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)*
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)*
12237C  **INSULIN LISPRO**, insulin lispro 100 units/mL injection, 5 x 3 mL pen devices *(Humalog 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  **Pharmaco Amlodipine**, CR – **AMLODIPINE**, amlodipine 5 mg tablet, 30
2752W  **Pharmaco 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
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<th>Brand</th>
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<tr>
<td>10529E</td>
<td>APO-Lurasidone, TX – LURASIDONE</td>
<td>lurasidone hydrochloride 80 mg tablet, 30</td>
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<td>3124K</td>
<td>Uramet, AS – METHENAMINE HIPPURATE</td>
<td>methenamine hippurate 1 g tablet, 100</td>
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<td>1594X</td>
<td>Zotren 4, RF – ONDANSETRON</td>
<td>ondansetron 4 mg tablet, 10</td>
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<td>8224W</td>
<td>Zotren 4, RF – ONDANSETRON</td>
<td>ondansetron 4 mg tablet, 4</td>
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<td>1595Y</td>
<td>Zotren 8, RF – ONDANSETRON</td>
<td>ondansetron 8 mg tablet, 10</td>
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<td>8225X</td>
<td>Zotren 8, RF – ONDANSETRON</td>
<td>ondansetron 8 mg tablet, 4</td>
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<td>12022R</td>
<td>APX-Paracetamol/Codeine, TY – PARACETAMOL + CODEINE</td>
<td>paracetamol 500 mg + codeine phosphate hemihydrate 30 mg tablet, 20</td>
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<td>12066C</td>
<td>APX-Paracetamol/Codeine, TY – PARACETAMOL + CODEINE</td>
<td>paracetamol 500 mg + codeine phosphate hemihydrate 30 mg tablet, 20</td>
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<td>1215Y</td>
<td>APX-Paracetamol/Codeine, TY – PARACETAMOL + CODEINE</td>
<td>paracetamol 500 mg + codeine phosphate hemihydrate 30 mg tablet, 20</td>
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<td>3316M</td>
<td>APX-Paracetamol/Codeine, TY – PARACETAMOL + CODEINE</td>
<td>paracetamol 500 mg + codeine phosphate hemihydrate 30 mg tablet, 20</td>
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<td>10460M</td>
<td>POSACONAZOLE DR.REDDY’S, RZ – POSACONAZOLE</td>
<td>posaconazole 100 mg modified release tablet, 24</td>
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<td>10460M</td>
<td>Pharmacor Posaconazole, CR – POSACONAZOLE</td>
<td>posaconazole 100 mg modified release tablet, 24</td>
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<td>2339D</td>
<td>Spironolactone Mylan 25, AL – SPIRONOLACTONE</td>
<td>spironolactone 25 mg tablet, 100</td>
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<td>2340E</td>
<td>Spironolactone Mylan 100, AL – SPIRONOLACTONE</td>
<td>spironolactone 100 mg tablet, 100</td>
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<td>2856H</td>
<td>FLUOXETINE, fluoxetine 20 mg capsule, 28 (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)</td>
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<tr>
<td>2856H</td>
<td>PHENELZINE, phenelzine 15 mg tablet, 100 (Nardil)</td>
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<tr>
<td>1109J</td>
<td>Artane, RW – TRIHEXYPHENIDYL (BENZHEXOL), trihexyphenidyl (benzhexol) hydrochloride 2 mg tablet, 200</td>
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<tr>
<td>1109J</td>
<td>TRIHEXYPHENIDYL (BENZHEXOL), trihexyphenidyl (benzhexol) hydrochloride 2 mg tablet, 200 (Artane)</td>
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**Additions**

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<tr>
<th>Code</th>
<th>Brand</th>
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<tr>
<td>1109J</td>
<td>Artane, RW – TRIHEXYPHENIDYL (BENZHEXOL), trihexyphenidyl (benzhexol) hydrochloride 2 mg tablet, 200</td>
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**Deletions**

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<th>Description</th>
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<tr>
<td>10947E</td>
<td>OCRIPLASMIN</td>
<td>ocriplasmin 500 microgram/0.2 mL injection, 0.2 mL vial (Jetrea)</td>
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<tr>
<td>11713L</td>
<td>PHENELZINE, phenelzine 15 mg tablet, 60 (Nardil)</td>
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**Alterations**

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<th>Code</th>
<th>Brand</th>
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<tr>
<td>8609D</td>
<td>INSULIN ASPART + INSULIN ASPART PROTAMINE</td>
<td>insulin aspart 30 units/mL + insulin aspart protamine 70 units/mL injection, 5 x 3 mL syringes (NovoMix 30 FlexPen, NovoMix 30 Penfill 3 mL)</td>
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<tr>
<td>8609D</td>
<td>INSULIN ASPART + INSULIN ASPART PROTAMINE</td>
<td>insulin aspart 30 units/mL + insulin aspart protamine 70 units/mL injection, 5 x 3 mL cartridges (NovoMix 30 FlexPen, NovoMix 30 Penfill 3 mL)</td>
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**Alterations – Note**

