

**PB 4 of 2021**

**National Health (Highly specialised drugs program) Special Arrangement Amendment Instrument 2021 (No. 1)**

*National Health Act 1953*

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I, BEN SLADIC, Assistant Secretary, Pharmacy Branch, Technology Assessment and Access Division, Department of Health, delegate of the Minister for Health, make this Amendment Instrument under subsection 100(2) of the *National Health Act 1953*.

Dated 27 January 2021

**BEN SLADIC**

Assistant Secretary

Pharmacy Branch

Technology Assessment and Access Division

Department of Health

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1. **Name of Instrument**
2. This Instrument is the *National Health (Highly specialised drugs program) Special Arrangement Amendment Instrument 2021 (No. 1)*.
3. This Instrument may also be cited as PB 4 of 2021.
4. **Commencement**

This Instrument commences on 1 February 2021.

1. **Amendment of *National Health (Highly specialised drugs program) Special Arrangement 2010* (PB 116 of 2010)**

Schedule 1 amends the *National Health (Highly specialised drugs program) Special Arrangement 2010* (PB 116 of 2010).

**Schedule 1 Amendments**

1. Schedule 1, entry for Ambrisentan in each of the forms: Tablet 5 mg; and Tablet 10 mg
2. *omit from the column headed “Circumstances” (all instances):* C11007 C11008 C11010 C11024 C11037
3. *insert in numerical order in the column headed “Circumstances” (all instances):* C11189 C11191 C11229 C11239 C11256 C11257
4. *omit from the column headed “Responsible Person” for the brand “Volibris”:* GK  *substitute:* ZE
5. Schedule 1, entry for Bosentan in the form Tablet 62.5 mg (as monohydrate)
6. *omit from the column headed “Circumstances” (all instances):* C11004 C11022 C11023 C11044 C11064
7. *insert in numerical order in the column headed “Circumstances” (all instances):* C11229 C11231 C11232 C11253 C11282 C11295
8. *insert in the columns in the order indicated, and in alphabetical order for the column headed “Brand”:*

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | Bosentan Cipla | LR | C10228 C10238 C10924 C10945 C11229 C11231 C11232 C11253 C11282 C11295 |  | See Note 1 | See Note 2 | D |

1. *omit from the column headed “Brand”:* BOSENTAN DR. REDDY’S *substitute:* BOSENTAN DR.REDDY’S
2. Schedule 1, entry for Bosentan in the form Tablet 125 mg (as monohydrate)
3. *omit from the column headed “Circumstances” (all instances):* C11004 C11022 C11023 C11036 C11044
4. *insert in numerical order in the column headed “Circumstances” (all instances):* C11229 C11231 C11232 C11253 C11282 C11295
5. *insert in the columns in the order indicated, and in alphabetical order for the column headed “Brand”:*

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | Bosentan Cipla | LR | C10228 C10924 C10945 C11229 C11231 C11232 C11253 C11282 C11295 |  | See Note 1 | See Note 2 | D |

1. *omit from the column headed “Brand”:* BOSENTAN DR. REDDY’S *substitute:* BOSENTAN DR.REDDY’S
2. Schedule 1, entry for Eculizumab

*substitute:*

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Eculizumab | Solution concentrate for I.V. infusion 300 mg in 30 mL | Injection | Soliris | XI | C6626 C6637 C6642 C6668 C6686 C6687 C6688 |  | See Note 1 | See Note 2 | D |

1. Schedule 1, entry for Eltrombopag in each of the forms: Tablet 25 mg (as olamine); and Tablet 50 mg (as olamine)

*omit from the column headed “Circumstances”:* C6724 C6725 C6738 C6739 C6790 *substitute:* C11199 C11202 C11244 C11262 C11263

1. Schedule 1, entry for Ivacaftor

*substitute:*

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Ivacaftor | Sachet containing granules  50 mg | Oral | Kalydeco | VR | C9889 C9890 |  | See Note 1 | See Note 2 | D |
|  | Sachet containing granules  75 mg | Oral | Kalydeco | VR | C9889 C9890 |  | See Note 1 | See Note 2 | D |
|  | Tablet 150 mg | Oral | Kalydeco | VR | C9889 C9890 |  | See Note 1 | See Note 2 | D |

