



Australian Government

Department of Health



Schedule of Pharmaceutical Benefits

Summary of Changes

Effective 1 February 2021



Fees, Patient Contributions and Safety Net Thresholds

The following fees, patient contributions and safety net thresholds apply as at 1 February 2021 and are included, where applicable, in prices published in the Schedule —

Dispensing Fees:	Ready-prepared	\$7.74
	Dangerous drug fee	\$4.80
	Extemporaneously-prepared	\$9.78
	Allowable additional patient charge*	\$4.42
Additional Fees (for safety net prices):	Ready-prepared	\$1.29
	Extemporaneously-prepared	\$1.66
Patient Co-payments:	General	\$41.30
	Concessional	\$6.60
Safety Net Thresholds:	General	\$1497.20
	Concessional	\$316.80
Safety Net Card Issue Fee:		\$10.34

* 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

These changes to the Schedule of Pharmaceutical Benefits are effective from 1 February 2021. The Schedule is updated on the first day of each month and is available on the internet at www.pbs.gov.au.

General Pharmaceutical Benefits

Additions

Addition – Item

- 12256C **FLUOXETINE**, fluoxetine 20 mg capsule, 100 (*Fluoxetine Capsule (USP)*)
- 12254Y **INSULIN ASPART**, insulin aspart 100 units/mL injection, 5 x 3 mL pen devices (*NovoRapid FlexPen*)
- 12238D **INSULIN ASPART + INSULIN ASPART PROTAMINE**, insulin aspart 30 units/mL + insulin aspart protamine 70 units/mL injection, 5 x 3 mL pen devices (*NovoMix 30 FlexPen*)
- 12236B **INSULIN DETEMIR**, insulin detemir 100 units/mL injection, 5 x 3 mL pen devices (*Levemir FlexPen*)
- 12268Q **INSULIN GLULISINE**, insulin glulisine 100 units/mL injection, 5 x 3 mL pen devices (*Apidra SoloStar*)
- 12262J **INSULIN ISOPHANE HUMAN**, insulin isophane human 100 units/mL injection, 5 x 3 mL pen devices (*Protaphane InnoLet*)
- 12255B **INSULIN ISOPHANE HUMAN + INSULIN NEUTRAL HUMAN**, insulin isophane human 70 units/mL + insulin neutral human 30 units/mL injection, 5 x 3 mL pen devices (*Mixtard 30/70 InnoLet*)
- 12237C **INSULIN LISPRO**, insulin lispro 100 units/mL injection, 5 x 3 mL pen devices (*Humalog KwikPen*)
- 12234X **INSULIN LISPRO + INSULIN LISPRO PROTAMINE**, insulin lispro 25 units/mL + insulin lispro protamine 75 units/mL injection, 5 x 3 mL pen devices (*Humalog Mix25 KwikPen*)
- 12261H **INSULIN LISPRO + INSULIN LISPRO PROTAMINE**, insulin lispro 50 units/mL + insulin lispro protamine 50 units/mL injection, 5 x 3 mL pen devices (*Humalog Mix50 KwikPen*)
- 12239E **PHENELZINE**, phenelzine 15 mg tablet, 60 (*Phenelzine sulfate USP (Generic Health)*)
- 12267P **TERBUTALINE**, terbutaline sulfate 500 microgram/actuation powder for inhalation, 120 actuations (*Bricanyl Turbuhaler*)
- 12250R **TRIHEXYPHENIDYL (BENZHEXOL)**, trihexyphenidyl (benzhexol) hydrochloride 2 mg tablet, 100 (*Trihexyphenidyl hydrochloride USP (Medsurge)*)

Addition – Brand

- 2751T *Pharmacor Amlodipine, CR* – **AMLODIPINE**, amlodipine 5 mg tablet, 30
- 2752W *Pharmacor Amlodipine, CR* – **AMLODIPINE**, amlodipine 10 mg tablet, 30
- 11692J *Esomeprazole Mylan, AL* – **ESOMEPRAZOLE**, esomeprazole 20 mg enteric tablet, 30
- 8600P *Esomeprazole Mylan, AL* – **ESOMEPRAZOLE**, esomeprazole 20 mg enteric tablet, 30
- 8886Q *Esomeprazole Mylan, AL* – **ESOMEPRAZOLE**, esomeprazole 20 mg enteric tablet, 30
- 3401B *Esomeprazole Mylan, AL* – **ESOMEPRAZOLE**, esomeprazole 40 mg enteric tablet, 30
- 8601Q *Esomeprazole Mylan, AL* – **ESOMEPRAZOLE**, esomeprazole 40 mg enteric tablet, 30
- 11815W *Optisulin SoloStar, WA* – **INSULIN GLARGINE**, insulin glargine 100 units/mL injection, 5 x 3 mL pen devices
- 2591J *Isotretinoin GX, SZ* – **ISOTRETINOIN**, isotretinoin 10 mg capsule, 60
- 2592K *Isotretinoin GX, SZ* – **ISOTRETINOIN**, isotretinoin 20 mg capsule, 60
- 10526B *APO-Lurasidone, TX* – **LURASIDONE**, lurasidone hydrochloride 40 mg tablet, 30

10529E	<i>APO-Lurasidone, TX</i> – LURASIDONE , lurasidone hydrochloride 80 mg tablet, 30
3124K	<i>Uramet, AS</i> – METHENAMINE HIPPURATE , methenamine hippurate 1 g tablet, 100
1594X	<i>Zotren 4, RF</i> – ONDANSETRON , ondansetron 4 mg tablet, 10
8224W	<i>Zotren 4, RF</i> – ONDANSETRON , ondansetron 4 mg tablet, 4
1595Y	<i>Zotren 8, RF</i> – ONDANSETRON , ondansetron 8 mg tablet, 10
8225X	<i>Zotren 8, RF</i> – ONDANSETRON , ondansetron 8 mg tablet, 4
12022R	<i>APX-Paracetamol/Codeine, TY</i> – PARACETAMOL + CODEINE , paracetamol 500 mg + codeine phosphate hemihydrate 30 mg tablet, 20
12066C	<i>APX-Paracetamol/Codeine, TY</i> – PARACETAMOL + CODEINE , paracetamol 500 mg + codeine phosphate hemihydrate 30 mg tablet, 20
1215Y	<i>APX-Paracetamol/Codeine, TY</i> – PARACETAMOL + CODEINE , paracetamol 500 mg + codeine phosphate hemihydrate 30 mg tablet, 20
3316M	<i>APX-Paracetamol/Codeine, TY</i> – PARACETAMOL + CODEINE , paracetamol 500 mg + codeine phosphate hemihydrate 30 mg tablet, 20
10460M	<i>POSACONAZOLE DR.REDDY'S, RZ</i> – POSACONAZOLE , posaconazole 100 mg modified release tablet, 24
10460M	<i>Pharmacor Posaconazole, CR</i> – POSACONAZOLE , posaconazole 100 mg modified release tablet, 24
2339D	<i>Spiroinolactone Mylan 25, AL</i> – SPIRONOLACTONE , spironolactone 25 mg tablet, 100
2340E	<i>Spiroinolactone Mylan 100, AL</i> – SPIRONOLACTONE , spironolactone 100 mg tablet, 100

Addition – Equivalence Indicator

3124K	<i>Hiprex, IL</i> – METHENAMINE HIPPURATE , methenamine hippurate 1 g tablet, 100
2856H	<i>Nardil, LM</i> – PHENELZINE , phenelzine 15 mg tablet, 100
1109J	<i>Artane, RW</i> – TRIHEXYPHENIDYL (BENZHEXOL) , trihexyphenidyl (benzhexol) hydrochloride 2 mg tablet, 200

Addition – Note

1434L	FLUOXETINE , fluoxetine 20 mg capsule, 28 (<i>APO-Fluoxetine, Auscap Aspen, BTC Fluoxetine, Blooms the Chemist Fluoxetine, FLUOTEX, Fluoxetine AN, Fluoxetine APOTEX, Fluoxetine Sandoz, Fluoxetine generichealth, Fluoxetine-GA, Lovan, Prozac 20, Zactin</i>)
2856H	PHENELZINE , phenelzine 15 mg tablet, 100 (<i>Nardil</i>)
1109J	TRIHEXYPHENIDYL (BENZHEXOL) , trihexyphenidyl (benzhexol) hydrochloride 2 mg tablet, 200 (<i>Artane</i>)

Addition – Restriction

1109J	TRIHEXYPHENIDYL (BENZHEXOL) , trihexyphenidyl (benzhexol) hydrochloride 2 mg tablet, 200 (<i>Artane</i>)
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Deletions

Deletion – Item

10947E	OCRIPLASMIN , ocriplasmin 500 microgram/0.2 mL injection, 0.2 mL vial (<i>Jetrea</i>)
11713L	PHENELZINE , phenelzine 15 mg tablet, 60 (<i>Nardil</i>)

Alterations

Alteration – Item Description

From

8609D	INSULIN ASPART + INSULIN ASPART PROTAMINE , insulin aspart 30 units/mL + insulin aspart protamine 70 units/mL injection, 5 x 3 mL syringes (<i>NovoMix 30 FlexPen, NovoMix 30 Penfill 3 mL</i>)
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To

8609D	INSULIN ASPART + INSULIN ASPART PROTAMINE , insulin aspart 30 units/mL + insulin aspart protamine 70 units/mL injection, 5 x 3 mL cartridges (<i>NovoMix 30 FlexPen, NovoMix 30 Penfill 3 mL</i>)
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Alteration – Note

11815W	INSULIN GLARGINE , insulin glargine 100 units/mL injection, 5 x 3 mL pen devices (<i>Optisulin SoloStar, Semglee</i>)
9039R	INSULIN GLARGINE , insulin glargine 100 units/mL injection, 5 x 3 mL cartridges (<i>Optisulin SoloStar, Optisulin</i>)
11884L	LISDEXAMFETAMINE , lisdexamfetamine dimesilate 20 mg capsule, 30 (<i>Vyvanse</i>)
10486X	LISDEXAMFETAMINE , lisdexamfetamine dimesilate 30 mg capsule, 30 (<i>Vyvanse</i>)
11898F	LISDEXAMFETAMINE , lisdexamfetamine dimesilate 40 mg capsule, 30 (<i>Vyvanse</i>)

10474G **LISDEXAMFETAMINE**, lisdexamfetamine dimesilate 50 mg capsule, 30 (*Vyvanse*)
 11897E **LISDEXAMFETAMINE**, lisdexamfetamine dimesilate 60 mg capsule, 30 (*Vyvanse*)
 10492F **LISDEXAMFETAMINE**, lisdexamfetamine dimesilate 70 mg capsule, 30 (*Vyvanse*)
 3440C **METHYLPHENIDATE**, methylphenidate hydrochloride 10 mg modified release capsule, 30 (*Ritalin LA*)
 2276T **METHYLPHENIDATE**, methylphenidate hydrochloride 20 mg modified release capsule, 30 (*Ritalin LA*)
 2280B **METHYLPHENIDATE**, methylphenidate hydrochloride 30 mg modified release capsule, 30 (*Ritalin LA*)
 2283E **METHYLPHENIDATE**, methylphenidate hydrochloride 40 mg modified release capsule, 30 (*Ritalin LA*)
 12116Q **METHYLPHENIDATE**, methylphenidate hydrochloride 60 mg modified release capsule, 30 (*Ritalin LA*)
 2387P **METHYLPHENIDATE**, methylphenidate hydrochloride 18 mg modified release tablet, 30 (*Concerta*)
 2172H **METHYLPHENIDATE**, methylphenidate hydrochloride 27 mg modified release tablet, 30 (*Concerta*)
 2388Q **METHYLPHENIDATE**, methylphenidate hydrochloride 36 mg modified release tablet, 30 (*Concerta*)
 2432B **METHYLPHENIDATE**, methylphenidate hydrochloride 54 mg modified release tablet, 30 (*Concerta*)
 10614P **RUXOLITINIB**, ruxolitinib 5 mg tablet, 56 (*Jakavi*)
 10913J **RUXOLITINIB**, ruxolitinib 10 mg tablet, 56 (*Jakavi*)
 10619X **RUXOLITINIB**, ruxolitinib 15 mg tablet, 56 (*Jakavi*)
 10618W **RUXOLITINIB**, ruxolitinib 20 mg tablet, 56 (*Jakavi*)

Alteration – Restriction

11884L **LISDEXAMFETAMINE**, lisdexamfetamine dimesilate 20 mg capsule, 30 (*Vyvanse*)
 10486X **LISDEXAMFETAMINE**, lisdexamfetamine dimesilate 30 mg capsule, 30 (*Vyvanse*)
 11898F **LISDEXAMFETAMINE**, lisdexamfetamine dimesilate 40 mg capsule, 30 (*Vyvanse*)
 10474G **LISDEXAMFETAMINE**, lisdexamfetamine dimesilate 50 mg capsule, 30 (*Vyvanse*)
 11897E **LISDEXAMFETAMINE**, lisdexamfetamine dimesilate 60 mg capsule, 30 (*Vyvanse*)
 10492F **LISDEXAMFETAMINE**, lisdexamfetamine dimesilate 70 mg capsule, 30 (*Vyvanse*)
 3440C **METHYLPHENIDATE**, methylphenidate hydrochloride 10 mg modified release capsule, 30 (*Ritalin LA*)
 2276T **METHYLPHENIDATE**, methylphenidate hydrochloride 20 mg modified release capsule, 30 (*Ritalin LA*)
 2280B **METHYLPHENIDATE**, methylphenidate hydrochloride 30 mg modified release capsule, 30 (*Ritalin LA*)
 2283E **METHYLPHENIDATE**, methylphenidate hydrochloride 40 mg modified release capsule, 30 (*Ritalin LA*)
 12116Q **METHYLPHENIDATE**, methylphenidate hydrochloride 60 mg modified release capsule, 30 (*Ritalin LA*)
 2387P **METHYLPHENIDATE**, methylphenidate hydrochloride 18 mg modified release tablet, 30 (*Concerta*)
 2172H **METHYLPHENIDATE**, methylphenidate hydrochloride 27 mg modified release tablet, 30 (*Concerta*)
 2388Q **METHYLPHENIDATE**, methylphenidate hydrochloride 36 mg modified release tablet, 30 (*Concerta*)
 2432B **METHYLPHENIDATE**, methylphenidate hydrochloride 54 mg modified release tablet, 30 (*Concerta*)
 10614P **RUXOLITINIB**, ruxolitinib 5 mg tablet, 56 (*Jakavi*)
 10913J **RUXOLITINIB**, ruxolitinib 10 mg tablet, 56 (*Jakavi*)
 10619X **RUXOLITINIB**, ruxolitinib 15 mg tablet, 56 (*Jakavi*)
 10618W **RUXOLITINIB**, ruxolitinib 20 mg tablet, 56 (*Jakavi*)

Alteration – Manufacturer Code

		<i>From</i>	<i>To</i>
3145M	<i>Catapres 100</i> – CLONIDINE , clonidine hydrochloride 100 microgram tablet, 100	BY	IX
3141H	<i>Catapres</i> – CLONIDINE , clonidine hydrochloride 150 microgram tablet, 100	BY	IX
12025X	<i>Oxycodone BNM</i> – OXYCODONE , oxycodone hydrochloride 5 mg capsule, 20	LI	BZ
12044X	<i>Oxycodone BNM</i> – OXYCODONE , oxycodone hydrochloride 5 mg capsule, 20	LI	BZ
5191F	<i>Oxycodone BNM</i> – OXYCODONE , oxycodone hydrochloride 5 mg capsule, 20	LI	BZ
8464L	<i>Oxycodone BNM</i> – OXYCODONE , oxycodone hydrochloride 5 mg capsule, 20	LI	BZ

12031F	<i>Oxycodone BNM</i> – OXYCODONE , oxycodone hydrochloride 10 mg capsule, 20	LI	BZ
12074L	<i>Oxycodone BNM</i> – OXYCODONE , oxycodone hydrochloride 10 mg capsule, 20	LI	BZ
5197M	<i>Oxycodone BNM</i> – OXYCODONE , oxycodone hydrochloride 10 mg capsule, 20	LI	BZ
8501K	<i>Oxycodone BNM</i> – OXYCODONE , oxycodone hydrochloride 10 mg capsule, 20	LI	BZ
8502L	<i>Oxycodone BNM</i> – OXYCODONE , oxycodone hydrochloride 20 mg capsule, 20	LI	BZ

Supply Only

From 1 November 2020 when a product is deleted from the Schedule it may now be available under new Supply Only rules. Supply Only items/ brands are available on the Schedule for dispensing but not for prescribing, usually for a period of up to 12 months from when it was deleted.

Substitution of Supply Only items/brands with products flagged as "equivalent for substitution" still apply as specified in the Schedule at the time the script was written. Further information on Supply Only arrangements is available at www.pbs.gov.au

Supply Only commencing 1 February 2021

1269T	<i>Cyprocur 50, AS</i> – CYPROTERONE , cyproterone acetate 50 mg tablet, 20
1270W	<i>Cyprocur 50, AS</i> – CYPROTERONE , cyproterone acetate 50 mg tablet, 50
8019C	<i>Cyprocur 100, AS</i> – CYPROTERONE , cyproterone acetate 100 mg tablet, 50
8435Y	<i>NovoRapid FlexPen, NF</i> – INSULIN ASPART , insulin aspart 100 units/mL injection, 5 x 3 mL cartridges
8609D	<i>NovoMix 30 FlexPen, NF</i> – INSULIN ASPART + INSULIN ASPART PROTAMINE , insulin aspart 30 units/mL + insulin aspart protamine 70 units/mL injection, 5 x 3 mL cartridges
9040T	<i>Levemir FlexPen, NF</i> – INSULIN DETEMIR , insulin detemir 100 units/mL injection, 5 x 3 mL cartridges
9039R	<i>Optisulin SoloStar, WA</i> – INSULIN GLARGINE , insulin glargine 100 units/mL injection, 5 x 3 mL cartridges
1921D	<i>Apidra SoloStar, SW</i> – INSULIN GLULISINE , insulin glulisine 100 units/mL injection, 5 x 3 mL cartridges
1761Q	<i>Protaphane InnoLet, NI</i> – INSULIN ISOPHANE HUMAN , insulin isophane human 100 units/mL injection, 5 x 3 mL cartridges
1763T	<i>Mixtard 30/70 InnoLet, NI</i> – INSULIN ISOPHANE HUMAN + INSULIN NEUTRAL HUMAN , insulin isophane human 70 units/mL + insulin neutral human 30 units/mL injection, 5 x 3 mL cartridges
8212F	<i>Humalog KwikPen, KP</i> – INSULIN LISPRO , insulin lispro 100 units/mL injection, 5 x 3 mL cartridges
8390N	<i>Humalog Mix25 KwikPen, KP</i> – INSULIN LISPRO + INSULIN LISPRO PROTAMINE , insulin lispro 25 units/mL + insulin lispro protamine 75 units/mL injection, 5 x 3 mL cartridges
8874C	<i>Humalog Mix50 KwikPen, KP</i> – INSULIN LISPRO + INSULIN LISPRO PROTAMINE , insulin lispro 50 units/mL + insulin lispro protamine 50 units/mL injection, 5 x 3 mL cartridges
10555M	<i>Ostira, PF</i> – ZOLEDRONIC ACID , zoledronic acid 5 mg/100 mL injection, 100 mL bag
10571J	<i>Ostira, PF</i> – ZOLEDRONIC ACID , zoledronic acid 5 mg/100 mL injection, 100 mL bag

Advance Notices

1 March 2021

Deletion – Brand

10822N	<i>PKU Baby, OH</i> – AMINO ACID FORMULA WITH FAT, CARBOHYDRATE, VITAMINS, MINERALS AND LONG CHAIN POLYUNSATURATED FATTY ACIDS WITHOUT PHENYLALANINE AND SUPPLEMENTED WITH DOCOSAHEXAENOIC ACID , amino acid formula with fat, carbohydrate, vitamins, minerals and long chain polyunsaturated fatty acids without phenylalanine and supplemented with docosahexaenoic acid oral liquid, 20 x 500 mL bottles
1147J	<i>Captopril Sandoz, SZ</i> – CAPTOPRIL , captopril 12.5 mg tablet, 90
2964B	<i>DBL Cephalothin, PF</i> – CEFALOTIN , cefalotin 1 g injection, 10 vials
3376Q	<i>DBL Cephalothin, PF</i> – CEFALOTIN , cefalotin 1 g injection, 10 vials
1158Y	<i>Magicul 400, AF</i> – CIMETIDINE , cimetidine 400 mg tablet, 60
11011M	<i>Zepatier, MK</i> – ELBASVIR + GRAZOPREVR , elbasvir 50 mg + grazoprevir 100 mg tablet, 28
11021C	<i>Zepatier, MK</i> – ELBASVIR + GRAZOPREVR , elbasvir 50 mg + grazoprevir 100 mg tablet, 28
10789W	<i>E-Mycin, AF</i> – ERYTHROMYCIN ETHYLSUCCINATE , erythromycin (as ethylsuccinate) 400 mg tablet, 25
2750R	<i>E-Mycin, AF</i> – ERYTHROMYCIN ETHYLSUCCINATE , erythromycin (as ethylsuccinate) 400 mg tablet, 25
3336N	<i>E-Mycin, AF</i> – ERYTHROMYCIN ETHYLSUCCINATE , erythromycin (as ethylsuccinate) 400 mg tablet, 25

1434L	<i>Auscap Aspen, RW</i> – FLUOXETINE , fluoxetine 20 mg capsule, 28
8534E	<i>Lercanidipine Sandoz, SZ</i> – LERCANIDIPINE , lercanidipine hydrochloride 10 mg tablet, 28
8679T	<i>Lercanidipine Sandoz, SZ</i> – LERCANIDIPINE , lercanidipine hydrochloride 20 mg tablet, 28
8810Q	<i>Glucovance 500mg/2.5mg, AL</i> – METFORMIN + GLIBENCLAMIDE , metformin hydrochloride 500 mg + glibenclamide 2.5 mg tablet, 90
8811R	<i>Glucovance 500mg/5mg, AL</i> – METFORMIN + GLIBENCLAMIDE , metformin hydrochloride 500 mg + glibenclamide 5 mg tablet, 90
8838E	<i>Glucovance 250mg/1.25mg, AL</i> – METFORMIN + GLIBENCLAMIDE , metformin hydrochloride 250 mg + glibenclamide 1.25 mg tablet, 90
2055E	<i>Carafate, AF</i> – SUCRALFATE , sucralfate 1 g tablet, 120
2109B	<i>Genox 10, AF</i> – TAMOXIFEN , tamoxifen 10 mg tablet, 60
1248Q	<i>Anpec 40, AF</i> – VERAPAMIL , verapamil hydrochloride 40 mg tablet, 100

1 April 2021

Deletion – Brand

10685J	<i>Fraxiparine, AS</i> – NADROPARIN , nadroparin calcium 3800 anti-Xa units/0.4 mL injection, 2 x 0.4 mL syringes
10686K	<i>Fraxiparine, AS</i> – NADROPARIN , nadroparin calcium 2850 anti-Xa units/0.3 mL injection, 2 x 0.3 mL syringes
10687L	<i>Fraxiparine, AS</i> – NADROPARIN , nadroparin calcium 1900 anti-Xa units/0.2 mL injection, 2 x 0.2 mL syringes
10701F	<i>Fraxiparine, AS</i> – NADROPARIN , nadroparin calcium 2850 anti-Xa units/0.3 mL injection, 2 x 0.3 mL syringes
10702G	<i>Fraxiparine, AS</i> – NADROPARIN , nadroparin calcium 9500 anti-Xa units/mL injection, 2 x 1 mL syringes
10706L	<i>Fraxiparine Forte, AS</i> – NADROPARIN , nadroparin calcium 11 400 anti-Xa units/0.6 mL injection, 2 x 0.6 mL syringes
10707M	<i>Fraxiparine Forte, AS</i> – NADROPARIN , nadroparin calcium 19 000 anti-Xa units/mL injection, 2 x 1 mL syringes
10716B	<i>Fraxiparine, AS</i> – NADROPARIN , nadroparin calcium 5700 anti-Xa units/0.6 mL injection, 2 x 0.6 mL syringes
10717C	<i>Fraxiparine, AS</i> – NADROPARIN , nadroparin calcium 3800 anti-Xa units/0.4 mL injection, 2 x 0.4 mL syringes
10718D	<i>Fraxiparine, AS</i> – NADROPARIN , nadroparin calcium 5700 anti-Xa units/0.6 mL injection, 2 x 0.6 mL syringes
10725L	<i>Fraxiparine Forte, AS</i> – NADROPARIN , nadroparin calcium 15 200 anti-Xa units/0.8 mL injection, 2 x 0.8 mL syringes
10733X	<i>Fraxiparine, AS</i> – NADROPARIN , nadroparin calcium 9500 anti-Xa units/mL injection, 2 x 1 mL syringes
10734Y	<i>Fraxiparine, AS</i> – NADROPARIN , nadroparin calcium 7600 anti-Xa units/0.8 mL injection, 2 x 0.8 mL syringes
10735B	<i>Fraxiparine, AS</i> – NADROPARIN , nadroparin calcium 1900 anti-Xa units/0.2 mL injection, 2 x 0.2 mL syringes
10740G	<i>Fraxiparine, AS</i> – NADROPARIN , nadroparin calcium 7600 anti-Xa units/0.8 mL injection, 2 x 0.8 mL syringes

Palliative Care

Advance Notices

1 April 2021

Deletion – Brand

5319Y	<i>Panadol, GC</i> – PARACETAMOL , paracetamol 500 mg suppository, 24
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Highly Specialised Drugs Program (Private Hospital)

Additions

Addition – Item

12241G	SELEXIPAG , selexipag 200 microgram tablet, 140 (<i>Uptravi</i>)
12242H	SELEXIPAG , selexipag 200 microgram tablet, 60 (<i>Uptravi</i>)
12260G	SELEXIPAG , selexipag 400 microgram tablet, 60 (<i>Uptravi</i>)
12248P	SELEXIPAG , selexipag 600 microgram tablet, 60 (<i>Uptravi</i>)
12246M	SELEXIPAG , selexipag 800 microgram tablet, 60 (<i>Uptravi</i>)
12253X	SELEXIPAG , selexipag 800 microgram tablet, 60 (<i>Uptravi</i>)
12245L	SELEXIPAG , selexipag 1 mg tablet, 60 (<i>Uptravi</i>)