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<th>Description</th>
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<tr>
<td>11815W</td>
<td>INSULIN GLARGINE</td>
<td>insulin glargine 100 units/mL injection, 5 x 3 mL pen devices (Optisulin SoloStar, Semglee)</td>
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<tr>
<td>9039R</td>
<td>INSULIN GLARGINE</td>
<td>insulin glargine 100 units/mL injection, 5 x 3 mL cartridges (Optisulin SoloStar, Optisulin)</td>
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<td>11884L</td>
<td>LISDEXAMFETAMINE</td>
<td>lisdexamfetamine dimesilate 20 mg capsule, 30 (Vyvanse)</td>
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<tr>
<td>10486X</td>
<td>LISDEXAMFETAMINE</td>
<td>lisdexamfetamine dimesilate 30 mg capsule, 30 (Vyvanse)</td>
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<tr>
<td>11898F</td>
<td>LISDEXAMFETAMINE</td>
<td>lisdexamfetamine dimesilate 40 mg capsule, 30 (Vyvanse)</td>
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LISDEXAMFETAMINE, lisdexamfetamine dimesilate 50 mg capsule, 30 (Vyvanse)

LISDEXAMFETAMINE, lisdexamfetamine dimesilate 60 mg capsule, 30 (Vyvanse)

LISDEXAMFETAMINE, lisdexamfetamine dimesilate 70 mg capsule, 30 (Vyvanse)

METHYLPHENIDATE, methylphenidate hydrochloride 10 mg modified release capsule, 30 (Ritalin LA)

METHYLPHENIDATE, methylphenidate hydrochloride 20 mg modified release capsule, 30 (Ritalin LA)

METHYLPHENIDATE, methylphenidate hydrochloride 30 mg modified release capsule, 30 (Ritalin LA)

METHYLPHENIDATE, methylphenidate hydrochloride 40 mg modified release capsule, 30 (Ritalin LA)

METHYLPHENIDATE, methylphenidate hydrochloride 60 mg modified release capsule, 30 (Ritalin LA)

METHYLPHENIDATE, methylphenidate hydrochloride 18 mg modified release tablet, 30 (Concerta)

METHYLPHENIDATE, methylphenidate hydrochloride 27 mg modified release tablet, 30 (Concerta)

METHYLPHENIDATE, methylphenidate hydrochloride 36 mg modified release tablet, 30 (Concerta)

METHYLPHENIDATE, methylphenidate hydrochloride 54 mg modified release tablet, 30 (Concerta)

RUXOLITINIB, ruxolitinib 5 mg tablet, 56 (Jakavi)

RUXOLITINIB, ruxolitinib 10 mg tablet, 56 (Jakavi)

RUXOLITINIB, ruxolitinib 15 mg tablet, 56 (Jakavi)

RUXOLITINIB, ruxolitinib 20 mg tablet, 56 (Jakavi)

Alteration – Restriction

LISDEXAMFETAMINE, lisdexamfetamine dimesilate 20 mg capsule, 30 (Vyvanse)

METHYLPHENIDATE, methylphenidate hydrochloride 10 mg modified release capsule, 30 (Ritalin LA)

METHYLPHENIDATE, methylphenidate hydrochloride 20 mg modified release capsule, 30 (Ritalin LA)

METHYLPHENIDATE, methylphenidate hydrochloride 30 mg modified release capsule, 30 (Ritalin LA)

METHYLPHENIDATE, methylphenidate hydrochloride 40 mg modified release capsule, 30 (Ritalin LA)

METHYLPHENIDATE, methylphenidate hydrochloride 60 mg modified release capsule, 30 (Ritalin LA)

METHYLPHENIDATE, methylphenidate hydrochloride 18 mg modified release tablet, 30 (Concerta)

METHYLPHENIDATE, methylphenidate hydrochloride 27 mg modified release tablet, 30 (Concerta)

METHYLPHENIDATE, methylphenidate hydrochloride 36 mg modified release tablet, 30 (Concerta)

METHYLPHENIDATE, methylphenidate hydrochloride 54 mg modified release tablet, 30 (Concerta)

RUXOLITINIB, ruxolitinib 5 mg tablet, 56 (Jakavi)

RUXOLITINIB, ruxolitinib 10 mg tablet, 56 (Jakavi)

RUXOLITINIB, ruxolitinib 15 mg tablet, 56 (Jakavi)

RUXOLITINIB, ruxolitinib 20 mg tablet, 56 (Jakavi)

Alteration – Manufacturer Code

Catapres 100 – CLONIDINE, clonidine hydrochloride 100 microgram tablet, 100

Catapres – CLONIDINE, clonidine hydrochloride 150 microgram tablet, 100

Oxycodone BNM – OXYCODONE, oxycodone hydrochloride 5 mg capsule, 20

Oxycodone BNM – OXYCODONE, oxycodone hydrochloride 5 mg capsule, 20

Oxycodone BNM – OXYCODONE, oxycodone hydrochloride 5 mg capsule, 20

Oxycodone BNM – OXYCODONE, oxycodone hydrochloride 5 mg capsule, 20
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