1. Schedule 1, entry for Lumacaftor with ivacaftor

*substitute:*

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Lumacaftor with ivacaftor | Sachet containing granules, lumacaftor 100 mg and ivacaftor 125 mg | Oral | Orkambi | VR | C10005 C10007 |  | See Note 1 | See Note 2 | D |
|  | Sachet containing granules, lumacaftor 150 mg and ivacaftor 188 mg | Oral | Orkambi | VR | C10005 C10007 |  | See Note 1 | See Note 2 | D |
|  | Tablet containing lumacaftor  100 mg with ivacaftor 125 mg | Oral | Orkambi | VR | C9891 C9920 |  | See Note 1 | See Note 2 | D |
|  | Tablet containing lumacaftor  200 mg with ivacaftor 125 mg | Oral | Orkambi | VR | C9857 C9943 |  | See Note 1 | See Note 2 | D |

1. Schedule 1, entry for Macitentan
2. *omit from the column headed “Circumstances”:* C11021 C11033 C11034 C11043 C11071
3. *insert in numerical order in the column headed “Circumstances”:* C11186 C11229 C11237 C11275 C11276 C11285
4. *omit from the column headed “Maximum Quantity”:* 30  *substitute:* See Note 1
5. *omit from the column headed “Number of Repeats”:* 5  *substitute:* See Note 2
6. Schedule 1, entry for Mepolizumab

*substitute:*

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Mepolizumab | Injection 100 mg in 1 mL single dose pre-filled pen | Injection | Nucala | GK | C9885 C10221 C10222 C10280 C10483 C10484 |  | See Note 1 | See Note 2 | D |
|  | Powder for injection 100 mg | Injection | Nucala | GK | C9885 C10221 C10222 C10280 |  | See Note 1 | See Note 2 | D |

1. Schedule 1, entry for Midostaurin

*substitute:*

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Midostaurin | Capsule 25 mg | Oral | Rydapt | NV | C8138 C8177 C8193 C8218 |  | See Note 1 | See Note 2 | D |

1. Schedule 1, entry for Pomalidomide

*substitute:*

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Pomalidomide | Capsule 3 mg | Oral | Pomalyst | CJ | C7791 C7952 |  | See Note 1 | See Note 2 | D |
|  | Capsule 4 mg | Oral | Pomalyst | CJ | C7791 C7952 |  | See Note 1 | See Note 2 | D |

1. Schedule 1, entry for Romiplostim in each of the forms: Powder for injection 375 micrograms; and Powder for injection 625 micrograms

*omit from the column headed “Circumstances”:* C6694 C6737 C6738 C6766 C6789 *substitute:* C11205 C11246 C11266 C11267 C11289

1. Schedule 1, after entry for Saquinavir

*insert:*

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Selexipag | Tablet 200 micrograms | Oral | Uptravi | JC | C11193 C11195 C11241 C11261 | P11193 P11195 P11241 | 60 | 5 | D |
|  |  |  |  |  | C11193 C11195 C11241 C11261 | P11241 P11261 | 140 | 2 | D |
|  | Tablet 400 micrograms | Oral | Uptravi | JC | C11193 C11195 C11241 |  | 60 | 5 | D |
|  | Tablet 600 micrograms | Oral | Uptravi | JC | C11193 C11195 C11241 |  | 60 | 5 | D |
|  | Tablet 800 micrograms | Oral | Uptravi | JC | C11193 C11195 C11241 C11261 | P11261 | 60 | 3 | D |
|  |  |  |  |  | C11193 C11195 C11241 C11261 | P11193 P11195 P11241 | 60 | 5 | D |
|  | Tablet 1 mg | Oral | Uptravi | JC | C11193 C11195 C11241 |  | 60 | 5 | D |
|  | Tablet 1.2 mg | Oral | Uptravi | JC | C11193 C11195 C11241 |  | 60 | 5 | D |
|  | Tablet 1.4 mg | Oral | Uptravi | JC | C11193 C11195 C11241 |  | 60 | 5 | D |
|  | Tablet 1.6 mg | Oral | Uptravi | JC | C11193 C11195 C11241 |  | 60 | 5 | D |

