Q	Powder for I.V. infusion 1.5 mg (base) with diluent (Public)	1	..		83.37	Flolan	GK
6478Y	Powder for I.V. infusion 1.5 mg (base) with diluent (Private)	1	..		93.79	Flolan	GK

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;

HIGHLY SPECIALISED DRUGS PROGRAM

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 \$	
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));							
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.							
<u>Authority required (STREAMLINED)</u>							
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.							
9692D	Injection 300 micrograms in 0.5 mL single use pre-filled syringe (Public)		20	11		*2515.54	Nivestim HH
9694F	Injection 480 micrograms in 0.5 mL single use pre-filled syringe (Public)		20	11		*4032.58	Nivestim HH

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

HIGHLY SPECIALISED DRUGS PROGRAM

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
					\$	\$	
	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.						
	<u>Authority required</u>						
	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;						
	A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in sarcoma.						
9693E	Injection 300 micrograms in 0.5 mL single use pre-filled syringe (Private)	20	11			*2561.96	Nivestim HH
9695G	Injection 480 micrograms in 0.5 mL single use pre-filled syringe (Private)	20	11			*4079.00	Nivestim HH

ILOPROST TROMETAMOL

Note:

Any queries concerning the arrangements to prescribe iloprost trometamol 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;

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,

HIGHLY SPECIALISED DRUGS PROGRAM

						Dispensed Price for Max. Qty	Maximum Recordable Value for Safety Net	
Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	\$	\$	Brand Name and Manufacturer	
	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.)

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

HIGHLY SPECIALISED DRUGS PROGRAM

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
					\$	\$	

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.

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.

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:

HIGHLY SPECIALISED DRUGS PROGRAM

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					\$	\$	

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 patients)

Application for initial PBS-subsidised treatment with iloprost trometamol of patients who have not received prior PBS-subsidised treatment with iloprost and who have been assessed by a physician from a designated hospital to have:

WHO Functional Class III drug-induced pulmonary arterial hypertension and a mean right atrial pressure of 8 mmHg or less, as measured by RHC, or, where a RHC cannot be performed on clinical grounds, right ventricular function as assessed by ECHO.

Patients must have failed to respond [see Note for definition of response] to 6 or more weeks of appropriate vasodilator treatment unless intolerance or a contraindication to such treatment exists.

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].

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					\$	\$	

Details of prior vasodilator treatment, including the dose and duration of treatment, must be provided at the time of application. Where the patient has an adverse event to a vasodilator or where vasodilator treatment is contraindicated, details on the nature of the adverse event or contraindication according to the TGA-approved Product Information must also be provided with the application.

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)

Application for initial PBS-subsidised treatment with iloprost trometamol of patients 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:

- (a) WHO Functional Class III drug-induced pulmonary arterial hypertension and a mean right atrial pressure greater than 8 mmHg, as measured by RHC, or, where a RHC cannot be performed on clinical grounds, right ventricular function as assessed by ECHO; OR
- (b) WHO Functional Class IV primary pulmonary hypertension; OR
- (c) WHO Functional Class IV pulmonary arterial hypertension secondary to connective tissue disease; OR
- (d) WHO Functional Class IV drug-induced pulmonary arterial 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 (change or re-commencement for all patients)

Application for initial PBS-subsidised treatment with iloprost trometamol of patients with one of the following:

- (a) primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease who wish to re-commence PBS-subsidised iloprost trometamol after a break in therapy and who have demonstrated a response to their most recent course of PBS-subsidised treatment with iloprost trometamol; OR
- (b) WHO Functional Class IV primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease and who have received prior treatment with a PBS-subsidised PAH agent other than iloprost trometamol; OR
- (c) WHO Functional Class III primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease 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 iloprost trometamol, 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).