Advance Notices
1 March 2021
Deletion – Brand
### Auscap Aspen, RW – FLUOXETINE, fluoxetine 20 mg capsule, 28

<table>
<thead>
<tr>
<th>Item</th>
<th>Brand</th>
<th>Description</th>
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<tr>
<td>8534E</td>
<td>Lercanidipine Sandoz, SZ – LERCANIDIPINE, lercanidipine hydrochloride 10 mg tablet, 28</td>
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<tr>
<td>8679T</td>
<td>Lercanidipine Sandoz, SZ – LERCANIDIPINE, lercanidipine hydrochloride 20 mg tablet, 28</td>
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<tr>
<td>8810Q</td>
<td>Glucovance 500mg/2.5mg, AL – METFORMIN + GLIBENCLAMIDE, metformin hydrochloride 500 mg + glibenclamide 2.5 mg tablet, 90</td>
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<tr>
<td>8811R</td>
<td>Glucovance 500mg/5mg, AL – METFORMIN + GLIBENCLAMIDE, metformin hydrochloride 500 mg + glibenclamide 5 mg tablet, 90</td>
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<tr>
<td>8838E</td>
<td>Glucovance 250mg/1.25mg, AL – METFORMIN + GLIBENCLAMIDE, metformin hydrochloride 250 mg + glibenclamide 1.25 mg tablet, 90</td>
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### Carafate, AF – SUCRALFATE, sucralfate 1 g tablet, 120

1 April 2021

#### Deletion – Brand

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

#### Advance Notices

1 April 2021

#### Deletion – Brand

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

#### Additions

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<tr>
<td>12241G</td>
<td>SELEXIPAG, selexipag 200 microgram tablet, 140 (Uptravi)</td>
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<tr>
<td>12242H</td>
<td>SELEXIPAG, selexipag 200 microgram tablet, 60 (Uptravi)</td>
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<tr>
<td>12260G</td>
<td>SELEXIPAG, selexipag 400 microgram tablet, 60 (Uptravi)</td>
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<td>12248P</td>
<td>SELEXIPAG, selexipag 600 microgram tablet, 60 (Uptravi)</td>
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<td>12246M</td>
<td>SELEXIPAG, selexipag 800 microgram tablet, 60 (Uptravi)</td>
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<td>12253X</td>
<td>SELEXIPAG, selexipag 800 microgram tablet, 60 (Uptravi)</td>
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<td>12245L</td>
<td>SELEXIPAG, selexipag 1 mg tablet, 60 (Uptravi)</td>
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<td>12257D</td>
<td>SELEXIPIG, selexipag 1.2 mg tablet, 60</td>
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<td>12251T</td>
<td>SELEXIPIG, selexipag 1.4 mg tablet, 60</td>
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<td>12264L</td>
<td>SELEXIPIG, selexipag 1.6 mg tablet, 60</td>
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<td>12139X</td>
<td>BOSENTAN Cipla, LR – BOSENTAN, bosentan 62.5 mg tablet, 60</td>
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<td>12143D</td>
<td>BOSENTAN Cipla, LR – BOSENTAN, bosentan 62.5 mg tablet, 60</td>
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<td>12148J</td>
<td>BOSENTAN Cipla, LR – BOSENTAN, bosentan 62.5 mg tablet, 60</td>
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<td>6429J</td>
<td>BOSENTAN Cipla, LR – BOSENTAN, bosentan 62.5 mg tablet, 60</td>
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<td>12146G</td>
<td>BOSENTAN Cipla, LR – BOSENTAN, bosentan 125 mg tablet, 60</td>
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<td>6430K</td>
<td>BOSENTAN Cipla, LR – BOSENTAN, bosentan 125 mg tablet, 60</td>
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<td>12138W</td>
<td>Sildenafil PHT APOTEX, TY – SILDENAFIL, sildenafil 20 mg tablet, 90</td>
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<td>9605M</td>
<td>Sildenafil PHT APOTEX, TY – SILDENAFIL, sildenafil 20 mg tablet, 90</td>
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**Addition – Brand**