1. Schedule 1, entry for Sildenafil
2. *omit from the column headed “Circumstances” (all instances)”:* C10998 C11012 C11020 C11032 C11045
3. *insert in numerical order in the column headed “Circumstances” (all instances):* **C11228 C11229 C11230 C11280 C11281 C11299**
4. *insert in the columns in the order indicated, and in alphabetical order for the column headed “Brand”:*

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | Sildenafil PHT APOTEX | TY | C10228 C10234 C10304 C11228 C11229 C11230 C11280 C11281 C11299 |  | See Note 1 | See Note 2 | D |

1. Schedule 1, entry for Tadalafil
2. *omit from the column headed “Circumstances” (all instances):* C10998 C11012 C11020 C11032 C11045
3. *insert in numerical order in the column headed “Circumstances” (all instances):* C11228 C11229 C11240 C11277 C11278 C11281
4. Schedule 2, after details relevant to Responsible Person code TX

*insert:*

|  |  |  |
| --- | --- | --- |
| TY | Apotex Pty Ltd | 52 096 916 148 |

1. Schedule 2, after details relevant to Responsible Person code YC

*insert:*

|  |  |  |
| --- | --- | --- |
| ZE | Seekwell Pty Ltd | 91 624 401 618 |

1. Schedule 3, entry for Ambrisentan
2. *omit:*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | C11007 |  | Pulmonary arterial hypertension (PAH) Continuing treatment (dual therapy) 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. 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. | Compliance with Authority Required procedures |
|  | C11008 |  | Pulmonary arterial hypertension (PAH) Grandfathered patients (dual therapy) 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; AND Patient must have been assessed by a physician with expertise in the management of PAH; AND 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. | Compliance with Written Authority Required procedures |
|  | C11010 |  | Pulmonary arterial hypertension (PAH) Initial 3 (dual therapy - change) 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. 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. | Compliance with Authority Required procedures |
|  | C11024 |  | Pulmonary arterial hypertension (PAH) Initial 2 (dual therapy - previously treated patients) 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. 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. | Compliance with Authority Required procedures |
|  | C11037 |  | Pulmonary arterial hypertension (PAH) Initial 1 (dual therapy - previously untreated patients) Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent; AND Patient must have been assessed by a physician with expertise in the management of PAH; AND 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. | Compliance with Written Authority Required procedures |

1. *insert in numerical order after existing text:*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | C11189 |  | Pulmonary arterial hypertension (PAH) Initial 3 (dual therapy - change) 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. 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. | Compliance with Authority Required procedures |
|  | C11191 |  | Pulmonary arterial hypertension (PAH) Grandfathered patients (dual therapy) 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. 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. 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. | Compliance with Written Authority Required procedures |
|  | C11229 |  | Pulmonary arterial hypertension (PAH) Triple therapy - Initial treatment or continuing treatment of triple combination therapy (including dual therapy in lieu of triple therapy) that includes selexipag 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 phoshodiesterase-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'). 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. | Compliance with Authority Required procedures |
|  | C11239 |  | Pulmonary arterial hypertension (PAH) Continuing treatment (dual therapy) 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. 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. | Compliance with Authority Required procedures |
|  | C11256 |  | Pulmonary arterial hypertension (PAH) Initial 1 (dual therapy - previously untreated patients) Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent. 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. 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. | Compliance with Written Authority Required procedures |
|  | C11257 |  | Pulmonary arterial hypertension (PAH) Initial 2 (dual therapy - previously treated patients) 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. 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. | Compliance with Authority Required procedures |