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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
<u>Authority required</u>							
Continuing treatment (all patients)							
Continuing PBS-subsidised treatment with iloprost trometamol of patients who have received approval for initial PBS-subsidised treatment with iloprost trometamol, and who have been assessed by a physician from a designated hospital to have achieved a response to their most recent course of iloprost trometamol 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).							
Special Pricing Arrangements apply.							
5751Q	Solution for inhalation 20 micrograms (base) in 2 mL (Public)		30	..		1076.00	Ventavis SC
6456T	Solution for inhalation 20 micrograms (base) in 2 mL (Private)		30	..		1122.42	Ventavis SC

INFLIXIMAB

Note:

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

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe infliximab should be forwarded to:

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

TREATMENT OF COMPLEX REFRACTORY FISTULISING CROHN DISEASE

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab and infliximab for patients with complex refractory fistulising Crohn disease. Where the term 'tumour necrosis factor (TNF) alfa antagonist' appears in the following NOTES and restrictions, it refers to adalimumab and infliximab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 2 TNF-alfa antagonists at any 1 time.

From 1 April 2011, under the PBS, all patients will be able to commence a treatment cycle where they may trial each PBS-subsidised TNF-alfa antagonist without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a TNF-alfa antagonist while they continue to show a response to therapy.

A patient who received PBS-subsidised TNF-alfa antagonist treatment prior to 1 April 2011 is considered to be in their first cycle as of 1 April 2011.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised TNF-alfa antagonist more than twice.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised TNF-alfa antagonist therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised TNF-alfa antagonist treatment in the most recent cycle to the date of the

HIGHLY SPECIALISED DRUGS PROGRAM

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					Max. Qty	Safety Net	
					\$	\$	
	first application for initial treatment with a TNF-alfa antagonist under the new treatment cycle.						

A patient who has failed fewer than 3 trials of TNF-alfa antagonists in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of TNF-alfa antagonists in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised TNF-alfa antagonist therapy after 1 April 2011.

(a) Initial treatment.

Applications for initial treatment should be made where:

- (i) a patient has received no prior PBS-subsidised TNF-alfa antagonist treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
- (ii) a patient has received prior PBS-subsidised (initial or continuing) TNF-alfa antagonist therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
- (iii) a patient wishes to re-commence treatment with a specific TNF-alfa antagonist following a break in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and 14 weeks of therapy for infliximab.

From 1 April 2011, a patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.

For second and subsequent courses of PBS-subsidised TNF-alfa antagonist treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

Adalimumab only: Two completed authority prescriptions must be submitted with every initial application for adalimumab. One prescription must be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats. The second prescription must be written for 2 doses of 40 mg and 2 repeats.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific TNF-alfa antagonist, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing TNF-alfa antagonist treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted TNF-alfa antagonist supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised TNF-alfa antagonist is approved, a patient may swap if eligible to the alternate TNF-alfa antagonist within the same treatment cycle.

A patient may trial the alternate TNF-alfa antagonist at any time, regardless of whether they are receiving therapy (initial or continuing) with a TNF-alfa antagonist at the time of the application. However, they cannot swap to a particular TNF-alfa antagonist if they have failed to respond to prior treatment with that drug two times within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to the alternate TNF-alfa antagonist should be accompanied by the approved authority prescription or remaining repeats for the TNF-alfa antagonist the patient is ceasing.

(3) Baseline measurements to determine response.

HIGHLY SPECIALISED DRUGS PROGRAM

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
					\$	\$	

Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements submitted with the first authority application for a TNF-alfa antagonist. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and Medicare Australia will assess response according to these revised baseline measurements.

(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised TNF-alfa antagonist therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity.

(5) Patients 'grandfathered' onto PBS-subsidised treatment with adalimumab or infliximab.

A patient who commenced treatment with adalimumab for complex refractory fistulising Crohn disease prior to 4 November 2010 or infliximab prior to 10 March 2010 and who continues to receive treatment at the time of application, may qualify for treatment under the initial 'grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment with adalimumab or infliximab will be authorised under this criterion.