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<th>Dosage</th>
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<td>12180C</td>
<td>AMBRISIDENTAN, ambrisentan 5 mg tablet, 30</td>
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<td>(Ambrisentan Mylan, Cipla Ambrisentan, PULMORIS, Volibris)</td>
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<tr>
<td>12148J</td>
<td>BOSENTAN, bosentan 62.5 mg tablet, 60</td>
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<td>(BOSENTAN DR.REDDY’S, BOSLEER, Bosentan APO, Bosentan Cipla, Bosentan Mylan, Bosentan RBX, Bosentan Sandoz, Tracleer)</td>
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<tr>
<td>12146G</td>
<td>BOSENTAN, bosentan 125 mg tablet, 60</td>
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<td>(BOSENTAN DR.REDDY’S, BOSLEER, Bosentan APO, Bosentan Cipla, Bosentan GH, Bosentan Mylan, Bosentan RBX, Bosentan Sandoz, Tracleer)</td>
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<td>12135Q</td>
<td>MACITENTAN, macitentan 10 mg tablet, 30</td>
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<td>(Opsumit)</td>
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<td>12138W</td>
<td>SILDENAFIL, sildenafil 20 mg tablet, 90</td>
<td></td>
<td>(APO-Sildenafil PHT, Revatio, SILDATIO PHT, Sildenafil AN PHT 20, Sildenafil PHT APOTEX, Sildenafil Sandoz PHT 20)</td>
</tr>
<tr>
<td>12150L</td>
<td>TADALAFIL, tadalafil 20 mg tablet, 56</td>
<td></td>
<td>(Adcirca, TADALIS 20, Tadalca)</td>
</tr>
</tbody>
</table>

**Alterations**

**Alteration – Brand Name**

<table>
<thead>
<tr>
<th>Code</th>
<th>Name</th>
<th>Dosage</th>
<th>Brand</th>
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<tbody>
<tr>
<td>12139X</td>
<td>BOSENTAN DR. REDDY’S, RI – BOSENTAN, bosentan 62.5 mg tablet, 60</td>
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<td>BOSENTAN DR. REDDY’S, RI – BOSENTAN, bosentan 62.5 mg tablet, 60</td>
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<td>BOSENTAN DR. REDDY’S, RI – BOSENTAN, bosentan 62.5 mg tablet, 60</td>
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<td>12138W</td>
<td>SILDENAFIL, sildenafil 20 mg tablet, 90</td>
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<td>(APO-Sildenafil PHT, Revatio, SILDATIO PHT, Sildenafil AN PHT 20, Sildenafil PHT APOTEX, Sildenafil Sandoz PHT 20)</td>
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**Alteration – Note**

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<th>Dosage</th>
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<tbody>
<tr>
<td>5827Q</td>
<td>ELTROMBOPAG, eltrombopag 25 mg tablet, 28</td>
<td></td>
<td>(Revolade)</td>
</tr>
<tr>
<td>5828R</td>
<td>ELTROMBOPAG, eltrombopag 50 mg tablet, 28</td>
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<td>(Revolade)</td>
</tr>
<tr>
<td>9697J</td>
<td>ROMIPLOSTIM, romiplostim 250 microgram injection, 1 vial</td>
<td></td>
<td>(Nplate)</td>
</tr>
</tbody>
</table>
9699L ROMIPLOSTIM, romiplostim 500 microgram injection, 1 vial (Nplate)

Alteration – Restriction
12201E AMBRISENTAN, ambrisantan 5 mg tablet, 30 (Ambrisantan Mylan, Cipla Ambrisantan, PULMORIS, Volibris)
12180C AMBRISENTAN, ambrisantan 10 mg tablet, 30 (Ambrisantan Mylan, Cipla Ambrisantan, 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
12201E Volibris – AMBRISENTAN, ambrisantan 5 mg tablet, 30 From GK To ZE
9648T Volibris – AMBRISENTAN, ambrisantan 5 mg tablet, 30 From GK To ZE
12180C Volibris – AMBRISENTAN, ambrisantan 10 mg tablet, 30 From GK To ZE
9649W Volibris – AMBRISENTAN, ambrisantan 10 mg tablet, 30 From GK To 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
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)
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<td>12266N</td>
<td><strong>SELEXIPAG</strong>, selexipag 800 microgram tablet, 60 (Uptravi)</td>
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<tr>
<td>12259F</td>
<td><strong>SELEXIPAG</strong>, selexipag 1 mg tablet, 60 (Uptravi)</td>
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<tr>
<td>12252W</td>
<td><strong>SELEXIPAG</strong>, selexipag 1.2 mg tablet, 60 (Uptravi)</td>
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<td>12240F</td>
<td><strong>SELEXIPAG</strong>, selexipag 1.4 mg tablet, 60 (Uptravi)</td>
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<td>12265M</td>
<td><strong>SELEXIPAG</strong>, selexipag 1.6 mg tablet, 60 (Uptravi)</td>
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**Addition – Brand**