1. Schedule 3, entry for Bosentan
2. *omit:*

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|  | C11004 |  | Pulmonary arterial hypertension (PAH) Grandfathered patients (dual therapy) 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; AND Patient must have been assessed by a physician with expertise in the management of PAH; AND 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. | Compliance with Written Authority Required procedures |
|  | C11022 |  | Pulmonary arterial hypertension (PAH) Initial 3 (dual therapy - change) 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. 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. | Compliance with Authority Required procedures |
|  | C11023 |  | Pulmonary arterial hypertension (PAH) Continuing treatment (dual therapy) 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. 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. | Compliance with Authority Required procedures |
|  | C11036 |  | Pulmonary arterial hypertension (PAH) Initial 1 (dual therapy - previously untreated patients) Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent; AND Patient must have been assessed by a physician with expertise in the management of PAH; AND 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. | Compliance with Written Authority Required procedures |
|  | C11044 |  | Pulmonary arterial hypertension (PAH) Initial 2 (dual therapy - previously treated patients) 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. 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. | Compliance with Authority Required procedures |
|  | C11064 |  | Pulmonary arterial hypertension (PAH) Initial 1 (dual therapy - previously untreated patients) Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent; AND Patient must have been assessed by a physician with expertise in the management of PAH; AND 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. | Compliance with Written Authority Required procedures |

1. *insert in numerical order after existing text:*

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|  | C11229 |  | Pulmonary arterial hypertension (PAH) Triple therapy - Initial treatment or continuing treatment of triple combination therapy (including dual therapy in lieu of triple therapy) that includes selexipag 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 phoshodiesterase-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'). 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. | Compliance with Authority Required procedures |
|  | C11231 |  | Pulmonary arterial hypertension (PAH) Initial 3 (dual therapy - change) 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. 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. | Compliance with Authority Required procedures |
|  | C11232 |  | Pulmonary arterial hypertension (PAH) Grandfathered patients (dual therapy) 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. 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. 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. | Compliance with Written Authority Required procedures |
|  | C11253 |  | Pulmonary arterial hypertension (PAH) Initial 2 (dual therapy - previously treated patients) 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. 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. | Compliance with Authority Required procedures |
|  | C11282 |  | Pulmonary arterial hypertension (PAH) Initial 1 (dual therapy - previously untreated patients) Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent. 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. 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. | Compliance with Written Authority Required procedures |
|  | C11295 |  | Pulmonary arterial hypertension (PAH) Continuing treatment (dual therapy) 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. 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. | Compliance with Authority Required procedures |

1. Schedule 3, entry for Eltrombopag

*substitute:*

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| Eltrombopag | C11199 |  | Severe thrombocytopenia Second or subsequent Continuing treatment 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. 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. | Compliance with Authority Required procedures |
|  | C11202 |  | Severe thrombocytopenia Initial treatment 1 - New patient 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. 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. | Compliance with Written Authority Required procedures |
|  | C11244 |  | Severe thrombocytopenia Balance of supply or change of therapy within 24 weeks initial treatment 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. 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. | Compliance with Authority Required procedures |
|  | C11262 |  | Severe thrombocytopenia Initial treatment 2 - New patient 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. Patient must be aged 18 years or older. The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of initial application; (a) a platelet count of less than or equal to 20,000 million per L; OR (b) a platelet count of 20,000 million to 30,000 million per L, where the patient is experiencing significant bleeding or has a history of significant bleeding in this platelet range. Where intolerance to treatment with corticosteroid and immunoglobulin therapy developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application. The authority application must be made in writing and must include: (1) a completed authority prescription form, (2) a completed Idiopathic Thrombocytopenic Purpura Initial PBS Authority Application - Supporting Information Form, (3) details of a platelet count supporting the diagnosis of ITP, and (4) details of the reason of medical contraindication for surgery and date of assessment. The platelet count must be no more than 4 weeks old at the time of application. A maximum of 24 weeks of treatment with this drug will be authorised under this criterion. Patients will be able to trial either eltrombopag or romiplostim within the initial 24 weeks treatment period. Where a patient has started initial treatment with one of the two agents, change of therapy to the alternative agent may be authorised under the Balance of supply or change of therapy restriction to complete up to 24 weeks initial treatment. Patients who fail to demonstrate a response to treatment with eltrombopag and/or romiplostim after completion of 24 weeks initial therapy will not be eligible to receive further PBS-subsidised treatment with either of these drugs. | Compliance with Written Authority Required procedures |
|  | C11263 |  | Severe thrombocytopenia First Continuing treatment or Re-initiation of interrupted continuing treatment 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. Patient must be aged 18 years or older. For the purposes of this restriction, a sustained platelet response is defined as: (a) use of rescue medication (corticosteroids or immunoglobulins) on no more than one occasion during the initial period of PBS-subsidised treatment with this drug, AND either of the following: (b) a platelet count greater than or equal to 50,000 million per L on at least four (4) occasions, each at least one week apart; OR (c) a platelet count greater than 30,000 million per L and which is double the baseline (pre-treatment) platelet count on at least four (4) occasions, each at least one week apart. Applications for the First continuing PBS-subsidised treatment or Re-initiation of interrupted PBS-subsidised continuing treatment must be made in writing and must include: (1) a completed authority prescription form, and (2) a completed Idiopathic Thrombocytopenic Purpura Continuing PBS Authority Application - Supporting Information Form, and (3) the most recent platelet count. The platelet count must be conducted no later than 4 weeks from the date of completion of the most recent PBS-subsidised course of treatment with this drug. A maximum of 24 weeks of treatment with this drug will be authorised under this criterion. | Compliance with Written Authority Required procedures |