12257D **SELEXIPAG**, selexipag 1.2 mg tablet, 60 (*Uptravi*)
12251T **SELEXIPAG**, selexipag 1.4 mg tablet, 60 (*Uptravi*)
12264L **SELEXIPAG**, selexipag 1.6 mg tablet, 60 (*Uptravi*)

Addition – Brand

12139X *Bosentan Cipla, LR* – **BOSENTAN**, bosentan 62.5 mg tablet, 60
12143D *Bosentan Cipla, LR* – **BOSENTAN**, bosentan 62.5 mg tablet, 60
12148J *Bosentan Cipla, LR* – **BOSENTAN**, bosentan 62.5 mg tablet, 60
6429J *Bosentan Cipla, LR* – **BOSENTAN**, bosentan 62.5 mg tablet, 60
12146G *Bosentan Cipla, LR* – **BOSENTAN**, bosentan 125 mg tablet, 60
6430K *Bosentan Cipla, LR* – **BOSENTAN**, bosentan 125 mg tablet, 60
12138W *Sildenafil PHT APOTEX, TY* – **SILDENAFIL**, sildenafil 20 mg tablet, 90
9605M *Sildenafil PHT APOTEX, TY* – **SILDENAFIL**, sildenafil 20 mg tablet, 90

Addition – Note

12201E **AMBRISENTAN**, ambrisentan 5 mg tablet, 30 (*Ambrisentan Mylan, Cipla Ambrisentan, PULMORIS, Volibris*)
12180C **AMBRISENTAN**, ambrisentan 10 mg tablet, 30 (*Ambrisentan Mylan, Cipla Ambrisentan, PULMORIS, Volibris*)
12148J **BOSENTAN**, bosentan 62.5 mg tablet, 60 (*BOSENTAN DR.REDDY'S, BOSLEER, Bosentan APO, Bosentan Cipla, Bosentan Mylan, Bosentan RBX, Bosentan Sandoz, Tracleer*)
12146G **BOSENTAN**, bosentan 125 mg tablet, 60 (*BOSENTAN DR.REDDY'S, BOSLEER, Bosentan APO, Bosentan Cipla, Bosentan GH, Bosentan Mylan, Bosentan RBX, Bosentan Sandoz, Tracleer*)
12135Q **MACITENTAN**, macitentan 10 mg tablet, 30 (*Opsumit*)
12138W **SILDENAFIL**, sildenafil 20 mg tablet, 90 (*APO-Sildenafil PHT, Revatio, SILDATIO PHT, Sildenafil AN PHT 20, Sildenafil PHT APOTEX, Sildenafil Sandoz PHT 20*)
12150L **TADALAFIL**, tadalafil 20 mg tablet, 56 (*Adcirca, TADALIS 20, Tadalca*)

Alterations

Alteration – Brand Name

From
12139X *BOSENTAN DR. REDDY'S, RI* – **BOSENTAN**, bosentan 62.5 mg tablet, 60
To
12139X *BOSENTAN DR.REDDY'S, RI* – **BOSENTAN**, bosentan 62.5 mg tablet, 60
From
12143D *BOSENTAN DR. REDDY'S, RI* – **BOSENTAN**, bosentan 62.5 mg tablet, 60
To
12143D *BOSENTAN DR.REDDY'S, RI* – **BOSENTAN**, bosentan 62.5 mg tablet, 60
From
12148J *BOSENTAN DR. REDDY'S, RI* – **BOSENTAN**, bosentan 62.5 mg tablet, 60
To
12148J *BOSENTAN DR.REDDY'S, RI* – **BOSENTAN**, bosentan 62.5 mg tablet, 60
From
6429J *BOSENTAN DR. REDDY'S, RI* – **BOSENTAN**, bosentan 62.5 mg tablet, 60
To
6429J *BOSENTAN DR.REDDY'S, RI* – **BOSENTAN**, bosentan 62.5 mg tablet, 60
From
12146G *BOSENTAN DR. REDDY'S, RI* – **BOSENTAN**, bosentan 125 mg tablet, 60
To
12146G *BOSENTAN DR.REDDY'S, RI* – **BOSENTAN**, bosentan 125 mg tablet, 60
From
6430K *BOSENTAN DR. REDDY'S, RI* – **BOSENTAN**, bosentan 125 mg tablet, 60
To
6430K *BOSENTAN DR.REDDY'S, RI* – **BOSENTAN**, bosentan 125 mg tablet, 60

Alteration – Note

5827Q **ELTROMBOPAG**, eltrombopag 25 mg tablet, 28 (*Revolade*)
5828R **ELTROMBOPAG**, eltrombopag 50 mg tablet, 28 (*Revolade*)
9697J **ROMIPLOSTIM**, romiplostim 250 microgram injection, 1 vial (*Nplate*)

9699L **ROMIPLOSTIM**, romiplostim 500 microgram injection, 1 vial (*Nplate*)

Alteration – Restriction

12201E **AMBRISENTAN**, ambrisentan 5 mg tablet, 30 (*Ambrisentan Mylan, Cipla Ambrisentan, PULMORIS, Volibris*)

12180C **AMBRISENTAN**, ambrisentan 10 mg tablet, 30 (*Ambrisentan Mylan, Cipla Ambrisentan, PULMORIS, Volibris*)

12139X **BOSENTAN**, bosentan 62.5 mg tablet, 60 (*BOSENTAN DR.REDDY'S, BOSLEER, Bosentan APO, Bosentan Cipla, Bosentan Mylan, Bosentan RBX, Bosentan Sandoz, Tracleer*)

12148J **BOSENTAN**, bosentan 62.5 mg tablet, 60 (*BOSENTAN DR.REDDY'S, BOSLEER, Bosentan APO, Bosentan Cipla, Bosentan Mylan, Bosentan RBX, Bosentan Sandoz, Tracleer*)

12146G **BOSENTAN**, bosentan 125 mg tablet, 60 (*BOSENTAN DR.REDDY'S, BOSLEER, Bosentan APO, Bosentan Cipla, Bosentan GH, Bosentan Mylan, Bosentan RBX, Bosentan Sandoz, Tracleer*)

5827Q **ELTROMBOPAG**, eltrombopag 25 mg tablet, 28 (*Revolade*)

5828R **ELTROMBOPAG**, eltrombopag 50 mg tablet, 28 (*Revolade*)

12135Q **MACITENTAN**, macitentan 10 mg tablet, 30 (*Opsumit*)

9697J **ROMIPLOSTIM**, romiplostim 250 microgram injection, 1 vial (*Nplate*)

9699L **ROMIPLOSTIM**, romiplostim 500 microgram injection, 1 vial (*Nplate*)

12138W **SILDENAFIL**, sildenafil 20 mg tablet, 90 (*APO-Sildenafil PHT, Revatio, SILDATIO PHT, Sildenafil AN PHT 20, Sildenafil PHT APOTEX, Sildenafil Sandoz PHT 20*)

12150L **TADALAFIL**, tadalafil 20 mg tablet, 56 (*Adcirca, TADALIS 20, Tadalca*)

Alteration – Manufacturer Code

		<i>From</i>	<i>To</i>
12201E	<i>Volibris</i> – AMBRISENTAN , ambrisentan 5 mg tablet, 30	GK	ZE
9648T	<i>Volibris</i> – AMBRISENTAN , ambrisentan 5 mg tablet, 30	GK	ZE
12180C	<i>Volibris</i> – AMBRISENTAN , ambrisentan 10 mg tablet, 30	GK	ZE
9649W	<i>Volibris</i> – AMBRISENTAN , ambrisentan 10 mg tablet, 30	GK	ZE

Supply Only

From 1 November 2020 when a product is deleted from the Schedule it may now be available under new Supply Only rules. Supply Only items/ brands are available on the Schedule for dispensing but not for prescribing, usually for a period of up to 12 months from when it was deleted.

Substitution of Supply Only items/brands with products flagged as "equivalent for substitution" still apply as specified in the Schedule at the time the script was written. Further information on Supply Only arrangements is available at www.pbs.gov.au

Supply Only commencing 1 February 2021

10542W DBL Zoledronic Acid, *PF* – **ZOLEDRONIC ACID**, zoledronic acid 4 mg/100 mL injection, 100 mL bag

Advance Notices

1 March 2021

Deletion – Brand

10979W *Zepatier, MK* – **ELBASVIR + GRAZOPREVIR**, elbasvir 50 mg + grazoprevir 100 mg tablet, 28

10991L *Zepatier, MK* – **ELBASVIR + GRAZOPREVIR**, elbasvir 50 mg + grazoprevir 100 mg tablet, 28

6332G *Somatuline LA, IS* – **LANREOTIDE**, lanreotide 30 mg modified release injection [1 vial] (&) inert substance diluent [2 mL ampoule], 1 pack

Highly Specialised Drugs Program (Public Hospital)

Additions

Addition – Item

12247N **SELEXIPAG**, selexipag 200 microgram tablet, 60 (*Uptravi*)

12258E **SELEXIPAG**, selexipag 200 microgram tablet, 140 (*Uptravi*)

12235Y **SELEXIPAG**, selexipag 400 microgram tablet, 60 (*Uptravi*)

12263K **SELEXIPAG**, selexipag 600 microgram tablet, 60 (*Uptravi*)

12249Q **SELEXIPAG**, selexipag 800 microgram tablet, 60 (*Uptravi*)

12266N **SELEXIPAG**, selexipag 800 microgram tablet, 60 (*Uptravi*)
 12259F **SELEXIPAG**, selexipag 1 mg tablet, 60 (*Uptravi*)
 12252W **SELEXIPAG**, selexipag 1.2 mg tablet, 60 (*Uptravi*)
 12240F **SELEXIPAG**, selexipag 1.4 mg tablet, 60 (*Uptravi*)
 12265M **SELEXIPAG**, selexipag 1.6 mg tablet, 60 (*Uptravi*)

Addition – Brand

12134P *Bosentan Cipla, LR* – **BOSENTAN**, bosentan 62.5 mg tablet, 60
 12140Y *Bosentan Cipla, LR* – **BOSENTAN**, bosentan 62.5 mg tablet, 60
 12145F *Bosentan Cipla, LR* – **BOSENTAN**, bosentan 62.5 mg tablet, 60
 5618Q *Bosentan Cipla, LR* – **BOSENTAN**, bosentan 62.5 mg tablet, 60
 12149K *Bosentan Cipla, LR* – **BOSENTAN**, bosentan 125 mg tablet, 60
 5619R *Bosentan Cipla, LR* – **BOSENTAN**, bosentan 125 mg tablet, 60
 12144E *Sildenafil PHT APOTEX, TY* – **SILDENAFIL**, sildenafil 20 mg tablet, 90
 9547L *Sildenafil PHT APOTEX, TY* – **SILDENAFIL**, sildenafil 20 mg tablet, 90

Addition – Note

12212R **AMBRISENTAN**, ambrisentan 5 mg tablet, 30 (*Ambrisentan Mylan, Cipla Ambrisentan, PULMORIS, Volibris*)
 12186J **AMBRISENTAN**, ambrisentan 10 mg tablet, 30 (*Ambrisentan Mylan, Cipla Ambrisentan, PULMORIS, Volibris*)
 12145F **BOSENTAN**, bosentan 62.5 mg tablet, 60 (*BOSENTAN DR.REDDY'S, BOSLEER, Bosentan APO, Bosentan Cipla, Bosentan Mylan, Bosentan RBX, Bosentan Sandoz, Tracleer*)
 12149K **BOSENTAN**, bosentan 125 mg tablet, 60 (*BOSENTAN DR.REDDY'S, BOSLEER, Bosentan APO, Bosentan Cipla, Bosentan GH, Bosentan Mylan, Bosentan RBX, Bosentan Sandoz, Tracleer*)
 12147H **MACITENTAN**, macitentan 10 mg tablet, 30 (*Opsumit*)
 12144E **SILDENAFIL**, sildenafil 20 mg tablet, 90 (*APO-Sildenafil PHT, Revatio, SILDATIO PHT, Sildenafil AN PHT 20, Sildenafil PHT APOTEX, Sildenafil Sandoz PHT 20*)
 12151M **TADALAFIL**, tadalafil 20 mg tablet, 56 (*Adcirca, TADALIS 20, Tadalca*)

Alterations

Alteration – Brand Name

From
 12134P *BOSENTAN DR. REDDY'S, RI* – **BOSENTAN**, bosentan 62.5 mg tablet, 60
To
 12134P *BOSENTAN DR.REDDY'S, RI* – **BOSENTAN**, bosentan 62.5 mg tablet, 60
From
 12140Y *BOSENTAN DR. REDDY'S, RI* – **BOSENTAN**, bosentan 62.5 mg tablet, 60
To
 12140Y *BOSENTAN DR.REDDY'S, RI* – **BOSENTAN**, bosentan 62.5 mg tablet, 60
From
 12145F *BOSENTAN DR. REDDY'S, RI* – **BOSENTAN**, bosentan 62.5 mg tablet, 60
To
 12145F *BOSENTAN DR.REDDY'S, RI* – **BOSENTAN**, bosentan 62.5 mg tablet, 60
From
 5618Q *BOSENTAN DR. REDDY'S, RI* – **BOSENTAN**, bosentan 62.5 mg tablet, 60
To
 5618Q *BOSENTAN DR.REDDY'S, RI* – **BOSENTAN**, bosentan 62.5 mg tablet, 60
From
 12149K *BOSENTAN DR. REDDY'S, RI* – **BOSENTAN**, bosentan 125 mg tablet, 60
To
 12149K *BOSENTAN DR.REDDY'S, RI* – **BOSENTAN**, bosentan 125 mg tablet, 60
From
 5619R *BOSENTAN DR. REDDY'S, RI* – **BOSENTAN**, bosentan 125 mg tablet, 60
To
 5619R *BOSENTAN DR.REDDY'S, RI* – **BOSENTAN**, bosentan 125 mg tablet, 60

Alteration – Note

- 5825N **ELTROMBOPAG**, eltrombopag 25 mg tablet, 28 (*Revolade*)
5826P **ELTROMBOPAG**, eltrombopag 50 mg tablet, 28 (*Revolade*)
9696H **ROMIPLOSTIM**, romiplostim 250 microgram injection, 1 vial (*Nplate*)
9698K **ROMIPLOSTIM**, romiplostim 500 microgram injection, 1 vial (*Nplate*)

Alteration – Restriction

- 12212R **AMBRISENTAN**, ambrisentan 5 mg tablet, 30 (*Ambrisentan Mylan, Cipla Ambrisentan, PULMORIS, Volibris*)
12186J **AMBRISENTAN**, ambrisentan 10 mg tablet, 30 (*Ambrisentan Mylan, Cipla Ambrisentan, PULMORIS, Volibris*)
12134P **BOSENTAN**, bosentan 62.5 mg tablet, 60 (*BOSENTAN DR.REDDY'S, BOSLEER, Bosentan APO, Bosentan Cipla, Bosentan Mylan, Bosentan RBX, Bosentan Sandoz, Tracleer*)
12145F **BOSENTAN**, bosentan 62.5 mg tablet, 60 (*BOSENTAN DR.REDDY'S, BOSLEER, Bosentan APO, Bosentan Cipla, Bosentan Mylan, Bosentan RBX, Bosentan Sandoz, Tracleer*)
12149K **BOSENTAN**, bosentan 125 mg tablet, 60 (*BOSENTAN DR.REDDY'S, BOSLEER, Bosentan APO, Bosentan Cipla, Bosentan GH, Bosentan Mylan, Bosentan RBX, Bosentan Sandoz, Tracleer*)
5825N **ELTROMBOPAG**, eltrombopag 25 mg tablet, 28 (*Revolade*)
5826P **ELTROMBOPAG**, eltrombopag 50 mg tablet, 28 (*Revolade*)
12147H **MACITENTAN**, macitentan 10 mg tablet, 30 (*Opsumit*)
9696H **ROMIPLOSTIM**, romiplostim 250 microgram injection, 1 vial (*Nplate*)
9698K **ROMIPLOSTIM**, romiplostim 500 microgram injection, 1 vial (*Nplate*)
12144E **SILDENAFIL**, sildenafil 20 mg tablet, 90 (*APO-Sildenafil PHT, Revatio, SILDATIO PHT, Sildenafil AN PHT 20, Sildenafil PHT APOTEX, Sildenafil Sandoz PHT 20*)
12151M **TADALAFIL**, tadalafil 20 mg tablet, 56 (*Adcirca, TADALIS 20, Tadalca*)

Alteration – Manufacturer Code

		<i>From</i>	<i>To</i>
12212R	<i>Volibris</i> – AMBRISENTAN , ambrisentan 5 mg tablet, 30	GK	ZE
5607D	<i>Volibris</i> – AMBRISENTAN , ambrisentan 5 mg tablet, 30	GK	ZE
12186J	<i>Volibris</i> – AMBRISENTAN , ambrisentan 10 mg tablet, 30	GK	ZE
5608E	<i>Volibris</i> – AMBRISENTAN , ambrisentan 10 mg tablet, 30	GK	ZE

Supply Only

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Substitution of Supply Only items/brands with products flagged as "equivalent for substitution" still apply as specified in the Schedule at the time the script was written. Further information on Supply Only arrangements is available at www.pbs.gov.au

Supply Only commencing 1 February 2021

- 10561W DBL Zoledronic Acid, PF – **ZOLEDRONIC ACID**, zoledronic acid 4 mg/100 mL injection, 100 mL bag

Advance Notices

1 March 2021

Deletion – Brand

- 10978T *Zepatier, MK* – **ELBASVIR + GRAZOPREVR**, elbasvir 50 mg + grazoprevir 100 mg tablet, 28
10986F *Zepatier, MK* – **ELBASVIR + GRAZOPREVR**, elbasvir 50 mg + grazoprevir 100 mg tablet, 28
5776B *Somatuline LA, IS* – **LANREOTIDE**, lanreotide 30 mg modified release injection [1 vial] (&) inert substance diluent [2 mL ampoule], 1 pack

Highly Specialised Drugs Program (Community Access)

Advance Notices

1 March 2021

Deletion – Brand

- 10275T *Stocrin, MK* – **EFAVIRENZ**, efavirenz 30 mg/mL oral liquid, 180 mL

Growth Hormone Program

Advance Notices

1 April 2021

Deletion – Brand

10437H	<i>Norditropin SimpleXx, NO</i> – SOMATROPIN , somatropin 5 mg/1.5 mL injection, 1.5 mL cartridge
10439K	<i>Norditropin SimpleXx, NO</i> – SOMATROPIN , somatropin 10 mg/1.5 mL injection, 1.5 mL cartridge
10448X	<i>Norditropin SimpleXx, NO</i> – SOMATROPIN , somatropin 10 mg/1.5 mL injection, 1.5 mL cartridge
10468Y	<i>Norditropin SimpleXx, NO</i> – SOMATROPIN , somatropin 15 mg/1.5 mL injection, 1.5 mL cartridge
10469B	<i>Norditropin SimpleXx, NO</i> – SOMATROPIN , somatropin 5 mg/1.5 mL injection, 1.5 mL cartridge
10470C	<i>Norditropin SimpleXx, NO</i> – SOMATROPIN , somatropin 15 mg/1.5 mL injection, 1.5 mL cartridge
6295H	<i>Norditropin SimpleXx, NO</i> – SOMATROPIN , somatropin 5 mg/1.5 mL injection, 1.5 mL cartridge
6296J	<i>Norditropin SimpleXx, NO</i> – SOMATROPIN , somatropin 10 mg/1.5 mL injection, 1.5 mL cartridge
6297K	<i>Norditropin SimpleXx, NO</i> – SOMATROPIN , somatropin 15 mg/1.5 mL injection, 1.5 mL cartridge

Repatriation Pharmaceutical Benefits

Alterations

Alteration – Item Description

From

4909J **DRESSING TULLE NON GAUZE PARAFFIN**, dressing tulle non gauze paraffin 7.6 cm x 7.6 cm dressing, 1
(*Adaptic 2012*)

To

4909J **DRESSING TULLE NON-ADHERENT PRIMARY WOUND CONTACT LAYER PARAFFIN**, dressing tulle non-adherent primary wound contact layer paraffin 7.6 cm x 7.6 cm dressing, 1 (*Adaptic 2012*)

General Pharmaceutical Benefits

FLUOXETINE

Note Pharmaceutical benefits that have the form fluoxetine 20 mg capsule are equivalent for the purposes of substitution.


Restricted benefit

Major depressive disorders


Restricted benefit

Obsessive-compulsive disorder

fluoxetine 20 mg capsule, 100


12256C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	0.3	5	..	*24.01	25.30	^a Fluoxetine Capsule (USP) [DZ]

fluoxetine 20 mg capsule, 28

1434L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	15.88	17.17	^a APO-Fluoxetine [TX] ^a Blooms the Chemist Fluoxetine [IB] ^a FLUOTEX [RF] ^a Fluoxetine APOTEX [TY] ^a Fluoxetine generichealth [GQ] ^a Lovan [AL]	^a Auscap Aspen [RW] ^a BTC Fluoxetine [JB] ^a Fluoxetine AN [EA] ^a Fluoxetine-GA [ED] ^a Fluoxetine Sandoz [SZ] ^a Zactin [AF]
			^b 1.10	16.98	17.17	^a Prozac 20 [LY]	


INSULIN ASPART

insulin aspart 100 units/mL injection, 5 x 3 mL pen devices

12254Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	5	1	..	*211.49	41.30	NovoRapid FlexPen [NF]

INSULIN ASPART + INSULIN ASPART PROTAMINE

insulin aspart 30 units/mL + insulin aspart protamine 70 units/mL injection, 5 x 3 mL pen devices

12238D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	5	1	..	*211.49	41.30	NovoMix 30 FlexPen [NF]


INSULIN DETEMIR

Note Special Pricing Arrangements apply.

Restricted benefit

Type 1 diabetes

insulin detemir 100 units/mL injection, 5 x 3 mL pen devices


12236B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	5	1	..	*354.79	41.30	Levemir FlexPen [NF]

INSULIN GLARGINE

Note Biosimilar prescribing policy Prescribing of the biosimilar brand, Semglee, is encouraged for treatment naive patients. Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Biosimilar Awareness Initiative webpage (www.health.gov.au/biosimilars).

Note Pharmaceutical benefits that have the brand Optisulin SoloStar 100 units/mL injection, 5 x 3 mL and pharmaceutical benefits that have the brand Semglee 100 units/mL injection, 5 x 3 mL are equivalent for the purposes of substitution.

insulin glargine 100 units/mL injection, 5 x 3 mL pen devices

11815W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	5	1	..	*185.99	41.30	^a Optisulin SoloStar [WA] ^a Semglee [AF]	

insulin glargine 100 units/mL injection, 5 x 3 mL cartridges

9039R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	5	1	..	*185.99	41.30	Optisulin [GZ]

■ INSULIN GLULISINE**insulin glulisine 100 units/mL injection, 5 x 3 mL pen devices**

12268Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	5	1	..	*222.34	41.30	Apidra SoloStar [SW]

■ INSULIN ISOPHANE HUMAN**insulin isophane human 100 units/mL injection, 5 x 3 mL pen devices**

12262J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	5	1	..	*177.49	41.30	Protaphane InnoLet [NI]

■ INSULIN ISOPHANE HUMAN + INSULIN NEUTRAL HUMAN**insulin isophane human 70 units/mL + insulin neutral human 30 units/mL injection, 5 x 3 mL pen devices**

12255B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	5	1	..	*177.49	41.30	Mixtard 30/70 InnoLet [NI]

■ INSULIN LISPRO**insulin lispro 100 units/mL injection, 5 x 3 mL pen devices**

12237C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	5	1	..	*211.49	41.30	Humalog KwikPen [KP]

■ INSULIN LISPRO + INSULIN LISPRO PROTAMINE**insulin lispro 50 units/mL + insulin lispro protamine 50 units/mL injection, 5 x 3 mL pen devices**

12261H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	5	1	..	*211.49	41.30	Humalog Mix50 KwikPen [KP]

insulin lispro 25 units/mL + insulin lispro protamine 75 units/mL injection, 5 x 3 mL pen devices

12234X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	5	1	..	*211.49	41.30	Humalog Mix25 KwikPen [KP]

■ LISDEXAMFETAMINE**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Note In accordance with the Therapeutic Goods Administration (TGA)-approved Product Information, this PBS listing currently intends for once daily dosing only. Divided dosing is not intended (e.g. 20 mg in the mornings, 30 mg in the evenings). Where applications (either on the same day or on separate days) for multiple strengths are sought, repeats should only be sought for the listed target strength.

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

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

Authority required

Attention deficit hyperactivity disorder

Clinical criteria:

- Patient must require continuous coverage over 12 hours, **AND**
- The treatment must not exceed a maximum daily dose of 70 mg with this drug.

Population criteria:

- Patient must be aged between the ages of 6 and 18 years inclusive; OR
- Patient must have had a diagnosis of ADHD prior to turning 18 years of age if PBS-subsidised treatment is continuing beyond 18 years of age; OR
- Patient must have a retrospective diagnosis of ADHD if PBS-subsidised treatment is commencing after turning 18 years of age; OR
- Patient must have had a retrospective diagnosis of ADHD if PBS-subsidised treatment is continuing in a patient who commenced PBS-subsidised treatment after turning 18 years of age.

A retrospective diagnosis of ADHD for the purposes of administering this restriction is:

- (i) the presence of pre-existing childhood symptoms of ADHD (onset during the developmental period, typically early to mid-childhood); and

(ii) documentation in the patient's medical records that an in-depth clinical interview with, or, obtaining of evidence from, either a: (a) parent, (b) teacher, (c) sibling, (d) third party, has occurred and which supports point (i) above.

lisdexamfetamine dimesilate 60 mg capsule, 30

11897E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	102.94	41.30	Vyvanse [TK]

lisdexamfetamine dimesilate 40 mg capsule, 30

11898F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	102.94	41.30	Vyvanse [TK]

lisdexamfetamine dimesilate 20 mg capsule, 30

11884L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	102.94	41.30	Vyvanse [TK]

lisdexamfetamine dimesilate 50 mg capsule, 30

10474G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	102.94	41.30	Vyvanse [TK]

lisdexamfetamine dimesilate 70 mg capsule, 30

10492F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	102.94	41.30	Vyvanse [TK]

lisdexamfetamine dimesilate 30 mg capsule, 30

10486X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	102.94	41.30	Vyvanse [TK]

■ METHYLPHENIDATE

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Note In accordance with the Therapeutic Goods Administration (TGA)-approved Product Information, this PBS listing currently intends for once daily dosing only. Divided dosing is not intended (e.g. 18 mg in the mornings, 36 mg in the evenings).