Following completion of the initial PBS-subsidised course, further applications for treatment with adalimumab or infliximab will be assessed under the continuing treatment restriction.

'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must requalify for initial treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' above for further details.

Authority required

Initial 1

Initial treatment of complex refractory FISTULISING CROHN DISEASE.

Initial PBS-subsidised treatment with infliximab by a gastroenterologist or a consultant physician as specified in the NOTE below, of a patient with complex refractory fistulising Crohn disease who:

- (a) has confirmed Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician as specified in the NOTE below; and
- (b) has an externally draining enterocutaneous or rectovaginal fistula; and
- (c) has signed a patient acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criteria for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

Authority applications must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Fistulising Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
 - (i) a completed current Fistula Assessment Form including the date of assessment of the patient's condition; and
 - (ii) a signed patient acknowledgement.

The most recent fistula assessment must be no more than 1 month old at the time of application.

A maximum quantity and number of repeats to provide for an initial course of infliximab consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6 will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete 3 doses of infliximab 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). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

An assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (up to 6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.

This assessment must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab.

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment.

HIGHLY SPECIALISED DRUGS PROGRAM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty	Maximum Recordable Value for Safety Net	Brand Name and Manufacturer
					\$	\$	

Authority required

Initial 2

Change or re-commencement of treatment of complex refractory FISTULISING CROHN DISEASE.

Initial PBS-subsidised treatment with infliximab of complex refractory fistulising Crohn disease by a gastroenterologist or a consultant physician as specified in the NOTE below, of a patient with complex refractory fistulising Crohn disease who:

- (a) has a documented history of complex refractory fistulising Crohn disease; and
- (b) in this treatment cycle, has received prior PBS-subsidised treatment with adalimumab or infliximab for a draining enterocutaneous or rectovaginal fistula; and
- (c) has not failed PBS-subsidised therapy with infliximab for this condition more than once in the current treatment cycle.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

To demonstrate a response to treatment the application must be accompanied by the results of the most recent course of TNF-alfa antagonist therapy within the timeframes specified in the relevant restriction.

Where the most recent course of PBS-subsidised TNF-alfa antagonist treatment was approved under an initial treatment restriction, the patient must have been assessed for response to that course following a minimum of 12 weeks therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

If the response assessment to the previous course of TNF-alfa antagonist treatment is not submitted as detailed above, the patient will be deemed to have failed therapy with that particular course of TNF-alfa antagonist.

Authority applications must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Fistulising Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
 - (i) a completed current Fistula Assessment Form including the date of assessment of the patient's condition; and
 - (ii) details of prior TNF-alfa antagonist treatment including details of date and duration of treatment.

The most recent fistula assessment must be no more than 1 month old at the time of application.

A maximum quantity and number of repeats to provide for an initial course of infliximab consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete 3 doses of infliximab 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). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

An assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (up to 6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.

This assessment must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab.

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment.

Authority required

Initial 3 (grandfather)

Initial PBS-subsidised treatment of complex refractory FISTULISING CROHN DISEASE in a patient who has previously received non-PBS-subsidised therapy with infliximab.

Initial PBS-subsidised supply for continuing treatment with infliximab by a gastroenterologist, a consultant physician as specified in the NOTE below, or other consultant physician in consultation with a gastroenterologist of a patient who satisfies the following criteria:

- (a) has a documented history of complex refractory fistulising Crohn disease and was receiving treatment with infliximab prior to 1 March 2010; and
- (b) had a draining enterocutaneous or rectovaginal fistula(e) prior to commencing treatment with infliximab; and
- (c) has signed a patient acknowledgement indicating that they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criteria for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and
- (d) is receiving treatment with infliximab at the time of application; and
- (e) has demonstrated or sustained an adequate response to treatment with infliximab.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

HIGHLY SPECIALISED DRUGS PROGRAM

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
					\$	\$	

An adequate response to infliximab treatment is defined as:

- (a) a decrease from baseline in the number of open draining fistulae of greater than or equal to 50%; and/or
- (b) a marked reduction in drainage of all fistula(e) from baseline, together with less pain and induration as reported by the patient.