1. Schedule 3, entry for Macitentan
2. *omit:*

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|  | C11021 |  | Pulmonary arterial hypertension (PAH) Initial 1 (dual therapy - previously untreated patients) Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent; AND Patient must have been assessed by a physician with expertise in the management of PAH; AND 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. | Compliance with Written Authority Required procedures |
|  | C11033 |  | Pulmonary arterial hypertension (PAH) Initial 2 (dual therapy - previously treated patients) 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. 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. | Compliance with Authority Required procedures |
|  | C11034 |  | Pulmonary arterial hypertension (PAH) Continuing treatment (dual therapy) 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. 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. | Compliance with Authority Required procedures |
|  | C11043 |  | Pulmonary arterial hypertension (PAH) Initial 3 (dual therapy - change) 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. 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. | Compliance with Authority Required procedures |
|  | C11071 |  | Pulmonary arterial hypertension (PAH) Grandfathered patients (dual therapy) 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; AND Patient must have been assessed by a physician with expertise in the management of PAH; AND 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. | Compliance with Written Authority Required procedures |

1. *insert in numerical order after existing text:*

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|  | C11186 |  | Pulmonary arterial hypertension (PAH) Initial 1 (dual therapy - previously untreated patients) Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent. 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. 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. | Compliance with Written Authority Required procedures |
|  | C11229 |  | Pulmonary arterial hypertension (PAH) Triple therapy - Initial treatment or continuing treatment of triple combination therapy (including dual therapy in lieu of triple therapy) that includes selexipag 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 phoshodiesterase-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'). 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. | Compliance with Authority Required procedures |
|  | C11237 |  | Pulmonary arterial hypertension (PAH) Grandfathered patients (dual therapy) 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. 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. 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. | Compliance with Written Authority Required procedures |
|  | C11275 |  | Pulmonary arterial hypertension (PAH) Initial 2 (dual therapy - previously treated patients) 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. 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. | Compliance with Authority Required procedures |
|  | C11276 |  | Pulmonary arterial hypertension (PAH) Initial 3 (dual therapy - change) 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. 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. | Compliance with Authority Required procedures |
|  | C11285 |  | Pulmonary arterial hypertension (PAH) Continuing treatment (dual therapy) 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. 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. | Compliance with Authority Required procedures |