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

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required

Attention deficit hyperactivity disorder

Population criteria:

- Patient must be or have been diagnosed between the ages of 6 and 18 years inclusive.

Clinical criteria:

- Patient must have demonstrated a response to immediate-release methylphenidate hydrochloride with no emergence of serious adverse events, **AND**
- Patient must require continuous coverage over 12 hours, **AND**
- The treatment must not exceed a maximum daily dose of 72 mg with this drug.

methylphenidate hydrochloride 36 mg modified release tablet, 30

2388Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	62.78	41.30	Concerta [JC]

methylphenidate hydrochloride 18 mg modified release tablet, 30

2387P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	54.51	41.30	Concerta [JC]

methylphenidate hydrochloride 27 mg modified release tablet, 30

2172H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	58.65	41.30	Concerta [JC]

methylphenidate hydrochloride 54 mg modified release tablet, 30

2432B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	71.93	41.30	Concerta [JC]

■ METHYLPHENIDATE

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Note In accordance with the Therapeutic Goods Administration (TGA)-approved Product Information, this PBS listing currently intends for once daily dosing only. Divided dosing is not intended (e.g. 20 mg in the mornings, 30 mg in the evenings).

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

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

Authority required

Attention deficit hyperactivity disorder

Population criteria:

- Patient must be or have been diagnosed between the ages of 6 and 18 years inclusive.

Clinical criteria:

- Patient must have demonstrated a response to immediate-release methylphenidate hydrochloride with no emergence of serious adverse events, **AND**
- Patient must require continuous coverage over 8 hours, **AND**
- The treatment must not exceed a maximum daily dose of 80 mg with this drug.

methylphenidate hydrochloride 30 mg modified release capsule, 30

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
2280B	1	5	..	55.22	41.30	Ritalin LA [NV]

NP

methylphenidate hydrochloride 10 mg modified release capsule, 30

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
3440C	1	5	..	38.49	39.78	Ritalin LA [NV]

NP

methylphenidate hydrochloride 60 mg modified release capsule, 30

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
12116Q	1	5	..	71.67	41.30	Ritalin LA [NV]

NP

methylphenidate hydrochloride 40 mg modified release capsule, 30

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
2283E	1	5	..	57.75	41.30	Ritalin LA [NV]

NP

methylphenidate hydrochloride 20 mg modified release capsule, 30

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
2276T	1	5	..	47.76	41.30	Ritalin LA [NV]

NP

▪ **PHENELZINE**

Caution This drug is an irreversible monoamine oxidase inhibitor.

Note Pharmaceutical benefits that have the form phenelzine 15 mg tablet, 60 and pharmaceutical benefits that have the form phenelzine 15 mg tablet, 100 are equivalent for the purposes of substitution.

Restricted benefit

Depression

Clinical criteria:

- The treatment must be for when all other anti-depressant therapy has failed; OR
- The treatment must be for when all other anti-depressant therapy is inappropriate.

phenelzine 15 mg tablet, 60

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
12239E	1.7	1	..	*175.18	41.30	^a Phenelzine sulfate USP (Generic Health) [GQ]

phenelzine 15 mg tablet, 100

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
2856H	1	1	..	81.19	41.30	^a Nardil [LM]

▪ **RUXOLITINIB**

Note Risk of myelofibrosis is defined in accordance with the Myelofibrosis International Prognostic Scoring System (IPSS) OR the Dynamic International Prognostic Scoring System (DIPSS) OR the Age-Adjusted DIPSS.

Note No increase in the maximum quantity may be authorised for the 15 mg and 20 mg dose strengths.

Note Special Pricing Arrangements apply.

Note Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos Or mailed to:
Services Australia

Authority required

High risk and intermediate-2 risk myelofibrosis
Treatment Phase: Initial treatment

Clinical criteria:

- The condition must be primary myelofibrosis or post-polycythemia vera myelofibrosis or post-essential thrombocythemia myelofibrosis.

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

- (1) A completed authority prescription form; and
- (2) A completed Myelofibrosis Authority Application Supporting Information Form, which includes all of the following:
 - (a) A copy of the bone marrow biopsy report confirming diagnosis of myelofibrosis; and
 - (b) A classification of risk of myelofibrosis according to either the IPSS, DIPSS, or the Age-Adjusted DIPSS.

Authority required

Intermediate-1 risk myelofibrosis
Treatment Phase: Initial treatment

Clinical criteria:

- The condition must be primary myelofibrosis or post-polycythemia vera myelofibrosis or post-essential thrombocythemia myelofibrosis, **AND**
- Patient must have severe disease-related symptoms that are resistant, refractory or intolerant to available therapy.

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

- (1) A completed authority prescription form; and
- (2) A completed Myelofibrosis Authority Application Supporting Information Form, which includes all of the following:
 - a) A copy of the bone marrow biopsy report confirming diagnosis of myelofibrosis;
 - b) A classification of risk of myelofibrosis according to either the IPSS, DIPSS, or the Age-Adjusted DIPSS; and
 - c) A confirmation that the patient's disease related symptoms are resistant, refractory or intolerant to available therapy.

ruxolitinib 5 mg tablet, 56

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
10614P	2	*5161.16	41.30	Jakavi [NV]

ruxolitinib 15 mg tablet, 56

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
10619X	1	5161.16	41.30	Jakavi [NV]

ruxolitinib 20 mg tablet, 56

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
10618W	1	5161.16	41.30	Jakavi [NV]

ruxolitinib 10 mg tablet, 56

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
10913J	1	5161.16	41.30	Jakavi [NV]

▪ **TERBUTALINE**

Authority required (STREAMLINED)

9828

Bronchospasm

Clinical criteria:

- Patient must be unable to achieve co-ordinated use of a metered dose inhaler containing a short-acting beta-2 agonist;
OR
- Patient must have developed a clinically important product-related adverse event during treatment with another short-acting beta-2 agonist.

Device (inhaler) technique should be reviewed at each clinical visit and before initiating treatment with this medicine.

terbutaline sulfate 500 microgram/actuation powder for inhalation, 120 actuations

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
12267P	2	5	..	*26.68	27.97	Bricanyl Turbuhaler [AP]

NP

▪ **TRIHXYPHENIDYL (BENZHEXOL)**


Note Pharmaceutical benefits that have the form trihexyphenidyl hydrochloride 2 mg tablet, 200 and pharmaceutical benefits that have the form trihexyphenidyl hydrochloride 2 mg tablet, 100 are equivalent for the purposes of substitution.

trihexyphenidyl (benzhexol) hydrochloride 2 mg tablet, 100

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
12250R	2	2	..	*69.68	41.30	^a Trihexyphenidyl hydrochloride USP (Medsurge) [DZ]

NP

trihexyphenidyl (benzhexol) hydrochloride 2 mg tablet, 200

1109J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	18.65	19.94	^a Artane [RW]

Highly Specialised Drugs Program (Private Hospital)

▪ AMBRISENTAN

Caution This 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 therapy.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 (dual therapy - previously untreated patients)

Clinical criteria:

- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

Clinical criteria:

- Patient must currently have WHO Functional Class III PAH or WHO Functional Class IV PAH, **AND**
- The treatment must be in combination with a PBS-subsidised phosphodiesterase-5 inhibitor (PDE-5i) for this condition. The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

For the purposes of PBS subsidy, dual therapy refers to combined use of an endothelin receptor antagonist (ERA) and a phosphodiesterase-5 inhibitor (PDE-5i).

(i) An ERA includes ambrisentan, bosentan monohydrate, or macitentan.

(ii) A PDE-5i includes sildenafil citrate, or tadalafil.

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

PAH (WHO Group 1 pulmonary hypertension) is defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than or equal to 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than or equal to 15 mmHg; or

(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

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 which includes results from the three tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6 Minute Walk Test (6MWT).

Where it is not possible to perform all 3 tests 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 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.

Where a RHC cannot be performed on clinical grounds, confirmation of the reason(s) must be provided with the authority application by a second PAH physician or cardiologist with expertise in the management of PAH.

The test results provided must not be more than 2 months old at the time of 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.

Note PAH (WHO Group 1 pulmonary hypertension) currently includes the following subtypes: Idiopathic PAH

- Heritable PAH
 - BMPR2 mutation
 - ALK-1, ENG, SMAD9, CAV1, KCNK3 mutations
 - Other mutations
- Drugs and toxins induced PAH
- PAH associated with:
 - Connective tissue disease
 - Human immunodeficiency virus (HIV) infection
 - Portal hypertension
 - Congenital heart disease
 - Schistosomiasis

Note Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 2 (dual therapy - previously treated patients)

Clinical criteria:

- Patient must have documented WHO Functional Class III PAH or WHO Functional Class IV PAH, **AND**
- Patient must have documented a failure to achieve or maintain WHO Functional Class II status with prior PBS-subsidised monotherapy treatment with a phosphodiesterase-5 inhibitor (PDE-5i) for this condition, **AND**
- The treatment must be in combination with the PBS-subsidised PDE-5i for this condition.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

For the purposes of PBS subsidy, dual therapy refers to combined use of an endothelin receptor antagonist (ERA) and a phosphodiesterase-5 inhibitor (PDE-5i).

(i) An ERA includes ambrisentan, bosentan monohydrate, or macitentan.

(ii) A PDE-5i includes sildenafil citrate, or tadalafil.

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

PAH (WHO Group 1 pulmonary hypertension) is defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than or equal to 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than or equal to 15 mmHg; or

(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

The results and date of the RHC, ECHO and 6 MWT as applicable must be included in the patient's medical record. Where a RHC cannot be performed on clinical grounds, the written confirmation of the reasons why must also be included in the patient's medical record.

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.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 3 (dual therapy - change)

Clinical criteria:

- Patient must have had their most recent course of PBS-subsidised dual therapy with a phosphodiesterase-5 inhibitor (PDE-5i) and an endothelin receptor antagonist (ERA) other than this agent for this condition.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

For the purposes of PBS subsidy, dual therapy refers to combined use of an endothelin receptor antagonist (ERA) and a phosphodiesterase-5 inhibitor (PDE-5i).

(i) An ERA includes ambrisentan, bosentan monohydrate, or macitentan.

(ii) A PDE-5i includes sildenafil citrate, or tadalafil.

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

Swapping between PAH agents: Patients can access PAH agents through the PBS according to the relevant restrictions.

Once patients are approved dual therapy with a PAH agent from the PDE-5i class; or a PAH agent from the ERA class, they may swap between PAH agents within the same class. This means that patients may commence treatment with another PAH agent in the same class, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted.

Applications to swap within a PAH agent class must be made under the relevant initial treatment restriction.

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.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Continuing treatment (dual therapy)

Clinical criteria:

- Patient must have received their most recent course of PBS-subsidised dual therapy with this PAH agent and a phosphodiesterase-5 inhibitor (PDE-5i) for this condition.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

For the purposes of PBS subsidy, dual therapy refers to combined use of an endothelin receptor antagonist (ERA) and a phosphodiesterase-5 inhibitor (PDE-5i).

(i) An ERA includes ambrisentan, bosentan monohydrate, or macitentan.

(ii) A PDE-5i includes sildenafil citrate, or tadalafil.

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

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.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Grandfathered patients (dual therapy)

Clinical criteria:

- Patient must be receiving dual therapy with this non PBS-subsidised pulmonary arterial hypertension (PAH) agent and a non PBS-subsidised phosphodiesterase-5 inhibitor (PDE-5i) for this condition prior to 1 December 2020.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

Clinical criteria:

- Patient must have documented WHO Functional Class III PAH or WHO Functional Class IV PAH.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

For the purposes of PBS subsidy, dual therapy refers to combined use of an endothelin receptor antagonist (ERA) and a phosphodiesterase-5 inhibitor (PDE-5i).

(i) An ERA includes ambrisentan, bosentan monohydrate, or macitentan.

(ii) A PDE-5i includes sildenafil citrate, or tadalafil.

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

PAH (WHO Group 1 pulmonary hypertension) is defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than or equal to 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than or equal to 15 mmHg; or

(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

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 which includes results from the three tests below, where available:

- (i) RHC composite assessment; and
- (ii) ECHO composite assessment; and
- (iii) 6 Minute Walk Test (6MWT).

Where it was not possible to perform all 3 tests 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 could not be performed on clinical grounds, applications may be submitted 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 were 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.

Where a RHC could not be performed on clinical grounds, confirmation of the reason(s) must be provided with the authority application by a second PAH physician or cardiologist with expertise in the management of PAH.

A patient may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria for dual therapy for this condition.

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.

Note PAH (WHO Group 1 pulmonary hypertension) currently includes the following subtypes: Idiopathic PAH

- Heritable PAH
 - BMPR2 mutation
 - ALK-1, ENG, SMAD9, CAV1, KCNK3 mutations
 - Other mutations
- Drugs and toxins induced PAH
- PAH associated with:
 - Connective tissue disease
 - Human immunodeficiency virus (HIV) infection
 - Portal hypertension
 - Congenital heart disease
 - Schistosomiasis

Note Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Triple therapy - Initial treatment or continuing treatment of triple combination therapy (including dual therapy in lieu of triple therapy) that includes selexipag

Clinical criteria:

- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) PBS-subsidised selexipag (referred to as 'triple therapy'); OR
- The treatment must form part of dual combination therapy consisting of either: (i) PBS-subsidised selexipag with one endothelin receptor antagonist, (ii) PBS-subsidised selexipag with one phosphodiesterase-5 inhibitor, as triple combination therapy with selexipag-an endothelin receptor antagonist-a phosphodiesterase-5 inhibitor is not possible due to an intolerance/contraindication to the endothelin receptor antagonist class/phosphodiesterase-5 inhibitor class (referred to as 'dual therapy in lieu of triple therapy').

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

The authority application for selexipag must be approved prior to the authority application for this agent.

For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil.

PBS-subsidy does not cover patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

PAH (WHO Group 1 pulmonary hypertension) is defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than or equal to 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than or equal to 15 mmHg; or

(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

The results and date of the RHC, ECHO and 6 MWT as applicable must be included in the patient's medical record. Where a RHC cannot be performed on clinical grounds, the written confirmation of the reasons why must also be included in the patient's medical record.

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.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Note Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

ambrisentan 10 mg tablet, 30

12180C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	1892.28	^a Ambrisentan Mylan [AF] ^a PULMORIS [YC]	^a Cipla Ambrisentan [LR] ^a Volibris [ZE]

ambrisentan 5 mg tablet, 30

12201E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	1892.28	^a Ambrisentan Mylan [AF] ^a PULMORIS [YC]	^a Cipla Ambrisentan [LR] ^a Volibris [ZE]

■ BOSENTAN

Caution This 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 therapy.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Continuing treatment (dual therapy)

Clinical criteria:

- Patient must have received their most recent course of PBS-subsidised dual therapy with this PAH agent and a phosphodiesterase-5 inhibitor (PDE-5i) for this condition.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

For the purposes of PBS subsidy, dual therapy refers to combined use of an endothelin receptor antagonist (ERA) and a phosphodiesterase-5 inhibitor (PDE-5i).

(i) An ERA includes ambrisentan, bosentan monohydrate, or macitentan.

(ii) A PDE-5i includes sildenafil citrate, or tadalafil.

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

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.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Grandfathered patients (dual therapy)

Clinical criteria:

- Patient must be receiving dual therapy with this non PBS-subsidised pulmonary arterial hypertension (PAH) agent and a non PBS-subsidised phosphodiesterase-5 inhibitor (PDE-5i) for this condition prior to 1 October 2020.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

Clinical criteria:

- Patient must have documented WHO Functional Class III PAH or WHO Functional Class IV PAH.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

For the purposes of PBS subsidy, dual therapy refers to combined use of an endothelin receptor antagonist (ERA) and a phosphodiesterase-5 inhibitor (PDE-5i).

(i) An ERA includes ambrisentan, bosentan monohydrate, or macitentan.

(ii) A PDE-5i includes sildenafil citrate, or tadalafil.

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

PAH (WHO Group 1 pulmonary hypertension) is defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than or equal to 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than or equal to 15 mmHg; or

(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

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 which includes results from the three tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6 Minute Walk Test (6MWT).

Where it was not possible to perform all 3 tests 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 could not be performed on clinical grounds, applications may be submitted 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 were 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.

Where a RHC could not be performed on clinical grounds, confirmation of the reason(s) must be provided with the authority application by a second PAH physician or cardiologist with expertise in the management of PAH.

A patient may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria for dual therapy for this condition.

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.

Note PAH (WHO Group 1 pulmonary hypertension) currently includes the following subtypes: Idiopathic PAH

- Heritable PAH
 - BMPR2 mutation
 - ALK-1, ENG, SMAD9, CAV1, KCNK3 mutations
 - Other mutations
- Drugs and toxins induced PAH
- PAH associated with:
 - Connective tissue disease
 - Human immunodeficiency virus (HIV) infection
 - Portal hypertension
 - Congenital heart disease
 - Schistosomiasis

Note Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

bosentan 62.5 mg tablet, 60

12139X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	941.93	^a Bosentan APO [GX]	^a Bosentan Cipla [LR]
					^a BOSENTAN DR.REDDY'S [RI]	^a Bosentan Mylan [AF]
					^a Bosentan RBX [RA]	^a Bosentan Sandoz [SZ]
					^a BOSLEER [RW]	^a Tracleer [JC]

■ BOSENTAN

Caution This 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 therapy.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 (dual therapy - previously untreated patients)

Clinical criteria:

- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

Clinical criteria:

- Patient must currently have WHO Functional Class III PAH or WHO Functional Class IV PAH, **AND**
- The treatment must be in combination with a PBS-subsidised phosphodiesterase-5 inhibitor (PDE-5i) for this condition. The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

For the purposes of PBS subsidy, dual therapy refers to combined use of an endothelin receptor antagonist (ERA) and a phosphodiesterase-5 inhibitor (PDE-5i).

(i) An ERA includes ambrisentan, bosentan monohydrate, or macitentan.

(ii) A PDE-5i includes sildenafil citrate, or tadalafil.

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

PAH (WHO Group 1 pulmonary hypertension) is defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than or equal to 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than or equal to 15 mmHg; or

(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

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 which includes results from the three tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6 Minute Walk Test (6MWT).

Where it is not possible to perform all 3 tests 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 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.

Where a RHC cannot be performed on clinical grounds, confirmation of the reason(s) must be provided with the authority application by a second PAH physician or cardiologist with expertise in the management of PAH.

The test results provided must not be more than 2 months old at the time of application.

If patients will be taking 62.5mg for the first month then 125 mg, prescribers should request the first authority prescription of therapy with the 62.5 mg tablet strength, with the quantity for one month of treatment, based on the dosage recommendations in the TGA-approved Product Information and no repeats.

Prescribers should request the second authority prescription of therapy with the 125 mg tablet strengths, with a quantity for one month of treatment, based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 4 repeats.

If patients will be taking 62.5mg for longer than 1 month, prescribers should request the first authority prescription of therapy with the 62.5 mg tablet strength, with the quantity for one month of treatment and a maximum of 5 repeats based on the dosage recommendations in the TGA-approved Product Information.

Note PAH (WHO Group 1 pulmonary hypertension) currently includes the following subtypes: Idiopathic PAH

- Heritable PAH
 - BMPR2 mutation
 - ALK-1, ENG, SMAD9, CAV1, KCNK3 mutations
 - Other mutations
- Drugs and toxins induced PAH
- PAH associated with:
 - Connective tissue disease
 - Human immunodeficiency virus (HIV) infection
 - Portal hypertension
 - Congenital heart disease
 - Schistosomiasis

Note Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 2 (dual therapy - previously treated patients)

Clinical criteria:

- Patient must have documented WHO Functional Class III PAH or WHO Functional Class IV PAH, **AND**
- Patient must have documented a failure to achieve or maintain WHO Functional Class II status with prior PBS-subsidised monotherapy treatment with a phosphodiesterase-5 inhibitor (PDE-5i) for this condition, **AND**
- The treatment must be in combination with the PBS-subsidised PDE-5i for this condition.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

For the purposes of PBS subsidy, dual therapy refers to combined use of an endothelin receptor antagonist (ERA) and a phosphodiesterase-5 inhibitor (PDE-5i).

(i) An ERA includes ambrisentan, bosentan monohydrate, or macitentan.

(ii) A PDE-5i includes sildenafil citrate, or tadalafil.

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

PAH (WHO Group 1 pulmonary hypertension) is defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than or equal to 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than or equal to 15 mmHg; or

(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

The results and date of the RHC, ECHO and 6 MWT as applicable must be included in the patient's medical record. Where a RHC cannot be performed on clinical grounds, the written confirmation of the reasons why must also be included in the patient's medical record.

If patients will be taking 62.5mg for the first month then 125 mg, prescribers should request the first authority prescription of therapy with the 62.5 mg tablet strength, with the quantity for one month of treatment, based on the dosage recommendations in the TGA-approved Product Information and no repeats.

Prescribers should request the second authority prescription of therapy with the 125 mg tablet strengths, with a quantity for one month of treatment, based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 4 repeats.

If patients will be taking 62.5mg for longer than 1 month, prescribers should request the first authority prescription of therapy with the 62.5 mg tablet strength, with the quantity for one month of treatment and a maximum of 5 repeats based on the dosage recommendations in the TGA-approved Product Information.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 3 (dual therapy - change)

Clinical criteria:

- Patient must have had their most recent course of PBS-subsidised dual therapy with a phosphodiesterase-5 inhibitor (PDE-5i) and an endothelin receptor antagonist (ERA) other than this agent for this condition.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

For the purposes of PBS subsidy, dual therapy refers to combined use of an endothelin receptor antagonist (ERA) and a phosphodiesterase-5 inhibitor (PDE-5i).

(i) An ERA includes ambrisentan, bosentan monohydrate, or macitentan.

(ii) A PDE-5i includes sildenafil citrate, or tadalafil.

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

Swapping between PAH agents: Patients can access PAH agents through the PBS according to the relevant restrictions.

Once patients are approved dual therapy with a PAH agent from the PDE-5i class; or a PAH agent from the ERA class, they may swap between PAH agents within the same class. This means that patients may commence treatment with another PAH agent in the same class, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted.

Applications to swap within a PAH agent class must be made under the relevant initial treatment restriction.

If patients will be taking 62.5mg for the first month then 125 mg, prescribers should request the first authority prescription of therapy with the 62.5 mg tablet strength, with the quantity for one month of treatment, based on the dosage recommendations in the TGA-approved Product Information and no repeats.

Prescribers should request the second authority prescription of therapy with the 125 mg tablet strengths, with a quantity for one month of treatment, based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 4 repeats.

If patients will be taking 62.5mg for longer than 1 month, prescribers should request the first authority prescription of therapy with the 62.5 mg tablet strength, with the quantity for one month of treatment and a maximum of 5 repeats based on the dosage recommendations in the TGA-approved Product Information.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Triple therapy - Initial treatment or continuing treatment of triple combination therapy (including dual therapy in lieu of triple therapy) that includes selexipag

Clinical criteria:

- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) PBS-subsidised selexipag (referred to as 'triple therapy'); OR
- The treatment must form part of dual combination therapy consisting of either: (i) PBS-subsidised selexipag with one endothelin receptor antagonist, (ii) PBS-subsidised selexipag with one phosphodiesterase-5 inhibitor, as triple combination therapy with selexipag-an endothelin receptor antagonist-a phosphodiesterase-5 inhibitor is not possible due to an intolerance/contraindication to the endothelin receptor antagonist class/phosphodiesterase-5 inhibitor class (referred to as 'dual therapy in lieu of triple therapy').

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

The authority application for selexipag must be approved prior to the authority application for this agent.

For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil.

PBS-subsidy does not cover patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

PAH (WHO Group 1 pulmonary hypertension) is defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than or equal to 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than or equal to 15 mmHg; or

(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

The results and date of the RHC, ECHO and 6 MWT as applicable must be included in the patient's medical record. Where a RHC cannot be performed on clinical grounds, the written confirmation of the reasons why must also be included in the patient's medical record.

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.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Note Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

bosentan 62.5 mg tablet, 60

12148J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	941.93	^a Bosentan APO [GX]	^a Bosentan Cipla [LR]
					^a BOSENTAN DR.REDDY'S [RI]	^a Bosentan Mylan [AF]
					^a Bosentan RBX [RA]	^a Bosentan Sandoz [SZ]
					^a BOSLEER [RW]	^a Tracleer [JC]

■ BOSENTAN

Caution This 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 therapy.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 (dual therapy - previously untreated patients)

Clinical criteria:

- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

Clinical criteria:

- Patient must currently have WHO Functional Class III PAH or WHO Functional Class IV PAH, **AND**
- The treatment must be in combination with a PBS-subsidised phosphodiesterase-5 inhibitor (PDE-5i) for this condition. The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

For the purposes of PBS subsidy, dual therapy refers to combined use of an endothelin receptor antagonist (ERA) and a phosphodiesterase-5 inhibitor (PDE-5i).

(i) An ERA includes ambrisentan, bosentan monohydrate, or macitentan.

(ii) A PDE-5i includes sildenafil citrate, or tadalafil.

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

PAH (WHO Group 1 pulmonary hypertension) is defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than or equal to 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than or equal to 15 mmHg; or

(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

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 which includes results from the three tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6 Minute Walk Test (6MWT).

Where it is not possible to perform all 3 tests 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 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.

Where a RHC cannot be performed on clinical grounds, confirmation of the reason(s) must be provided with the authority application by a second PAH physician or cardiologist with expertise in the management of PAH.

The test results provided must not be more than 2 months old at the time of application.

If patients will be taking 62.5mg for the first month then 125 mg, prescribers should request the first authority prescription of therapy with the 62.5 mg tablet strength, with the quantity for one month of treatment, based on the dosage recommendations in the TGA-approved Product Information and no repeats.

Prescribers should request the second authority prescription of therapy with the 125 mg tablet strengths, with a quantity for one month of treatment, based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 4 repeats.

If patients will be taking 62.5mg for longer than 1 month, prescribers should request the first authority prescription of therapy with the 62.5 mg tablet strength, with the quantity for one month of treatment and a maximum of 5 repeats based on the dosage recommendations in the TGA-approved Product Information.