Applications for authorisation must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Fistulising Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
 - (i) a completed current and baseline Fistula Assessment form including the date of assessment of the patient's condition; and
 - (ii) a signed patient acknowledgement.

The current fistula assessment must be no more than 1 month old at the time of application.

The baseline fistula assessment must be from immediately prior to commencing treatment with infliximab.

An assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criteria.

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with infliximab.

Patients are eligible to receive continuing infliximab treatment in courses of up to 24 weeks providing they continue to sustain the response.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats will be authorised. No applications for increased repeats will be authorised.

Where fewer than 2 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 24 weeks 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).

Patients may qualify for PBS-subsidised treatment under this restriction once only.

Authority required

Continuing treatment of complex refractory FISTULISING CROHN DISEASE.

Continuing PBS-subsidised treatment with infliximab by a gastroenterologist, a consultant physician as specified in the NOTE below or other consultant physician in consultation with a gastroenterologist, of a patient who:

- (a) has a documented history of complex refractory fistulising Crohn disease; and
- (b) has demonstrated or sustained an adequate response to treatment with infliximab.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

An adequate response is defined as:

- (a) a decrease from baseline in the number of open draining fistulae of greater than or equal to 50%; and/or
- (b) a marked reduction in drainage of all fistula(e) from baseline, together with less pain and induration as reported by the patient.

Authority applications must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Fistulising Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes a completed Fistula Assessment form including the date of the assessment of the patient's condition.

The fistula assessment must be no more than 1 month old at the time of application.

If the application is the first application for continuing treatment with infliximab, an assessment of the patient's response must be made up to 12 weeks after the first dose so that there is adequate time for a response to be demonstrated.

An assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criteria.

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with infliximab.

Patients are eligible to receive continuing infliximab treatment in courses of up to 24 weeks providing they continue to sustain the response.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to

HIGHLY SPECIALISED DRUGS PROGRAM

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
					\$	\$	
	provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats will be authorised. No applications for increased repeats will be authorised.						
	Where fewer than 2 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 24 weeks 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).						
9654D	Powder for I.V. infusion 100 mg (Public)		1	..		751.70	Remicade SH
9674E	Powder for I.V. infusion 100 mg (Private)		1	..		788.19	Remicade SH

ROMIPILOSTIM

Note:

Romiplostim is not PBS-subsidised as an alternative to splenectomy.

Any queries concerning the arrangements to prescribe romiplostim 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 romiplostim should be forwarded to:

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

Further prescribing information is on the Medicare Australia website at www.medicareaustralia.gov.au.

Authority required

Initial (new patients)

Initial treatment of severe thrombocytopenia in an adult patient with severe chronic immune (idiopathic) thrombocytopenic purpura (ITP) who is:

(1) Splenectomised and:

(a) has had an inadequate response to, or is intolerant to, corticosteroid therapy post splenectomy; and

(b) has had an inadequate response to, or is intolerant to, immunoglobulin therapy post splenectomy;

OR

(2) Not splenectomised and:

(a) has had an inadequate response, or is intolerant to, corticosteroid therapy at a dose equivalent to 0.5-2 mg/kg/day of prednisone for at least 4-6 weeks; and

(b) has had an inadequate response, or is intolerant to, immunoglobulin therapy; and

(c) in whom splenectomy is contraindicated for medical reasons.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of initial application:

(a) a platelet count of less than or equal to 20,000 million per L OR

(b) a platelet count of 20-30,000 million per L, where the patient is experiencing significant bleeding or has a history of significant bleeding in this platelet range.