1. Schedule 3, entry for Romiplostim

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| Romiplostim | C11205 |  | Severe thrombocytopenia Initial treatment 2 - New patient 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. 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. | Compliance with Written Authority Required procedures |
|  | C11246 |  | Severe thrombocytopenia Balance of supply or change of therapy within 24 weeks initial treatment 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. 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. | Compliance with Authority Required procedures |
|  | C11266 |  | Severe thrombocytopenia Initial treatment 1 - New patient 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. Patient must be aged 18 years or older. The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of initial application; (a) a platelet count of less than or equal to 20,000 million per L; OR (b) a platelet count of 20,000 million to 30,000 million per L, where the patient is experiencing significant bleeding or has a history of significant bleeding in this platelet range. Where intolerance to treatment with corticosteroid and immunoglobulin therapy developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application. At the time of the written authority application, medical practitioners should request the appropriate quantity of vials of appropriate strength to provide sufficient drug for a single treatment at a dose of 1 microgram/kg. Up to 1 repeat may be requested with the initial written application. Subsequently during the initial period of dose titration, authority applications for a single dose and up to 1 repeat may be requested by telephone. The dose (microgram/kg/week) must be provided at the time of application. Once a patient's dose has been stable for a period of 4 weeks, authority approvals for sufficient vials of appropriate strength based on the weight of the patient and dose (microgram/kg/week) for up to 4 weeks of treatment and up to 4 repeats may be granted, as long as the total period of treatment authorised under this restriction does not exceed 24 weeks. Authority approval will not be given for doses higher than 10 micrograms/kg/week The authority application must be made in writing and must include: (1) a completed authority prescription form, (2) a completed Idiopathic Thrombocytopenic Purpura Initial PBS Authority Application - Supporting Information Form, (3) details of a platelet count supporting the diagnosis of ITP. The platelet count must be no more than 4 weeks old at the time of application. Patients will be able to trial either eltrombopag or romiplostim within the initial 24 weeks treatment period. Where a patient has started initial treatment with one of the two agents, change of therapy to the alternative agent may be authorised under the Balance of supply or change of therapy restriction to complete up to 24 weeks initial treatment. Patients who fail to demonstrate a response to treatment with eltrombopag and/or romiplostim after completion of 24 weeks initial therapy will not be eligible to receive further PBS-subsidised treatment with either of these drugs. | Compliance with Written Authority Required procedures |
|  | C11267 |  | Severe thrombocytopenia First Continuing treatment or Re-initiation of interrupted continuing treatment 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. 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. | Compliance with Written Authority Required procedures |
|  | C11289 |  | Severe thrombocytopenia Second or Subsequent Continuing treatment 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. 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 | Compliance with Authority Required procedures |

1. Schedule 3, after entry for Saquinavir

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| Selexipag | C11193 | P11193 | Pulmonary arterial hypertension (PAH) Continuing treatment 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 phoshodiesterase-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. 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. | Compliance with Authority Required procedures |
|  | C11195 | P11195 | Pulmonary arterial hypertension (PAH) Initial treatment following dose titration 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 phoshodiesterase-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. 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. 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, tadalfil, 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. | Compliance with Authority Required procedures |
|  | C11241 | P11241 | Pulmonary arterial hypertension (PAH) Transitioning from non-PBS subsidised to PBS-subsidised supply - 'Grandfather' treatment 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 phoshodiesterase-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. 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. 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, tadalfil, 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. | Compliance with Authority Required procedures |
|  | C11261 | P11261 | Pulmonary arterial hypertension (PAH) Initial treatment - dose titration 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 phoshodiesterase-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. 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. 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, tadalfil, 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. | Compliance with Authority Required procedures |

1. Schedule 3, entry for Sildenafil
2. *omit:*

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|  | C10998 |  | Pulmonary arterial hypertension (PAH) Continuing treatment (dual therapy) 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. 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. | Compliance with Authority Required procedures |
|  | C11012 |  | Pulmonary arterial hypertension (PAH) Initial 3 (dual therapy - change) 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. 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. | Compliance with Authority Required procedures |
|  | C11020 |  | Pulmonary arterial hypertension (PAH) Initial 2 (dual therapy - previously treated patients) 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. 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. | Compliance with Authority Required procedures |
|  | C11032 |  | Pulmonary arterial hypertension (PAH) Initial 1 (dual therapy - previously untreated patients) Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent; AND Patient must have been assessed by a physician with expertise in the management of PAH; AND 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. | Compliance with Written Authority Required procedures |
|  | C11045 |  | Pulmonary arterial hypertension (PAH) Grandfathered patients (dual therapy) 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; AND Patient must have been assessed by a physician with expertise in the management of PAH; AND 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. | Compliance with Written Authority Required procedures |