<table>
<thead>
<tr>
<th>Code</th>
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<tbody>
<tr>
<td>12134P</td>
<td>Bosentan Cipla, LR – <strong>BOSENTAN</strong>, bosentan 62.5 mg tablet, 60</td>
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<tr>
<td>12140Y</td>
<td>Bosentan Cipla, LR – <strong>BOSENTAN</strong>, bosentan 62.5 mg tablet, 60</td>
</tr>
<tr>
<td>12145F</td>
<td>Bosentan Cipla, LR – <strong>BOSENTAN</strong>, bosentan 62.5 mg tablet, 60</td>
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<tr>
<td>5618Q</td>
<td>Bosentan Cipla, LR – <strong>BOSENTAN</strong>, bosentan 62.5 mg tablet, 60</td>
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<tr>
<td>12149K</td>
<td>Bosentan Cipla, LR – <strong>BOSENTAN</strong>, bosentan 125 mg tablet, 60</td>
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<tr>
<td>5619R</td>
<td>Bosentan Cipla, LR – <strong>BOSENTAN</strong>, bosentan 125 mg tablet, 60</td>
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<td>12144E</td>
<td><strong>Sildenafil PHT APOTEX</strong>, TY – <strong>SILDENAFIL</strong>, sildenafil 20 mg tablet, 90</td>
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<td>9547L</td>
<td><strong>Sildenafil PHT APOTEX</strong>, TY – <strong>SILDENAFIL</strong>, sildenafil 20 mg tablet, 90</td>
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**Addition – Note**

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

**Alteration – Brand Name**

<table>
<thead>
<tr>
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<tr>
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<td>12149K</td>
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<table>
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<tbody>
<tr>
<td>12134P</td>
<td>BOSENTAN DR. REDDY’S, RI – BOSENTAN, bosentan 62.5 mg tablet, 60</td>
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<tr>
<td>12140Y</td>
<td>BOSENTAN DR. REDDY’S, RI – BOSENTAN, bosentan 62.5 mg tablet, 60</td>
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<tr>
<td>12145F</td>
<td>BOSENTAN DR. REDDY’S, RI – BOSENTAN, bosentan 62.5 mg tablet, 60</td>
</tr>
<tr>
<td>5618Q</td>
<td>BOSENTAN DR. REDDY’S, RI – BOSENTAN, bosentan 62.5 mg tablet, 60</td>
</tr>
<tr>
<td>12149K</td>
<td>BOSENTAN DR. REDDY’S, RI – BOSENTAN, bosentan 125 mg tablet, 60</td>
</tr>
<tr>
<td>5619R</td>
<td>BOSENTAN DR. REDDY’S, RI – BOSENTAN, bosentan 125 mg tablet, 60</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>From</th>
<th>To</th>
</tr>
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<tbody>
<tr>
<td>12134P</td>
<td>BOSENTAN DR. REDDY’S, RI – BOSENTAN, bosentan 62.5 mg tablet, 60</td>
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<tr>
<td>12140Y</td>
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<td>12145F</td>
<td>BOSENTAN DR. REDDY’S, RI – BOSENTAN, bosentan 62.5 mg tablet, 60</td>
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<tr>
<td>5618Q</td>
<td>BOSENTAN DR. REDDY’S, RI – BOSENTAN, bosentan 62.5 mg tablet, 60</td>
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<tr>
<td>12149K</td>
<td>BOSENTAN DR. REDDY’S, RI – BOSENTAN, bosentan 125 mg tablet, 60</td>
</tr>
<tr>
<td>5619R</td>
<td>BOSENTAN DR. REDDY’S, RI – BOSENTAN, bosentan 125 mg tablet, 60</td>
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</table>
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)

Alteration – Manufacturer Code
12212R Volibris – AMBRISENTAN, ambrisentan 5 mg tablet, 30
5607D Volibris – AMBRISENTAN, ambrisentan 5 mg tablet, 30
12186J Volibris – AMBRISENTAN, ambrisentan 10 mg tablet, 30
5608E Volibris – AMBRISENTAN, ambrisentan 10 mg tablet, 30

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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 + GRAZOPREVIR, elbasvir 50 mg + grazoprevir 100 mg tablet, 28
10986F Zepatier, MK – ELBASVIR + GRAZOPREVIR, elbasvir 50 mg + grazoprevir 100 mg tablet, 28
5776B Somatuline LA, IS – LANREOTIDE, lanreotide 30 mg modified release injection [1 vial] (8) 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  Norditropin SimpleXx, NO – SOMATROPIN, somatropin 5 mg/1.5 mL injection, 1.5 mL cartridge
10439K  Norditropin SimpleXx, NO – SOMATROPIN, somatropin 10 mg/1.5 mL injection, 1.5 mL cartridge
10448X  Norditropin SimpleXx, NO – SOMATROPIN, somatropin 10 mg/1.5 mL injection, 1.5 mL cartridge
10468Y  Norditropin SimpleXx, NO – SOMATROPIN, somatropin 15 mg/1.5 mL injection, 1.5 mL cartridge
10469B  Norditropin SimpleXx, NO – SOMATROPIN, somatropin 5 mg/1.5 mL injection, 1.5 mL cartridge
10470C  Norditropin SimpleXx, NO – SOMATROPIN, somatropin 15 mg/1.5 mL injection, 1.5 mL cartridge
6295H   Norditropin SimpleXx, NO – SOMATROPIN, somatropin 5 mg/1.5 mL injection, 1.5 mL cartridge
6296J   Norditropin SimpleXx, NO – SOMATROPIN, somatropin 10 mg/1.5 mL injection, 1.5 mL cartridge
6297K   Norditropin SimpleXx, NO – 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)
**FLUOXETINE**