Note PAH (WHO Group 1 pulmonary hypertension) currently includes the following subtypes: Idiopathic PAH

- Heritable PAH
 - BMPR2 mutation
 - ALK-1, ENG, SMAD9, CAV1, KCNK3 mutations
 - Other mutations
- Drugs and toxins induced PAH
- PAH associated with:
 - Connective tissue disease
 - Human immunodeficiency virus (HIV) infection
 - Portal hypertension
 - Congenital heart disease
 - Schistosomiasis

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Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 2 (dual therapy - previously treated patients)

Clinical criteria:

- Patient must have documented WHO Functional Class III PAH or WHO Functional Class IV PAH, **AND**
- Patient must have documented a failure to achieve or maintain WHO Functional Class II status with prior PBS-subsidised monotherapy treatment with a phosphodiesterase-5 inhibitor (PDE-5i) for this condition, **AND**
- The treatment must be in combination with the PBS-subsidised PDE-5i for this condition.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

For the purposes of PBS subsidy, dual therapy refers to combined use of an endothelin receptor antagonist (ERA) and a phosphodiesterase-5 inhibitor (PDE-5i).

(i) An ERA includes ambrisentan, bosentan monohydrate, or macitentan.

(ii) A PDE-5i includes sildenafil citrate, or tadalafil.

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

PAH (WHO Group 1 pulmonary hypertension) is defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than or equal to 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than or equal to 15 mmHg; or

(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

The results and date of the RHC, ECHO and 6 MWT as applicable must be included in the patient's medical record. Where a RHC cannot be performed on clinical grounds, the written confirmation of the reasons why must also be included in the patient's medical record.

If patients will be taking 62.5mg for the first month then 125 mg, prescribers should request the first authority prescription of therapy with the 62.5 mg tablet strength, with the quantity for one month of treatment, based on the dosage recommendations in the TGA-approved Product Information and no repeats.

Prescribers should request the second authority prescription of therapy with the 125 mg tablet strengths, with a quantity for one month of treatment, based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 4 repeats.

If patients will be taking 62.5mg for longer than 1 month, prescribers should request the first authority prescription of therapy with the 62.5 mg tablet strength, with the quantity for one month of treatment and a maximum of 5 repeats based on the dosage recommendations in the TGA-approved Product Information.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 3 (dual therapy - change)

Clinical criteria:

- Patient must have had their most recent course of PBS-subsidised dual therapy with a phosphodiesterase-5 inhibitor (PDE-5i) and an endothelin receptor antagonist (ERA) other than this agent for this condition.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

For the purposes of PBS subsidy, dual therapy refers to combined use of an endothelin receptor antagonist (ERA) and a phosphodiesterase-5 inhibitor (PDE-5i).

(i) An ERA includes ambrisentan, bosentan monohydrate, or macitentan.

(ii) A PDE-5i includes sildenafil citrate, or tadalafil.

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

Swapping between PAH agents: Patients can access PAH agents through the PBS according to the relevant restrictions.

Once patients are approved dual therapy with a PAH agent from the PDE-5i class; or a PAH agent from the ERA class, they may swap between PAH agents within the same class. This means that patients may commence treatment with another PAH agent in the same class, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted.

Applications to swap within a PAH agent class must be made under the relevant initial treatment restriction.

If patients will be taking 62.5mg for the first month then 125 mg, prescribers should request the first authority prescription of therapy with the 62.5 mg tablet strength, with the quantity for one month of treatment, based on the dosage recommendations in the TGA-approved Product Information and no repeats.

Prescribers should request the second authority prescription of therapy with the 125 mg tablet strengths, with a quantity for one month of treatment, based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 4 repeats.

If patients will be taking 62.5mg for longer than 1 month, prescribers should request the first authority prescription of therapy with the 62.5 mg tablet strength, with the quantity for one month of treatment and a maximum of 5 repeats based on the dosage recommendations in the TGA-approved Product Information.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Continuing treatment (dual therapy)

Clinical criteria:

- Patient must have received their most recent course of PBS-subsidised dual therapy with this PAH agent and a phosphodiesterase-5 inhibitor (PDE-5i) for this condition.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

For the purposes of PBS subsidy, dual therapy refers to combined use of an endothelin receptor antagonist (ERA) and a phosphodiesterase-5 inhibitor (PDE-5i).

(i) An ERA includes ambrisentan, bosentan monohydrate, or macitentan.

(ii) A PDE-5i includes sildenafil citrate, or tadalafil.

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

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.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Grandfathered patients (dual therapy)

Clinical criteria:

- Patient must be receiving dual therapy with this non PBS-subsidised pulmonary arterial hypertension (PAH) agent and a non PBS-subsidised phosphodiesterase-5 inhibitor (PDE-5i) for this condition prior to 1 October 2020.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

Clinical criteria:

- Patient must have documented WHO Functional Class III PAH or WHO Functional Class IV PAH.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

For the purposes of PBS subsidy, dual therapy refers to combined use of an endothelin receptor antagonist (ERA) and a phosphodiesterase-5 inhibitor (PDE-5i).

(i) An ERA includes ambrisentan, bosentan monohydrate, or macitentan.

(ii) A PDE-5i includes sildenafil citrate, or tadalafil.

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

PAH (WHO Group 1 pulmonary hypertension) is defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than or equal to 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than or equal to 15 mmHg; or

(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

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 which includes results from the three tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6 Minute Walk Test (6MWT).

Where it was not possible to perform all 3 tests 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 could not be performed on clinical grounds, applications may be submitted 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 were 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.

Where a RHC could not be performed on clinical grounds, confirmation of the reason(s) must be provided with the authority application by a second PAH physician or cardiologist with expertise in the management of PAH.

A patient may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria for dual therapy for this condition.

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.

Note PAH (WHO Group 1 pulmonary hypertension) currently includes the following subtypes: Idiopathic PAH

- Heritable PAH
 - BMPR2 mutation
 - ALK-1, ENG, SMAD9, CAV1, KCNK3 mutations
 - Other mutations
- Drugs and toxins induced PAH
- PAH associated with:
 - Connective tissue disease
 - Human immunodeficiency virus (HIV) infection
 - Portal hypertension
 - Congenital heart disease
 - Schistosomiasis

Note Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Triple therapy - Initial treatment or continuing treatment of triple combination therapy (including dual therapy in lieu of triple therapy) that includes selexipag

Clinical criteria:

- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) PBS-subsidised selexipag (referred to as 'triple therapy'); OR
- The treatment must form part of dual combination therapy consisting of either: (i) PBS-subsidised selexipag with one endothelin receptor antagonist, (ii) PBS-subsidised selexipag with one phosphodiesterase-5 inhibitor, as triple combination therapy with selexipag-an endothelin receptor antagonist-a phosphodiesterase-5 inhibitor is not possible due to an intolerance/contraindication to the endothelin receptor antagonist class/phosphodiesterase-5 inhibitor class (referred to as 'dual therapy in lieu of triple therapy').

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

The authority application for selexipag must be approved prior to the authority application for this agent.

For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil.

PBS-subsidy does not cover patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

PAH (WHO Group 1 pulmonary hypertension) is defined as follows:

- (i) mean pulmonary artery pressure (mPAP) greater than or equal to 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than or equal to 15 mmHg; or
- (ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

The results and date of the RHC, ECHO and 6 MWT as applicable must be included in the patient's medical record. Where a RHC cannot be performed on clinical grounds, the written confirmation of the reasons why must also be included in the patient's medical record.

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.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Note Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

bosentan 125 mg tablet, 60

12146G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	941.93	^a Bosentan APO [GX] ^a BOSENTAN DR.REDDY'S [RI] ^a Bosentan Mylan [AF] ^a Bosentan Sandoz [SZ] ^a Tracleer [JC]	^a Bosentan Cipla [LR] ^a Bosentan GH [GQ] ^a Bosentan RBX [RA] ^a BOSLEER [RW]

■ ELTROMBOPAG

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required

Severe thrombocytopenia

Treatment Phase: Initial treatment 1 - New patient

Clinical criteria:

- The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), **AND**
- Patient must have had a splenectomy, **AND**
- Patient must have failed to achieve an adequate response to, or be intolerant to, corticosteroid therapy following the splenectomy, **AND**
- Patient must have failed to achieve an adequate response to, or be intolerant to, immunoglobulin therapy following the splenectomy, **AND**
- The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition.

Population criteria:

- Patient must be aged 18 years or older.

The following criteria indicate failure to achieve an adequate response and must be demonstrated 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 20,000 million to 30,000 million per L, where the patient is experiencing significant bleeding or has a history of significant bleeding in this platelet range.

Where intolerance to treatment with corticosteroid and immunoglobulin therapy developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

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

- (1) a completed authority prescription form,
- (2) a completed Idiopathic Thrombocytopenic Purpura Initial PBS Authority Application - Supporting Information Form,
- (3) details of a platelet count supporting the diagnosis of ITP.

The platelet count must be no more than 4 weeks old at the time of application.

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

Patients will be able to trial either eltrombopag or romiplostim within the initial 24 weeks treatment period. Where a patient has started initial treatment with one of the two agents, change of therapy to the alternative agent may be authorised under the Balance of supply or change of therapy restriction to complete up to 24 weeks initial treatment. Patients who fail to demonstrate a response to treatment with eltrombopag and/or romiplostim after completion of 24 weeks initial therapy will not be eligible to receive further PBS-subsidised treatment with either of these drugs.

Note Eltrombopag is not PBS-subsidised as an alternative to splenectomy.

Note Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to treatment with eltrombopag and/or romiplostim should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe thrombocytopenia

Treatment Phase: Initial treatment 2 - New patient

Clinical criteria:

- The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), **AND**
- Patient must not have had a splenectomy, **AND**
- Patient must have failed to achieve an adequate response to, or be intolerant to, corticosteroid therapy at a dose equivalent to 0.5-2 mg/kg/day of prednisone for at least 4-6 weeks, **AND**
- Patient must have failed to achieve an adequate response to, or be intolerant to, immunoglobulin therapy, **AND**
- Patient must be unsuitable for splenectomy due to medical reasons, **AND**
- The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition.

Population criteria:

- Patient must be aged 18 years or older.

The following criteria indicate failure to achieve an adequate response and must be demonstrated 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 20,000 million to 30,000 million per L, where the patient is experiencing significant bleeding or has a history of significant bleeding in this platelet range.

Where intolerance to treatment with corticosteroid and immunoglobulin therapy developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

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

- (1) a completed authority prescription form,
- (2) a completed Idiopathic Thrombocytopenic Purpura Initial PBS Authority Application - Supporting Information Form,
- (3) details of a platelet count supporting the diagnosis of ITP, and
- (4) details of the reason of medical contraindication for surgery and date of assessment.

The platelet count must be no more than 4 weeks old at the time of application.

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

Patients will be able to trial either eltrombopag or romiplostim within the initial 24 weeks treatment period. Where a patient has started initial treatment with one of the two agents, change of therapy to the alternative agent may be authorised under the Balance of supply or change of therapy restriction to complete up to 24 weeks initial treatment. Patients who fail to demonstrate a response to treatment with eltrombopag and/or romiplostim after completion of 24 weeks initial therapy will not be eligible to receive further PBS-subsidised treatment with either of these drugs.

Note Eltrombopag is not PBS-subsidised as an alternative to splenectomy.

Note Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe thrombocytopenia

Treatment Phase: First Continuing treatment or Re-initiation of interrupted continuing treatment

Clinical criteria:

- The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), **AND**
- Patient must have demonstrated a sustained platelet response to PBS-subsidised treatment with this drug for this condition under the Initial treatment restriction if the patient has not had a treatment break; OR
- Patient must have demonstrated a sustained platelet response to the most recent PBS-subsidised treatment with this drug for this condition prior to interrupted treatment, **AND**
- Patient must not have previously received PBS-subsidised continuing treatment with romiplostim for this condition, **AND**
- The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition.

Population criteria:

- Patient must be aged 18 years or older.

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 treatment with this drug,

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 continuing PBS-subsidised treatment or Re-initiation of interrupted PBS-subsidised continuing treatment must be made in writing and must include:

- (1) a completed authority prescription form, and

(2) a completed Idiopathic Thrombocytopenic Purpura Continuing PBS Authority Application - Supporting Information Form, and

(3) the most recent platelet count.

The platelet count must be conducted no later than 4 weeks from the date of completion of the most recent PBS-subsidised course of treatment with this drug.

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

Note Eltrombopag is not PBS-subsidised as an alternative to splenectomy.

Note Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Severe thrombocytopenia

Treatment Phase: Second or subsequent Continuing treatment

Clinical criteria:

- The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition under first continuing or re-initiation of interrupted continuing treatment restriction, **AND**
- Patient must have demonstrated a continuing response to PBS-subsidised treatment with this drug, **AND**
- The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition.

Population criteria:

- Patient must be aged 18 years or older.

For the purpose of this restriction, a continuing response to treatment with drug 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 this drug

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.

The platelet count must be no more than 4 weeks old at the time of application.

Note Eltrombopag is not PBS-subsidised as an alternative to splenectomy.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required

Severe thrombocytopenia

Treatment Phase: Balance of supply or change of therapy within 24 weeks initial treatment

Clinical criteria:

- The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), **AND**
- The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition, **AND**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 restriction to complete 24 weeks treatment; OR
- Patient must be swapping therapy from romiplostim to this drug for this condition within the initial 24 weeks of treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the First Continuing treatment or Re-initiation of interrupted continuing treatment restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Second and subsequent Continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

Population criteria:

- Patient must be aged 18 years or older.

Patients will be able to trial either eltrombopag or romiplostim within the initial 24 weeks treatment period. Where a patient has started initial treatment with one of the two agents, change of therapy to the alternative agent may be authorised under the Balance of supply or change of therapy restriction to complete up to 24 weeks initial treatment. Patients who fail to demonstrate a response to treatment with eltrombopag and/or romiplostim after completion of 24 weeks initial therapy will not be eligible to receive further PBS-subsidised treatment with either of these drugs.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

eltrombopag 25 mg tablet, 28

5827Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	1340.50	Revolade [NV]

eltrombopag 50 mg tablet, 28

5828R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	2633.26	Revolade [NV]

■ MACITENTAN

Caution This 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 therapy.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 (dual therapy - previously untreated patients)

Clinical criteria:

- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

Clinical criteria:

- Patient must currently have WHO Functional Class III PAH or WHO Functional Class IV PAH, **AND**
- The treatment must be in combination with a PBS-subsidised phosphodiesterase-5 inhibitor (PDE-5i) for this condition. The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

For the purposes of PBS subsidy, dual therapy refers to combined use of an endothelin receptor antagonist (ERA) and a phosphodiesterase-5 inhibitor (PDE-5i).

(i) An ERA includes ambrisentan, bosentan monohydrate, or macitentan.

(ii) A PDE-5i includes sildenafil citrate, or tadalafil.

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

PAH (WHO Group 1 pulmonary hypertension) is defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than or equal to 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than or equal to 15 mmHg; or

(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

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 which includes results from the three tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6 Minute Walk Test (6MWT).

Where it is not possible to perform all 3 tests 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 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.

Where a RHC cannot be performed on clinical grounds, confirmation of the reason(s) must be provided with the authority application by a second PAH physician or cardiologist with expertise in the management of PAH.

The test results provided must not be more than 2 months old at the time of 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.

Note PAH (WHO Group 1 pulmonary hypertension) currently includes the following subtypes: Idiopathic PAH

- Heritable PAH
 - BMPR2 mutation
 - ALK-1, ENG, SMAD9, CAV1, KCNK3 mutations
 - Other mutations

- Drugs and toxins induced PAH
- PAH associated with:
 - Connective tissue disease
 - Human immunodeficiency virus (HIV) infection
 - Portal hypertension
 - Congenital heart disease
 - Schistosomiasis

Note Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au. Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos. Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 2 (dual therapy - previously treated patients)

Clinical criteria:

- Patient must have documented WHO Functional Class III PAH or WHO Functional Class IV PAH, **AND**
- Patient must have documented a failure to achieve or maintain WHO Functional Class II status with prior PBS-subsidised monotherapy treatment with a phosphodiesterase-5 inhibitor (PDE-5i) for this condition, **AND**
- The treatment must be in combination with the PBS-subsidised PDE-5i for this condition.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

For the purposes of PBS subsidy, dual therapy refers to combined use of an endothelin receptor antagonist (ERA) and a phosphodiesterase-5 inhibitor (PDE-5i).

(i) An ERA includes ambrisentan, bosentan monohydrate, or macitentan.

(ii) A PDE-5i includes sildenafil citrate, or tadalafil.

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

PAH (WHO Group 1 pulmonary hypertension) is defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than or equal to 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than or equal to 15 mmHg; or

(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

The results and date of the RHC, ECHO and 6 MWT as applicable must be included in the patient's medical record. Where a RHC cannot be performed on clinical grounds, the written confirmation of the reasons why must also be included in the patient's medical record.

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.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 3 (dual therapy - change)

Clinical criteria:

- Patient must have had their most recent course of PBS-subsidised dual therapy with a phosphodiesterase-5 inhibitor (PDE-5i) and an endothelin receptor antagonist (ERA) other than this agent for this condition.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

For the purposes of PBS subsidy, dual therapy refers to combined use of an endothelin receptor antagonist (ERA) and a phosphodiesterase-5 inhibitor (PDE-5i).

(i) An ERA includes ambrisentan, bosentan monohydrate, or macitentan.

(ii) A PDE-5i includes sildenafil citrate, or tadalafil.

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

Swapping between PAH agents: Patients can access PAH agents through the PBS according to the relevant restrictions.

Once patients are approved dual therapy with a PAH agent from the PDE-5i class; or a PAH agent from the ERA class, they may swap between PAH agents within the same class. This means that patients may commence treatment with another PAH agent in the same class, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted.

Applications to swap within a PAH agent class must be made under the relevant initial treatment restriction.

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.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Continuing treatment (dual therapy)

Clinical criteria:

- Patient must have received their most recent course of PBS-subsidised dual therapy with this PAH agent and a phosphodiesterase-5 inhibitor (PDE-5i) for this condition.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

For the purposes of PBS subsidy, dual therapy refers to combined use of an endothelin receptor antagonist (ERA) and a phosphodiesterase-5 inhibitor (PDE-5i).

(i) An ERA includes ambrisentan, bosentan monohydrate, or macitentan.

(ii) A PDE-5i includes sildenafil citrate, or tadalafil.

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

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.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Grandfathered patients (dual therapy)

Clinical criteria:

- Patient must be receiving dual therapy with this non PBS-subsidised pulmonary arterial hypertension (PAH) agent and a non PBS-subsidised phosphodiesterase-5 inhibitor (PDE-5i) for this condition prior to 1 October 2020.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

Clinical criteria:

- Patient must have documented WHO Functional Class III PAH or WHO Functional Class IV PAH.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

For the purposes of PBS subsidy, dual therapy refers to combined use of an endothelin receptor antagonist (ERA) and a phosphodiesterase-5 inhibitor (PDE-5i).

(i) An ERA includes ambrisentan, bosentan monohydrate, or macitentan.

(ii) A PDE-5i includes sildenafil citrate, or tadalafil.

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

PAH (WHO Group 1 pulmonary hypertension) is defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than or equal to 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than or equal to 15 mmHg; or

(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

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 which includes results from the three tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6 Minute Walk Test (6MWT).

Where it was not possible to perform all 3 tests 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 could not be performed on clinical grounds, applications may be submitted 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 were 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.

Where a RHC could not be performed on clinical grounds, confirmation of the reason(s) must be provided with the authority application by a second PAH physician or cardiologist with expertise in the management of PAH.

A patient may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria for dual therapy for this condition.

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.

Note PAH (WHO Group 1 pulmonary hypertension) currently includes the following subtypes: Idiopathic PAH

- Heritable PAH
 - BMPR2 mutation
 - ALK-1, ENG, SMAD9, CAV1, KCNK3 mutations
 - Other mutations
- Drugs and toxins induced PAH
- PAH associated with:
 - Connective tissue disease
 - Human immunodeficiency virus (HIV) infection
 - Portal hypertension
 - Congenital heart disease
 - Schistosomiasis

Note Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Triple therapy - Initial treatment or continuing treatment of triple combination therapy (including dual therapy in lieu of triple therapy) that includes selexipag

Clinical criteria:

- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) PBS-subsidised selexipag (referred to as 'triple therapy'); OR
- The treatment must form part of dual combination therapy consisting of either: (i) PBS-subsidised selexipag with one endothelin receptor antagonist, (ii) PBS-subsidised selexipag with one phosphodiesterase-5 inhibitor, as triple combination therapy with selexipag-an endothelin receptor antagonist-a phosphodiesterase-5 inhibitor is not possible due to an intolerance/contraindication to the endothelin receptor antagonist class/phosphodiesterase-5 inhibitor class (referred to as 'dual therapy in lieu of triple therapy').

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

The authority application for selexipag must be approved prior to the authority application for this agent.

For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil.

PBS-subsidy does not cover patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

PAH (WHO Group 1 pulmonary hypertension) is defined as follows:

- (i) mean pulmonary artery pressure (mPAP) greater than or equal to 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than or equal to 15 mmHg; or
- (ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

The results and date of the RHC, ECHO and 6 MWT as applicable must be included in the patient's medical record. Where a RHC cannot be performed on clinical grounds, the written confirmation of the reasons why must also be included in the patient's medical record.

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.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Note Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

macitentan 10 mg tablet, 30

12135Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	2780.39	Opsumit [JC]

■ ROMIPILOSTIM

Authority required

Severe thrombocytopenia

Treatment Phase: Initial treatment 1 - New patient

Clinical criteria:

- The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), **AND**
- Patient must have had a splenectomy, **AND**
- Patient must have failed to achieve an adequate response to, or be intolerant to, corticosteroid therapy following the splenectomy, **AND**
- Patient must have failed to achieve an adequate response to, or be intolerant to, immunoglobulin therapy following the splenectomy, **AND**
- The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition.

Population criteria:

- Patient must be aged 18 years or older.

The following criteria indicate failure to achieve an adequate response and must be demonstrated 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 20,000 million to 30,000 million per L, where the patient is experiencing significant bleeding or has a history of significant bleeding in this platelet range.

Where intolerance to treatment with corticosteroid and immunoglobulin therapy developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided 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 requested by telephone. 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.

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

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

- (1) a completed authority prescription form,
- (2) a completed Idiopathic Thrombocytopenic Purpura Initial PBS Authority Application - Supporting Information Form,
- (3) details of a platelet count supporting the diagnosis of ITP.

The platelet count must be no more than 4 weeks old at the time of application.

Patients will be able to trial either eltrombopag or romiplostim within the initial 24 weeks treatment period. Where a patient has started initial treatment with one of the two agents, change of therapy to the alternative agent may be authorised under the Balance of supply or change of therapy restriction to complete up to 24 weeks initial treatment. Patients who fail to demonstrate a response to treatment with eltrombopag and/or romiplostim after completion of 24 weeks initial therapy will not be eligible to receive further PBS-subsidised treatment with either of these drugs.

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

Note Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Severe thrombocytopenia

Treatment Phase: Initial treatment 2 - New patient

Clinical criteria:

- The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), **AND**
- Patient must not have had a splenectomy, **AND**
- Patient must have failed to achieve an adequate response to, or be intolerant to, corticosteroid therapy at a dose equivalent to 0.5-2 mg/kg/day of prednisone for at least 4-6 weeks, **AND**
- Patient must have failed to achieve an adequate response to, or be intolerant to, immunoglobulin therapy, **AND**
- Patient must be unsuitable for splenectomy due to medical reasons, **AND**
- The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition.

Population criteria:

- Patient must be aged 18 years or older.

The following criteria indicate failure to achieve an adequate response and must be demonstrated 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 20,000 million to 30,000 million per L, where the patient is experiencing significant bleeding or has a history of significant bleeding in this platelet range.

Where intolerance to treatment with corticosteroid and immunoglobulin therapy developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided 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 requested by telephone. 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.

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

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

- (1) a completed authority prescription form,
- (2) a completed Idiopathic Thrombocytopenic Purpura Initial PBS Authority Application - Supporting Information Form,
- (3) details of a platelet count supporting the diagnosis of ITP, and
- (4) details of the reason of medical contraindication for surgery and date of assessment.

The platelet count must be no more than 4 weeks old at the time of application.

Patients will be able to trial either eltrombopag or romiplostim within the initial 24 weeks treatment period. Where a patient has started initial treatment with one of the two agents, change of therapy to the alternative agent may be authorised under the Balance of supply or change of therapy restriction to complete up to 24 weeks initial treatment. Patients who fail to demonstrate a response to treatment with eltrombopag and/or romiplostim after completion of 24 weeks initial therapy will not be eligible to receive further PBS-subsidised treatment with either of these drugs.

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

Note Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe thrombocytopenia

Treatment Phase: First Continuing treatment or Re-initiation of interrupted continuing treatment

Clinical criteria:

- The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), **AND**
- Patient must have demonstrated a sustained platelet response to PBS-subsidised treatment with this drug for this condition under the Initial treatment restriction if the patient has not had a treatment break; OR
- Patient must have demonstrated a sustained platelet response to the most recent PBS-subsidised treatment with this drug for this condition prior to interrupted treatment, **AND**
- Patient must not have previously received PBS-subsidised continuing treatment with eltrombopag for this condition, **AND**
- The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition.

Population criteria:

- Patient must be aged 18 years or older.

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 treatment with this drug,

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.

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 higher than 10 micrograms/kg/week

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

(1) a completed authority prescription form, and

(2) a completed Idiopathic Thrombocytopenic Purpura Continuing PBS Authority Application - Supporting Information Form, and

(3) the most recent platelet count.

The platelet count must be conducted no later than 4 weeks from the date of completion of the most recent PBS-subsidised course of treatment with this drug.

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

Note Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Severe thrombocytopenia

Treatment Phase: Second or Subsequent Continuing treatment

Clinical criteria:

- The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition under first continuing or re-initiation of interrupted continuing treatment restriction, **AND**
- Patient must have demonstrated a continuing response to PBS-subsidised treatment with this drug, **AND**
- The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition.

Population criteria:

- Patient must be aged 18 years or older.

For the purpose of this restriction, a continuing response to treatment with drug 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 this drug

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.

The platelet count must be no more than 4 weeks 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.

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

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

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required

Severe thrombocytopenia

Treatment Phase: Balance of supply or change of therapy within 24 weeks initial treatment

Clinical criteria:

- The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), **AND**
- The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition, **AND**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 restriction to complete 24 weeks treatment; OR

- Patient must be swapping therapy from eltrombopag to this drug for this condition within the initial 24 weeks of treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the First Continuing treatment or Re-initiation of interrupted continuing treatment restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Second and subsequent Continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

Population criteria:

- Patient must be aged 18 years or older.