The authority application must be made in writing and must include:

(1) a completed authority prescription form,

(2) a signed patient acknowledgement,

(3) a completed Romiplostim PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)],

(4) a copy of a full blood count pathology report supporting the diagnosis of ITP, and

(5) where the application is sought on the basis of a medical contraindication to surgery, a signed and dated letter from the clinician making this assessment which includes the date upon which the patient was assessed for surgery and the clinical grounds upon which surgery is contraindicated.

The full blood count must be no more than 1 month old at the time of application.

At the time of the written authority application, medical practitioners should request the appropriate quantity of vials of appropriate strength to provide sufficient drug for a single treatment at a dose of 1 microgram/kg. Up to 1 repeat may be requested with the initial written application.

Subsequently during the initial period of dose titration, authority applications for a single dose and up to 1 repeat may be made by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). The dose (microgram/kg/week) must be provided at the time of application.

Once a patient's dose has been stable for a period of 4 weeks, authority approvals for sufficient vials of appropriate strength based on the weight of the patient and dose (microgram/kg/week) for up to 4 weeks of treatment and up to 4 repeats may be granted, as long as the total period of treatment authorised under this restriction does not exceed 24 weeks.

HIGHLY SPECIALISED DRUGS PROGRAM

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 \$	

Authority approval will not be given for doses of higher than 10 micrograms/kg/week.

Authority required

Initial (grandfather patients)

Initial PBS-subsidised treatment of severe thrombocytopenia in an adult patient with severe chronic immune (idiopathic) thrombocytopenic purpura (ITP) who was receiving treatment with romiplostim prior to 1 April 2011 and in whom the criteria for initial treatment can be demonstrated to have been met at the time romiplostim was commenced.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form,
- (2) a signed patient acknowledgement,
- (3) a completed Romiplostim PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)], and
- (4) where the application is sought on the basis of a medical contraindication to surgery, a signed and dated letter from the clinician making this assessment which includes the date upon which the patient was assessed for surgery and the clinical grounds upon which surgery is contraindicated.

For patients whose dose of romiplostim had been stable for at least 4 weeks at the time of the initial application for PBS-subsidy, the medical practitioner should request sufficient number of vials based on the weight of the patient and dose (microgram/kg/week) to provide up to 4 weeks of treatment. Up to a maximum of 5 repeats may be authorised.

Where the patient is in the titration phase of treatment with romiplostim, medical practitioners should request the appropriate quantity of vials of appropriate strength to provide sufficient drug for a single treatment at a dose of 1 microgram/kg. Up to 1 repeat may be requested with the initial written application.

Subsequently during the initial period of dose titration, authority applications for a single dose and up to 1 repeat may be made by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). The dose (microgram/kg/week) must be provided at the time of application.

Once a patient's dose has been stable for a period of 4 weeks, authority approvals for sufficient vials of appropriate strength based on the weight of the patient and dose (microgram/kg/week) for up to 4 weeks of treatment and up to 4 repeats may be granted, as long as the total period of treatment authorised under this restriction does not exceed 24 weeks.

For patients whose dose of romiplostim had been stable for at least 4 weeks at the time of the initial application for PBS-subsidy, the medical practitioner should request sufficient number of vials of appropriate strength based on the weight of the patient and dose (microgram/kg/week) to provide up to 4 weeks of treatment. Up to a maximum of 5 repeats may be authorised.

Authority approval will not be given for doses of higher than 10 micrograms/kg/week.

Authority required

Continuing therapy or re-initiation after a break in therapy

First period of PBS-subsidised continuing treatment or re-initiation of interrupted PBS-subsidised treatment of severe thrombocytopenia in an adult patient with chronic immune (idiopathic) thrombocytopenic purpura (ITP) who has displayed a sustained platelet response to treatment with romiplostim during the initial period of PBS-subsidised treatment.

For the purposes of this restriction, a sustained platelet response is defined as:

- (a) use of rescue medication (corticosteroids or immunoglobulins) on no more than one occasion during the initial period of PBS-subsidised romiplostim,
- AND either of the following:
- (b) a platelet count greater than or equal to 50,000 million per L on at least four (4) occasions, each at least one week apart;
- OR
- (c) a platelet count greater than 30,000 million per L and which is double the baseline (pre-treatment) platelet count on at least four (4) occasions, each at least one week apart.