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

<table>
<thead>
<tr>
<th>Restricted benefit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Major depressive disorders</td>
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<tr>
<td>Obsessive-compulsive disorder</td>
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**fluoxetine 20 mg capsule, 100**

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<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
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<td>12256C</td>
<td>0.3</td>
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<td>*24.01</td>
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**fluoxetine 20 mg capsule, 28**

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<td>* Blooms the Chemist Fluoxetine [IB]</td>
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<td>* FLUOTEX [RF]</td>
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<td>* Fluoxetine Sandoz [SZ]</td>
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<td>* Zactin [AF]</td>
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**INSULIN ASPART**

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

<table>
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<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
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<td>5</td>
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**INSULIN ASPART + INSULIN ASPART PROTAMINE**

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

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<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
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<th>Brand Name and Manufacturer</th>
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**INSULIN DETEMIR**

*Note* Special Pricing Arrangements apply.

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<th>Restricted benefit</th>
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<td>Type 1 diabetes</td>
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**insulin detemir 100 units/mL injection, 5 x 3 mL pen devices**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
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<tbody>
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<td>Levemir FlexPen [NF]</td>
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</table>

**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**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>11815W</td>
<td>5</td>
<td>1</td>
<td>..</td>
<td>185.99</td>
<td>* Optisulin SoloStar [WA]</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Semglee [AF]</td>
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</table>

General Pharmaceutical Benefits
### INSULIN GLULISINE

- **insulin glulisine 100 units/mL injection, 5 x 3 mL cartridges**

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Brand Name</th>
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<th>Premium</th>
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</thead>
<tbody>
<tr>
<td>Optisulin GZ</td>
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### INSULIN ISOPHANE HUMAN

- **insulin isophane human 100 units/mL injection, 5 x 3 mL pen devices**

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Brand Name</th>
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<th>MRVSN</th>
<th>Premium</th>
</tr>
</thead>
<tbody>
<tr>
<td>Protaphane InnoLet NI</td>
<td>Protaphane InnoLet</td>
<td>177.49</td>
<td>41.30</td>
<td></td>
</tr>
</tbody>
</table>

- **insulin isophane human 70 units/mL + insulin neutral human 30 units/mL injection, 5 x 3 mL pen devices**

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Brand Name</th>
<th>DPMQ</th>
<th>MRVSN</th>
<th>Premium</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mixtard 30/70 InnoLet NI</td>
<td>Mixtard 30/70 InnoLet</td>
<td>177.49</td>
<td>41.30</td>
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</table>

### INSULIN LISPRO

- **insulin lispro 100 units/mL injection, 5 x 3 mL pen devices**

<table>
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<tr>
<th>Manufacturer</th>
<th>Brand Name</th>
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<th>MRVSN</th>
<th>Premium</th>
</tr>
</thead>
<tbody>
<tr>
<td>Humalog KwikPen KP</td>
<td>Humalog KwikPen</td>
<td>211.49</td>
<td>41.30</td>
<td></td>
</tr>
</tbody>
</table>

- **insulin lispro 50 units/mL + insulin lispro protamine 50 units/mL injection, 5 x 3 mL pen devices**

<table>
<thead>
<tr>
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<th>Brand Name</th>
<th>DPMQ</th>
<th>MRVSN</th>
<th>Premium</th>
</tr>
</thead>
<tbody>
<tr>
<td>Humalog Mlx50 KwikPen KP</td>
<td>Humalog Mlx50 KwikPen</td>
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</tbody>
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- **insulin lispro 25 units/mL + insulin lispro protamine 75 units/mL injection, 5 x 3 mL pen devices**

<table>
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<th>MRVSN</th>
<th>Premium</th>
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<tbody>
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<td>Humalog Mlx25 KwikPen KP</td>
<td>Humalog Mlx25 KwikPen</td>
<td>211.49</td>
<td>41.30</td>
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</table>

### 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** 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.

<table>
<thead>
<tr>
<th>Authority required</th>
<th>Attention deficit hyperactivity disorder</th>
</tr>
</thead>
</table>

**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**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
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<tbody>
<tr>
<td></td>
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<td></td>
<td>102.94</td>
<td>41.30 Vyvanse [TK]</td>
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**lisdexamfetamine dimesilate 40 mg capsule, 30**

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<tr>
<td></td>
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<td>5</td>
<td></td>
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<td>41.30 Vyvanse [TK]</td>
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**lisdexamfetamine dimesilate 20 mg capsule, 30**

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<tbody>
<tr>
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<td>5</td>
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<td>41.30 Vyvanse [TK]</td>
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**lisdexamfetamine dimesilate 50 mg capsule, 30**