Patients will be able to trial either eltrombopag or romiplostim within the initial 24 weeks treatment period. Where a patient has started initial treatment with one of the two agents, change of therapy to the alternative agent may be authorised under the Balance of supply or change of therapy restriction to complete up to 24 weeks initial treatment. Patients who fail to demonstrate a response to treatment with eltrombopag and/or romiplostim after completion of 24 weeks initial therapy will not be eligible to receive further PBS-subsidised treatment with either of these drugs.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

romiplostim 500 microgram injection, 1 vial

9699L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	1145.78	Nplate [AN]

romiplostim 250 microgram injection, 1 vial

9697J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	578.72	Nplate [AN]

▪ **SELEXIPAG**

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

Note PAH (WHO Group 1 pulmonary hypertension) currently includes the following subtypes: Idiopathic PAH

- Heritable PAH
 - BMPR2 mutation
 - ALK-1, ENG, SMAD9, CAV1, KCNK3 mutations
 - Other mutations
- Drugs and toxins induced PAH
- PAH associated with:
 - Connective tissue disease
 - Human immunodeficiency virus (HIV) infection
 - Portal hypertension
 - Congenital heart disease
 - Schistosomiasis

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial treatment - dose titration

Clinical criteria:

- Patient must have failed to achieve/maintain a WHO Functional Class II status with PAH agents (other than this agent) given as dual therapy, **AND**
- Patient must have WHO Functional Class III PAH at treatment initiation with this drug; OR
- Patient must have WHO Functional Class IV PAH at treatment initiation with this drug, **AND**
- The treatment must be for dose titration purposes with the intent of completing the titration within 12 weeks, **AND**
- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) selexipag (referred to as 'triple therapy'); OR
- The treatment must form part of dual combination therapy consisting of either: (i) selexipag with one endothelin receptor antagonist, (ii) selexipag with one phosphodiesterase-5 inhibitor, as triple combination therapy with selexipag-an endothelin receptor antagonist-a phosphodiesterase-5 inhibitor is not possible due to an intolerance/contraindication to the endothelin receptor antagonist class/phosphodiesterase-5 inhibitor class (referred to as 'dual therapy in lieu of triple therapy'), **AND**
- The treatment must not be as monotherapy.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

Population criteria:

- Patient must have had at least one PBS-subsidised PAH agent prior to this authority application. A prior PAH agent is any of: ambrisentan, bosentan, macitentan, sildenafil, tadalafil, epoprostenol, iloprost, riociguat. For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil.
- PBS-subsidy does not cover patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.
- PAH (WHO Group 1 pulmonary hypertension) is defined as follows:
- (i) mean pulmonary artery pressure (mPAP) greater than or equal to 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than or equal to 15 mmHg; or
 - (ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

selexipag 800 microgram tablet, 60

12253X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	3	..	3497.74	Upravi [JC]

▪ SELEXIPAG

- Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
- Note** No increase in the maximum quantity or number of units may be authorised.
- Note** No increase in the maximum number of repeats may be authorised.
- Note** Special Pricing Arrangements apply.
- Note** Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.
- Note** PAH (WHO Group 1 pulmonary hypertension) currently includes the following subtypes: Idiopathic PAH
- Heritable PAH
 - BMPR2 mutation
 - ALK-1, ENG, SMAD9, CAV1, KCNK3 mutations
 - Other mutations
 - Drugs and toxins induced PAH
 - PAH associated with:
 - Connective tissue disease
 - Human immunodeficiency virus (HIV) infection
 - Portal hypertension
 - Congenital heart disease
 - Schistosomiasis

Authority required

Pulmonary arterial hypertension (PAH)
Treatment Phase: Initial treatment - dose titration

Clinical criteria:

- Patient must have failed to achieve/maintain a WHO Functional Class II status with PAH agents (other than this agent) given as dual therapy, **AND**
- Patient must have WHO Functional Class III PAH at treatment initiation with this drug; OR
- Patient must have WHO Functional Class IV PAH at treatment initiation with this drug, **AND**
- The treatment must be for dose titration purposes with the intent of completing the titration within 12 weeks, **AND**
- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) selexipag (referred to as 'triple therapy'); OR
- The treatment must form part of dual combination therapy consisting of either: (i) selexipag with one endothelin receptor antagonist, (ii) selexipag with one phosphodiesterase-5 inhibitor, as triple combination therapy with selexipag-an endothelin receptor antagonist-a phosphodiesterase-5 inhibitor is not possible due to an intolerance/contraindication to the endothelin receptor antagonist class/phosphodiesterase-5 inhibitor class (referred to as 'dual therapy in lieu of triple therapy'), **AND**
- The treatment must not be as monotherapy.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

Population criteria:

- Patient must have had at least one PBS-subsidised PAH agent prior to this authority application. A prior PAH agent is any of: ambrisentan, bosentan, macitentan, sildenafil, tadalafil, epoprostenol, iloprost, riociguat. For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil.
- PBS-subsidy does not cover patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.
- PAH (WHO Group 1 pulmonary hypertension) is defined as follows:
- (i) mean pulmonary artery pressure (mPAP) greater than or equal to 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than or equal to 15 mmHg; or

(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Transitioning from non-PBS subsidised to PBS-subsidised supply - 'Grandfather' treatment

Clinical criteria:

- Patient must have received non-PBS subsidised treatment with this drug prior to 1 February 2021, **AND**
- Patient must have failed to achieve/maintain a WHO Functional Class II status with PAH agents (other than this agent) given as dual therapy, prior to treatment initiation with this drug, **AND**
- Patient must have had WHO Functional Class III PAH at treatment initiation with this drug; OR
- Patient must have had WHO Functional Class IV PAH at treatment initiation with this drug, **AND**
- Patient must not have developed disease progression while receiving treatment with this drug for this condition, **AND**
- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) selexipag (referred to as 'triple therapy'); OR
- The treatment must form part of dual combination therapy consisting of either: (i) selexipag with one endothelin receptor antagonist, (ii) selexipag with one phosphodiesterase-5 inhibitor, as triple combination therapy with selexipag-an endothelin receptor antagonist-a phosphodiesterase-5 inhibitor is not possible due to an intolerance/contraindication to the endothelin receptor antagonist class/phosphodiesterase-5 inhibitor class (referred to as 'dual therapy in lieu of triple therapy'), **AND**
- The treatment must not be as monotherapy.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

Population criteria:

- Patient must have had at least one PBS-subsidised PAH agent prior to this authority application.

A prior PAH agent is any of: ambrisentan, bosentan, macitentan, sildenafil, tadalafil, epoprostenol, iloprost, riociguat.

For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil.

For the purposes of administering this restriction, disease progression has developed if at least one of the following has occurred:

- (i) Hospitalisation due to worsening PAH;
- (ii) Deterioration of aerobic capacity/endurance, consisting of at least a 15% decrease in 6-Minute Walk Distance from baseline, combined with worsening of WHO functional class status;
- (iii) Deterioration of aerobic capacity/endurance, consisting of at least a 15% decrease in 6-Minute Walk Distance from baseline, combined with the need for additional PAH-specific therapy;
- (iv) Initiation of parenteral prostanoid therapy or long-term oxygen therapy for worsening of PAH;
- (v) Need for lung transplantation or balloon atrial septostomy for worsening of PAH.

PBS-subsidy does not cover patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

PAH (WHO Group 1 pulmonary hypertension) is defined as follows:

- (i) mean pulmonary artery pressure (mPAP) greater than or equal to 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than or equal to 15 mmHg; or
- (ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Note Patients may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a 'Grandfathered' patient must qualify under the 'Continuing treatment' criteria.

Note This grandfather restriction will cease to operate from 12 months after the date specified in the clinical criteria.

selexipag 200 microgram tablet, 140

12241G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	2	..	8097.74	Upravi [JC]

SELEXIPAG

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial treatment following dose titration

Clinical criteria:

- Patient must have WHO Functional Class III PAH at treatment initiation with this drug; OR
- Patient must have WHO Functional Class IV PAH at treatment initiation with this drug, **AND**

- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) selexipag (referred to as 'triple therapy'); OR
- The treatment must form part of dual combination therapy consisting of either: (i) selexipag with one endothelin receptor antagonist, (ii) selexipag with one phosphodiesterase-5 inhibitor, as triple combination therapy with selexipag-an endothelin receptor antagonist-a phosphodiesterase-5 inhibitor is not possible due to an intolerance/contraindication to the endothelin receptor antagonist class/phosphodiesterase-5 inhibitor class (referred to as 'dual therapy in lieu of triple therapy'), **AND**
- Patient must have completed the dose titration phase, **AND**
- The treatment must not be as monotherapy.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

Population criteria:

- Patient must have had at least one PBS-subsidised PAH agent prior to this authority application.

Select one appropriate strength (determined under the 'Initial treatment - dose titration' phase) and apply under this treatment phase (Initial treatment following dose titration) once only. Should future dose adjustments be required, apply under the 'Continuing treatment' restriction.

A prior PAH agent is any of: ambrisentan, bosentan, macitentan, sildenafil, tadalafil, epoprostenol, iloprost, riociguat.

For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil.

PBS-subsidy does not cover patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

PAH (WHO Group 1 pulmonary hypertension) is defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than or equal to 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than or equal to 15 mmHg; or

(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Note PAH (WHO Group 1 pulmonary hypertension) currently includes the following subtypes: Idiopathic PAH

- Heritable PAH
 - BMPR2 mutation
 - ALK-1, ENG, SMAD9, CAV1, KCNK3 mutations
 - Other mutations
- Drugs and toxins induced PAH
- PAH associated with:
 - Connective tissue disease
 - Human immunodeficiency virus (HIV) infection
 - Portal hypertension
 - Congenital heart disease
 - Schistosomiasis

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have developed disease progression while receiving treatment with this drug for this condition, **AND**
- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) selexipag (referred to as 'triple therapy'); OR
- The treatment must form part of dual combination therapy consisting of either: (i) selexipag with one endothelin receptor antagonist, (ii) selexipag with one phosphodiesterase-5 inhibitor, as triple combination therapy with selexipag-an endothelin receptor antagonist-a phosphodiesterase-5 inhibitor is not possible due to an intolerance/contraindication to the endothelin receptor antagonist class/phosphodiesterase-5 inhibitor class (referred to as 'dual therapy in lieu of triple therapy'), **AND**
- The treatment must not be as monotherapy.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil.

For the purposes of administering this restriction, disease progression has developed if at least one of the following has occurred:

- Hospitalisation due to worsening PAH;
- Deterioration of aerobic capacity/endurance, consisting of at least a 15% decrease in 6-Minute Walk Distance from baseline, combined with worsening of WHO functional class status;
- Deterioration of aerobic capacity/endurance, consisting of at least a 15% decrease in 6-Minute Walk Distance from baseline, combined with the need for additional PAH-specific therapy;
- Initiation of parenteral prostanoid therapy or long-term oxygen therapy for worsening of PAH;
- Need for lung transplantation or balloon atrial septostomy for worsening of PAH.

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Transitioning from non-PBS subsidised to PBS-subsidised supply - 'Grandfather' treatment

Clinical criteria:

- Patient must have received non-PBS subsidised treatment with this drug prior to 1 February 2021, **AND**
- Patient must have failed to achieve/maintain a WHO Functional Class II status with PAH agents (other than this agent) given as dual therapy, prior to treatment initiation with this drug, **AND**
- Patient must have had WHO Functional Class III PAH at treatment initiation with this drug; OR
- Patient must have had WHO Functional Class IV PAH at treatment initiation with this drug, **AND**
- Patient must not have developed disease progression while receiving treatment with this drug for this condition, **AND**
- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) selexipag (referred to as 'triple therapy'); OR
- The treatment must form part of dual combination therapy consisting of either: (i) selexipag with one endothelin receptor antagonist, (ii) selexipag with one phosphodiesterase-5 inhibitor, as triple combination therapy with selexipag-an endothelin receptor antagonist-a phosphodiesterase-5 inhibitor is not possible due to an intolerance/contraindication to the endothelin receptor antagonist class/phosphodiesterase-5 inhibitor class (referred to as 'dual therapy in lieu of triple therapy'), **AND**
- The treatment must not be as monotherapy.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

Population criteria:

- Patient must have had at least one PBS-subsidised PAH agent prior to this authority application.

A prior PAH agent is any of: ambrisentan, bosentan, macitentan, sildenafil, tadalafil, epoprostenol, iloprost, riociguat.

For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil.

For the purposes of administering this restriction, disease progression has developed if at least one of the following has occurred:

- (i) Hospitalisation due to worsening PAH;
- (ii) Deterioration of aerobic capacity/endurance, consisting of at least a 15% decrease in 6-Minute Walk Distance from baseline, combined with worsening of WHO functional class status;
- (iii) Deterioration of aerobic capacity/endurance, consisting of at least a 15% decrease in 6-Minute Walk Distance from baseline, combined with the need for additional PAH-specific therapy;
- (iv) Initiation of parenteral prostanoid therapy or long-term oxygen therapy for worsening of PAH;
- (v) Need for lung transplantation or balloon atrial septostomy for worsening of PAH.

PBS-subsidy does not cover patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

PAH (WHO Group 1 pulmonary hypertension) is defined as follows:

- (i) mean pulmonary artery pressure (mPAP) greater than or equal to 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than or equal to 15 mmHg; or
- (ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Note PAH (WHO Group 1 pulmonary hypertension) currently includes the following subtypes: Idiopathic PAH

- Heritable PAH
 - BMPR2 mutation
 - ALK-1, ENG, SMAD9, CAV1, KCNK3 mutations
 - Other mutations
- Drugs and toxins induced PAH
- PAH associated with:
 - Connective tissue disease
 - Human immunodeficiency virus (HIV) infection
 - Portal hypertension
 - Congenital heart disease
 - Schistosomiasis

Note Patients may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a 'Grandfathered' patient must qualify under the 'Continuing treatment' criteria.

Note This grandfather restriction will cease to operate from 12 months after the date specified in the clinical criteria.

selexipag 200 microgram tablet, 60

12242H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	3497.74	Uptravi [JC]

selexipag 400 microgram tablet, 60

12260G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	3497.74	Uptravi [JC]

selexipag 1.2 mg tablet, 60

12257D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	3497.74	Upravi [JC]

selexipag 800 microgram tablet, 60

12246M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	3497.74	Upravi [JC]

selexipag 1.6 mg tablet, 60

12264L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	3497.74	Upravi [JC]

selexipag 1 mg tablet, 60

12245L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	3497.74	Upravi [JC]

selexipag 1.4 mg tablet, 60

12251T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	3497.74	Upravi [JC]

selexipag 600 microgram tablet, 60

12248P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	3497.74	Upravi [JC]

▪ SILDENAFIL

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 (dual therapy - previously untreated patients)

Clinical criteria:

- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

Clinical criteria:

- Patient must currently have WHO Functional Class III PAH or WHO Functional Class IV PAH, **AND**
- The treatment must be in combination with a PBS-subsidised endothelin receptor antagonist (ERA) for this condition. The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

For the purposes of PBS subsidy, dual therapy refers to combined use of an endothelin receptor antagonist (ERA) and a phosphodiesterase-5 inhibitor (PDE-5i).

(i) An ERA includes ambrisentan, bosentan monohydrate, or macitentan.

(ii) A PDE-5i includes sildenafil citrate, or tadalafil.

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

PAH (WHO Group 1 pulmonary hypertension) is defined as follows:

- (i) mean pulmonary artery pressure (mPAP) greater than or equal to 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than or equal to 15 mmHg; or
- (ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

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 which includes results from the three tests below, where available:
 - (i) RHC composite assessment; and
 - (ii) ECHO composite assessment; and
 - (iii) 6 Minute Walk Test (6MWT).

Where it is not possible to perform all 3 tests 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 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.

Where a RHC cannot be performed on clinical grounds, confirmation of the reason(s) must be provided with the authority application by a second PAH physician or cardiologist with expertise in the management of PAH.

The test results provided must not be more than 2 months old at the time of 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.

Note PAH (WHO Group 1 pulmonary hypertension) currently includes the following subtypes: Idiopathic PAH

- Heritable PAH
 - BMPR2 mutation
 - ALK-1, ENG, SMAD9, CAV1, KCNK3 mutations
 - Other mutations
- Drugs and toxins induced PAH
- PAH associated with:
 - Connective tissue disease
 - Human immunodeficiency virus (HIV) infection
 - Portal hypertension
 - Congenital heart disease
 - Schistosomiasis

Note Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 2 (dual therapy - previously treated patients)

Clinical criteria:

- Patient must have documented WHO Functional Class III PAH or WHO Functional Class IV PAH, **AND**
- Patient must have documented a failure to achieve or maintain WHO Functional Class II status with prior PBS-subsidised monotherapy treatment with an endothelin receptor antagonist (ERA) for this condition, **AND**
- The treatment must be in combination with a PBS-subsidised endothelin receptor antagonist (ERA) for this condition.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

For the purposes of PBS subsidy, dual therapy refers to combined use of an endothelin receptor antagonist (ERA) and a phosphodiesterase-5 inhibitor (PDE-5i).

(i) An ERA includes ambrisentan, bosentan monohydrate, or macitentan.

(ii) A PDE-5i includes sildenafil citrate, or tadalafil.

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

PAH (WHO Group 1 pulmonary hypertension) is defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than or equal to 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than or equal to 15 mmHg; or

(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

The results and date of the RHC, ECHO and 6 MWT as applicable must be included in the patient's medical record. Where a RHC cannot be performed on clinical grounds, the written confirmation of the reasons why must also be included in the patient's medical record.

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.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 3 (dual therapy - change)

Clinical criteria:

- Patient must have had their most recent course of PBS-subsidised dual therapy with an endothelin receptor antagonist (ERA) and a phosphodiesterase-5 inhibitor (PDE-5i) other than this agent for this condition.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

For the purposes of PBS subsidy, dual therapy refers to combined use of an endothelin receptor antagonist (ERA) and a phosphodiesterase-5 inhibitor (PDE-5i).

(i) An ERA includes ambrisentan, bosentan monohydrate, or macitentan.

(ii) A PDE-5i includes sildenafil citrate, or tadalafil.

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

Swapping between PAH agents: Patients can access PAH agents through the PBS according to the relevant restrictions.

Once patients are approved dual therapy with a PAH agent from the PDE-5i class; or a PAH agent from the ERA class, they may swap between PAH agents within the same class. This means that patients may commence treatment with another PAH agent in the same class, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted.

Applications to swap within a PAH agent class must be made under the relevant initial treatment restriction.

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.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Continuing treatment (dual therapy)

Clinical criteria:

- Patient must have received their most recent course of PBS-subsidised treatment with this PAH agent and an endothelin receptor antagonist (ERA) for this condition.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

For the purposes of PBS subsidy, dual therapy refers to combined use of an endothelin receptor antagonist (ERA) and a phosphodiesterase-5 inhibitor (PDE-5i).

(i) An ERA includes ambrisentan, bosentan monohydrate, or macitentan.

(ii) A PDE-5i includes sildenafil citrate, or tadalafil.

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

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.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Grandfathered patients (dual therapy)

Clinical criteria:

- Patient must be receiving dual therapy with this non PBS-subsidised pulmonary arterial hypertension (PAH) agent and a non PBS-subsidised endothelin receptor antagonist (ERA) for this condition prior to 1 October 2020.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

Clinical criteria:

- Patient must have documented WHO Functional Class III PAH or WHO Functional Class IV PAH.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

For the purposes of PBS subsidy, dual therapy refers to combined use of an endothelin receptor antagonist (ERA) and a phosphodiesterase-5 inhibitor (PDE-5i).

(i) An ERA includes ambrisentan, bosentan monohydrate, or macitentan.

(ii) A PDE-5i includes sildenafil citrate, or tadalafil.

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

PAH (WHO Group 1 pulmonary hypertension) is defined as follows:

- (i) mean pulmonary artery pressure (mPAP) greater than or equal to 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than or equal to 15 mmHg; or
- (ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

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 which includes results from the three tests below, where available:
 - (i) RHC composite assessment; and
 - (ii) ECHO composite assessment; and
 - (iii) 6 Minute Walk Test (6MWT).

Where it was not possible to perform all 3 tests 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 could not be performed on clinical grounds, applications may be submitted 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 were 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.

Where a RHC could not be performed on clinical grounds, confirmation of the reason(s) must be provided with the authority application by a second PAH physician or cardiologist with expertise in the management of PAH.

A patient may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria for dual therapy for this condition.

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.

Note PAH (WHO Group 1 pulmonary hypertension) currently includes the following subtypes: Idiopathic PAH

- Heritable PAH
 - BMPR2 mutation
 - ALK-1, ENG, SMAD9, CAV1, KCNK3 mutations
 - Other mutations
- Drugs and toxins induced PAH
- PAH associated with:
 - Connective tissue disease
 - Human immunodeficiency virus (HIV) infection
 - Portal hypertension
 - Congenital heart disease
 - Schistosomiasis

Note Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Triple therapy - Initial treatment or continuing treatment of triple combination therapy (including dual therapy in lieu of triple therapy) that includes selexipag

Clinical criteria:

- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) PBS-subsidised selexipag (referred to as 'triple therapy'); OR
- The treatment must form part of dual combination therapy consisting of either: (i) PBS-subsidised selexipag with one endothelin receptor antagonist, (ii) PBS-subsidised selexipag with one phosphodiesterase-5 inhibitor, as triple combination therapy with selexipag-an endothelin receptor antagonist-a phosphodiesterase-5 inhibitor is not possible due to an intolerance/contraindication to the endothelin receptor antagonist class/phosphodiesterase-5 inhibitor class (referred to as 'dual therapy in lieu of triple therapy').

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

The authority application for selexipag must be approved prior to the authority application for this agent. For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil.

PBS-subsidy does not cover patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

PAH (WHO Group 1 pulmonary hypertension) is defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than or equal to 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than or equal to 15 mmHg; or

(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

The results and date of the RHC, ECHO and 6 MWT as applicable must be included in the patient's medical record. Where a RHC cannot be performed on clinical grounds, the written confirmation of the reasons why must also be included in the patient's medical record.

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.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicessaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Note Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

sildenafil 20 mg tablet, 90

12138W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	272.22	^a APO-Sildenafil PHT [TX]	^a Revatio [UJ]
					^a SILDATIO PHT [RW]	^a Sildenafil AN PHT 20 [EA]
					^a Sildenafil PHT APOTEX [TY]	^a Sildenafil Sandoz PHT 20 [SZ]

▪ TADALAFIL

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 (dual therapy - previously untreated patients)

Clinical criteria:

- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

Clinical criteria:

- Patient must currently have WHO Functional Class III PAH or WHO Functional Class IV PAH, **AND**
- The treatment must be in combination with a PBS-subsidised endothelin receptor antagonist (ERA) for this condition. The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

For the purposes of PBS subsidy, dual therapy refers to combined use of an endothelin receptor antagonist (ERA) and a phosphodiesterase-5 inhibitor (PDE-5i).

(i) An ERA includes ambrisentan, bosentan monohydrate, or macitentan.

(ii) A PDE-5i includes sildenafil citrate, or tadalafil.

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

PAH (WHO Group 1 pulmonary hypertension) is defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than or equal to 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than or equal to 15 mmHg; or

(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

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 which includes results from the three tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6 Minute Walk Test (6MWT).

Where it is not possible to perform all 3 tests 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 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.

Where a RHC cannot be performed on clinical grounds, confirmation of the reason(s) must be provided with the authority application by a second PAH physician or cardiologist with expertise in the management of PAH.

The test results provided must not be more than 2 months old at the time of 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.

Note PAH (WHO Group 1 pulmonary hypertension) currently includes the following subtypes: Idiopathic PAH

- Heritable PAH
 - BMPR2 mutation
 - ALK-1, ENG, SMAD9, CAV1, KCNK3 mutations
 - Other mutations
- Drugs and toxins induced PAH
- PAH associated with:
 - Connective tissue disease
 - Human immunodeficiency virus (HIV) infection
 - Portal hypertension
 - Congenital heart disease
 - Schistosomiasis

Note Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 2 (dual therapy - previously treated patients)

Clinical criteria:

- Patient must have documented WHO Functional Class III PAH or WHO Functional Class IV PAH, **AND**
- Patient must have documented a failure to achieve or maintain WHO Functional Class II status with prior PBS-subsidised monotherapy treatment with an endothelin receptor antagonist (ERA) for this condition, **AND**
- The treatment must be in combination with a PBS-subsidised endothelin receptor antagonist (ERA) for this condition.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

For the purposes of PBS subsidy, dual therapy refers to combined use of an endothelin receptor antagonist (ERA) and a phosphodiesterase-5 inhibitor (PDE-5i).

(i) An ERA includes ambrisentan, bosentan monohydrate, or macitentan.

(ii) A PDE-5i includes sildenafil citrate, or tadalafil.

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

PAH (WHO Group 1 pulmonary hypertension) is defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than or equal to 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than or equal to 15 mmHg; or

(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

The results and date of the RHC, ECHO and 6 MWT as applicable must be included in the patient's medical record. Where a RHC cannot be performed on clinical grounds, the written confirmation of the reasons why must also be included in the patient's medical record.

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.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 3 (dual therapy - change)

Clinical criteria:

- Patient must have had their most recent course of PBS-subsidised dual therapy with an endothelin receptor antagonist (ERA) and a phosphodiesterase-5 inhibitor (PDE-5i) other than this agent for this condition.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

For the purposes of PBS subsidy, dual therapy refers to combined use of an endothelin receptor antagonist (ERA) and a phosphodiesterase-5 inhibitor (PDE-5i).

(i) An ERA includes ambrisentan, bosentan monohydrate, or macitentan.

(ii) A PDE-5i includes sildenafil citrate, or tadalafil.

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

Swapping between PAH agents: Patients can access PAH agents through the PBS according to the relevant restrictions.

Once patients are approved dual therapy with a PAH agent from the PDE-5i class; or a PAH agent from the ERA class, they may swap between PAH agents within the same class. This means that patients may commence treatment with another PAH agent in the same class, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted.

Applications to swap within a PAH agent class must be made under the relevant initial treatment restriction.

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.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Continuing treatment (dual therapy)

Clinical criteria:

- Patient must have received their most recent course of PBS-subsidised treatment with this PAH agent and an endothelin receptor antagonist (ERA) for this condition.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

For the purposes of PBS subsidy, dual therapy refers to combined use of an endothelin receptor antagonist (ERA) and a phosphodiesterase-5 inhibitor (PDE-5i).