Applications for the first period of continuing PBS-subsidised treatment or re-initiation of interrupted treatment must be made in writing and must include:

- (1) a completed authority prescription form, and
- (2) a completed Romiplostim PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)],
- (3) copies of the platelet count pathology reports (unless previously provided for patients re-initiating therapy).

The most recent platelet count must be no more than one month old at the time of application.

The medical practitioner should request sufficient number of vials of appropriate strength based on the weight of the patient and dose (microgram/kg/week) to provide 4 weeks of treatment. Up to a maximum of 5 repeats may be authorised.

Where fewer than 5 repeats are initially requested with the authority prescription, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be made by telephone.

Authority approval will not be given for doses of higher than 10 micrograms/kg/week.

HIGHLY SPECIALISED DRUGS PROGRAM

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
<u>Authority required</u>							
Second and subsequent applications for continuing therapy							
Continuing treatment of severe thrombocytopenia in an adult patient with chronic immune (idiopathic) thrombocytopenic purpura (ITP) who has previously received PBS-subsidised therapy with romiplostim and who continues to display a response to treatment with romiplostim.							
For the purposes of this restriction, a continuing response to treatment with romiplostim is defined as:							
(a) use of rescue medication (corticosteroids or immunoglobulins) on no more than one occasion during the most recent 24 week period of PBS-subsidised treatment with romiplostim,							
AND either of the following:							
(b) a platelet count greater than or equal to 50,000 million per L							
OR							
(c) a platelet count greater than 30,000 million per L and which is double the baseline platelet count.							
Platelet counts must be no more than 1 month old at the time of application.							
Authority applications for second and subsequent periods of continuing therapy may be made by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).							
The medical practitioner should request sufficient number of vials of appropriate strength based on the weight of the patient and dose (microgram/kg/week) to provide 4 weeks of treatment. Up to a maximum of 5 repeats may be authorised.							
Authority approval will not be given for doses of higher than 10 micrograms/kg/week.							
Note:							
Special Pricing Arrangements apply.							
9696H	Powder for injection 375 micrograms (250 micrograms in 0.5 mL when reconstituted)		1	..		977.50	Nplate AN
	(Public)						
9697J	Powder for injection 375 micrograms (250 micrograms in 0.5 mL when reconstituted)		1	..		1023.02	Nplate AN
	(Private)						
9698K	Powder for injection 625 micrograms (500 micrograms in 1 mL when reconstituted)		1	..		1955.00	Nplate AN
	(Public)						
9699L	Powder for injection 625 micrograms (500 micrograms in 1 mL when reconstituted)		1	..		2001.42	Nplate AN
	(Private)						

SILDENAFIL CITRATE

Note:

Any queries concerning the arrangements to prescribe sildenafil citrate 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;

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:

HIGHLY SPECIALISED DRUGS PROGRAM

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
					\$	\$	
	— 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.)

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.

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

(a) Initiation of treatment.

HIGHLY SPECIALISED DRUGS PROGRAM

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
					\$	\$	

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.

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

HIGHLY SPECIALISED DRUGS PROGRAM

						Dispensed Price for Max. Qty	Maximum Recordable Value for Safety Net	
Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	\$	\$	Brand Name and Manufacturer	
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 patients)

Application for initial PBS-subsidised treatment with sildenafil citrate of patients 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:

- (a) WHO Functional Class III primary pulmonary hypertension and a mean right atrial pressure of 8 mmHg or less, as measured by RHC, or, where a RHC cannot be performed on clinical grounds, right ventricular function as assessed by ECHO; OR
- (b) WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease and a mean right atrial pressure of 8 mmHg or less, as measured by RHC, or, where a RHC cannot be performed on clinical grounds, right ventricular function as assessed by ECHO.