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<tr>
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**lisdexamfetamine dimesilate 70 mg capsule, 30**

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<td>102.94</td>
<td>41.30 Vyvanse [TK]</td>
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**lisdexamfetamine dimesilate 30 mg capsule, 30**

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<td>5</td>
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<td>102.94</td>
<td>41.30 Vyvanse [TK]</td>
</tr>
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</table>

### 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**

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<tbody>
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**methylphenidate hydrochloride 18 mg modified release tablet, 30**

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<td>54.51</td>
<td>41.30 Concerta [JC]</td>
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**methylphenidate hydrochloride 27 mg modified release tablet, 30**

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<td>41.30 Concerta [JC]</td>
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**methylphenidate hydrochloride 54 mg modified release tablet, 30**

<table>
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<tr>
<td></td>
<td>1</td>
<td>5</td>
<td></td>
<td>71.93</td>
<td>41.30 Concerta [JC]</td>
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</table>

### 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

<table>
<thead>
<tr>
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methylphenidate hydrochloride 10 mg modified release capsule, 30

<table>
<thead>
<tr>
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<td>Ritalin LA [NV]</td>
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methylphenidate hydrochloride 60 mg modified release capsule, 30

<table>
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methylphenidate hydrochloride 40 mg modified release capsule, 30

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methylphenidate hydrochloride 20 mg modified release capsule, 30

<table>
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<td>2276T</td>
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<td>47.76</td>
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</tbody>
</table>

• 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

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
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<td>*175.18</td>
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<td>Phelenzine sulfate USP (Generic Health) [GQ]</td>
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phenelzine 15 mg tablet, 100

<table>
<thead>
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</table>

• 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 thrombocytopenia 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 thrombocytopenia 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;
   c. A confirmation that the patient's disease related symptoms are resistant, refractory or intolerant to available therapy.

ruxolitinib 5 mg tablet, 56
10614P

<table>
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<tr>
<th>Max Qty Packs</th>
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ruxolitinib 15 mg tablet, 56
10619X

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ruxolitinib 20 mg tablet, 56
10618W

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ruxolitinib 10 mg tablet, 56
10913J

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<tr>
<td>1</td>
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<td></td>
<td>5161.16</td>
<td>41.30</td>
<td>Jakavi [NV]</td>
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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
12267P

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
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<th>DPMQ $</th>
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<td>2</td>
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<td></td>
<td>*26.68</td>
<td>27.97</td>
<td>Bricanyl Turbuhaler [AP]</td>
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TRIHEXYPHENIDYL (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
12250R

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trihexyphenidyl (benzhexol) hydrochloride 2 mg tablet, 200
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)

**Clinical criteria:**

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

**Treatement 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: I

- 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’.

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- **Ambrisentan**
  - **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.

**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** 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)**

**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)**

**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

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**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.
Highly Specialised Drugs (Program (Private Hospital))

**Note** No increase in the maximum number of repeats 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 62.5 mg 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 62.5 mg 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

Applications for authorisation under this restriction may be made in real time using the Online PBS Authorit

Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Pulmonary arterial hypertension (PAH)

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

Clinical criteria:

- Patient must have had the 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.

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:

- 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
- 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 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.

- An ERA includes ambrisentan, bosentan monohydrate, or macitentan.
- 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:
  - 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
  - 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 second authority prescription of therapy with the 125 mg tablet strengths, with a 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 the 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.

- An ERA includes ambrisentan, bosentan monohydrate, or macitentan.
- 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-Si 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 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

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<td>BOSLEER [RW]</td>
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#### 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
- BMPFR2 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 treatment 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-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’.

### ELTROMBOPAG

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

Note Special Pricing Arrangements apply.

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**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 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
Highly Specialised Drugs Program (Private Hospital)

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 platelet count of less than or equal to 20,000 million per L; OR
- 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:
- a completed authority prescription form,
- a completed Idiopathic Thrombocytopenic Purpura Initial PBS Authority Application - Supporting Information Form,
- details of a platelet count supporting the diagnosis of ITP, and
- 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:
- use of rescue medication (corticosteroids or immunoglobulins) on no more than one occasion during the initial period of PBS-subsidised treatment with this drug,
- either of the following:
- 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
- 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:
- a completed authority prescription form, and
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).

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**
(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).
### 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.

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**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

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• PAH associated with:
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  • 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
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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:
   - RHC composite assessment; and
   - ECHO composite assessment; and
   - 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 class/phosphodiesterase-5 inhibitor class 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.
Highly Specialised Drugs Program (Private Hospital)

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’.

### ROMIPLOSTIM

**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:
  1. (a) a platelet count of less than or equal to 20,000 million per L, OR
  2. (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. (1) a completed authority prescription form,
2. (2) a completed Idiopathic Thrombocytopenic Purpura Initial PBS Authority Application - Supporting Information Form,
3. (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

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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.

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

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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.

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).