(i) An ERA includes ambrisentan, bosentan monohydrate, or macitentan.

(ii) A PDE-5i includes sildenafil citrate, or tadalafil.

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

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.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Grandfathered patients (dual therapy)

Clinical criteria:

- Patient must be receiving dual therapy with this non PBS-subsidised pulmonary arterial hypertension (PAH) agent and a non PBS-subsidised endothelin receptor antagonist (ERA) for this condition prior to 1 October 2020.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

Clinical criteria:

- Patient must have documented WHO Functional Class III PAH or WHO Functional Class IV PAH.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

For the purposes of PBS subsidy, dual therapy refers to combined use of an endothelin receptor antagonist (ERA) and a phosphodiesterase-5 inhibitor (PDE-5i).

(i) An ERA includes ambrisentan, bosentan monohydrate, or macitentan.

(ii) A PDE-5i includes sildenafil citrate, or tadalafil.

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

PAH (WHO Group 1 pulmonary hypertension) is defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than or equal to 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than or equal to 15 mmHg; or

(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

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 which includes results from the three tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6 Minute Walk Test (6MWT).

Where it was not possible to perform all 3 tests 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 could not be performed on clinical grounds, applications may be submitted 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 were 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.

Where a RHC could not be performed on clinical grounds, confirmation of the reason(s) must be provided with the authority application by a second PAH physician or cardiologist with expertise in the management of PAH.

A patient may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria for dual therapy for this condition.

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.

Note PAH (WHO Group 1 pulmonary hypertension) currently includes the following subtypes: Idiopathic PAH

- Heritable PAH
 - BMPR2 mutation
 - ALK-1, ENG, SMAD9, CAV1, KCNK3 mutations
 - Other mutations
- Drugs and toxins induced PAH
- PAH associated with:
 - Connective tissue disease
 - Human immunodeficiency virus (HIV) infection
 - Portal hypertension
 - Congenital heart disease
 - Schistosomiasis

Note Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Triple therapy - Initial treatment or continuing treatment of triple combination therapy (including dual therapy in lieu of triple therapy) that includes selexipag

Clinical criteria:

- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) PBS-subsidised selexipag (referred to as 'triple therapy'); OR
- The treatment must form part of dual combination therapy consisting of either: (i) PBS-subsidised selexipag with one endothelin receptor antagonist, (ii) PBS-subsidised selexipag with one phosphodiesterase-5 inhibitor, as triple combination therapy with selexipag-an endothelin receptor antagonist-a phosphodiesterase-5 inhibitor is not possible due to an intolerance/contraindication to the endothelin receptor antagonist class/phosphodiesterase-5 inhibitor class (referred to as 'dual therapy in lieu of triple therapy').

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

The authority application for selexipag must be approved prior to the authority application for this agent.

For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil.

PBS-subsidy does not cover patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

PAH (WHO Group 1 pulmonary hypertension) is defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than or equal to 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than or equal to 15 mmHg; or

(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

The results and date of the RHC, ECHO and 6 MWT as applicable must be included in the patient's medical record. Where a RHC cannot be performed on clinical grounds, the written confirmation of the reasons why must also be included in the patient's medical record.

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.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Note Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

tadalafil 20 mg tablet, 56

12150L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	502.30	^a Adcirca [LY] ^a TADALIS 20 [LR]	^a Tadalca [CR]

Highly Specialised Drugs Program (Public Hospital)

▪ AMBRISENTAN

Caution This 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 therapy.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 (dual therapy - previously untreated patients)

Clinical criteria:

- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

Clinical criteria:

- Patient must currently have WHO Functional Class III PAH or WHO Functional Class IV PAH, **AND**
- The treatment must be in combination with a PBS-subsidised phosphodiesterase-5 inhibitor (PDE-5i) for this condition. The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

For the purposes of PBS subsidy, dual therapy refers to combined use of an endothelin receptor antagonist (ERA) and a phosphodiesterase-5 inhibitor (PDE-5i).

(i) An ERA includes ambrisentan, bosentan monohydrate, or macitentan.

(ii) A PDE-5i includes sildenafil citrate, or tadalafil.

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

PAH (WHO Group 1 pulmonary hypertension) is defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than or equal to 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than or equal to 15 mmHg; or

(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

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 which includes results from the three tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6 Minute Walk Test (6MWT).

Where it is not possible to perform all 3 tests 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 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.

Where a RHC cannot be performed on clinical grounds, confirmation of the reason(s) must be provided with the authority application by a second PAH physician or cardiologist with expertise in the management of PAH.

The test results provided must not be more than 2 months old at the time of 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.

Note PAH (WHO Group 1 pulmonary hypertension) currently includes the following subtypes: Idiopathic PAH

- Heritable PAH
 - BMPR2 mutation
 - ALK-1, ENG, SMAD9, CAV1, KCNK3 mutations
 - Other mutations
- Drugs and toxins induced PAH
- PAH associated with:
 - Connective tissue disease
 - Human immunodeficiency virus (HIV) infection
 - Portal hypertension
 - Congenital heart disease
 - Schistosomiasis

Note Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au. Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos. Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 2 (dual therapy - previously treated patients)

Clinical criteria:

- Patient must have documented WHO Functional Class III PAH or WHO Functional Class IV PAH, **AND**
- Patient must have documented a failure to achieve or maintain WHO Functional Class II status with prior PBS-subsidised monotherapy treatment with a phosphodiesterase-5 inhibitor (PDE-5i) for this condition, **AND**
- The treatment must be in combination with the PBS-subsidised PDE-5i for this condition.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

For the purposes of PBS subsidy, dual therapy refers to combined use of an endothelin receptor antagonist (ERA) and a phosphodiesterase-5 inhibitor (PDE-5i).

(i) An ERA includes ambrisentan, bosentan monohydrate, or macitentan.

(ii) A PDE-5i includes sildenafil citrate, or tadalafil.

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

PAH (WHO Group 1 pulmonary hypertension) is defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than or equal to 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than or equal to 15 mmHg; or

(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

The results and date of the RHC, ECHO and 6 MWT as applicable must be included in the patient's medical record. Where a RHC cannot be performed on clinical grounds, the written confirmation of the reasons why must also be included in the patient's medical record.

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.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 3 (dual therapy - change)

Clinical criteria:

- Patient must have had their most recent course of PBS-subsidised dual therapy with a phosphodiesterase-5 inhibitor (PDE-5i) and an endothelin receptor antagonist (ERA) other than this agent for this condition.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

For the purposes of PBS subsidy, dual therapy refers to combined use of an endothelin receptor antagonist (ERA) and a phosphodiesterase-5 inhibitor (PDE-5i).

(i) An ERA includes ambrisentan, bosentan monohydrate, or macitentan.

(ii) A PDE-5i includes sildenafil citrate, or tadalafil.

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

Swapping between PAH agents: Patients can access PAH agents through the PBS according to the relevant restrictions.

Once patients are approved dual therapy with a PAH agent from the PDE-5i class; or a PAH agent from the ERA class, they may swap between PAH agents within the same class. This means that patients may commence treatment with another PAH agent in the same class, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted.

Applications to swap within a PAH agent class must be made under the relevant initial treatment restriction.

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.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Continuing treatment (dual therapy)

Clinical criteria:

- Patient must have received their most recent course of PBS-subsidised dual therapy with this PAH agent and a phosphodiesterase-5 inhibitor (PDE-5i) for this condition.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

For the purposes of PBS subsidy, dual therapy refers to combined use of an endothelin receptor antagonist (ERA) and a phosphodiesterase-5 inhibitor (PDE-5i).

(i) An ERA includes ambrisentan, bosentan monohydrate, or macitentan.

(ii) A PDE-5i includes sildenafil citrate, or tadalafil.

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

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.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Grandfathered patients (dual therapy)

Clinical criteria:

- Patient must be receiving dual therapy with this non PBS-subsidised pulmonary arterial hypertension (PAH) agent and a non PBS-subsidised phosphodiesterase-5 inhibitor (PDE-5i) for this condition prior to 1 December 2020.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

Clinical criteria:

- Patient must have documented WHO Functional Class III PAH or WHO Functional Class IV PAH.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

For the purposes of PBS subsidy, dual therapy refers to combined use of an endothelin receptor antagonist (ERA) and a phosphodiesterase-5 inhibitor (PDE-5i).

(i) An ERA includes ambrisentan, bosentan monohydrate, or macitentan.

(ii) A PDE-5i includes sildenafil citrate, or tadalafil.

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

PAH (WHO Group 1 pulmonary hypertension) is defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than or equal to 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than or equal to 15 mmHg; or

(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

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 which includes results from the three tests below, where available:

- (i) RHC composite assessment; and
- (ii) ECHO composite assessment; and
- (iii) 6 Minute Walk Test (6MWT).

Where it was not possible to perform all 3 tests 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 could not be performed on clinical grounds, applications may be submitted 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 were 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.

Where a RHC could not be performed on clinical grounds, confirmation of the reason(s) must be provided with the authority application by a second PAH physician or cardiologist with expertise in the management of PAH.

A patient may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria for dual therapy for this condition.

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.

Note PAH (WHO Group 1 pulmonary hypertension) currently includes the following subtypes: Idiopathic PAH

- Heritable PAH
 - BMPR2 mutation
 - ALK-1, ENG, SMAD9, CAV1, KCNK3 mutations
 - Other mutations
- Drugs and toxins induced PAH
- PAH associated with:
 - Connective tissue disease
 - Human immunodeficiency virus (HIV) infection
 - Portal hypertension
 - Congenital heart disease
 - Schistosomiasis

Note Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Triple therapy - Initial treatment or continuing treatment of triple combination therapy (including dual therapy in lieu of triple therapy) that includes selexipag

Clinical criteria:

- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) PBS-subsidised selexipag (referred to as 'triple therapy'); OR
- The treatment must form part of dual combination therapy consisting of either: (i) PBS-subsidised selexipag with one endothelin receptor antagonist, (ii) PBS-subsidised selexipag with one phosphodiesterase-5 inhibitor, as triple combination therapy with selexipag-an endothelin receptor antagonist-a phosphodiesterase-5 inhibitor is not possible due to an intolerance/contraindication to the endothelin receptor antagonist class/phosphodiesterase-5 inhibitor class (referred to as 'dual therapy in lieu of triple therapy').

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

The authority application for selexipag must be approved prior to the authority application for this agent.

For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil.

PBS-subsidy does not cover patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

PAH (WHO Group 1 pulmonary hypertension) is defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than or equal to 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than or equal to 15 mmHg; or

(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

The results and date of the RHC, ECHO and 6 MWT as applicable must be included in the patient's medical record. Where a RHC cannot be performed on clinical grounds, the written confirmation of the reasons why must also be included in the patient's medical record.

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.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Note Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

ambrisentan 10 mg tablet, 30

12186J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	1844.54	^a Ambrisentan Mylan [AF] ^a PULMORIS [YC]	^a Cipla Ambrisentan [LR] ^a Volibris [ZE]

ambrisentan 5 mg tablet, 30

12212R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	1844.54	^a Ambrisentan Mylan [AF] ^a PULMORIS [YC]	^a Cipla Ambrisentan [LR] ^a Volibris [ZE]

■ BOSENTAN

Caution This 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 therapy.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Continuing treatment (dual therapy)

Clinical criteria:

- Patient must have received their most recent course of PBS-subsidised dual therapy with this PAH agent and a phosphodiesterase-5 inhibitor (PDE-5i) for this condition.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

For the purposes of PBS subsidy, dual therapy refers to combined use of an endothelin receptor antagonist (ERA) and a phosphodiesterase-5 inhibitor (PDE-5i).

(i) An ERA includes ambrisentan, bosentan monohydrate, or macitentan.

(ii) A PDE-5i includes sildenafil citrate, or tadalafil.

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

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.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Grandfathered patients (dual therapy)

Clinical criteria:

- Patient must be receiving dual therapy with this non PBS-subsidised pulmonary arterial hypertension (PAH) agent and a non PBS-subsidised phosphodiesterase-5 inhibitor (PDE-5i) for this condition prior to 1 October 2020.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

Clinical criteria:

- Patient must have documented WHO Functional Class III PAH or WHO Functional Class IV PAH.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

For the purposes of PBS subsidy, dual therapy refers to combined use of an endothelin receptor antagonist (ERA) and a phosphodiesterase-5 inhibitor (PDE-5i).

(i) An ERA includes ambrisentan, bosentan monohydrate, or macitentan.

(ii) A PDE-5i includes sildenafil citrate, or tadalafil.

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

PAH (WHO Group 1 pulmonary hypertension) is defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than or equal to 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than or equal to 15 mmHg; or

(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

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 which includes results from the three tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6 Minute Walk Test (6MWT).

Where it was not possible to perform all 3 tests 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 could not be performed on clinical grounds, applications may be submitted 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 were 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.

Where a RHC could not be performed on clinical grounds, confirmation of the reason(s) must be provided with the authority application by a second PAH physician or cardiologist with expertise in the management of PAH.

A patient may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria for dual therapy for this condition.

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.

Note PAH (WHO Group 1 pulmonary hypertension) currently includes the following subtypes: Idiopathic PAH

- Heritable PAH
 - BMPR2 mutation
 - ALK-1, ENG, SMAD9, CAV1, KCNK3 mutations
 - Other mutations
- Drugs and toxins induced PAH
- PAH associated with:
 - Connective tissue disease
 - Human immunodeficiency virus (HIV) infection
 - Portal hypertension
 - Congenital heart disease
 - Schistosomiasis

Note Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

bosentan 62.5 mg tablet, 60

12134P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	898.26	^a Bosentan APO [GX] ^a BOSENTAN DR.REDDY'S [RI] ^a Bosentan RBX [RA] ^a BOSLEER [RW]	^a Bosentan Cipla [LR] ^a Bosentan Mylan [AF] ^a Bosentan Sandoz [SZ] ^a Tracleer [JC]

■ BOSENTAN

Caution This 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 therapy.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 (dual therapy - previously untreated patients)

Clinical criteria:

- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

Clinical criteria:

- Patient must currently have WHO Functional Class III PAH or WHO Functional Class IV PAH, **AND**
- The treatment must be in combination with a PBS-subsidised phosphodiesterase-5 inhibitor (PDE-5i) for this condition. The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

For the purposes of PBS subsidy, dual therapy refers to combined use of an endothelin receptor antagonist (ERA) and a phosphodiesterase-5 inhibitor (PDE-5i).

(i) An ERA includes ambrisentan, bosentan monohydrate, or macitentan.

(ii) A PDE-5i includes sildenafil citrate, or tadalafil.

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

PAH (WHO Group 1 pulmonary hypertension) is defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than or equal to 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than or equal to 15 mmHg; or

(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

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 which includes results from the three tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6 Minute Walk Test (6MWT).

Where it is not possible to perform all 3 tests 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 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.

Where a RHC cannot be performed on clinical grounds, confirmation of the reason(s) must be provided with the authority application by a second PAH physician or cardiologist with expertise in the management of PAH.

The test results provided must not be more than 2 months old at the time of application.

If patients will be taking 62.5mg for the first month then 125 mg, prescribers should request the first authority prescription of therapy with the 62.5 mg tablet strength, with the quantity for one month of treatment, based on the dosage recommendations in the TGA-approved Product Information and no repeats.

Prescribers should request the second authority prescription of therapy with the 125 mg tablet strengths, with a quantity for one month of treatment, based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 4 repeats.

If patients will be taking 62.5mg for longer than 1 month, prescribers should request the first authority prescription of therapy with the 62.5 mg tablet strength, with the quantity for one month of treatment and a maximum of 5 repeats based on the dosage recommendations in the TGA-approved Product Information.

Note PAH (WHO Group 1 pulmonary hypertension) currently includes the following subtypes: Idiopathic PAH

- Heritable PAH
 - BMPR2 mutation
 - ALK-1, ENG, SMAD9, CAV1, KCNK3 mutations
 - Other mutations
- Drugs and toxins induced PAH
- PAH associated with:
 - Connective tissue disease
 - Human immunodeficiency virus (HIV) infection
 - Portal hypertension
 - Congenital heart disease
 - Schistosomiasis

Note Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 2 (dual therapy - previously treated patients)

Clinical criteria:

- Patient must have documented WHO Functional Class III PAH or WHO Functional Class IV PAH, **AND**
- Patient must have documented a failure to achieve or maintain WHO Functional Class II status with prior PBS-subsidised monotherapy treatment with a phosphodiesterase-5 inhibitor (PDE-5i) for this condition, **AND**
- The treatment must be in combination with the PBS-subsidised PDE-5i for this condition.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

For the purposes of PBS subsidy, dual therapy refers to combined use of an endothelin receptor antagonist (ERA) and a phosphodiesterase-5 inhibitor (PDE-5i).

(i) An ERA includes ambrisentan, bosentan monohydrate, or macitentan.

(ii) A PDE-5i includes sildenafil citrate, or tadalafil.

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

PAH (WHO Group 1 pulmonary hypertension) is defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than or equal to 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than or equal to 15 mmHg; or

(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

The results and date of the RHC, ECHO and 6 MWT as applicable must be included in the patient's medical record. Where a RHC cannot be performed on clinical grounds, the written confirmation of the reasons why must also be included in the patient's medical record.

If patients will be taking 62.5mg for the first month then 125 mg, prescribers should request the first authority prescription of therapy with the 62.5 mg tablet strength, with the quantity for one month of treatment, based on the dosage recommendations in the TGA-approved Product Information and no repeats.

Prescribers should request the second authority prescription of therapy with the 125 mg tablet strengths, with a quantity for one month of treatment, based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 4 repeats.

If patients will be taking 62.5mg for longer than 1 month, prescribers should request the first authority prescription of therapy with the 62.5 mg tablet strength, with the quantity for one month of treatment and a maximum of 5 repeats based on the dosage recommendations in the TGA-approved Product Information.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 3 (dual therapy - change)

Clinical criteria:

- Patient must have had their most recent course of PBS-subsidised dual therapy with a phosphodiesterase-5 inhibitor (PDE-5i) and an endothelin receptor antagonist (ERA) other than this agent for this condition.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

For the purposes of PBS subsidy, dual therapy refers to combined use of an endothelin receptor antagonist (ERA) and a phosphodiesterase-5 inhibitor (PDE-5i).

(i) An ERA includes ambrisentan, bosentan monohydrate, or macitentan.

(ii) A PDE-5i includes sildenafil citrate, or tadalafil.

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

Swapping between PAH agents: Patients can access PAH agents through the PBS according to the relevant restrictions.

Once patients are approved dual therapy with a PAH agent from the PDE-5i class; or a PAH agent from the ERA class, they may swap between PAH agents within the same class. This means that patients may commence treatment with another PAH agent in the same class, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted.

Applications to swap within a PAH agent class must be made under the relevant initial treatment restriction.

If patients will be taking 62.5mg for the first month then 125 mg, prescribers should request the first authority prescription of therapy with the 62.5 mg tablet strength, with the quantity for one month of treatment, based on the dosage recommendations in the TGA-approved Product Information and no repeats.

Prescribers should request the second authority prescription of therapy with the 125 mg tablet strengths, with a quantity for one month of treatment, based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 4 repeats.

If patients will be taking 62.5mg for longer than 1 month, prescribers should request the first authority prescription of therapy with the 62.5 mg tablet strength, with the quantity for one month of treatment and a maximum of 5 repeats based on the dosage recommendations in the TGA-approved Product Information.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Triple therapy - Initial treatment or continuing treatment of triple combination therapy (including dual therapy in lieu of triple therapy) that includes selexipag

Clinical criteria:

- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) PBS-subsidised selexipag (referred to as 'triple therapy'); OR
- The treatment must form part of dual combination therapy consisting of either: (i) PBS-subsidised selexipag with one endothelin receptor antagonist, (ii) PBS-subsidised selexipag with one phosphodiesterase-5 inhibitor, as triple combination therapy with selexipag-an endothelin receptor antagonist-a phosphodiesterase-5 inhibitor is not possible due to an intolerance/contraindication to the endothelin receptor antagonist class/phosphodiesterase-5 inhibitor class (referred to as 'dual therapy in lieu of triple therapy').

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

The authority application for selexipag must be approved prior to the authority application for this agent.

For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil.

PBS-subsidy does not cover patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

PAH (WHO Group 1 pulmonary hypertension) is defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than or equal to 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than or equal to 15 mmHg; or

(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

The results and date of the RHC, ECHO and 6 MWT as applicable must be included in the patient's medical record. Where a RHC cannot be performed on clinical grounds, the written confirmation of the reasons why must also be included in the patient's medical record.

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.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Note Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

bosentan 62.5 mg tablet, 60

12145F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	898.26	^a Bosentan APO [GX]	^a Bosentan Cipla [LR]
					^a BOSENTAN DR.REDDY'S [RI]	^a Bosentan Mylan [AF]
					^a Bosentan RBX [RA]	^a Bosentan Sandoz [SZ]
					^a BOSLEER [RW]	^a Tracleer [JC]

■ BOSENTAN

Caution This 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 therapy.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 (dual therapy - previously untreated patients)

Clinical criteria:

- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

Clinical criteria:

- Patient must currently have WHO Functional Class III PAH or WHO Functional Class IV PAH, **AND**
- The treatment must be in combination with a PBS-subsidised phosphodiesterase-5 inhibitor (PDE-5i) for this condition. The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

For the purposes of PBS subsidy, dual therapy refers to combined use of an endothelin receptor antagonist (ERA) and a phosphodiesterase-5 inhibitor (PDE-5i).

(i) An ERA includes ambrisentan, bosentan monohydrate, or macitentan.

(ii) A PDE-5i includes sildenafil citrate, or tadalafil.

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

PAH (WHO Group 1 pulmonary hypertension) is defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than or equal to 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than or equal to 15 mmHg; or

(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

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 which includes results from the three tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6 Minute Walk Test (6MWT).

Where it is not possible to perform all 3 tests 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 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.

Where a RHC cannot be performed on clinical grounds, confirmation of the reason(s) must be provided with the authority application by a second PAH physician or cardiologist with expertise in the management of PAH.

The test results provided must not be more than 2 months old at the time of application.

If patients will be taking 62.5mg for the first month then 125 mg, prescribers should request the first authority prescription of therapy with the 62.5 mg tablet strength, with the quantity for one month of treatment, based on the dosage recommendations in the TGA-approved Product Information and no repeats.

Prescribers should request the second authority prescription of therapy with the 125 mg tablet strengths, with a quantity for one month of treatment, based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 4 repeats.

If patients will be taking 62.5mg for longer than 1 month, prescribers should request the first authority prescription of therapy with the 62.5 mg tablet strength, with the quantity for one month of treatment and a maximum of 5 repeats based on the dosage recommendations in the TGA-approved Product Information.

Note PAH (WHO Group 1 pulmonary hypertension) currently includes the following subtypes: Idiopathic PAH

- Heritable PAH
 - BMPR2 mutation
 - ALK-1, ENG, SMAD9, CAV1, KCNK3 mutations
 - Other mutations
- Drugs and toxins induced PAH
- PAH associated with:
 - Connective tissue disease
 - Human immunodeficiency virus (HIV) infection
 - Portal hypertension
 - Congenital heart disease
 - Schistosomiasis

Note Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 2 (dual therapy - previously treated patients)

Clinical criteria:

- Patient must have documented WHO Functional Class III PAH or WHO Functional Class IV PAH, **AND**
- Patient must have documented a failure to achieve or maintain WHO Functional Class II status with prior PBS-subsidised monotherapy treatment with a phosphodiesterase-5 inhibitor (PDE-5i) for this condition, **AND**
- The treatment must be in combination with the PBS-subsidised PDE-5i for this condition.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

For the purposes of PBS subsidy, dual therapy refers to combined use of an endothelin receptor antagonist (ERA) and a phosphodiesterase-5 inhibitor (PDE-5i).

(i) An ERA includes ambrisentan, bosentan monohydrate, or macitentan.

(ii) A PDE-5i includes sildenafil citrate, or tadalafil.

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

PAH (WHO Group 1 pulmonary hypertension) is defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than or equal to 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than or equal to 15 mmHg; or

(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

The results and date of the RHC, ECHO and 6 MWT as applicable must be included in the patient's medical record. Where a RHC cannot be performed on clinical grounds, the written confirmation of the reasons why must also be included in the patient's medical record.

If patients will be taking 62.5mg for the first month then 125 mg, prescribers should request the first authority prescription of therapy with the 62.5 mg tablet strength, with the quantity for one month of treatment, based on the dosage recommendations in the TGA-approved Product Information and no repeats.

Prescribers should request the second authority prescription of therapy with the 125 mg tablet strengths, with a quantity for one month of treatment, based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 4 repeats.

If patients will be taking 62.5mg for longer than 1 month, prescribers should request the first authority prescription of therapy with the 62.5 mg tablet strength, with the quantity for one month of treatment and a maximum of 5 repeats based on the dosage recommendations in the TGA-approved Product Information.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 3 (dual therapy - change)

Clinical criteria:

- Patient must have had their most recent course of PBS-subsidised dual therapy with a phosphodiesterase-5 inhibitor (PDE-5i) and an endothelin receptor antagonist (ERA) other than this agent for this condition.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

For the purposes of PBS subsidy, dual therapy refers to combined use of an endothelin receptor antagonist (ERA) and a phosphodiesterase-5 inhibitor (PDE-5i).

(i) An ERA includes ambrisentan, bosentan monohydrate, or macitentan.

(ii) A PDE-5i includes sildenafil citrate, or tadalafil.

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

Swapping between PAH agents: Patients can access PAH agents through the PBS according to the relevant restrictions.

Once patients are approved dual therapy with a PAH agent from the PDE-5i class; or a PAH agent from the ERA class, they may swap between PAH agents within the same class. This means that patients may commence treatment with another PAH agent in the same class, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted.

Applications to swap within a PAH agent class must be made under the relevant initial treatment restriction.

If patients will be taking 62.5mg for the first month then 125 mg, prescribers should request the first authority prescription of therapy with the 62.5 mg tablet strength, with the quantity for one month of treatment, based on the dosage recommendations in the TGA-approved Product Information and no repeats.

Prescribers should request the second authority prescription of therapy with the 125 mg tablet strengths, with a quantity for one month of treatment, based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 4 repeats.