Patients must have failed to respond [see Note for definition of response] to 6 or more weeks of appropriate vasodilator treatment unless intolerance or a contraindication to such treatment exists.

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].

Details of prior vasodilator treatment, including the dose and duration of treatment, must be provided at the time of application. Where the patient has an adverse event to a vasodilator or where vasodilator treatment is contraindicated, details on the nature of the adverse event or contraindication according to the TGA-approved Product Information must also be provided with the application.

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).

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Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty	Maximum Recordable Value for Safety Net	Brand Name and Manufacturer
					\$	\$	

Authority required

Initial (new patients)

Application for initial PBS-subsidised treatment with sildenafil citrate of patients 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:

- (a) WHO Functional Class III primary pulmonary hypertension and a mean right atrial pressure greater than 8 mmHg, as measured by RHC, or, where a RHC cannot be performed on clinical grounds, right ventricular function as assessed by ECHO; OR
- (b) WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease and a mean right atrial pressure greater than 8 mmHg, as measured by RHC, or, where a RHC cannot be performed on clinical grounds, right ventricular function as assessed by ECHO.

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 (change or re-commencement for all patients)

Application for initial PBS-subsidised treatment with sildenafil citrate of patients with one of the following:

- (a) WHO Functional Class III primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease who wish to re-commence PBS-subsidised sildenafil citrate after a break in therapy and who have demonstrated a response to their most recent course of PBS-subsidised treatment with sildenafil citrate; OR
- (b) WHO Functional Class III primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease and whose most recent course of PBS-subsidised treatment was with a PAH agent other than sildenafil citrate.

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.

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 sildenafil citrate of patients who have received approval for initial PBS-subsidised treatment with sildenafil citrate, and who have been assessed by a physician from a designated hospital to have achieved a response to their most recent course of sildenafil citrate 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.

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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
					\$	\$	

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).

9547L	Tablet 20 mg (base) (Public)		90	..		898.43	Revatio	PF
9605M	Tablet 20 mg (base) (Private)		90	..		940.79	Revatio	PF

VALACICLOVIR

Authority required

Prophylaxis of cytomegalovirus (CMV) infection and disease following renal transplantation in patients at risk of CMV disease.

6280M	Tablet 500 mg (as hydrochloride) (Private)		500	2		*2162.32	^a APO-Valaciclovir	TX
							^a Valtrex	GK

VALACICLOVIR

Authority required (STREAMLINED)

3419

Prophylaxis of cytomegalovirus (CMV) infection and disease following renal transplantation in patients at risk of CMV disease.

9568N	Tablet 500 mg (as hydrochloride) (Public)		500	2		*2115.90	^a APO-Valaciclovir	TX
							^a Valtrex	GK

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	
CARMELLOSE SODIUM								
4568K	Mouth spray 10 mg per mL, 25 mL	‡1	1		10.79	5.60	Aquae	VT
4569L	Mouth spray 10 mg per mL, 100 mL	‡1	..		12.46	5.60	Aquae	VT
GABAPENTIN								
<u>Authority required</u>								
To be approved for the treatment of refractory neuropathic pain not controlled by other drugs.								
4592Q	Capsule 300 mg	100	5		59.23	5.60	^a DBL Gabapentin	HH
							^a Gabahexal 300mg	SZ
							^a Gabatine 300	SI
							^a Gantin	GN
							^a GenRx Gabapentin	GX
							^a Nupentin 300	AF
					60.18	5.60	^a Neurontin	PF
4593R	Capsule 400 mg	100	5		78.45	5.60	^a DBL Gabapentin	HH
							^a Gabahexal 400mg	SZ
							^a Gabatine 400	SI
							^a Gantin	GN
							^a GenRx Gabapentin	GX
							^a Nupentin 400	AF
					79.41	5.60	^a Neurontin	PF
4595W	Tablet 800 mg	100	5		158.84	5.60	^a Gantin	GN
					159.78	5.60	^a Neurontin	PF