**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

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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-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:**

- 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.

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### selexipag 200 microgram tablet, 140

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**SELEXIPAG**

**Note**

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**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'.

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**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:
  1. 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
  2. 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
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- 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:
  1. Hospitalisation due to worsening PAH;
  2. 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;
  3. 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;
  4. Initiation of parenteral prostanoid therapy or long-term oxygen therapy for worsening of PAH;
  5. Need for lung transplantation or balloon atrial septostomy for worsening of PAH.

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**Highly Specialised Drugs Program (Private Hospital)**
**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 prostanooid 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.

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Highly Specialised Drugs Program (Private Hospital)

### Highly Specialised Drugs

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### 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; and
    - (2) RHC composite assessment plus 6MWT; and
    - (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; and
      - (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).
- An ERA includes ambrisentan, bosentan monohydrate, or macitentan.
- 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 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).
- An ERA includes ambrisentan, bosentan monohydrate, or macitentan.
- 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).
- An ERA includes ambrisentan, bosentan monohydrate, or macitentan.
- 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

**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).
**Highly Specialised Drugs Program (Private Hospital)**

**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).

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**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).

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**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.
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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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:
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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-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’.

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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).
  - An ERA includes ambrisentan, bosentan monohydrate, or macitentan.
  - 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.
Highly Specialised Drugs Program (Public Hospital)

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.
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). A maximum of 5 repeats may be requested.

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**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.

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: Grandfathered patients (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 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:

- 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'.

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### 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)

**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) for this condition prior to 1 October 2020.

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)

**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.

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  

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**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 number of repeats 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 demonstrated 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.

### 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-Si 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: 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'.

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**boselectan 62.5 mg tablet, 60**

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### BOSELENTAN

**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.
Highly Specialised Drugs Program (Public Hospital) 67

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: Grandfathered patients (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: 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 4 repeats may be requested.

**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 (6MWVT).
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’.

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- **Bosentan APO [GX]**
- **BOSENTAN DR REDDY’S [RI]**
- **Bosentan Mylan [AF]**
- **Bosentan Sandoz [SZ]**
- **Tracleer [JC]**
- **Bosentan Cipla [LR]**
- **Bosentan GH [GQ]**
- **Bosentan RBX [RA]**
- **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** E 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
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 platelet count of less than or equal to 20,000 million per L; OR
  - 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.

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

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 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 be unsuitable for splenectomy due to medical reasons, AND
- Patient must have failed to achieve an adequate response to, or be intolerant to, immunoglobulin therapy, 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:
  - the 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:
  - 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
  - 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:
- a completed authority prescription form, and
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).

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

Eltrombopag is not PBS subsidised as an alternative to splenectomy.

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).

The platelet count must be no more than 30,000 million per L and which is double the baseline platelet count.

OR

(a) use of rescue medication (corticosteroids or immunoglobulins) on no more than one occasion during the most recent 24 weeks period of PBS-subsitised 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.

Eltrombopag is not PBS-subsitised as an alternative to splenectomy.

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).

Severe thrombocytopenia

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-subsitised 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-subsitised treatment with this drug, AND
- The treatment must be the sole PBS-subsitised 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-subsitised 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.

Eltrombopag is not PBS-subsitised as an alternative to splenectomy.

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).

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

Eltrombopag is not PBS subsidised as an alternative to splenectomy.

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).

Severe thrombocytopenia

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-subsitised 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-subsitised 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

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### eltrombopag 50 mg tablet, 28

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## 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:
   - RHC composite assessment; and
   - ECHO composite assessment; and
   - 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).

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**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).
  1. An ERA includes ambrisentan, bosentan monohydrate, or macitentan.
  2. 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).

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**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).
  1. An ERA includes ambrisentan, bosentan monohydrate, or macitentan.
  2. 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:
  1. RHC composite assessment; and
  2. ECHO composite assessment; and
  3. 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.

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
- 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-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’.

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**ROMIPLOSTIM**

**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 treatment 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 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: 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).

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**romiplostim 500 microgram injection, 1 vial**

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**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
- BMP2R mutation
- ALK-1, ENG, SMAD9, CAV1, KNCN3 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

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### 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**
- **Note:** 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:

1. Hospitalisation due to worsening PAH;
2. 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;
3. 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;
4. Initiation of parenteral prostanoioid therapy or long-term oxygen therapy for worsening of PAH;
5. Need for lung transplantation or balloon atrial septostomy for worsening of PAH.  

**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.  

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

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**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’.

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**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
  - Hentable 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:
  - (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.
**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.
 history of 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
  - BMP2R 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.

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- **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 dual therapy 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.

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 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’.

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### 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)

**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

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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-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’.

<table>
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<th>Brand Name and Manufacturer</th>
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<tr>
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<td>* Tadalca [CR]</td>
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<td>* TADALIS 20 [LR]</td>
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**tadalafil 20 mg tablet, 56**

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<th>Max Qty Packs</th>
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