If patients will be taking 62.5mg for longer than 1 month, prescribers should request the first authority prescription of therapy with the 62.5 mg tablet strength, with the quantity for one month of treatment and a maximum of 5 repeats based on the dosage recommendations in the TGA-approved Product Information.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Continuing treatment (dual therapy)

Clinical criteria:

- Patient must have received their most recent course of PBS-subsidised dual therapy with this PAH agent and a phosphodiesterase-5 inhibitor (PDE-5i) for this condition.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

For the purposes of PBS subsidy, dual therapy refers to combined use of an endothelin receptor antagonist (ERA) and a phosphodiesterase-5 inhibitor (PDE-5i).

(i) An ERA includes ambrisentan, bosentan monohydrate, or macitentan.

(ii) A PDE-5i includes sildenafil citrate, or tadalafil.

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

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.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Grandfathered patients (dual therapy)

Clinical criteria:

- Patient must be receiving dual therapy with this non PBS-subsidised pulmonary arterial hypertension (PAH) agent and a non PBS-subsidised phosphodiesterase-5 inhibitor (PDE-5i) for this condition prior to 1 October 2020.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

Clinical criteria:

- Patient must have documented WHO Functional Class III PAH or WHO Functional Class IV PAH.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

For the purposes of PBS subsidy, dual therapy refers to combined use of an endothelin receptor antagonist (ERA) and a phosphodiesterase-5 inhibitor (PDE-5i).

(i) An ERA includes ambrisentan, bosentan monohydrate, or macitentan.

(ii) A PDE-5i includes sildenafil citrate, or tadalafil.

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

PAH (WHO Group 1 pulmonary hypertension) is defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than or equal to 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than or equal to 15 mmHg; or

(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

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 which includes results from the three tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6 Minute Walk Test (6MWT).

Where it was not possible to perform all 3 tests 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 could not be performed on clinical grounds, applications may be submitted 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 were 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.

Where a RHC could not be performed on clinical grounds, confirmation of the reason(s) must be provided with the authority application by a second PAH physician or cardiologist with expertise in the management of PAH.

A patient may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria for dual therapy for this condition.

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.

Note PAH (WHO Group 1 pulmonary hypertension) currently includes the following subtypes: Idiopathic PAH

- Heritable PAH
 - BMPR2 mutation
 - ALK-1, ENG, SMAD9, CAV1, KCNK3 mutations
 - Other mutations
- Drugs and toxins induced PAH
- PAH associated with:
 - Connective tissue disease
 - Human immunodeficiency virus (HIV) infection
 - Portal hypertension
 - Congenital heart disease
 - Schistosomiasis

Note Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Triple therapy - Initial treatment or continuing treatment of triple combination therapy (including dual therapy in lieu of triple therapy) that includes selexipag

Clinical criteria:

- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) PBS-subsidised selexipag (referred to as 'triple therapy'); OR
- The treatment must form part of dual combination therapy consisting of either: (i) PBS-subsidised selexipag with one endothelin receptor antagonist, (ii) PBS-subsidised selexipag with one phosphodiesterase-5 inhibitor, as triple combination therapy with selexipag-an endothelin receptor antagonist-a phosphodiesterase-5 inhibitor is not possible due to an intolerance/contraindication to the endothelin receptor antagonist class/phosphodiesterase-5 inhibitor class (referred to as 'dual therapy in lieu of triple therapy').

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

The authority application for selexipag must be approved prior to the authority application for this agent.

For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil.

PBS-subsidy does not cover patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

PAH (WHO Group 1 pulmonary hypertension) is defined as follows:

- (i) mean pulmonary artery pressure (mPAP) greater than or equal to 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than or equal to 15 mmHg; or
- (ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

The results and date of the RHC, ECHO and 6 MWT as applicable must be included in the patient's medical record. Where a RHC cannot be performed on clinical grounds, the written confirmation of the reasons why must also be included in the patient's medical record.

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.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Note Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

bosentan 125 mg tablet, 60

12149K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	898.26	^a Bosentan APO [GX] ^a BOSENTAN DR.REDDY'S [RI] ^a Bosentan Mylan [AF] ^a Bosentan Sandoz [SZ] ^a Tracleer [JC]	^a Bosentan Cipla [LR] ^a Bosentan GH [GQ] ^a Bosentan RBX [RA] ^a BOSLEER [RW]

▪ ELTROMBOPAG

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required

Severe thrombocytopenia

Treatment Phase: Initial treatment 1 - New patient

Clinical criteria:

- The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), **AND**
- Patient must have had a splenectomy, **AND**
- Patient must have failed to achieve an adequate response to, or be intolerant to, corticosteroid therapy following the splenectomy, **AND**
- Patient must have failed to achieve an adequate response to, or be intolerant to, immunoglobulin therapy following the splenectomy, **AND**
- The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition.

Population criteria:

- Patient must be aged 18 years or older.

The following criteria indicate failure to achieve an adequate response and must be demonstrated 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 20,000 million to 30,000 million per L, where the patient is experiencing significant bleeding or has a history of significant bleeding in this platelet range.

Where intolerance to treatment with corticosteroid and immunoglobulin therapy developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

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

- (1) a completed authority prescription form,
- (2) a completed Idiopathic Thrombocytopenic Purpura Initial PBS Authority Application - Supporting Information Form,
- (3) details of a platelet count supporting the diagnosis of ITP.

The platelet count must be no more than 4 weeks old at the time of application.

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

Patients will be able to trial either eltrombopag or romiplostim within the initial 24 weeks treatment period. Where a patient has started initial treatment with one of the two agents, change of therapy to the alternative agent may be authorised under the Balance of supply or change of therapy restriction to complete up to 24 weeks initial treatment. Patients who fail to demonstrate a response to treatment with eltrombopag and/or romiplostim after completion of 24 weeks initial therapy will not be eligible to receive further PBS-subsidised treatment with either of these drugs.

Note Eltrombopag is not PBS-subsidised as an alternative to splenectomy.

Note Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

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Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe thrombocytopenia

Treatment Phase: Initial treatment 2 - New patient

Clinical criteria:

- The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), **AND**
- Patient must not have had a splenectomy, **AND**
- Patient must have failed to achieve an adequate response to, or be intolerant to, corticosteroid therapy at a dose equivalent to 0.5-2 mg/kg/day of prednisone for at least 4-6 weeks, **AND**
- Patient must have failed to achieve an adequate response to, or be intolerant to, immunoglobulin therapy, **AND**
- Patient must be unsuitable for splenectomy due to medical reasons, **AND**
- The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition.

Population criteria:

- Patient must be aged 18 years or older.

The following criteria indicate failure to achieve an adequate response and must be demonstrated 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 20,000 million to 30,000 million per L, where the patient is experiencing significant bleeding or has a history of significant bleeding in this platelet range.

Where intolerance to treatment with corticosteroid and immunoglobulin therapy developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

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

- (1) a completed authority prescription form,
- (2) a completed Idiopathic Thrombocytopenic Purpura Initial PBS Authority Application - Supporting Information Form,
- (3) details of a platelet count supporting the diagnosis of ITP, and
- (4) details of the reason of medical contraindication for surgery and date of assessment.

The platelet count must be no more than 4 weeks old at the time of application.

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

Patients will be able to trial either eltrombopag or romiplostim within the initial 24 weeks treatment period. Where a patient has started initial treatment with one of the two agents, change of therapy to the alternative agent may be authorised under the Balance of supply or change of therapy restriction to complete up to 24 weeks initial treatment. Patients who fail to demonstrate a response to treatment with eltrombopag and/or romiplostim after completion of 24 weeks initial therapy will not be eligible to receive further PBS-subsidised treatment with either of these drugs.

Note Eltrombopag is not PBS-subsidised as an alternative to splenectomy.

Note Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

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Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe thrombocytopenia

Treatment Phase: First Continuing treatment or Re-initiation of interrupted continuing treatment

Clinical criteria:

- The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), **AND**
- Patient must have demonstrated a sustained platelet response to PBS-subsidised treatment with this drug for this condition under the Initial treatment restriction if the patient has not had a treatment break; OR
- Patient must have demonstrated a sustained platelet response to the most recent PBS-subsidised treatment with this drug for this condition prior to interrupted treatment, **AND**
- Patient must not have previously received PBS-subsidised continuing treatment with romiplostim for this condition, **AND**
- The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition.

Population criteria:

- Patient must be aged 18 years or older.

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 treatment with this drug,

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 continuing PBS-subsidised treatment or Re-initiation of interrupted PBS-subsidised continuing treatment must be made in writing and must include:

- (1) a completed authority prescription form, and

(2) a completed Idiopathic Thrombocytopenic Purpura Continuing PBS Authority Application - Supporting Information Form, and
(3) the most recent platelet count.

The platelet count must be conducted no later than 4 weeks from the date of completion of the most recent PBS-subsidised course of treatment with this drug.

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

Note Eltrombopag is not PBS-subsidised as an alternative to splenectomy.

Note Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Severe thrombocytopenia

Treatment Phase: Second or subsequent Continuing treatment

Clinical criteria:

- The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition under first continuing or re-initiation of interrupted continuing treatment restriction, **AND**
- Patient must have demonstrated a continuing response to PBS-subsidised treatment with this drug, **AND**
- The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition.

Population criteria:

- Patient must be aged 18 years or older.

For the purpose of this restriction, a continuing response to treatment with drug 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 this drug

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.

The platelet count must be no more than 4 weeks old at the time of application.

Note Eltrombopag is not PBS-subsidised as an alternative to splenectomy.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required

Severe thrombocytopenia

Treatment Phase: Balance of supply or change of therapy within 24 weeks initial treatment

Clinical criteria:

- The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), **AND**
- The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition, **AND**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 restriction to complete 24 weeks treatment; OR
- Patient must be swapping therapy from romiplostim to this drug for this condition within the initial 24 weeks of treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the First Continuing treatment or Re-initiation of interrupted continuing treatment restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Second and subsequent Continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

Population criteria:

- Patient must be aged 18 years or older.

Patients will be able to trial either eltrombopag or romiplostim within the initial 24 weeks treatment period. Where a patient has started initial treatment with one of the two agents, change of therapy to the alternative agent may be authorised under the Balance of supply or change of therapy restriction to complete up to 24 weeks initial treatment. Patients who fail to demonstrate a response to treatment with eltrombopag and/or romiplostim after completion of 24 weeks initial therapy will not be eligible to receive further PBS-subsidised treatment with either of these drugs.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

eltrombopag 25 mg tablet, 28

5825N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	1292.76	Revolade [NV]

eltrombopag 50 mg tablet, 28

5826P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	2585.52	Revolade [NV]

■ MACITENTAN

Caution This 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 therapy.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 (dual therapy - previously untreated patients)

Clinical criteria:

- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

Clinical criteria:

- Patient must currently have WHO Functional Class III PAH or WHO Functional Class IV PAH, **AND**
- The treatment must be in combination with a PBS-subsidised phosphodiesterase-5 inhibitor (PDE-5i) for this condition. The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

For the purposes of PBS subsidy, dual therapy refers to combined use of an endothelin receptor antagonist (ERA) and a phosphodiesterase-5 inhibitor (PDE-5i).

(i) An ERA includes ambrisentan, bosentan monohydrate, or macitentan.

(ii) A PDE-5i includes sildenafil citrate, or tadalafil.

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

PAH (WHO Group 1 pulmonary hypertension) is defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than or equal to 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than or equal to 15 mmHg; or

(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

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 which includes results from the three tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6 Minute Walk Test (6MWT).

Where it is not possible to perform all 3 tests 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 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.

Where a RHC cannot be performed on clinical grounds, confirmation of the reason(s) must be provided with the authority application by a second PAH physician or cardiologist with expertise in the management of PAH.

The test results provided must not be more than 2 months old at the time of 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.

Note PAH (WHO Group 1 pulmonary hypertension) currently includes the following subtypes: Idiopathic PAH

- Heritable PAH
 - BMPR2 mutation
 - ALK-1, ENG, SMAD9, CAV1, KCNK3 mutations
 - Other mutations

- Drugs and toxins induced PAH
- PAH associated with:
 - Connective tissue disease
 - Human immunodeficiency virus (HIV) infection
 - Portal hypertension
 - Congenital heart disease
 - Schistosomiasis

Note Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au. Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos. Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 2 (dual therapy - previously treated patients)

Clinical criteria:

- Patient must have documented WHO Functional Class III PAH or WHO Functional Class IV PAH, **AND**
- Patient must have documented a failure to achieve or maintain WHO Functional Class II status with prior PBS-subsidised monotherapy treatment with a phosphodiesterase-5 inhibitor (PDE-5i) for this condition, **AND**
- The treatment must be in combination with the PBS-subsidised PDE-5i for this condition.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

For the purposes of PBS subsidy, dual therapy refers to combined use of an endothelin receptor antagonist (ERA) and a phosphodiesterase-5 inhibitor (PDE-5i).

(i) An ERA includes ambrisentan, bosentan monohydrate, or macitentan.

(ii) A PDE-5i includes sildenafil citrate, or tadalafil.

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

PAH (WHO Group 1 pulmonary hypertension) is defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than or equal to 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than or equal to 15 mmHg; or

(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

The results and date of the RHC, ECHO and 6 MWT as applicable must be included in the patient's medical record. Where a RHC cannot be performed on clinical grounds, the written confirmation of the reasons why must also be included in the patient's medical record.

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.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 3 (dual therapy - change)

Clinical criteria:

- Patient must have had their most recent course of PBS-subsidised dual therapy with a phosphodiesterase-5 inhibitor (PDE-5i) and an endothelin receptor antagonist (ERA) other than this agent for this condition.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

For the purposes of PBS subsidy, dual therapy refers to combined use of an endothelin receptor antagonist (ERA) and a phosphodiesterase-5 inhibitor (PDE-5i).

(i) An ERA includes ambrisentan, bosentan monohydrate, or macitentan.

(ii) A PDE-5i includes sildenafil citrate, or tadalafil.

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

Swapping between PAH agents: Patients can access PAH agents through the PBS according to the relevant restrictions.

Once patients are approved dual therapy with a PAH agent from the PDE-5i class; or a PAH agent from the ERA class, they may swap between PAH agents within the same class. This means that patients may commence treatment with another PAH agent in the same class, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted.

Applications to swap within a PAH agent class must be made under the relevant initial treatment restriction.

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.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Continuing treatment (dual therapy)

Clinical criteria:

- Patient must have received their most recent course of PBS-subsidised dual therapy with this PAH agent and a phosphodiesterase-5 inhibitor (PDE-5i) for this condition.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

For the purposes of PBS subsidy, dual therapy refers to combined use of an endothelin receptor antagonist (ERA) and a phosphodiesterase-5 inhibitor (PDE-5i).

(i) An ERA includes ambrisentan, bosentan monohydrate, or macitentan.

(ii) A PDE-5i includes sildenafil citrate, or tadalafil.

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

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.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Grandfathered patients (dual therapy)

Clinical criteria:

- Patient must be receiving dual therapy with this non PBS-subsidised pulmonary arterial hypertension (PAH) agent and a non PBS-subsidised phosphodiesterase-5 inhibitor (PDE-5i) for this condition prior to 1 October 2020.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

Clinical criteria:

- Patient must have documented WHO Functional Class III PAH or WHO Functional Class IV PAH.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

For the purposes of PBS subsidy, dual therapy refers to combined use of an endothelin receptor antagonist (ERA) and a phosphodiesterase-5 inhibitor (PDE-5i).

(i) An ERA includes ambrisentan, bosentan monohydrate, or macitentan.

(ii) A PDE-5i includes sildenafil citrate, or tadalafil.

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

PAH (WHO Group 1 pulmonary hypertension) is defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than or equal to 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than or equal to 15 mmHg; or

(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

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 which includes results from the three tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6 Minute Walk Test (6MWT).

Where it was not possible to perform all 3 tests 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 could not be performed on clinical grounds, applications may be submitted 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 were 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.

Where a RHC could not be performed on clinical grounds, confirmation of the reason(s) must be provided with the authority application by a second PAH physician or cardiologist with expertise in the management of PAH.

A patient may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria for dual therapy for this condition.

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.

Note PAH (WHO Group 1 pulmonary hypertension) currently includes the following subtypes: Idiopathic PAH

- Heritable PAH
 - BMPR2 mutation
 - ALK-1, ENG, SMAD9, CAV1, KCNK3 mutations
 - Other mutations
- Drugs and toxins induced PAH
- PAH associated with:
 - Connective tissue disease
 - Human immunodeficiency virus (HIV) infection
 - Portal hypertension
 - Congenital heart disease
 - Schistosomiasis

Note Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Triple therapy - Initial treatment or continuing treatment of triple combination therapy (including dual therapy in lieu of triple therapy) that includes selexipag

Clinical criteria:

- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) PBS-subsidised selexipag (referred to as 'triple therapy'); OR
- The treatment must form part of dual combination therapy consisting of either: (i) PBS-subsidised selexipag with one endothelin receptor antagonist, (ii) PBS-subsidised selexipag with one phosphodiesterase-5 inhibitor, as triple combination therapy with selexipag-an endothelin receptor antagonist-a phosphodiesterase-5 inhibitor is not possible due to an intolerance/contraindication to the endothelin receptor antagonist class/phosphodiesterase-5 inhibitor class (referred to as 'dual therapy in lieu of triple therapy').

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

The authority application for selexipag must be approved prior to the authority application for this agent.

For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil.

PBS-subsidy does not cover patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

PAH (WHO Group 1 pulmonary hypertension) is defined as follows:

- (i) mean pulmonary artery pressure (mPAP) greater than or equal to 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than or equal to 15 mmHg; or
- (ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

The results and date of the RHC, ECHO and 6 MWT as applicable must be included in the patient's medical record. Where a RHC cannot be performed on clinical grounds, the written confirmation of the reasons why must also be included in the patient's medical record.

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.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Note Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

macitentan 10 mg tablet, 30

12147H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	2732.65	Opsumit [JC]

■ ROMIPILOSTIM

Authority required

Severe thrombocytopenia

Treatment Phase: Initial treatment 1 - New patient

Clinical criteria:

- The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), **AND**
- Patient must have had a splenectomy, **AND**
- Patient must have failed to achieve an adequate response to, or be intolerant to, corticosteroid therapy following the splenectomy, **AND**
- Patient must have failed to achieve an adequate response to, or be intolerant to, immunoglobulin therapy following the splenectomy, **AND**
- The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition.

Population criteria:

- Patient must be aged 18 years or older.

The following criteria indicate failure to achieve an adequate response and must be demonstrated 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 20,000 million to 30,000 million per L, where the patient is experiencing significant bleeding or has a history of significant bleeding in this platelet range.

Where intolerance to treatment with corticosteroid and immunoglobulin therapy developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided 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 requested by telephone. 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.

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

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

- (1) a completed authority prescription form,
- (2) a completed Idiopathic Thrombocytopenic Purpura Initial PBS Authority Application - Supporting Information Form,
- (3) details of a platelet count supporting the diagnosis of ITP.

The platelet count must be no more than 4 weeks old at the time of application.

Patients will be able to trial either eltrombopag or romiplostim within the initial 24 weeks treatment period. Where a patient has started initial treatment with one of the two agents, change of therapy to the alternative agent may be authorised under the Balance of supply or change of therapy restriction to complete up to 24 weeks initial treatment. Patients who fail to demonstrate a response to treatment with eltrombopag and/or romiplostim after completion of 24 weeks initial therapy will not be eligible to receive further PBS-subsidised treatment with either of these drugs.

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

Note Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe thrombocytopenia

Treatment Phase: Initial treatment 2 - New patient

Clinical criteria:

- The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), **AND**
- Patient must not have had a splenectomy, **AND**
- Patient must have failed to achieve an adequate response to, or be intolerant to, corticosteroid therapy at a dose equivalent to 0.5-2 mg/kg/day of prednisone for at least 4-6 weeks, **AND**
- Patient must have failed to achieve an adequate response to, or be intolerant to, immunoglobulin therapy, **AND**
- Patient must be unsuitable for splenectomy due to medical reasons, **AND**
- The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition.

Population criteria:

- Patient must be aged 18 years or older.

The following criteria indicate failure to achieve an adequate response and must be demonstrated 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 20,000 million to 30,000 million per L, where the patient is experiencing significant bleeding or has a history of significant bleeding in this platelet range.

Where intolerance to treatment with corticosteroid and immunoglobulin therapy developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided 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 requested by telephone. 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.

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

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

- (1) a completed authority prescription form,
- (2) a completed Idiopathic Thrombocytopenic Purpura Initial PBS Authority Application - Supporting Information Form,
- (3) details of a platelet count supporting the diagnosis of ITP, and
- (4) details of the reason of medical contraindication for surgery and date of assessment.

The platelet count must be no more than 4 weeks old at the time of application.

Patients will be able to trial either eltrombopag or romiplostim within the initial 24 weeks treatment period. Where a patient has started initial treatment with one of the two agents, change of therapy to the alternative agent may be authorised under the Balance of supply or change of therapy restriction to complete up to 24 weeks initial treatment. Patients who fail to demonstrate a response to treatment with eltrombopag and/or romiplostim after completion of 24 weeks initial therapy will not be eligible to receive further PBS-subsidised treatment with either of these drugs.

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

Note Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe thrombocytopenia

Treatment Phase: First Continuing treatment or Re-initiation of interrupted continuing treatment

Clinical criteria:

- The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), **AND**
- Patient must have demonstrated a sustained platelet response to PBS-subsidised treatment with this drug for this condition under the Initial treatment restriction if the patient has not had a treatment break; OR
- Patient must have demonstrated a sustained platelet response to the most recent PBS-subsidised treatment with this drug for this condition prior to interrupted treatment, **AND**
- Patient must not have previously received PBS-subsidised continuing treatment with eltrombopag for this condition, **AND**
- The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition.

Population criteria:

- Patient must be aged 18 years or older.

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 treatment with this drug,

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.

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 higher than 10 micrograms/kg/week

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

(1) a completed authority prescription form, and

(2) a completed Idiopathic Thrombocytopenic Purpura Continuing PBS Authority Application - Supporting Information Form, and

(3) the most recent platelet count.

The platelet count must be conducted no later than 4 weeks from the date of completion of the most recent PBS-subsidised course of treatment with this drug.

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

Note Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Severe thrombocytopenia

Treatment Phase: Second or Subsequent Continuing treatment

Clinical criteria:

- The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition under first continuing or re-initiation of interrupted continuing treatment restriction, **AND**
- Patient must have demonstrated a continuing response to PBS-subsidised treatment with this drug, **AND**
- The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition.

Population criteria:

- Patient must be aged 18 years or older.

For the purpose of this restriction, a continuing response to treatment with drug 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 this drug

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.

The platelet count must be no more than 4 weeks 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.

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

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

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required

Severe thrombocytopenia

Treatment Phase: Balance of supply or change of therapy within 24 weeks initial treatment

Clinical criteria:

- The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), **AND**
- The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition, **AND**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 restriction to complete 24 weeks treatment; OR

- Patient must be swapping therapy from eltrombopag to this drug for this condition within the initial 24 weeks of treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the First Continuing treatment or Re-initiation of interrupted continuing treatment restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Second and subsequent Continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

Population criteria:

- Patient must be aged 18 years or older.

Patients will be able to trial either eltrombopag or romiplostim within the initial 24 weeks treatment period. Where a patient has started initial treatment with one of the two agents, change of therapy to the alternative agent may be authorised under the Balance of supply or change of therapy restriction to complete up to 24 weeks initial treatment. Patients who fail to demonstrate a response to treatment with eltrombopag and/or romiplostim after completion of 24 weeks initial therapy will not be eligible to receive further PBS-subsidised treatment with either of these drugs.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

romiplostim 500 microgram injection, 1 vial

9698K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	1098.04	Nplate [AN]

romiplostim 250 microgram injection, 1 vial

9696H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	549.02	Nplate [AN]

▪ **SELEXIPAG**

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

Note Special Pricing Arrangements apply.