1. *insert in numerical order after existing text:*

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|  | C11228 |  | Pulmonary arterial hypertension (PAH) Initial 1 (dual therapy - previously untreated patients) Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent. 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. 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. | Compliance with Written Authority Required procedures |
|  | C11229 |  | Pulmonary arterial hypertension (PAH) Triple therapy - Initial treatment or continuing treatment of triple combination therapy (including dual therapy in lieu of triple therapy) that includes selexipag 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 phoshodiesterase-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'). 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. | Compliance with Authority Required procedures |
|  | C11230 |  | Pulmonary arterial hypertension (PAH) Initial 3 (dual therapy - change) 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. 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. | Compliance with Authority Required procedures |
|  | C11280 |  | Pulmonary arterial hypertension (PAH) Continuing treatment (dual therapy) 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. 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. | Compliance with Authority Required procedures |
|  | C11281 |  | Pulmonary arterial hypertension (PAH) Grandfathered patients (dual therapy) 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. 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. 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. | Compliance with Written Authority Required procedures |
|  | C11299 |  | Pulmonary arterial hypertension (PAH) Initial 2 (dual therapy - previously treated patients) 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. 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. | Compliance with Authority Required procedures |

1. Schedule 3, entry for Tadalafil
2. *omit:*

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|  | C10998 |  | Pulmonary arterial hypertension (PAH) Continuing treatment (dual therapy) 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. 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. | Compliance with Authority Required procedures |
|  | C11012 |  | Pulmonary arterial hypertension (PAH) Initial 3 (dual therapy - change) 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. 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. | Compliance with Authority Required procedures |
|  | C11020 |  | Pulmonary arterial hypertension (PAH) Initial 2 (dual therapy - previously treated patients) 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. 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. | Compliance with Authority Required procedures |
|  | C11032 |  | Pulmonary arterial hypertension (PAH) Initial 1 (dual therapy - previously untreated patients) Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent; AND Patient must have been assessed by a physician with expertise in the management of PAH; AND 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. | Compliance with Written Authority Required procedures |
|  | C11045 |  | Pulmonary arterial hypertension (PAH) Grandfathered patients (dual therapy) 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; AND Patient must have been assessed by a physician with expertise in the management of PAH; AND 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. | Compliance with Written Authority Required procedures |

1. *insert in numerical order after existing text:*

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|  | C11228 |  | Pulmonary arterial hypertension (PAH) Initial 1 (dual therapy - previously untreated patients) Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent. 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. 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. | Compliance with Written Authority Required procedures |
|  | C11229 |  | Pulmonary arterial hypertension (PAH) Triple therapy - Initial treatment or continuing treatment of triple combination therapy (including dual therapy in lieu of triple therapy) that includes selexipag 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 phoshodiesterase-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'). 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. | Compliance with Authority Required procedures |
|  | C11240 |  | Pulmonary arterial hypertension (PAH) Initial 3 (dual therapy - change) 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. 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. | Compliance with Authority Required procedures |
|  | C11277 |  | Pulmonary arterial hypertension (PAH) Initial 2 (dual therapy - previously treated patients) 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. 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. | Compliance with Authority Required procedures |
|  | C11278 |  | Pulmonary arterial hypertension (PAH) Continuing treatment (dual therapy) 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. 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. | Compliance with Authority Required procedures |
|  | C11281 |  | Pulmonary arterial hypertension (PAH) Grandfathered patients (dual therapy) 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. 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. 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. | Compliance with Written Authority Required procedures |