Note PAH (WHO Group 1 pulmonary hypertension) currently includes the following subtypes: Idiopathic PAH

- Heritable PAH
 - BMPR2 mutation
 - ALK-1, ENG, SMAD9, CAV1, KCNK3 mutations
 - Other mutations
- Drugs and toxins induced PAH
- PAH associated with:
 - Connective tissue disease
 - Human immunodeficiency virus (HIV) infection
 - Portal hypertension
 - Congenital heart disease
 - Schistosomiasis

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial treatment - dose titration

Clinical criteria:

- Patient must have failed to achieve/maintain a WHO Functional Class II status with PAH agents (other than this agent) given as dual therapy, **AND**
- Patient must have WHO Functional Class III PAH at treatment initiation with this drug; OR
- Patient must have WHO Functional Class IV PAH at treatment initiation with this drug, **AND**
- The treatment must be for dose titration purposes with the intent of completing the titration within 12 weeks, **AND**
- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) selexipag (referred to as 'triple therapy'); OR
- The treatment must form part of dual combination therapy consisting of either: (i) selexipag with one endothelin receptor antagonist, (ii) selexipag with one phosphodiesterase-5 inhibitor, as triple combination therapy with selexipag-an endothelin receptor antagonist-a phosphodiesterase-5 inhibitor is not possible due to an intolerance/contraindication to the endothelin receptor antagonist class/phosphodiesterase-5 inhibitor class (referred to as 'dual therapy in lieu of triple therapy'), **AND**
- The treatment must not be as monotherapy.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

Population criteria:

- Patient must have had at least one PBS-subsidised PAH agent prior to this authority application. A prior PAH agent is any of: ambrisentan, bosentan, macitentan, sildenafil, tadalafil, epoprostenol, iloprost, riociguat. For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil.
- PBS-subsidy does not cover patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.
- PAH (WHO Group 1 pulmonary hypertension) is defined as follows:
- (i) mean pulmonary artery pressure (mPAP) greater than or equal to 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than or equal to 15 mmHg; or
 - (ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

selexipag 800 microgram tablet, 60

12266N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	3	..	3450.00	Upravi [JC]

▪ SELEXIPAG

- Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
- Note** No increase in the maximum quantity or number of units may be authorised.
- Note** No increase in the maximum number of repeats may be authorised.
- Note** Special Pricing Arrangements apply.
- Note** Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.
- Note** PAH (WHO Group 1 pulmonary hypertension) currently includes the following subtypes: Idiopathic PAH
- Heritable PAH
 - BMPR2 mutation
 - ALK-1, ENG, SMAD9, CAV1, KCNK3 mutations
 - Other mutations
 - Drugs and toxins induced PAH
 - PAH associated with:
 - Connective tissue disease
 - Human immunodeficiency virus (HIV) infection
 - Portal hypertension
 - Congenital heart disease
 - Schistosomiasis

Authority required

Pulmonary arterial hypertension (PAH)
Treatment Phase: Initial treatment - dose titration

Clinical criteria:

- Patient must have failed to achieve/maintain a WHO Functional Class II status with PAH agents (other than this agent) given as dual therapy, **AND**
- Patient must have WHO Functional Class III PAH at treatment initiation with this drug; OR
- Patient must have WHO Functional Class IV PAH at treatment initiation with this drug, **AND**
- The treatment must be for dose titration purposes with the intent of completing the titration within 12 weeks, **AND**
- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) selexipag (referred to as 'triple therapy'); OR
- The treatment must form part of dual combination therapy consisting of either: (i) selexipag with one endothelin receptor antagonist, (ii) selexipag with one phosphodiesterase-5 inhibitor, as triple combination therapy with selexipag-an endothelin receptor antagonist-a phosphodiesterase-5 inhibitor is not possible due to an intolerance/contraindication to the endothelin receptor antagonist class/phosphodiesterase-5 inhibitor class (referred to as 'dual therapy in lieu of triple therapy'), **AND**
- The treatment must not be as monotherapy.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

Population criteria:

- Patient must have had at least one PBS-subsidised PAH agent prior to this authority application. A prior PAH agent is any of: ambrisentan, bosentan, macitentan, sildenafil, tadalafil, epoprostenol, iloprost, riociguat. For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil.
- PBS-subsidy does not cover patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.
- PAH (WHO Group 1 pulmonary hypertension) is defined as follows:
- (i) mean pulmonary artery pressure (mPAP) greater than or equal to 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than or equal to 15 mmHg; or

(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Transitioning from non-PBS subsidised to PBS-subsidised supply - 'Grandfather' treatment

Clinical criteria:

- Patient must have received non-PBS subsidised treatment with this drug prior to 1 February 2021, **AND**
- Patient must have failed to achieve/maintain a WHO Functional Class II status with PAH agents (other than this agent) given as dual therapy, prior to treatment initiation with this drug, **AND**
- Patient must have had WHO Functional Class III PAH at treatment initiation with this drug; OR
- Patient must have had WHO Functional Class IV PAH at treatment initiation with this drug, **AND**
- Patient must not have developed disease progression while receiving treatment with this drug for this condition, **AND**
- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) selexipag (referred to as 'triple therapy'); OR
- The treatment must form part of dual combination therapy consisting of either: (i) selexipag with one endothelin receptor antagonist, (ii) selexipag with one phosphodiesterase-5 inhibitor, as triple combination therapy with selexipag-an endothelin receptor antagonist-a phosphodiesterase-5 inhibitor is not possible due to an intolerance/contraindication to the endothelin receptor antagonist class/phosphodiesterase-5 inhibitor class (referred to as 'dual therapy in lieu of triple therapy'), **AND**
- The treatment must not be as monotherapy.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

Population criteria:

- Patient must have had at least one PBS-subsidised PAH agent prior to this authority application.

A prior PAH agent is any of: ambrisentan, bosentan, macitentan, sildenafil, tadalafil, epoprostenol, iloprost, riociguat.

For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil.

For the purposes of administering this restriction, disease progression has developed if at least one of the following has occurred:

- (i) Hospitalisation due to worsening PAH;
- (ii) Deterioration of aerobic capacity/endurance, consisting of at least a 15% decrease in 6-Minute Walk Distance from baseline, combined with worsening of WHO functional class status;
- (iii) Deterioration of aerobic capacity/endurance, consisting of at least a 15% decrease in 6-Minute Walk Distance from baseline, combined with the need for additional PAH-specific therapy;
- (iv) Initiation of parenteral prostanoid therapy or long-term oxygen therapy for worsening of PAH;
- (v) Need for lung transplantation or balloon atrial septostomy for worsening of PAH.

PBS-subsidy does not cover patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

PAH (WHO Group 1 pulmonary hypertension) is defined as follows:

- (i) mean pulmonary artery pressure (mPAP) greater than or equal to 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than or equal to 15 mmHg; or
- (ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Note Patients may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a 'Grandfathered' patient must qualify under the 'Continuing treatment' criteria.

Note This grandfather restriction will cease to operate from 12 months after the date specified in the clinical criteria.

selexipag 200 microgram tablet, 140

12258E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	2	..	8050.00	Upravi [JC]

SELEXIPAG

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial treatment following dose titration

Clinical criteria:

- Patient must have WHO Functional Class III PAH at treatment initiation with this drug; OR
- Patient must have WHO Functional Class IV PAH at treatment initiation with this drug, **AND**

- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) selexipag (referred to as 'triple therapy'); OR
- The treatment must form part of dual combination therapy consisting of either: (i) selexipag with one endothelin receptor antagonist, (ii) selexipag with one phosphodiesterase-5 inhibitor, as triple combination therapy with selexipag-an endothelin receptor antagonist-a phosphodiesterase-5 inhibitor is not possible due to an intolerance/contraindication to the endothelin receptor antagonist class/phosphodiesterase-5 inhibitor class (referred to as 'dual therapy in lieu of triple therapy'), **AND**
- Patient must have completed the dose titration phase, **AND**
- The treatment must not be as monotherapy.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

Population criteria:

- Patient must have had at least one PBS-subsidised PAH agent prior to this authority application.

Select one appropriate strength (determined under the 'Initial treatment - dose titration' phase) and apply under this treatment phase (Initial treatment following dose titration) once only. Should future dose adjustments be required, apply under the 'Continuing treatment' restriction.

A prior PAH agent is any of: ambrisentan, bosentan, macitentan, sildenafil, tadalafil, epoprostenol, iloprost, riociguat.

For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil.

PBS-subsidy does not cover patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

PAH (WHO Group 1 pulmonary hypertension) is defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than or equal to 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than or equal to 15 mmHg; or

(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Note PAH (WHO Group 1 pulmonary hypertension) currently includes the following subtypes: Idiopathic PAH

- Heritable PAH
 - BMPR2 mutation
 - ALK-1, ENG, SMAD9, CAV1, KCNK3 mutations
 - Other mutations
- Drugs and toxins induced PAH
- PAH associated with:
 - Connective tissue disease
 - Human immunodeficiency virus (HIV) infection
 - Portal hypertension
 - Congenital heart disease
 - Schistosomiasis

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have developed disease progression while receiving treatment with this drug for this condition, **AND**
- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) selexipag (referred to as 'triple therapy'); OR
- The treatment must form part of dual combination therapy consisting of either: (i) selexipag with one endothelin receptor antagonist, (ii) selexipag with one phosphodiesterase-5 inhibitor, as triple combination therapy with selexipag-an endothelin receptor antagonist-a phosphodiesterase-5 inhibitor is not possible due to an intolerance/contraindication to the endothelin receptor antagonist class/phosphodiesterase-5 inhibitor class (referred to as 'dual therapy in lieu of triple therapy'), **AND**
- The treatment must not be as monotherapy.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil.

For the purposes of administering this restriction, disease progression has developed if at least one of the following has occurred:

- Hospitalisation due to worsening PAH;
- Deterioration of aerobic capacity/endurance, consisting of at least a 15% decrease in 6-Minute Walk Distance from baseline, combined with worsening of WHO functional class status;
- Deterioration of aerobic capacity/endurance, consisting of at least a 15% decrease in 6-Minute Walk Distance from baseline, combined with the need for additional PAH-specific therapy;
- Initiation of parenteral prostanoid therapy or long-term oxygen therapy for worsening of PAH;
- Need for lung transplantation or balloon atrial septostomy for worsening of PAH.

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Transitioning from non-PBS subsidised to PBS-subsidised supply - 'Grandfather' treatment

Clinical criteria:

- Patient must have received non-PBS subsidised treatment with this drug prior to 1 February 2021, **AND**
- Patient must have failed to achieve/maintain a WHO Functional Class II status with PAH agents (other than this agent) given as dual therapy, prior to treatment initiation with this drug, **AND**
- Patient must have had WHO Functional Class III PAH at treatment initiation with this drug; OR
- Patient must have had WHO Functional Class IV PAH at treatment initiation with this drug, **AND**
- Patient must not have developed disease progression while receiving treatment with this drug for this condition, **AND**
- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) selexipag (referred to as 'triple therapy'); OR
- The treatment must form part of dual combination therapy consisting of either: (i) selexipag with one endothelin receptor antagonist, (ii) selexipag with one phosphodiesterase-5 inhibitor, as triple combination therapy with selexipag-an endothelin receptor antagonist-a phosphodiesterase-5 inhibitor is not possible due to an intolerance/contraindication to the endothelin receptor antagonist class/phosphodiesterase-5 inhibitor class (referred to as 'dual therapy in lieu of triple therapy'), **AND**
- The treatment must not be as monotherapy.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

Population criteria:

- Patient must have had at least one PBS-subsidised PAH agent prior to this authority application.

A prior PAH agent is any of: ambrisentan, bosentan, macitentan, sildenafil, tadalafil, epoprostenol, iloprost, riociguat.

For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil.

For the purposes of administering this restriction, disease progression has developed if at least one of the following has occurred:

- (i) Hospitalisation due to worsening PAH;
- (ii) Deterioration of aerobic capacity/endurance, consisting of at least a 15% decrease in 6-Minute Walk Distance from baseline, combined with worsening of WHO functional class status;
- (iii) Deterioration of aerobic capacity/endurance, consisting of at least a 15% decrease in 6-Minute Walk Distance from baseline, combined with the need for additional PAH-specific therapy;
- (iv) Initiation of parenteral prostanoid therapy or long-term oxygen therapy for worsening of PAH;
- (v) Need for lung transplantation or balloon atrial septostomy for worsening of PAH.

PBS-subsidy does not cover patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

PAH (WHO Group 1 pulmonary hypertension) is defined as follows:

- (i) mean pulmonary artery pressure (mPAP) greater than or equal to 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than or equal to 15 mmHg; or
- (ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Note PAH (WHO Group 1 pulmonary hypertension) currently includes the following subtypes: Idiopathic PAH

- Heritable PAH
 - BMPR2 mutation
 - ALK-1, ENG, SMAD9, CAV1, KCNK3 mutations
 - Other mutations
- Drugs and toxins induced PAH
- PAH associated with:
 - Connective tissue disease
 - Human immunodeficiency virus (HIV) infection
 - Portal hypertension
 - Congenital heart disease
 - Schistosomiasis

Note Patients may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a 'Grandfathered' patient must qualify under the 'Continuing treatment' criteria.

Note This grandfather restriction will cease to operate from 12 months after the date specified in the clinical criteria.

selexipag 200 microgram tablet, 60

12247N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	3450.00	Uptravi [JC]

selexipag 400 microgram tablet, 60

12235Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	3450.00	Uptravi [JC]

selexipag 1.2 mg tablet, 60

12252W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	3450.00	Upravi [JC]

selexipag 800 microgram tablet, 60

12249Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	3450.00	Upravi [JC]

selexipag 1.6 mg tablet, 60

12265M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	3450.00	Upravi [JC]

selexipag 1 mg tablet, 60

12259F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	3450.00	Upravi [JC]

selexipag 1.4 mg tablet, 60

12240F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	3450.00	Upravi [JC]

selexipag 600 microgram tablet, 60

12263K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	3450.00	Upravi [JC]

▪ SILDENAFIL

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 (dual therapy - previously untreated patients)

Clinical criteria:

- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

Clinical criteria:

- Patient must currently have WHO Functional Class III PAH or WHO Functional Class IV PAH, **AND**
- The treatment must be in combination with a PBS-subsidised endothelin receptor antagonist (ERA) for this condition. The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

For the purposes of PBS subsidy, dual therapy refers to combined use of an endothelin receptor antagonist (ERA) and a phosphodiesterase-5 inhibitor (PDE-5i).

(i) An ERA includes ambrisentan, bosentan monohydrate, or macitentan.

(ii) A PDE-5i includes sildenafil citrate, or tadalafil.

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

PAH (WHO Group 1 pulmonary hypertension) is defined as follows:

- (i) mean pulmonary artery pressure (mPAP) greater than or equal to 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than or equal to 15 mmHg; or
- (ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

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 which includes results from the three tests below, where available:
 - (i) RHC composite assessment; and
 - (ii) ECHO composite assessment; and
 - (iii) 6 Minute Walk Test (6MWT).

Where it is not possible to perform all 3 tests 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 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.

Where a RHC cannot be performed on clinical grounds, confirmation of the reason(s) must be provided with the authority application by a second PAH physician or cardiologist with expertise in the management of PAH.

The test results provided must not be more than 2 months old at the time of 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.

Note PAH (WHO Group 1 pulmonary hypertension) currently includes the following subtypes: Idiopathic PAH

- Heritable PAH
 - BMPR2 mutation
 - ALK-1, ENG, SMAD9, CAV1, KCNK3 mutations
 - Other mutations
- Drugs and toxins induced PAH
- PAH associated with:
 - Connective tissue disease
 - Human immunodeficiency virus (HIV) infection
 - Portal hypertension
 - Congenital heart disease
 - Schistosomiasis

Note Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 2 (dual therapy - previously treated patients)

Clinical criteria:

- Patient must have documented WHO Functional Class III PAH or WHO Functional Class IV PAH, **AND**
- Patient must have documented a failure to achieve or maintain WHO Functional Class II status with prior PBS-subsidised monotherapy treatment with an endothelin receptor antagonist (ERA) for this condition, **AND**
- The treatment must be in combination with a PBS-subsidised endothelin receptor antagonist (ERA) for this condition.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

For the purposes of PBS subsidy, dual therapy refers to combined use of an endothelin receptor antagonist (ERA) and a phosphodiesterase-5 inhibitor (PDE-5i).

(i) An ERA includes ambrisentan, bosentan monohydrate, or macitentan.

(ii) A PDE-5i includes sildenafil citrate, or tadalafil.

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

PAH (WHO Group 1 pulmonary hypertension) is defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than or equal to 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than or equal to 15 mmHg; or

(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

The results and date of the RHC, ECHO and 6 MWT as applicable must be included in the patient's medical record. Where a RHC cannot be performed on clinical grounds, the written confirmation of the reasons why must also be included in the patient's medical record.

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.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 3 (dual therapy - change)

Clinical criteria:

- Patient must have had their most recent course of PBS-subsidised dual therapy with an endothelin receptor antagonist (ERA) and a phosphodiesterase-5 inhibitor (PDE-5i) other than this agent for this condition.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

For the purposes of PBS subsidy, dual therapy refers to combined use of an endothelin receptor antagonist (ERA) and a phosphodiesterase-5 inhibitor (PDE-5i).

(i) An ERA includes ambrisentan, bosentan monohydrate, or macitentan.

(ii) A PDE-5i includes sildenafil citrate, or tadalafil.

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

Swapping between PAH agents: Patients can access PAH agents through the PBS according to the relevant restrictions.

Once patients are approved dual therapy with a PAH agent from the PDE-5i class; or a PAH agent from the ERA class, they may swap between PAH agents within the same class. This means that patients may commence treatment with another PAH agent in the same class, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted.

Applications to swap within a PAH agent class must be made under the relevant initial treatment restriction.

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.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Continuing treatment (dual therapy)

Clinical criteria:

- Patient must have received their most recent course of PBS-subsidised treatment with this PAH agent and an endothelin receptor antagonist (ERA) for this condition.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

For the purposes of PBS subsidy, dual therapy refers to combined use of an endothelin receptor antagonist (ERA) and a phosphodiesterase-5 inhibitor (PDE-5i).

(i) An ERA includes ambrisentan, bosentan monohydrate, or macitentan.

(ii) A PDE-5i includes sildenafil citrate, or tadalafil.

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

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.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Grandfathered patients (dual therapy)

Clinical criteria:

- Patient must be receiving dual therapy with this non PBS-subsidised pulmonary arterial hypertension (PAH) agent and a non PBS-subsidised endothelin receptor antagonist (ERA) for this condition prior to 1 October 2020.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

Clinical criteria:

- Patient must have documented WHO Functional Class III PAH or WHO Functional Class IV PAH.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

For the purposes of PBS subsidy, dual therapy refers to combined use of an endothelin receptor antagonist (ERA) and a phosphodiesterase-5 inhibitor (PDE-5i).

(i) An ERA includes ambrisentan, bosentan monohydrate, or macitentan.

(ii) A PDE-5i includes sildenafil citrate, or tadalafil.

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

PAH (WHO Group 1 pulmonary hypertension) is defined as follows:

- (i) mean pulmonary artery pressure (mPAP) greater than or equal to 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than or equal to 15 mmHg; or
- (ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

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 which includes results from the three tests below, where available:

- (i) RHC composite assessment; and
- (ii) ECHO composite assessment; and
- (iii) 6 Minute Walk Test (6MWT).

Where it was not possible to perform all 3 tests 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 could not be performed on clinical grounds, applications may be submitted 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 were 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.

Where a RHC could not be performed on clinical grounds, confirmation of the reason(s) must be provided with the authority application by a second PAH physician or cardiologist with expertise in the management of PAH.

A patient may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria for dual therapy for this condition.

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.

Note PAH (WHO Group 1 pulmonary hypertension) currently includes the following subtypes: Idiopathic PAH

- Heritable PAH
 - BMPR2 mutation
 - ALK-1, ENG, SMAD9, CAV1, KCNK3 mutations
 - Other mutations
- Drugs and toxins induced PAH
- PAH associated with:
 - Connective tissue disease
 - Human immunodeficiency virus (HIV) infection
 - Portal hypertension
 - Congenital heart disease
 - Schistosomiasis

Note Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Triple therapy - Initial treatment or continuing treatment of triple combination therapy (including dual therapy in lieu of triple therapy) that includes selexipag

Clinical criteria:

- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) PBS-subsidised selexipag (referred to as 'triple therapy'); OR
- The treatment must form part of dual combination therapy consisting of either: (i) PBS-subsidised selexipag with one endothelin receptor antagonist, (ii) PBS-subsidised selexipag with one phosphodiesterase-5 inhibitor, as triple combination therapy with selexipag-an endothelin receptor antagonist-a phosphodiesterase-5 inhibitor is not possible due to an intolerance/contraindication to the endothelin receptor antagonist class/phosphodiesterase-5 inhibitor class (referred to as 'dual therapy in lieu of triple therapy').

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

The authority application for selexipag must be approved prior to the authority application for this agent. For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil.

PBS-subsidy does not cover patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

PAH (WHO Group 1 pulmonary hypertension) is defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than or equal to 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than or equal to 15 mmHg; or

(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

The results and date of the RHC, ECHO and 6 MWT as applicable must be included in the patient's medical record. Where a RHC cannot be performed on clinical grounds, the written confirmation of the reasons why must also be included in the patient's medical record.

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.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicessaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Note Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

sildenafil 20 mg tablet, 90

12144E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	254.31	^a APO-Sildenafil PHT [TX]	^a Revatio [UJ]
					^a SILDATIO PHT [RW]	^a Sildenafil AN PHT 20 [EA]
					^a Sildenafil PHT APOTEX [TY]	^a Sildenafil Sandoz PHT 20 [SZ]

▪ TADALAFIL

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 (dual therapy - previously untreated patients)

Clinical criteria:

- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

Clinical criteria:

- Patient must currently have WHO Functional Class III PAH or WHO Functional Class IV PAH, **AND**
- The treatment must be in combination with a PBS-subsidised endothelin receptor antagonist (ERA) for this condition. The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

For the purposes of PBS subsidy, dual therapy refers to combined use of an endothelin receptor antagonist (ERA) and a phosphodiesterase-5 inhibitor (PDE-5i).

(i) An ERA includes ambrisentan, bosentan monohydrate, or macitentan.

(ii) A PDE-5i includes sildenafil citrate, or tadalafil.

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

PAH (WHO Group 1 pulmonary hypertension) is defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than or equal to 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than or equal to 15 mmHg; or

(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

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 which includes results from the three tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6 Minute Walk Test (6MWT).

Where it is not possible to perform all 3 tests 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 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.

Where a RHC cannot be performed on clinical grounds, confirmation of the reason(s) must be provided with the authority application by a second PAH physician or cardiologist with expertise in the management of PAH.

The test results provided must not be more than 2 months old at the time of 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.

Note PAH (WHO Group 1 pulmonary hypertension) currently includes the following subtypes: Idiopathic PAH

- Heritable PAH
 - BMPR2 mutation
 - ALK-1, ENG, SMAD9, CAV1, KCNK3 mutations
 - Other mutations
- Drugs and toxins induced PAH
- PAH associated with:
 - Connective tissue disease
 - Human immunodeficiency virus (HIV) infection
 - Portal hypertension
 - Congenital heart disease
 - Schistosomiasis

Note Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 2 (dual therapy - previously treated patients)

Clinical criteria:

- Patient must have documented WHO Functional Class III PAH or WHO Functional Class IV PAH, **AND**
- Patient must have documented a failure to achieve or maintain WHO Functional Class II status with prior PBS-subsidised monotherapy treatment with an endothelin receptor antagonist (ERA) for this condition, **AND**
- The treatment must be in combination with a PBS-subsidised endothelin receptor antagonist (ERA) for this condition.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

For the purposes of PBS subsidy, dual therapy refers to combined use of an endothelin receptor antagonist (ERA) and a phosphodiesterase-5 inhibitor (PDE-5i).

(i) An ERA includes ambrisentan, bosentan monohydrate, or macitentan.

(ii) A PDE-5i includes sildenafil citrate, or tadalafil.

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

PAH (WHO Group 1 pulmonary hypertension) is defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than or equal to 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than or equal to 15 mmHg; or

(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

The results and date of the RHC, ECHO and 6 MWT as applicable must be included in the patient's medical record. Where a RHC cannot be performed on clinical grounds, the written confirmation of the reasons why must also be included in the patient's medical record.

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.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 3 (dual therapy - change)

Clinical criteria:

- Patient must have had their most recent course of PBS-subsidised dual therapy with an endothelin receptor antagonist (ERA) and a phosphodiesterase-5 inhibitor (PDE-5i) other than this agent for this condition.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

For the purposes of PBS subsidy, dual therapy refers to combined use of an endothelin receptor antagonist (ERA) and a phosphodiesterase-5 inhibitor (PDE-5i).

(i) An ERA includes ambrisentan, bosentan monohydrate, or macitentan.

(ii) A PDE-5i includes sildenafil citrate, or tadalafil.

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

Swapping between PAH agents: Patients can access PAH agents through the PBS according to the relevant restrictions.

Once patients are approved dual therapy with a PAH agent from the PDE-5i class; or a PAH agent from the ERA class, they may swap between PAH agents within the same class. This means that patients may commence treatment with another PAH agent in the same class, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted.

Applications to swap within a PAH agent class must be made under the relevant initial treatment restriction.

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.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Continuing treatment (dual therapy)

Clinical criteria:

- Patient must have received their most recent course of PBS-subsidised treatment with this PAH agent and an endothelin receptor antagonist (ERA) for this condition.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

For the purposes of PBS subsidy, dual therapy refers to combined use of an endothelin receptor antagonist (ERA) and a phosphodiesterase-5 inhibitor (PDE-5i).

(i) An ERA includes ambrisentan, bosentan monohydrate, or macitentan.

(ii) A PDE-5i includes sildenafil citrate, or tadalafil.

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

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.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Grandfathered patients (dual therapy)

Clinical criteria:

- Patient must be receiving dual therapy with this non PBS-subsidised pulmonary arterial hypertension (PAH) agent and a non PBS-subsidised endothelin receptor antagonist (ERA) for this condition prior to 1 October 2020.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

Clinical criteria:

- Patient must have documented WHO Functional Class III PAH or WHO Functional Class IV PAH.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

For the purposes of PBS subsidy, dual therapy refers to combined use of an endothelin receptor antagonist (ERA) and a phosphodiesterase-5 inhibitor (PDE-5i).

(i) An ERA includes ambrisentan, bosentan monohydrate, or macitentan.

(ii) A PDE-5i includes sildenafil citrate, or tadalafil.

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

PAH (WHO Group 1 pulmonary hypertension) is defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than or equal to 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than or equal to 15 mmHg; or

(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

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 which includes results from the three tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6 Minute Walk Test (6MWT).

Where it was not possible to perform all 3 tests 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 could not be performed on clinical grounds, applications may be submitted 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 were 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.

Where a RHC could not be performed on clinical grounds, confirmation of the reason(s) must be provided with the authority application by a second PAH physician or cardiologist with expertise in the management of PAH.

A patient may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria for dual therapy for this condition.

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.

Note PAH (WHO Group 1 pulmonary hypertension) currently includes the following subtypes: Idiopathic PAH

- Heritable PAH
 - BMPR2 mutation
 - ALK-1, ENG, SMAD9, CAV1, KCNK3 mutations
 - Other mutations
- Drugs and toxins induced PAH
- PAH associated with:
 - Connective tissue disease
 - Human immunodeficiency virus (HIV) infection
 - Portal hypertension
 - Congenital heart disease
 - Schistosomiasis

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

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Or mailed to:

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Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Triple therapy - Initial treatment or continuing treatment of triple combination therapy (including dual therapy in lieu of triple therapy) that includes selexipag

Clinical criteria:

- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) PBS-subsidised selexipag (referred to as 'triple therapy'); OR
- The treatment must form part of dual combination therapy consisting of either: (i) PBS-subsidised selexipag with one endothelin receptor antagonist, (ii) PBS-subsidised selexipag with one phosphodiesterase-5 inhibitor, as triple combination therapy with selexipag-an endothelin receptor antagonist-a phosphodiesterase-5 inhibitor is not possible due to an intolerance/contraindication to the endothelin receptor antagonist class/phosphodiesterase-5 inhibitor class (referred to as 'dual therapy in lieu of triple therapy').

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

The authority application for selexipag must be approved prior to the authority application for this agent.

For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil.

PBS-subsidy does not cover patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

PAH (WHO Group 1 pulmonary hypertension) is defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than or equal to 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than or equal to 15 mmHg; or

(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

The results and date of the RHC, ECHO and 6 MWT as applicable must be included in the patient's medical record. Where a RHC cannot be performed on clinical grounds, the written confirmation of the reasons why must also be included in the patient's medical record.

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.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Note Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

tadalafil 20 mg tablet, 56

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
12151M	1	5	..	475.54	^a Adcirca [LY] ^a TADALIS 20 [LR]	^a Tadalca [CR]
